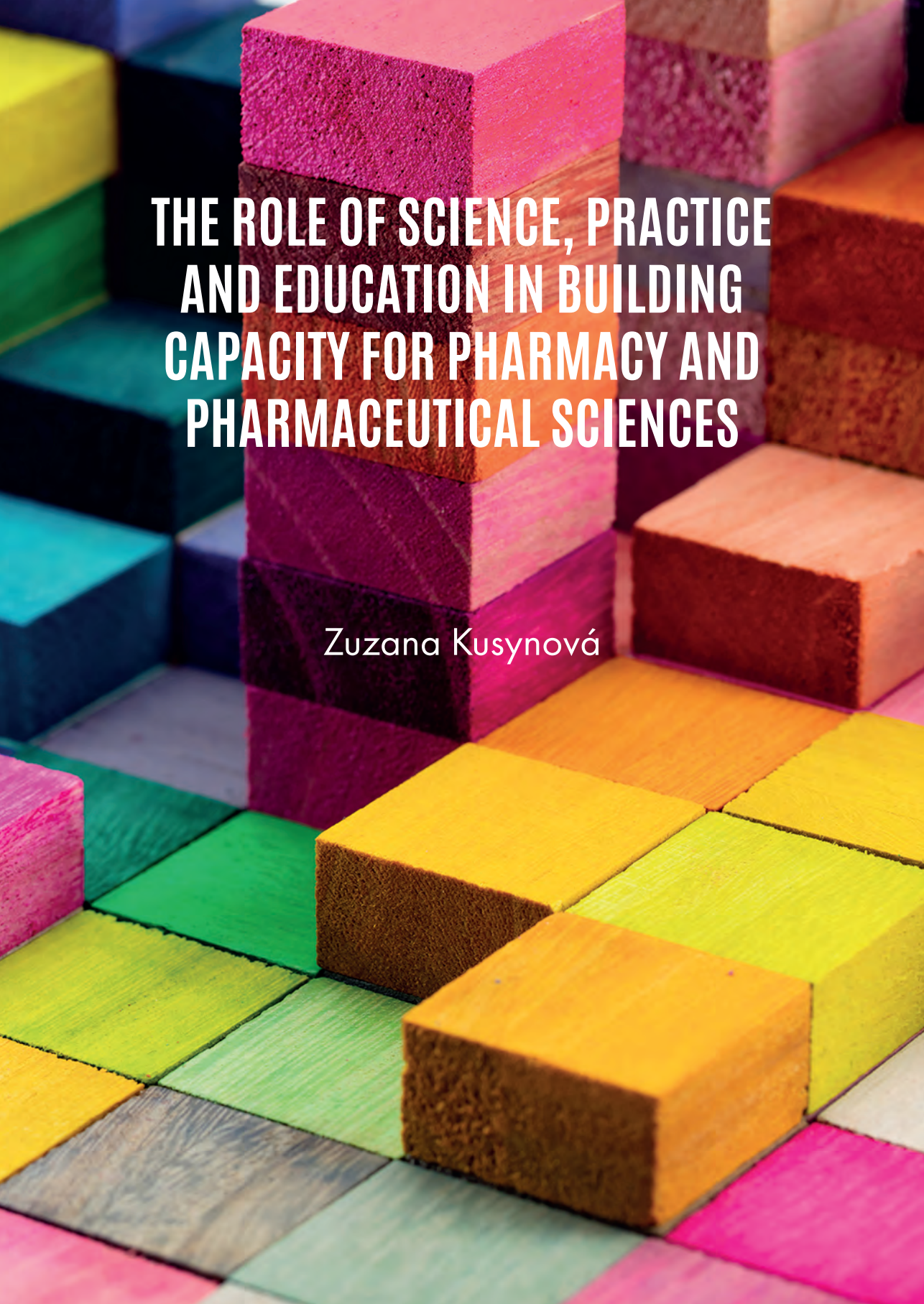

THE ROLE OF SCIENCE, PRACTICE AND EDUCATION IN BUILDING CAPACITY FOR PHARMACY AND PHARMACEUTICAL SCIENCES

Zuzana Kusynová

The role of science, practice and education in building capacity for pharmacy and pharmaceutical sciences

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Colophon

The research presented in this PhD thesis was conducted under the umbrella of the Utrecht World Health Organization (WHO) Collaborating Centre for Pharmaceutical Policy and Regulation, Utrecht Institute for Pharmaceutical Sciences (UIPS), Faculty of Science, Utrecht University, the Netherlands. The Collaborating Centre aims to develop new methods for independent pharmaceutical policy research, evidence-based policy analysis and conceptual innovation in the area of policy making and evaluation in general. The research was conducted in collaboration with the International Pharmaceutical Federation (FIP), The Hague, the Netherlands. The views expressed in this manuscript are the personal views of the author and must not be understood or quoted as being made on behalf of FIP.

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The role of science, practice and education in building capacity for pharmacy and pharmaceutical sciences

De rol van wetenschap, praktijk en onderwijs bij de capaciteitsopbouw in de farmacie en farmaceutische wetenschappen

(met een samenvatting in het Nederlands)

Rola vedy, praxe a vzdelávania pri budovaní kapacít v oblasti farmácie a farmaceutických vied

(so zhrnutím v slovenskom jazyku)

Proefschrift

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"The impediment to action advances action. What stands in the way becomes the way."

Marcus Aurelius

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1 General introduction

The United Nations (UN) established 17 Sustainable Development Goals (SDGs) as a global call to action to alleviate poverty, protect the planet and improve people's lives and opportunities globally.[1] One of the SDGs related to health is SDG3: "Good health and wellbeing", crucial for achieving other SDGs since they are connected and interlinked.[2] Indeed, "health as a fundamental human right" is a core concept for the leadership of the World Health Organization (WHO) in recognition that health is a critical component of a sustainable world.[3]

These are ambitious goals. Despite the aspirations of nations worldwide to accomplish them, the attainment of health has not been realized, as shown by the persistent global burden of disease.[4] There are many diseases that contribute to this disease burden. All regions and countries are being affected, especially by increasing trends in mental disorders and non-communicable diseases like cardiovascular diseases, cancer, diabetes, and chronic respiratory conditions.[4] Low- and middle-income countries are more vulnerable due to a multitude of geographic, demographic and socio-economic factors, and are in parallel also more exposed to communicable diseases as HIV/AIDS, malaria, tuberculosis, diarrheal and acute respiratory infections.[4] These are still causing high mortality rates in these countries.

Gaps in the pharmaceutical landscape

Pharmaceuticals have long been delivering on significant illness reduction. In the future, humanity may be able to treat or fully eliminate diseases even before they present themselves via advanced gene editing and futuristic preventative technologies.[5] But for now, and probably for decades ahead, pharmaceuticals remain the principal vehicle for disease treatment.[5,6]

However, as mentioned above, significant gaps remain. The 2013 Report on Priority Medicines for Europe and the World stressed the need for pharmaceutical research into the development of new medicines and the improvement of medicines in use.[7] It furthermore helped us to understand where the gaps in pharmaceutical research are.[7] The gaps are, unfortunately, in both existing treatments (due to the risk of becoming ineffective soon, such as antimicrobials), and their inappropriate delivery mechanism or formulation for the target patient group (e.g. for cardiovascular diseases, AIDS/HIV, neuroleptics, diabetes, etc.).[7] And, indeed, there are areas where there is virtually no treatment, concerning both highly prevalent diseases (e.g., stroke, dementias, hearing/vision impairment, etc.) and rare diseases.[7] Pharmaceutical innovation could address all of these.

Yet, pharmaceutical innovation is often hindered by financial, regulatory and policy barriers and these are abundantly described. Specifically, literature assisted us to comprehend what reforms of regulatory, reimbursement and pricing policies can improve the situation to some extent across countries.[7-10] However, pharmaceutical innovation goes beyond new medicines, it encompasses learning from practice.[11-13] This explains why gaps persist also in areas where appropriate treatments already exist. Gaps often occur due to access issues as a result of marketing authorisation and reimbursement decisions.[8,14] In addition, and of particular interest, are the studies showing negative effects of inefficient medicines use.[15] These are affecting wide areas of medication safety, polypharmacy and interactions, treatment adherence, medication waste and administration, to name a few.[15-18] The IMS Institute for Healthcare Informatics estimated in 2012 that almost 500 billion

USD was the annual avoidable cost to healthcare due to the lack of responsible use of medicines.[19] Despite various advances in the past decade, many of these practices and gaps still persist. Furthermore, access to medicines should always go hand in hand with access to pharmaceutical expertise. Lack of awareness or guidance in practice by health care professionals is thus another important barrier.[19,20] These areas where pharmaceutical research meets practice and vice-versa, are offering a large potential for closing the gaps with an important role for (continuous) education and capacity building. These are also the areas this thesis examines.

Capacity building

It is a fundamental truth that there can be no health without an underlying health workforce.[21] Workforce is central to well performing health systems, and should be built to achieve its full capacity in national and global health goals.[21,22] This is even more so in light of growing concerns about the projected global shortage of 18 million health workers by 2030.[23] Nearly all countries are challenged by these concerns, and especially in the poorest countries the workforce is under assault by inadequate investment into building capacity.[24]

The topic of capacity building has become more dominant in policy discourses on international development.[21,22] Global health workforce capacity building has witnessed a resurgence of policy attention, partly driven by imperatives to achieve national and global health objectives as set out by the SDGs.[21,22] Capacity building has come to be interpreted and operationalized in many different ways, thereby making capacity building more of an umbrella concept rather than a clearly defined process.[25] In a general sense, the term is understood as "the process of enhancing individual skills or strengthening the competence of an organisation or set of organisations to undertake specific tasks".[25] The WHO Global Strategy describes that Workforce 2030 identifies as one of its four strategic objectives, "to build the capacity [...] on human resources for health."[26]

Within the health workforce, the pharmaceutical workforce plays a key role in improving health outcomes through the responsible use of medicines and optimising their effective choice and use.[27,28] Pharmaceutical workforce refers to the whole of the pharmacy-related workforce, composed primarily of pharmacists (registered pharmacist practitioners working in a diversity of settings with their support cadres) and pharmaceutical scientists.[28,29] When pharmaceutical scientists together with pharmacists accepted responsibility and accountability for improving global health and patient outcomes by the development, distribution and responsible use of medicines,[30] education was deemed critical to facilitate these.[31,32] Thus, the three main cornerstones of pharmaceutical workforce are practice, science and education. These three components are interlinked – and in 2016 were formalised as the three pillars for advancing pharmacy.[33,34] The concept of practice-driven and science-based capacity helps us studying the role of each of these three components in building capacity for pharmacy and pharmaceutical sciences (Figure 1).

Changing roles of pharmaceutical sciences and practice

The roles that pharmacists and pharmaceutical scientists cover have been described by global organisations such as the WHO and the Organisation for Economic Co-operation and Development

Figure 1. Building capacity for pharmacy and pharmaceutical sciences[35]

(OECD), to name a few, and by ample research.[20,28,36-44] The roots of pharmacy and pharmaceutical sciences lie back before 19th century, with apothecaries that offered traditional trial-and-error interventions based on centuries of folk knowledge.[45] Since then, pharmaceutical research and practice have come a long way. Scientific discoveries, such as isolating insulin in 1921, foreshadowed the arrival of the pharmaceutical industry and care as we know it today. Penicillin, a profound discovery of an unparalleled impact in 1928, not only saved lives, it also marked a new era for drug development. Research & development flourished and translated into wide plethora of life-saving and well-being-improvement products: anti-contraceptives, anti-inflammatories, analgesics, psychotropic drugs, and statins, to name a few. Ever-increasing understanding of basic sciences enabled systematic, rather than serendipitous discoveries. Science boosted as researchers competed to be the creator of the next big blockbuster.[45]

Rowland et al. described the numerous pharmaceutical innovations in the 20th century and how pharmaceutical sciences played a crucial role in massively improving health and standards of living.[46] Then, since the beginning of the millennium, expanding knowledge of genetics has translated into new immunotherapies, and treatment of the underlying causes of many illnesses, including cancer. For example, chimeric antigen receptor T-cell (CAR-T) medicines are capable of genetically modifying the patient's own cells to fight cancer.[5,41,47] Biotechnology recently allowed impressive progress not only in such high-prevalent areas as cancer, e.g. with use of antisense technology, but also in orphan diseases, e.g. cystic fibrosis transmembrane conductance regulator (CFTR) modulators for treatment of cystic fibrosis.[41,47-49]

There is an enormous amount of evidence on how pharmaceutical scientists are fundamental in enabling (innovative) therapeutic options for patients regionally and globally.[46,50] They possess a wide ranging expertise in science and technology related to medical products. These include

understanding the impact of chemical and biological compounds on the human body and their effect on the prevention and treatment of disease.[46,51] They are needed in all phases of drug research – from basic sciences discovery research to clinical development, manufacturing, quality assurance and post-marketing monitoring.[46]

On the practice side, pharmacists have a responsibility to guide patients to make the best use of the medicine. Evidence shows pharmacists' indispensable role in handling all the medication-related needs, from simple cures for minor ailments to complex treatments and from small molecules to biologicals, in both inpatient and outpatient care.[38] Pharmacists are not only expected to address acute health needs, they increasingly address and promote burden of chronic diseases and promote wellness.[52,53] They are a team player and collaborate with other health care team members in the health system.[38,54] The literature is abundant on positioning pharmacists as one of the most accessible health professionals providing a variety of services for the health of both individuals and the community.[38,53-55] Additionally, vast evidence supports that pharmacists improve health system efficiency and safety, e.g. by preventing medication harm, thus ensuring patient safety.[56,57]

It is obvious that we need well trained pharmaceutical scientists (and others in pharmaceutical industry to support them) to ensure that (new) pharmaceuticals come on the market. We equally need well trained practitioners to ensure optimal access to existing medicines coupled with pharmaceutical expertise. Although the literature clearly indicates apparent benefits, or even imperatives of having these in place, there is a lack of ongoing assessment and continuous improvement in reality. Pharmaceutical workforce – both in their scientific and practitioners role – is not being used to their full potential to bridge the bench and clinical research with current, real-world practice. Capacity building should promote these, with the ultimate goal to readily respond to patient needs.

A lot has been written on capacity building, however, it is hardly the subject of primary research because it is a difficult concept to assess and primarily not an analysable or even observable phenomenon. Capacity relates to a potential, it demonstrates itself through seeing this potential coming into action. Education, critical for capacity building, produces a potential, which has to be used, before it is clear what difference this potential makes.[25,58] Education plays a key role in capacity building and can be studied and measured.

Integrating practice and science in education

While there are clear attempts to study, and consequently, build capacity for pharmacy and pharmaceutical sciences as a whole, it is not an easy task.[33] The terms of pharmaceutical scientists and pharmacist have been defined,[38,51] and as the proverbial notion says "all pharmacists are pharmaceutical scientists…". But while practitioners see themselves as scientists at the core, this is not necessarily true vice versa – as the notion continues "… while not all pharmaceutical scientists are pharmacists". Pharmaceutical sciences also increasingly encompass scientists that are trained completely outside of the pharmacy educational system and regulations.[28,51] The International Pharmaceutical Federation (FIP), the global organisation representing pharmacists and pharmaceutical scientists, has been long striving to advance both counterparts under one

pharmaceutical workforce umbrella. FIP supports pharmaceutical workforce development, acknowledging that the elements of this workforce can also come from other backgrounds.[51]

The struggle of integrating practice and science is not an alien concept in education, it is in fact commonly debated in the medical field. To address this struggle, the well-known so-called Flexner report, an authoritative report commissioned in 1910 by the Carnegie Foundation for the Advancement of Teaching in USA, dictated that undergraduate (preclinical) medical education must encompass basic sciences.[59] Since then, this concept has been widely embraced in many countries, and the undergraduate medical, or more widely, clinical curriculum (including pharmacy) have strived to increase the integration of basic sciences and clinical application.[60] Around the 40's, standards were set to direct curricular development in pharmacy and in clinical sciences in general. By the 80's they started to define the pharmaceutical care concept, continuing until the start of the millennium. In 2016, the Accreditation Council for Pharmacy Education (ACPE) standards for pharmacy in the USA were last updated, expecting graduates to develop, integrate, and apply foundational science knowledge to solve clinical problems.[60] Pharmacy curricula attempted to evolve with the practice of pharmacy and intermingled the teaching of both the basic and clinical sciences. This is, nevertheless, not an easy task. In a recent reflection paper, Engels took an example of pharmacology where he argues that thorough understanding of scientific principles is needed for demonstrating competencies in effective pharmacotherapy. Pharmacology is being taught in a variety of contexts and audiences, including medicine, nursing, pharmacy, dentistry, physiotherapy, and veterinary medicine as well as research-oriented programmes (e.g. biomedical technicians). Therefore, depending on the context, careful consideration of teaching strategies is needed in pharmacology education, thus integrating the science differently in various practices.[61]

In addition, education needs to constantly keep up with the aforementioned evolving roles in science and practice. Incorporating these in education is not an easy endeavour. Curriculum revisions are usually extensive undertakings. They may entail re-organisation of the conceptual design of the curriculum, modifications in structure, content, methods and approaches. The changes demand new concepts of teaching, content, textbooks, etc. Despite nearly a century of debates around what and how to teach and learn to make use of cutting-edge science to inform practice, there is no magic formula on how to incorporate new practice insights and scientific developments in capacity building.[60-64] Especially in case of potential health threats, needs-based interventions are needed on relatively short notice. We can learn from success stories, and this thesis presents a case study for this reason.

Needs-based interventions

Let's take the case of major global health threats aggravating the burden of diseases. One such threat is posed by substandard and falsified (SF) medical products.[65] SF medical products are a global issue exacerbating antimicrobial resistance and causing economic and humanitarian harm. WHO issued strategies to tackling SF medical products problem, and improvement in education is one of the eight strategic areas in this fight.[65] Pharmaceutical workforce specifically can make

a difference in tackling this public health threat.[65] There is however scarce literature on education of pharmaceutical workforce on SF medical products.

More broadly, there are existing examples of adaptation of pharmaceutical education to new practice paradigms in light of medical needs or health threats.[66-69] Studying these can aid outlining lessons learned for smaller training adaptations as well as large curricular reforms. One example of fast adaptation was amid COVID-19 pandemic, when educators were challenged to design effective at-home online courses or accommodate emerging science content (e.g. on m-RNA vaccines).[70]

It is hard to discuss capacity building without first determining what kind of capacity is needed and what it should look like in operation. Without this clarity, discussions on capacity development tend to become general exchanges on what makes for good development practice.[25]

But knowing what will be needed is difficult, given the healthcare and its players' roles are evolving rapidly. Despite well-defined visionary goals, most transitions to new situations are difficult to anticipate. Capacity building needs long-term, yet adaptable planning. Technological and demographic changes, coupled with environmental and political challenges, pose many uncertainties ahead.[24,71] For the long term, we need to have insight in what the future may bring. Literature offers help in forming mental maps to stimulate creative thinking on the future. Analyses leading to logical frameworks facilitate depicting alternative stories to take into account. Anticipating and debating various scenarios can show how the future may play out. This can support academia, policy makers, clinicians and scientists in identifying the explicit and tacit elements of both formal and informal education, that may facilitate the integration of scientific knowledge into the growth of adaptive expertise and the formation of professional identity.[41,63,72-74]

Objectives of the thesis

This thesis presents studies on the changing role of science, practice and education in building capacity for pharmacy and pharmaceutical sciences, given the many transitions in current health care and society at large. First of all, its objective is to evaluate advancements in the pharmaceutical landscape, taking into account both the scientific and practical aspects and the blurred intersections between them. We hypothesise that there is a changing and greater role for both pharmaceutical scientists and pharmacists to address public health imperatives and that these roles are interlinked, and we study what this means for capacity building. Furthermore, we study education as an important part of capacity building. We assess whether a competency-based education for undergraduate students can be a useful model in response to a contemporary, real-world need. And finally, we build and examine various elements of potential future scenarios and analyse how capacity building can be better equipped to navigate the ongoing challenges of complexity and uncertainty in a strategic manner.

Thesis outline

This thesis consists of six studies structured in three chapters. Firstly, after the introduction, **Chapter 2** consists of two sub-chapters studying (specific aspects of) the pharmaceutical landscape. In particular, **Chapter 2.1** focuses primarily on the pharmaceutical science. It examines the driving forces in pharmaceutical sciences research with a focus on unmet medical need.

Chapter 2.2 then focuses on the pharmaceutical practice counterpart. It presents a longitudinal analysis of how the roles pharmacists fulfil are being reflected in the annual world pharmacy congresses over a 17-year period of time.

Secondly, **Chapter 3** uses a major global health issue of SF medical products as a specific case study to analyse adaptation of pharmaceutical education to health threats and new practice paradigms. **Chapter 3.1** first maps the existing pharmaceutical education in this area in different countries around the world with the aim to identify (potential) gaps in this education. **Chapter 3.2** then offers "action", or "an intervention" to close these gaps. A new course on SF medical products was introduced into a pharmacy curriculum. The study examines the effects on knowledge improvement of the students that followed this course. It also identifies key barriers and enablers for such curricular change.

And thirdly, **Chapter 4** assesses the evolving environment in pharmaceutical sciences and practice affecting capacity building. **Chapter 4.1** delineates different scenarios for the future of pharmaceutical science, innovation and social policy in 2030. This general analysis of the broad environment is then scrutinised in **Chapter 4.2** on capacity building in detail.

Finally, **Chapter 5** offers perspectives in a general discussion and draws lessons from the different papers conducted in the thesis. It presents conclusions and policy recommendations from all the studies. The chapter highlights methodological challenges and areas of improvement as well as provides recommendations for future studies in the area.

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2 Developments in the landscape of pharmaceutical science and practice

2.1 Unmet medical need as a driver for pharmaceutical sciences – a survey among scientists

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Abstract

Historical antecedents of pharmaceutical sciences are sound on product orientation based on (analytical) chemistry, drug delivery and basic pharmacology. Over the last decades we have seen a transition towards a stronger disease orientation. This raises questions on whether, how and to what extent unmet medical need (UMN) is important in priority setting, funding and impact in pharmaceutical sciences. An online survey in 2020 collected perspectives of internationally recognised pharmaceutical scientists (N=92), mainly from academia and industry, on drivers and influencing factors in pharmaceutical sciences. The study offers a unique global perspective, demonstrating a solid command of the global needs in pharmaceutical sciences. The survey revealed that UMN is currently seen as one of the three most important drivers, also in addition to emerging trends in science and opportunities driven by collaboration. There are expectations that UMN's impact becomes more influential. This was consistent for both industry and academic respondents. The majority of respondents also indicated that anticipated lessons learned from COVID-19 will strengthen the impact of UMN on science and leadership. This is important as prioritisation of research towards UMN can address the clinical needs where needed the most.

Introduction

Historically, pharmaceutical innovation tended to be focused on the pharmacological level, where results of scientists' preferred research areas were, eventually, leading to approved treatment options. Major breakthroughs in pharmaceutical sciences in the past century were primarily driven by advances in medicinal and analytical chemistry, pharmaceutics, cell biology or receptor pharmacology.[1] Prior to the early 1960s, there were no safe and effective therapies for common illnesses such as atherosclerosis and essential hypertension, that carry an increased risk for of premature death.[2] Similarly, no such treatments were available for a whole host of incapacitating and fatal infectious and parasitic diseases that have affected many millions, especially in low- and middle- income countries.[3] Indeed, the majority of today's most generally prescribed medications such as the calcium channel blocking agents, statins, oral contraceptives, and bisphosphonates were after the 60s introduced as new therapies, alongside with advancements in many other therapeutical classes, such as antibiotics and antimalarials.[4] Surgical treatment of peptic and duodenal ulcers despite its associated risks was relatively common before the introduction of the proton pump inhibitors.[5]

Many more examples of how in the past, pharmaceutical scientists have been fundamental in enabling innovative therapeutic options for patients regionally and globally can be seen throughout history.[6] But many of these advances started rather at the lab bench than in the clinic. In the 1990s 'Drugs looking for a disease' was still a well-established concept.[7] Danhof *et al*. coined a paradigm shift from chemistry-biology based to pathology-of-disease medicine occurring around 2010.[8] With further continuous discoveries in disease-causing mechanisms, translating the findings into patients' unmet medical needs remained a challenge, but became a desired goal.[9,10]

Unmet medical need (UMN) is a widely used term in the healthcare sector with no single universal definition. Definitions of UNM in literature include (impact of) available treatments, patient population size or disease severity.[11] For the purpose of this study we defined UMN simply as medical needs in society (societal values) to be addressed by scientists by providing a therapy where none exists (e.g. pandemics, orphan diseases) or providing a therapy which may be potentially better than available alternatives (e.g. antimicrobial resistance).[12] While addressing UMN has always been a topic of some importance for pharmaceutical scientists since the beginning of their existence, it was mainly implicitly and not as a primary driver. [1, 10, 13,14] But that picture is changing – and questions on whether, how and to what extent UMN is important in priority setting, funding and impact in pharmaceutical sciences are raised.

In order to answer these, we asked pharmaceutical scientists for their perspectives. Pharmaceutical scientists as a group cover a heterogenous mixture of expertise and training in many aspects of science and technology related to medical products.[15] This heterogenicity includes [but is not limited to] discovery, development, manufacturing, regulation, and utilisation of medical products - embracing how medicines work, how safe and effective products are brought to the market, their impact on the body and their effect on the prevention and treatment of disease.[15] Pharmaceutical scientists are mainly employed by academia and the pharmaceutical industry, but increasingly also by regulatory authorities, non-governmental organisations (NGOs) or public-

private entities.[16,17] While (pre-clinical phase) basic discovery research is significantly led by academia and public institutions and funded primarily by government or by philanthropic organisations, late-stage (clinical phase) development is mainly led and funded by pharmaceutical industry.[18] Pharmaceutical industry is also typically more involved in manufacturing and quality assurance.[17,18] And industry is much more driven by business opportunities and targets compared to academia.[17]

Steering the focus of pharmaceutical sciences towards UMN is essential to address the clinical needs where needed the most. Addressing the above-mentioned questions on the how and what of UMN, this study offers a unique global insight into perspectives of experienced pharmaceutical scientists from various countries and backgrounds on the current environment of pharmaceutical sciences, main factors affecting priority setting and how these may change in the future, and on whether and how UMN has a role in all this. In addition, the study was conducted amid the acute global UMN of COVID-19 disease. This gave us the opportunity to mirror our findings in the context of this dramatic global event.

Methods

Setting and Participants

In the summer of 2020, an online survey was sent to speakers and/or chairs (n=380) who participated in the past three Pharmaceutical Sciences World Congresses (PSWC), organised by the International Pharmaceutical Federation (FIP), in Montréal (2020, virtual), Stockholm (2017), and Melbourne (2014). FIP is the global umbrella federation representing pharmacists and pharmaceutical scientists worldwide. We selected this group for our study, as PSWC speakers and/or chairs are selected by the International Scientific Programming Committee based on their international merit and recognised leadership in pharmaceutical sciences worldwide. We expected to collect a well thought-out set of views and perspectives from this group.

Data Collection

The survey was created using LimeSurvey® software and consisted of 14 multiple-choice questions and several open questions, divided into 3 sections. The first section of 5 questions covered general information about the participants (e.g., name, gender, age, country) and their background (pharmaceutical sciences specialty area, position, education background, years of experience). Furthermore, participants were asked to indicate the current closest match of their affiliation(s).

The second section of the survey concerned the perspectives on pharmaceutical sciences and consisted of questions on a 5-point Likert scale covering: most influential factors on research focus, most important drivers of pharmaceutical sciences research and most important factors shaping the future of pharmaceutical sciences. UMN was included in each of the questions as one of the options out of 8-9 pre-defined options and all factors were presented in an equal, random, manner. Given there is no one definition of UMN, different wording was used to indicate (unmet) medical need: unmet medical needs; medical need, societal values; and medical needs, pandemics and these responses were categorised as being related to UMN. The full wording of the survey questions is included in the Supplementary material.

Given the pertinent and global UMN of COVID-19 disease, we also asked an open question about how the COVID-19 pandemic may change pharmaceutical sciences now and in the future.

Data Analysis

We compared the demographic (gender, age, country) and professional (education background, affiliation, pharmaceutical sciences specialty area, position) profile of the respondents with the demographic profile of the speakers and chairs of PSWC we reached out to.

Questions with 5-scale Likert scale answer options were analysed quantitatively using Microsoft Excel 2016 and descriptive statistics were calculated. Responses were converted into a numerical scale with 1 point allocated to strongly disagree/not at all (or equivalent wording) and 5 points to strongly agree/very likely (or equivalent wording) and were analysed describing frequencies. Next, the mean and standard deviation were calculated to examine whether the items contributed equally to the total scale score. Furthermore, we compared responses from the most prevalent groups in the survey, i.e. participants coming from academia and from pharmaceutical industry, using descriptive statistics and analysing describing frequencies, as well as calculating the mean and standard deviation to examine whether the items contributed equally to the total scale score. The answers on open questions were organised into prevalent themes and analysed accordingly.

Results

Demography

We received, after two reminders, 92 responses out of 380 surveys sent (24% response rate). The demographics (gender, country) and professional (education background, pharmaceutical sciences specialty area, position, years of experience) profile of the respondents are displayed in Table 1.

The demographic profile of the respondents corresponded with the demographic profile of the original group we reached out to (Table 1). Most of the participants' affiliations were from academia (n=64) and the industry (n=17). These were the two most represented groups. Among those, a small fraction (<5%) of respondents indicated affiliation to both academia and industry. A small number of participants indicated the following sectors – solely or in combination with another affiliation: non-governmental institution (n=6); governmental institution, international body and healthcare (each n=5). There were four participants from private research institutions, three participants from a philanthropic foundation, or charity and one from regulatory, quality control. Similarly, the original group of all invited respondents consisted mostly of academia (n=242, 64%) and the industry (n=54, 14%) as the biggest represented groups.

Perspectives on the drivers in pharmaceutical sciences

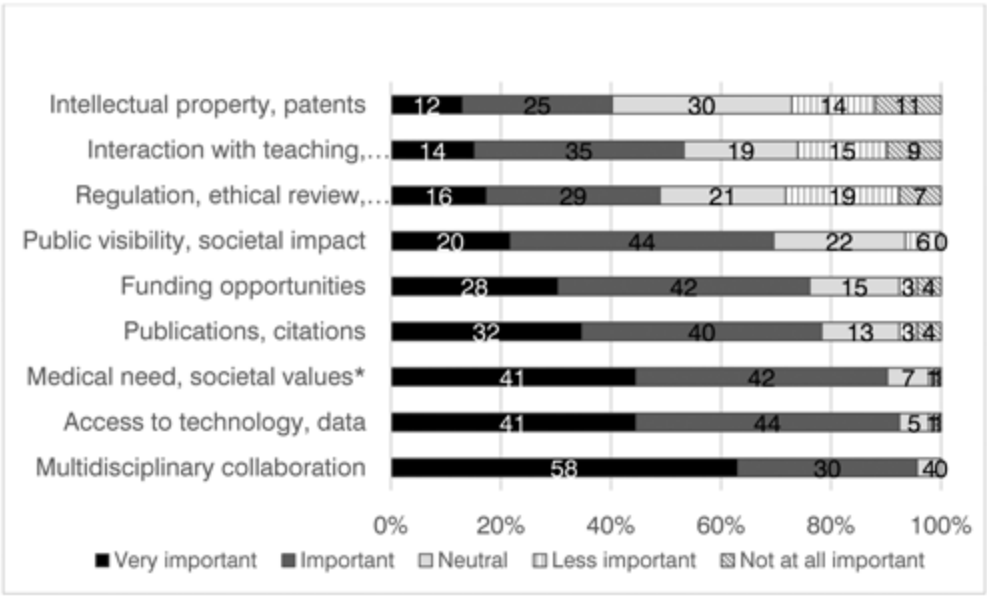
We asked the survey respondents about 'How important are the following aspects in your research?' In Figure 1 the results of this question are summarised indicating that multidisciplinary collaboration, access to technology (and data) and unmet medical need (UMN) and societal values are in the top three of most important drivers influencing how the pharmaceutical sciences are

shaped. Interestingly, factors like funding opportunities, patents or interactions with students were seen as less relevant.

Table 1. Descriptive statistics for the pharmaceutical scientists who participated in the study (n=92) and in the originally surveyed group (n=380)

	Respondents No. (%)	**Surveyed group No. (%)**
Gender		
Female	25 (27)	96 (25)
Male	64 (70)	284 (75)
Not disclosed	3 (3)	0 (0)
Geographical region [a]		
European Region	37 (40)	145 (38)
Region of the Americas	30 (33)	136 (36)
Western Pacific Region	19 (21)	88 (23)
Other	6 (6)	11 (3)
Academic rank / professional position		
Full professor	42 (46)	
Research director, management lead	19 (21)	
Associate professor, senior researcher	12 (13)	
Postdoc, junior researcher	8 (9)	
PhD student	6 (7)	
Other	5 (5)	
Educational background (highest degree)		
Pharmaceutical sciences	43 (47)	
Pharmacy	22 (24)	
(Medicinal) chemistry	5 (5)	
Biology, biotechnology	5 (5)	
Medicine, epidemiology	3 (3)	
Biophysics/physics	3 (3)	
Other (e.g., data science, humanities, etc.)	11 (12)	
Pharmaceutical sciences specialty area (currently active in)		
Drug formulation, pharmaceutics	29 (32)	
Clinical pharmacology, drug development	17 (18)	
Health systems, policy, regulation	13 (14)	
Clinical pharmacy, pharmacy practice	10 (11)	
(Cell) biology, systems biology, disease models	8 (9)	
(Medicinal) chemistry, drug discovery	6 (7)	
Pharmacology, drug action	5 (5)	
Analytical sciences and quality control	4 (4)	
Years of experience		
40+	20 (22)	
30+	22 (24)	
20+	17 (18)	
10+	12 (13)	
≤10	21 (23)	

[a] Based on World Health Organisation (WHO) regions



*Response categorised under unmet medical need (UMN)

Figure 1. The most important drivers of pharmaceutical sciences research.

In Table 2 the same question is addressed, showing the three most relevant drivers for all respondents, stratified for academia and industry.

For respondents from academia, UMN was the fourth most influential, surpassed by multidisciplinary collaboration and access to technology (and data) but also publications, and citations. Industry respondents indicated UMN at third place, surpassed by the same two factors of multidisciplinary collaboration and access to technology (and data).

We did the same for ranking the top three most influential factors when choosing research focus, also stratified for academia and industry (Table 3). Also here intrinsic scientific factors (i.e. trends in science, UMN and collaboration) surpassed other factors.

We also asked the respondents about their views on the *future* of pharmaceutical sciences, with overall, and stratified for academia and industry, strong agreement on UMN as being the most critical factor to shape pharmaceutical sciences (Table 4). Also available technologies and breakthrough successes were seen as convincing building blocks for the future.

When asked to identify three contemporary research questions or areas in the pharmaceutical sciences where one would invest in if one would get a million EUR/USD grant, we received a total of 224 ideas - 93% of those were directly or indirectly related to solving UMN. This included suggestions directly related to solve UMN using translational science applications (e.g., drug delivery, gene & cell therapy, personalised medicines, nanomedicines, etc., n=75, 36%) and various clinical areas (e.g., rare diseases, communicable diseases, non-communicable diseases, etc., n=66, 32%). Furthermore, 68 (38%) suggestions were related to UMN indirectly, through improvement of available therapies or improvement of access to medicines, themed mostly around: technology (e.g. use of technology

Table 2. The most important *drivers* of pharmaceutical sciences research

Drivers:	Nr. order [a]	Mean (SD) [b]	Very important, No. (%)	Important, No. (%)	Neutral, No. (%)	Less important, No. (%)	Not at all important, No. (%)
Multidisciplinary collaboration[c]	#1	4.6 (0.6)	58 (63)	30 (33)	4 (4)	0 (0)	0 (0)
Academia	#1	4.6 (0.5)	41 (64)	21 (33)	2 (3)	0 (0)	0 (0)
Industry	#1	4.5 (0.6)	10 (59)	6 (35)	1 (6)	0 (0)	0 (0)
Access to technology, data[c]	#2	4.3 (0.8)	41 (45)	44 (48)	5 (5)	1 (1)	1 (1)
Academia	#2	4.4 (0.7)	29 (45)	32 (50)	2 (3)	0 (0)	1 (2)
Industry	#2	4.4 (0.6)	8 (47)	8 (47)	1 (6)	0 (0)	0 (0)
Unmet medical need[c]	#3	4.3 (0.9)	41 (45)	42 (46)	7 (8)	1 (1)	1 (1)
Academia	#4	4.3 (0.7)	26 (41)	34 (53)	3 (5)	0 (0)	1 (2)
Industry	#3	4.2 (0.9)	8 (47)	6 (35)	2 (12)	1 (6)	0 (0)

[a] Order of the drivers that scored highest in the category very important, out of 9 drivers

[b] Based on a 5-point Likert Scale on which 1 = not at all important and 5=very important

[c] 92 participants answered

[d] Survey wording used was "Medical need, societal values"

Abbreviations: SD = standard deviation

Table 3. The most influential factors when choosing a research *focus* in pharmaceutical sciences

Research focus choice factors:	Nr. order [a]	Mean (SD) [b]	Very influential, No. (%)	Influential, No. (%)	Neutral, No. (%)	Rather not influential, No. (%)	Not at all influential, No. (%)
Emerging trends in science[c]	#2	4.0 (0.9)	27 (29)	46 (50)	12 (13)	5 (5)	2 (2)
Academia	#2	4.0 (0.8)	17 (27)	36 (56)	8 (13)	3 (5)	0 (0)
Industry	#3	3.6 (1.3)	5 (29)	7 (41)	1 (6)	2 (12)	2 (12)
Unmet medical need[c, d]	#1	3.9 (1.1)	31 (34)	35 (38)	14 (15)	7 (8)	5 (5)
Academia	#1	3.9 (1.1)	22 (34)	24 (38)	11 (17)	5 (8)	2 (3)
Industry	#2	3.8 (1.3)	6 (35)	7 (41)	1 (6)	1 (6)	2 (12)
Opportunities driven by collaboration[c]	#3	3.8 (0.9)	20 (22)	49 (53)	15 (16)	5 (5)	3 (3)
Academia	#3	3.9 (0.9)	14 (22)	39 (61)	5 (8)	4 (6)	2 (3)
Industry	#4	3.9 (0.8)	4 (24)	7 (41)	6 (35)	0 (0)	0 (0)

[a] Order of the factors that scored highest in the very influential category, out of 8 factors

[b] Based on a 5-point Likert Scale on which 1 = not at influential and 5=very influential

[c] 92 participants answered

[d] Survey wording used was "Unmet medical needs (e.g., COVID-19, orphan diseases, antimicrobial resistance)"

Abbreviations: SD = standard deviation

Table 4. The most important factors shaping *future* of pharmaceutical sciences

Factors shaping future of pharmaceutical sciences:	**Nr. order** [a]	**Mean (SD)** [b]	**Strongly agree, No. (%)**	**Agree, No. (%)**	**Neutral, No. (%)**	**Disagree, No. (%)**	**Strongly disagree, No. (%)**
Unmet medical need[c]	#1	4.4 (0.8)	48 (52)	38 (41)	3 (3)	2 (2)	1 (1)
Academia	#2	4.4 (0.6)	29 (45)	32 (50)	2 (3)	1 (2)	0 (0)
Industry	#1	4.5 (0.7)	11 (65)	5 (29)	1 6()	0 (0)	0 (0)
Technology in preventing and treating disease [c]	#2	4.3 (0.8)	46 (50)	35 (38)	8 (9)	1 (1)	2 (2)
Academia	#1	4.3 (1.0)	31 (48)	24 (38)	6 (9)	1 (2)	2 (3)
Industry	#2	4.4 (0.7)	10 (59)	6 (35)	1 (6)	0 (0)	0 (0)
Breakthroughs / successes[c]	#3	4.2 (0.9)	38 (41)	42 (46)	7 (8)	3 (3)	2 (2)
Academia	#3	4.1 (1.0)	26 (41)	27 (42)	7 (11)	2 (3)	2 (3)
Industry	#3	4.5 (0.5)	9 (53)	8 (47)	0 (0)	0 (0)	0 (0)

[a] Order of the frequency of the of the factors that scored the highest in the strongly agree, out of 8

[b] Based on a 5-point Likert Scale on which 1 = strongly disagree and 5=strongly agree

[c] 92 participants answered

[d] Survey wording used was "Medical needs, pandemics"

Abbreviations: SD = standard deviation

and computing power for drug discovery, etc.; n=17, 8%), but also in areas of policy/regulation (e.g., earlier access to innovative drug products, improved clinical trial design, etc., n=21, 10%), practice/care systems (e.g., improved patient outcomes, minimising adverse drug effects, n=19, 9%), and basic sciences (epidemiology, immunology, pathway biology, mathematical modelling, n=11, 5%). Fifteen answers (7%) were not at all related to UMN, with topics around education, increasing the efficiency of health services, environmental impact of medicines, for example.

Perspectives on COVID-19 and its effect on other unmet medical needs

In response to the open question of how eminent scientists thought the COVID-19 pandemic will change pharmaceutical sciences now and in the future in their region or globally, there were 60 respondents (65%) that indicated the COVID-19 pandemic will change pharmaceutical sciences. The COVID-19 pandemic was perceived as impactful in the near future. There were 10% (n=9) respondents who indicated no visible impact at this stage and 25% (n=23) did not answer this question.

The respondents gave their perspectives on the lessons learned on UMN for pharmaceutical sciences from the COVID-19 disease. Five themes, i.e. Reprioritisation of funding, Drug development: new research tools & study designs, Regulatory procedures optimisation, Interdisciplinary teamwork and Public engagement and advocacy, emerged when analysing the perspectives given etc. Table 5 summarises these perspectives and provides multiple examples for each theme.

Discussion

Prioritising the focus of pharmaceutical sciences towards UMN is critical to address the patients' needs where needed the most. The study results demonstrate a solid command of the global UMN in pharmaceutical sciences, confirmed through a unique perspective of pharmaceutical scientists from around the world. In addition to being the current influential driver, there are expectations on further increase of UMN influence in driving pharmaceutical sciences. This was also confirmed by looking specifically at the case of UMN in the context of the COVID-19 pandemic, where the majority of respondents indicated COVID-19 being a catalyst of strengthening the influence of UNM in shaping the future of pharmaceutical sciences. They anticipated lessons learned from COVID-19 will strengthen the impact of UMN on science, which will in turn enhance sciences' leadership to help address the UMN. Interestingly, responses by the academia and industry were aligned on prioritising UMN. A small difference to highlight was that industry participants indicated UMN most frequently as the second most influential factor, surpassed by the research policy/strategy of the institute or company.

UMN was also dominating the research choice in the open question as well, where nearly all of respondents' suggestions for contemporary research questions or areas in the pharmaceutical sciences (if given a generous, one million EUR/USD grant for any research of their choice) were related to solving UMN – by typically closing a research gap in various clinical / diseases areas, improvement of existing therapies (dosage, absorption, safety, quality, personalised therapy, etc.), innovation (use of new technologies, improving pharmaceutical services) and/or modernisation of the research / regulatory environment.

