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ABSTRACT

With the imminent arrival of oncology biosimilars in the therapeutic paradigm, stakeholders including a clinician, specialist nurse, patient advocate, regulator and economist provide their perspective on optimising the uptake of these new agents in the treatment of cancer. A number of key messages emerge, based on the discussion that took place during a session of the European Society for Medical Oncology's Annual Congress, ESMO Madrid 2017. First, for successful integration of biosimilars into the global healthcare paradigm, informing and educating the full scope of stakeholders, including clinicians, nurses, pharmacists and patients, is primordial. Success is dependent on providing solid evidence and ensuring all voices are heard. Second, for oncology medicines, much can be learnt from the growing experience of approved biosimilars in other disease indications, with success stories for patients, their healthcare providers and healthcare budgets alike. Finally, effective sustainability of the impact on healthcare budgets and the redirection of these savings require education and transparency.

INTRODUCTION

Following the introduction of legislation regarding biosimilars in 2001 in the European Commission's Directive 2001/83/EC, as of January 2018 the European Medicines Agency (EMA) has reviewed 59 biosimilar marketing authorisation applications, 39 of which were approved and marketed (corresponding to 25 distinct biosimilars).[1] The rate of arrival of biosimilars on the market is accelerating with approval of 14 new molecules in 2017 alone, compared with no more than five annual approvals since 2006, when the first biosimilar (somatropin) was approved. The year 2017 also saw approval of the first oncology biosimilar monoclonal antibodies which have to date taken a backseat in this emerging therapeutics domain. However, the tide is now turning with 6 rituximab biosimilars, 1 bevacizumab and 1 trastuzumab already approved, and of the 15 marketing applications currently under consideration, 3 are for trastuzumab biosimilars.

Monoclonal antibody biosimilars represent a novel advance in the field of oncology, and their integration into routine clinical practice will contend with the same challenges burdening existing biosimilars in the face of various dogmas. A position paper published by the European Society for Medical Oncology (ESMO) in 2016 highlighted many of them.[2] In the biosimilar setting, the traditional approach of medicines development in which the burden-of-proof lies at the clinical end of the process needs to be revisited with the balance shifting to comparative studies focusing on non-clinical and analytical functional tests (figure 1). The active substance of a biosimilar must be similar, in molecular and biological terms, to the active substance of the reference medicinal product (RMP). For example, for an active substance that is a protein, the amino acid sequence is expected to be the same.[3] Nevertheless, the nature of biologicals and hence of biosimilars, which are medicinal products containing a highly similar version of the active substance of their originator biological reference product, means that they are inherently variable; thus, batches may display a small degree of variability.

It is the manufacturers' and regulators' role to guarantee consistency, which is achieved by defining measurable product quality attributes, establishing specifications and specifying proven acceptability ranges.[4] The manufacturing process of a biological is likely to undergo changes to improve or adapt the process during its life-cycle, as reflected in an EMA report in May 2016 that over 400 manufacturing changes have been authorised for 29 monoclonal antibodies on the market.[5] Comparability is a well-established scientific principle used for decades by regulators to assess changes in the manufacturing of biologicals produced by biotechnology. Similarly, comparability in the context of biosimilar development lies in a stringent head-to-head comparison between a biosimilar and its reference product in terms of structure and biological activity, thus ruling out potential differences that may affect safety and efficacy.

