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Challenges for the adoption of future biosimilars

Ellen HM Moors, PhD

Hospital pharmacists and physicians are responsible not only for the prescription and delivery of biopharmaceutical drugs, but also for hospital formularies and drug budgets. What are the challenges for these key professionals to adopt biosimilars in the future?

Introduction

The development of recombinant DNA (rDNA) technology has led to various new protein based pharmaceutical drugs. The first generation of biopharmaceuticals were introduced in the 1980s and based on rDNA versions of natural products, such as human insulin, interferon and growth hormone. In the 1990s the second generation of rDNA techniques began to use protein engineering to produce slight variations in the natural rDNA based products. Such techniques involve the identification of the various functions performed by the different parts of a natural molecule, followed by a modification of specific parts to improve its performance (site-directed mutagenesis), e.g. engineered insulins, hybrid molecules such as Enbrel and hyperglycosylated products.

The expiring of the patents of the first generation of biopharmaceuticals has paved the way for biosimilars or follow-on biologics, as they are called in the US, with two biosimilar growth hormones, Valtropin and Omnitrope, already on the market. As biopharmaceuticals are very expensive, and the healthcare sector is nowadays dominated by cost containment measures with a critical attitude towards new drug developments, the cost of a drug can determine its clinical and economic success. Additionally, other criteria such as scientific or clinical knowledge can fine-tune drug assessment outcomes. Finally, factors, such as trust, interest, attitude and behaviour of future users can determine the rate of adoption and prescription of a specific drug. This poses an interesting question - which criteria play a role in the adoption of biosimilars by potential users (e.g. hospital pharmacists, medical specialists, physicians and patients)?

Unravelling the adoption of biosimilars

Drug development represents a science-based innovation trajectory, carried out by a network of interrelated participants, such as universities and research institutes, pharmaceutical companies, hospitals, governments and patient organisations. It is based on demand-driven conditions, which are reflected in the medical needs and expectations about potential users and drug innovation and adoption. If large-scale drug adoption is expected to be high, then the willingness to develop such a drug will be large for reasons of competitive advantage and the return on investments. The economic and clinical success of a drug is measured in terms of the adoption rate, and a model of innovation adoption and diffusion is used to study these processes [1-5].

> **The cost of a drug can determine its clinical and economic success.**

Adoption is defined as "a decision to make full use of an innovation as the best course of action available" [3]. The adoption of innovations takes place through the innovation–decision process. The different stages of this process are dominated by the goal to reduce uncertainty about the features of a new product, or in this case drug, through information gathering. The adoption process, as such, is based on assessments and decisions of various stakeholders involved in the (future) use of biosimilars, such as pharmacists, physicians and patients. There are several key innovation criteria relevant to the process of adoption:

- relative advantage
- compatibility
- complexity
- trialability
- observability

First of all, *relative advantage* is the degree to which an innovation is perceived as better than its predecessor. This feature depends on the number of alternatives and the added value of the new drug (i.e. biosimilar product) compared with the standard therapy (i.e. the original biopharmaceutical product). The added value is measured in terms of economic benefits, including financial risk, non-financial benefits (for example, business factors and regulatory issues), and social prestige (image). In general, drug development is associated with several uncertainties. A new drug has to be evidence-based, therapeutically needed and financially profitable to be developed. The same holds for biosimilars. Pharmaceutical companies have to cope with considerable financial uncertainties about whether they will receive sufficient revenue after market introduction to cover the initial R&D costs of drug development, due to lengthy pipelines and complex, administrative regulatory procedures. Consequently, companies are inclined to select the most profitable opportunities, sometimes securing their specialities market share

by extensive branding, sometimes also being partly involved in the development of biosimilars.

Compatibility is the degree to which an innovation is perceived as being consistent with the existing values, past experiences, and needs of potential adopters. Compatibility is high when the development involved fits the company well. The development trajectory of all drugs involves preclinical and clinical studies, approval and post-marketing surveillance. As biosimilars have shorter development and approval trajectories, only parts of the drug development pipeline need to fit with the companies core competencies. New biotechnology firms increasingly tend to focus on distinct stages in the drug development process, covering only parts of the value chain [6].

Complexity is the degree to which an innovation is perceived as being difficult to use. Adverse effects of biopharmaceuticals maybe product or even batch-related and could include immunogenicity problems. The therapeutic effects of biopharmaceuticals depend on their complex structure. Showing similarity is a serious barrier to biosimilar drug development. Current analytical tools are insufficient to fully characterise the product and to predict clinical and biological properties. Therefore, all aspects in the development pipeline of biosimilars need special attention [7].

Trialability is the degree to which an innovation may be experimented with on a limited basis before adoption. Regarding drug adoption, the trialability of a drug depends on the overall clinical experience with the specific drug. The trialability of biosimilars suffers from the difficulties in clinical studies of proving bio-equivalence with the original biopharmaceutical product.

Finally, *observability* is the degree to which the results of an innovation are observable to others. It could be argued that the advancement of research into biosimilars is less observable, due to the lack of information at each stage of development, shorter approval procedures and no original ground breaking research results which were often the basis of the innovative drugs. Additionally, pharmacists and physicians may be persistent in demanding specific branded biopharmaceuticals, which may steer their adoption decision. Furthermore, behavioural criteria have to be taken into account in the adoption process such as the interest, knowledge, and attitude and habits of potential users [8]. As the adoption of a biosimilar is defined as its general acceptance and continuous use, the attitude of pharmacists, physicians and patients towards biosimilars is dependent on the information about biosimilars, the attitude towards speciality products and the costs, which in its turn is dependent on the knowledge and prior experiences with biopharmaceuticals and costs.

Challenges for biosimilars

Exploratory studies on the potential adoption of biosimilar erythropoietins by medical specialists showed that the intentions of prescribers (e.g. nephrologists, oncologists, surgeons) to adopt biosimilars are influenced by various factors. They judge safety as the most important adoption criterion. Furthermore, the lower costs of biosimilars in comparison to the currently available biopharmaceuticals, the development of biosimilars approval procedures by the EMEA and FDA, the services already provided by erythropoietin biopharmaceutical producers, and their positive experiences with the use of biopharmaceutical medications in general, are of importance.

Conclusions

Important criteria for the adoption of biosimilars include its relative advantage, compatibility, complexity, trialability, observability and the habit formation of potential users. These adoption criteria could support hospital pharmacists in the decision-making process of choosing either the original biopharmaceutical or the biosimilar product. This selection should not only be based on habit and price (drug budget), but also on the added value, the availability of adequate information on biosimilars, particularly regarding bio-equivalence and drug delivery issues. Especially important in biosimilar adoption is the reimbursement by national social insurance schemes and, for example, the ways in which biosimilar drug assessment is the subject of specific (inter)national regulations, such as specific medical guidelines. Meeting these adoption criteria could positively influence the future success of biosimilars development.

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