Informing Patients about Biosimilar Medicines

Subjects: Others

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Biosimilar medicines support the sustainability of national healthcare systems, by reducing costs of biological therapies through increased competition. However, their adoption into clinical practice largely depends on the acceptance of healthcare providers and patients. Patients are different from health care professionals (HCPs), who are informing themselves professionally. For patients, the biosimilar debate only becomes actual when they are confronted with disease and drug choices.

Keywords: biosimilar ; biological ; patient ; education ; biopharmaceutical ; Europe

1. Introduction

Educating patients about biosimilars is crucial to provide clarity and prevent misinformation [1][2][3]. Patients need access to understandable and evidence-based information that allows them to make informed decisions about their treatment. Regulatory authorities, medical scientific associations, and patient organizations have therefore been active in developing and disseminating educational material on biosimilars for European patients during past years. However, information and educational material are widespread, requiring a mapping of the available material [1][4]. Mapping the available information or material for patients makes it possible to have an overview of what material exists, and to verify the information found for its scientific correctness. In addition, a proper inventory will facilitate the dissemination of information through collaboration between stakeholders.

This review aimed to provide an overview of existing scientific literature on how to inform patients about biosimilars and compile available information about biosimilars for patients, developed or disseminated by European patient associations. Based on this review, an overview of the important aspects when talking to patients about biosimilars is provided for policymakers, healthcare providers, patient organizations, and other relevant stakeholders, in support of a sustainable market for off-patent biological and biosimilar medicines in Europe.

2. Communication Strategies to Inform Patients about Biosimilars

Five main points of attention were identified when informing patients about biosimilars. **First** of all, information has to be provided in an understandable way. Patients generally have no scientific background, so one must make sure not to overly complicate the given message [5][6][7][8]. **Second**, a positive attitude when talking to patients about medicines in general is paramount [2][6][9][10]. Emphasis must be put on the similarities between biosimilars and their reference product, rather than the possible differences. This can be done by conveying the message that the biosimilar has similar clinical outcomes, instead of no expected differences [11]. An open and positive way of communicating has shown to generate trust, and subsequently improve treatment outcomes and adherence [12][13]. HCPs should therefore be trained on the proper use of such communication strategies with patients. **Third**, a one-size-fits-all approach is not desirable when communicating directly to patients since each patient's individual needs and level of understanding might differ [4][14][15][16][17]. A tailored approach is therefore preferred. It is the task of each member of the multidisciplinary team to assess these needs and to adapt their communication strategy accordingly. This brings us to the **fourth** point of attention, the *one voice* principle. In essence, this means that everyone informing patients about biosimilars has to provide a coherent message. Communication towards patients must be consistent across channels, thereby avoiding suspicion by generating trust between healthcare providers and patients [2][18][19][9][20]. **Fifth**, the use of supportive audiovisual material (i.e., videos, infographics, brochures) may help bringing the information across in a clear and understandable way [1][5][7][21]. Such supportive material closes the gap between the complexity of the biosimilar concepts and the need for understandable information.

A series of studies pointed to a lack of knowledge and trust in biosimilars in various relevant patient populations, making clear the necessity of education [22][23][24][25][26][27][19][12][28][29][30]. However, the purpose of informing patients should not be to create a high level of knowledge among the whole patient population. This would not be feasible, nor desirable. After

all, it is not intended to inform all patients about a treatment the vast majority will not need. Instead, information about biosimilars should be reaching those patients who require such information. In other words, patients who may or will be treated with biosimilars in the near future. This approach differs from informing HCPs about biosimilars, as they all need to have a good understanding of biosimilars.

Educating patients about medicines in general, but in particular biosimilars, should always be a multistakeholder effort [4][2][14][31]. Each stakeholder has its own role to fulfill in order to provide correct, unbiased, understandable, and coherent information. Physicians, nurses, and pharmacists have a coordinating role and are key partners to remove doubts and generate trust in biosimilars, as for any kind of medicine [7][14][32][33]. In addition, other parties such as regulatory authorities, medical societies, and patient associations have a supporting role in informing patients. They are all regarded by patients as reliable sources of information. However, the identified list of stakeholders is not exhaustive, since other stakeholders that were not mentioned in the literature may also play a role. For example, academia might support the development of evidence-based information as a trusted and unbiased source of information. Other national authorities, such as payers and health technology assessment (HTA) bodies, could also disseminate information about biosimilars to patients. Some stakeholders may be of particular importance in the creation of information or educational material (e.g., scientific associations, professional associations, academia), whereas others (e.g., healthcare providers, patient associations, regulatory authorities) in the dissemination of information to patients. Moreover, pharmaceutical companies also play a role in informing the wider public about biosimilar medicines. One must acknowledge that many informational campaigns are supported by pharmaceutical industry, thereby facilitating the development of factual information as well.