In the past, pharmaceutical sciences in their focus on basic sciences and product orientation had an ambiguous relationship to UMN. However, that picture is changing with UMN becoming the main driver of the direction and focus of pharmaceutical sciences.[1,8] Also the results of this

Table 5. Impact of COVID-19 on pharmaceutical sciences through the lens of tackling future Unmet Medical Need (UMN)

Area	Projections
Reprioritisation of funding	Paradigm shift: fast re-prioritisation and mobilisation of funding towards UMN at global level is possible. Infectious diseases research to strengthen (learning from recent epidemics, i.e., severe acute respiratory syndrome (SARS), Ebola, Zika, COVID-19). Resources to redirect towards epidemic preparedness and fighting threats, such as antimicrobial resistance (i.e., finding new antibiotics). UMN as a driver of scientific leadership to gain importance, long-term including UNM outside of infectious diseases.
Drug development: new research tools & study designs	Drug development to become speedier and more efficient with new research tools, innovative study designs, interdisciplinary teamwork, optimised regulatory procedures. Basic sciences, such as chemistry for small molecules, to gain prominence in drug discovery. Social sciences to increase presence in pharmaceutical sciences. Landscape of clinical trial phases I-III typically pursued in the drug development chain – to conditional on priority UMN and applied to UNM affecting small populations (e.g., rare diseases). Innovation progress in one UMN applied to stimulate progress in other UMN (accelerating pharmaceutical research in ribonucleic acid (RNA) therapies for COVID-19 vaccines, and vice versa learning from COVID-19 for other areas such as cancer therapies and brining more advanced therapies to more patients). Mechanisms in place to prevent severe restrictions/interruptions in the supply chains across countries: pharmaceutical supply chain research to increase and speed up, e.g., distributed manufacturing (continuous flow modular manufacturing, etc.) accepted and pursued more broadly, as well as increased local production.
Regulatory procedures optimisation	Pace of regulatory approval to increase. Less stringent regulation criteria for clinical trials and reduced animal trials. Once adopted in post-COVID-19 regulatory frameworks, the drug development and good practices in procurement and supply to be re-evaluated and strengthened to meet the UMN and overcome challenges faster. Regulation criteria and support to embrace scientific progress and gain of knowledge in the context of uncertainty (i.e., relative truth vs. absolute truth in scientific investigation, importance of lessons learnt for overall scientific progress).
Interdisciplinary teamwork	Greater willingness to cooperate, both by sharing expertise and sharing materials and equipment. More multidisciplinary and multi-stakeholder collaboration to further ensure the academic research environment are applied to other UMN. Information technologies and communication strategies disciplines to better integrate in pharmaceutical sciences.

Table 5. (continued)

Area	Projections
Public engagement and advocacy	Scientific leadership driven by UMN to align prioritisation among all stakeholders. All stakeholders (public, private industry, policy makers, payers, etc.) to become more interested in solving UMN and related social healthcare problems, strengthening of health systems, preparedness for outbreaks, global responsibility, and urgent need for international collaboration in tackling UMN. Scientists to better communicate the scientific advances addressing UMN to the public. Public to become critical in engagement in the scientific discourse around UMN (e.g., adoption of Schrödinger's uncertainty principle). More emphasis to be given to patient engagement and self-care on prevention side, as well as personalised health care on treatment side.

study support that transition. Still we see mixed perspectives in the literature. On one hand, available data on research funding and investment are supporting the notion that UMN is driving the pharmaceutical sciences.[19,20,21,22] On the other hand, there are several studies that have pointed out that pharmaceutical sciences are reactive rather than proactive to UMN, where focus and funding of clinical research particularly by the pharmaceutical industry is strongly associated with commercial viability, being attentive to UMN particularly through market analysis.[23,24] This may not be a sustainable way forward to tackle UMN, due to skyrocketing costs of R&D and plummeting innovation productivity (caused largely by increased complexities of therapy targets and stringent regulatory demands).[25] Lack of proper or systematic funding is particularly apparent in the niche areas of UMN, i.e. rare or neglected tropical diseases, where return of investment is low and many priority research gaps still exist.[26] Therefore, it comes as a surprise that the availability of funding was not considered to be of particular importance for respondents with an academic nor with an industry background.

Nonetheless, UMN can be found in a plethora of non-orphan and non-neglected disease categories, where funding is not the main reason for stagnation, but it is the scientific bottlenecks who are the main contributors to underperformance. Alzheimer's disease, dementia, cardiovascular disease, chronic pain conditions, osteoporosis, are but a few examples of areas with little progress despite relatively generous funding.[27,28] Importantly, it is not only neglected diseases where UMN remains, but many diseases of high-income countries are also affected.[9] Globalisation of diseases (communicable diseases like COVID-19, AIDS, SARS etc.) as well as wide spread of non-communicable diseases for which there is still no cure (cancer, dementia, etc.) is exacerbating the problem overall, in high-, middle- and low-income countries alike. UMN remains both in large indications (e.g., Alzheimer's disease) and in niche indications (e.g., Huntington disease).[29]

This is where COVID-19 can show example of unprecedented coordinated and speedy efforts – both in mobilising available scientific information (e.g., learning from m-RNA therapies initially used for cancer) and implementing supporting measures (e.g., removing obstacles to the free flow of research data and ideas).[30,31,32] In line with the opinions expressed by our respondents, lessons can be learned from finding and distributing COVID-19 therapeutics and vaccine and from

evidence-informed planning to overcoming accompanying challenges. The hope is that these lessons, for example, the benefits of scientists-led multi-stakeholder collaboration, extensive communication of scientific advances, removing regulatory barriers, etc. will eventually bring more advanced therapies to more patients. However, it may be necessary to wait until the pandemic is over to allow objectively examining the effect of COVID-19 pandemic. Also, more research is needed to analyse the full spectrum applicable to other UMN. Table 5 which outlined five thematic areas can serve as the starting point for the development of such analysis.

As UMN gains importance in pharmaceutical sciences and research priority setting, some standardisation is needed for its scope. UMN can mean different things to different people and also for the purpose of this study, different wording was used to indicate UMN. Lu et al pointed out that while "UMN" has important research prioritisation and regulatory implications, there is no empirical analysis of its real world usage and it currently describes both rare indications with no or few treatment options, as well as clinically indolent, commonly occurring indications.[33] Sandman and Hofmann (2019) criticised UMN being used to feed into criteria guiding research priority decision-making without underlying structured conceptual and normative considerations.[34] Further deliberations on the role of UMN as a driver remains important, especially given recent reflections on drivers and enablers of adaptive drug development pathways, where, as argued by Eichler et al (2015), one should not separate UMN from other value elements regardless of the existing need. Therefore, UMN alone should not drive decisions on prioritisation.[35]

Albeit we could observe a clear priority for UMN among our survey respondents, we should not forget that basic, curiosity driven pharmaceutical research without a clear view on expected benefits for society and health systems, also may deliver many years later. Our findings should not be interpreted as a plea for a defund of basic research. We also acknowledge that opinions of our survey respondents, who are chairing or speaking at a global conference, may not reflect the opinions of many other pharmaceutical scientists, especially young researchers. Albeit that the survey was conducted in a population of a primarily established generation of pharmaceutical researchers, we could find a shift towards more clinical and UMN research topics. This finding indicates that the future will show more to come on UMN when younger generations will fly in. Further studies are needed to explore the opinions in different groups that are outside of the scope of this study.

Overall, this study highlights that pharmaceutical scientists consider UMN being one of the major driving forces of pharmaceutical sciences, also in addition to emerging trends in science and opportunities driven by collaboration. They anticipate that the role of UMN will strengthen in the future. As a matter of a fact, through demonstrating UMN being the driving force in pharmaceutical sciences, pharmaceutical scientists can take leadership to better articulate the benefits for all stakeholders (for patients / payers / industry), show how real needs are being met by science, and advocate for orientating the funds given to research towards real needs. The findings in this study can support these efforts, for example they can be employed in the development of vision and strategic planning for addressing UMN as main driver for pharmaceutical sciences and research, both in academia and in industry. Some question whether the direction of pharmaceutical sciences is aligned with what society needs today. Therefore, demonstrating UMN being the driving force

in pharmaceutical sciences can help pharmaceutical scientists take the leadership in this timely endeavour to bring more advanced therapies to more patients.

Strengths and limitations

This study gathered perspectives from pharmaceutical scientists, with international merit, and recognised leadership in pharmaceutical sciences worldwide, contributing to the strengths of this study. There are several limitations to note. First, there was a relatively small sample size identified by a single international pharmaceutical federation and some geographical regions were underrepresented, as well as the opinions of general researchers, and especially young researchers might not be reflected. Secondly, this was limited to experts from the pharmaceutical sciences largely coming from academia and industry. Thirdly, the survey was running during the COVID-19 pandemic which may have negatively impacted the response rate. And finally, different wording related to (unmet) medical needs of the society was used to describe UMN, given there is no universal definition of UMN. While these limitations can constrain generalisability, the methods provided a rich depth of information and promoted trustworthiness of findings. Clear and consistent themes emerged, representing expert viewpoints from various regions and diverse specialisations within the pharmaceutical sciences.

Conclusions

According to perspectives of pharmaceutical scientists involved in this study, with backgrounds from both academia and industry, UMN is increasingly a driver for the direction of pharmaceutical sciences. Majority of participants anticipate COVID-19 disease, being an UMN itself, will strengthen the driving force of UMN in pharmaceutical sciences in the future to address the clinical needs where needed the most.

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Supplementary material

Table S1. Multiple-choice questions included in the survey

Question	Pre-defined answer options
Which sources are funding your current research? Please choose on Likert scale (never-sometimes-neutral-often-most of the times) the most relevant options.	a. Academic institution b. Government c. Intergovernmental body (e.g., World Health Organization) d. Public-private partnership (e.g., Innovative Medicines Initiative IMI) e. Public institutes (e.g., regulatory body or public research institute) f. Pharmaceutical (or other) industry g. Other private funding (e.g., pharmacy or patient association) h. Philanthropic foundations (e.g., Gates Foundation, Cancer Funds) i. Insurance companies, payers j. Other, please specify:
What is for you most influential in choosing your research focus? (Likert scale)	a. Emerging trends in science (e.g., new discoveries leading to new questions) b. Research policy/strategy of the institute or company c. Emerging trends in technology (e.g., artificial intelligence, mass spectrometry, imaging) d. Unmet medical needs (e.g., COVID-19, orphan diseases, antimicrobial resistance)* e. Inspiration by teaching, student interactions f. Opportunities driven by availability of data (e.g., access to patient/clinical data) g. Opportunities driven by collaboration (e.g., approached by colleagues, international consortia) h. Funding driven opportunities (or availability of funding) i. Other, please specify:
How important are the following aspects in your research (Likert scale)	a. Multidisciplinary collaboration b. Access to technology, data c. Interaction with teaching, students d. Funding opportunities e. Publications, citations f. Public visibility, societal impact g. Intellectual property, patents h. Regulation, ethical review, governance i. Medical need, societal values* j. Other, please specify:
Regarding the future of pharmaceutical science, which factors will most likely shape this future? (Likert scale)	a. Culture of science, vocational, entrepreneurial b. Medical needs, pandemics* c. Regulation, governance d. Trust in corporate pharma e. Funding opportunities f. Role of technology in preventing and treating disease g. Ethics, social values, sustainability h. Breakthroughs/successes in cancer, pandemics, Alzheimer i. Other, please specify:

* Responses categorised under unmet medical need (UMN)

Longitudinal study of Good Pharmacy Practice roles covered at the annual world pharmacy congresses 2003-2019

2.2

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Abstract

Background

Globally accepted roles of pharmacists are described in the Good Pharmacy Practice (GPP) standards, published by the World Health Organization (WHO) and the International Pharmaceutical Federation (FIP) in 2011. These standards provide a wide-ranging description of four main roles pharmacists fulfil. The global platform, where pertinent discussions around excellence and innovation in various pharmacy roles take place, is the annual congress of the pharmacy organisation representing the profession globally, FIP.

Objectives

Given the world pharmacy congresses present and reflect on the most topical and contemporary matters, this longitudinal study aimed at creating a historical overview of the frequency of appearance of the different GPP roles in the programmes of the past 17 congresses (2003-2019). This is to distinguish the dominance of different roles over time and thus their relevance for the profession.

Methods

The GPP standards served as a framework to create a set of keywords that were analysed for their frequencies of appearance in the programmes through text analysis. Trends in the four overarching GPP roles and at individual keyword level were analysed descriptively over time.

Results

The study found that all four GPP roles appeared in the programme each year and none of them was significantly missing, neither in the decade preceding the publication of the GPP standards nor in the decade thereafter. Role 3 "Maintain and improve professional performance" was most frequently represented, also demonstrating an upward trend in appearance, together with Role 4: "Contribute to improve effectiveness of the health-care system and public health". Trends emerged towards patient-centred clinical focus and positioning pharmacy as an important player in the health-care system – observed also at individual keywords level in areas such as health promotion – away from the more traditional product-centred practice roles such as compounding.

Conclusions

GPP roles have been already covered by the FIP annual congresses (long) before 2011, when the GPP roles were formally adopted, and they stayed relevant in the decade after. The more pronounced dominance toward the roles related to improving professional performance and positioning pharmacy are in line with the trend that the rather technical topics in pharmacy are increasingly covered by specialised meetings and that the FIP annual congresses have moved toward more general, scholarly platforms for dialogue and conversation.

Background

The World Health Organization (WHO) and the International Pharmaceutical Federation (FIP) have clearly described the significant role of pharmacists in the increasing health demands.[1] In the past 20 years, the society's expectations towards health care have changed. The changes in regulation of medicines led to greater accessibility to quality assured medicines. Supplying medicines alone, however, is not sufficient to achieve the desired treatment outcomes. Promoting medication adherence and minimising potential adverse effects have become an integral part of good dispensing practices.[2] The ever-growing and complicated variety of medications and non-adherence to prescribed medications have compelled the pharmacist's position to evolve into a more patient-centred health care professional (e.g. pharmaceutical care giver).[3] Pharmacists nowadays have a greater responsibility to handle all the medication-related needs and to help patients to make the best use of the medicine while at the same time treatments have become complex (e.g., a shift from small molecules to biologicals or individualised treatment). They are not only expected to address acute health needs, but also to address the burden of chronic diseases and promote wellness.[3,4] Finally, as an integral healthcare team member, pharmacists collaborate with other members in the health system and contribute to its efficiency. Together with the prescriber, they are responsible for the health outcomes of the patient.[3,5]

Pharmacists are described as sensitive to the needs of the society and the profession has a potential to evolve its roles accordingly.[6] The globally accepted roles of pharmacists are described in the Good Pharmacy Practice (GPP) standards, published in 2011 jointly by the WHO and FIP. The GPP standards are intended to encourage national pharmaceutical organisations around the globe to focus the attention of community and hospital pharmacists on translating the roles described into the practice they provide.[1] These standards provide a wide-ranging description of four main roles pharmacists fulfil, in all settings, but especially community and hospital pharmacy settings. Each of the four roles is supported by respective functions that pharmacists fulfil, to respond to the health needs of the people through optimal, evidence-based care.[1]

The GPP standards are still considered valid standards of today. However, over the past two decades, a number of factors have directly or indirectly contributed to evolution of pharmacy practice roles.[6] Therefore, questions arise whether the GPP roles described are still relevant, if they have been equally covered in past decade(s), and whether any of the roles became more prominent than others, or whether any roles diminished. The global platform, where pertinent discussions around excellence and innovation in various pharmacy roles in all settings takes place, is the annual congress of the pharmacy organisation representing the profession globally, FIP.[7] Here, pharmacists and pharmaceutical scientists present and reflect on the most topical professional and scientific activities at that time. As such these congresses act as a 'mirror' of what's going on, of what's hot, of what should be addressed and discussed, keeping in mind all the regional and national variation in priorities and cultural flavours.

In order to observe the evolution of different pharmacy roles, this study aimed at creating a historical overview of the frequency of appearance of the different roles of the pharmacists in the programme of the past nearly two decades. The study examined whether GPP roles described

were already being reflected in the programme in the decade preceding their publication and also whether any of the roles became more prominent than others, or whether any roles diminished in the decade after their publication, indicating a gap. This is to distinguish the dominance of different roles over time and thus their relevance for the profession.

Methods

Pharmacy practice roles' framework selection

The Good Pharmacy Practice (GPP) standards,[1] which contain a comprehensive, internationally recognised framework of pharmacy practice roles as standards for quality of pharmacy services, served as a framework for the analysis. The GPP standards outline four key roles for pharmacists: Role 1: Prepare, obtain, store, secure, distribute, administer, dispense and dispose of medical products; Role 2: Provide effective medication therapy management; Role 3: Maintain and improve professional performance; and, Role 4: Contribute to improve effectiveness of the health-care system and public health. Each Role is supported by respective Functions that pharmacists fulfil in their practice. These are described in Table 1.

Keywords identification and categorisation

The GPP standards were scrutinised with the objective to identify the keywords representing each of the GPP Roles and respective Functions. For the keywords either the exact wording in the description of the role was used, or if not deemed suitable the wording was adjusted by the researchers. The keywords were categorised under each Role and respective Function based on the judgement of the researcher (Z.K.) and independently validated by a second researcher (H.A.vdH.). In case of doubt, the final choices were selected based on a discussion between the researchers.

The final framework (see Table 1) contained only the keywords that were comprehensive, clearly characterising the pharmacy practice Role and respective Function. Seventy keywords were selected for the text analysis. The keywords were complemented with synonyms and/or equivalent words under each keyword. For example, counterfeit medicines was the preferred term used mostly until 2011, replaced by the official term SSFFC (substandard, spurious, falsely labelled, falsified, and counterfeit) in 2012-2017 and substandard and falsified (SF) medicines used after 2017.[8] Adding synonyms or equivalent and related words from the same area led to a total of 142 keywords.

Congresses programmes selection

The appearance of GPP roles in the annual congress programmes of FIP were analysed for the period of the past 17 years (2003-2019), as these programmes are available in an electronic format and thus suitable for analysis. Moreover, this timespan covers 8 years before the formal introduction of the GPP roles and 8 years thereafter, covering nearly two decades altogether. The congresses of 2020 and 2021 were cancelled due to COVID-19 pandemic, therefore excluded from the analysis.

These annual pharmaceutical congresses organised by FIP, called the World Congress of Pharmacy and Pharmaceutical Sciences, were chosen because they are the biggest global annual congress for pharmacists. The programme is comprehensive and touches on a wide variety of areas

of pharmaceutical practice and importantly, is aligned with the input and priority topics of the largest global network of national pharmacy organisations. The congresses attract a rather stable audience mainly through the international membership. They are managed by the longstanding staff under long-term quality standards, in a uniform venue, format and timing/term. Other conferences or events organised by FIP were excluded from the analysis.

Data analysis

The keywords were used for text analysis of the congress programmes, and the frequency of appearance of keywords was counted under each Role and Function. Both identification of keywords in the GPP document and text analysis of the congress programmes were performed using MS Excel and Adobe Reader. The number of keyword synonyms and/or equivalent words were manually counted under each Role and respective Function as they appeared. Another researcher (H.A.vdH.) validated this step by counting the frequencies of keywords from a random sample (n=10%) of programmes independently. No inconsistencies were found.

Keyword frequencies were summed up and the averages were calculated for comparison under each Function. Average of the Functions' frequencies was calculated for each Role. Roles were compared in a graphical overview with trendlines displayed (linear regression R^2 value was calculated to assess variability in the trend) and average annual growth change was calculated for comparison for each Role. To account for the difference in total number of keywords per year, the relative distributions of the four roles over the years were displayed in a stacked bar chart.

In addition, an average of keyword appearance over the years was calculated to find the most frequent keywords. The standard deviation was calculated to reflect the width of data distribution, for illustration. Lastly, the frequencies were colour coded based on a threshold (top 10%) to highlight peaks of appearance and facilitate trend identification. For these keywords where trends were concluded, linear regression R^2 value was calculated to assess variability in the trend.

Results

All GPP roles were reflected in each of the programmes at least once, already in the decade preceding their publication, and also in the decade after their publication. Table 1 lists the average appearances per year and Figure 1 outlines the annual frequencies of the Roles' appearance corrected for the number of functions, and their respective trends.

Role 3: Maintain and improve professional performance was represented most frequently in all years except three, with the highest peak in 2018. Role 2: Provide effective medication therapy management was the second most represented except for 2019, when it was the least represented Role, and in 2009, where it was the most represented Role. Roles 4: Contribute to improve effectiveness of the health-care system and public health and Role 1: Prepare, obtain, store, secure, distribute, administer, dispense and dispose of medical products were represented steadily but with lower frequencies. Looking at the trends, all Roles demonstrated an upward trend. Role 4: Contribute to improve effectiveness of the health-care system and public health demonstrated the highest average annual change (6.3%), followed by Role 3 (5.0%). For Role 1 and Role 2 the annual increase was 2.4% and 2.3% respectively.

Table 1. Keywords framework based on Good Pharmacy Practice standards

Keywords framework based on GPP			
Role characterised by keyword	**Keywords including synonyms and related words**	**Search terms used**	**Average number of appearances per year**
Role 1. Prepare, obtain, store, secure, distribute, administer, dispense and dispose of medical products.			
Function 1A: Prepare extemporaneous medicine preparations and medical products			**8**
Compound	compounding	compound*; extemporaneous	4
(Ensure) quality of medicines'	quality of medicines	quality*	16
Prepare (drug) formulation'	(drug) formulation	formulat* (ion)	3
Function 1B: Obtain, store and secure medicine preparations and medical products			**7**
Ensure access (to medicines)	access (to medicines)	access*	9
Store medicines properly / ensure proper storage (conditions)	storage (conditions); stability (of medicines)	stor*; stabili*	1
Procure (medicines)	procurement (of medicines)	procure*	1
Select (medicines)'	selection (of medicines)	select*	1
Manage shortage (of medicines)	shortage; stock-out	shortage; stock*	4
Manage controlled substances	controlled substances; opioid (medicines)	control*; opioid*	1
Prevent substandard and falsified medicines	substandard and falsified (medicines); substandard (medicines); substandard/spurious/ falsely-labelled/falsified/counterfeit (medicines); SF (medicines); SSFFC (medicines) fake (medicines); adulterated (medicines) unlicensed (medicines); counterfeit	substandard and falsified; substandard; falsif*; spurious; SF; SSFFC; fake; adulterate*; unlicensed; counterfeit*	10

Table 1. (continued)

Keywords framework based on GPP			
Role characterised by keyword	**Keywords including synonyms and related words**	**Search terms used**	**Average number of appearances per year**
Ensure medication / patient safety / safety of medicines'	(safeguarding) safety (of medicines); patient safety; reporting (errors)	safe*; safety*; patient safety; report*	29
Function 1C: Distribute medicine preparations and medical products			**8**
Supply (medicines)	supply (of medicines); distribution (of medicines)	supply*; distrib*	12
Supply essential medicines	essential medicines	essential*	2
Ensure disaster or pandemic (preparedness)	disaster (response); emergency (response/ preparedness); humanitarian (environment)	disast*; emergency; humanit*	14
Supply new medicines	new medicines (& drugs & therapies)	new*	4
Monitor adverse events and safety issues	reporting adverse events; pharmacovigilance	report*; vigilan*	8
Function 1D: Administration of medicines, vaccines and other injectable medications			**2**
Administer (medicines)	administration (of medicines)	admin*	2
Immunise / Vaccinate	Immunisation; Vaccination	vaccinat*; immuni*	5
Participate in directly observed therapy (DOT) programmes	Directly observed therapy (DOT) programmes	directly observed therapy (DOT)	0
Manage infectious diseases'	Infectious / communicable diseases (management)	infectio*; communicable	3

Table 1. (continued)

Keywords framework based on GPP			
Role characterised by keyword	**Keywords including synonyms and related words**	**Search terms used**	**Average number of appearances per year**
Function 1E: Dispensing of medical products			**2**
Dispense (medical products)	dispensing (practices)	dispens*	5
Counsel'	counselling	counsel*	3
Document / assure documentation	documentation (practices)	documentation	1
Evaluate prescription (of medicines)	prescription (of medicines)	prescription	1
Evaluate electronic prescription (of medicines)'	electronic prescription (of medicines); e-Health	e* -prescription; eHealth; e-Health	1
Perform generic substitution	generic substitution	generic*	0
Ensure (patient / consumer) confidentiality	patient data; (patient or consumer) confidentiality	confidential*; data*	4
Function 1F: Dispose of medicine preparations and medical products			**3**
Dispose (medicines)	(medicines) disposal; (medicines) waste (disposal); environmental impact	dispos*; wast*; environment*	6
Monitor inventory	inventory	inventory	0
Role 2. Provide effective medication therapy management			
Function 2A: Assess patient health status and needs			**2**
Assess health and needs (of patient or consumer)	(individual) (patient or consumer) assessment (of health and needs)	assess*	1

Table 1. (continued)

Keywords framework based on GPP			
Role characterised by keyword	**Keywords including synonyms and related words**	**Search terms used**	**Average number of appearances per year**
Use Electronic Patient Health Record (for health assessment)'	Electronic Patient Health Record	Electronic Patient Health Record	1
Assess health literacy	(health) literacy (assessment)	litera*	4
Function 2B: Manage patient medication therapy			**8**
Assure rational use (of medicines)	responsible use of medicines; rational use of medicines; appropriate use of medicines; prudent use of medicines; quality use of medicines; cost-effective use of medicines	responsible use; rational use; appropriate use; prudent use; quality use; cost-effective use*	4
Assure cost-effectiveness (of medicines)	Pharmacoeconomics; pricing (of medicines); cost of medicines; cost of care	economic*; pric*; cost*; cost*	14
Observe treatment guidelines	treatment guidelines; therapeutic guidelines	treatment guid*; therapeutic guid*	1
Select appropriate medication dosage	(medicine) dosage; individualised therapy; personalised therapy; drug delivery systems; drug absorption; bioavailability/ bioequivalence; pharmacokinetics and pharmacodynamics (PK/PD)	dosage*; personalised therapy; individualised therapy; (drug) delivery; (drug) absor*; bioavailab*; *kinetic*	21
Coordinate medication therapy management	Medication/Drug Therapy Management; MTM	* therapy management; MTM	1
Monitor (therapy)	(therapy) monitoring	monitor* (therapy)	1
Improve adherence'	adherence; compliance	adher*; complian*	17

Table 1. (continued)

Keywords framework based on GPP			
Role characterised by keyword	**Keywords including synonyms and related words**	**Search terms used**	**Average number of appearances per year**
Ensure continuity of care	continuity of care; transition of care across healthcare system; transfer (of care); transfer (of information); (patient) referral (to other healthcare professional);	continuity (of care) transit* (of care) transfer* (of care) transfer* (of information) referral + refer* (context of referring patients)	1
Manage noncommunicable diseases'	noncommunicable diseases (management); NCDs; chronic (diseases management)	non-communicable*; non communicable*; noncommunicable*; NCD*; chronic*	4
Function 2C: Monitor patient progress and outcomes			**14**
Monitor outcomes	outcomes monitoring	outcome	22
Assess drug utilisation'	drug utilisation	utili*	1
Consider patient diagnosis'	patient diagnosis	diagnos*	5
Function 2D: Provide information about medicines and health-related issues			**13**
Role characterised by keyword	**Keywords including synonyms and related words**	**Search terms used**	
Provide information (medicine / health related)	(medicine / health) information	info* (medicine / health)	30
Empower (patient or consumer)	(patient or consumer) empowerment; consultation (with patient or consumer)	empower*; consult*	3
Reduce antimicrobial resistance	antimicrobial (or antibiotic) resistance	resistan*	6

Table 1. (continued)

Keywords framework based on GPP			
Role characterised by keyword	**Keywords including synonyms and related words**	**Search terms used**	**Average number of appearances per year**
Role 3: Maintain and improve professional performance			
Function 3A: Plan and implement continuing professional development strategies to improve current and future performance			**15**
Adopt continuing professional development strategies	continuing education; continuing professional development	educat*; Continuing Professional Development	10
Implement workforce development strategies'	workforce (development) human resources (development)	workforce human resource*	13
Update knowledge and skills about complementary therapies	complementary therapies; alternative therapies; herbal therapies; traditional Chinese therapies; supplements; homeopathy	complementary; alternative*; herbal*; Chinese* (therapies); supplement*; homeopath*	10
Update knowledge on new technologies	new technologies; biotechnology; digital technology	technolog*; biotech*; digital*	25
Role 4: Contribute to improve effectiveness of the health-care system and public health			
Function 4A: Disseminate evaluated information about medicines and various aspects of self-care			**5**
Contribute to improved effectiveness of the health system	health system (strengthening)	health system*	3
Contribute to improved public health	public health	public health*	10
Improve self-care	self-care; self care; selfcare	self-care; self care; selfcare	1
Assure evidence-based care	evidence-based (care)	evidence-based	4

Table 1. (continued)

Keywords framework based on GPP			
Role characterised by keyword	**Keywords including synonyms and related words**	**Search terms used**	**Average number of appearances per year**
Provide care to patient populations with wide range of age groups	age population; children; paediatric; elderly (therapy)	age; child*; paediatr; * elderly	9
Provide care to patient populations with wide range of health literacy levels	health literacy (improve)	litera*	4
Advise on Internet-obtained information	Internet; social media	Internet; social media	4
Function 4B: Engage in preventive care activities and services			**2**
Engage in health promotion	health promotion; (disease) prevention; preventive care	health promot*; preventi*; preventive care	5
Engage in harm reduction'	harm reduction; drug abuse	harm*; abus*	0
Provide smoking cessation	smoking cessation	smok*	1
Provide point-of-care testing	point-of-care testing	point-of-care*	1
Provide screening	screening	screen*	2
Function 4C: Comply with national professional obligations, guidelines and legislations			**9**
Comply with the provisions of a national standards of ethics	code of ethics; ethics; oath	ethic*; ethic*; oath	8
Comply with accreditation standards'	accreditation standards	accredit*	1
Comply with regulation / standards'	regulation; harmonisation; Pharmacopeia	regulat*; harmoni*; harmoni*	19

Table 1. (continued)

Keywords framework based on GPP			
Role characterised by keyword	**Keywords including synonyms and related words**	**Search terms used**	**Average number of appearances per year**
Function 4D: Advocate and support national policies that promote improved health outcomes			**8**
Advocate (for improved health outcomes)	advocacy	advoca*	4
Support healthcare policies	healthcare policies	polic*; policy-makers + policy makers	14
Collaborate with other health care professionals	interprofessional collaboration	collaborat*	13
Ensure integrated care[†]	integrated care	integrated care	1

[†] The explicit wording under respective GPP role was adjusted

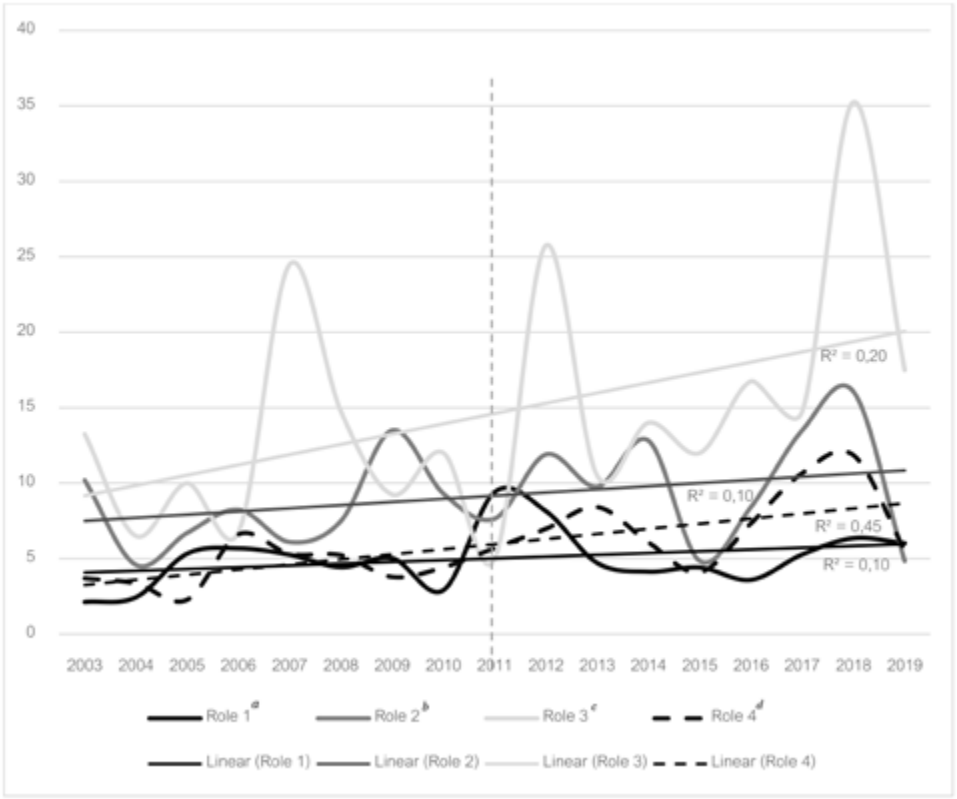

Figure 1. Good Pharmacy Practice (GPP) roles represented in annual congresses

[a] Corresponding to n=6 Functions

[b] Corresponding to n=4 Functions

[c] Corresponding to n=1 Functions

[d] Corresponding to n=4 Functions

Caption: Role 1: Prepare, obtain, store, secure, distribute, administer, dispense and dispose of medical products; Role 2: Provide effective medication therapy management; Role 3: Maintain and improve professional performance; and, Role 4: Contribute to improve effectiveness of the health-care system and public health.

Figure 2 depicts the relative distributions of the four roles over the years. The percentage contribution of each of the roles shows a rather homogeneous distribution over the years, with dominance of Role 3 in all year except one year 2009.

Looking at individual keywords, all the keywords (n=70, 100%) appeared in at least one congress, while most of the keywords (n=61, 87%) appeared in each of the congresses. When looking for upward trends, a theme that clearly emerged is responsibilities related to health promotion and preventive activities and services, with a spike after 2015 (Role 4), see Figure 3. Another example of a theme with upward trend is collaboration with other health care professionals, a theme under Role 4 that clearly emerged after 2005, with major spikes in 2008, 2010 and 2013.

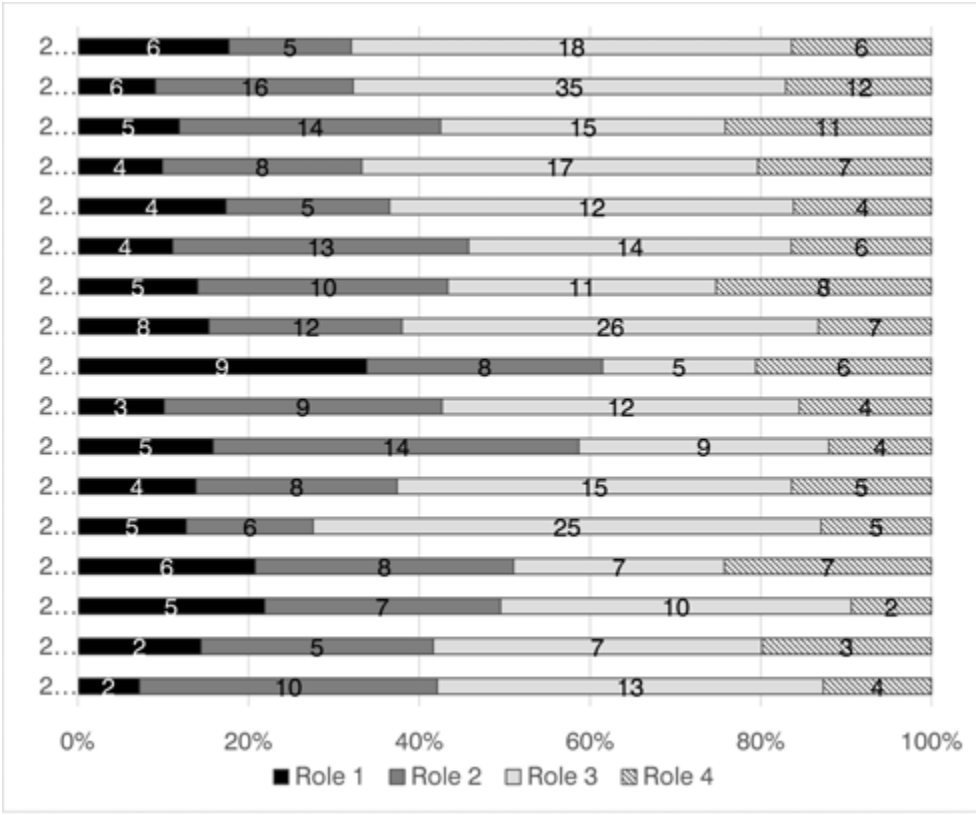

Figure 2. Roles' relative contribution (%) to the congress programme

On the other hand, there were keywords that diminished in frequency. One downward trend identified was for keywords related to preventing substandard and falsified (SF) medicines (average = 10, SD = 11.1, highest peak n=37 in 2006, Role 1), see Figure 4. Downward trends were further identified in keywords related to reducing antimicrobial resistance (average = 6, SD = 6.0, highest peak n=22 in 2010, Role 2) and activities improving self-care (average = 1, SD = 2.8, highest peak n=12 in 2007, Role 4).

There were also keywords that were mentioned in certain periods more than in others with no conclusive upwards or downwards pattens. For example, compounding (Role 1) appeared on average 4 times per year (SD=6.6) with peaks in 2009 (n=21) and in 2013 (n=20), with no clear time trend.

Discussion

This longitudinal study aimed at creating a historical overview of trends in the appearance of the different pharmacy practice roles, as defined by the GPP standards, in the programme of the past 17 world pharmacy congresses (2003-2019). The study found that all the four roles were already being reflected in all programmes in the decade preceding their publication (2011), and

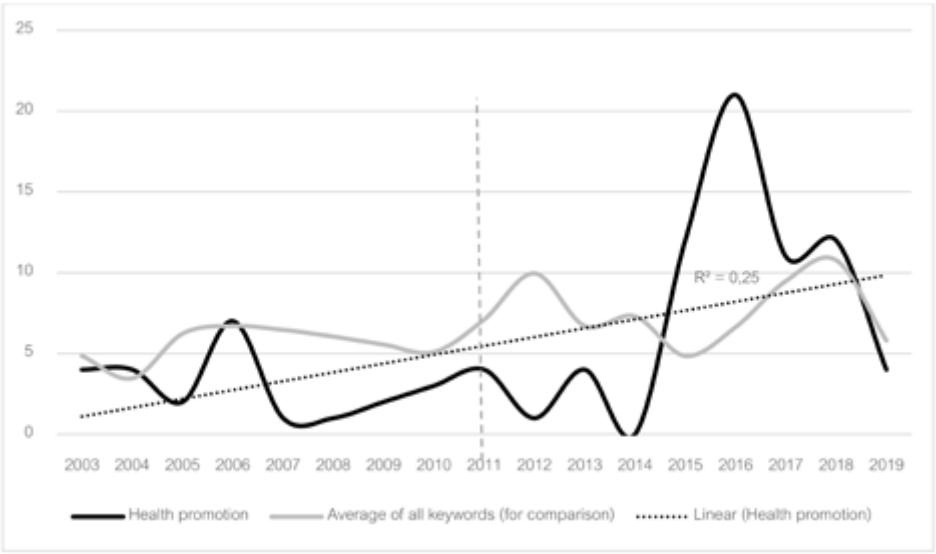

Figure 3. Appearance of keywords related to health promotion by pharmacist

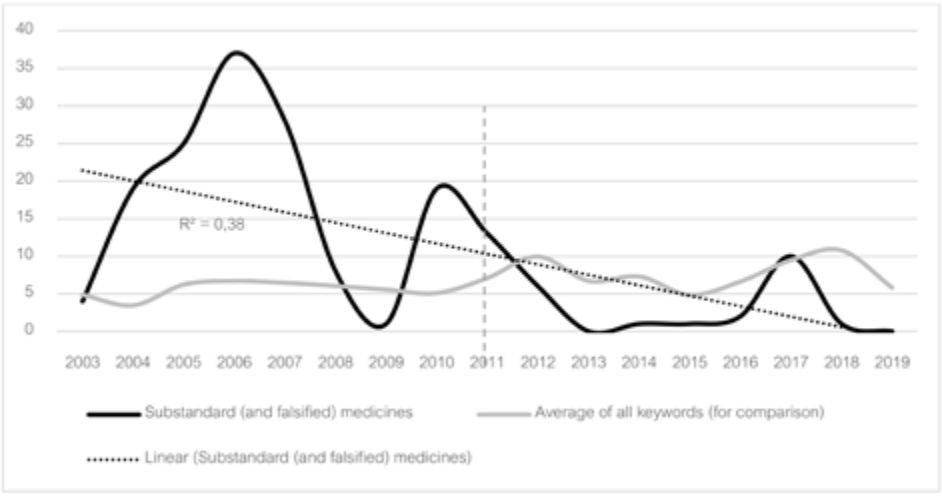

Figure 4. Appearance of keywords related to minimising substandard and falsified (SF) medicines

also in the decade after their publication. This is pointing out that these Roles were relevant for the profession already before the GPP were published and stayed relevant even long after their publication. They were nonetheless not equally covered in the selected period, with Role 3 (Maintain and improve professional performance) being the most frequently represented. Under this Role, pharmacists plan and implement continuing professional development strategies to improve their

current and future performance. As society demands better, innovative care, pharmacists need to keep themselves abreast on current events and attend formal lifelong learning systems (e.g. continuing education) to sustain their competences and ensure the provision of quality patient care.[3] The aim of the world congress is also to fulfil this role. Moreover, in 2016, education has been formalised as an important part of pharmacy, complementing practice and science.[7,9] Many discussions have preceded this formalisation as well as the important role of education in facilitating the full implementation of clinical pharmacy.[10,11]

Role 3 was also the role with a clear upward time trend, together with Role 4: Contribute to improve effectiveness of the health-care system and public health. For example, under this role pharmacists are involved in public health through delivery of health prevention programmes. Both roles 3 and 4 position pharmacy in a vital place in the health system, where practice is underpinned by the willingness to increasingly provide patient-centred services. Such positioning is accompanied by discussions focused on embracing innovative services by pharmacists – by education and through public health advocacy,[12-14] corresponding back to Roles 3 and 4. Although high-income countries are debating futuristic approaches, clinical skills, and expanding pharmacy services for these Roles, a large majority of low-to-middle-income countries still lag behind in strengthening pharmacy practice.[15,16] In comparison, product-focused Role 1 may not have sparked as many discussions, given it is considered business-as-usual in dispensing and administering of medicines. Indeed, the upward trend in Role 1 and 2 was much milder.

The official publication of GPP may be seen as an important milestone, when the profession agreed on the global standards both internally within pharmacy (from FIP's side) and externally within health care (from WHO's side).[1] What we observed is that after the publication, in the immediate congress that followed in 2012, there was a sharp increase in the frequency of appearance of Role 3, and a mild increase in Role 2 and Role 4, while Role 1 decreased. This is similar to the observed overall long-term trends described earlier, and in line with the notion that patient-centred roles sparked more discussion than the product-focused role.

Individual keywords

One of the strong examples of an increase of appearance of new services that bring pharmacists closer to the patient is health promotion (Role 4). These are activities by pharmacists related to disease prevention and preventive care. Health promotion itself as a concept was defined in 1998,[17] however only in 2016 it was linked to the UN Sustainable Development Goals.[18] Pharmacists were already advocating for recognition at global level ahead of this milestone[19-21] and the frequent appearance of this theme in 2015 was related to the key joint session with the World Health Organization (WHO) on health promotion activities by pharmacists. These were later highlighted by the strengthening of the position of pharmacists in the global primary health care agenda[22-24] as well as in the congress programmes.

Another example is collaboration with other clinical care professionals (Role 4), a theme that clearly emerged after 2005, with major spikes in 2008, 2010 and 2013. The spike in year 2010 coincides with the WHO's global action framework[25] in this area, further supported by the 2013 joint

statement of the World Health Professions Alliance (WHPA) strengthening the collaboration of dentists, nurses, physical therapists, physicians and pharmacists.[26] Literature was long criticising the siloed approach, that is now shifting towards improved collaboration in the last decade.[27-29]

Examples above illustrate that pharmaceutical practice / care as a concept has moved the pharmacy profession from primarily focusing on the product (the medicine itself) to the clinical area of patient's therapy and how it should be optimised for the individual patient.[9] Pharmacists irrespective of their work setting interact and provide direct patient care as a clinical service, that has established its role within the society and the healthcare system.[30] On the other hand, traditional roles centred around the product such as compounding were sporadically featured, as a rather closed topic on the international agenda. A further research could examine the reasons for dominance of each of the Roles, e.g. through qualitative studies linking the findings of this study with overall trends in pharmacy.

Some of the topics that were prominently featured in the past diminished in recent years. Examples include the minimising of substandard and falsified medicines, reducing antimicrobial resistance or promoting self-care. They did not appear at the congresses but are discussed more at strategic level – led by international organisations (e.g., in collaboration with global bodies, such as WHO). This may be caused by the fact that in order to progress on these different roles (e.g., in minimising AMR), more discussion is needed both within pharmacy but also with a broader set of players in the health care system.[31-33] Some of these topics may then re-appear at the congress in the future or become institutionalised. This analysis may help the balancing of the agenda and programme planning and feed into strategic planning.