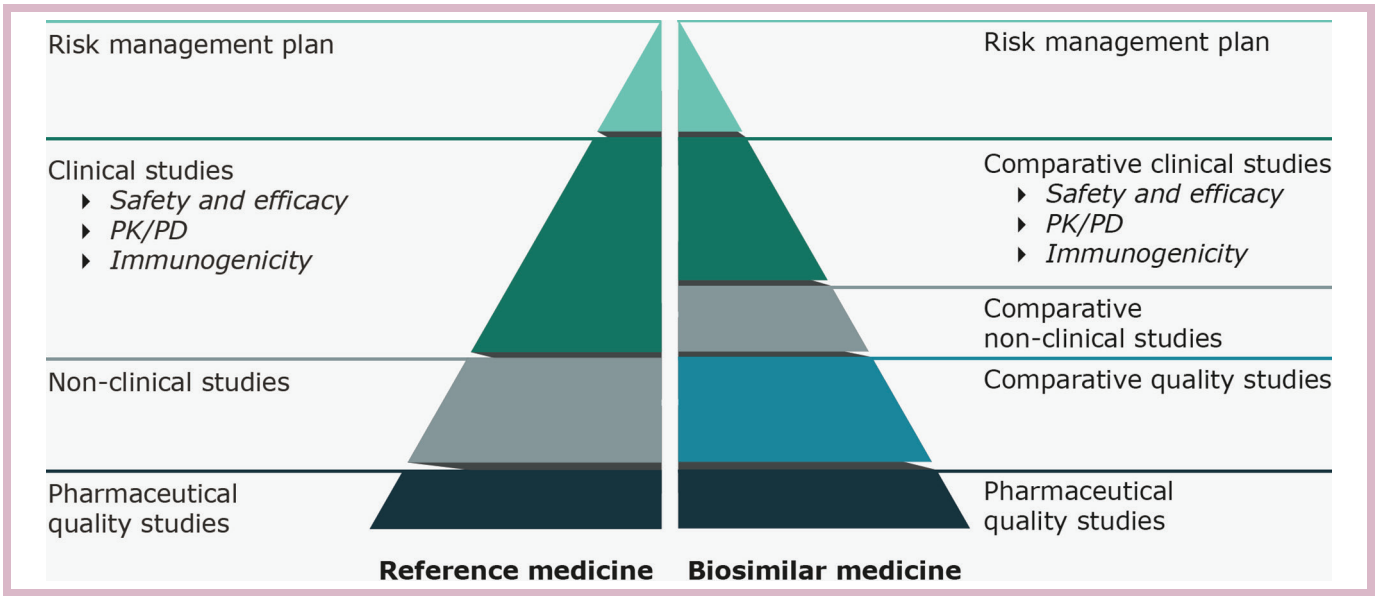

Figure 1 Distribution of data requirements for approval of a biosimilar versus a reference medicine. (PK/PD - pharmacokinetic/pharmacodynamic studies)

The urgency of the need to address the arrival of oncology biologicals cannot be downplayed. Global costs of oncology care reached $113 billion in 2016, a figure which continues to increase dramatically, and the rate of marketing applications and approvals of biosimilars continues to increase rapidly.[6] Spending across the European Union (EU) in cancer therapeutics was €24.2 billion in 2016 (a 14% increase in 1 year), of which biologicals account for just under 40% of the total.[7] Most of the top 10 oncology medicines (in terms of sales) in the EU have already reached patent expiration or will by 2020. Biosimilars represent an undeniable opportunity to reduce the burden of already overstretched oncology healthcare budgets, offering a significant contribution to sustainability of the system. More importantly, the introduction of biosimilars is expected to increase availability of therapeutics for patients in the EU who would not otherwise be treated with biologicals, mainly due to economic constraints, with consequent improved access to optimal healthcare. Here we present the perspectives of key stakeholders, healthcare providers, patients, regulators and health economists, and their proposals for optimising the entry of biosimilars into the therapeutic paradigm.

CLINICIAN'S PERSPECTIVE: BUILDING CONFIDENCE FOR PRESCRIBING BIOSIMILARS

Clinicians are voicing a number of specific considerations in relation to biosimilars. Underlying them is a clear need for scientific data and guidance, which are prerequisites for an accurate and informative discussion with their patients. A number of areas have been brought to the forefront. First, comprehensive information on the results of clinical trials conducted to support the marketing authorisation of biosimilars should be readily available, particularly with respect to the sensitive patient population studied and the sensitivity of the endpoints used. Second, data relating to extrapolation, interchangeability (switching and substitution) and immunogenicity should be addressed with clarity, to reassure both clinicians and patients. Finally, awareness of the pharmacovigilance plan (risk management plan) is a key point. This body of data should be transparent and easily accessible, with the Summary of Product Characteristics (SmPC) and the European Public Assessment Report (EPAR) representing an invaluable source of information.[1]

Extrapolation (ie, use of a biosimilar in an indication approved for the reference product but in which the biosimilar has not undergone comparative clinical testing) can be applied to biosimilars when adequate comparability studies for safety and efficacy of the biosimilar are available in one therapeutic indication, and these data can be extrapolated to other approved indications for the reference medicine. The message must be made clear that extrapolation is dependent on robust scientific evidence addressing all aspects of these indications, including mode of action, and potentially unique safety or immunogenicity aspects. For clinicians to be convinced there must be relevant analytical, preclinical, pharmacokinetic, pharmacodynamic, safety and efficacy data available for the biosimilar in the evaluated indication.

