All MAAs offered a simple discount patient access scheme and/or a reduced drug cost commercial access agreement. **CONCLUSIONS:** New NICE approved MAAs increased each year since 2015, were characterised by a standard format structured around the data required to answer key uncertainties and always included financial agreements to minimise NHS treatment costs during the MAA period.

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DEVELOPMENT OF THE UNIFIED SYSTEM OF ASSESSMENT OF LEVELS OF EVIDENCE AND GRADES OF RECOMMENDATIONS FOR THE RUSSIAN FEDERATION

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OBJECTIVES: Until recently authors of clinical guidelines in Russia had no unified approach for assessment of levels of evidence (LOE) and grades of recommendations (GOR). Professional associations used different systems from international practice. Furthermore, considerable proportion of Russian clinical guidelines was not based on systematic reviews of evidence. The aim of this research was to develop unified scales for the assessment of LOE and GOR for Russia in accordance with the directive of the Ministry of Health to standardize and improve quality of clinical guidelines. **METHODS:** Systematic literature review (SR) was conducted to identify LOE and GOR scales used in international practice. The working group of multidisciplinary experts (physicians, specialists in evidence-based medicine, healthcare decision-makers) was created to discuss the SR results and establish a common understanding of advantages and challenges of existing scales. Finally, experts pointed out key elements of international systems to be used in the unified scales for Russia. **RESULTS:** The working group selected different aspects from widely recognized GRADE and Oxford Centre for Evidence-based Medicine systems to create unified scales (taking into account experts skills, limited time and budget for clinical guidelines development). Main priorities when developing unified system were robust methodology, its transparency and feasibility in Russia. Two types of scales were made: 1) for medicines, rehabilitation, preventive and surgical interventions; 2) for diagnostic methods. The LOE scales are based on the hierarchy of designs of clinical trials (CT) identified by SR which is mandatory for every recommendation; GOR scales include assessment of methodological quality of CTs, consistency of their results (if several) and clinical significance of outcomes used in CTs. The proposed scales are being implemented presently. **CONCLUSIONS:** Expert opinion based on SR helped to create unified scales for LOE and GOR assessment suitable for the process of clinical guidelines development in Russia.

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PROFESSIONALS' PERSPECTIVE OF FACTORS INFLUENCING THE DEVELOPMENT OF A SUCCESSFUL PHARMACEUTICAL PRODUCT. THEMATIC ANALYSIS

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OBJECTIVES: The development of pharmaceutical products can take a lot of time and involves many stakeholders carrying out various tasks. There are multiple factors that can facilitate or impede the development of pharmaceutical products. This study surveyed the professionals working in the field of health economics and outcomes research about factors that could influence the successful development of pharmaceutical products from their perspective. **METHODS:** A questionnaire survey was carried out for the present study, administered at the ISPOR Glasgow to 104 participants; professionals from various backgrounds. They were asked about their opinion of factors that would influence the development of a successful pharmaceutical product. Thematic analysis was carried out to categorise answers to identify the factors that, in the opinion of the professionals surveyed could influence the development of a successful pharmaceutical product. **RESULTS:** A total of 104 responses were collected; 11 participants were from academia, 33 from consultancy firms, and 12 from healthcare sector, 2 payers and 46 from Pharmaceutical Companies. Answers were categorised under seven domains as follows: access, communication, cost, efficacy, external factors, quality of life (QoL) and safety. Of the factors, the most cited as influential were cost, external factors and QoL with 76%, 72% and 67% of respondents identifying these items. Communication, safety and efficacy were also mentioned by at least half of respondents (50%, 55% and 64%, respectively). The factor viewed as least important in the development of pharmaceutical products was access with only 28% of respondents. **CONCLUSIONS:** The majority of professionals that participated in the study believed that cost, external factors, QoL, efficacy, safety and communication are important in the development of pharmaceutical products. However, access was the least important factor. Professionals should consider these important factors when planning the development of a pharmaceutical product.

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THE FRENCH COMPASSIONATE USE OF MEDICINAL PRODUCTS PROGRAM (2012-2017): HEALTH TECHNOLOGY ASSESSMENT AND PRICING IMPLICATIONS