Our finding that all the four GPP roles were being well reflected in the programmes of the FIP annual congresses should not be taken as a surprise. The GPP roles are the heart of the Federation, as the annual congresses are. Both can be seen as two sides of the same coin. What this study adds and makes interesting is two-fold. First, the GGP roles, both literary and in terms of context have been already covered by the FIP annual congresses (long) before 2011, when the GGP roles were formally adopted. So FIP annual congress may have acted as nurseries, as sandboxes so to say, for the ideas, directions, and philosophy for the GPPs under development. Second, the prominent appearance of the roles related to improving professional performance and positioning pharmacy, i.e., most non-technical roles, are in harmony with the trend that the FIP annual congresses have moved toward educational platforms for dialogue and conversation, while the technical topics in pharmacy are increasingly covered by expert meetings.

Limitations

There are several limitations to note in this study. Firstly, the final keywords selection and selection of synonyms and equivalent and/or related words representing GPP framework was based on authors' judgement, although validated by teamwork of two researchers. In addition, the study did not intend to find keywords covered in the programmes that fell outside of the GPP standards. Secondly, the FIP congresses programmes, while taking into consideration the input from its global membership and being selected by an independent programme committee, may not thoroughly

cover all topics pertinent for pharmacy practice. While the main congress audience is pharmacy practitioners, smaller but considerable part of the audience is composed of pharmacists working in pharmaceutical science, academia, or industry. Therefore, choosing what will feature on the agenda may lead to exclusion of certain topics. In addition, the study focused solely on pharmacy practice related topics and excluded pharmaceutical sciences topics while these could also have been discussed at the congress, however outside of the scope of this study. Similarly, some activities may not yet be described by the GPP and therefore were potentially not captured by this study, given that pharmacy practice continues expanding in different countries or jurisdictions all over the world.[2,6,30,34] For example, in some jurisdictions pharmacists assume the authority to prescribe medications for minor ailments in defined situations[35] or they perform de-prescribing (e.g. in elderly patients with multiple treatments).[36] While examples above do not seem to be robust enough to form another Role as such, they could be included under some of the existing ones. Lastly, while we observed some changes in the frequency of appearance of the different GPP roles before and after their official publication in 2011, a more detailed quantitative analysis is not possible given uncertainty around the real length of the consultation process. Despite these limitations, the methods provided a rich depth of information and promoted trustworthiness of findings and clear and consistent themes emerged.

Conclusions

All the four GPP roles were being reflected in the FIP annual congress programmes, both in the decade preceding their publication and in the decade after their publication. The more pronounced dominance toward the roles related to improving professional performance and positioning pharmacy are in line with the trend that the more technical topics in pharmacy are increasingly covered by specialised meetings and that the FIP annual congresses have moved toward more general, scholarly platforms for dialogue and conversation.

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3

Needs-driven capacity building: an intervention in the area of substandard and falsified medical products

3.1 Identifying the teaching content on substandard and falsified medical products in global pharmacy education as critical public health issue

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Abstract

Aim

To gain insight into the education about substandard and falsified (SF) medical products.

Method

A digital survey was sent to 173 different schools of pharmacy around the world.

Results

The response rate was 32% (55 responses, 37 countries). Most schools taught about SF medical products as a stand-alone course or as part of another course or module (67%), whereas 33% did not teach about the subject. The main focus of teaching was on detection (21%) and prevention (21%) of SF medical products, while reporting was taught the least (12%), indicating a knowledge gap in that area. A key barrier to introducing a new course that could close the gaps was insufficient time in pharmacy curriculum (n=33; 60%), while availability of ready-to-adopt course materials was considered as a helpful enabler.

Conclusion

These insights can improve the understanding on what is already being taught on SF medical products, where the gaps are and inform the curriculum needed globally.

Introduction

Substandard and falsified (SF) medical products are a substantial and understudied problem most prevalent in low- and middle-income countries.[1,2] According to the definition of the World Health Organization (WHO), substandard medical products fail to meet either national or international quality standards and/or specifications. Falsified medical products mispresent deliberately or fraudulently their identity, composition, or source.[3] The importance of addressing the potential danger of SF medical products is confirmed by the WHO's mandate in tackling SF medical products[4] with prioritisation of eight high-level activities to counter SF medical products. These include improvement and focus on education and training.[5] Furthermore, WHO developed a prevention-detection-response strategy.[6] With regards to prevention of SF medical products, the desired outcome is improved product quality (e.g. strengthened oversight by regulators, improved manufacturing and supply chain integrity) and improved education and awareness. This requires the full involvement of the healthcare professionals working the closest with medical products and patients: the pharmacists.[7,8]

Pharmacists are crucial for not only ensuring pharmaceutical care and proper use and administration of medicines, but also are essential in assuring the integrity of the supply chain by taking up different roles from manufacturing to the safe procurement of medical products.[7,8] In addition, they play a key role in assuring the safety and quality of medical products, including prevention and detection of SF medical products, and in maintaining a reliable backward supply chain, e.g. product withdrawal and batch recall.[9] In many countries, pharmacists also have important roles in medical regulatory authorities,[10] e.g. approval of (new) medicines, inspection of production facilities or fulfilling the role of a Qualified Person (QP).[9]

Initial training and education of pharmacists vary by country, region and institution, but usually include a number of aspects related to quality in the production and safe use of medicines.[7] Nevertheless, the United States Accreditation Council for Pharmacy Education pharmacy program of 2016 does not mention substandard or falsified medicines in their curriculum.[11] Moreover, a 2018 review of national pharmacy curricula in eight low- to middle-income countries (six Sub-Saharan African and two Asian countries) found only one country teaching about SF medical products.[12] Another study in the United Kingdom found that training on SF medical products was not included in the core pharmacy curriculum but was only provided as an elective global health module.[13]

Globally, pharmacy educators need to adapt to new practice paradigms and stay ahead of the practice curve by providing students with the right knowledge and experience for the challenges they will be faced with as professionals.[14,15] Therefore, the aim of this study was to gain a global perspective of the current education of undergraduate pharmacy students (i.e. those finishing with a pharmacy diploma, typically ending with a Master or Doctor of pharmacy degree) on SF medical products and the approach universities take towards it. This insight will improve the understanding of what is already being taught on SF medical products and where the gaps are. In addition, this study tried to identify possible barriers and enablers for introducing new modules on this subject into the pharmacy curriculum.

Methods

Setting and participants

An online survey was sent to the director or head of 173 schools of pharmacy all over the world listed in the FIP Academic Institutional Members database. The authors have selected this international database as it collates active schools of pharmacy and pharmaceutical sciences participating in the global arena activities shaping the future of pharmacy education and practice. For demographic analysis, countries were indexed in low-, middle- and high-income countries using the World Bank list of economies.[16] Countries were additionally divided into different regions based on WHO 2020 region indication.[17] Data were collected in November and December 2020. The authors compared the respondents to the original group surveyed.

Data collection

The survey was created using LimeSurvey® software and consisted of 27 mainly single and multiple-choice questions, divided into four sections. The first section of five questions covered general information about the participants (e.g. name, position, country) and their institution (undergraduate programme offered, number of academic years).

The second section of the survey concerned the courses offered about SF medical products. This section asked whether the school of pharmacy provides any education and, in case of a positive response, whether education is offered as a standalone course on SF medical products or if it is part of another module/course. The next nine questions concerned: if the subject SF medical products are being taught as a mandatory or elective course and/or through an optional certificate programme, what specific course(s) and/or lecture(s) are given about SF medical products, in which study year(s) are these courses/lectures given, what are the total hours that students spend on SF medical products (including all mandatory and elective hours), what prerequisite courses are required for students to take prior to the SF medical products course; as well as questions about course materials, classroom settings, evaluation methods of students' assessment and the academic background of the educators teaching the courses.

The third section of the survey concerned education content about SF medical products. Questions 16 to 23 concerned the specific topics covered on SF medical products in the pharmacy curriculum. The topics were selected based on the recently developed curriculum guide by the FIP in collaboration with the WHO, supported by the respective FIP competency framework.[8] The FIP competency framework maps to six teaching modules that deliver the competencies defined.

Next, there was a multiple-choice question about competencies linked to learning outcomes of SF medical products related courses in their pharmacy school (e.g. leadership, professionalism and social responsibility in responding to SF medical products, application of the scientific method in managing and investigating SF medical products) and lastly an open question concerning specification of materials used (e.g. key case studies, textbooks) for teaching about SF medicine topics corresponding to Modules A-F mentioned above.

The final survey section consisted of four questions with regard to potentially changing the current pharmacy curriculum of the participant's institution and the willingness to introduce

a standalone course on SF medical products newly developed by the FIP in collaboration with the WHO. Two questions were multiple-choice questions about who approves the introduction of a new module into the current curriculum and what the possible barriers for implementation are. The last two questions used a quantitative five-point Likert scale concerning the likelihood of introducing a standalone module on SF medical products and the competencies of students with regard to detecting and action if exposed to SF medical products.

Data analysis

Quantitative data were analysed using Microsoft Excel 2013, and descriptive statistics were calculated. Open questions were analysed on keywords and key terms.

The number of total hours of students' education about SF medical products was quantified into a discrete number of total hours and divided into three groups indicating few (<5 hours), moderate (5-15 hours) and high (>15 hours) number of hours. In cases where a range was given (e.g. 10-15 hours), the higher range number was taken. Answers in the form of "x" number of credits or "y" hours per calendar period were excluded from the results.

In terms of the content covered concerning SF medical products, the responses were averaged out to find out which module was being taught the most. Answers "None of the above" were excluded. Results for each module were presented in relation to other modules in order to improve the understanding of what is already being taught on SF medical products, where the gaps are and inform the curriculum needed globally.

The two five-point Likert scale questions were analysed, describing frequencies. Each point was converted into a linear distribution with an even interval of one to five: one = strongly disagree/ not at all and five = strongly agree/very likely. The mean and standard deviation were calculated to examine whether the items contributed equally to the total scale score.

Results

Demographics

After three follow-up reminders, a total of 55 participants, representing faculties from 37 countries, completed the questionnaire (response rate of 32%). Respondents came from middle- and high-income countries (n=29, (53%) and n=26, (47%) respectively). The majority of participants came from the European Region (EUR, n=16, 29%), followed by the Eastern Mediterranean Region (EMR, n=11, 20%), and the Western Pacific Region (WPR, n=11, 20%) (Table 1). This corresponds to the original group surveyed from the FIP AIM database (n=173), with majority of schools in middle- (n=72, 42%) and high-income (n=100, 58%) countries; and regionally spread representation: the Region of the Americas (AMR, n=52, 30%); the European Region (EUR, n=35, 20%), the Western Pacific Region (WPR, n=29, 17%), the Eastern Mediterranean Region (EMR, n=26, 15%), the South-East Asia Region (SEAR, n=18, 10%) and the African Region (AFR, n=13, 8%).

Most institutions provided undergraduate programmes with a bachelor in pharmacy (B.Pharm, n=38, 69%), followed by a master of pharmacy (M.Pharm, n=28, 51%), doctor(ate) of pharmacy (PharmD, n=18, 33%) and/or other degree (n=5, 9%, e.g. Bachelor or Doctoral Pharmaceutical

Table 1. WHO regions participants

WHO region	n	(%)
AFR	5	9%
EMR	11	20%
EUR	16	29%
AMR	7	13%
SEAR	5	9%
WPR	11	20%
Total	**55**	**100%**

Abbreviations: AFR = African Region; EMR = Eastern Mediterranean Region; EUR = European Region; AMR = Region of the Americas; SEAR = South-East Asia Region; WPR = Western Pacific Region

Sciences). Furthermore, most undergraduate pharmacy programmes offered lasted four (n=21, 38%) or five years (n=22, 40%), whereas 11% (n=6) of programmes had a duration of six years and 7% (n=4) more than six years.

Course information

Of all universities, 33% (n=18) did not teach about SF medical products specifically. A further 37 (67%) schools taught about SF medical products as part of another course or module (n=35) or as a standalone course (n=2). Most of them taught about SF medical products as a mandatory course (n=32, 86%) and some as an elective course (n=6, 16%, three institutions provide both elective as mandatory courses). Two respondents did not know the course status for their university (5%). None of the schools offered an optional certificate programme on SF medical products. Supplementary Table S1 shows the results of the analysis of open questions based on key terms used, i.e. lists the specific course(s) and/or lecture(s) given about SF medical products provided by participants.

Moreover, a majority of institutions tended to teach SF medical products in the middle-later years (Figure 1).

As for the total number of hours students spent on SF medical product education, 33 institutions replied. 14 (42%) universities provided less than five hours of education, eight (24%) between 5-15 hours and 11 (33%) more than 15 hours. Regarding prerequisites required for students prior to taking the course on SF medical products, the focus was on analytical chemistry (qualitative and quantitative analysis, n=26, 70%) followed by pharmaceutical chemistry (n=22, 60%) (Figure 2).

With regard to course methods used for education about SF medical products, traditional methods (e.g. lectures, seminars, tutorials) were the most prevalent (n=34, 92%) followed by 46% (n=17) of institutions using non-traditional methods like problem-, team- and case-based learning. A further three schools indicated other means: field visits (n=1, 3%) and laboratory practices (n=2; 5%).

Almost all universities taught in a classroom setting (n=36, 97%). In addition, 11 universities taught in a practice setting as well (e.g. hospital, 30%) and 16 by virtual means (before COVID-19, n=16, 43%), whereas four universities indicated other means: laboratory practicals (n=3, 8%) and, placement in industry and regulatory bodies (n=1, 3%).

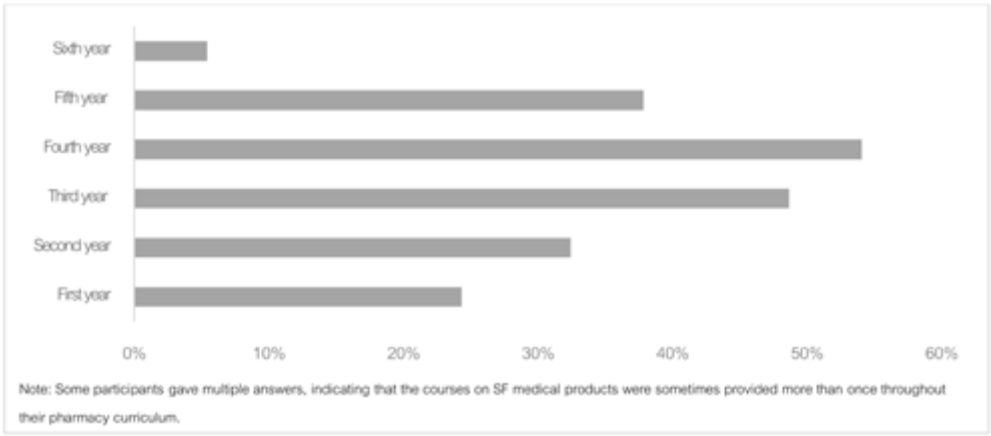

Figure 1. Overview of which study year(s) courses/lectures about SF medical products are provided (multiple answers possible, %, n=37)

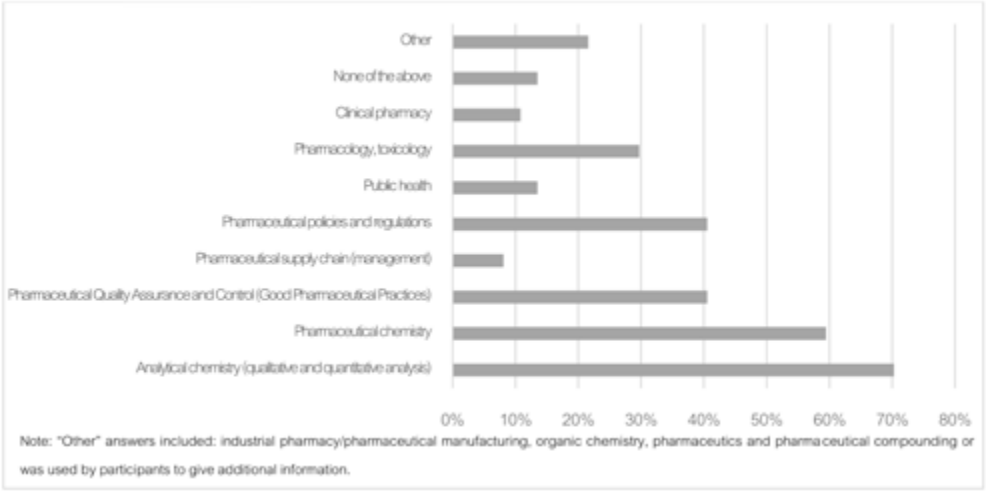

Figure 2. Courses required for students to take prior to taking the courses on SF medical products (multiple answers possible, %, n=37)

Evaluations used to assess students' education about SF medical products were mostly done as a written exam (n=36, 97%) or laboratory examination (n=17, 46%). Other forms of evaluations were oral exam (n=9, 24%), essay writing (n=7, 19%), testimonials from practice (n= 5, 14%), role play (n=4, 11%) and portfolio (n=3, 8%).

Moreover, the educational background of educators teaching about SF medical products were mainly university-employed pharmacists with regular or minimal patient contact (respectively n=22, 59%; n=21, 57%), followed by practising pharmacists (n=14, 38%), non-pharmacists (n=6, 16%) and non-

pharmacy medically qualified staff (n=5, 14%). Furthermore, three universities (8%) indicated other: background in industrial pharmacy (n=1, 3%), chemistry (n=1, 3%) and college faculty (n=1, 3%).

Materials used (e.g. key case studies, textbooks or resources) to teach about the SF medical products are listed in Supplementary Table S2.

Course content

With regard to the total of SF medical education, each of the total of six modules were (partly) covered by the responding programmes combined. Table 2 shows the contribution of each module to this total. Module C (prevention) and D (detection) were relatively to other modules being taught the most (both 21%), followed by Module A (introduction to SF medical products, 17%).

Each module contained questions about the subtopics taught concerning SF medical products. Under Module A (introduction to SF medical products), most schools taught about legislation and regulation protecting the integrity of the supply chain (e.g. quality assurance, surveillance), while 2% (n=5) did not teach about this subtopic. For Module B (identification), most schools taught about the characteristics of medical products at risk, risks of online and illegal markets and the importance of good pharmaceutical care, while 3% (n=6) did not teach about identification of SF medical products. For Module C (prevention), most schools taught about the principles of pharmaceutical Quality Assurance (e.g. good practice guidelines), while 4% (n=7) did not teach about this subtopic. For Module D (detection), Quality Control (e.g. pharmacopeia, compliance with regulatory requirements) was taught the most, while 3% (n=5) did not teach about this subtopic. For Module E (reporting), most schools taught about reporting incidences of SF medical products through national authorities, while 14% (n=15) did not teach about this subtopic. For Module F (intervention), most schools taught about recognising the effects of exposure to SF medical products (e.g. pharmacology, toxicology of (SF) medical products), while 13% (n=18) did not teach about this subtopic (Table 3).

The competencies that were linked most to the learning outcomes of SF medical products were appropriate communications to educate, build, report and engage healthcare professionals (n=31, 56%) and patients concerning SF medical product incidents (n=29, 53%) (Figure 3).

Table 2. Modules A-F covered

Modules	Percentage
Module A	17%
Module B	16%
Module C	21%
Module D	21%
Module E	12%
Module F	13%

Module A = general introduction to SF medical products; Module B = identification of medical products at risk; Module C = prevention of SF medical products (from entering the supply chain); Module D = detection strategies for SF medical products; Module E = reporting SF medical products; Module F = intervention after coming in contact with SF medical products. Answers "None of the above" were excluded.

Table 3. Number (and percentage) of schools teaching content of Modules A-F

Number (and percentage) of schools teaching content of Modules A-F	
Module A: introduction to SF medical products Proportion of all modules': 17%	Legislation and regulation protecting the integrity of the supply chain (e.g. quality assurance, surveillance) (n=38; 15%) Regulation of medical products (e.g. pharmacovigilance and drug inspection) (n=36, 15%) Internationally accepted terminology (e.g. substandard and falsified medical products vs counterfeit) and definitions (n=33, 13%) Health, social and economic consequences (n=32, 13%) Pharmaceutical policy (n=30, 12%) SF medical products contributing to antimicrobial resistance (AMR) (n=21, 8%) The history of incidences of SF medical products (n=20, 8%) Advocacy at national, regional, and international levels (n=17, 7%) Key stakeholders in the fight and campaign against SF medical products and their roles and activities (n=16, 6%) None of the above (n=5, 2%)
Module B: identification Proportion of all modules': 16%	Characteristics of medical products that are most at risk of being substandard and/or falsified (e.g. expensive/lifestyle medicines) (n=31, 17%) Risks of online market & illegal online pharmacies (n=31, 17%) The importance of good pharmaceutical care (n=31, 17%) Contributing factors (e.g. medicines shortages, weak legislation, ineffective data sharing) (n=25, 14%) Resources to find factual, reliable information on SF medical products (n=21, 12%) Extent of incidences and scale of the problem (e.g. through pharmacoepidemiology and investigating medicine use) (n=19, 11%) Drivers (e.g. socio-economic drivers) (n=14, 8%) None of the above (n=6, 3%)
Module C: prevention Proportion of all modules': 21%	Principles of pharmaceutical Quality Assurance (e.g. Good practice (GxP) guidelines) (n=40, 23%) Safe procurement principles (e.g. to ensure purchase of medicines with appropriate quality, pharmaceuticals complying with specifications) (n=34, 20%) Principles of safeguarding the pharmaceutical supply chain (e.g. pharmaceutical supply chain management, industrial pharmacy quality requirements) (n=34, 20%) Education of patients (e.g. opportunistic counselling on risks of obtaining medicines from unauthorised sources) (n=30, 17%) Education of the public (e.g. raising public awareness) (n=27, 16%) None of the above (n=7, 4%)
Module D: detection Proportion of all modules': 21%	Quality Control (e.g. pharmacopeia, compliance with regulatory requirements) (n=44, 26%) Pharmaceutical analysis and principles of chemical inspection of the medical product through laboratory testing (e.g. dissolution test, chromatography) (n=40, 24%) Pharmacovigilance (n=33, 19%)

Table 3. (continued)

Number (and percentage) of schools teaching content of Modules A-F	
	Principles of physical inspection (n=31, 18%) Detection tools and verification systems (e.g. medicines tracking, portable screening devices) (n=17, 10%) None of the above (n=5, 3%)
Module E: reporting Proportion of all modules': 12%	Reporting through national authorities (n=36, 33%) Reporting up the supply chain (e.g. performing batch recall) (n=22, 20%) None of the above (n=15, 14%) Principles and advantages of data collecting and sharing incidence of SF medical products (n=14, 13%) Reporting through international authorities (WHO Rapid Alert Form) (n=11, 10%) Importance of the development of reporting systems (e.g. smartphone applications) (n=11, 10%)
Module F: intervention Proportion of all modules': 13%	Recognising the effects of exposure to SF medical products (e.g. pharmacology, toxicology of (SF) medical products) (n=27, 19%) Counselling in case of exposure to SF medical products (n=22, 15%) Providing pharmaceutical care in case of the effects of exposure to SF medical products (n=21, 15%) Communication of information on incidence to colleagues, patients and public (n=21, 15%) Obtaining and documenting relevant patient medication history (n=18, 13%) None of the above (n=18, 13%) Referring to follow-up care (n=17, 12%)

Note: Modules are corresponding to the curriculum for pharmacy students on substandard and falsified medicines of the FIP[8] that contains six Modules (A-F) integrating trainings elements for pharmacists.

' Answers "None of the above" were excluded.

' For example, when a pharmacy institute taught about SF medical products, Module A would represent on average 16% of the subject being taught.

Barriers and enablers for introducing a new module in the pharmacy curriculum

Approval of the introduction of a new module in the existing pharmacy curriculum was for the most part done by the Head/Director of the institution (n=30, 55%), proceeded by a regulatory body (n=22, 40%), the Ministry of Health (n=3, 5%) or other (n=19, 35%), mainly curriculum committees or programme councils.

With regard to barriers for the implementation of a new module the most prevalent problem was not having sufficient space in their pharmacy curriculum (n=33, 60%) and lack of educator's time to deliver classes (n=17, 31%) (Figure 4).

Regarding enablers, most institutions (n=27, 50%) indicated that implementation of a new module would be most likely enabled by an existing course on SF medical products that is ready-to-adopt and integrated as part of an existing course (Table 4).

Most institutions agreed with the statement that their students were adequately equipped to detect and take action if exposed to substandard and falsified medical products after graduation. Furthermore, almost all of the institutions agreed with the statement that their institution was able

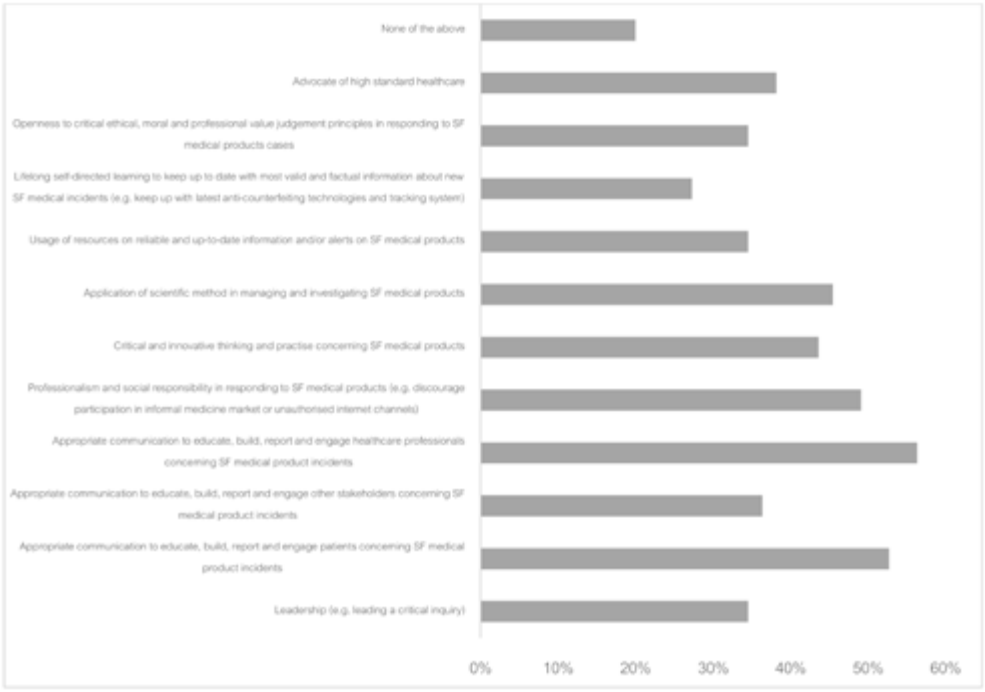

Figure 3. Competencies that are linked by participants to learning outcomes of SF medical product-related courses (multiple answers possible, %, n=55)

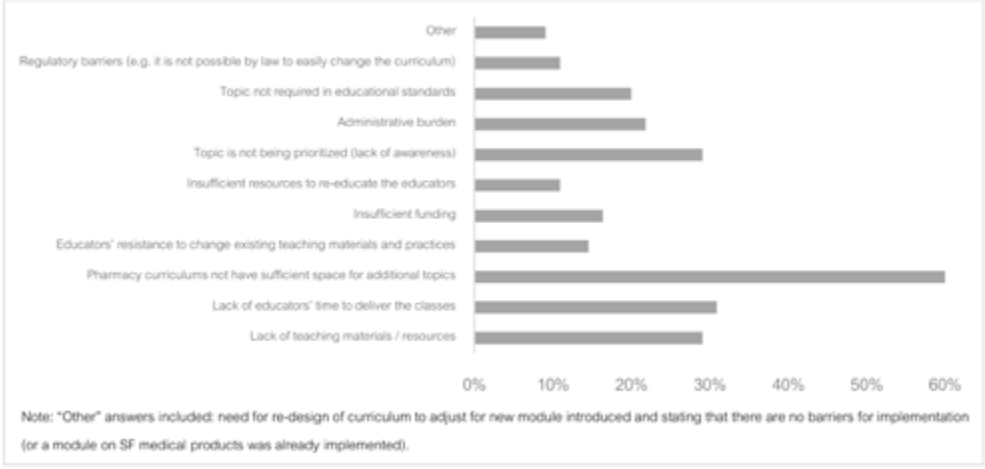

Figure 4. Barriers for implementation of a new module (multiple answers possible, %, n=55)

to readily identify and include new skills/competencies in the pharmacy curriculum as they emerge in practice (Table 5).

Discussion

This study was conducted to understand how and to what extent the topic of substandard or falsified (SF) medical products courses are taught in pharmacy educational institutions around the world. This study found that one out of three pharmacy schools does not offer any targeted education on SF medical products. Only two of the responding universities taught a standalone course on SF medical products, and a majority of schools taught about SF medical products as part of another course. For the institutions that do teach about SF medical products, the study found that the majority of schools tended to do this in the middle-later years. This can be due to the need for prerequisite courses for students enrolled in such courses. These were reported to be mostly analytical chemistry (qualitative and quantitative analysis), to understand the detection strategies and analytical tools that can be used for this purpose, as well as pharmaceutical chemistry and pharmaceutical quality assurance and control necessary to understand the issues related to substandard products. Pharmaceutical policies and regulations, as well as the basics of pharmacology and toxicology for the clinical understanding of impact are other important prerequisites for the SF

Table 4. Intentions of SF medical products course

Introduction as:	Mean (SD)[†]	Not at all, No. (%)	Not very likely, No. (%)	Neutral, No. (%)	Likely, No. (%)	Very likely, No. (%)
Stand-alone module[‡]	3.2 (1.3)	6 (11)	13 (24)	7 (13)	19 (35)	9 (17)
Part of an existing course[‡]	4.3 (0.9)	1 (2)	1 (2)	5 (9)	20 (37)	27 (50)

Abbreviations: SD = standard deviation, No. = numero, number

[†] Based on a five-point Likert Scale on which 1 = not at all and 5 = very likely

[‡] 54 participants answered

Table 5. Agreement with statements on student competencies and skills in practice

	Mean (SD)[†]	Strongly disagree, No. (%)	Disagree, No. (%)	Neutral, No. (%)	Agree, No. (%)	Strongly agree, No. (%)
My students are equipped with the competencies to detect and take action if exposed to substandard and falsified medicines after graduation[‡]	3.6 (1.0)	1 (2)	9 (16)	10 (18)	24 (44)	11 (20)
In the light of SF medical products becoming a major threat, my institution of pharmacy is able to readily identify and include new skills/ competencies in the pharmacy curriculum as they emerge in practice[‡]	4.1 (0.8)	1 (2)	0 (0)	11 (20)	23 (42)	20 (36)

Abbreviations: SD = standard deviation, No. = numero, number

[†] Based on a five-point Likert Scale on which 1 = strongly disagree and 5 = strongly agree

[‡] 55 participants answered

medical products courses. When considering the implementation of SF medical products courses in the future, schools should take into consideration the courses students have to take and pass before they are ready to take the SF course.

Universities that have been teaching matters related to SF medical products reported using traditional methods (e.g. lectures, seminars, tutorials) and teaching in classroom setting as the most dominant one, and written exams being the most common assessment. The educators were typically university-employed pharmacists with regular or minimal patient contact. However, the competency development framework developed by FIP[8] recommends that some of the modules, such as the modules on detection or reporting, are to include some non-traditional methods like problem-, team- and case-based learning, and in practice settings (e.g. in hospital). This can provide students with a relevant opportunity to see theory in practice, and require them to develop analytic, communicative and collaborative skills along with content knowledge. Such an approach, however, was reported by only half of the respondents.

The most common teaching topics regarding SF medical products are focused on modules concerning the prevention and detection of SF medical products. This can be explained by the fact that analytical chemistry is a common part of pharmacy curricula around the globe. They already contain basics of qualitative and quantitative analysis, important for quality assurance and detection of substandard products.[11,18] This corresponds to the findings from this study, as Quality Control (e.g. pharmacopeia, compliance with regulatory requirements) was reported to be the most taught subtopic.

The topics on identification of characteristics of medical products that are most at risk of being substandard and/or falsified were less prevalent. The results revealed the biggest gaps were in the topic of reporting of SF medical products, which was being taught the least. However, one third of all schools did not teach any of the listed topics. Gaps were also identified in the topics around patient intervention, where 15 out of 55 schools indicated that there was no content regarding recognising or counselling on the effects of exposure to SF medical products or providing pharmaceutical or follow-up care in case of exposure to SF medical products. Neither obtaining or communicating related information and documentation on incidence to colleagues, patients and public. However, literature argues that pharmacists do need to understand how substandard and falsified medical products affect pharmacy practice and their detrimental effects on health. Ferrairo and Wirtz highlighted that including mandatory education on SF medical products (e.g. a module on 'Quality of Medicines and Public Health') in basic pharmacists' training would ensure that all incoming workforce are exposed to the same foundation.[7,12] This would be more sustainable than ad hoc training on the job (e.g. for regulatory authorities), which requires additional resources.[7] Findings from this survey study, specifically the overview of teaching content corresponding to the content areas of the FIP curriculum (Table 3), could provide a starting point to help academics understand where the gaps in content are the most prevalent and where they most likely need to be closed.

Most institutions agreed with the statement that their students were adequately equipped to detect and take action if exposed to SF medical products after graduation and almost all of the institutions agreed that their institution was able to readily identify and include new skills/

competencies in the pharmacy curriculum as they emerge in practice. While this finding is rather optimistic, based on the content gaps, the authors argue there is still much to do in establishing a ready and responsive pharmacy education to meet the fast-paced challenges in public health. Future studies are needed to measure the impact of SF medical products education on combatting SF medical products in practice.

In addition, this study identified possible barriers and enablers in introducing a new course or module into the pharmacy curriculum. The majority of schools indicated that the most common barrier for the implementation of a new module was the lack of sufficient space in their pharmacy curriculum. Over one third indicated that the educators lacked the time to deliver classes, this had also been noted in previous studies where a lack of time in medical-related curricula was rated the most significant barrier.[19-21] For example, Blanco and the authors found the 'lack of time in curriculum' to be a significant barrier in implementing an evidence-based medicine curriculum in the United States and Canadian medical schools.[21] On the other hand, the regulatory barriers were indicated as the least impactful, e.g. not being able to easily change the curriculum by law. This can be explained by the fact that approval of the introduction of a new module in the existing pharmacy curriculum was reported for the most part to be done by the Head/Director of the institution.

Some of the barriers to the introduction of a course on SF medical products can be overcome by the availability of the ready-to-adopt curriculum as an enabler to change. The majority of respondents indicated that if a standalone module (supported by a competency framework) on SF medical products is available, it would be very likely to be introduced as part of an existing course and likely to be introduced as a standalone course. Meats and the authors also recommend that having a common competency framework would further inform and guide curricular efforts to close the gaps in teaching.[20] More studies are needed to understand the barriers and enablers specific to implementing courses or modules addressing new topics in an undergraduate pharmacy curriculum at a global level.

One such course was developed by the FIP in collaboration with the WHO specifically for countries most vulnerable to SF medical products: low-income countries, and in particular, Sub-Saharan Africa.[1] In 2019, an initiative to enhance training on SF medical products in pharmacy curricula was introduced as a joint pilot project funded by the European Commission (EC) and led by the WHO and FIP, with contribution of the Francophone Order of Pharmacists (CIOPF) and the Commonwealth Pharmacists' Association (CPA). They work together on developing a compulsory education component on SF medical products in five pilot Universities in Africa.[8] The project aims to develop and deploy a curriculum on the threat of SF medical products as a compulsory education component for undergraduate pharmacy students in Sub-Saharan Africa, where the need is great. The project is currently running, with the estimated completion planned for 2021. In addition, FIP has been working on educational reforms to advance research, training, and curriculum development in pharmacy education.[18] Such projects can be beneficial enablers for universities who would like to adopt the curriculum in the future.

Limitations

This survey is the first global study to bring insight into the education in substandard and falsified (SF) medical products in schools of pharmacy around the world. The schools of pharmacy listed in the FIP Academic Institutional Members database were surveyed. This database gathers internationally active schools of pharmacy and pharmaceutical sciences and despite it does not contain all the pharmacy schools around the globe, it provided a good starting point for this research.

This survey covered respondents across all the WHO regions. However, there was a skewed distribution among the different income groups; for example, this study did not have respondents from low-income countries. Therefore, our results cannot directly be translated to low-income countries, even though SF medicines are mostly a problem in low- and middle-income countries.[1,2] On initial scanning of the data, the authors found no apparent differences in results between high and middle income countries, and low numbers hampered any strong conclusions on the differences. It is worth noting that the survey was running during the COVID-19 pandemic, which may have negatively impacted the response rate due to university lockdowns. Finally, among surveyed academics, the respondents were mostly deans or directors, and this may interfere with the extent of their knowledge with regards to details of teaching activity in the institution and thus might be underreported in our results.

Considering the limitations cited, the survey presents mapping in terms of teaching content, skills and knowledge gap as well as readiness or possible barriers exacerbating the gap. It is providing supporting evidence for highlighting the gap in SF medical products education and can be used to support universities in changing curricula to include modules on this topic, as well as guide frameworks and policies at the institutional, national, or regional level. It can also inform the initiatives at global level, e.g. joint FIP-WHO projects on training on SF medical products on the existing gaps.

Conclusions

While this study found that the majority of pharmacy schools do not offer any dedicated standalone education on SF medical products, most of the pharmacy schools do offer some teaching on SF medical products as part of existing curricula, mostly concerning the prevention and detection of SF medical products. This study found significant gaps in the teaching content, mostly in reporting of SF medical products, but also in teaching methods. Availability of ready-to-adopt curriculum materials can help overcome some of the barriers to their implementation, leading to better prepared pharmacists in combatting SF medical products. Future research should focus on the best way to integrate information on SF medical products, as well as to measure the impact of SF medical products education on combatting SF medical products in practice.

Acknowledgements

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Supplementary material

Table S1. Specific course(s) and/or lecture(s) given about SF medical products

Main subject	Subtopics
Pharmaceutical analysis (analytical chemistry)	Pharmaceutical analysis; including quantitate and qualitative analysis Pharmacognosy; physical inspection and qualitative tests for medical plants Analytical chemistry; analytical techniques and procedures to detect substandard products Physical Pharmaceutics and Formulation; scientific concepts behind designing and using liquid or semi-solid pharmaceutical dosage forms to deliver a drug
Quality Assurance	Drug dissolution systems (DDS); product quality specification during dissolution section of DDS; definitions and examples of adulteration and misbranding during DDS; during discussion of raw material quality as part of micromeritics and formulation sections of DDS; brief reference to shipment tracking in DDS. Quality assurance and role of qualified person Criteria for quality of medical products vs counterfeit products, quality control of tablets, capsules, creams, ointments, emulsion, suspension and other pharmaceutical products; dosage forms and drug delivery; medicines standardisation Pharmaceutical technologies and biopharmacy Pharmacopeia and national formulary; in relation to active pharmaceutical ingredients and excipients Good manufacturing practice Internet and medicines (quality aspects) Advanced medicine supply management Reporting SF medical products; medicines verification system Registration of products and National Pharmaceutical Regulatory Affairs Agency; marketing authorisation process; principles of New Drug Application (NDA) of Investigational New Drug (IND); labelling; orphan medicines Forensic pharmacy Regulations and standards for pharmacy Pharmacy law Pharmacovigilance Role of authorities' measures in controlling SF medical products
Regulatory sciences	Drug dissolution systems (DDS); product quality specification during dissolution section of DDS; definitions and examples of adulteration and misbranding during DDS; during discussion of raw material quality as part of micromeritics and formulation sections of DDS; brief reference to shipment tracking in DDS. Quality assurance and role of qualified person Criteria for quality of medical products vs counterfeit products, quality control of tablets, capsules, creams, ointments, emulsion, suspension and other pharmaceutical products; dosage forms and drug delivery; medicines standardisation Pharmaceutical technologies and biopharmacy Pharmacopeia and national formulary; in relation to active pharmaceutical ingredients and excipients

Table S1. (continued)

Main subject	Subtopics
	Good manufacturing practice Internet and medicines (quality aspects) Advanced medicine supply management Reporting SF medical products; medicines verification system
Pharmaceutical Policy (analysis)	Health, pharmaceutical, and medicines legislation Legal framework and quality standards; definition of substandard drugs Economy of the SF medical products market Falsified Medicines Directive (FMD): introduction, explanation; difference between falsified and counterfeit medicines
Pharmaceutical industry	Good manufacturing practice; GXP; Quality Management Systems Industrial pharmacy
Pharmacology	Principles of medicines action
Toxicology	Principles of pharmaceutical toxicology; medical consequences of SF medical products
Pharmacoepidemiology	Principles of pharmacoepidemiology
Pharmacy practice and pharmaceutical care	Regulating manufacturing and distribution of medicines Foundations of Pharmacy; complementary and alternative medicines Health care systems Global and public health; the dangers of SF on public health, the role of pharmacist in public awareness and education The Role of good pharmacy practice in detecting and reporting SF medical products
Ethics	Dispensing in pharmacy; pharmaceutical ethics and jurisprudence
Pharmaceutical supply chain management (medicines and medical supplies management)	The role of packaging; security labels of primary and secondary packaging; Risk and costs of SF medical products; tracking technologies and technological advancements; prevention of SF medical products in the supply chain

Table S2. Materials used to teach about the SF medical products

Internet/ webpages:	› European Medicines Agency – Science Medicines Health (2020). Retrieved from: https://www.ema.europa.eu/en › European Medicines Agency – Good Manufacturing Practice (2020. Retrieved from: https://www.ema.europa.eu/en/human-regulatory/research-development/compliance/good-manufacturing-practice › European Directorate for the Quality of Medicines & HealthCare. European Pharmacopeia (2020). Retrieved from: https://www.edqm.eu/en/ › Dutch inspection of health care [*Inspectie Gezondheidszorg en Jeugd* (IGJ)] (2020). Retrieved from: https://www.igj.nl/ › Dutch law (2020). Retrieved from: http://wetten.overheid.nl › United States Pharmacopeia and National Formulary (USP-NF) (2020). Retrieved from: https://www.uspnf.com/ › European Commission (16 February 2011). *Q&A: Directive on falsified medicines*. Retrieved from: https://ec.europa.eu/commission/presscorner/detail/en/MEMO_11_91 › Federal Institute for Drugs and Medical Devices (2011). *Falsified Medicines Directive*. Retrieved from: https://www.bfarm.de/EN/Drugs/licensing/folgeverfahren/variations/FalMedDirective/_artikel.html › International Institute of Research Against Counterfeit Medicine (IRACM) (7 May 2019). *Serialization I European Union falsified medicines directive.* Retrieved from: https://www.iracm.com/en/2019/05/serialization-european-union-falsified-medicines-directive/ › World Health Organization (WHO) (2020). *Full list of WHO medical product alerts.* Retrieved from: https://www.who.int/medicines/publications/drugalerts/en/ › AHPRA. (2015). Codes, guidelines and policies.. Retrieved from: http://www.pharmacyboard.gov.au/Codes-Guidelines.aspx › AsepTech_USP. (2017). Aseptic technique for sterile compounding. [Video file]. Retrieved from: https://www.youtube.com/watch?v=zssgmmMM1Zg › Blue STI. (2016). Sterile compounding of a gentamicin bag. [Video file]. Retrieved from: https://www.youtube.com/watch?v=QwB8YqGdGIA › PCCARx. (2013). Returning to the roots of medicine. [Video file]. Retrieved from: https://www.youtube.com/watch?v=zH7gqlSTfk4 › PCCARx. (2011). What is PCCA? [Video file]. Retrieved from: https://www.youtube.com/watch?v=5y2Oy3aBJtA › PSA. (2017). Professional practice standards. Retrieved from: http://www.psa.org.au/wp-content/uploads/Professional-Practice-Standards-V5-PDF-5.5mb.pdf › TGA Australia. (2009). Manufacturing principles for medicinal products. Retrieved from: https://www.tga.gov.au/publication/manufacturing-principles-medicinal-products › TGA Australia. (2014). The role of the TGA: Information for health professionals. [Video file]. Retrieved from: https://www.youtube.com/watch?v=tgI2Wigh2sg › TGA Australia. (2017). Guide to the interpretation of the PIC/S Guide to GMP for compounded medicinal products. Retrieved from: https://www.tga.gov.au/sites/default/files/compounded-medicines-and-good-manufacturing-practice-gmp.pdf › TGA Australia. (2017b). About recall actions. Retrieved from: https://www.tga.gov.au/about-recall-actions › TGA Australia. (2017c). Uniform recall procedure for therapeutic goods. Retrieved from: https://www.tga.gov.au/sites/default/files/recalls-urptg-170412.pdf

Table S2. (continued)

	› WUSF Channel. (2013). Sterile compounding: How it should work. [Video file]. Retrieved from: https://www.youtube.com/watch?v=oixmZSJYU5g › National Agency of Drug and Food Control in Indonesia [*Badan Pengawas Obat dan Makanan - Republik Indonesia*] (2020. Retrieved from: www.pom.go.id › National Health and Medical Research Council, Australia (2020). Retrieved from: https://www.nhmrc.gov.au/ › Australian Government – Department of Health (29 September 2017). *Good manufacturing practice - an overview*. Retrieved from: https://www.tga.gov.au/good-manufacturing-practice-overview
Textbooks	› Management Sciences for Health. *MDS-3: managing access to medicines and health technologies*. Arlington, VA: Management Sciences for Health. › Harris DC. *Quantitative Chemical Analysis*. 7th (2007) or 8th (2010) edition › Cartwright AC, and Matthews BR. International Pharmaceutical Product Registration › British Pharmacopeia (2020). Retrieved from: www.pharmacopoeia.com › Moffat AC, Osselton MD, Widdop B, Watts J. Clarke's Analysis of Drugs and Poisons. › Ahuja S, and Sapinski S. Handbook of Modern Pharmaceutical Analysis › Royal Society of Chemistry. Merck Index: An Encyclopaedia of Chemicals, Drugs, and Biologicals. › Loyd AV. The Art, Science, and Technology of Pharmaceutical Compounding › Davison M. Pharmaceutical Anti-Counterfeiting. Wiley, 2011

Improved knowledge on substandard and falsified (SF) medical products through a dedicated course for pharmacy students at three universities in Sub-Saharan Africa

3.2

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Abstract

Background

Too few pharmacists receive formal training on substandard and falsified (SF) medical products. Strengthening knowledge across pharmacists is considered a moral and ethical duty of academia, that is to build the health systems' capacities to combat this global health threat these poor-quality products represent. This study therefore aimed to evaluate whether a dedicated educational course for undergraduate pharmacy students can improve their knowledge on these products.