Interchangeability covers both switching and substitution, and falls within the remit of national legislation of each member state. Switching reflects the physician's decision to exchange one medicine for another with the same therapeutic intent. It principally applies for replacing an originator medicine with a biosimilar, although the inverse situation may also apply, while the possibility of replacing one biosimilar with another is becoming increasingly pertinent. In the absence of concerns over immunogenicity, safety or efficacy, for

physicians, switching is an entirely feasible option.[8 9] However, it is crucial that prescribing decisions remain the responsibility of the treating physician, with patients closely involved, informed and monitored. Substitution (automatic dispensing of one medicine instead of another equivalent and interchangeable medicines at the pharmacy level without consulting the prescriber) is not supported by ESMO and should be avoided.

Early surveys by different groups, the National Comprehensive Cancer Network (NCCN), the European Crohn's and Colitis Organisation (ECCO), and the Alliance for Safe Biologic Medicines (ASBM), reported an alarming lack of awareness among European physicians about biosimilars, along with poor practices, particularly with respect to labelling.[10–12] Encouragingly, an updated ECCO survey in a small sample of healthcare providers published in 2016 showed substantial improvements, with increased awareness and confidence, notably with respect to extrapolation and interchangeability.[13]

The responsibility of building public confidence lies with governments (at both the EU and the national levels; eg, national competent authorities), regulators, manufacturers, as well as academia. With over 10 years of safe and effective use of biosimilars, the EU has the largest biosimilar experience worldwide. As pioneers in this field, European regulators must keep in mind that compared with clinicians and patients, they have the advantage of a long history of biosimilar awareness. Their expertise is reassuring and certainly plays an important role in acceptance of these new agents. However, time is needed for both clinicians and patients to thoroughly understand this process. Interaction and collaboration among healthcare professionals and with regulators is essential for successful acceptance of biosimilars.

IMPROVING BIOSIMILAR USE IN THE CLINIC: THE CRUCIAL ROLE OF SPECIALIST NURSES

Specialist cancer nurses are central to optimal patient care, playing a dual role, directly impacting patient outcome, while also implementing and evaluating new treatments across the cancer spectrum. Overlooking the importance of their role in the process of introducing biosimilars will hamper our best efforts to effective outcomes. The process of a medicine reaching a patient from the pharmacy involves an interdisciplinary strategy, from selection and prescription by physicians, through preparation and dispensation by pharmacists, to receipt and delivery by nurses. Nurses are responsible for ensuring the patient receives the exact medicine prescribed (type of medicine, dose, administration route and timing) and can play an important role in instructing patients on handling different medicine presentations (eg, use of prefilled syringe vs an autoinjector). Their implication in identifying, reporting and managing treatment side effects, monitoring compliance, assisting with adherence, and collaborating in research with long-term monitoring, clinical trials and data management is equally as important. They may also be involved in educating healthcare providers, developing guidelines and safety procedures, and providing patient information. A poor understanding of biosimilars for specialist nurses leaves room for errors and could result in a lack of nurse and patient confidence in the medicine, non-adherence, medicine errors, side effects and delays in therapeutic gain for patients.

The lack of uniform regulations across Europe, affecting the evenness of implementation of treatments, is a source of frustration for nurses. A recurrent barrier is the ad hoc nature of training for nurses on newly approved products, which can lead to a lack of awareness of the complexity and consequences of using new drug biosimilars. Although studies evaluating understanding and level of confidence in biosimilars among healthcare providers are emerging, they tend to focus on the role of the physician. The NCCN survey published in 2011 demonstrated that a lack of familiarity and need for comprehensive information (scientific, economic and expert opinion) were more commonly reported by nurses than by physicians or pharmacists.[12] More extensive updated research and surveys will help identify and diminish the knowledge gaps.