3. The Role of European Patient Organizations

A variety of information and educational material for patients about biosimilar medicines is made public by European patient organizations. Yet, the quality and level of detail vary among different associations, and it is not clear whether the identified information is effectively reaching the patient. This overview of information was based on a web-based screening. However, one should be aware that information made accessible via the internet will not reach every patient who needs such information. After all, not every citizen across Europe has the opportunity to consult the internet. That is why it remains important that healthcare providers fulfill their role to reach patients, and that patient associations themselves do not limit themselves to disseminating information via their websites.

Patient associations often refer to the biosimilar brochure of the European Commission, which was translated in all European languages in recent years. Some patient organizations have developed educational brochures or position statements about the use of biosimilars by themselves. They generally all agree on the fact that biosimilars are equal treatment options ensuring a sustainable healthcare system and underline that the decision to prescribe a biosimilar should be a shared decision involving the patient. Nonetheless, some patient associations should be cautious not to fall prey to negatively framed, incorrect, or outdated information about biosimilars. Several patient associations provide detailed information on biosimilars, but express a rather negative attitude in particular towards transitioning from the reference product to a biosimilar (e.g., IDF Europe, Spanish Platform for Patient Organizations, and IFPA). Others provide or refer to incorrect or outdated information, such as EPDA, IDF Europe, and Flemish Patient Platform. The most pronounced example of this is IDF Europe, where they support their concerns about switching to biosimilar insulins by information that was incorrectly interpreted and taken out of context. Generally, national patient associations adopt the position on biosimilars of their European umbrella organization. However, this does not prevent national associations from formulating their own positions that differ from incorrect European ones. For example, the recommendations of the Dutch Diabetes Association about insulin biosimilars are in line with current scientific evidence and do therefore not correspond to those from IDF Europe [34]. A clear contrast was observed when looking at biosimilar information or educational material of DiCE and National Coalition of Dutch Patients. In particular, DiCE puts emphasis on the fact that if biosimilars are implemented on a wider scale, they could help closing the gap in gaining access to the highest standards of care for the treatment of colorectal cancer. The National Coalition of Dutch Patients repeatedly states that biosimilar medicines have the same efficacy, safety, and quality as their reference products. This is an example of positive framing since most information on biosimilars mentions that no meaningful differences are expected with originator biologicals, which is correct, yet framed more neutrally.

Information should always be evidence-based and therefore in line with the most recent scientific developments. As for all stakeholders, patient associations should distance themselves from positions or opinions about biosimilars that are not scientifically or incorrectly substantiated. Clear collaboration with independent and knowledgeable experts to develop such material is necessary to avoid incorrect information. With this overview, we have taken a critical look at the available information about biosimilars for patients developed by major European patient associations.

4. Future Perspectives

During past years, the way that most treatment decisions are made has evolved towards shared decision-making [35]. The choice for an originator biological or a biosimilar must therefore be based on a coherent information stream to the patient. Several communication strategies have been identified in this review, guaranteeing correct information is provided adequately to patients. However, not all communication strategies have proven effective in actually increasing patient knowledge and confidence in biosimilars. Moreover, they have not proven to meet the appropriate behavioral objectives among patients. Future research assessing the actual impact of communication strategies based on a behavioral model could help clarify these unmet needs.

Most recommendations identified during this literature review are based on empirical grounds. Communication strategies emerging from theoretical concepts could be explored as well in the future. This would contribute to the overall picture on how to inform patients about biosimilar medicines and increase the robustness of the conclusions.

5. Conclusions

It is important to set up a close collaboration between all stakeholders to develop and effectively disseminate correct information about biosimilars to patients, bringing together scientific associations, professional associations (including physicians, nurses, and pharmacists), regulatory authorities, and patient associations. Informing and educating patients on biosimilars should be part of a wider approach to support the adoption of biosimilars in Europe. European member states should consider informing patients on biosimilars in their policy frameworks more actively. It is imperative that European national authorities support biosimilar medicines to safeguard an affordable and sustainable healthcare system within their country.

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