Methods

A survey was conducted at 3 Sub-Saharan universities. Knowledge was assessed through scores on a 20-points questionnaire with questions related to the course content. Scores were compared before and after the course and a linear mixed-effects model analysis was used to analyze score differences. Students were furthermore asked for feedback and self-assessment. In addition, teachers were interviewed on the context of the course introduction. These data were analyzed descriptively.

Results

Among 335/355 students who completed the survey (n=41/53 in Cameroon, n=244/252 in Senegal and n=50/50 in Tanzania) knowledge of SF medical products was enhanced, with increase in all countries, overall, by 3.5 (95% CI 3.1-3.9) score points. Students improved in all offered modules in each country. Students confirmed their improvement through self-assessment.

The course was well-received among students and teachers. Barriers included time constraints and access to practical means (equipment availability, room allocation, internet accessibility and affordability). These barriers can be overcome by key enablers such as the support from university leadership, and early involvement of the university in the course design.

Conclusions

The course improved students' knowledge on SF medical products. These findings encourage further full implementation of this course in existing curricula beyond the pilot and can inform possible future scale-up. This has a potential for reinforcing the capacity of health systems to protect communities from SF medicines, by empowering all pharmacist across the health systems to intervene.

Introduction

Substandard and falsified (SF) medical products are a threat to public health.[1,2] In addition to the obvious harm caused to patients exposed to these poor-quality medical products, they also contribute to antimicrobial resistance, undermine immunization programmes, erode confidence in healthcare professionals, medicines and health systems, and waste precious financial resources through prolonged treatment.[3-6] They are morally unacceptable because they are not ordinary consumer goods and patients have the right to expect that the products they receive are safe and efficacious.

Countries with under-resourced regulatory authorities tend to be most vulnerable to SF medical products reaching patients.[7-9] Between September 2012 and February 2022, the World Health Organization (WHO) Global Surveillance and Monitoring System (GSMS) has received 3169 case reports from 139 countries.[8,10] Thirty-eight percent of reports originate from the African region.[7] Most serious incidents of SF medicines are often reported by healthcare professionals, in particular pharmacists.[8,11] However, too few pharmacists receive formal training on this issue during their undergraduate education.[12-14]

Pharmacists are important players at the interface between the health system and the patient (end-users) community. They constitute the last defense / checkpoint between patients and their treatment and thus have both ethical and professional responsibility to minimize any health risks. In order to address the training gap and advance the essential role of pharmacists in pharmaceutical and health systems, a course on SF medical products for undergraduate pharmacy students was developed as part of a pilot project funded by the European Commission, designed and implemented by the WHO and the International Pharmaceutical Federation (FIP) in 2019-2021 in close collaboration with the pilot universities.[15,16] This course was then deployed as a new component into the curriculum for pharmacists in the Sub-Saharan African region. It includes detailed information relating to the root causes of SF medical products, the products most at risk, early warning signals of their presence in the supply chain, how to avoid, detect, and report SF medical products, and advise patients and consumers.[15]

The main objective of this study was to assess the change in knowledge about the topic of SF medical products in undergraduate pharmacy students who participated in this course, that was delivered at three selected pilot pharmacy schools in Sub-Saharan Africa (Cameroon, Senegal and Tanzania). The study also looked at self-assessment of the students' knowledge prior to and after the course, and whether they found the course useful and worthy to recommend to other students. In addition, teachers were interviewed on the context of the course introduction and motivation of the students as well as main enablers and barriers of its implementation.

Methodology

Course characteristics

The course was developed by an informal expert group, composed by pharmacy experts from academia and practice from FIP, pilot universities, project partners of the Commonwealth Pharmacists Association (CPA) and La Conférence Internationale des Ordres de Pharmaciens

Francophones (CIOPF), local African experts with regulatory background and WHO, who sponsored the pilot project. It was developed through a consultative process, several meetings with multiple rounds of review and consultation were held until a consensus was reached. The consultation took into account multicultural dimension. The course is available in both English and French language. It is designed to cover comprehensive information about SF medical products in order to teach pharmacy students how to avoid, detect and report SF medical products, and how to advise affected patients. The course is composed of 6 modules on SF medical products: Module A on general introduction; Module B on identification of medical products at risk; Module C on prevention (from entering the supply chain); Module D on detection strategies; Module E on reporting; and Module F on intervention after coming in contact with them.[15] As this was a generic course, the pilot universities in Cameroon, Senegal and Tanzania were responsible for considering necessity of adjustment of the content, using the "adopt and adapt principle"[15] to contextualize the content and for flexibly incorporating the course into universities' existing curriculum based on their needs.[15]

The teaching materials included case studies. The module on detection (module D) also included practical lessons, with universities teaching visual inspection (all) and analytical inspection with qualitative and semi-quantitative investigations of medicines (Senegal and Tanzania).

The course was ready for deployment as of 2021. It was deployed face-to-face despite challenges and delays related to the COVID-19 pandemic. Each university deployed all 6 modules. An overview of the characteristics of the participating universities is included in Table 1.

Study sample

A total of 355 students participated (n=53 in Cameroon, n=252 in Senegal and n=50 in Tanzania) in this study. The pilot universities were chosen based on recommendations from the WHO and FIP, based on academic leadership and willingness to carry out the project. Two other universities who were also part of this pilot but did not yet deploy the course were excluded from the study. The students were at least in the third year of their study programme. The participation of the students in the evaluation was voluntary, and they were excluded from the analysis if they did not enter any information in the questionnaire.

Table 1. Characteristics of participating universities

Country	Teaching language	Total nr. Students	Total hours	Deployment period	Pharmacy school year	Nr. of teachers	Compulsory course	Standalone / part of another course
Cameroon	French	53	40	Nov 2020-Feb 2021	4th	4	Yes	Standalone
Senegal	French	252	16	Feb 2021-Apr 2021	3rd	3	No	Part of Physic-Chemical Tests and Drug Control course
Tanzania	English	50	15	Jul 2021-Aug 2021	3rd	2	Yes	Part of Quality Assurance course

Interviews with teachers

To understand how the course was deployed, a follow-up interview was conducted with the participating teachers from each university. These teachers were all directly involved in the implementation of the course after following a teaching (Train-the-Trainer) course themselves. A semi-structured interview was used to assess enablers and barriers in deployment of the course and motivation of the students. An interview guide was developed with a list of ten open-ended questions. The list of the open-ended questions that were used for the semi-structured interview and shared with the teachers beforehand in the interview guide can be found in the supplementary appendix.

Student survey

In the pre-assessment, students were asked in an open question to write out their prior knowledge about SF medical products. The answers were coded based on their correspondence to the course's 6 modules.

In the post-assessment, students were asked (1) to what extent their knowledge on SF medical products had improved after participation in the course, (2) to indicate in which areas (linked to each of the 6 modules) their knowledge had improved, (3) to what extent this course will be helpful in their professional life, and (4) if they would recommend this course to all pharmacy students and/or pharmacists. Answers were analyzed by using descriptive analysis.

Knowledge assessment

No suitable questionnaire or assessment was found in the available literature that could be used for knowledge assessment in the context of this study. Therefore, an assessment questionnaire was developed and validated by the expert group who developed the course. The assessment comprised of 20 multiple choice questions related to the learning objectives of the curriculum. Each correctly answered question yielded one point. No points were deducted for incorrectly answered questions. Assessment responses from the students were received via computers or mobile devices with a Web-based software tool, QuestionPro. None of the questions were mandatory. Fully uncompleted assessments, however, were excluded from the analysis.

The same assessment questions were used in the pre-and post-test, to ensure the compatibility of the results. The students were asked to fill out an assessment questionnaire before the course and after the course. The study approach is visualized in the supplementary appendix.

Data analysis

The effects of the course on assessment scores were examined via linear mixed-effects model analysis. This method was chosen to account for both within-person and across-person variability. The statistical model contains both fixed effects and random effects. In addition, it is an appropriate method of analysis when not all data can be matched. Some participants only completed the pre- or post-test leading to missing data, and linear mixed-effects model analysis allows to use all the data. One model was built with the assessment score as dependent variable and with fixed effects of

time (pre-or post-course). The country and subject number (student number) were considered as random effects. The validity of the statistical model was evaluated by using residuals to verify the normality assumption. The two-tailed significance level was set at =.05. All statistical analyses were performed with IBM SPSS Statistic, version 25 and Microsoft Excel 2016.

The questionnaire aimed to cover all modular areas, but the emphasis was not given to an equal distribution, therefore some questions were linked to more modules than others. Module E on reporting focuses on a national situation, and is therefore not suitable for a uniform questionnaire, thus was not part of the assessment. Initially, it was not the intention to assess improvement per module, but a post-hoc descriptive analysis was undertaken to explore this. The assessment scores were stratified by module and the total obtained score (percentages) per module was determined, both before (pre-test) and after (post-test) the course. The percentages were determined by dividing the obtained total score per module over the theoretical maximum score (number of questions per module multiplied by the number of students who completed the assessment) multiplied by 100%.

Data from the student survey and interview responses from the semi-structured interviews were clustered into four themes (enablers, barriers, motivation of students and important environmental factors) with important quotes highlighted.

Ethical considerations (patient and public involvement statement)

The study was conducted under Dutch legislation that indicates ethical approval is not required for this type of study. The study was conducted according to the principles of the Directive 95/46/EC General Data Protection Regulation (GDPR). Informed, specific and explicit consent was freely given by the students who participated in the study. Furthermore, informed, specific and explicit consent was freely given by the teachers who were interviewed, and the interview guide was shared at least one week beforehand. Participation by students and teachers was completely voluntary and could be terminated at any moment. The data was handled anonymously and none of the findings is traceable to the individual participant. Data is stored on a secure location and only accessible to the core research team.

Results

Pre-vs. post-assessment knowledge scores

A total number of 335 students (response rate 94.4%) filled out the questionnaire. Overall, as displayed in Table 2, student knowledge scores improved by 3.5 points (95% CI 3.1-3.9) out of 20 points after they took the course. When stratified by country, students showed a statistically significant improvement of 3.5 points (95% CI 2.2-4.8) in Cameroon, 3.4 points (95% CI 3.0-3.8) in Senegal and 5.3 points (95% CI 2.9-7.7) in Tanzania (Figure 1).

Students improved in each measured module across all countries (Figure 2). In Senegal, the biggest improvement (15.6%) was observed in module C, covering information about the prevention of SF medical products from entering the supply chain. In Cameroon the largest improvements (14.0%) were observed in module D on detection and in Tanzania (43.2%) in module B related to the identification of medical products at risk.

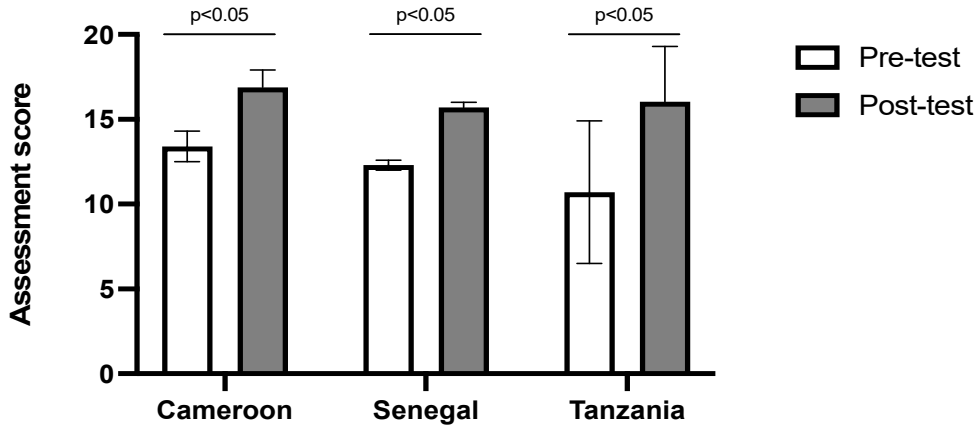

Figure 1. Assessment score pre- vs post- test

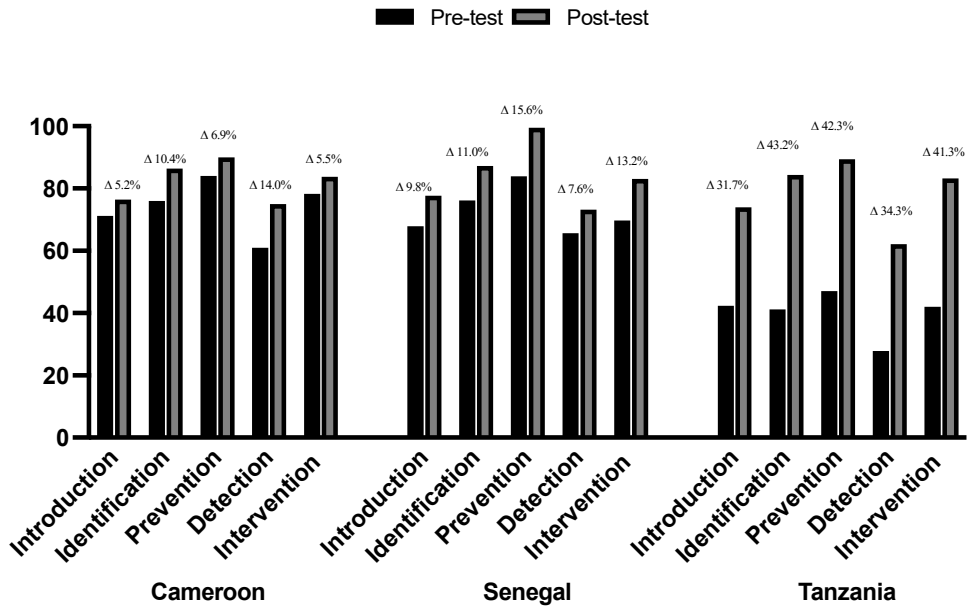

Figure 2. Percentages of questions answered correctly, stratified by modular theme in Cameroon, Senegal and Tanzania

Caption: "Introduction" is corresponding to Module A and n=5 questions; "Identification" is corresponding to Module B and n=3 questions; "Prevention" is corresponding to Module C and n=1 questions; "Detection" is corresponding to Module D and n=4 questions; "Intervention" is corresponding to Module F and n=7 questions.

Self-assessment by students

A total number of 246 students described their prior knowledge of SF medical products (Cameroon n=51, Senegal n=167, Tanzania n=28, response rate 69.3%). Among them, 36 students (14.6%) indicated no previous knowledge. If any knowledge was indicated, students in all three countries

indicated that they mostly had some prior knowledge of the general aspects about SF medical products (52.6% in Senegal; 42.9% Cameroon; 60.0% Tanzania). Prior knowledge per module per country can be found in the Appendix.

Students overall declared a similar improvement in all modules, approximately around 20% per module. The Appendix lists country-specific improvements per module. Most of the students indicated that their knowledge improved because of participating in the course (Figure 3). Also, the large majority found the course useful for their professional life and would recommend the course to all pharmacy students and/or pharmacists around the globe. No large differences were observed between countries.

Interview sessions with teachers

Interviews with the teachers helped to understand the context and key enablers and barriers of course deployment. These are listed in Table 2 with selected quotes included.

Discussion

This jointly developed educational course on SF medical products for undergraduate pharmacy students improved their knowledge on these poor-quality medical products. Knowledge overall and for each individual module in all countries, both as assessed through the questionnaire as well as according to student self-assessment. The course was well received among students and faculty, and enablers and barriers of deployment were identified. This may encourage further full implementation of this course in existing curricula beyond the pilot and inform possible future scale-up. It also indicates that prevention and detection of SF medical products should move from being a top-down exercise hold by specialists to being integrated into the pharmaceutical system through training of practitioners in a bottom-up approach.

The course was building on rather poor (self-reported) prior knowledge of students. Nearly one sixth of the responding students reported no previous knowledge, while others reported some knowledge, mainly related to general aspects about SF medical products. This does not

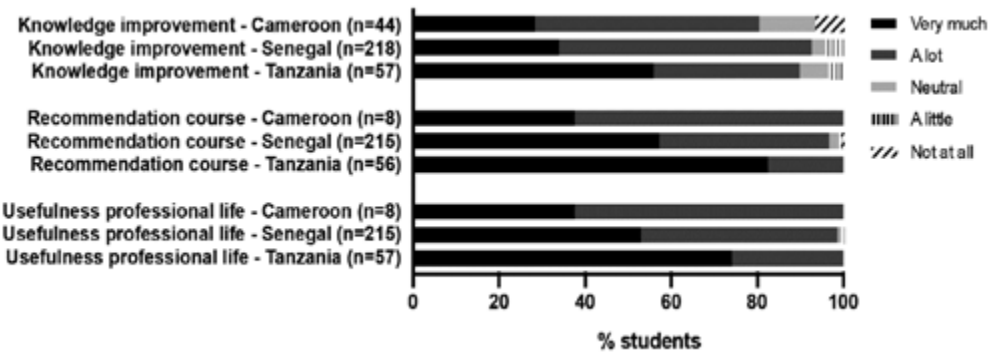

Figure 3. Students' attitudes towards knowledge improvement, future recommendation to others and usefulness of the course

Table 2. Deployment of SF course at different universities

Factors	Description	Quotes
Enablers	› Participation in course development and ownership › Support from WHO, FIP and other partners › Adequate preparation of teachers with Train-the-Trainers training › Availability of course materials; Bilingually available materials › Sufficient measures for alignment with existing pharmacy courses › Course development coincided with overall University curriculum revision - support from university leadership › With support from university leadership course is standalone and compulsory	› "Often when we prepare a lesson, we try to manage the documents with which we are going to prepare a training support, but here it is already prepared in advance, with updated data, excellent examples and very concrete cases. [...] We participated in the development providing our input and insights of what are likely to be the needs of our students." › "The project's start and course development coincided with major undergraduate pharmacy curriculum revision at the university. [...] Because we were involved in the development of the new course from the beginning, we were able to take sufficient measures to ensure that the course aligned well with other obligatory pharmacy courses at our university."
Barriers	› Time constrains for course delivery; Time constraints for pre-deployment preparation › Lack of equipment for practical case studies, e.g., provision of reference standards for Mini-Labs as university could not buy the reference tablets and equipment for practical case studies (e.g., use of Mini-Labs, detection tools, terrain work etc.) › Lack of adequate teaching space (room size) › Lack of Internet access (and affordability) , e.g., some students had to buy internet passes to connect for the assessment › Lack of support from university leadership to run the course as mandatory part of pharmacy curriculum › Lack of support from the local authorities	› "The level of difficulty is in relation to the timing. [...] If we had the authorization of the deanery to integrate the modules in the courses, it could facilitate the management of the timing, so that we would have an agenda with the necessary time to meet the objectives." › "We thought the course will take a shorter time, but once we started teaching, we realized we needed more time. When you are teaching, you are not simply reading the slides, you have to explain to the students, and give examples as it is a new topic for them, it was time more consuming." › "Students [...] need practicals. For example, using kits to demonstrate so that after graduation, they know what is about. We have a good experience of Minilab, we would have used it for this course but the reference standards have expired." › "Solvents we can easily replace but we are not able to buy the reference tablets anymore."

Table 2. (continued)

Factors	Description	Quotes
Motivation of students	› Lot of interest from the students in this topic, with main feedback of it being useful for their future professional life › Students could relate the teaching material to media reports › The classes were full	› "Students were very participative during the lectures." › "Students were very interested, [...] because it is directly related to the daily life as pharmacists."
Important environmental factors	› COVID-19 related restrictions, e.g., social distance, students wearing masks in class › Context of the revival of the pharmaceutical industry as part of stimulation of local production to achieve therapeutic sovereignty and consequently, pharmacy reforms are expected › Overall university curriculum revision	› "We taught in the circumstances of COVID-19, for example, students had to wear masks." › "[...] there is a revival of the local pharmaceutical industry, which interests the students a lot. This course allows them to better communicate and inform the population."

come as a surprise given earlier observations from WHO and others.[3,8,12] While of high importance, current pharmacy school curricula largely lack systematic teaching on SF medical products.[13] When introducing a new topic in a healthcare curriculum, the implementation typically undergoes different phases, from the exploration phase where the topic is being explored via early-adopting programmes (such as this pilot programme) to the initiation phase during which adoption across healthcare educational programmes is enacted. This phase will require continuous feedback to adjust appropriate educational delivery mechanisms. After this follows a standardization phase in which knowledge is spread throughout the profession.[17]

To inform such process, it is important to identify key barriers and enablers of course implementation.[18] One of the key barriers observed was insufficient time. In all countries, teachers reported that they would welcome more hours to be either dedicated to this course or to the preparation that preceded the deployment. Insufficient time in pharmacy or medical-related curricula is a well-known barrier to a new course introduction.[13,19-21] This barrier can be overcome by support from university leadership,[12] which was observed in Tanzania in the present study where the course development coincided with overall university curriculum revision, which resulted in more support for this course as well. Furthermore, the course would benefit from removing barriers of access to practical means, and more resources to provide for equipment, sufficient teaching space, Internet accessibility and affordability, etc.

On the enablers side, the readily available teaching materials were considered very helpful resources for the teachers to facilitate the delivery. As previous studies found, availability of ready-to-adopt course materials is an important enabler.[13] Participation of universities in the course development, providing input and insights of what is likely to be the needs of their students and

overall ownership and commitment in the pilot project was a crucial enabler of success as has been reported previously.[22]

The course was developed as a modular one. When looking at individual themes, even though the universities eventually decided not to carry out the course per module and instead run the modules interchangeably, students improved in all measured modules in each country. The results therefore indicate the students improved in various areas of the course content. This was also reflected in the overall improvement across all modules in the student's self-assessment. This indicates that the course was effective in reaching its objective of increasing student's knowledge on SF medical products. Yet, this is not reason to stand still. As Dizeon et al. showed, even if students (momentarily) improve their knowledge through training, they still need to continue developing such knowledge and skills.[23] The importance of continuous (lifelong) learning is consistently highlighted.[24-26] This calls for efforts to integrate training on SF medical products into continuous education for pharmacists.

Strengths and limitations

This is the first study bringing insight into the education on SF medical products and deployment of the comprehensive and dedicated undergraduate pharmacy course in Sub-Saharan Africa, but there are several limitations to note. Firstly, not all participating students completed both the pre-and post-assessment questions due to practical issues. Therefore, a linear mixed-effects model was used to be able to include all the available data.

Secondly, the number of questions was not equally distributed across modules – balancing between optimizing the length (and respective time burden on students) with a total of 20 questions only, and full representation of the course content. Moreover, each university had the possibility to adjust the teaching content to their needs. Therefore, knowledge questions related mainly to common aspects across modules.

Thirdly, as the same assessment questions were used in the pre-and post-test, students could theoretically have memorized the questions in favor of the post-test scores. However, the assessment answers were not shared after completing the pre-test, making this assumption less plausible. Fourthly, although the course has led to a statistically significant increase in knowledge, it is uncertain how sustainable the knowledge acquired is. Also, it is unclear how long this increase will remain, which is subject for further research. It was also not the aim of the study to compare the countries given the differences in the implementation context. Although there were differences across schools, it is difficult to draw any conclusions.

Despite the limitations cited, the study presents supporting evidence for the success in this pilot course implementation with the aim to close the gap in SF medical products education.

Future directions

The findings of this study can inform future pilots and institutionalization of the training. As soon as the two other universities who were initially involved at the pilot project but have not yet introduced the course (Nigeria and Uganda) will deploy the course, findings can be compared across the whole

pilot. This would also allow to investigate further the bilingual (francophone and anglophone) and cultural aspect of the curriculum, as this has been a unique feature of this course. The results could be compared against insight studies on awareness/risks/access in the similar socio-economic segments of the general population in each country. Recent studies conducted by the WHO in Uganda and Nigeria can serve as a starting point.

Future insights could be given into long-term knowledge acquisition (namely whether the score would change in 2-5 years). Furthermore, it could be investigated whether the students used the acquired knowledge in their practice-oriented professional careers. Continuous professional development for the (wider) workforce also needs consideration.

While this course was implemented in Sub-Saharan Africa, clear and consistent themes emerged that can be applied in expanding this course to other geographical regions – a step toward providing pharmacists with the knowledge to contribute to minimizing of the threat to the populations around the globe. Adaptations of this course (language, scope, etc.) could then be deemed elsewhere.

Conclusions

The undergraduate pharmacy students who participated in the dedicated educational course improved their knowledge of SF medical products. Knowledge improved in all countries across all measured modules, both as assessed through an assessment as well as according to student self-assessment. The course was well received among students and teachers, who found the course useful and would recommend the course further. Enablers and barriers to deployment were identified, which can inform further full implementation of this course in existing curricula beyond the pilot and possible future scale-up to other pharmacy schools. Empowering all pharmacist across the health systems - instead of specialist training only - to address the socially and ethically unacceptable issue of SF medical products has a potential for reinforcing health systems' capacity and safeguarding public health.

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Supplementary material

Visualization of the timeline of the methodology

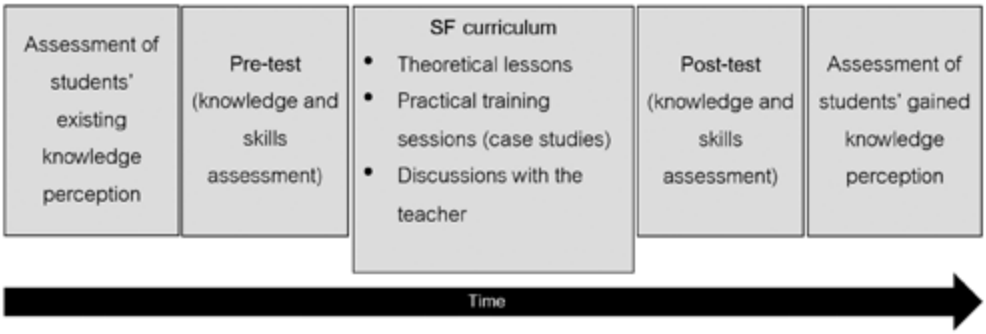

Figure S1. Visualization of the timeline of the methodology

Prior knowledge of SF products, self-assessed by students

A total number of 246 students filled out this open question (Cameroon n=51, Senegal n=167, Tanzania n=28, response rate 69.3% from 355 total participants) to describe their prior knowledge of SF medical products. There were no students who completed only part of the assessment, the assessment was either fully completed or not completed. A total number of 36 students (14.6% from total of 246 students who filled out the open question in the survey) indicated no previous knowledge (Cameroon n=18, Senegal n=13, Tanzania n=5). If any knowledge was indicated, students (n=144, 58.5% from total of 246 students who filled out the open question in the survey) in all three countries indicated that they mostly had some prior knowledge of the general aspects about SF medical products (Cameroon n=24, Senegal n=102, Tanzania n=18). No students in Cameroon and Tanzania indicated any prior knowledge about identification of medical products most at risk being falsified (module B), reporting SF medical products (module E) and counseling of patients exposed to falsified medical products (module F). The latter two were similar in Senegal, with no student indicating prior knowledge in these.

Pre-test: The distribution of the coded answers is presented in Table 1 and Figure 2.

The number of responses is higher compared to the number of students who completed this open question, because multiple modules (i.e., codes) could correlate to the given answer.

Areas of improvement: self-assessment

A total number of 281 students (response rate 79.2% from total of 355 participants) answered the question on self-assessment per module (Cameroon: $n_{students}$=8, $n_{responses}$=36; Senegal $n_{students}$=215, $n_{responses}$=998; Tanzania $n_{students}$=57, $n_{responses}$=291). Students overall declared a similar improvement in all modules, approximately around 20% per module.

Specifically, students from Senegal indicated that they improved the most in module A ($n_{responses}$=197; 19.7% out of 998), which gives a general introduction to SF medical products.

Table S1. Distribution of coded responses to the question about prior knowledge of SF medication as self-assessed by students, stratified by country

	Percentage (%) of responses		
	Cameroon	**Senegal**	**Tanzania**
Introducing the problem /general information about SF medical products (module A)	42.9	52.6	60.0
Identification (module B)	0.0	2.1	0.0
Prevention (module C)	3.6	8.8	10.0
Detection (module D)	10.7	11.9	13.3
Report (module E)	0.0	0.0	0.0
Advisement (module F)	0.0	0.0	0.0
Nothing/no prior knowledge	32.1	6.7	16.7
Knowledge about other courses	10.7	18.0	0.0

Caption: The sum of the percentages as presented may not be 100 due to rounding.

Table S2. Distribution of responses to the question about gained knowledge of SF medical products as self-assessed by students, stratified by country

	Percentage (%) of responses		
	Cameroon	**Senegal**	**Tanzania**
Introducing the problem of SF medical products/general information (module A)	22.2	19.7	17.5
Identification (module B)	22.2	17.3	17.9
Prevention (module C)	22.2	16.8	16.5
Detection (module D)	16.7	17.9	16.5
Report (module E)	5.6	17.0	16.5
Advisement (module F)	11.1	11.1	15.1

Caption: The sum of the percentages as presented may not be 100 due to rounding.

The students indicated that they improved the least in module F ($n_{responses}$=111; 11.1% out of 998), which is about interventions after encountering SF medical products.

In Cameroon, a different distribution was observed, with students reporting an equal amount of knowledge improvement related to the content of modules A, B and C ($n_{responses}$=8; 22.2% each out of 36). For module D, E and F students reported less knowledge improvement ($n_{responses}$=6; 16.7%, $n_{responses}$=2; 5.6% and $n_{responses}$=4; 11.1%, respectively, thus, n responses divided over total of 36 responses).

In Tanzania, students indicated that they improved the most in module B ($n_{responses}$=52; 17.9% out of 291), which is about identification of medical products at risk. Comparable to the results in Senegal, the students from Tanzanian students self-assessed that they improved the least in module F ($n_{responses}$=44; 15.1% out of 291). Table 2 and Figure 3 summarizes the distribution.

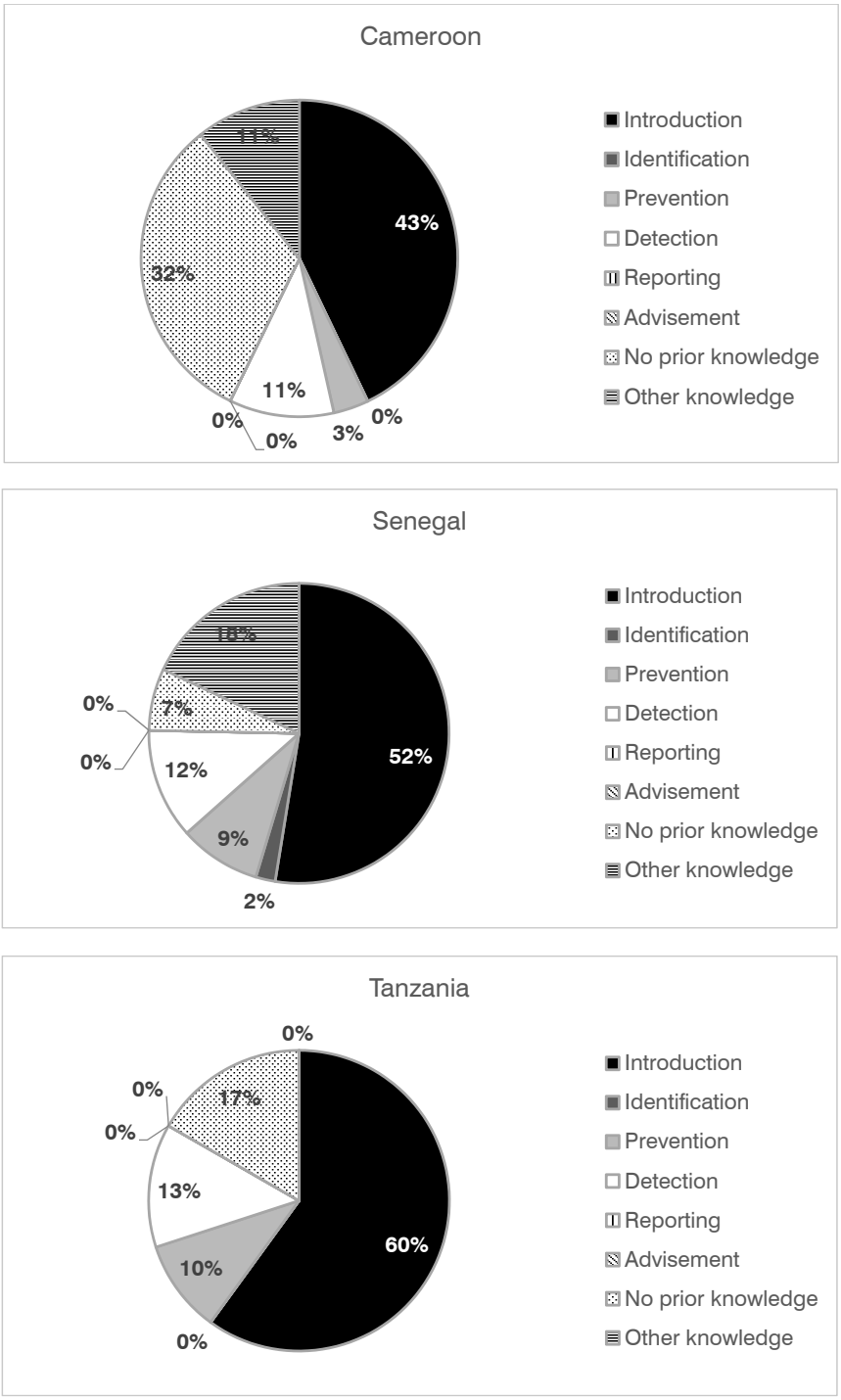

Figure S2. Distribution of coded responses (%) on question about prior knowledge among students from Cameroon, Senegal and Tanzania

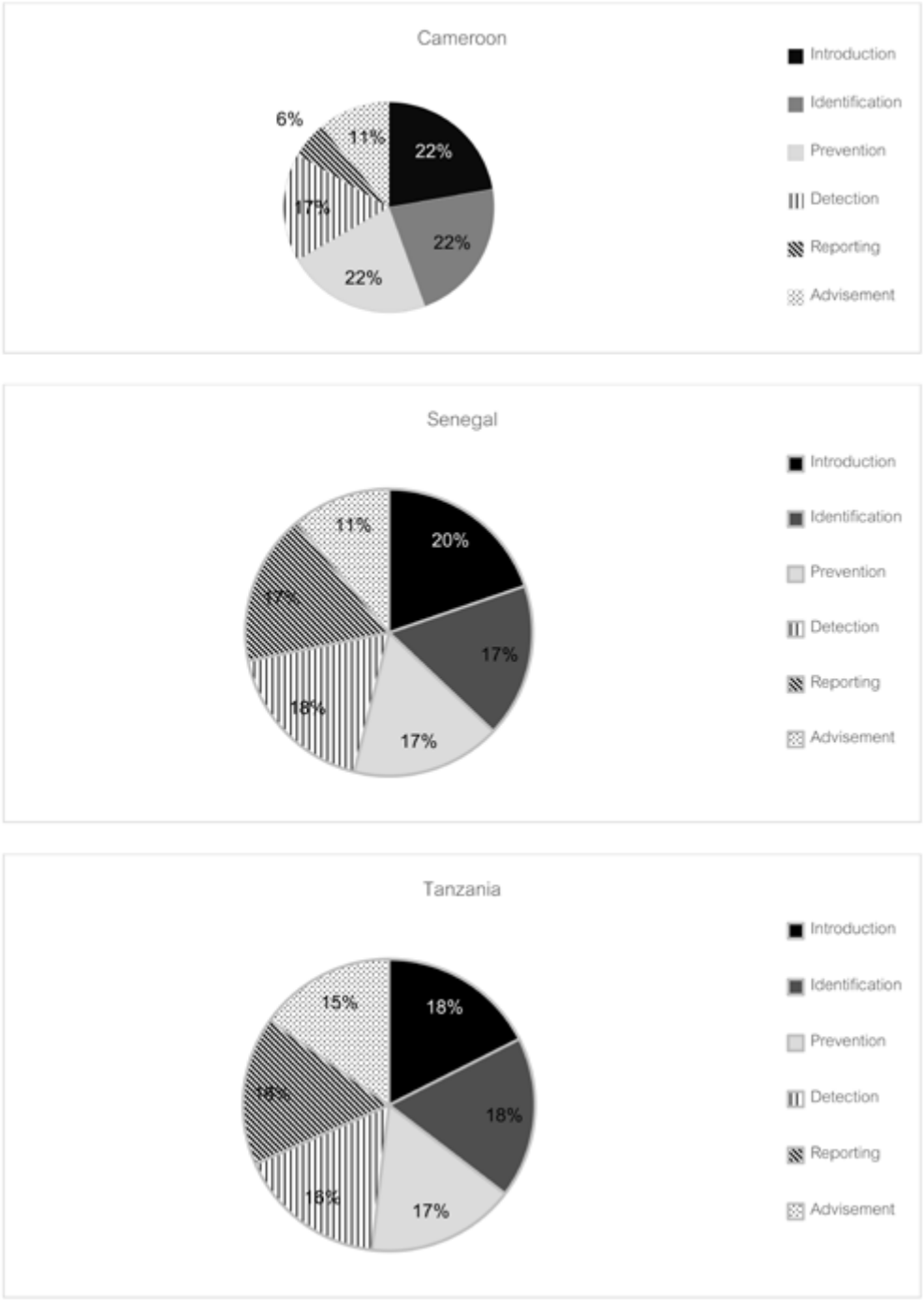

Figure S3. Distribution of responses to the question about gained knowledge of SF medical products as self-assessed by students, stratified by country

The assessment questionnaire

The assessment questionnaire can be requested by contacting the corresponding author on confidential basis. Given the programme is ongoing in other African universities, it is important that students who may read the published article are not aware in advance of the questions they will be asked.

The list of open-ended questions used in the semi-structured interview

The following open-ended questions were used for the semi-structured interview and shared with the teachers beforehand in the interview guide:

Question 1 – Preparation

Were you adequately prepared for the teaching of the course (1) and what feedback would you give for improvement of the preparation? (2)

- What tools were helpful in your teaching preparation?
- Was the Train the Trainers useful in your preparation?
- Was the Curriculum Guide useful in your preparation?
- Was the Competency Framework useful in your preparation?
- Was the Moodle platform useful in your preparation?

Question 2 – Time investment

How long did the course last?

- Did you think this was enough time to properly teach all the modules?
- If not, which modules/parts needed more time?

Question 3 - Time path course

Have you been able to complete the entire course (in accordance with the predefined learning objectives)?

- What modules (Modules A-F) did you deliver?
- If not, what were the reasons for this? Which parts have been excluded and which considerations played a role in this?

Question 4 – Obligations

Was it a compulsory course or an elective course for the students?

- Are the modules of the course part of another course or was it a stand-alone course?
- Was there an attendance requirement for the students? If not, can you indicate something about the degree of presence (compared to other (obligatory) courses)?

Question 5 – Quality of the course

What feedback would you give for improvement of the course?

Do you think there are any differences in the quality of the SF medicines course compared to other (longer existing) Pharmacy courses?

- Is the course set up in a similar way to other Pharmacy courses (teaching methods used, teaching material used, class size, level of difficulty etc.)?
- Do you think the students experienced the teaching material as challenging (enough)?

Question 6 – Motivation among students

Do you think that the students were motivated for the course?

- What impression did the student have on you?
- What do you think can help students to become more motivated to take the course (1) and to complete the assessment (2)?

Question 7 – Limitations

Did you lack any materials, support or knowledge in the implementation of the course (1) or during the evaluation phase (2) (when students took the assessment survey)?

Question 8 – Completion of the course

How is the course completed?

- In case of a compulsory final exam, what form of testing was used? Can the teachers share some information about average mark and/or pass percentage?
- In case of a compulsory final exam, did the teacher think the students were good enough informed about the learning objectives of the course?
- In other cases, why did the university choose not to have a compulsory final exam for this course?

Question 9 – Unforeseen circumstances

Are there any specific circumstances that may have influenced the education and/or implementation of the course?

- How does the COVID-19 situation influence student activities at your university?
- Any political, economic, social developments in the region?
- Any technical issues (Internet connection, face-to-face access to University, etc.)

Question 10 – Future perspectives

Would you recommend the course to other universities/countries around the globe?

- What tip/advice would you give other universities/teachers if they also strive for a successful implementation of the SF medicine curriculum?

Structured authors' reflexivity statement

Given this research was conducted from international partnerships, a structured authors' reflexivity statement summarizes the measures authors put in place in their efforts to promote equitable authorship in this publication.

Table S3. Structured authors' reflexivity statement

Study conceptualisation	**1. How does this study address local research and policy priorities?** The main objective of this study was to assess the change in knowledge regarding substandard and falsified (SF) medical products as understood by undergraduate pharmacy students. The paper focuses on the course delivered in three selected pilot pharmacy schools in Sub-Saharan Africa (Cameroon, Senegal and Tanzania). This topic is of great importance in these countries given it is a major public health issue. **2. How were local researchers involved in study design?** The protocol for the study design was developed in collaboration with local university teachers / professors (from LMIC) who were responsible for the deployment of the courses in their universities. Multiple meetings were held to discuss the design of the content, progress of the course, and status of the research project.
Research management	**3. How has funding been used to support the local research team(s)?** The local researchers from LMIC were the same university teachers who helped to design and implement the course. They are also staff members receiving salary from their universities. The funding benefitted them by providing them with material to use in their daily practice (e.g., the guide for teachers). The funding was invested to build their capacity and deployment capability (e.g., though Train-the-Trainer course).
Data acquisition and analysis	**4. How are research staff who conducted data collection acknowledged?** These are all co-authors of the paper that resulted from the research and are acknowledged in the curriculum guide that was developed to also implement the course. **5. How have members of the research partnership been provided with access to study data?** Involved local university teachers from LMIC are all experts within the field of SF medical products and those responsible within their respective universities for the deployment of the course within the pharmacy curriculum. They have been involved in conceptualising the study, collecting the data, evaluating the results and reviewing multiple versions of the manuscript. The research team relied heavily on their interpretation of the data and providing the context to the results. All local university teachers were included as co-authors in the manuscript. For ethical reasons and protection of personal information, the pooled study data was only accessible to the core team. **6. How were data used to develop analytical skills within the partnership?** The local university teachers from LMIC were involved in conceptualising the study and provided input at different stages. The data analysis was done by the first and the second author with supervision and help of senior university professors. A statistician was onboarded to ensure correct performance of the analysis. Results were presented to all co-authors and critically discussed and reviewed.
Data interpretation	**7. How have research partners collaborated in interpreting study data?** Results were reviewed by all co-authors and interpretation of the results was done using the local context, with valuable input from the local university teachers.