THE PATIENT'S PERSPECTIVE: WHAT HAVE WE LEARNT AND WHAT CAN BE IMPROVED?

The European Federation of Crohn's and Ulcerative Colitis Associations (EFCCA) is an umbrella organisation for over 30 patient associations, and one of the first such groups to deal with biosimilars. Two infliximab biosimilars were the first monoclonal antibodies to be approved by the EMA, Health Canada and several other countries in 2013, followed by the US Food and Drug Administration (FDA) in 2016 on the basis of clinical data from the phase III PLANETRA study in rheumatoid arthritis and the phase I PLANETAS study in patients with ankylosing spondylitis (AS).[14 15] The PLANETRA study compared the efficacy and safety of the infliximab orinator to its biosimilar, in active rheumatoid arthiritis patients with inadequate response to methotrexate treatment, whereas the PLANETAS study compared the pharmacokinetics, safety and efficacy of the two medicinal products to patients with active AS.[14 15] Approval in indications other than those studied, including Crohn's disease and ulcerative colitis, was by extrapolation and led to some initial concern by healthcare professionals as different mechanisms of action could be involved.[16 17] However, it is noteworthy that by 2016 the full label (ie, including all indications) had been approved by all major regulatory bodies (EU, FDA, Canada, Japan and Australia), suggesting a high level of agreement on the total scientific evidence presented by the applicant, thus justifying extrapolation. This concept is pivotal in understanding the development paradigm of biosimilars and—although counterintuitive—why it can be thoroughly justified to study patients

with autoimmune disease and be possible to extrapolate to oncology indications without further clinical data.[18]

In 2014, an EFCCA survey on biosimilars carried out in over 1000 European patients highlighted a number of important outcomes.[19] First—and very importantly—many patients were unaware of biosimilars, while those who had heard of biosimilars expressed strong scepticism over extrapolation. While interchangeability was considered acceptable under certain conditions, transparency to properly understand their medication was paramount. Finally, traceability was noted as a concern, with patients expressing confusion over product naming and batches. Patients wish to be well informed about the choice of their treatment (requesting more than a brief talk with a treating physician or a consensus paper) and to be involved in the decision-making process. Progress has been made, with the European Parliament holding a Patient Advocacy and Safety Conference in November 2016 to explore biologicals and biosimilars with patient advocate groups and how different policies and practices across Europe impact patients.[20] Patients raised concerns over sufficient patient education, extrapolation, switching, traceability, informed consent and access to information.

Patient advocacy has a critical role to play in engineering acceptance of biosimilar use, and oncology patient advocates can learn much from the experience of the EFCCA and other inflammatory bowel disease groups. Advocacy is important to build awareness among patient communities over issues impacting access to biologicals and biosimilars, and also contributes to patients' basic understanding of the science and issues surrounding these agents. Advocates must provide training on effective advocacy and communication strategies to raise awareness and understanding among key policy makers. The different geographical locations of advocacy groups offer an opportunity to network and extend sharing of best practices.

PROVIDING REGULATORY TRANSPARENCY FOR BIOSIMILARS

Providing the public with clear, unbiased and transparent information on the benefits and risks of the medicines it evaluates is an essential role of the EMA. The main objective of this information is to reflect the rationale underpinning the decision by EMA's scientific committees that the benefits of a given medicine outweigh its risks. Appropriate information must be—and is—addressed to two distinct audiences, healthcare professionals and patients. For the former group information is available from three sources. The EPAR contains the Assessment Report, a thorough summary of the analytical, preclinical and clinical data obtained in the comparability exercise of the biosimilar with its RMP. It also reflects input from scientific committees, including the Committee for Medicinal Products for Human Use (CHMP) and the Pharmacovigilance Risk Assessment Committee (PRAC), which led to a positive benefit risk assessment. The SmPC is also publicly available on the EMA website, is part of the EPAR, and provides information on prescribing, posology, dosing, safety, efficacy and conditions of use of the medicine. As the biosimilar and the RMP are different versions of the same active substance, which will be used in the same way (posology and route of administration of the biosimilar must be the same as those of the RMP),[3] the SmPCs should be largely identical.[21–23] Finally, emerging safety information obtained postmarketing is communicated to healthcare professionals via the EMA's safety communications. A lay audience equivalent to each of these three information sources is made available to patients: the EPAR summary for the public, the patient information leaflet and a specific section for patients within the EMA safety communications.