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OBJECTIVES: In France, before market authorisation, drugs can be available through a temporary authorisation for cohort use (ATUc) scheme at a price freely fixed by manufacturers. This analysis aims to study the market access pathway of these drugs (from ATUc starting to official price publication date). **METHODS:** A retrospective analysis of the market access pathway of ATUc granted from 2012 to 2017 was conducted, based on publicly available databases. The variables analyzed were therapeutic area, actual benefit (SMR), improvement of actual benefit (ASMR), time between ATUc starting date and publication date of the official price in the French Official Gazette. We also extracted from the French DRG based information system (PMSI) the ATUc price and compared it with the negotiated official price. **RESULTS:** ATUc were granted to 75 drugs (81 indications among which 41% in oncology). In 71% of the indications, an important SMR was given while in 16% the reimbursement was not recommended. One third was considered as innovative and acquired an ASMR I-III. The official price has been published for only 33 drugs (44%). For those considered as innovative, the official price is on average 8% lower than the ATUc price whereas this difference is estimated at -23% for the non-innovative ones (ASMR IV-V). The average time between ATUc starting date and official price publication date is 624 days. **CONCLUSIONS:** If ATUc scheme was implemented to improve early access for patients in therapeutic need to promising therapies intended to treat serious or rare diseases, a significant proportion of ATUc showed an insufficient actual benefit. The discrepancy between the official price and the ATUc price is well related to the acquired ASMR. This might be considered by stakeholders to predict the official price for ATUc drugs.

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CHALLENGES IN ACHIEVING MARKET ACCESS SUCCESS FOR ADVANCED THERAPIES IN EUROPE: A CASE STUDY

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OBJECTIVES: Advanced Therapy Medicinal Product (ATMPs) hold great promise as treatments for previously incurable diseases. While expectations are high and full pipelines are observed, few ATMPs are currently on the EU market. This study aimed to identify root-causes of challenges experienced in achieving successful market access (MA) for commercially developed ATMPs in Europe. **METHODS:** We completed a qualitative case study by conducting 10 semi-structured interviews amongst ATMP company representatives. MA success was defined as receiving reimbursement for an authorized product in at least one Member State. Company MA actions, strategies, experiences and know-how were questioned, as well as how was dealt with encountered challenges. Developers in the study sample differed in: ATMP type (cell and gene therapies), development stage, (Phase I-II, Phase III, regulatory application, Phase IV, discontinued) and company size (Small-Medium-sized Enterprises (SMEs) and large companies). Interviews were recorded, transcribed and coded. Recurring themes were classified via thematic content analysis. **RESULTS:** Large companies had more experience developing non-ATMP products, giving them an advantage over SMEs in creating value dossiers and HTA authority contact. Large companies also experienced more financial stability. Therefore, they were able to look ahead, while SMEs were also occupied funding their current development stage. Developers who early on involved MA expertise (in-house or external) and had a detailed business plan from the start, seemed more successful. Respondents mentioned a business plan should at least include: short- and long-term goals, market access strategy and return on investment predictions. Some SMEs partnered with large companies to solve funding issues and utilize expertise. No differences between cell and gene therapies were found. **CONCLUSIONS:** Obtaining market access for ATMP development requires more planning and specialised skills compared to more traditional pharmaceutical development. A MA strategy and business plan should be drafted as soon as possible in ATMP development.

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AMBULATORY CARE TRENDS IN THE EMERGENCY DEPARTMENT

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OBJECTIVES: Ambulatory Care Sensitive Conditions (ACSCs) are illnesses where management should be achieved by regular consultation with a primary care physician. ACSCs are often a metric for access to primary care. The Patient Protection and Affordable Care Act(ACA) of 2010 offered significant regulatory changes expanding access to low income insurance (Medicaid). By evaluating the rate of ACSCs in the Emergency Department(ED) over time, we aimed to evaluate the impact of ACA Medicaid expansion. **METHODS:** The US National Emergency Department Sample—a representative 20 percent sample of ED visits– offering a sample of 25 million in 2006 and 31 million by 2014. ACSCs were adapted from the Agency for Healthcare Quality and Research(AHRQ) prevention quality indicators guidebook. Dental insurance was not impacted by ACA and therefore Dental ACSCs were evaluated as a baseline comparison. **RESULTS:** The rates of ACSCs remained largely unchanged at 7.68% of observations with a decrease of 0.33% over the study period. Dental specific ACSC rates were consistent as well starting at 1.63% and ending at 1.66%. Age, gender, and income bracket characteristics were consistent throughout the 9 year period. Congestive Heart Failure had the largest decrease of 0.55%. Urinary Tract Infections was the highest at 2.15% and grew the most by 0.32%. Evaluation of primary payer amongst ACSC specific events revealed the rate of privately insured patients decreased by 5.02% and Medicaid recipients increased by 9.63%. The rate of self-pay and Medicare offered slight decreases of 1.49% and 2.65% each. **CONCLUSIONS:** Payer changes indicate a significant shift in healthcare costs. Stable income bracket frequency juxtaposed to primary payer changes may reveal poorer citizens dropping low quality private plans upon Medicaid qualification. Despite payer shifts and payment access, there has not been a reduction in ACSC's. Study extension is needed for further evaluation as States continue with ACA implementation.