Table S3. (continued)

Drafting and revising for intellectual content	**8. How were research partners supported to develop writing skills?** The first author drafted the paper, and it was critically reviewed by all co-authors in multiple rounds. **9. How will research products be shared to address local needs?** Results from this study will be used to improve subsequent editions of the course within the universities and serve as guide for other universities to "adapt and adopt" for implementation. The programme is intended to run continuously in the future.
Authorship	**10. How is the leadership, contribution and ownership of this work by LMIC researchers recognised within the authorship?** Involved university teachers from LMIC are all experts within the field of SF medical products and those responsible within their respective universities for the deployment of the course within the pharmacy curriculum. They have been involved in conceptualizing the study, collecting the data, evaluating the results and reviewing multiple versions of the manuscript. The team relied heavily on their interpretation of the data and providing the context to the results. All researchers were included as co-authors in the manuscript. **11. How have early career researchers across the partnership been included within the authorship team?** The first and the second author of this paper are early career researchers, a PhD student and a master student respectively. **12. How has gender balance been addressed within the authorship?** There is an ensured gender balance with co-authors being both female and male, with majority of females (7 out of total 9 co-authors).
Training	**13. How has the project contributed to training of LMIC researchers?** This project trained the involved LMIC teachers in educational research, which provides evidence of the impact of new courses within the pharmacy curriculum. Scientific advice on educational research was obtained from a well-known expert at Utrecht University who was acknowledged in the relevant section of the paper. It should be noted that in the context of this project, the research partners based in LMIC gave guidance to the authors of this paper (i.e. researcher training was bi-directional) in particular to help adapt, contextualise, and interpret several elements.
Infrastructure	**14. How has the project contributed to improvements in local infrastructure?** The project demonstrated the need for specific demonstration equipment in universities - especially for the module on detection, and namely screening devices. This research and publication will be used as evidence for WHO and other partners to supply field screening devices to the pilot universities, so that the students can apply the theoretical knowledge and practice with adequate equipment.
Governance	**15. What safeguarding procedures were used to protect local study participants and researchers?** Study participants are students and evaluations are expected as part of the curriculum as for any course. Ethical advice was sought at Utrecht University. Informed consent was given by study participants and data are presented anonymously were possible. No personal data was used in the research and participants were able to withdraw their participation at any point in time.

4

Getting ready for what is ahead: perspectives and considerations for the future

4.1

Four scenarios for the future of medicines and social policy in 2030

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Abstract

The future of medicines is likely determined by an array of scientific, socioeconomic, policy, medical need, and geopolitical factors, with many uncertainties ahead. Here, we report from a scenario project, analyzing various trends, crucial and complex developments in the medicines' space. From a range of 'critical uncertainties' we derived two scenario drivers: global convergence, ranging from very high (trust and solidarity), to very low (fragmented ecosystems); and disease orientation, ranging from public health first to interceptive medicine. This resulted in four contrasting portraits of the future of medicines and social policy: deprioritizing the high-end; sustainable flow; transformative healing; and global divide. All those involved in drug discovery and development can use these for strengthening preparedness for the crucial challenges ahead.

Introduction

The history of drug discovery and development shows that science-based medicines did not enter the clinic earlier than during the mid-1950s of the previous century.[1] Before this, health threats, especially communicable diseases, were lacking vaccines or antibiotics, not to mention antivirals or monoclonal antibodies.[2] Thus, in a timespan of one or two generations, tremendous progress in biomedical innovation has been realized, from effective products for hypertension, diabetes, or rheumatoid arthritis to chimeric antigen receptor (CAR) T cell products and mRNA vaccines. However, it is not all good news. We see governments and healthcare systems struggling with rising pharmaceutical costs and drug shortages.[3,4,5] The global annual spending on oncology drugs was ~US$150 billion in 2020, a troublesome economic burden for any health system.[4] There is increased pressure from policy-makers, social activists, and also financial investors, on the private sector to rethink its business model. Moreover, the global divide in access to essential medicines is an escalating concern.[6]

Many foresee coronavirus disease 2019 (COVID-19) as a catalyst for change.[7] COVID-19 amplifies the very best and the very worst of nations and health systems in combatting a global health crisis. On the positive side, we see enormous resources for research being mobilized and scientists working round-the-clock shifts in labs, both in the private and public sector.[8] We see also increased international collaboration on regulatory reviews and setting vaccine standards.[9] On the negative side, we see nationalism, fragmentation, and lack of solidarity for ensuring timely and equal access to vaccines across the globe.[10] In May 2021, the WHO estimated that, at that moment, four out of five COVID-19 vaccines went to high- and upper middle-income countries, leaving low-income countries largely deprived from necessary immunization.[11] The ongoing debate on vaccine patent waivers and their potential impact on vaccine manufacturing shows a troubled combination of divergent arguments, including fairness and morality to back such waivers and minimizing adverse effects on future pandemic preparedness. In addition, there are also doubts whether transferring of intellectual property (IP) rights as a single factor could make any difference for global vaccine production.[12]

Changes to the ecosystem of how medicines are discovered, developed, and used in clinical practice have always been a mixture of top-down and bottom-up transitions, and more incremental advances through adaptive flows of events. Interactions between science, technology readiness, and societal demands (e.g., medical needs, bioethics, and equal access) have been driving various social outcomes, often wanted and appreciated, sometimes seen as negative and opposed. The highly variable impact across the globe of, for instance, regenerative medicine on new therapies has been illustrative for the ambiguities associated with such interactions.[13,14]

The medicines space across the globe is inherently connected to myriad ambitions and policies, whether we talk about the Pharmaceutical Strategy for Europe or the European Union (EU) New Green Alliance or advancing global health by WHO.[15,16,17] There is no such thing as medicines development and pharmaceutical science in splendid isolation.

Previous scenario work on the future of medicines and pharmaceutical science revealed many critical trends and uncertainties in science, health systems, economics and society at

large.[18,19] Analysts from academia, nongovernmental organizations (NGOs), policy-makers, and the business environment have sketched and expressed arrays of plausible scenarios for the future of medicines based on thoughtful analyses of predetermined elements (e.g., demography, scientific advances in cell biology, or data science) and critical uncertainties (e.g., trust in science and equity in access to medicines). In particular, analyses of critical uncertainties have been used in scenario planning for selecting drivers of the highest importance and the greatest uncertainty as axes creating a 2D space to plot different contrasting scenario stories. Typical examples of such scenario drivers include 'societal trust in technology', 'culture of academic science', 'level of public control', 'power of institutions', or 'more or less market economy'.

In January 2020, various pivotal trends and challenges for the future of domains such as precision medicine, pharmacovigilance, and clinical pharmacology at large, were coined.[20] In addition, reflections on the future of real-world data (RWD), innovative trial design, and preclinical research were shared. However, whether and how these scientific advances will have an impact on the future of medicines, thinking in the context of such scenario drivers, remains difficult to say. Nevertheless, scenarios could help here to gain a better understanding and insight.

Scenario building

In this review, we report from a scenario project in which we analyzed in a systematic and analytical way various trends, and crucial and complex developments in medicines space. We worked around these by thinking from the lab to the patient in a scientific and global context, rooted in current challenges and societal ambiguities. Scenarios in the sense we have applied them in this project do not intend to 'predict' the future.[18,19] Their real value lies far beyond that. Scenario analyses act as 'thinking devices' to guide stakeholders' policy and strategy ambitions and to communicate with a broader academic, health sector, and public audience. As such, they are also time capsules that signify what is seen as important at a certain moment in time.[21]

Given COVID-19 restrictions, scenario inputs were collected through 'Digital tables' in autumn 2020 with 37 international experts, thought leaders, and boundary spanners from the public and private sector, academia, NGOs, philanthropy, and different time zones, with a North–South balance in (see Supplementary Appendix A in the supplementary material for a more detailed description of the methods applied).

Based on the observations, dialog, and reflections during the 'Digital Tables', we engaged in an analytical process of selecting those trends and drivers with relatively high certainty, called 'predetermined elements', and those with a high level of doubt on impact or direction, called 'critical uncertainties' (Box 1, Box 2). 'Predetermined elements' are considered relevant, and as relatively stable and predictable for the backbone of the scenario space and are part of all the scenarios described herein.

From the range of 'critical uncertainties' we derived, through iterative weighing and selecting, two scenario drivers: (i) global convergence, ranging from very high (supranational collaboration, trust in institutions, and solidarity), to very low (fragmented ecosystem, nationalism, and geopolitical tensions); and (ii) disease orientation, ranging from public health first (population focus,

- Science and technology will continue to deliver; more on precision andtransformative medicine; blurring boundaries between pharma, artificial intelligence and MedTech.
- Growing concern about the global divide in access to and affordability of(new) medicines; pharma business models under critical scrutiny.
- Future medicines are more complex, need more monitoring andguidance for use; critical role of clinical practice after approval.
- International and interdisciplinary collaborations will advance pharmaceutical science; more interconnectivity and open science.
- Geopolitical tensions, nationalism, failed states and climate change have an impact on science direction and progress.
- Role of and trust in science are at stake; fake news, science skepticism and political capture of science are threatening credibility.

Box 1. Predetermined elements

- Future direction of clinical evidence building remains uncertain; what kind of methods will be acceptable, will real world data (RWD) and real world evidence (RWE) add to randomised clinical trials (RCTs)?
- Ambiguity about role of regulators: facilitators of innovation or gatekeepers?; variation in support of health technology assessment (HTA) for expedited regulatory pathways.
- Broken incentive system for drug development and usage; many alternatives are suggested, few have shown to work, what's next?
- Will prioritization of cancer and other high-end medicines remain or will we see a broader spectrum of diseases (e.g. pandemics, antimicrobial resistance)?
- Power of international institutions and global collaboration are at stake; what will be the risk of fragmentation and lack of leadership?
- Science policies are moving in various directions; top-down vs bottom- up, role of philanthropy and public-private, more open science?

Box 2. Critical uncertainties

communicable diseases, lifestyle, and prevention) to interceptive medicine (cancer focus remains, rare diseases, and early disease interception). These scenario drivers served as axes creating a 2D matrix to plot four contrasting portraits of the future (Figure 1).

Scenario 1: Deprioritizing the high-end

The deprioritizing the high-end scenario is positioned in the lower-left quadrant of the scenario space, reflecting a dramatic and, for many years, unexpected shift in disease orientation away from high-end oncology and medicines for rare diseases in a fragmented science and global pharma

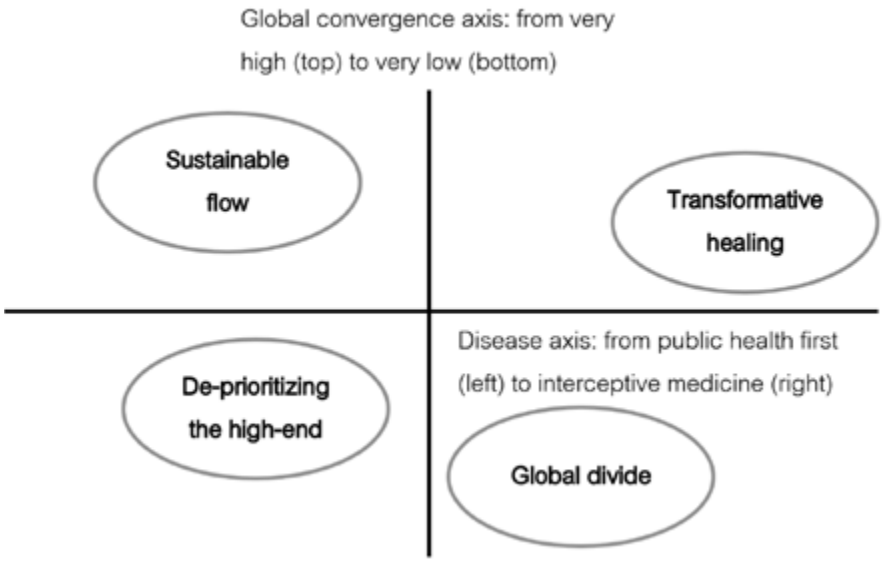


Figure 1. Four scenarios for the future of medicines and social policy in 2030

ecosystem. This is a scenario of disease reorientation, of broken expectations, and of promises of high-end technological solutions.

Frustration in terms of all the resources that went into high-end medicines with mixed outcomes collide with major economic and social concerns. For decades, scientific advances in cell biology, genomics, and biochemistry had major impacts in oncology and some impact in rare diseases. Since the end of World War II, the American Cancer Society has funded 49 investigators who went on to win a Nobel Prize.[22] The Nobel Prize for Chemistry 2020, awarded to Charpentier and Doudna for their ground-breaking work on CRISPR/Cas9, was a sign of opening new avenues for innovative cancer therapies.[23] Over many years, the spirit of 'this research will pay off in cancer' has been an influential factor in almost all areas of the life sciences. From research funding, building infrastructure, and conducting trials, oncology has paved the road to many advances in novel drug targets and signaling pathways, product delivery and targeting, monoclonal antibody platforms, COVID-19 vaccines, nanoscience, biomarkers, and personalized medicine. The pipelines of biosimilars and next-generation biotherapeutics have been catalyzed by expired patents of some major blockbuster biologicals in oncology.

From 2010 to 2020, the proportion of oncology products entering the global market increased from 30% to over 50% of total new drug launches, particularly for rare, hematological types of cancer. In 2020, of all products in late-stage pipeline development, more than 30% were anticancer drugs.[24] To compare, for cardiovascular or vaccine products, these proportions were less than 5%.

In this scenario, a tipping point in the dominant position of oncology and other high-end products is reached. Several triggers contribute. First, what oncology products really mean in terms of clinical and societal benefit is heavily debated, and contested. The temperature of the debate goes up and down, but in the end, criticism appears to prevail. Progression-free survival gain of 4 months

between treated and nontreated, a response rate of 65%, but no survival benefit, single-arm studies with challenges to interpret the results, agnostic indications with all the inherent discussions about robustness of evidence and clinical meaning: all of these stir feelings of uncertainty and scepticism around oncology. Medicines for rare diseases, pharma's high-end favorite for about two decades, receive similar critical exposure. Also in the business arena, the flow of capital takes another route away from oncology and high-end products (too risky, too complex, and too many competitors for an acceptable return of investment).

Patients and physicians struggle, the medical needs in cancer have not disappeared, but there is an increased common desire for more quality of life instead of more years of survival or some improvement on a biomarker or surrogate endpoint. Although this is obviously not everywhere; some patient advocates still march for enabling everything that is possible.

What really moves this scenario are rising healthcare costs with increased spending on high-end medicines, reaching unsustainable levels for many countries, including affluent ones. Payers and Health Technology Assessment (HTA) bodies push very hard for the defunding of the high-end. They hold regulators responsible for being too flexible on approving oncology products with relatively modest, incremental, and uncertain benefits. They themselves are blamed for using clinical arguments as an excuse for budget concerns. However, their influence becomes stronger when industry leaders also admit that the underlying business model of oncology and rare diseases [i.e., high prices for low-volume products, often acquired from small- and mid-sized enterprises (SMEs) for huge amounts of money] is out. This upward spiral comes to an end.

In 2030, we observe a shift in pharmaceutical and biomedical sciences away from dissecting deep complex molecular mechanisms. It becomes increasingly difficult to collect sufficient funding to run labs and conduct clinical trials. Competition for research funding is devastating. Science is less seen as part of the solution. Lifestyle interventions and disease prevention peak on policy agendas. The pharma ecosystem is becoming fragmented. Practice research and repurposing, getting more out of existing and off-patent pharmaceutical products, appear to blossom, not as priority choice, but as a last resort option to push innovation.

Scenario 2: Sustainable flow

The sustainable flow scenario is one of a new social contract, a clear reset after the public sector being in command in many places during the COVID-19 pandemic. There is a convincing push to rethink the existing global pharma ecosystem. This is not a scenario of skyscraper pharmaceutical innovation; instead, it is about prioritizing social policy in innovation, including transparency, digital ethics, and open science models.

Investing massive resources in the few contrasts with the health needs of the many, backed by business models that do not appear to be helpful in shifting investments to priority medicines and public health needs. Although this is not a new observation, it is a wakeup call that resonates more loudly at a time when ensuring equal access to pharma innovations (e.g., COVID-19 vaccines or medicines for rare diseases) and restoring trust in global institutions are embraced at many levels. In addition, the learnings from the commons (i.e., something central to life but not owned

or controlled by one person, company or state) give impetus to major changes in the way that medicines are developed and marketed. Originally applied in areas such as climate change and biodiversity, such thoughts give inspiration to translate these to change and renewed policies and strategies in the life sciences and pharma business space. Flow of capital is increasingly driven by sustainability, fairness, and social justice.

This scenario is positioned in the upper-left quadrant of the scenario space, reflecting a shift in disease orientation and convergence of science and the global pharma ecosystem. The access debate highlights divisions at the high-end with innovative therapies only accessible and affordable for the lucky few, which is less accepted. There is increasing focus on structural inequalities and the economic and social context of the divide. Societies in many regions of the world want innovations to be better aligned with societal demands. Greater weight is placed on developing the infrastructure, skills, and capabilities needed for scientific advances in medicines translating to public health benefits. Scientific excellence is not enough. Research agendas and funding are navigated to do more for the greater good.

Pharmaceutical science in this scenario is based on increased knowledge sharing, open science, and partnerships with citizen science. We observe a push for smart innovation (i.e., public–private alliances), widespread technology transfer, and social entrepreneurship. In terms of capacity building, we see an influx of the humanities, social science, and knowledge sharing in a field that traditionally was hosted by (bio)chemistry, pharmaceutics, and biology. Connectors are in the hot seat. Life-time scientists become exceptions, science and society integrate. However, academics struggle with these new responsibilities. Prioritizing societal impact of research is not without failures (i.e., acting on new reward systems incentivizes also prioritizing short-term hypes in science).

Marching for universal healthcare when it comes to access to essential medicines is high on many health policy agendas. Ensuring the availability and affordability of medicines at the global level is in a rather progressive roll-out. Calling for alternative economic models to counter high prices and monopolies goes hand in hand with a rethink of patents and IP. Not that they disappear, but alternative forms of private and public IP sharing are gaining momentum. In this scenario, we see a smart mix of for-profit and community players in drug development and investments, especially with a larger role for end-users. Responsible licensing, new stick-and-carrot models with more balanced levels of fairness, are key. Academic institutions are much better organized than in the past; they become stronger players in the ecosystem and there is more interconnectivity. The role of empowered patients, healthcare workers, and researchers from low-and middle-income countries (LMICs) changes rapidly (i.e., becoming more engaged and more demanding).

Regulators also collaborate by referencing, convergence, and sharing data. There is far-reaching harmonization and strong support for LMICs to strengthen their own regulatory systems, nationally or in the region. We see a greater role for global institutions, such as WHO, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), or the Global Alliance for Vaccines and Immunizations (GAVI). Philanthropy peaks on ethical leadership and maximum societal impact.

However, this not all good news for delivering new innovations. Healthcare practice is increasingly politicized and technology aversity is widespread. Law makers, governments, NGOs,

and civil society interact, interfere, and push agendas. Although there are many attempts to march for win-wins, this scenario is poor on, for instance, finding solutions for mental health or building successfully pandemic preparedness for the future.

Scenario 3: Transformative healing

Transformative healing is the scenario of harvesting major scientific breakthroughs in cell biology, medicinal chemistry, and nano- or data science. There is widespread optimism about the role of science and entrepreneurship for bringing health benefits to society. This is a scenario of high hopes and promises of cure, although, in many aspects, with challenges for ensuring equity, digital ethics, or other social values.

This scenario is positioned in the upper-right quadrant of the scenario space, reflecting a high-end disease orientation and a coordinated science and global pharma ecosystem. The successes of pharma leveraging effective and safe pandemic vaccines to the world so swiftly, brings new confidence to the private sector. mRNA platforms, glycobiology, exosomes and follow-up technologies, artificial intelligence (AI) and big data, all are well funded. Philanthropic funding is skyrocketing. De-siloing and blurring lines between sciences and technologies are important features of the bioscience landscape. The role of academic entrepreneurship, SMEs in generating IP, and acquisition opportunities for big pharma is unprecedented. China leads the new 'Silk Road' for pharmaceutical research. The United States of America (USA) and Europe follow at a distance.

The combination of pharmaceutical science, bioinformatics, and MedTech has become a game changer. There is ample interest in advanced therapies (e.g., gene and cell therapies) making curative, long-term treatments a reality. Early disease interruption strategies are becoming successful while targeting the origins of distortions of biological systems in a very early and pre-symptomatic phase. Machine learning, real-world evidence (RWE) for evidence generation, 3D printing, wearables, logistic chain technologies, all appear to have immense opportunities. In addition, technology giants, such as Google and Amazon, have stepped in. They link and integrate through advanced AI networks the various medical needs to high-end diagnostic and therapeutic platforms.

The nature of medicines has changed dramatically. More curative, transformative strategies enter the system. We see more platform technologies, not everybody gets the same therapy, and medicines are becoming less forgiving of the usage context (i.e., in 2030, about four out of five approved medicines have prescribing limitations, specific directions, and conditions for use). They are not easily fit for use in community settings, more limited to secondary and highly specialized centres. This is a trend to stay, with major implications for healthcare practice. The underlying business model remains attractive for the private sector. Technological innovation is also seen in less affluent regions, such as drones delivering medicines in rural Africa or speedy mobile labs in Brazil.

The clinical trial industry has become extremely lean and efficient. Better study designs, better clinical data sets, and a buy-in of regulators and HTA bodies to adaptive and flexible approaches for unmet medical needs, are the main drivers. Omics and robust approaches for *in vitro*/*in vivo* correlation are used to decrease trial times and data complexities. Alignment with clinical

practice (e.g., physicians and pharmacists) has been very developed in enabling translational science. Big companies keep buying promising projects and IP from SMEs. This market is very competitive (i.e., more buyers than sellers), leading to huge acquisition costs and high prices to recoup investments, but the financial ecosystem remains resilient. Flow of capital is still sustainable. The rewards for innovation remain high and attractive. However, healthcare costs are on the rise, solidarity is at stake, and political opposition to counter is weak.

Trust in science is a major driver of this scenario. Push for entrepreneurship and value creation is back again at university campuses. Knowledge sharing and open science are seen as old school ambitions. Collecting IP instrumental to foster innovation and economic return is celebrated and contributes to academic successes.

International medicines regulation is at a crossroads. Global regulators are contributing to this transformative wave with various expedited frameworks enabling efficient trials, rolling reviews, and conditional pathways. Regulatory science is pivotal to underpin these balancing acts. We see more international collaboration, convergence, and reliance. Impact of European Medicines Agency (EMA) or US Food and Drug Administration (FDA) decisions on regulatory processes in neighboring regions in South America, Asia, or Africa is there to stay. HTA agencies are less on the solidarity track and more on enabling diversity of choice options. International competition and a greater role for patients as end-users are key drivers for innovation. With bed-side manufacturing, advanced biomarker strategies, and high-tech dispensing, medical practice is in transition.

Scenario 4: Global divide

Global divide is a scenario of a serious geopolitical clash and chaos in the aftermath of the COVID-19 pandemic. This is a 'dark' scenario from a global perspective (e.g., decline of the institutions, innovation gaps, and persistent mistrust between nations and regions). However, some regions, particularly in Asia and South America, are doing very well.

The messy global manufacturing and distribution of COVID-19 vaccines, failed virus containment policies, and increased nationalism all contribute to make this scenario happen. It is positioned in the lower-right quadrant of the scenario space, reflecting a fragmented science and global pharma ecosystem. Disease orientation has become a mixed basket of existing priorities and national preferences, a defunding of global health needs. Bilateral alliances between nations tailor pharmaceutical needs and priorities toward their own political agendas, whereas taking care of the great global good is far away.

There are major changes in the geopolitical situation with significant power shifts, such as the rise of Africa and some regions in South America (e.g., Brazil), and the boosting of China and other regions in Asia (e.g., Japan and Singapore). The USA tries to reshape its leadership internationally and UK restores bonds with old friends, such as Canada and Australia. We see the EU struggling with post-Brexit decisions, fighting internally on how to position between the USA, Russia and China. Moreover, the EU is heavily engaged in a delicate balancing act between economic and industrial policies and the long political wish list on climate change, data ethics (battling the power of tech giants and AI), solidarity, social justice, and human rights. Global institutions, such as the WHO,

World Bank, and Organisation for Economic Co-operation and Development (OECD), fail to bridge and lead. The global commons appear to be forgotten.

As a result of increased global fragmentation, the international pharma chain is under great pressure. Seamless production, logistics, and trade between countries and regions are hampered by the lack of coherent regulation, bureaucratic and political complexities, unilateral decisions, and clientelism. This spiral catalyzes a broken global pharmaceutical market. Drug shortages, lack of trust, and delays in almost everything, from research, conducting clinical trials, regulation, and production to market access, dominate the ecosystem. On top of industrialized production, there is more on individualized bed-side preparation of high-end products, local production, and pharmacy compounding as alternatives for drug shortages or high-priced medicines. Not to forget the 'Do-It-Yourself' movement in which interested parties (e.g., patients and some NGOs) create their own enabling context of drug development and production.

This situation raises many regulatory, economic, and professional questions. Regulators respond to national, often political and ad hoc, pressure. We see less harmonization in decision making and regulatory systems. Groups such as the ICH and the International Coalition of Medicines Regulatory Authorities (ICMRA) struggle to survive and WHO is unable to compensate. There are more differences between countries and regions when new products are allowed to enter the market. What was seen during the 1980s (i.e., drug lags) is back again.

Increased disintegration in science, from priority setting to conduct and outreach, is reaching momentum. However, from a contents and metrics perspective, the situation for the pharmaceutical sciences in this scenario is not as bad. We see peaks in molecular biology (e.g., RNAi or antisense nucleotides) and glycan science; identification of new drug targets progresses quickly. Combinations of pharmaceutical science, bioinformatics, and MedTech is blossoming, particularly in China and the broader Asian region. Capital flow follows. In addition, tech giants, such as Google or Amazon, are ready to step in. Knowledge sharing, open science, and collaboration are over the hill and dreams of the past. 'Forget ethics and social justice, innovate …' is a slogan that resonates widely.[25] Sovereignty and top-down national policies drive research agendas and funding. The increased role of philanthropy fits well with this fragmented landscape. What once started as humanitarian and altruistic is taking a bigger power stake in research agenda setting and driving the interests of donors. Philanthropy drives certain high-end clinical domains for the few willing and able to pay, while overall public health investments are lagging behind.

In 2030, we observe an increasingly scattered pharma landscape, with some regions doing very well in biopharmaceutical research, but many others lagging far behind. The existing global health divide is more pertinent than ever before. Pharmaceutical research is fragmented when it comes to priority setting, collaboration, and funding. Failed solutions for climate change, biodiversity, and sustainable energy contribute to the global misery.

Discussion

The four scenarios depicted above are narratives of plausible, contrasting futures of medicines and social policy. The scenarios are no predictions, no dreams, and no warnings.[21] All four of these futures

could happen. They are intended to confront key players in the field with alternative portraits of the world ahead. The scenarios are built on several realistic assumptions, collected insights, and analyses from Digital Tables with international experts and thought leaders. However, there are large differences between all four scenarios, not on all aspects, but on critical ones (Table 1).

Essentially, scenarios are qualitative stories. However, the direction, tone, and story line of the narratives allow for quantitative modeling and underpinning. In Figure 2, Figure 3, the 2020–2030 weighted estimates derived from the substance of the four scenarios (real data 2010–2019, standardized for 2020 = 100) of two indicators on clinical development for all therapeutic categories and early-stage pipeline for oncology are presented. The estimates of overall clinical development of new medicines doubles in the transformative healing-scenario, whereas, for the deprioritizing the high-end scenario, new entrants in clinical development slow down with about 20%. Only in the sustainable flow-scenario is no change seen. For the early-stage oncology pipeline, the 2030 picture will be different for all four scenarios. Whereas between 2010 and 2019 this indicator increased from 40 to 100 (standardized), the curves flatten or decline in all four scenarios between 2020 and 2030, most dramatically in the deprioritizing the high-end scenario.

In Figure 4, we present medical patent filing data to translate plausible impact on medical innovation potential for the four scenarios in major geographical regions across the globe. In all four scenarios, Europe's share in the global medical innovation potential decreases to below 20%; in 2010, this was still 30%. The USA remains close to China in innovation potential (i.e., 25–35%) in all scenarios except in the global divide scenario. In the latter, China is by far the patent champion, with about a 50% share in global innovation potential, leaving the USA and Europe far behind.

Table 1. The four scenarios in key words

	Scenario			
Pivotal theme	**Deprioritizing the high-end**	**Sustainable flow**	**Transformative healing**	**Global divide**
Science and technology	Decline, broken promises and dreams	Openness, citizen science, de-siloing	Competitive, high-end focus, rise, promise	Highly fragmented, forget ethics, innovate
Incentive structures for innovation	Frustration, pharma ecosystem fragmented	Pull focus, IP sharing, ethical philanthropy	Push focus, IP driven, rich capital flow	Scattered landscape, China as global lead
Access and affordability	Stringent regulation, limited access	Regulatory rethink, equity high priority	Regulatory flexibility, high willingness to pay	Uncoordinated regulatory space, unequal access
Addressing global health needs	Priority for primary care, basics	Universal health care, global dialogue	Not a priority, except for willing payers	Decline of institutions, huge health divide
Healthcare practice	Repurposing, practice innovation	Public health, community drive	Innovative, tech heaven, highly specialized	Fragmented, highs and lows, Do-It-Yourself

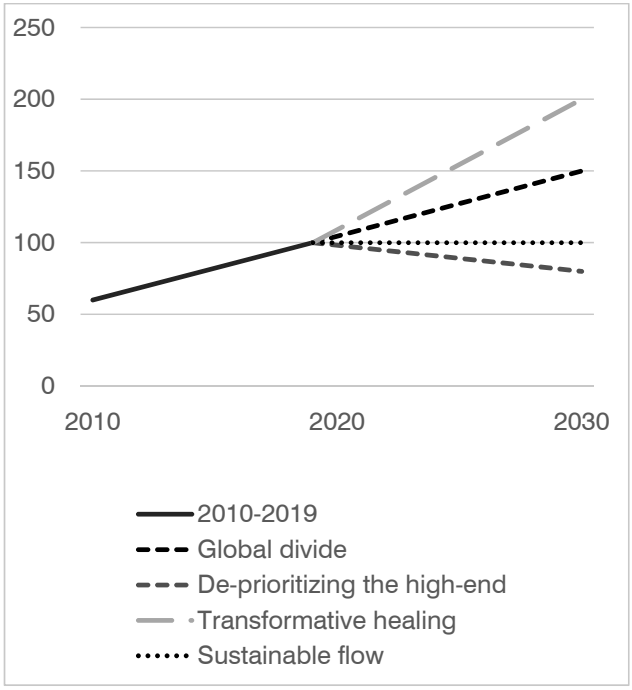


Figure 2. New entrants in clinical development (Phase II) in all therapeutic categories

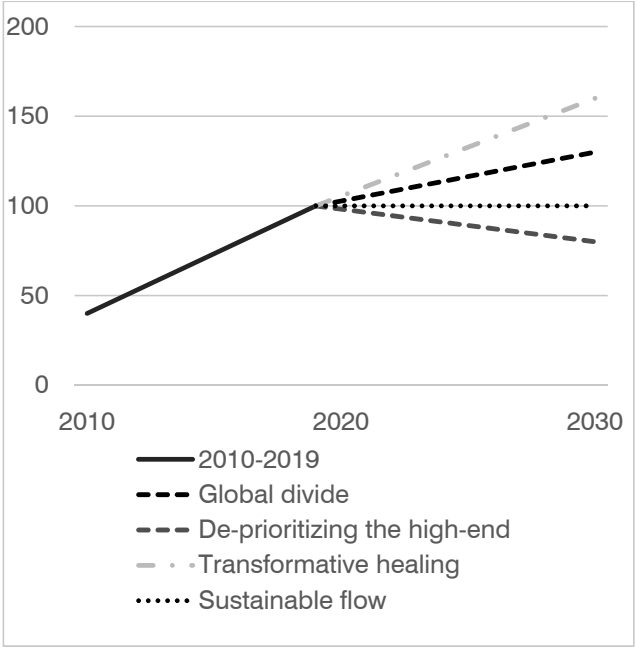
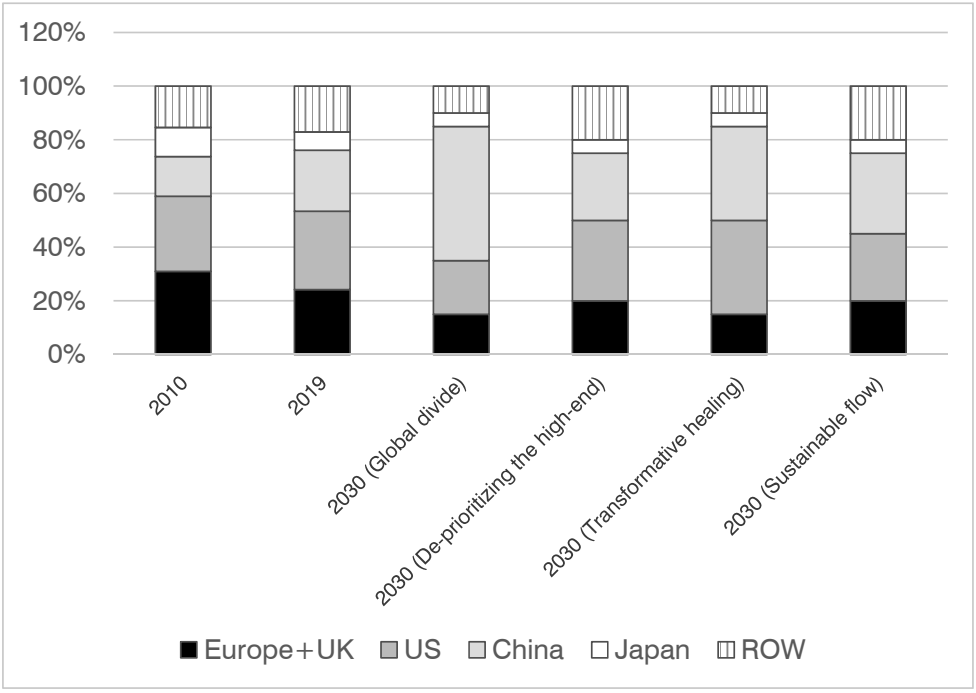


Figure 3. Early-stage oncology pipeline, including discovery, preclinical, and Phase I



Abbreviations: UK = United Kingdom, US = United States of America, ROW = Rest of the World

Figure 4. Patent filing by country (World Intellectual Property Organization stratified for medical innovation)

A key aspect regarding medicines and social policy has always been the intriguing, and often troubled role of industry, and the private sector in general, in an environment full of public expectations, demands, and social concerns. There is probably no sector in society, depending of course in which part of the world you live, where the confrontation between public and private is so loaded with public outcry to control, regulate, or incentivize. History shows for good reasons. There is ample frustration about drug prices, about lack of equity in access, but also about research priorities leading to therapeutic gaps (e.g., antimicrobial resistance and neglected diseases). Whether public interventions have always delivered and whether they are proportionate and effective remains controversial. Interestingly, COVID-19 also here inspires for lengthy recipe books for 'doing things differently'. In all four scenarios, the balancing act between public and private sector is highly visible, particularly when contrasting the transformative healing scenario (i.e., private sector in the lead) and the sustainable flow scenario (i.e., public sector push).

All four scenarios portray science practice, research priorities, and trust in science in a sketchy manner. Trust in science is high in the sustainable flow and transformative healing scenarios. However, science culture and practice are very different between the two (e.g., open, vocational, and collaborative in the sustainable flow scenario, whereas entrepreneurial and competitive in the transformative healing scenario). Trust in science is broken in the deprioritizing the high-end scenario, whereas, in the global divide scenario, science is fragmented globally, with China

dominantly in the lead. These contrasts work out differently when looking at progress in the clinical development of new medicines. Here, transformative healing and global divide continue to rise, whereas a drop in progress is seen in the other two scenarios (Figure 2). The four scenarios do not differ very much on the science contents, given that these are a predetermined element (e.g., more on cell biology and data science, blurring borderlines between pharma and MedTech).

The role of regulators and their requirements for evidence building for making decisions on quality, safety, and efficacy vary across the four scenarios. Particularly in the space of clinical evidence building, we see heavy debates on study design and endpoints, data, and measurements.[26, 27] Most regulatory systems as we know them today were established 50–60 years ago. Since their inception, there has been a heated debate on how much and what kind of evidence is needed and how much uncertainty is acceptable. Several scholars in the field of regulatory science have underscored the shift over the past decades to less rigorous methods of evaluating clinical benefit, with inherent challenges for drug labeling and HTA, fuelling pertinent questions on future directions.[28, 29] Given that medicines regulation has many international dimensions, the level of global coherence is key.[30, 31, 32] As a consequence, the sustainable flow and transformative healing scenarios both peak on this axis (Figure 1). In both scenarios, global coherence of regulatory requirements and procedures are important features. By contrast, we see the opposite in the deprioritizing the high-end and global divide scenarios. Thinking through the four scenarios presented here could help to strengthen the field and fuel strategic thinking ahead.[33]

When looking at the four scenarios, stakeholder or personal preferences can color appreciation of the chance or likelihood that the world will be as sketched in the four individual narratives. The transformative healing scenario might be seen as a blessing by industry, whereas the same could be true for NGOs or patient activists when looking at the sustainable flow scenario. The global divide scenario is possibly terrifying for many in the Western world, particularly in Europe, whereas the deprioritizing the high-end scenario might be the most unlikely or illusory one. Who wants to deprioritize innovation in cancer? Ask people in your local high street.

Readers are invited to stir their imagination, to think loudly. Readers might find one or two scenarios more preferable or more likely to happen than the others. Some readers might find bits and pieces they like in all four scenarios and prefer to sketch their own most preferred or likely scenario.

Readers are most welcome to play around with the four narratives, moving their position in the 2D scenario space, amplifying or downgrading certain scenario features. However, at the end, the four narratives aim to stimulate thinking, reflecting, and asking the right follow-up questions given that the world in 10–15 years might look like that depicted here. What does that mean for me as prescriber, me as clinical scientist, me as regulator, me as policy maker and even me as a patient or citizen? Who will win, who will lose? These are tough questions that are not easy to answer, but are significant and useful for being prepared for an uncertain future. Scenarios are intellectual devices for being confronted and for bolstering future preparedness. COVID-19 has showed us in an alarming way that the world was not very well equipped to think ahead, despite numerous warnings in the past that serious emerging infectious diseases were never far away and that trust is needed to

overcome the challenges ahead.[34] Pandemic preparedness appeared to be always more in minds or plans rather than in reality.

The scenario analysis presented here results from various choices on methodology, invites of experts for the Digital Tables, time horizon, and the authors' own positions and roles. We selected for an academic, multiangle approach, but cannot exclude that our own presumptions and biases have affected the outcome of the analysis. The same is true for the selection of the participants of the Digital Tables. Most were global thought leaders with relatively high-level positions in the ecosystem. Thus, we might have missed relevant odd or outsider perspectives. Along similar lines, we selected our Digital Table participants for their strategic and overseeing competences which might also have been done at the expense of diversity, equity, and inclusion (DEI).

Concluding remarks

The future of medicines and social policy will affect us all, as pharmaceutical scientists, healthcare professionals, clinical pharmacologists, policy makers, patients, or citizens. There are many uncertainties ahead, some more pertinent than others. We present four plausible scenarios for that future as an invitation to use these for strengthening preparedness for the critical challenges that are there and those that will come.

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Supplementary material: Appendix A

The following are the Supplementary data to this article:

Scenario building methodology

Domain of the analysis

The first step in the scenario analysis was identifying the time frame and analysis domain of the scenario building process.[1,2] The study was designed in 2020 and following previous scenario analyses, we decided to cover a time frame of ten years building scenarios for the future of medicines and social policy in 2030.[1,3] We chose for 'medicines' as a more broad term including disciplines ranging from drug discovery to post-marketing research and diagnostic tools and devices in the pharmaceutical sphere as far as these are an integral part of delivering the drug to the patient or optimizing therapy for the individual patient.[3] The term 'medicines' extends to pharmaceutical development and use in the broader context of knowledge generation, regulation, innovation, healthcare practice, ethics and (social) policy. Following this line of thinking, we made this explicit by centring the analysis on five pivotal themes: [1] Science and technology, [2] Incentive structures for innovation, [3] Access and affordability, [4] Global health needs and [5] Health care practice. The choice of these pivotal themes was made by the study team, based on earlier scenario analysis experiences.

Participants and data collection

Participants were invited to participate in 'Digital tables' in the fall of 2020. We selected international thought leaders and boundary spanners in the pharmaceutical sciences taking into account a balance between public and private sector, academia, NGOs and North-South (see participant list below). The 37 experts who participated received a briefing package that included background publications with findings of a previous scenario analysis on pharmaceutical sciences in 2020[3] and two guiding questions that served as starting point for the discussion:

- When thinking about pharmaceutical sciences of 2030, in your opinion, what are predictable elements that will have shaped the pharmaceutical sciences of 2030? Both in general, and within your area of expertise.
- When thinking about pharmaceutical sciences of 2030, in your opinion, what are unpredictable elements that may or may not have a significant impact on the pharmaceutical sciences of 2030? Both in general, and within your area of expertise.

The insights from experts on these questions were then collected over two days through open discussions at eight digital tables, with each table having 4-6 participants and lasting for one hour. All tables were chaired using a conversation protocol and multiple note takers took notes on a structured form. Roles of chairs and note takers were shifted between tables and all chairs and note takers are authors on the publication.

Identification of driving forces

During day one the aim of the digital tables was to identify driving forces that could have a large impact on the pharmaceutical sciences in 2030. We also discussed the extent to which there was uncertainty about these driving forces, in order to distinguish between so-called critical uncertainties (driving forces with high impact and high uncertainty) and predetermined elements (driving forces with high impact but low uncertainty). At the end of day one, the study team created in an iterative fashion an overview of the predetermined elements and critical uncertainties that were most often mentioned and deemed most significant. During day one the created overview was presented to the participants at each table for validation purposes and to discuss any missing elements. The aim of these discussions was also to provide in-depth understanding and anatomy of the specific types of impact expected from the identified driving forces in the context of the five pivotal themes.

Scenario analysis

After the meetings, the study team engaged in several rounds of thematic coding of the notes of all digital tables, using the five pivotal themes as main themes in the coding process. Identified themes and driving forces were then ranked and clustered by the entire study team through iterative discussions in several meetings to identify the two most critical scenario drivers. These drivers serve as axes in a two-dimensional matrix to plot four contrasting portraits of the future, all four with their own story plot and logic. After the two axes were decided upon, identified themes were allocated to each of the four scenarios in order to flesh out feasible future stories of the pharmaceutical sciences ahead. The first author then engaged in writing down the narrative for all four scenarios which were discussed and enriched based on the input of the study team in several meetings.

One of the building blocks of this process was adding quantitative analyses of a number of selected key variables in order to strengthen the fleshing out of the plot and logic of the presented narratives. The scenarios were documented quantitatively with plausible, scenario story derived, weighted estimates for 2025 and 2030 based on firm facts and data for 2020 (source IQVIA), complemented by underpinning from the experts.

List of international experts who have contributed to the scenario building process. All experts have given written consent to be included in this list. They are not responsible for the scenario analysis and/or the contents of the manuscript. The first affiliation concerns the connection at the moment of the scenario building; if appropriate a current or former affiliation is also listed.