Since the approval of docetaxel by the EMA in 1995, major improvements have been seen in the transparency of information for both professionals and patients. At that time, a simple statement was provided affirming the CHMP's decision that the data were sufficient to support a positive recommendation. Today, the EPAR contains a multipage comprehensive report detailing discussions on all aspects of the comparability exercise (quality, preclinical and clinical data), that is, PK/PD (pharmacokinetics/pharmacodynamics) and phase III clinical results with a justification for extrapolation and discussion on the positive benefit–risk balance also in the extrapolated indications. Furthermore, these changes are mirrored in the level of information provided for patients.

The introduction of biosimilars to the array of agents the EMA is called on to approve generated misunderstandings in terms of their clinical development and misconceptions, revealing new communication challenges. Healthcare professionals and patients have voiced a clear need for unbiased information to help them make informed treatment decisions. Conveying the biosimilar concept is complex and challenging, due mainly to a generalised lack of understanding of the development of biological/biotechnological medicines, to the challenge of convincing audiences that the same standards of safety and efficacy apply without the need for repeating clinical studies in each disease indication, and because of the difficulty of balancing precise regulatory concepts with public-friendly messages. There is an important need to address these communication challenges, given on the one hand the increasing number of biosimilars reaching the market, and on the other that misconceptions could hinder the widespread acceptance and uptake of biosimilars. This could, in turn, impact the sustainability of our healthcare systems.

The EMA joined forces with the European Commission to provide clear and comprehensible information that is scientifically accurate and also contains sufficient regulatory references to assure proper regulatory review and oversight. The result was the publication in April 2017 of the Information Guide for Healthcare Professionals on Biosimilars in the EU, which is publicly available.[21] In addition to the European Commission, scientific experts

Box 1 Content of the EMA Information Guide for Healthcare Professionals on Biosimilars in the EU[21]

- Key principles of biologicals, biosimilars and reference medicines.
- Why biosimilars cannot be considered generic medicines.
- Development and approval of biosimilars in the EU (comparability, extrapolation, immunogenicity, safety, traceability).
- Data in the EU prescribing information and EPAR.
- Rigorous standards for approval.
- Implications of the availability of biosimilars.
- Interchangeability, switching and substitution: EU definitions, EMA vs member state responsibility.
- Communicating with patients on biosimilars.

EMA, European Medicines Agency; EPAR, European Public Assessment Report; EU, European Union.

from all EU member states, EMA's Biosimilar Medicinal Products Working Party (BMWP), healthcare professionals, patients and consumers also collaborated on the document. ESMO also provided valuable contributions with input from experts and clinicians to ensure the guide also addresses information needs for the oncology community. The Information Guide summarises the major issues concerning biosimilars (box 1), is written with simple language and a minimum of regulatory jargon, and includes illustrations and tables. To ensure widespread access, a dissemination strategy was put in place via a variety of channels, including email, online access, social media, professional journals, the EU Regulatory Network, learned societies, European medical/pharmacy students and faculty associations. Feedback will be monitored at the EMA's Healthcare Professionals' Working Party meetings.

IMPACT OF ONCOLOGY BIOSIMILARS ON THE SUSTAINABILITY OF HEALTHCARE SYSTEMS

With multiple biosimilars for rituximab, trastuzumab and bevacizumab (representing the top 3 oncology biological medicines) already approved by the EMA, and many more currently under review, integration of biosimilars into oncology therapeutic management represents an unprecedented opportunity for savings. Economic advantages with biosimilar use can be expected within a relatively short-term period, with economic modelling showing that the introduction of biosimilars for the top 3 oncology agents is estimated to add up to as much as €2 billion in savings across all European markets in 2021 alone.[7] Significant cross-country (and within-country) variability can be expected, influenced by the awareness and acceptance of healthcare providers and patients (thus impacting prescription), and national negotiations in terms of pricing and substitution guidelines.