Aaron Kesselheim	Department of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, USA
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Alex Rusu	Global Policy and External Affairs, Merck KGaA, Darmstadt, Germany
Ames Dhai	University of the Witwatersrand and SA Medical Research Council, Johannesburg, South Africa
Arnold Chan	Health Data Research Center, National Taiwan University, Taipei, Taiwan
Bob Vanderstichele	Department of Clinical Pharmacology, Ghent University, Ghent, Belgium
Bruno Flamion	Department of Clinical Pharmacology, University of Namur, Namur, Belgium
Carla Hollak	Department of Internal Medicine, Amsterdam University Medical Centre, Amsterdam, The Netherlands
Catherine Duggan	International Pharmaceutical Federation (FIP), The Hague, The Netherlands
Cees de Joncheere	Netherlands Antibiotics Development Platform; formerly Essential Medicines at World Health Organization (WHO), Geneva, Switzerland
Christoph Conrad	Unit Major Policy Issues, International Relations, Paul-Ehrlich-Institute, Langen, Germany
Daan Crommelin	Department of Pharmaceutics, Utrecht Institute for Pharmaceutical Sciences (UIPS), Utrecht, The Netherlands
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Erem Bilensoy	Department of Pharmaceutical Technology, Hacettepe University Faculty of Pharmacy, Ankara, Turkey
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Giovanni Tafuri	International Market Access and Policy, Apellis Switzerland GmbH, Zug, Switzerland
Hans Georg Eichler	European Medicines Agency, Amsterdam, The Netherlands; currently Association of Austrian Social Insurance Bodies Vienna, Austria
Hans Schikan	Top Sector Life Sciences and Health, The Hague, The Netherlands
Hiroshi Suzuki	Pharmaceutical Department, The University of Tokyo Hospital, Tokyo, Japan
John Lim	Centre of Regulatory Excellence, Duke-NUS Medical School and Consortium for Clinical Research and Innovation Singapore (CRIS), Singapore
Jon de Vlieger	Lygature, Pioneering Medicine - Together, Utrecht, The Netherlands
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Lembit Rago	Council for International Organizations of Medical Sciences (CIOMS), Geneva, Switzerland
Lukas Roth	U.S. Pharmacopeia (USP), Rockville, Maryland, USA and the University of Sydney, Sydney, Australia
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List of international experts who have contributed to the scenario building process. (continued)

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Richard Laing	Department of Global Health, Boston University School of Public Health, Boston, USA
Rogerio Gaspar	Faculty of Pharmacy, University of Lisbon, Lisbon, Portugal; currently Regulation and Prequalification Department of World Health Organization (WHO), Geneva, Switzerland
Ross McKinnon	College of Medicine and Public Health, Flinders University, Adelaide, Australia
Saco de Visser	Future Affordable and Sustainable Therapies (FAST) and Netherlands Organisation for Health Research and Development (ZonMw), The Hague, The Netherlands
Sophie Bloemen	Commons Network, Amsterdam, The Netherlands
Tim Reed	Health Action International (HAI), Amsterdam, The Netherlands
Tom Achoki	Africa Institute for Health Policy, Nairobi, Kenya

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4.2

Pharmaceutical scientists' perspectives on capacity building in pharmaceutical sciences

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Abstract

With the anticipated health challenges brought by demographic and technological changes, ensuring capacity in underlying workforce in place is essential for addressing patients' needs. Therefore, a timely identification of important drivers facilitating capacity building is important for strategic decisions and workforce planning. In 2020, internationally renowned pharmaceutical scientists (N=92), largely from the academia and pharmaceutical industry, with mostly pharmacy and pharmaceutical sciences educational background were approached (through a questionnaire) for their considerations on influencing drivers to facilitate meeting current capacity in pharmaceutical sciences research. From a global view, based on the results of the questionnaire, the top drivers were better alignment with patient needs as well as strengthening education – both through continuous learning and deeper specialisation. The study also showed that capacity building is more than simply increasing the influx of graduates. Pharmaceutical sciences are being influenced by other disciplines, and we can expect more diversity in scientific background and training. Capacity building of pharmaceutical scientists should allow flexibility for rapid change driven by the clinic and need for specialised science and it should be underpinned by lifelong learning.

Introduction

Demographic and technological changes in the 21st century inevitably bring health challenges, both locally and globally.[1] Epidemiological profiles are evolving with the rise of lifestyle-related conditions and noncommunicable diseases, ageing populations, and the emergence of new disease threats and conditions linked to climate and other environmental changes.[2] The United Nations Sustainable Development Goals (SDGs) call for good health and well-being for all (SDG 3), and universal health coverage by 2030.[3] However, it is clear nothing can be achieved without an underlying pharmaceutical workforce.[4]

Unfortunately, there is a projected staff shortfall of 18 million by 2030.[5] Especially low- and middle-income countries have human resource gaps at many levels.[6] Approximately 85% of World Health Organization (WHO) Member States report having less than one pharmaceutical personnel per 1,000 inhabitants.[6] Recent intelligence confirmed these concerns. A 2018 analysis suggests an increase in the global capacity of pharmaceutical workforce, namely pharmacists,[7] but the outlook can be bleak especially in light of workforce migration and the COVID-19 pandemic that brought widespread staffing shortages.[8] While these staff shortage projections data are primarily available for health care practitioners,[7] shortages have also affected the pharmaceutical sciences. Here routinely collected data on numbers of pharmaceutical scientists is lacking, but we see it indirectly as self-reported by life sciences companies. For 75% of them the role of their human resources has significantly transformed since the pandemic began, and 52% of them claim talent scarcity as the biggest impact on their business.[9] The demand for talent in the pharmaceutical sector is increasing in both high- and low- and middle- income countries.[10] For example, in India the attrition rate rose from 10% in 2020 to 20% in 2021 while this sector is expected to grow three times in the next decade.[11] One third of innovative pharmaceutical companies wishing to establish themselves in the Netherlands have a problem finding suitable (bio) pharmaceutical scientists.[12] Moreover, there is an urgent, growing talent gap as the skills of the pharmaceutical workforce have not yet aligned with the new world of cutting-edge therapies, such as biotechnology, precision and gene therapies, to name a few.[13,14] Influx of other disciplines and (digital) technologies will likely exacerbate this gap, for example artificial intelligence is expected to expand the market in global healthcare with $31.3 billion by 2025.[15] While the future lies with many uncertainties ahead, all these changes will stir the pharmaceutical landscape and consequently affect the asks for capacity building for pharmaceutical scientists.[16]

As an important group in the health and pharmaceutical sector, pharmaceutical scientists possess wide range of expertise in science and technology related to medical products. This concerns medical products' discovery and development, as well as manufacturing, regulation, and utilisation.[17] Pharmaceutical scientists are predominantly active in academia and the pharmaceutical industry, with a slightly different research focus: while basic discovery research is significantly led by academia and public research institutions funded by the government (pre-clinical stage), development, manufacturing and quality assurance is generally led by pharmaceutical industry (late- and clinical- stage).[18,19]

Building the capacity of pharmaceutical scientists to perform high-quality research which advances the knowledge base in pharmaceutical sciences, translates into new scientific discoveries and enables evidence-generation for novel therapies, is critical in order to drive continuous improvement and ultimately, to address unmet medical need.[18,20,21] "Capacity" is a broad term, interpreted and operationalized in many different ways. In a general sense, the term is understood as "the process of enhancing individual skills or strengthening the competence of an organization or set of organizations to undertake specific tasks."[22] For the purpose of this study, meeting capacity in pharmaceutical sciences research means having adequately competent and sufficiently numbered pharmaceutical scientists in place, to sustainably meet needs in new discoveries, development, clinical utilisation, marketing regulations, and the economic assessment of medical products.[23,24]

As the contribution of pharmaceutical scientists' to meeting overall health and well-being challenges through delivery of novel therapies increases, so too does the expectation that pharmaceutical scientists will continue to bring safe, effective and sustainable therapies to those who can benefit most.[24] Therefore, a timely identification of important drivers that facilitate meeting current capacity in pharmaceutical sciences research can be important for strategic decisions and workforce planning. If left unassessed, a misalignment could hinder innovation and create shortages of skilled human resources.

Therefore, the aim of this study was to gain perspectives from pharmaceutical scientists on the drivers important for meeting this capacity. We hypothesised differences between views from respondents from various educational backgrounds and affiliations exist. These views can help inform careful and strategic investing in and planning of the underlying workforce. Pharmaceutical scientists should take leadership in this process.

Methods

Participants and settings

The International Pharmaceutical Federation (FIP), the global organization representing pharmacists and pharmaceutical scientists, is organising the Pharmaceutical Sciences World Congresses (PSWC) on a bi- or triennial basis, for the global audience of pharmaceutical sciences. The International Scientific Programming Committee carefully nominated PSWC speakers and chairs. These were the participants we approached for their thoughtful considerations and perspectives, given their international accomplishments and distinguished leadership in pharmaceutical sciences worldwide. In 2020, an online survey was sent to speakers and/or chairs (n=380) who participated in the past three PSWC congresses: in Australia (2014), Sweden (2017) and Canada (2020, online).

Data collection

The survey (LimeSurvey® software was used) comprised both multiple-choice and open questions. The questions were part of a wider survey on pharmaceutical sciences.25 The first section consisted of 7 questions about the demographics of the participants (e.g., age, country, gender) and their educational background, (pharmaceutical sciences) specialty areas, position, number of years of experience, and their main affiliation(s). The second survey section inquired the perspectives

of participants on "What would facilitate meeting current capacity in pharmaceutical sciences research?" Eight pre-defined factors were selected by the research team. Each of the factors was presented to the respondents and they were asked to rate the factors on a 5-point Likert scale. Furthermore, to outline the description of/what is the pharmaceutical scientist, the current (2015) definition[17] was presented and respondents were asked whether it is still relevant via a closed question. Lastly, respondents were prompted to indicate three contemporary research questions or areas in the pharmaceutical sciences for allocation of a considerable (one million EUR/USD grant) investment.

Data analysis

To assess if the sample was representative, the profiles of the respondents were compared with those of the speakers and chairs of PSWC we reached out to. Answer options of each of the 5-level-Likert-scale questions were analysed quantitatively (Microsoft Excel 2016 software was used). Descriptive statistics were applied. Numerical scale was used -- 5 points were allocated to "very important" and 1 point to "not at all important" responses, and these were analysed by describing frequencies. The mean and standard deviation were determined with the objective to assess how the elements contributed equally to the total scale score. Additionally, analyses were stratified for the most prevalent groups: participants coming from academia and from pharmaceutical industry, and participants with pharmacy (meaning with the education leading to legal right to license pharmacy) and from pharmaceutical sciences (meaning with the education in areas with a focus on pharmaceuticals, but not necessarily leading to legal right to license pharmacy) educational background. The open questions' answers were analysed and arranged into relevant themes.

Results

Demography

Ninety-two responses were received out of 380 invitations sent (response rate 24% after 2 reminders). The profile of the respondents and the overall group of speakers/chairs who were approached for the survey are displayed in Table 1.

Gender and geographical region were similar in both groups. The respondents self-reported to mostly have pharmaceutical sciences (n=43, 47%) and pharmacy (n=22, 24%) educational backgrounds, similar to the original group. The majority of participants' affiliations were from academia (n=64) and a large part came from pharmaceutical industry (n=17). A few participants (<5%) among these indicated affiliation to both academia and industry. Similarly, the initial surveyed group of all invited respondents consisted primarily of representatives from academia (n=242, 64%) and the industry (n=54, 14%).

Perspectives on the drivers facilitating meeting current capacity in pharmaceutical sciences

In Figure 1 the results of the question "What would facilitate meeting current capacity in pharmaceutical sciences research?" are summarised in a graphical overview.

Table 1. Characteristics of the pharmaceutical scientists who participated in the study (n=92) and in the originally surveyed group (n=380)

	Respondents No. (%) N=92	**Surveyed group No. (%) N=380**
Gender		
Female	25 (27)	96 (25)
Male	64 (70)	284 (75)
Undisclosed	3 (3)	0 (0)
Geographical region [a]		
European	37 (40)	145 (38)
Americas	30 (33)	136 (36)
Western Pacific	19 (21)	88 (23)
Other	6 (6)	11 (3)
Affiliation [b]		
Academia	64 (70)	242 (64)
Industry	17 (18)	54 (14)
Non-governmental and/or public institution	6 (7)	8 (2)
Governmental institution	5 (5)	20 (5)
International body	5 (5)	7 (2)
Healthcare	5 (5)	18 (5)
Private research institution	4 (4)	5 (1)
Philanthropic foundation, charity	3 (3)	6 (2)
Regulatory, quality control	1 (1)	19 (5)
Other	2 (2)	1 (0)
Educational background (highest degree)		
Pharmaceutical sciences	43 (47)	
Pharmacy	22 (24)	
Chemistry (medicinal)	5 (5)	
Biology, biotechnology	5 (5)	
Biophysics/physics	3 (3)	
Medicine, epidemiology	3 (3)	
Other (e.g., data science, humanities)	11 (12)	
Academic / professional rank / position		
Full professor	42 (46)	
Research director, management lead	19 (21)	
Associate professor, senior researcher	12 (13)	
Postdoc, junior researcher	8 (9)	
PhD student	6 (7)	
Other	5 (5)	
Pharmaceutical sciences specialty area (current)		
Drug formulation, pharmaceutics	29 (32)	
Clinical pharmacology, drug development	17 (18)	
Health systems, policy, regulation	13 (14)	
Clinical pharmacy, pharmacy practice	10 (11)	
(Cell) biology, systems biology, disease models	8 (9)	
(Medicinal) chemistry, drug discovery	6 (7)	
Pharmacology, drug action	5 (5)	
Analytical sciences and quality control	4 (4)	

Table 1. (continued)

	Respondents No. (%) N=92	**Surveyed group No. (%) N=380**
Number of years of experience		
40+	20 (22)	
30+	22 (24)	
20+	17 (18)	
10+	12 (13)	
≤10	21 (23)	

[a] Based on World Health Organisation (WHO) regions

[b] Not mutually exclusive groups

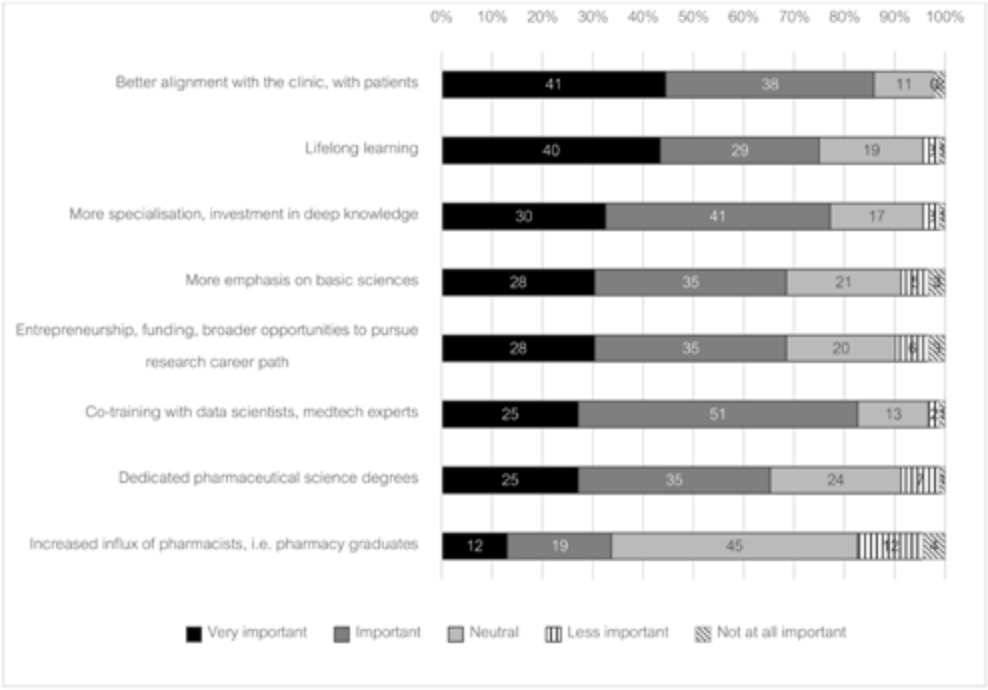

Figure 1. Factors facilitating meeting current capacity in pharmaceutical sciences research

The respondents indicated better alignment with clinic and with patients as the top one very important factor; followed by (2) lifelong learning, and (3) more specialization, investment in deep knowledge in the top three very important factors. Increased influx of pharmacists, i.e. pharmacy graduates was selected the least. Furthermore, in Table 2 the answers are stratified by professional (academia, industry) and educational (pharmaceutical sciences, pharmacy) background.

The same factors were selected by participants from the academia and from the industry. For the educational background stratification, there was a slight change for participants with

Table 2. Rating of the factors facilitating meeting current capacity in pharmaceutical sciences research, stratified for professional (academia, industry) and educational (pharmaceutical sciences, pharmacy) background

Drivers:	Nr. order [a]	Mean (SD) [b]	Very important, No. (%)	Important, No. (%)	Neutral, No. (%)	Less important, No. (%)	Not at all important, No. (%)
Better alignment with the clinic[c]	#1	4.3 (0.8)	41 (45)	38 (41)	11 (12)	0 (0)	2 (2)
Academia	#1	4.3 (0.9)	29 (45)	26 (41)	7 (11)	0 (0)	2 (3)
Industry	#2	4.3 (0.7)	8 (47)	6 (35)	3 (18)	0 (0)	0 (0)
Pharmacy	#1	4.5 (0.7)	14 (64)	6 (27)	2 (9)	0 (0)	0 (0)
Pharm. sciences	#4	4.0 (0.8)	13 (49)	21 (49)	8 (19)	0 (0)	1 (2)
Lifelong learning[c]	#2	4.1 (0.9)	40 (43)	29 (32)	19 (21)	3 (3)	1 (1)
Academia	#2	4.0 (0.9)	23 (36)	25 (39)	12 (19)	3 (5)	1 (2)
Industry	#1	4.2 (0.9)	9 (53)	2 (12)	6 (35)	0 (0)	0 (0)
Pharmacy	#3	4.0 (0.9)	8 (36)	7 (32)	6 (27)	1 (5)	0 (0)
Pharm. sciences	#1	4.1 (0.9)	16 (37)	17 (40)	8 (19)	2 (5)	0 (0)
More specialisation, investment in deep knowledge[c]	#3	4.0 (0.9)	30 (33)	41 (45)	17 (18)	3 (3)	1 (1)
Academia	#3	4.0 (0.9)	19 (30)	28 (44)	14 (22)	2 (3)	1 (2)
Industry	#3	4.3 (0.7)	7 (41)	8 (47)	2 (12)	0 (0)	0 (0)
Pharmacy	#2	4.2 (0.7)	9 (41)	9 (41)	4 (18)	0 (0)	0 (0)
Pharm. sciences	#2	4.0 (0.9)	15 (35)	16 (37)	10 (23)	1 (2)	1 (2)
More emphasis on basic sciences[c]	#4	3.9 (1.0)	28 (30)	35 (38)	21 (23)	5 (5)	3 (3)
Academia	#4	3.9 (0.9)	19 (30)	26 (41)	14 (22)	4 (6)	1 (2)
Industry	#7	3.7 (1.0)	4 (24)	6 (35)	6 (35)	0 (0)	1 (6)
Pharmacy	#5	3.6 (1.1)	7 (32)	4 (18)	8 (36)	2 (9)	1 (5)
Pharm. sciences	#7	4.0 (0.9)	12 (28)	22 (51)	6 (14)	2 (5)	1 (2)
Entrepreneurship, funding, broader opportunities to pursue research career path[c]	#5	3.9 (1.0)	28 (30)	35 (38)	20 (22)	6 (7)	3 (3)
Academia	#7	3.7 (1.1)	17 (27)	25 (39)	13 (20)	6 (9)	3 (5)
Industry	#6	4.0 (0.8)	5 (29)	7 (41)	5 (29)	0 (0)	0 (0)
Pharmacy	#7	3.6 (1.1)	5 (23)	7 (32)	7 (32)	2 (9)	1 (5)

Table 2. (continued)

Drivers:	Nr. order [a]	Mean (SD) [b]	Very important, No. (%)	Important, No. (%)	Neutral, No. (%)	Less important, No. (%)	Not at all important, No. (%)
Pharm. sciences	#3	4.0 (1.0)	15 (35)	18 (42)	5 (12)	4 (9)	1 (2)
Co-training with data scientists, medtech experts[c]	#6	4.1 (0.8)	25 (27)	51 (55)	13 (14)	2 (2)	1 (1)
Academia	#6	4.0 (0.8)	17 (27)	34 (53)	10 (16)	2 (3)	1 (2)
Industry	#4	4.2 (0.7)	6 (35)	8 (47)	3 (18)	0 (0)	0 (0)
Pharmacy	#6	4.0 (0.7)	5 (23)	13 (59)	3 (14)	1 (5)	0 (0)
Pharm. sciences	#5	4.1 (0.8)	13 (30)	21 (49)	8 (19)	1 (2)	0 (0)
Dedicated pharmaceutical science degrees[c]	#7	3.8 (1.0)	25 (27)	35 (38)	24 (26)	7 (8)	1 (1)
Academia	#5	3.8 (0.9)	19 (30)	21 (33)	19 (30)	5 (8)	0 (0)
Industry	#5	4.1 (0.8)	5 (29)	9 (53)	2 (12)	1 (6)	0 (0)
Pharmacy	#4	4.0 (0.9)	7 (32)	8 (36)	6 (27)	1 (5)	0 (0)
Pharm. sciences	#6	3.9 (0.9)	12 (28)	17 (40)	12 (28)	2 (5)	0 (0)
Increased influx of pharmacists, i.e. pharmacy graduates[c]	#8	3.3 (1.0)	12 (13)	19 (21)	45 (49)	12 (13)	4 (4)
Academia	#8	3.2 (1.0)	7 (11)	12 (19)	32 (50)	10 (16)	3 (5)
Industry	#8	3.5 (0.8)	3 (18)	4 (24)	9 (53)	1 (6)	0 (0)
Pharmacy	#8	3.2 (1.0)	3 (14)	3 (14)	13 (59)	2 (9)	1 (5)
Pharm. sciences	#8	3.3 (1.0)	7 (16)	10 (23)	18 (42)	7 (16)	1 (2)

[a] Order of the drivers that scored highest in the category very important, out of 8 drivers

[b] Based on a 5-point Likert Scale on which 1 = not at all important and 5=very important

[c] 92 participants answered

Abbreviations: SD = standard deviation, pharm. sciences = Pharmaceutical sciences

pharmaceutical sciences educational background. For them lifelong learning was more profound, being the leading factor. These participants also indicated funding/entrepreneurial opportunities to pursue a research career path as very important for building capacity in the top three factors. Alignment with the clinic was following these, sharing fourth place with co-training with data scientists and MedTech experts.

Perspectives on the scope of pharmaceutical sciences

When presented with the latest available definition of a pharmaceutical scientist (from 2015)17, 61 (66%) respondents found it still valid, while approximately one third of all respondents felt that this definition should also incorporate more clearly a patient 20 (22%) or disease 11 (12%) focus.

A total of 224 ideas was received for the open question on contemporary research questions/ areas in the pharmaceutical sciences. Out of this only 2 responses (0.9%) were devoted to capacity building and education.

Discussion

As confirmed through a unique perspective from pharmaceutical scientists from around the world who were respondents in our survey, critical drivers to facilitate meeting current capacity in pharmaceutical sciences research are better alignment with the patient needs as well as strengthening education – both through continuous (lifelong) learning and deeper specialisation. Building capacity in pharmaceutical sciences research is necessary for addressing the patients' needs where needed the most.[24]

But before we think of "how", we need to answer "what" – what/who are pharmaceutical scientists? Looking at the educational background of our pharmaceutical scientist- respondents, pharmacists are not the largest group. In fact, less than a quarter indicated having a pharmacy educational background and our results reflect the general mix of educational backgrounds of pharmaceutical scientists. Nearly half of the participants indicated having a pharmaceutical sciences background. Nearly one third indicated various other areas, for example (medicinal) chemistry; biology, biotechnology; medicine, epidemiology; data science, statistics; biophysics/ physics; engineering; social sciences, humanities or other areas. Scientific programme areas, as well as divisions and sections from regional organisations of pharmaceutical sciences, show a similar picture.[26-28] For example, only 5% of the members of the American Association of Pharmaceutical Scientists hold a clinical pharmacy degree (PharmD) in contrast to various master's (18%) and bachelor's (16%) degrees and PhDs (61%). Their field of study was listed as Pharmaceutics/Pharmacy for only 3% (in contrast to various basic- or advanced- sciences fields).[28] Rowland et al recognised that pharmaceutical science, the science behind the discovery, development, production and use of medicines, is possibly one of the most complex undertakings of mankind.[29] It often requires competencies from different traditional fields of sciences.[29] This corresponds to the background of the pharmaceutical scientists in our sample, that is based on a wide range of disciplines, where pharmacy is only one of many. Indeed, pharmaceutical science is key to the development of new medicines, with roles in formulation and development, drug delivery, product manufacture and

quality control, quality assurance and regulatory affairs, to name but a few. In the past, pharmacists often found a career within such roles, using the science content of their pharmacy degree to contribute to the quality and innovation of new medicines.[30] Nowadays, with pharmacists becoming more focused on clinical roles, the development of medicines relies increasingly on pharmaceutical scientists who may have a background in a wide variety of sciences, but not necessarily pharmacy.[31] In fact, scientists with varying backgrounds are needed to contribute to drug discovery, development, delivery, manufacturing and regulatory processes. Scientists with backgrounds in computational technologies such as artificial intelligence/data science, biology, biotechnology, engineering etc. are those needed to achieve the necessary increase in the pharmaceutical science workforce.[12] Pharmaceutical sciences are being influenced by other disciplines, and this trend will most likely continue. Therefore, to support capacity building in light of this trend, academic institutions should establish early collaboration with the medicines development units, the pharmaceutical industry and government agencies.[30,32,33]

As part of the "how" in meeting the current capacity in pharmaceutical sciences, it is encouraging to see that alignment with clinical need is a key driver for building capacity. A recent scenario analysis, a scientific method designed to outline multiple futures (scenarios) to create an overview of plausible futures that can be used for strategic planning, depicted alternative futures for the pharmaceutical landscape for the upcoming decade. The results of this analysis emphasize that while clinical needs as such may not disappear, different approaches will be needed for different scenarios.[16] For example, the future we may witness can be dividing towards or away from high-end medicines (costly medicines such as cancer or rare diseases treatment).[16] The latter direction, away from such medicines, may lead to science less in the lab and more "in translation" with pharmaceutical clinicians in primary health care (with common desire for more quality of life through palliative care). Therefore, being adaptable to where capacity is needed will be a vital approach. The good news is that clinical (unmet medical) need is important in priority setting, funding and impact in pharmaceutical sciences — and continued prioritisation of research towards these can address them where needed the most.[25] The definition of the pharmaceutical scientist and what this term is encompassing[17] may need to change accordingly, closer to the disease or to the patient, as indicated by our respondents.

Specialisation, identified as the second very important factor in the present study, calls for investment in deep, contemporary, cutting-edge knowledge. For example, in the increasingly important area of personalised medicine, pharmaceutical scientists will need to obtain specialist knowledge on genomics and the genetic basis for disease and treatment.[34] As outlined by the previously mentioned scenario analysis, specialists are sought for especially in an environment of global/international collaboration and consistency. They are then supported by widespread optimism about the role of science and entrepreneurship for bringing health benefits to society and blooming open science.[16] In this scenario, areas like biotechnology will be particularly thirsty for new talent.[35] But in case of a scenario of local- and national-isms, and increased global fragmentation,[16] will the demand shift towards generalists and multitaskers? If countries are "on their own", resolving supply chain gaps and unequal access can quickly become an urgency, leaving less space for deep specialisation. For example, increased "localism" during the recent pandemic has witnessed severe

drug shortages, which enhanced increased drug repurposing as a response.[36] These lessons can be used for future preparedness.

The above demonstrates that capacity building is not an easy task. In order for it to be translating into real world/practice changes, a long term and early planning is needed — which is at the same time difficult given the future direction of clinical needs is uncertain. Each transformation requires a diverse workforce that is prepared to provide leadership for change and lead the process to keep pace with continuous changes in science and patient needs.[18,37] This remains difficult, as even though we can assume future scenarios, the environment is fast-changing and, unfortunately, the field (academia, industry) is notoriously slow in responding.[38,39] Changes in academic programmes for pharmacy and pharmaceutical sciences, especially the big curriculums revisions, do not happen often enough.[39-44] In addition, academia tends to focus on undergraduate students. But how about the out-of-university workforce? Lifelong learning is very important, the top one factor for respondents coming from the industry as well as the ones with pharmaceutical sciences educational background. Indeed, industry and umbrella organizations are often filling the gaps, offering lifelong learning programmes to the practicing workforce.[45] Similarly, excellent PhD programmes and certified post-graduate courses offering a range of specialized training in varying areas could contribute to the solution, such as recent efforts from a drug safety professional training programme in Europe.[46] Similar programmes are needed to meet the drug development needs. On the opposite side, our respondents indicated that the influx of pharmacists, i.e. pharmacy graduates, was the least important factor, likewise in each of the sub-groups. This is surprising as recruiting new people is often what comes to mind first when talking about workforce shortage. One explanation could be that pharmacy and pharmaceutical education globally continues to face many issues that challenge the quality of teaching and learning at a time when there are limited resources to meet these challenges. An example of these challenges is rapid expansion in the number of schools of pharmacy and pharmaceutical sciences in some countries in light of demographic changes.[37,47-49] One effort to address the quality issue is an accreditation process for pharmaceutical sciences courses, as well as use of competency frameworks.[50] Another effort is to inform and shape capacity and workforce development through workforce intelligence activities. Workforce intelligence, collecting and analysing data on numbers in workforce labour, can directly contribute to realistic policy formation and workforce planning. Pharmaceutical workforce data over the 2006–2016 period were analysed,[7] expressed in the number of pharmacists per 10,000 population. However, in contrast to the regulated (licensed) pharmacy profession, there are no available data on numbers of pharmaceutical scientists. Yet, workforce planning would greatly benefit from collating and integrating data for the full range of the pharmaceutical workforce.[7] While out of scope for this study, collecting and analysing data on pharmaceutical scientists' capacity, including employment area, career pathways, density, distribution, and interactions with national or regional disease burden (as well as the impact of disease trends) are all needed in order to inform national strategic pharmacy workforce planning, including requirements for influx of graduates. The results of this survey could help this purpose.[7] Global umbrella organisations could take a leadership in this endeavour to inform evidence-driven capacity building policies.

All in all, building capacity – and doing it right — is vital and should be on top of peoples' minds.[24] There is increasing recognition of the need for a well-informed, strategic approach to building capacity. Unfortunately, with hardly one per cent of ideas on research questions and areas provided by our respondents were devoted to building capacity, we have to conclude this is not the case. Nevertheless, "academic capacity" is one of the FIP Development Goals, positioned in the first place among other goals.[51] In addition, the three outlined mechanisms for the scientific component of the FIP DG#1 is to [...] collaborate with academic leaders [...] and the pharmaceutical industry to define regional and global needs for the pharmaceutical sciences.[51] Further studies on this topic could bring the significance of this topic to the attention of the international community to meet these ambitious goals, with the ultimate aim to respond to the needs of the societies.

Strengths and limitations

As a major strength of this study, it offers a global perspective from well-established pharmaceutical scientists with distinguished leadership and international accomplishments. As for limitations, firstly, the sample group was identified by a single global pharmaceutical federation. Therefore, the geographical regions were not equally represented, and the opinions of general (and especially early career) researchers may not be reflected. Secondly, as the respondents were largely having academic or industrial affiliation, we need to keep in mind that the industry group respondents often have a history in academia. Due to lack of the data on the educational background of the original group we reached out to, we were not able to compare this parameter with the surveyed group. However, for the other parameters the representation seemed to be well corresponding so there is no indication this would be different for educational background. Thirdly, while workforce numbers is an important area for capacity building, this was out of scope for this study. Finally, the responses were collected in 2020 amid the pandemic and this may have affected the responses/priorities and response rate. Despite these limitations, the study offers expert perspectives from different regions and pharmaceutical sciences areas and coherent themes that emerged from these perspectives.

Conclusions

This study shows that capacity building in the pharmaceutical sciences is more than simply increasing the influx of graduates. The need for more pharmaceutical scientists, from the lab to the clinic, from basic sciences drug discovery to drug development, manufacturing and quality assurance, will increase in the next decades. Based on our study findings we may expect more diversity in training. It is clear that scientists with varying backgrounds are needed to address the imminent research issues. Where pharmaceutical scientists can make a difference, they will fill relevant positions. The same will be true for clinical experts — historically, trained pharmacists have had synergistic and bridging roles in the pharmaceutical sciences and given high levels of specialisation within the field more than ever before, we expect that will continue to happen. Capacity building should embrace these when planning of the underlying workforce, with commitment to sustained and life-long learning.

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5 General discussion

Sustainable Development Goals (SDGs) call for action to improve people's lives and prospects globally.[1] SDG3 aspires for "Good health and wellbeing" as crucial component of sustainable development.[2] Although impressive strides have been made in improving good health and quality of life, progress is uneven globally and the attainment of health has not been realised, as shown by the persistent global burden of disease.[3]

Significant gaps remain as highlighted by the 2013 Report on Priority Medicines for Europe and the World, which underlined the need for pharmaceutical research to support the improvement of existing medicines and the creation of new ones.[4] According to this report, the gaps in pharmaceutical research are in both existing treatments (which already shows signs of being ineffective due to risk of resistance to treatment, such as antibiotics), their inappropriate delivery mechanism or formulation (e.g., in diabetes, pulmonary diseases), or in having no treatment at all (orphan diseases but also highly prevalent mental and chronic illnesses).[4]

Pharmaceutical innovation is crucial for addressing the above gaps, and especially areas where pharmaceutical research meets practice and vice-versa are offering a large potential. Accordingly, pharmaceutical scientists together with pharmacists accepted responsibility and accountability for improving global health, well-being and patient outcomes.[5] Pharmaceutical scientists endeavour to sustainably meet needs in new discoveries, development, clinical utilisation, marketing regulations, post-marketing monitoring and the economic assessment of health products.[6] On the practice side, pharmacists as key health care professionals make a vital contribution to the populations' health and well-being and are able to increase efficiencies in the health care system. They strive to help patients to make the best use of their medications.[7]

Closing the gaps necessitates that pharmaceutical science and practice work in synergy to realise their potentials. Pharmaceutical education must support this to build capacity in both pharmaceutical science and practice. Education is a prerequisite for being able to adequately meet the growing demands of global public health.

This thesis assessed the optimal role of all three components: science, practice and education in building capacity for pharmacy and pharmaceutical sciences, with the ultimate goal of responding to the health needs around the globe. It evaluated the changing pharmaceutical landscape, both in terms of science and practice. In a dynamic environment, society has further expectations for pharmacists and pharmaceutical scientists. As these expectations change, the roles of pharmacists and pharmaceutical scientists are transforming, and education must keep up with these for ensuring optimal capacity. The thesis, therefore, furthermore analysed adaptation of pharmaceutical education to new situations and conducted a case study on substandard and falsified (SF) medical products to illustrate such adaptation. And finally, it delineated different scenarios to stimulate creative thinking on the future as well as important factors to consider when building capacity in ever-shifting circumstances.

Developments in the landscape of pharmaceutical science and practice

Pharmaceutical sciences have come a long way to successfully translate the early discoveries, leading to therapeutics, that made it from the proof-of-concept in human trials to a meaningful

impact on patients' lives. We have witnessed tremendous progress in this pharmaceutical development.[6] The pharmaceutical scientists operate in a dynamic atmosphere which is greatly influenced by its fluctuating conditions. As the environment around pharmaceuticals undergoes rapid transformation, the pharmaceutical research is under constant scrutiny and shapes into the mould of its new situation.[8]

In recent years, however, there have been sceptical voices of researchers who question whether the direction of pharmaceutical sciences is aligned with societal needs today. Indeed, many of the driving forces of change listed in the literature include powerful financial rewards, availability of funding, elevated demand for pharmaceuticals, strict medicine and business regulations, increased competition, healthcare legislation, etc.[9-11] While addressing health needs has always guided the research path for pharmaceutical scientists, it was rather indirectly and not as a premier driver.[6,12-14]

To complement these views, in **Chapter 2.1.**, we surveyed internationally recognised pharmaceutical scientists, mainly from academia and industry, on drivers and influencing factors in pharmaceutical sciences. Unmet medical need (UMN) was indicated as being one of the major driving forces of pharmaceutical sciences. This is encouraging, as this means pharmaceutical scientists themselves see research being driven by demands of providing a therapy where there is none or where potentially better alternatives are desperately required.[15] UMN also came out as crucial for capacity building — in **Chapter 4.2.** better alignment with patient needs was seen as the number 1 critical driver to facilitate meeting current capacity in pharmaceutical sciences research.

Similar to changes in pharmaceutical sciences, literature is abundant on studies describing how the roles of pharmacists have evolved in the past decades. Starting as apothecaries, relaying on mostly folk remedies centuries ago, pharmacists gradually transformed into scientist-practitioners primarily responsible for accurately and safely distributing medicines to a patient. Initially working in silos, nowadays, pharmacists are health care team players who provide a variety of services for the health of both individuals and the community and respond to the health needs of the people through optimal, evidence-based care.[16,17] The globally accepted roles of pharmacists are described in the World Health Organization (WHO) - International Pharmaceutical Federation (FIP) Good Pharmacy Practice (GPP) standards.[7] They comprehensively describe four main roles pharmacists fulfil, in all settings, but especially in community and hospital setting: (1) Prepare, obtain, store, secure, distribute, administer, dispense and dispose of medical products; (2) Provide effective medication therapy management; (3): Maintain and improve professional performance; and, (4) Contribute to improve effectiveness of the health-care system and public health.[7] These GPP standards are from 2011, but are still considered valid standards of today. Our results in **Chapter 2.2** reaffirmed this, given that all GPP roles were reflected at least once in each of the world pharmacy congress programmes over the observed period of nearly two decades (2003-2019) — already in the decade preceding the GPP publication, and also in the decade after their publication.

Additionally, our research confirmed the practice evolution described in the literature. The longitudinal analysis showed trends towards clinical roles focusing on the patient and positioning pharmacy as an important player in the health-care system. Indeed, pharmacy is strengthening

its clinical roles and services. The scope of pharmacy practice is expanding with new services, for example, in some jurisdictions pharmacists perform care planning services, prescribing, adapting prescriptions or triage diagnosis, and the (local) policy environment accommodated these services accordingly.[16-18] At the same time, there are jurisdictions, especially in low-to-middle-income countries, that still lag behind in strengthening pharmacy practice.[19,20] Yet, if adequate capacity building and educational investments are made, pharmacy should continue to serve as a global asset capable of generating progressively increasing health and welfare returns. It is expected that where there are needs, capacity will be required, both in science and practice.

Adaptation of pharmaceutical education to new practice paradigms: a case study in the area of substandard and falsified medical products

Universities are in a particularly good position to serve as centres of capacity-building.[21] In our example of needs-driven capacity building, pharmacists should understand how the threat of substandard and falsified (SF) medical products affects pharmacy practice and their detrimental effects on health and act accordingly.[22,23] It is important for educators to assist pharmacists and potentially pharmaceutical scientists in enhancing their understanding, already throughout pharmacy undergraduate education.

In **Chapter 3.1**, as the first step, our study characterised what is being taught on SF medical products in pharmacy schools around the globe. Ferrario et al. already warned that the issue on SF medical products is not taught enough by the schools of pharmacy.[22] We complemented this research and gained a global perspective of the current education of undergraduate pharmacy students (i.e. those finishing with a pharmacy diploma, typically ending with a Master in Pharmacy/ Sciences or Doctor of pharmacy degree) on SF medical products and the approach universities take towards it. Our study confirmed gaps, as it found that, sadly, one out of three pharmacy schools does not offer any targeted education on SF medical products.

Only two of the responding 55 universities taught a standalone course on SF medical products, and a majority of schools taught about SF medical products as part of another course. The most common teaching topics regarding SF medical products were focused on modules concerning the prevention (21%) and detection (21%) of SF medical products. This can be explained by the fact that analytical chemistry is a common part of pharmacy curricula around the globe. They already contain basics of qualitative and quantitative analysis, important for quality assurance of medical products.[23,24] This corresponds to the findings from our study, as quality control (e.g. pharmacopeia, compliance with regulatory requirements) was reported to be the most taught subtopic.

Data from WHO show poor reporting of SF medical products.[25] Our results contextualise these data, as reporting was taught the least (12%), indicating a knowledge gap in that area. Interestingly, results from **Chapter 3.2** also show that students from all measured universities had no knowledge about reporting prior to taking our course.

Subsequently, in **Chapter 3.2**, three Sub-Saharan universities in Cameroon, Senegal and Tanzania introduced a new course on SF medical products into their pharmacy curriculum. The need in these countries is great, as majority of reports of SF medical products (as recorded by WHO) originate

from the African region. Unfortunately, the awareness of health care professionals remains low. This is speculated to be largely because of the lack of education on this matter.[22] We found that a dedicated, competency-based educational course for undergraduate pharmacy students can improve their knowledge on these products. Our study confirmed that with this educational course, students improved in knowledge in all offered modules and in all three universities/countries, both on a score measured via an assessment questionnaire and via self-assessment.

There is a case for transformative change in pharmacy education to meet the health care needs of communities throughout Africa.[26] Sule et al. who examined the existing pharmacy curriculum in Nigeria warned that there is limited evidence to show that it responds to the societal demands. He recommended including additional relevant courses in the curriculum to meet the competence required for current professional practice and conformation with global trends.[27]

Our study showed one such successful deployment of an 'additional' course. Learning from this process, there are multiple implications for policy, further research and concerned stakeholders. These will be deliberated in the 'Implications' section.

Capacity building for the future: getting ready for what is ahead

In a capacity building context, scenarios are widely recognised as an effective tool for enabling concerned communities of practice, communities who share a common interest or profession and regularly interact with each other to learn and develop their skills and knowledge, to generate critical insights into the future.[28] Scenarios are powerful 'thinking vehicles' deliberating on how the underlying environment is likely to evolve. When devising predictions, policy/political, economic, and social phenomena are not assessable through quantitative methodologies or on the basis of causality. This is because they entail immeasurable, uncertain and complex elements and relationships. Scenario analysis solves this by structurally conceptualising multidimensional and unorganised problems into 'pictures' of the future. The method of scenario analysis is a well-established technique in policy design and strategic planning. It is particularly useful when thinking about the appropriate strategic measures and the optimal policy decisions to be taken based on these 'pictures'.

Although no methodology will ever be able to fully foretell the future reality, since the release of Van der Heijden's flagship book '*Scenarios: the art of strategic conversation',*[28] scenario analysis has been used as a tool for planning national or organisational strategies. For example, Douglas et al. who used the scenario analysis for decision-making for drugs for rare diseases in Canada demonstrated that scenarios are perceived to be useful by its participants and particularly helpful in identifying additional challenges.[29] This method was also used to delineate future of health care services in South Korea, mental health care in the community in the Netherlands, implications for doctors' training in the United Kingdom and health care workforce strategic planning in Malawi.[30-33] Furthermore, the scenario analysis of how the pharmaceutical sciences will look like in 2020 informed the strategic direction for the FIP's umbrella board for pharmaceutical sciences, the Board of Pharmaceutical Sciences (BPS).[34]

We performed a scenario analysis in **Chapter 4.1** and delineated plausible scenarios for the future of the pharmaceutical landscape based on insights from 40 international experts, thought leaders

and boundary spanners from public and private sector, academia, non-governmental organisations and philanthropy. The four contrasting scenarios were composed by thinking from the bench to bedside in a scientific and global context, rooted in current challenges and societal ambiguities. All scenarios depicted some degree of changes to the status quo based on innovation in the science and technology and thus need for enhanced collaboration so that pharmaceutical scientists work with the pharmacists together to translate these into improved patient outcomes. The potential high-impact uncertainties were laid out on a matrix that differentiated between contrasting possibilities in two dimensions: global convergence, ranging from very high (trust and solidarity), to very low (fragmented ecosystems); and disease orientation, ranging from public health first to interceptive medicine. The results were the four contrasting portraits of the future of medicines and social policy: deprioritising the high-end with fragmented innovation ecosystem but opportunities for primary care strengthening; sustainable flow with emphasis on equity for access to innovation and openness in science and technology; transformative healing with highly competitive environment but also highly innovative results; and global divide with nations answering primarily their own pharmaceutical and political priorities away from the global health emphasis.

Authors like Tucker et al. have delineated future challenges and opportunities for the pharmaceutical sciences from a global impact perspective,[8] and a lot has been speculated on the future of pharmacy.[16] Gregório et al. and others revealed that the future of (both community and clinical) pharmacists will depend on innovative pharmaceutical services beyond medicine dispensing, and on acquisition of competencies in management, technologies, and teamwork.[35,36]

However, what our analysis adds is the cross-disciplinary view from science, practice and education, elaborating on the future of medicines in the broader political, geographical and economic context of social policy. We envisioned it as a tool valuable not only for pharmacists and pharmaceutical scientists and their professional bodies, but also for other health care professionals, payers, managers, policy makers and other health care stakeholders.