The balance of the timing and impact of biosimilars on the market (and hence on healthcare budgets) hinges on three main criteria: the availability of evidence (for safety and efficacy from both regulatory and real-world perspectives), effective communication of this evidence by educating healthcare providers and patients, and incentive for investment in terms of an adequate prospect of profit.

Competition for developing biosimilars is increasing, influencing the dynamics of the market-place. The challenge is to maintain a vigorous market and balance it with the race to obtain the lowest possible prices. The notion of sustainability is increasingly important, given that low prices may be unsustainable for any length of time. It is important to avoid the pitfall of one biosimilar capturing a large share of the market with major cost cuts, leaving less room for manoeuvre for newly arriving biosimilars.

THE SCANDINAVIAN EXPERIENCE: A REAL-LIFE EXPERIMENT INTRODUCING A BIOSIMILAR

Since 2001, Stockholm has benefited from the 'Kloka Listan'—the 'Wise List', an annual publication by the Stockholm Pharmaceutical Committee listing recommended essential medicines used for common diseases in patients in the Stockholm metropolitan region. It has gained international interest,[24] with much of its success attributed to the collaborative approach used to compile it. Around 250 healthcare professionals (mainly physicians but also pharmacists and pharmacologists) and expert committees in different indications meet to discuss the efficacy, safety and medical suitability of medicines according to agreed guidelines.

A similar approach was implemented with the arrival of the first biosimilar on the Swedish market. Infliximab, an antitumour necrosis factor-α for treating autoimmune diseases, was introduced in Norway in January 2014 and then in Sweden and Denmark a year later. In early 2015, annual tenders in Norway and Denmark obtained a substantial discount (approximately 70%) off the originator price. In Denmark, an aggressive approach was used to push physicians to prescribe the biosimilar. This strategy proved successful from both a health economics perspective with very rapid uptake of its use, and clinically with an absence of reported adverse reactions, although it was largely unpopular with Danish physicians and patients. On the other hand in the Stockholm region, following apprehension and concern voiced by both doctors and patients, notably in terms of insufficient data, a consensus decision was made in 2014 at a regional level that doctors would not be obliged to switch from the originator to the biosimilar, with prescription maintained as a choice. The aim was that by foregoing a short-term financial gain, confidence in biosimilars and their role in the therapeutic portfolio would evolve organically, allowing subsequent biosimilars to be introduced more rapidly. As a result, infliximab uptake was considerably slower in the Stockholm region than in Norway and Denmark from its introduction in 2015 and throughout 2016, initially being primarily used in infliximab-naïve patients, representing a relatively small proportion of the market. Other regional healthcare authorities in Sweden followed a similar strategy.

In April 2016, a meeting was held in preparation for the next Stockholm tender in January 2017, bringing together expert subcommittees from a wide range of indications as well as hospital department heads. Two options were proposed, maintaining ongoing patients on originator and requesting the biosimilar for infliximab-naïve patients only, or requesting only the biosimilar. After extensive discussion, the consensus was for a single product tender, which ultimately also obtained a 70% price reduction. The result was that within approximately 4 months, the biosimilar had captured approximately 90% of the market share. Patients were informed by a letter in clear layperson language explaining the switch to a similar approved product; less than 1% of patients subsequently chose to switch back to the originator product. Once again, similar strategies have been used in other regions of Sweden. Sweden—and Stockholm in particular—has benefited from the experience of its neighbours and their collaborative approach has proven highly effective, with the second biosimilar (for etanercept) that entered the Swedish market rapidly occupying a large portion of the market within a year of its introduction.