In **Chapter 4.2** we scrutinised these through the viewpoints of internationally recognised pharmaceutical scientists (N=92) mainly from the academia and industry. One of the learnings that appeared in all scenarios and was even considered a "predefined element" was that future medicines will only become more complex, and will thus require more use guidance and monitoring. This implies clinicians and scientists must work together to navigate the optimal use of pharmaceuticals and the care ecosystem. Pharmaceutical companies should consider hiring more clinicians to accommodate this as well as they move into the care delivery space.[37] Multi-professional collaboration also came out as an important driver of research in **Chapter 2.1**.

Another point to consider is alignment with clinical need, as this was indicated as a key driver for building capacity in pharmaceutical sciences research **in Chapter 4.2**. Delivering content relevant to the real word was also one of the trends observed by Anderson & Arakawa in their editorial to 17 original articles on pharmaceutical education.[38] Acknowledging that while countries are at diverse levels of development with undergraduate and postgraduate pharmacy education, it is reassuring to see such trends.

We had similar findings in **Chapter 2.1**, in which unmet medical need was perceived as one of the major drivers for pharmaceutical sciences. This means that in the future, capacity building

as supported by education is expected to stay, or at least attempt to stay, close to patient health demands.

Implications for pharmaceutical policy and recommendations for further academic research

This thesis provided a helicopter view on the landscape in pharmaceutical science and practice and its constant developments. It points to areas for consideration when building capacity. Unless and until these considerations are taken into account, the future of pharmacy and pharmaceutical sciences will remain at best, unpredictable. There are then duties ahead for the academia, the international community of practitioners and researchers, international and national regulatory and/or accreditation associations and policy makers to fill the gaps identified in the results presented in this thesis. There are thus several implications from this thesis.

Capacity building is more than increasing influx of graduates

At the end of this decade, a global shortage of 18 million skilled health care workforce, including pharmaceutical workforce is projected. This poses an existential threat to public health systems and might lead to a public health crisis.[39] Some countries' policies focus on short-sighted efforts to bridge this workforce gap by concentrating on numbers of pharmaceutical workforce, by forcing universities to admit more students or by opening new universities, etc.[38,40,41] In Japan, the number of pharmacy schools increased by 28 in just 14 years (2002-2016), however, the newly opened schools have not yet properly established a quality assurance mechanism, and gaps were found in the assessment criteria.[38,41] This can be unhelpful and lead to a vicious cycle resulting in poor quality of care and eventually frustrated workforce leaving health system, only exacerbating the crisis.[38,42]

The view of our survey's respondents, who indicated that simply increasing the influx of graduates is not a solution in **Chapter 4.2**, complements these results. Policy makers should take this into account in capacity building polices and make informed decision on numbers as opposed to simply increasing it. Initiatives focused on gathering data intelligence on numbers of pharmaceutical workforce are helpful and could inform capacity building. While data exists for pharmacists (although not complete), future research in this area is needed to gather data for pharmaceutical scientists.[43] Furthermore, this will allow for determining more targeted and suitable courses of action in capacity building, and we will describe some considerations in the following paragraphs.

Strategic planning close to the clinic

We have shown in **Chapter 2** that both pharmaceutical sciences and practice see themselves operating close to the clinic, in fact, driven by unmet medical need (UMN). More broadly, UMN can drive capacity building in pharmaceutical sciences and practice, making it essential to address health challenges in society.[44] In **Chapter 4.2** better alignment with patient health demands was seen as a critical driver to meeting current capacity in pharmaceutical research.

As a matter of a fact, through demonstrating UMN being one of the major driving forces in pharmaceutical sciences, pharmaceutical scientists (through their professional bodies) must clearly communicate the benefits of their work to all stakeholders, including patients and policy makers. They must show how real needs are being met by science, and advocate for orientating resources towards research in areas where UMN prevails.[4] They should attract funding from both public and private sphere and engage policy makers in a dialogue to create a favourable policy environment. Similarly, pharmacists should develop suitable services close to the needs of their patients. At the same time, they must strive to practice these services in a legal and viable environment.

The findings in this thesis can aid all these efforts. As a starting point, for example, they can be deployed in the design of vision and strategic planning for pharmaceutical sciences and research, both in academia and in industry. Education will then have a responsibility in assisting future graduates to navigate and adapt to changing environments led by the patient needs.

Shifting towards a paradigm of responsive education

We have discussed that education must help future scientists and practitioners in navigating and adapting to changing environments led by patient needs. However, despite an availability of supportive frameworks and tools, the necessity to implement these is not all perceived and tackled with the urgency it would deserve. In fact, we see that in our survey in **Chapter 3.1** – despite the clear gap in pharmacists' education in SF medical products - most institutions (N=25, (64%)) agreed with the statement that their students were adequately equipped to detect and take action if exposed to SF medical products after graduation. The majority of the institutions (N=43, (78%)) agreed that their institution was able to readily identify and include new skills/competencies in the pharmacy curriculum as they emerge in practice. While this finding is rather optimistic, we argue there is still much to do in establishing a ready and responsive pharmacy education to meet the fast-paced challenges in public health. Findings from our research in **Chapter 3.1**, specifically the overview of teaching content corresponding to the content areas of the FIP curriculum (**Chapter 3.1**, Table 3), could provide a starting point to understand where the gaps in content are the most prevalent. Academics should use this information to revise and adapt teaching content, methods and strategies to close these gaps and meet patients' needs.

Fostering transformation through competency- and needs-based educational approaches

The patients' needs, and "the needs of the health system should shape the way in which the workforce is educated—not the other way around", the WHO attests.[45] In capacity building, the competency-based approach is developed around needs.[46-48] This educational approach is increasingly being used in educational reforms.[49,50] Many international professional accreditation bodies are demanding evidence of competency in medical and pharmacy curricula.[24,51] Similarly, the FIP, the global organisation representing pharmacists and pharmaceutical scientists, advocates for a needs-based model to guide pharmacy education, so that it is able to keep pace with demands of the society.[46,51-53]

A competency-based approach is a disciplined approach driven by specific needs to be addressed, where the requisite competencies of graduates for health system performance are identified and tailored to the curriculum. Competency-based education allows for a highly individualised learning process rather than the traditional, one-size-fits-all curriculum, and aims to ensure that new information and science breakthroughs make it into the pharmacy curriculum.[46,48,51-53]

The FIP's global competency framework for pharmaceutical workforce was firstly published in 2012 (and updated in 2021).[54] Since then, education curricula or courses based on competency frameworks have been successful in thematic areas like antimicrobial resistance,[55,56] patient safety,[57,58] universal health coverage[59] – both in pharmacy and more wider in health workforce. For example, a competency-based educational course on antimicrobial stewardship for physicians in training has shown to decrease antimicrobial usage in various settings and improved effective antimicrobial use.[60] Also, specific pharmacy services areas like medication reconciliation, improving patient safety, can benefit from additions to the curriculum – for instance, competency-based learning with medication reconciliation simulation with feedback tool was added to the pharmacy curriculum in Jordan to successfully supplement traditional teaching modalities.[61]

In **Chapter 3.2** we have used the competency-based education for undergraduate pharmacy students to improve their knowledge on SF medical products in a number of Sub-Saharan countries (Cameroon, Senegal and Tanzania), but it can also be applied for practicing pharmacists. Some examples already exist, supported by recently developed competency frameworks in the humanitarian and digital space.[62,63] Compared to more traditional approaches, by carefully aligning professionally relevant competencies with curriculum content, learners are advised to track how their learning aligns with the latest changes in their career fields.

Alfaifi S et al. highlighted that while most of the competencies listed in a generic international competency framework are relevant, modifications are required to be appropriate for the needs to the local pharmacy practice.[64] This was also highlighted in **Chapter 2.2** where we deliberate that pharmacists' roles expand with local demands. Furthermore, our study in **Chapter 3.2** encourages this, as universities adjusted and contextualised the content based on the "adopt and adapt principle" and they flexibly incorporated the course into universities' existing curricula.[65] There was a positive feedback from students, who found the obtained competencies useful for their professional life (self-assessed). Teachers were interviewed on the context of the course introduction and they confirmed that the course was well received. They also welcomed the supplied competency framework in supporting their teaching preparation and structuring of the course. Thus, schools should consider the availability of a competency framework as a potentially helpful tool for teachers in their course preparation.

On the down side, implementing competency-based education is a time-consuming and complicated process.[47,48] Decisions on all organisational levels are needed to guide curriculum development and optimisation, to achieve (and prove with assessment) desired learning outcomes.[47,66] We had secured these in our pilot project, contributing to the successful implementation. The national policy coupled with institutional leadership's support is required to assure continuous adaptation and teachers' professional development.[47] These can help the academia to continue beyond the timeline of the pilot projects.

Impact of pharmacy education in relation to the anticipated practice aspirations is rarely measured, thus the long-term capacity gains in this area are unknown. Improvements in skills and attitudes warrant further analysis — and while equally important, these were also outside of scope for our study in **Chapter 3.2**. As van Huyssteen & Bheekie recommended, routinely approaching and interviewing graduates could be an untapped resource to observe educational outcomes and how these can strengthen the healthcare system and benefit society.[67]

Breaking barriers and boosting enablers for educational change

Next to the paradigm shift described above, barriers to curricular change need to be removed. In line with our own findings in **Chapters 3.1** and **3.2**, the continued evolution of the pharmacy curriculum presents a major challenge to faculty, administrators, and external constituencies because of the overcrowded schedule. Indeed, one key barrier to introducing a new course that could close the gaps was insufficient time in the pharmacy curriculum (n=33; 60%, Chapter 3.1). Lack of time in an already packed pharmacy or medical-related curriculum is a well-known barrier to introduction of an additional course.[50,68,69] Engels argues though, that simply allocating more time for a certain subject is not the solution, and recommends conscious choices of teaching strategies (e.g. simulation, visualisation, problem solving, collaborative groupwork, etc.) as a better way to integrate new knowledge instead.[68]

The effective integration of new information into curriculum planning, implementation, and assessment processes is furthermore hindered by lack of adequately trained personnel with experience in both foundational and clinical sciences.[50,69] In our needs-based intervention, we overcame this by organising a special 'train the teachers' training course ahead of deployment, that received positive appreciation from teachers.

Other barriers notoriously listed in the literature are financial costs, changing nature of teaching and assessment methods, large scope of new material possibly impacting diverse areas of educational programme in place. Therefore it may not come as surprise that teachers in our study (**Chapter 3.2**) were also struggling with securing technical (Internet and computers access) and logistic supplies (adequately equipped and sized room) for the schooling. University leadership should therefore establish a dialogue with teachers on these barriers as a start on mitigating these for the future. Additionally, university leadership must then advocate for support to the funding and regulatory bodies. By framing an educational reform as a component of a larger curriculum revision, or as part of a regional or national effort to address industry or population needs, the argument for strengthening the workforce becomes even more compelling and urgent. As highlighted through the teachers' interviews in our study, such advocacy can then in turn support teachers in implementation of new features in the existing curricula. For example, after receiving the pilot study results, the WHO helped overcome the insufficient funding barrier for conducting practical experiments based on the feedback from teachers and provided them with detection devices for pharmaceutical analysis.[70]

On the other hand, availability of ready-to-adopt course materials (lectures content, handbook for teachers, teachers training materials, case studies, etc.) was considered as a helpful enabler.

In **Chapter 3.1**. our respondents claimed that if a standalone module (supported by a competency framework) on SF medical products is available, it would be "very likely" introduced as part of an existing course and "likely" as a standalone course. This is encouraging — academic institutions, non- and inter-governmental public health organisations should leverage this as a rationale to create such needs- and competency-based course materials. Complementary, in **Chapter 3.2** we describe in detail how the course material was successfully developed and how such projects can be beneficial enablers for universities who would like to adopt the curriculum in the future. Dissemination of this information should help other pharmacy schools to design approaches for integrating new material appropriately to their particular circumstances and mission. In fact, WHO in its plans for years ahead is expanding the project to make the curriculum materials widely available and adaptable to all countries, beyond the African region.[70]

Building partnerships among academic institutions, non-governmental, governmental and inter-governmental organisations is a powerful way to advance pharmacy education through sharing of challenges, solutions and good practices.[26] This could be done through university-affiliated practice- or science- based research network, engagement in student fundamental research initiatives, societal responsibility programmes, peer benchmarking contests, etc. The FIP UNESCO University Twinning and Networking (UNITWIN) Programme builds university networks and encourages inter-university cooperation worldwide.[26] An important aspect that should not be overlooked is the early involvement of all parties for enhanced ownership, collaboration and support from university leadership.

Science and practice as vital elements in pharmaceutical education

Staying close to the needs also means keeping pace with any related changes and developments. Modern science evolves at exponential rate. These advances are leading to a wealth of new knowledge, discoveries and technologies. This "new science" is touching vast areas embracing biotechnology, pharmacology, pharmacognosy, medicinal chemistry, molecular biology, genetic engineering, nanotechnology, information technology, etc.[8] While these have been around for some time, regrettably, the assimilation of this information into the pharmacy practice through a curriculum has been slow. This is a pity as these new powerful sciences may have the answers for patients who are anxiously waiting for their cures. **Chapter 4.2** revealed that pharmaceutical scientists embrace a wide range of educational backgrounds and even more variety (e.g. from data science, biotechnology, engineering) is desirable to nurture pharmaceutical innovation.

Integration of science into practice and vice versa is also generally debated in education in the medical field, such as medicine and dentistry. Sweeney claims that, frustratingly to basic scientists, much of clinical practice remains "unnecessarily unscientific".[71] Finnerty et al. however reasoned that "an understanding of basic science content remains essential to clinical practice" and "plays a foundational role in developing discipline and rigor in learners' thinking skills, including logical reasoning, critical appraisal, problem solving, decision making, and creativity".[72] Sciences should be prominent throughout the entire clinical education and thus integrated with clinical applications.[72]

Unfortunately, traditionally, pharmaceutical education discussions have focused on what "science" and "practice" is. Husband et al. highlighted that this created more of a competitive approach on which of these should be given the most time and space within the modern curriculum, as opposed to aim for synergies and combination of the two, if indeed they are separate subjects.[73] Science knowledge is essential for clinical practice, because it forms the basis of clinical reasoning and decision-making. We saw this confirmed in the case study in **Chapter 3.2**. where detection of SF products, a common activity in practice, is greatly facilitated by analytical chemistry and in Tanzania and Senegal, the course itself was part of the drug quality assurance course and most of the time took place in the lab.

Therefore, the pharmacy curriculum must incorporate both science and practice and should be considered as a whole.[73] One tool that educators are advised using to support this is the recently published FIP Global Competency Framework for Educators & Trainers in Pharmacy, in which science complements practice as one of the Pillars for Educational Quality – "a strong scientific and evidence base is to guide curriculum design and development for all activities, and competent educators to demonstrate expert skills and knowledge in their field and offer quality educational activities that are evidence-based".[74] Another way educators could strengthen integration of science into practice and vice-versa is through giving the students the opportunity to support collection of research data and implementation of research outcomes within practice setting. Koster et al. recommended utilising practice-based networks for students placement and, at the same time, pharmacy practice research, so that students gain in-depth insight into both pharmaceutical research and practice.[75] All in all, it is clear that both science and practice are essential components in pharmaceutical of education and are both vital for capacity building.

Embracing specialisation

Another learning to delineate for both science and practice is the need for specialisation. This was highlighted implicitly in the 'Digital Tables' that informed the scenario analysis in **Chapter 4.1** and implicitly through trends in pharmacists' GPP roles in **Chapter 2.2.** Likewise, specialisation was identified as the second very important factor in **Chapter 4.2**. It calls for investment in deep, contemporary, cutting edge knowledge. For example, in the increasingly important area of personalised medicine, pharmaceutical scientists will need to acquire specialist knowledge on genomics and the genetic basis for disease and treatment.[76] When cross-checking the anticipated trends with overall scenarios, we concluded that specialisation may become particularly important in an environment of international collaboration and global coherence, and fields such as biotechnology will seek for new talent.[77,78] However, we will see a contrasting picture in scenario of a local- and national-isms, and increased global fragmentation,[77] where the demand may shift towards generalists and multitaskers. Indeed, how will countries resolve supply chain gaps "on their own"? Unequal access may grow to be an urgency, leaving less space for deep-rooted specialisation. Coupled with emigration, in many developing countries it can exacerbate the deficit in workforce numbers, and principally for specialists.[38]

Morris et al. who in 2021 surveyed Master's programmes in the pharmaceutical sciences offered at schools/Colleges of Pharmacy (96 responses were received from universities from 23 countries) found that the predominant placement of students after graduation is the pharmaceutical industry (51%), followed by academia (27%).[79] Both areas typically offer highly specialised job positions – a postgraduate (PhD) scientist or a researcher in the pharmaceutical industry areas. Based on our study findings, the need for more pharmaceutical scientists, from 'bench to bedside', from basic sciences drug discovery to drug development, manufacturing, quality assurance, and post-marketing surveillance, will increase in the years to come. Therefore, policy and academic planning should proactively embrace more diversity in training and scientific background. For example, there are more and more specialised Master's programmes, e.g. health informatics, genetics, bio- and nanotechnologies. These are mostly for pharmaceutical scientists, but to some extent pharmacists will need to know ins and outs of these especially in translational roles in bridging the lab and the clinic. For example, as the need for advanced therapy medicinal products increases, pharmacists may need to deal with this specific bedside manufacturing innovation in the future.

As we see in **Chapter 2.2**, virtually all countries have regulatory and legal requirements for pharmacists' roles. Standards apply not only in practice, but also in more scientific roles, such as quality assurance, pharmacovigilance, qualified or responsible pharmaceutical person, to name a few. Academia should get ready to prepare the workforce for these roles for example through specialised certification, taking into consideration the accountability these roles carry. By drawing insights from the realm of competency-based education (e.g. mapping professionally relevant competencies to course content), academia is in an excellent position to provide guidance for regulatory or corporate entities to establish on-the-job trainings. This guidance would then serve another purpose, it would inform selection criteria and ease recruitment. To facilitate this process, educators must take a more critical stance to gain a better understanding of the (legal) standards that are (likely to be) applicable and the job market requirements, and then modify their programmes accordingly.

Investing in lifelong learning: an imperative

Academia generally tends to focus on undergraduate students, but what about the out-of-university workforce? This is where lifelong learning plays a key role, as the top one factor, according to our respondents coming from both the industry as well as the ones with pharmaceutical sciences educational background in **Chapter 4.2**. This is perhaps not surprising, as pharmaceutical industry and umbrella organisations are often offering 'on the job' training and lifelong learning programmes to the practicing personnel. Continuous education programmes that cover evolving technology in pharmaceutical science and span collaboratively across industry, academia and government are particularly relevant.[80] Lifelong learning will become an ever increasingly important tool to ensure that the cutting-edge, multidisciplinary science and technology will reach the already out-of-school workforce.

Lifelong learning in fact came out as a leading component in capacity building from all our studies. In our case study, one of the recommendations for future research was to replicate the undergraduate course into a continuing education one. Lessons learned from **Chapter 3.2**

could inform the development and assessment process. At the FIP annual congress, continuing education platform, the GPP role on 'Maintaining and improving professional performance', under which pharmacists keep themselves abreast on contemporary events and attend formal lifelong learning systems (e.g. continuing education),[17] was the most frequently represented in **Chapter 2.2**. The aim of the world congress is also to fulfil this role.

Academia is in an excellent position to take leadership in establishing lifelong learning though early collaboration with the medicines innovation units, government agencies, benevolent foundations, pharmaceutical industry, and professional organisations. Policy makers shall facilitate capacity building by reinforcing policies and articles to create lifelong learning systems.

Deciphering the future: fortune favors the prepared mind

Finally, capacity building is about preparing for what is ahead. Gathering perspectives from a multidisciplinary group composed of practitioners, scientists and educators can help decipher the future characterised by fast-paced changes, and allow better preparation for upcoming times. We have shown it in our scenario analysis in **Chapter 4.1** where scenarios are plausible, not probable or preferable, portraits of alternative futures.

For example, one of the scenarios sees science and entrepreneurship harvesting major scientific breakthroughs in cell biology, medicinal chemistry, and nano- or data science. Advanced Artificial Intelligence networks help integrating various medical needs to high-end diagnostic and therapeutic platforms. We already see life sciences companies making progress in adopting and deploying digital solutions and analytics.[81] Latest data show that half (n=55%) of pharma industries surveyed by McKinsey in 2023 have deployed some digital and analytics applications at scale.[81] These have a potential to lower the risks in drug discovery, accelerate clinical trials, reinvent engagement with practitioners and patients etc.[81] However, to unlock this potential, cross-functional teams are desired: with translators of both digital and analytics, and science (with knowledge of a specific therapeutic area).[81] Capacity should be built accordingly.

Complementary to scenario analysis, asking the pharmaceutical community for their perception on drivers and analysing these is also a useful exercise for trends identification (**Chapters 2.1** and **4.2**). Support of the community of practice (or in our case, 'community of science, practice and education') and their voices and perspectives represented is important not only for informing priority setting – crucial for strategic, long-term planning and resource allocation, but also for ownership and implementation of such actions.

It is not our aim to bring certainty to the picture of capacity building planning, as this is not possible, but what is possible is to stimulate debate and make reasoned judgements, giving voice to all three components – science, practice and education. The pharmaceutical community and health policy makers should use these to take a long term view in order to be prepared adequately for the future. They must early involve those who will eventually be implementing these at the grass-roots.

Conclusions

Global progress towards good health and quality of life has been uneven, as evidenced by the ongoing burden of disease. With the ultimate goal of responding to the societal health demands

around the globe, capacity ought to be built by using the intertwined roles of pharmaceutical science, practice and education to their full potential. Pharmaceutical scientists and pharmacists have demonstrated that they aspire and are in good position to meet populations needs even amid constant changes in the pharmaceutical landscape. Education, from undergraduate teaching to lifelong learning, is crucial for preparing them for these challenges, and we can expect some adaptation of the roles, for example through enhanced specialisation and embracing variety of scientific fields and cutting-edge developments. However, educational barriers remain to be removed. Academia, as well as professional bodies, funding institutions, workforce planning regulators, policy makers and other stakeholders should strive for improvements to methodologies and polices to better equip capacity building in an ever-ongoing quest for being strategic in face of the complexity and uncertainty of the future.

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6 Summaries

6.1 Summary

Capacity building involves development of human and institutional resources by enhancing individual skills and strengthening organisational competence to perform specific tasks more effectively. Mostly driven by imperatives to achieve national and global health objectives as set out by the Sustainable Development Goals, the topic of capacity building in healthcare is gaining more dominance in policy discourses on international development. Global health workforce capacity building is of a strategic importance — especially in light of persistent global burden of diseases, exacerbated by a projected shortfall of 18 million health workers by 2030, predominantly in low and lower-middle income countries. These challenges are prompting efforts to bridge the gaps in pharmaceutical research for the development of new medicines and the improvement of medicines in use. It is necessary that building capacity in health workforce is an integral part of these efforts. The pharmaceutical workforce, which within the health workforce refers to the whole of the pharmacy-related workforce, composed primarily of pharmacists (registered pharmacist practitioners working in a diversity of settings with their support cadres) and pharmaceutical scientists, plays a key role in improving health outcomes through the development of new medicines and the optimal use of existing medicines.

Against this background, the need for well-equipped pharmaceutical scientists and practitioners is evident in order to ensure optimal access to existing medicines coupled with pharmaceutical expertise. This is where capacity building can make a difference to ensure that they are used to their full potential to *readily* respond to patient needs by bridging the state-of-the-art pharmaceutical science with current, real-world pharmaceutical practice, underpinned by contemporary pharmaceutical education. Indeed, we emphasise *readily* as there are many transitions in current health care and society at large. Technological and demographic changes, coupled with environmental and political challenges, make the long-term planning in capacity building a challenge.

As is outlined in the introduction in **Chapter 1**, this thesis presents studies on the changing role of science, practice and education in building capacity for pharmacy and pharmaceutical sciences. This thesis assessed the optimal role of all these three components while considering the ultimate goal of addressing the health needs worldwide. The thesis is organised into five main chapters.

First of all, **Chapter 2** consists of two sub-chapters in which we studied the hypothesis that there is a changing role for both pharmaceutical scientists and pharmacists to progressively address public health imperatives. It describes that these roles are interlinked and thus there are considerations for capacity building, taking into account both the scientific and practical aspects and the blurred intersections between them.

Chapter 2.1 describes primarily pharmaceutical sciences and evaluates the importance of drivers of pharmaceutical research. With rapidly changing environment, the pharmaceutical research adapts to fit its new circumstances. The study examined the driving powers in pharmaceutical sciences research with a focus on unmet medical need (UMN). Given the complexity of these steering forces, questions arose on whether the direction of pharmaceutical sciences is aligned with what society needs from pharmaceutical sciences today. To this end, in 2020, we surveyed internationally recognised pharmaceutical scientists (n=92), mainly with academia and industry background, on drivers and influencing factors in pharmaceutical sciences through an online survey. The study

offered a distinctive global outlook, revealing that UMN was at that point in time seen as one of the three most important drivers, also in addition to emerging trends in science and opportunities driven by collaboration. The prioritisation of UMN demonstrated a solid command of the global needs in pharmaceutical sciences, and revealed an anticipation that UMN's impact will become even more influential in the future. This was consistent for both industry and academic respondents. The majority of respondents also indicated that anticipated lessons learned from the recent pandemic will strengthen the impact of UMN on science and leadership. This is important as this means pharmaceutical scientists themselves see research being driven by demands of providing a therapy where there is none or where more appropriate clinical alternatives are greatly needed. The findings in this study can be employed in shaping the vision and strategies for addressing UMN and related capacity building for pharmaceutical sciences and research, both in academia and in industry.

Chapter 2.2 focuses on the counterpart, pharmaceutical practice. It presents a longitudinal analysis of how the pharmacists' roles were being reflected in the annual world pharmacy congresses over time. The annual congresses of the pharmacy organisation representing the profession globally, the International Pharmaceutical Federation (FIP), reflect contemporary excellence and the latest innovations through pertinent discussions that take place in the educational sessions. The observed period spanned 17 years (2003-2019), covering nearly two decades. To encompass the globally accepted roles that pharmacists fulfil, the Good Pharmacy Practice (GPP) standards, developed jointly by the World Health Organization (WHO) and the FIP in 2011, served as the framework for generating a set of keywords. The keywords were then used in the text analysis to examine the frequencies of their appearance in the programmes. Descriptive analysis was performed to examine trends over time in both the four overarching GPP roles and at the individual keyword level.

Firstly, the analysis validated the relevance of GPP, showing the roles have been reflected in the congresses already before their formal adoption, and they stayed relevant in the decade after. Secondly, while all four GPP roles appeared in the programme each year the Role 3 "Maintain and improve professional performance" stood out as it was most frequently represented. Moreover, it displayed an upward trend in appearance, together with Role 4: "Contribute to improve effectiveness of the health-care system and public health". Trends occurred towards clinical, patient-centred focus. This was also confirmed through the individual keywords analysis in areas such as health promotion, demonstrating that pharmacists are increasingly being positioned as an important player in the healthcare system. In contrast, the more traditional product-centred practice roles such as compounding occurred less. These rather technical topics in pharmacy are mostly covered in the day to day working environment.

Chapter 3 provides insights into the education about substandard and falsified (SF) medical products, as these products present a significant and underexplored challenge for pharmacists and pharmaceutical scientists in all countries, with a particular prevalence in low- and middle-income countries. Substandard medical products fail to meet either national or international quality standards and/or specifications and falsified medical products mispresent deliberately or fraudulently their identity, composition, or source (WHO definition). Education is a prerequisite for being able to respond to global threats such as SF medical products, that pose danger to public health.

Chapter 3.1 maps what is already being taught on SF medical products and where the gaps are. The study collected responses from 37 countries (n=55 schools of pharmacy, 33% response rate) on teaching about SF medical products. Most schools taught about SF medical products as a stand-alone course or as part of another course or module (n=37, 67%). Alarmingly, 33% (n=18) did not teach about the subject at all. This confirms that too few pharmacists receive formal training on SF medical products.

For those who taught about SF medical products, the main focus for learning was on detection (21%) and prevention (21%) of SF medical products. Not surprisingly, reporting was taught the least (12%), indicating a knowledge gap in that area -- this also explains why there is so much underreporting for these products.

Academia views enhancing knowledge among pharmacists as a moral and ethical obligation. This can bolster health systems' capacities to tackle the global health threat posed by SF medical products. The schools were asked about the barriers and enablers to introducing a new course into the pharmacy curriculum. Insufficient time in already packed curriculum (n=33; 60%) posed the greatest barrier, while availability of ready-to-adopt course materials was deemed a helpful enabler.

These findings informed **Chapter 3.2** that assessed adaptation of pharmaceutical education to health threats and new practice paradigms. It contains a case study on SF medical products to illustrate such adaptation. In order to do so, a course on SF medical products was developed and subsequently introduced into several pharmacy curricula in Sub-Saharan Africa. The study examined the effects on knowledge improvement of the students that followed this course. Three Sub-Saharan universities participated in the study and their students were assessed in knowledge on the course content through scores on a 20-points questionnaire. Scores were compared before and after the course among 335/355 students who completed the survey (n=41/53 in Cameroon, n=244/252 in Senegal and n=50/50 in Tanzania). Once the score differences were compared with a linear mixed-effects model analysis, the results showed that the knowledge of SF medical products was enhanced, with increase in all countries (overall by 3.5 (95% CI 3.1-3.9) score points). Students improved in all offered modules in each country. In addition, students were asked to self-assess their knowledge gain and this assessment confirmed their improvement.

Teachers were interviewed on the context of the course introduction and their responses were analysed descriptively. Teachers reported time constraints and access to practical means (equipment availability, room allocation, internet accessibility and affordability) as main barriers to course introduction. They however managed to overcome these barriers by support from university leadership, and early involvement of the university in the course design. These were helpful enablers. Both students and teachers responded positively to the course.

This study confirmed that a dedicated educational course for undergraduate pharmacy students improved their knowledge on SF products. This is reassuring and can further stimulate implementation of this course in existing pharmacy curricula to other schools of pharmacy and provide information for potential future expansion of such efforts.

Subsequently, the thesis has explored the notion that capacity building should facilitate the navigation and adjustment to evolving environments shaped by patient needs. **Chapter 4**

presents the factors to take into account when preparing for the times ahead. It assesses how the evolving environment in pharmaceutical sciences and practice is affecting capacity building.

Namely, **Chapter 4.1** delineates distinct scenarios to ponder about the future of pharmaceutical science and practice, in the context of pharmaceutical innovation and broader social policies for the decade ahead. Predicting the exact future is challenging, as unknown advancements and uncertain factors in the scientific, socioeconomic, policy, medical need, and geopolitical environments are likely to shape the field in the coming years. Using the methods of scenario analysis, the study presented in this chapter examined patterns, essential trends and intricate developments in the area. Delineated 'critical uncertainties' formed two distinct scenario drivers: global convergence, on one end with high unity and fragmented ecosystems on the other end; and disease orientation, extending from public health first to interceptive medicine. The resulted framework then presented four contrasting portraits of the future of medicines and social policy: 1) deprioritising the high-end; 2) sustainable flow; 3) transformative healing; and 4) global divide portrait. As capacity building is about preparing for what lies ahead, these scenarios can help decipher the future characterised by fast-paced changes, and subsequently, allow better preparation. While all these scenarios are plausible, they are not probable, accurate or superior descriptions of futures. They however serve as food for thoughts for policy makers, academia, practitioners, scientists and effectively all stakeholders who are involved in preparations for the uncertain future. For example, all scenarios projected that both science and practice will harvest major innovative breakthroughs. Transformative healing scenario implies that data analysis and predictive modelling systems supported by Artificial Intelligence will revolutionise medicine by assisting in diagnosis, drug discovery, treatment optimisation, and will aid healthcare professionals in making more informed choices. There are then implications for practitioners, scientists and educators, so that they are ready to adopt and deploy these digital solutions and analytics to be able to respond to future needs of the population.

As a follow up to the scenario analysis, **Chapter 4.2** presents an analysis on how pharmaceutical scientists and practitioners can be better equipped to navigate the ongoing and anticipated challenges in a strategic manner. A survey (n=92, 24% response rate) was conducted to identify the important drivers facilitating capacity building in pharmaceutical sciences. The survey was sent to pharmaceutical scientists with international accomplishments and distinguished leadership in pharmaceutical sciences worldwide. The results revealed a trend of increased embracement of a plethora of educational backgrounds, not limited exclusively to pharmacy. This is already visible from the educational background of our pharmaceutical scientist- respondents (n=43, 47%, self-reported), where pharmacists were not the largest group (n=22, 24%, self-reported). Nearly one third (n=27, 29%, self-reported) of the participants indicated various other areas: (medicinal) chemistry; biology, biotechnology; medicine, epidemiology; data science, statistics; biophysics/physics; engineering; social sciences, humanities or other areas. The survey furthermore revealed that influx of specialised sciences is anticipated — such as data science, biotechnology, engineering, which will likely require more diversity in training. The respondents indicated better alignment with clinic (n=41, 45%) and with patients as the top one very important factor; followed by lifelong learning (n=40, 43%), and greater specialisation through investment in deep knowledge

(n=30, 33%) in the top three very important drivers facilitating capacity building in pharmaceutical sciences. Furthermore, it shows that to further nurture pharmaceutical innovation, capacity building must be more than simply increasing the influx of graduates, which was indicated the least (n=12, 13%). In the past, trained pharmacists were positioned as professionals who combined scientific expertise with practical skills, primarily responsible for accurately and safely distributing medicines to patients. However, these roles have shifted. As the studies in thesis confirmed, there will be expectations towards synergistic and translating roles between the practitioners and the scientists, and deepened levels of specialisation within the field more than ever before.

Chapter 5 draws lessons from the studies conducted in the thesis. It presents conclusions, policy recommendations and implications of the research. It presents points for consideration by various stakeholders, including academia, the international community of practitioners and researchers, international and national regulatory or accreditation associations, and policy makers.

Overall, the thesis implies the transformation of roles for pharmacists and pharmaceutical scientists and that education must keep up with these for ensuring optimal capacity.

The thesis identified the following implications for pharmaceutical policy and recommendations for further academic research:

- Capacity building is more than increasing influx of graduates; policy makers should take the broad context into account in order to make informed decision in capacity building polices.
- Strategic planning should stay close to the clinic; unmet medical need is a critical driver in capacity building in pharmaceutical sciences and practice, and thus addressing health challenges in society.
- There is a need for shifting towards a paradigm of responsive education; readily adaptable pharmacy education should reflect new realities as they emerge in science and practice.
- The educational transformation can be fostered through competency- and needs-based educational approaches; these methodologies are structured methods guided by particular needs that need to be tackled. They involve identifying and customising the essential skills and abilities of graduates to enhance their performance within the healthcare system.
- Cultivating adaptability is pivotal; shattering barriers and boosting enablers are crucial steps in driving transformative educational change worldwide.
- There is no science without practice and vice-versa; pharmaceutical education needs to be underpinned both by science and practice, while embracing specialisation.
- Investing in lifelong learning is essential. Nurturing policies and conducive settings is crucial to establish robust, sustainable lifelong learning systems for societal growth and individual progress for both (future) practitioners and scientists.

In conclusion, capacity building in pharmacy and pharmaceutical sciences remains a challenge – one where pharmaceutical science, practice and education can make a difference if used synergically and to their full potential. Assessment of current realities in all these three elements, outlining trends, anticipating various scenarios, and exploring unconventional interventions can enhance the readiness to augment capacity building. Therefore, academia, as well

as policy makers should aim to enhance methodologies and policies. Professional bodies, funding institutions, workforce planning regulators, and other stakeholders should join in these efforts. Their collective goal is then to strengthen the intertwined roles of pharmaceutical science, practice and education. The perpetual pursuit for being strategic in light of the intricacy and unpredictability of the future must be a continuous process, in order to swiftly respond to the ever-shifting global societal health needs.

6.2 Samenvatting

Capaciteitsopbouw omvat de ontwikkeling van menselijke en institutionele middelen door het verbeteren van individuele vaardigheden en het versterken van organisatorische competentie om specifieke taken effectiever uit te voeren. Grotendeels gedreven door de imperatieven om nationale en mondiale gezondheidsdoelstellingen te bereiken, zoals uiteengezet in de Duurzame Ontwikkelingsdoelen, wint het onderwerp capaciteitsopbouw in de gezondheidszorg steeds meer aan invloed in beleidsdiscussies over internationale ontwikkeling. Wereldwijde capaciteitsopbouw in de gezondheidszorg is van strategisch belang - vooral in het licht van de aanhoudende wereldwijde ziektelast, die nog wordt verergerd door een verwacht tekort van 18 miljoen gezondheidswerkers tegen 2030, voornamelijk in lage- en lagere-middeninkomenslanden. Door deze uitdagingen worden er veel inspanningen geleverd om nieuwe geneesmiddelen te ontwikkelen en bestaande medicijnen te verbeteren. Het is noodzakelijk dat capaciteitsopbouw in de gezondheidszorg een integraal onderdeel is van deze inspanningen. De farmaceutische beroepsbevolking, wat binnen de gezondheidszorg verwijst naar alle farmaceutisch gerelateerde arbeidskrachten, voornamelijk bestaande uit apothekers (geregistreerde apothekers die in verschillende omgevingen werken met hun ondersteunend personeel) en farmaceutische wetenschappers, speelt een belangrijke rol bij het verbeteren van de gezondheidsresultaten door de ontwikkeling van nieuwe geneesmiddelen en het optimale gebruik van bestaande geneesmiddelen.

Tegen deze achtergrond is er duidelijk behoefte aan goed uitgeruste farmaceutische wetenschappers en beroepsbeoefenaars om een optimale toegang tot bestaande geneesmiddelen te garanderen, gekoppeld aan farmaceutische expertise. Dit is waar capaciteitsopbouw een verschil kan maken om ervoor te zorgen dat ze ten volle worden benut om *snel te* reageren op de behoeften van patiënten door de state-of-the-art farmaceutische wetenschap te verbinden met de huidige farmaceutische praktijk, ondersteund door eigentijds farmaceutisch onderwijs. We benadrukken *'snel'* omdat er veel transities zijn in de huidige gezondheidszorg en de maatschappij in het algemeen. Technologische en demografische veranderingen, in combinatie met uitdagingen op het gebied van milieu en politiek, maken het plannen van capaciteitsopbouw op de lange termijn tot een uitdaging.

Zoals uiteengezet in de inleiding in **hoofdstuk 1**, presenteert dit proefschrift studies over de veranderende rol van wetenschap, praktijk en onderwijs in het opbouwen van capaciteit voor farmacie en farmaceutische wetenschappen. Dit proefschrift beoordeelde de optimale rol van al deze drie componenten met het uiteindelijke doel om wereldwijd in de gezondheidsbehoeften te voorzien. Het proefschrift is onderverdeeld in vijf hoofdstukken.

Allereerst bestaat **hoofdstuk 2** uit twee subhoofdstukken waarin we de hypothese hebben bestudeerd dat er een veranderende rol is voor zowel farmaceutische wetenschappers als apothekers om geleidelijk aan te voldoen aan de eisen van de volksgezondheid. Er wordt beschreven dat deze rollen onderling verbonden zijn en dat dit invloed heeft op de capaciteitsopbouw, zodat er rekening wordt gehouden met zowel de wetenschappelijke als de praktische aspecten en de vage raakvlakken daartussen.

Hoofdstuk 2.1 beschrijft in de eerste plaats de farmaceutische wetenschappen en evalueert het belang van de drijvende krachten achter farmaceutisch onderzoek. Met de snel veranderende omgeving past het farmaceutisch onderzoek zich aan de nieuwe omstandigheden aan. De studie

onderzocht de drijvende krachten in farmaceutisch wetenschappelijk onderzoek met een focus op onvervulde medische behoefte (Unmet Medical Need, UMN). Gezien de complexiteit van deze sturende krachten rees de vraag of de richting van de farmaceutische wetenschappen in lijn is met wat de maatschappij vandaag nodig heeft van de farmaceutische wetenschappen. Daartoe hebben we in 2020 internationaal erkende farmaceutische wetenschappers (n=92), voornamelijk met een academische en industriële achtergrond, via een online enquête bevraagd over sturende en beïnvloedende factoren in de farmaceutische wetenschappen. De studie bood een onderscheidende wereldwijde kijk, waaruit bleek dat UMN op dat moment werd gezien als een van de drie belangrijkste drijfveren, naast opkomende trends in de wetenschap en kansen die worden gedreven door samenwerking. De prioritering van UMN toonde een solide beeld van de wereldwijde behoeften op het gebied van farmaceutische wetenschappen en liet zien dat men verwacht dat de invloed van UMN in de toekomst nog groter zal worden. Dit was consistent voor zowel industriële als academische respondenten. De meerderheid van de respondenten gaf ook aan dat de verwachte lessen uit de recente pandemie de impact van UMN op wetenschap en leiderschap zullen versterken. Dit is belangrijk omdat dit betekent dat farmaceutische wetenschappers zelf zien dat onderzoek wordt gedreven door de vraag om een therapie te bieden waar er geen is of waar meer geschikte klinische alternatieven hard nodig zijn. De bevindingen in dit onderzoek kunnen worden gebruikt bij het vormgeven van de visie en strategieën voor het aanpakken van UMN en gerelateerde capaciteitsopbouw voor farmaceutische wetenschappen en onderzoek, zowel in de academische wereld als in de industrie.

Hoofdstuk 2.2 richt zich op de tegenhanger, de farmaceutische praktijk. Het presenteert een longitudinale analyse van hoe de rol van apothekers in de loop van de tijd werd weerspiegeld in de jaarlijkse wereldcongressen over farmacie. De jaarlijkse congressen van de apothekersorganisatie die het beroep wereldwijd vertegenwoordigt, de International Pharmaceutical Federation (FIP), weerspiegelen de huidige stand van zaken en de nieuwste innovaties door middel van relevante discussies die plaatsvinden in de educatieve sessies. De geobserveerde periode besloeg 17 jaar (2003-2019), bijna twee decennia. Om de wereldwijd geaccepteerde rollen die apothekers vervullen te omvatten, dienden de Good Pharmacy Practice (GPP) standaarden, gezamenlijk ontwikkeld door de Wereldgezondheidsorganisatie (WHO) en de FIP in 2011, als kader voor het genereren van een set trefwoorden. De sleutelwoorden werden vervolgens gebruikt in de tekstanalyse om de frequentie van hun voorkomen in de programma's te onderzoeken. Er werd een beschrijvende analyse uitgevoerd om trends in de tijd te onderzoeken, zowel voor de vier overkoepelende GPP-rollen als op het niveau van de afzonderlijke trefwoorden.

Ten eerste bevestigde de analyse de relevantie van GPP door aan te tonen dat de rollen al in de congressen aan bod kwamen voordat ze formeel werden aangenomen, en dat ze relevant bleven in het decennium daarna. Ten tweede, hoewel alle vier de GPP-rollen elk jaar in het programma voorkwamen, viel rol 3 "Behoud en verbetering van de professionele prestaties" op omdat deze het vaakst vertegenwoordigd was. Bovendien vertoonde deze rol een stijgende trend, samen met rol 4: "Bijdragen tot een grotere effectiviteit van het gezondheidszorgsysteem en de volksgezondheid". Er was een trend naar een klinische, patiëntgerichte focus. Dit werd ook bevestigd door de analyse van individuele sleutelwoorden op gebieden zoals gezondheidsbevordering, wat

aantoont dat apothekers steeds meer worden gepositioneerd als een belangrijke speler in het gezondheidszorgsysteem. Daarentegen kwamen de meer traditionele productgerichte praktijkrollen, zoals magistrale bereidingen, minder voor. Deze meer technische onderwerpen in de farmacie komen meestal aan bod in de dagelijkse werkomgeving.

Hoofdstuk 3 geeft inzicht in het onderwijs over medische producten (geneesmiddelen en vaccins) die ondermaats en/of vervalst zijn (Substandard and Falsified, SF). Deze producten vormen een belangrijke en onderbelichte uitdaging voor apothekers en farmaceutische wetenschappers in alle landen, maar met name in landen met een laag- en middeninkomen. Geneesmiddelen die ondermaats zijn, voldoen niet aan nationale of internationale kwaliteitsnormen en/of specificaties en van vervalste medische producten wordt opzettelijk of frauduleus een verkeerde voorstelling van hun identiteit, samenstelling of bron gegeven (vertaalde WHO-definitie). Onderwijs is een eerste vereiste om te kunnen reageren op wereldwijde bedreigingen zoals SF medische producten, die een gevaar vormen voor de volksgezondheid.