LESSONS LEARNT

Today several actions need to be coordinated to effectively move forward towards successful uptake of biosimilars in the field of oncology. Building confidence among all stakeholders is paramount and requires a multidisciplinary strategy. Currently the focus is on clarifying the science of approving biosimilar medicines from an alternative angle, moving the burden-of-proof from clinical efficacy and safety to comparability on an analytical and preclinical level. Investing in ongoing interdisciplinary and standardised education to improve scientific understanding, establishing collaborations between groups, and involving the patients and healthcare professionals in these processes will undoubtedly raise the standard of care. Education needs to intervene at all levels, involving physicians, nurses, pharmacists and patients. Guidance from key players, notably regulatory bodies and national representatives, is critical to successfully convey the message of the value of biosimilars. The Information Guide developed by the EMA and the European Commission[21] goes a long way towards addressing many of these aspects. Building collaborations and cross-specialty relations will allow newcomer biosimilars to benefit from previous experience. The ECCO position paper published in 2017 provides guidelines for implementing this process.[25] Collaborations such as that established in Sweden for the introduction of biosimilars, emphasising open discussion between all categories of healthcare professionals as well as patients, provide a role model for a successful approach. Educating patients is essential to dispel concerns about biosimilars and to equip them to participate in decision-making and policies.[26] This involves obtaining a consensus among patient groups to ensure credibility among physicians, educating and motivating patient groups, involving patients in clinical research and creating scientific advisory committees within patient groups. Strong collaborations in the patient community and at the EU, national and regional levels will help ensure visibility.

Analysis of real-life safety and efficacy data will feed confidence. To optimise this process and ensure smooth data collection, a number of logistical challenges need to be addressed, including the development of coherent registries (collecting the same data variables to allow optimal data exploitation) from a range of settings (real-life, clinical trials, compassionate-use, observational studies), robust and accessible pharmacovigilance data systems, and a marked improvement of interoperability of systems at both an international and national level. Examples for best practices exist, such as DANBIO, the Danish registry for patients with rheumatic diseases receiving biological therapies in which almost all patients are entered, and positive switch data are readily available to healthcare professionals, thus contributing to increasing the confidence in biosimilars.

The introduction of biosimilars to the market needs to be carefully controlled to ensure adequate prospects of profit for manufacturers to invest. Another important confidence driver for ensuring the value of using biosimilars lies in the need for transparency and planning in terms of the economic outcomes of introducing biosimilars into the therapeutic equation. Healthcare providers need to be educated on the implications of prescribing different medicines on the healthcare system costs. Wise use of the cost savings and informing the public as to the reallocation of these 'gained' funds to support sustainability of the healthcare system is needed at both a global and local hospital level.

It is important to identify knowledge gaps and educational needs among all healthcare providers, and patients and surveys may help clarify the status of progress and direct us towards areas needing more attention. Two specific areas of focus include switching and extrapolation. For now, the public jury is out over switching; from a regulatory standpoint, there are no major obstacles; however, confidence from physicians and patients must improve. Evidence-based standards and guidelines to ensure patient safety in the context of switching between a reference product and its biosimilar(s) are needed.[27] Studies such as the prospective randomised controlled NOR-SWITCH study demonstrating the safety of switching from the originator to the infliximab biosimilar will help increase confidence,[28] and equivalent prospective studies in oncology should be anticipated. In the NOR-SWITCH EXTENSION trial—a 26-week open label extension trial—concerning the inflammatory boweldisease (IBD) subgroup, the authors concluded there were no differences between the maintenance group and the switch group regarding disease worsening, thus supporting previous conclusions.[29] Extrapolation always requires scientific justification, which, it should be noted,

is not automatically granted. Extrapolation needs to be supported by all of the scientific evidence (the totality of evidence) generated in robust comparability studies, structural (quality) and functional (non-clinical and clinical data),[30 31] with an emphasis on quality. Additional supportive studies may be requested. Healthcare providers must be reminded that all approved indications of a medicine are granted based on scientific evidence. In the case of biosimilars the totality of evidence is pivotal for approval, with confirmation in at least one sensitive patient population, which can then be applied to several/all indications.[32] This reduces the need to repeat clinical trials for all indications, thus avoiding subjecting patients and healthy volunteers to unnecessary clinical trials, along with the associated costs.

In conclusion, with a rapidly increasing range of biological products and well-informed healthcare professionals and patients, biosimilars represent one of the ways forward to obtain sustainability and broaden access to biologicals in regions where their uptake is still low due to economic issues. Physicians will make decisions based on what is best for their patients, but to ensure that an informed decision on all treatment options is reached, it is crucial that all stakeholders—prescribers, pharmacists, nurses and patients—are adequately informed.

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