Hoofdstuk 3.1 brengt in kaart wat er al wordt onderwezen over SF-geneesmiddelen en waar de hiaten liggen. Voor deze studie werden reacties uit 37 landen verzameld (n=55 farmacie-opleidingen, respons 33%) met betrekking tot onderwijs over SF-geneesmiddelen. De meeste opleidingen onderwezen over SF-medische producten als een op zichzelf staande cursus of als onderdeel van een andere cursus of module (n=37, 67%). Het is alarmerend dat 33% (n=18) helemaal geen les gaf over het onderwerp. Dit bevestigt dat te weinig apothekers formele training krijgen over SF-geneesmiddelen.

Voor degenen die les gaven over SF-geneesmiddelen, lag de nadruk bij het onderwijzen op detectie (21%) en preventie (21%) van SF-geneesmiddelen. Het is geen verrassing dat het minst werd onderwezen over rapportage (12%), wat wijst op een kenniskloof op dat gebied -- dit verklaart ook waarom er zoveel onderrapportage is voor deze producten.

De academische wereld beschouwt het vergroten van kennis onder apothekers als een morele en ethische verplichting. Dit kan gezondheidssystemen beter in staat stellen om de wereldwijde bedreiging van de gezondheid door SF-geneesmiddelen aan te pakken. De opleidingen werd gevraagd naar de barrières en factoren die de invoering van een nieuwe cursus in het apotheekcurriculum in de weg stonden. Onvoldoende tijd in het reeds volle curriculum (n=33; 60%) vormde de grootste belemmering, terwijl de beschikbaarheid van kant-en-klaar cursusmateriaal als een nuttige stimulans werd beschouwd.

Deze bevindingen vormden de basis voor **hoofdstuk 3.2**, waarin de aanpassing van farmaceutische opleidingen aan gezondheidsbedreigingen en nieuwe praktijkparadigma's werd beoordeeld aan de hand van een casestudy over SF-geneesmiddelen. Hiertoe werd een cursus over SF-geneesmiddelen ontwikkeld en vervolgens geïntroduceerd in verschillende farmaciecurricula in Sub-Sahara Afrika. De studie onderzocht de effecten op kennisverbetering van de studenten die deze cursus volgden. Drie universiteiten in Sub-Sahara Afrika namen deel aan het onderzoek en hun studenten werden beoordeeld op hun kennis van de cursusinhoud door middel van scores op een vragenlijst met 20 punten. De scores werden voor en na de cursus vergeleken onder 335/355 studenten die de enquête invulden (n=41/53 in Kameroen, n=244/252 in Senegal en n=50/50 in Tanzania). Nadat de scoreverschillen waren vergeleken met een lineaire mixed-effects

modelanalyse, toonden de resultaten aan dat de kennis van SF-geneesmiddelen was verbeterd, met een toename in alle landen (in totaal met 3,5 (95% CI 3,1-3,9) scorepunten). Studenten verbeterden in alle aangeboden modules in elk land. Daarnaast werd studenten gevraagd om hun toegenomen kennis zelf te beoordelen en deze beoordeling bevestigde hun verbetering.

Docenten werden geïnterviewd over de context van de cursusintroductie en hun antwoorden werden beschrijvend geanalyseerd. Docenten noemden tijdsbeperkingen en toegang tot praktische middelen (beschikbaarheid van apparatuur, toewijzing van ruimtes, toegankelijkheid tot internet en betaalbaarheid) als belangrijkste barrières voor de introductie van de cursus. Ze slaagden er echter in om deze barrières te overwinnen door steun van de universiteitsleiding en door de universiteit in een vroeg stadium te betrekken bij het cursusontwerp. Dit waren factoren die de implementatie van de cursus mogelijk maakten. Zowel studenten als docenten reageerden positief op de cursus.

Deze studie bevestigde dat een specifieke cursus voor studenten farmacie hun kennis over SF-geneesmiddelen verbeterde. Dit is geruststellend en kan de implementatie van deze cursus in bestaande farmaciecurricula aan andere farmaciescholen verder stimuleren en informatie verschaffen voor mogelijke toekomstige uitbreiding van dergelijke inspanningen.

Vervolgens heeft het proefschrift onderzocht in hoeverre capaciteitsopbouw het navigeren en aanpassen aan veranderende omgevingen, gevormd door de behoeften van patiënten, kan vergemakkelijken. **Hoofdstuk 4** presenteert de factoren waarmee rekening moet worden gehouden bij de voorbereiding op de toekomst. Het beoordeelt hoe de veranderende omgeving in de farmaceutische wetenschappen en praktijk van invloed is op capaciteitsopbouw.

Hoofdstuk 4.1 schetst verschillende scenario's voor de toekomst van de farmaceutische wetenschappen en praktijk, in de context van farmaceutische innovatie en breder sociaal beleid voor het komende decennium. Het voorspellen van de exacte toekomst is een uitdaging, omdat onbekende ontwikkelingen en onzekere factoren in de wetenschappelijke, sociaaleconomische, beleidsmatige en geopolitieke omgeving en medische behoeften het vakgebied de komende jaren waarschijnlijk zullen vormgeven. Met behulp van scenario-analysemethoden werden in de studie die in dit hoofdstuk wordt gepresenteerd patronen, essentiële trends en complexe ontwikkelingen op dit gebied onderzocht. Afgebakende 'kritische onzekerheden' vormden twee verschillende drijvende krachten achter het scenario: wereldwijde convergentie met een hoge eenheid aan de ene kant en gefragmenteerde ecosystemen aan de andere kant; en ziekteoriëntatie, die zich uitstrekt van volksgezondheid tot (vroeg) behandelende geneeskunde. Het resulterende raamwerk presenteerde vervolgens vier contrasterende portretten van de toekomst van geneesmiddelen en sociaal beleid: 1) deprioritisering van de ‑high-end-; 2) duurzame flow; 3) transformatieve genezing; en 4) portret van wereldwijde verdeeldheid. Omdat capaciteitsopbouw gaat over voorbereiding op wat komen gaat, kunnen deze scenario's helpen om de toekomst die gekenmerkt wordt door snelle veranderingen te ontcijferen en vervolgens een betere voorbereiding mogelijk te maken. Hoewel al deze scenario's plausibel zijn, zijn het geen waarschijnlijke, nauwkeurige of superieure beschrijvingen van de toekomst. Ze dienen echter als stof tot nadenken voor beleidsmakers, de academische wereld, mensen uit de praktijk, wetenschappers en in feite alle belanghebbenden die betrokken zijn bij de voorbereidingen op de onzekere toekomst. Alle scenario's voorspellen bijvoorbeeld dat zowel de wetenschap als de praktijk grote innovatieve doorbraken zullen

oogsten. Het scenario Transformatieve genezing houdt in dat systemen voor gegevensanalyse en voorspellende modellering, ondersteund door kunstmatige intelligentie, een revolutie in de geneeskunde teweeg zullen brengen door te helpen bij het stellen van diagnoses, het ontdekken van geneesmiddelen en het optimaliseren van behandelingen. Ook kunnen ze professionals in de gezondheidszorg helpen bij het maken van beter geïnformeerde keuzes. Er zijn dan implicaties voor beoefenaars, wetenschappers en opleiders; ze moeten klaar zijn om deze digitale oplossingen en analyses aan te nemen en in te zetten om te kunnen reageren op toekomstige behoeften van de bevolking.

Als vervolg op de scenario-analyse presenteert **hoofdstuk 4.2** een analyse van hoe farmaceutische wetenschappers en beroepsbeoefenaars beter kunnen worden toegerust om de huidige en verwachte uitdagingen op een strategische manier aan te gaan. Er werd een enquête (n=92, respons 24%) uitgevoerd om de belangrijke factoren te identificeren die capaciteitsopbouw in de farmaceutische wetenschappen vergemakkelijken. De enquête werd verstuurd naar farmaceutische wetenschappers met internationale erkenning en leiderschap in de farmaceutische wetenschappen wereldwijd. De resultaten toonden een toenemende acceptatie van diverse educatieve achtergronden, die niet beperkt blijft tot de farmacie. Dit wordt duidelijk weerspiegeld in de opleidingsachtergrond van de respondenten onder de farmaceutische wetenschappers (n=43, 47%, zelfgerapporteerd), waarbij apothekers niet de grootste groep vormden (n=22, 24%, zelfgerapporteerd). Bijna een derde (n=27, 29%, zelfgerapporteerd) van de deelnemers gaf een of meer van de volgende verschillende andere gebieden aan: (medicinale) chemie; biologie, biotechnologie; geneeskunde, epidemiologie; data science, statistiek; biofysica/fysica; techniek; sociale wetenschappen, geesteswetenschappen of andere gebieden. Uit de enquête bleek verder dat er een instroom van gespecialiseerde wetenschappen wordt verwacht - zoals data science, biotechnologie, techniek, waarvoor waarschijnlijk meer diversiteit in het onderwijs nodig zal zijn. De respondenten gaven aan dat een betere afstemming op de klinische praktijk (n=41, 45%) en op de patiënt de belangrijkste factoren zijn die capaciteitsopbouw in de farmaceutische wetenschappen beïnvloeden. Hierop volgen een leven lang leren (n=40, 43%) en meer specialisatie door te investeren in diepgaande kennis (n=30, 33%) wat de top drie van zeer belangrijke factoren complementeert. Verder bleek dat om farmaceutische innovatie verder te voeden, capaciteitsopbouw meer moet zijn dan alleen het verhogen van de instroom van afgestudeerden, wat het minst belangrijk werd beschouwd (n=12, 13%). In het verleden werden opgeleide apothekers gepositioneerd als professionals die wetenschappelijke expertise combineerden met praktische vaardigheden, voornamelijk verantwoordelijk voor het nauwkeurig en veilig distribueren van geneesmiddelen aan patiënten. Deze rollen zijn echter verschoven. Zoals bevestigd wordt in de studies in dit proefschrift, wordt er meer dan ooit verwacht dat de zorgbeoefenaars en de wetenschappers synergetische en translerende rollen zullen spelen en dat de specialisatieniveaus binnen het vakgebied zullen worden verdiept.

Hoofdstuk 5 trekt lessen uit de onderzoeken die in dit proefschrift zijn beschreven. Het presenteert conclusies, beleidsaanbevelingen en implicaties van het onderzoek. Het presenteert aandachtspunten voor verschillende belanghebbenden, waaronder de academische wereld,

de internationale gemeenschap van zorgprofessionals en onderzoekers, internationale en nationale regulerende instanties en beleidsmakers.

Dit proefschrift impliceert dat de rollen van apothekers en farmaceutische wetenschappers veranderen en dat het onderwijs moet evolueren om optimale capaciteitsontwikkeling te waarborgen.

Het proefschrift identificeerde de volgende implicaties voor het farmaceutische beleid en doet aanbevelingen voor verder academisch onderzoek:

- Capaciteitsopbouw is meer dan het vergroten van de instroom van afgestudeerden; beleidsmakers moeten rekening houden met de brede context van de farmaceutische sector om weloverwogen beslissingen te kunnen nemen over beleid voor capaciteitsopbouw.
- Strategische planning moet nauw verbonden blijven met de klinische praktijk; onvervulde medische behoeften zijn een cruciale drijfveer voor capaciteitsopbouw in de farmaceutische wetenschap en praktijk en dus voor het aanpakken van de gezondheidsproblemen in de samenleving.
- Er is behoefte aan een verschuiving naar een paradigma van responsief onderwijs; gemakkelijk aanpasbaar onderwijs in de farmacie moet nieuwe ontwikkelingen weerspiegelen, zoals en naarmate die zich voordoen in de wetenschap en de praktijk.
- De transformatie van het onderwijs kan worden bevorderd door competentie- en behoeftegerichte onderwijsmethoden; deze gestructureerde methoden worden geleid door specifieke behoeften die moeten worden aangepakt. Ze omvatten het identificeren en aanpassen van de essentiële vaardigheden en bekwaamheden van afgestudeerden om hun prestaties binnen de gezondheidszorg te verbeteren.
- Het cultiveren van aanpassingsvermogen is cruciaal; het doorbreken van barrières en het bevorderen van stimulerende factoren zijn cruciale stappen in het aanjagen van transformatieve onderwijsveranderingen wereldwijd.
- Wetenschap en praktijk zijn onlosmakelijk met elkaar verbonden; farmaceutisch onderwijs moet zowel door wetenschap als praktijk worden ondersteund, terwijl specialisatie wordt omarmd.
- Investeren in een leven lang leren is van essentieel belang. Het stimuleren van beleid hiertoe en het creëren van een stimulerende omgeving is cruciaal om robuuste, duurzame systemen voor een leven lang leren op te zetten. Dit zal leiden tot maatschappelijke groei en individuele vooruitgang onder zowel (toekomstige) beroepsbeoefenaars als wetenschappers.

Concluderend kan worden gesteld dat capaciteitsopbouw in de farmacie en farmaceutische wetenschappen een uitdaging blijft - een uitdaging waarbij farmaceutische wetenschap, praktijk en onderwijs een verschil kunnen maken als ze synergetisch en volledig worden ingezet. Beoordeling van de huidige situatie in al deze drie elementen, het schetsen van trends, het anticiperen op verschillende scenario's en het verkennen van onconventionele interventies kunnen de bereidheid vergroten om de capaciteitsopbouw aan te pakken. Daarom moeten de academische wereld en beleidsmakers zich richten op het verbeteren van methodologieën en beleid. Beroepsorganisaties, financieringsinstellingen, regelgevende instanties voor personeelsplanning en andere

belanghebbenden moeten zich bij deze inspanningen aansluiten. Hun gezamenlijke doel is dan om de verweven rollen van farmaceutische wetenschap, praktijk en onderwijs te versterken. Het voortdurende streven naar strategische aanpassing aan de complexiteit en onvoorspelbaarheid van de toekomst moet een continu proces zijn om snel te kunnen reageren op de steeds veranderende wereldwijde maatschappelijke gezondheidsbehoeften.

6.3 Zhrnutie

Budovanie kapacít zahŕňa rozvoj ľudských a inštitucionálnych zdrojov prostredníctvom zlepšovania individuálnych zručností a posilňovania organizačných kompetencií. Cieľom je efektívnejšie vykonávať špecifické úlohy. Téma budovania kapacít v zdravotníctve získava čoraz významnejšie postavenie v politických diskusiách o medzinárodnom rozvoji, a je často motivovaná požiadavkami národných a globálnych zdravotných míľnikov stanovených v rámci Cieľov udržateľného rozvoja. Budovanie kapacít zdravotníckych pracovníkov má strategický význam, najmä vzhľadom na pretrvávajúce globálne zaťaženie chorobami. Toto zaťaženie sa ešte zhoršuje v dôsledku predpokladaného nedostatku 18 miliónov zdravotníckych pracovníkov do roku 2030, predovšetkým v krajinách s nízkymi a nižšími strednými príjmami. Tento vývoj podnecuje snahu preklenúť medzery vo farmaceutickom výskume s cieľom vyvinúť nové lieky a zlepšiť užívanie existujúcich liekov. Neoddeliteľnou súčasťou tohto úsilia je rozvoj kapacít zdravotníckych pracovníkov. Farmaceutická pracovná sila, ktorá sa vzťahuje na všetkých farmaceutov (t.j. kvalifikovaní lekárnici pracujúci so svojimi podpornými kádrami v rôznych prostrediach) a taktiež farmaceutických vedcov, hrá kľúčovú úlohu pri zlepšovaní zdravotných výsledkov prostredníctvom vývoja nových liekov a optimálneho využívania tých existujúcich.

V tejto súvislosti je zrejmá potreba kvalifikovaných farmaceutických vedcov a odborníkov, ktorí disponujú odbornými znalosťami, aby sa zabezpečil optimálny prístup k existujúcim liekom. Rozvoj kapacít v tejto oblasti je kľúčový pre plné využitie týchto znalostí na *pohotovú* reakciu na potreby pacientov. Ide o spojenie najnovších poznatkov z farmaceutickej vedy s aktuálnou farmaceutickou praxou, podporené neustálym vzdelávaním farmaceutov. Je dôležité zdôrazniť, že potrebujeme *pohotovú* reakciu, pretože v súčasnom zdravotníctve a celkovo v spoločnosti dochádza k mnohým zmenám. Technologické a demografické zmeny spolu s environmentálnymi a politickými udalosťami predstavujú výzvu pre dlhodobé plánovanie v oblasti rozvoja kapacít.

Ako sa uvádza v úvode v **kapitole 1**, táto práca predstavuje štúdie o vyvíjajúcej sa úlohe vedy, praxe a vzdelávania pri budovaní kapacít pre farmáciu a farmaceutické vedy. V tejto práci sa posudzovala optimálna úloha všetkých týchto troch zložiek pri zohľadnení konečného cieľa, ktorým je riešenie potrieb zdravotnej starostlivosti na celom svete. Práca je rozdelená do piatich hlavných kapitol.

Kapitola 2 sa skladá z dvoch podkapitol, v ktorých sme skúmali hypotézu, že úloha farmaceutických vedcov aj farmaceutov sa mení podľa požiadaviek zdravotnej starostlivosti. Opisuje sa v nej, že ich úlohy sú vzájomne prepojené, a preto sa pri budovaní kapacít zohľadňujú vedecké aj praktické aspekty a ich neostré prieniky.

V **kapitole 2.1** sa opisujú predovšetkým farmaceutické vedy a hodnotí sa význam hnacích síl farmaceutického výskumu. S rýchlymi zmenami v okolitom prostredí sa farmaceutický výskum prispôsobuje novým podmienkam. Táto štúdia sa zameriava na identifikáciu hnacích síl vo farmaceutickom výskume, s dôrazom na nesplnené zdravotnícke potreby (anglicky unmet medical need (UMN), pozn. preklad.). Vzhľadom na zložitosť týchto hnacích síl sa kládol dôraz na otázku, či smerovanie farmaceutického výskumu zodpovedá tomu, čo dnešná spoločnosť od farmaceutického výskumu očakáva. Na tento účel sme v roku 2020 prostredníctvom online prieskumu oslovili medzinárodne uznávaných farmaceutických vedcov (n=92), prevažne s akademickým a vedecko-priemyselným vzdelaním, s otázkami týkajúcimi sa hnacích

síl a ovplyvňujúcich faktorov vo farmaceutických vedách. Náš prieskum ponúkol osobitý globálny pohľad a odhalil, že nesplnené zdravotnícke potreby sa v danom čase považovali za jeden z troch najdôležitejších faktorov, popri nových trendoch vo vede a príležitostiach, ktoré sú podmienené spoluprácou. Stanovenie nesplnených zdravotníckych potrieb ako priority ukázalo hlboké pochopenie globálnych potrieb vo farmaceutickom výskume a naznačilo, že vplyv týchto potrieb bude v budúcnosti ešte výraznejší. Toto zistenie sa týkalo respondenov z priemyslu ako aj z akademickej obce. Väčšina respondentov taktiež zdôraznila, že vplyv nesplnených zdravotníckych potrieb na vedu a výskum bude ešte väčší po skúsenostiach z nedávnej pandémie. Toto taktiež znamená, že samotní farmaceutickí vedci vidia, že výskum je poháňaný požiadavkami poskytnúť terapiu tam, kde žiadna nie je, alebo tam, kde sú veľmi potrebné vhodnejšie klinické alternatívy. Zistenia tejto štúdie možno využiť pri formovaní vízie a stratégií riešenia nesplnených zdravotníckych potrieb a súvisiaceho budovania kapacít pre farmaceutické vedy a výskum, a to tak na akademickej pôde, ako aj vo farmaceutickom priemysle.

Kapitola 2.2 sa zameriava na druhý protipól, farmaceutickú prax. Predstavuje longitudinálnu analýzu úloh lekárnikov a toho, ako sa tieto úlohy časom odrážali na výročných svetových farmaceutických kongresoch. Výročné kongresy Medzinárodnej farmaceutickej federácie, organizácie zastupujúcej farmaceutickú profesiu na celom svete, odrážajú súčasnú špičkovú úroveň a najnovšie inovácie vo farmácií prostredníctvom relevantných diskusií, ktoré sa konajú na vzdelávacích zasadnutiach. Sledované obdobie trvalo 17 rokov (2003 - 2019), čo pokrýva takmer dve desaťročia. Na obsiahnutie celosvetovo uznávaných úloh, ktoré lekárnici plnia, slúžili ako rámec na vytvorenie súboru kľúčových slov normy Správnej lekárenskej praxe (SLP), ktoré v roku 2011 spoločne vypracovali Svetová zdravotnícka organizácia a Medzinárodná farmaceutická federácia. Kľúčové slová sa potom použili pri analýze textu na preskúmanie frekvencie ich výskytu vo vzdelávacích programoch. Deskriptívna analýza sa vykonala s cieľom preskúmať trendy v čase v štyroch zastrešujúcich úlohách SLP ako aj na úrovni jednotlivých kľúčových slov.

Po prvé, analýza potvrdila relevantnosť SLP a ukázala, že úlohy sa na kongresoch odrážali už pred ich formálnym prijatím a zostali relevantné aj v nasledujúcom desaťročí. Po druhé, hoci sa všetky štyri úlohy SLP objavovali v programe každý rok, úloha 3 "Udržiavanie a zlepšovanie profesionálneho výkonu" vynikala, pretože bola zastúpená najčastejšie. Okrem toho vykazovala stúpajúcu tendenciu výskytu spolu s úlohou 4: "Prispievať k zlepšeniu účinnosti systému zdravotnej starostlivosti a verejného zdravia". Vyskytli sa tendencie smerujúce ku klinickému, na pacienta orientovanému zameraniu. Potvrdila to aj analýza jednotlivých kľúčových slov v oblastiach, ako je podpora zdravia, čo dokazuje, že lekárnici sú čoraz viac stavaní do pozície dôležitého aktéra v systéme zdravotnej starostlivosti. Naopak, menej sa vyskytovali tradičnejšie praktické úlohy zamerané na produkty, ako je napríklad príprava liekov. Tieto najmä technické témy v lekárenstve sú väčšinou obsiahnuté v každodennom pracovnom prostredí.

Kapitola 3 poskytuje poznatky o vzdelávaní v oblasti neštandardných a falošných (NF) liekov a zdravotníckych potrieb. Tieto výrobky predstavujú významný a nedostatočne preskúmaný problém pre farmaceutov a farmaceutických vedcov a to vo všetkých krajinách, ale hlavne v krajinách s nízkymi a strednými príjmami. Neštandardné lieky nespĺňajú národné alebo medzinárodné normy kvality a/alebo špecifikácie a falošné lieky zámerne alebo podvodom uvádzajú nesprávnu

identitu, zloženie alebo zdroj lieku (definícia Svetovej zdravotníckej organizácie). Vzdelávanie je nevyhnutným predpokladom na to, aby bolo možné reagovať na globálne hrozby, ako sú napríklad neštandardné zdravotnícke výrobky, ktoré predstavujú pre pacientov nebezpečenstvo.

Kapitola 3.1 mapuje, čo sa už vyučuje o NF liekoch a zdravotníckych pomôckach a kde sú nedostatky. V štúdii boli zhromaždené odpovede z 37 krajín (n=55 farmaceutických škôl, 33 % miera odpovedí) o výučbe o NF liekoch a zdravotníckych pomôckach. Väčšina škôl vyučovala o NF liekoch a zdravotníckych pomôckach ako samostatný predmet a/alebo ako súčasť iného predmetu či modulu (n=37, 67 %). Alarmujúce je, že 33 % (n=18) o tejto tématike vôbec nevyučovalo. To potvrdzuje, že príliš málo farmaceutov absolvuje formálnu odbornú prípravu o NF liekoch a zdravotníckych pomôckach.

Tí, ktorí učili o NF liekoch a zdravotníckych pomôckach, sa pri učení zamerali najmä na detekciu (21 %) a prevenciu (21 %) zdravotníckych výrobkov zo SF. Nie je prekvapujúce, že najmenej sa učilo o hlásení (12 %), čo poukazuje na nedostatok vedomostí v tejto oblasti - to tiež vysvetľuje, prečo je v prípade týchto liekov a zdravotníckych pomôcok toľko nedostatočných hlásení.

Akademická obec považuje za svoju morálnu a etickú povinnosť poskytovať farmaceutickým odborníkom rozšírenie vedomostí prostredníctvom vzdelávania. To môže napomáhať zvýšeniu kapacít zdravotných systémov pri riešení globálnej zdravotnej hrozby, ktorú predstavujú NF lieky a zdravotnícke pomôcky. Školy boli požiadané o poskytnutie informácií o prekážkach a faktoroch, ktoré im bránia v zavedení nového kurzu do ich študijného programu farmácie. Najväčšiu prekážku predstavoval nedostatok času v už aj tak nabitých učebných osnovách (n=33; 60 %), zatiaľ čo dostupnosť hotových učebných materiálov sa považovala za užitočný faktor.

Tieto zistenia boli podkladom pre **kapitolu 3.2**, ktorá hodnotí prispôsobenie farmaceutického vzdelávania zdravotným hrozbám a novým paradigmám praxe. Obsahuje prípadovú štúdiu o NF liekoch a zdravotníckych pomôckach, ktorá ilustruje takéto prispôsobenie. Za týmto účelom bol vypracovaný kurz o NF liekoch a zdravotníckych pomôckach, ktorý bol následne zavedený do niekoľkých študijných programov farmácie v subsaharskej Afrike. V štúdii sa skúmali účinky na zlepšenie vedomostí študentov, ktorí absolvovali tento kurz. Na štúdii sa zúčastnili tri subsaharské univerzity a ich študenti boli hodnotení vo vedomostiach o obsahu kurzu prostredníctvom výsledkov v 20-bodovom dotazníku. Skóre sa porovnávalo pred a po kurze medzi 335/355 študentmi, ktorí vyplnili dotazník (n=41/53 v Kamerune, n=244/252 v Senegale a n=50/50 v Tanzánii). Po porovnaní rozdielov v skóre pomocou lineárnej analýzy modelu zmiešaných efektov výsledky ukázali, že znalosti o NF liekoch a zdravotníckych pomôckach sa zlepšili, pričom vo všetkých krajinách sa zvýšili (celkovo o 3,5 (95 % CI 3,1 - 3,9) skóre). Študenti sa zlepšili vo všetkých ponúkaných moduloch v každej z troch krajín. Okrem toho boli študenti požiadaní, aby sami zhodnotili svoj nárast vedomostí, a toto hodnotenie potvrdilo ich zlepšenie.

Učitelia boli dotazovaní na kontext zavedenia kurzu a ich odpovede boli deskriptívne analyzované. Učitelia uviedli ako hlavné prekážky zavedenia kurzu časové obmedzenia a prístup k praktickým prostriedkom (dostupnosť zariadenia, pridelenie miestnosti, dostupnosť internetu a cenová dostupnosť). Tieto prekážky sa im však podarilo prekonať vďaka podpore zo strany vedenia univerzity a včasnému zapojeniu univerzity do návrhu kurzu, čo boli užitočné podporné faktory. Študenti aj učitelia reagovali na kurz pozitívne.

Táto štúdia potvrdila, že špecializovaný vzdelávací kurz pre vysokoškolských študentov farmácie zlepšil ich vedomosti o NF liekoch a zdravotníckych pomôckach. Je to povzbudzujúce a môže to ďalej stimulovať implementáciu tohto kurzu do existujúcich učebných osnov farmácie na iných farmaceutických fakultách a poskytnúť informácie pre potenciálne budúce rozšírenie takýchto snáh.

Následne sa práca zaoberala myšlienkou, že budovanie kapacít by malo uľahčiť navigáciu a prispôsobenie sa vyvíjajúcemu sa prostrediu, ktoré je formované potrebami pacientov. V **kapitole 4** sú uvedené faktory, ktoré treba zohľadniť pri príprave na budúce obdobie. Posudzuje, ako vyvíjajúce sa prostredie vo farmaceutických vedách a praxi ovplyvňuje budovanie kapacít.

V **kapitole 4.1** sa konkrétne uvádzajú rôzne scenáre, o ktorých je potrebné uvažovať v súvislosti s budúcnosťou farmaceutickej vedy a praxe, v kontexte farmaceutických inovácií a širších sociálnych politík na najbližšie desaťročie, pretože neustály vývoj a neisté faktory v rámci vedy, spoločensko-ekonomickej sféry, politiky, medicíny a geopolitiky budú pravdepodobne formovať túto oblasť v nasledujúcich rokoch. Pomocou metód analýzy scenárov sa v štúdii predloženej v tejto kapitole skúmali zákonitosti, základné trendy a komplexný vývoj v tejto oblasti. Vymedzené "kritické neistoty" vytvorili dva odlišné hnacie motory scenárov: globálna konvergencia s vysokou jednotou na jednom konci a fragmentovanými ekosystémami na druhom konci; a orientácia na choroby, ktorá sa rozširuje od verejného zdravia najprv k intercepčnej medicíne. Výsledný rámec potom predstavil štyri kontrastné portréty budúcnosti liekov a sociálnej politiky: 1) depriorizácia vysokých hodnôt; 2) udržateľný tok; 3) transformačné liečenie; a 4) portrét globálneho rozdelenia. Keďže pri budovaní kapacít ide o prípravu na to, čo nás čaká, tieto scenáre môžu pomôcť dešifrovať budúcnosť charakterizovanú rýchlymi zmenami a následne umožniť na ňu lepšiu prípravu. Hoci sú všetky tieto scenáre možné, nie sú pravdepodobnými, presnými ani nadradenými opismi budúcnosti. Slúžia však ako podnet na zamyslenie pre tvorcov politík, akademickú obec, odborníkov z praxe, vedcov a vlastne všetky zainteresované strany, ktoré sa podieľajú na prípravách na neistú budúcnosť. Napríklad všetky scenáre predpokladali, že veda aj prax prinesú významné inovačné objavy. Scenár transformačného liečenia predpokladá, že systémy analýzy údajov a prediktívneho modelovania podporované umelou inteligenciou spôsobia revolúciu v medicíne tým, že pomôžu pri diagnostike, objavovaní liekov, optimalizácii liečby a pomôžu zdravotníckym pracovníkom pri prijímaní informovanejších rozhodnutí. Z toho potom vyplývajú dôsledky pre zdravotníkov, vedcov a pedagógov, aby boli pripravení prijať a zaviesť tieto digitálne riešenia a analytiku, aby boli schopní reagovať na budúce potreby obyvateľstva.

V nadväznosti na analýzu scenárov sa v **kapitole 4.2** uvádza analýza, ako môžu byť farmaceutickí vedci a odborníci z praxe strategicky vybavení na zvládnutie súčasných a očakávaných výziev. Na identifikáciu dôležitých faktorov uľahčujúcich budovanie kapacít vo farmaceutických vedách sa uskutočnil prieskum (n=92, 24 % miera odpovedí). Prieskum bol zaslaný medzinárodne uznávaným farmaceutickým vedcom z celého sveta s významným vedúcim postavením vo farmaceutických vedách. Výsledky odhalili trend zvýšeného množstva špecializovaných vedných odborov v rámci farmaceutických vied, ktoré sa neobmedzuje výlučne na farmáciu. Je to viditeľné už na základe vzdelania našich farmaceutických vedcov - respondentov (n=43, 47 %, vlastné vyjadrenie), kde farmaceuti nepredstavovali najpočetnejšiu skupinu (n=22, 24 %, vlastné vyjadrenie). Takmer tretina

účastníkov (n=27, 29 %, vlastné vyjadrenie) uviedla rôzne iné oblasti: (lekárska) chémia; biológia, biotechnológie; medicína, epidemiológia; dátové vedy, štatistika; biofyzika/fyzika; inžinierstvo; spoločenské vedy, humanitné vedy alebo iné oblasti. Z prieskumu ďalej vyplynulo, že sa očakáva prílev špecializovaných vedných odborov - napríklad dátová veda, biotechnológie, inžinierstvo, ktoré si pravdepodobne budú vyžadovať väčšiu rozmanitosť odbornej prípravy. Respondenti uviedli ako prvý veľmi dôležitý faktor lepšie zosúladenie s klinikou (n=41, 45 %) a s pacientmi; v prvej trojke veľmi dôležitých faktorov uľahčujúcich budovanie kapacít vo farmaceutických vedách nasledovalo celoživotné vzdelávanie (n=40, 43 %) a väčšia špecializácia prostredníctvom investícií do hlbokých znalostí (n=30, 33 %). Okrem toho sa ukazuje, že na ďalšiu podporu farmaceutických inovácií musí byť budovanie kapacít viac než len zvýšenie prílevu absolventov, čo bolo uvedené najmenej (n=12, 13 %). V minulosti boli farmaceuti vyškolení ako odborníci, ktorých hlavnou úlohou bolo zabezpečiť presnú a bezpečnú distribúciu liekov pacientom. Avšak tieto úlohy sa v priebehu času zmenili. Ako potvrdili štúdie v tejto práci, dnes sa očakáva väčšia synergická a translačná úloha medzi praktickými a vedeckými farmaceutickými pracovníkmi a kombinovanie vedeckých znalostí s praktickými zručnosťami. Taktiež sa očakáva, že dôjde k hlbšej špecializácii v rámci tohto odboru.

V **kapitole 5** sa uvádzajú poznatky zo štúdií vykonaných v tejto práci. Uvádza závery, politické odporúčania a dôsledky výskumu. Uvádza body, ktoré by mali byť zvážené rôznymi zainteresovanými stranami, vrátane akademickej obce, medzinárodnej komunity odborníkov z praxe a výskumníkov, ako aj medzinárodných a národných regulačných alebo akreditačných organizácií a tvorcov politík.

Celkovo z práce vyplýva, že úlohy farmaceutov a farmaceutických vedcov sa menia a že vzdelávanie musí s nimi držať krok, aby sa zabezpečila optimálna kapacita. **V práci boli identifikované nasledujúce dôsledky pre farmaceutickú politiku a odporúčania pre ďalší akademický výskum:**

- Budovanie kapacít je viac než len zvyšovanie prílevu absolventov; tvorcovia politík by mali zohľadniť širší kontext, aby mohli prijímať informované rozhodnutia v oblasti budovania kapacít.
- Strategické plánovanie by malo kopírovať potreby kliniky; nesplnené zdravotnícke potreby sú rozhodujúcim faktorom pri budovaní kapacít vo farmaceutických vedách a praxi, a tým aj pri riešení zdravotných problémov v spoločnosti.
- Je potrebné prejsť na paradigmu flexibilného vzdelávania; ľahko prispôsobiteľné farmaceutické vzdelávanie by malo odrážať nové skutočnosti, ktoré sa objavujú vo vede a praxi.
- Transformáciu vzdelávania možno podporiť prostredníctvom vzdelávacích prístupov založených na kompetenciách a potrebách; tieto metodiky sú štruktúrované metódy, ktoré sa riadia konkrétnymi potrebami, ktoré je potrebné riešiť. Zahŕňajú identifikáciu a prispôsobenie základných zručností a schopností absolventov s cieľom zlepšiť ich výkon v systéme zdravotnej starostlivosti.
- Kultivácia prispôsobivosti je kľúčová; odstraňovanie prekážok a posilňovanie podporných faktorov sú kľúčové kroky pri presadzovaní transformačných zmien vo vzdelávaní na celom svete.
- Bez praxe neexistuje veda a naopak; farmaceutické vzdelávanie musí byť založené na vede aj praxi a zároveň musí zahŕňať špecializáciu.

- Investície do celoživotného vzdelávania sú nevyhnutné. Podpora politík a priaznivého prostredia je kľúčová pre vytvorenie spoľahlivých a udržateľných systémov celoživotného vzdelávania pre rast spoločnosti a individuálny pokrok (budúcich) odborníkov z praxe aj vedy.

Na záver možno konštatovať, že rozvoj kapacít v oblasti farmácie a farmaceutických vied predstavuje výzvu, pri ktorej môže synergia a plné využitie potenciálu farmaceutickej vedy, praxe a vzdelávania priniesť pozitívne zmeny. Posúdenie súčasnej reality vo všetkých týchto troch prvkoch, načrtnutie trendov, predvídanie rôznych scenárov a skúmanie netradičných intervencií môže zvýšiť schopnosť posilnenia budovania kapacít. Preto by sa akademická obec, ako aj tvorcovia politík mali zamerať na zlepšovanie metodík a politík. Do tohto ú*silia by sa mali zapojiť aj profesijné organizácie, financujúce inštitúcie, regulačné orgány v oblasti plánovania pracovných síl a ďalšie zainteresované strany. Ich spoločným cieľom je potom posilniť vzájomne prepojené úlohy farmaceutickej vedy, praxe a vzdelávania. Pretože budúcnosť je komplexná a nepredvídateľná, snažiť sa o strategickú orientáciu by malo byť trvalým procesom, ktorý sa neustále vyvíja, aby bolo možné rýchlo reagovať na neustále sa meniace potreby globálnej spoločnosti v oblasti zdravia.

7 Appendices

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7.2

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7.3 Author's contribution

Chapter 1 General Introduction

ZK wrote the general introduction. Her PhD supervisory team reviewed various versions of the general introduction. ZK implemented their feedback, and her PhD supervisory team approved the final version.

Chapter 2.1. Unmet medical need as a driver for pharmaceutical sciences – a survey among scientists

Z.K. and H.G.M.L. conceptualised the study in consultation with H.A.vdH., G.M.P. and A.K.M.-T.. Z.K. collected and analysed the data. Z.K. drafted the manuscript and all authors reviewed the paper. A.K.M.-T. and H.G.M.L. served as the overall guarantors for the study. All authors have read and agreed to the published version of the manuscript.

Chapter 2.2. Longitudinal study of Good Pharmacy Practice roles covered at the annual world pharmacy congresses 2003-2019

Z.K., H.A.vdH., H.G.M.L. conceptualised the study in consultation with A.K.M.-T.. Z.K. collected and analysed the data, these were then independently validated by H.A.vdH. Z.K. drafted the manuscript and all authors reviewed the paper. A.K.M.-T. served as the overall guarantor for the study. All authors have read and agreed to the published version of the manuscript.

Chapter 3.1. Identifying the teaching content on substandard and falsified medical products in global pharmacy education as critical public health issue

Z.K. conceptualised the study in consultation with all authors, and led the methodology, software, validation, formal analysis, and writing. Z.K. and M.K. collected and analysed the data. Z.K. drafted the manuscript with help of M.K., and all authors reviewed the paper. A.K.M.-T. served as the overall guarantor for the study. All authors have read and agreed to the published version of the manuscript.

Chapter 3.2. Improved knowledge on substandard and falsified (SF) medical products through a dedicated course for pharmacy students at three universities in Sub-Saharan Africa

Z.K. led the conceptualisation of the study, and all authors were involved in evolution of overarching research aims. Z.K. and Y.B. collected and analysed the data with the support of and in consultation with H.A.vdH. and with the local help of G.E.-L., E.K. and S.O.S.. Z.K. and Y.B. drafted the manuscript and all authors reviewed the paper. A.K.M.-T. served as the overall guarantor for the study.

Chapter 4.1. Four scenarios for the future of medicines and social policy in 2030

H.G.M.L. and P.S. initiated the project and approached FIP and IQVIA for collaboration. The collaboration with FIP brought Z.K. in the lead for mapping analyses, background material and project oversight. Subsequently, all authors contributed to the Digital Tables and collaboratively

worked on the scenario analysis. Each of the authors led the first draft of one of the scenarios (e.g., Z.K. and K.K. drafted the scenario on Transformative Healing). M.A., P.S. and K.K. provided background material and analyses for the quantitative modelling of the scenarios. H.G.M.L., Z.K. and A.K.M.-T. contributed equally to the iterative drafting and editing of the manuscript. All other authors provided multiple rounds of feedback and added critical comments.

Chapter 4.2. Pharmaceutical scientists' perspectives on capacity building in pharmaceutical sciences

Z.K. conceptualised the study in consultation with H.A.vdH., H.G.M.L. and A.K.M.-T.. Z.K. collected and analysed the data. Z.K. drafted the manuscript and all authors reviewed the paper. A.K.M.-T. and H.G.M.L. served as the overall guarantors for the study. All authors have read and agreed to the published version of the manuscript.

Chapter 5 General Discussion

ZK wrote the general discussion. Her PhD supervisory team reviewed various versions of the general discussion. ZK implemented their feedback, and her PhD supervisory team approved the final version.

7.4 List of publications

Presented in this thesis

Kusynová Z, Pauletti G.M., van den Ham H.A., Leufkens H.G.M., Mantel-Teeuwisse A.K. Unmet medical need as a driver for pharmaceutical sciences - a survey among scientists. Journal of Pharmaceutical Sciences. 2022;111(5):1318-1324.

Kusynová Z., van den Ham H.A., Leufkens H.G.M., Mantel-Teeuwisse A.K. Longitudinal study of Good Pharmacy Practice roles covered at the annual world pharmacy congresses 2003-2019. Journal of Pharmaceutical Policy and Practice. 2022;15(1):94.

Kusynová Z., Kicken M.P., van den Ham H.A., Mantel-Teeuwisse A.K. Identifying the teaching content on substandard and falsified medical products in global pharmacy education as critical public health issue. Pharmacy Education Journal. 2021;21(1):504-516.

Kusynová Z., Bais Y., van den Ham H.A., Mantel-Teeuwisse A.K., Etamé-Loé G., Kaale E., Sarr S.O., Guiet-Mati F., Bourdillon- Estève P. Improved knowledge on substandard and falsified (SF) medical products through a dedicated course for pharmacy students at three universities in Sub-Saharan Africa. BMJ Global Health. 2023;6:e009367.

Leufkens H.G.M., Kusynová Z., Aitken M., Hoekman J., Stolk P., Klein K., Mantel-Teeuwisse A.K. Four scenarios for the future of medicines and social policy in 2030. Drug Discovery Today. 2022;27(8):2252-2260.

Kusynová Z., van den Ham H.A., Leufkens H.G.M., Mantel-Teeuwisse A.K. Pharmaceutical scientists- perspectives on capacity building in pharmaceutical sciences. Journal of Pharmaceutical Sciences. 2023;(5):0022-3549.

Other publications

Uzman N., Kusynová Z., Manikkath J., Duggan C. Making the profession attractive for our future and young pharmacists, the game changers for primary health care. Journal of Pharmacy Practice and Research. 2019; 49(4):373-375.

Bader L., Kusynová Z., Duggan C. FIP Perspectives: Realising global patient safety goals requires an integrated approach with pharmacy at the core. Research in Social and Administrative Pharmacy. 2019; 15(7):815-817.

Hudmon K., Elkhadragy N., Kusynová Z., Besançon L., Brock T., Corelli R. (2017). Global sale of tobacco products and electronic nicotine delivery systems in community pharmacies. Tobacco control. 26(e2):e127-e129

7.5 About the author

Ms Zuzana Kusynová is lead for policy, practice and compliance and a programme lead at the International Pharmaceutical Federation (FIP), the global umbrella organisation representing pharmacists and pharmaceutical scientists. FIP aims to improve global health by enabling better discovery, development, access to and safe use of appropriate, cost-effective, quality medicines worldwide.

She advises on pharmaceutical policies pertaining to medication usage, safety, and pharmaceutical care. She actively engages in technical and strategic discussions within the global health arena. Her pivotal roles include participation in the World Health Assembly and ministerial summits, where she advocates for FIP's objectives.

With over a decade in her capacity as the focal point for FIP's collaborative efforts, she forges strong partnerships with organisations such as the World Health Organization (WHO). Within FIP, she assumes leadership of international working groups and projects that drive meaningful change. For example, she led a joint WHO-FIP initiative commissioned by the European Commission, aimed at combating substandard and falsified medical products in Sub-Saharan Africa. She guided this project through its entire lifecycle, from conception and design to implementation, as well as subsequent evaluation of its outcomes.

Beyond her project management, she has contributed to various WHO initiatives, including the development of capacity building tools like the Health Workers' Education and Training on Antimicrobial Resistance (AMR): Curricula Guide, Competency Framework for Health Workers' Education and Training on AMR and the new edition of the Multi-professional Curriculum Guide on Patient Safety. These resources aim to enhance the capabilities of healthcare professionals worldwide in delivering high-quality care.

Her academic background encompasses a postgraduate degree in pharmacy (PharmDr) and a Master's degree in management. Her career in health policy commenced in 2012 within the Pharmaceutical Group of the European Union (PGEU), representing European community pharmacists, based in Brussels, Belgium. With over a decade of experience in her field, she remains actively engaged in policy and collaboration efforts from her base in The Hague, the Netherlands.