



EDITORIAL

Considerations for the US health-system pharmacist in a world of biosimilars

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Abstract

As numerous biosimilar products are forecast to enter the US market in the coming years, health-system pharmacists will be faced with novel challenges while incorporating them into clinical practice. The current regulatory approval framework and guidance from the US Food and Drug Administration do not address many real-world scenarios that pharmacists will encounter. We provide an overview of the evolving healthcare landscape shaped by the entry of multiple biosimilars, including for a given reference product, and their impact on the health-

system pharmacist with respect to formulary assessment, implementation, and education of various health-system stakeholders, including patients.

Keywords: biologics, biosimilars, clinical pharmacists, drug substitution, pharmacoeconomics, rheumatology.

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Introduction

The United States Biologics Price Competition and Innovation Act (BPCIA) of 2009 established an abbreviated and less costly biologics approval pathway for a biosimilar relative to its reference product (RP).¹ Under the 351(k) pathway, a biosimilar must be shown to have no clinically meaningful differences relative to its RP in terms of safety, purity, and potency.² However, a product that is approved under the 351(k) pathway is granted only a 'biosimilar' designation; thus, it is not considered identical to or interchangeable with its RP, as biologic products are produced in living systems and inherently subject to variability. This is in contrast to small-molecule generics, which are considered interchangeable and can be automatically substituted by the pharmacist (i.e., without input from or notification of the prescriber). Additional clinical studies need to be undertaken for a biosimilar to receive an 'interchangeability' designation. These studies must demonstrate that the approved biosimilar would produce the same clinical result as its RP in any given patient and, for products given more than once, that the risk of alternating or switching between a biosimilar and its RP is no greater than continued use of the RP.³

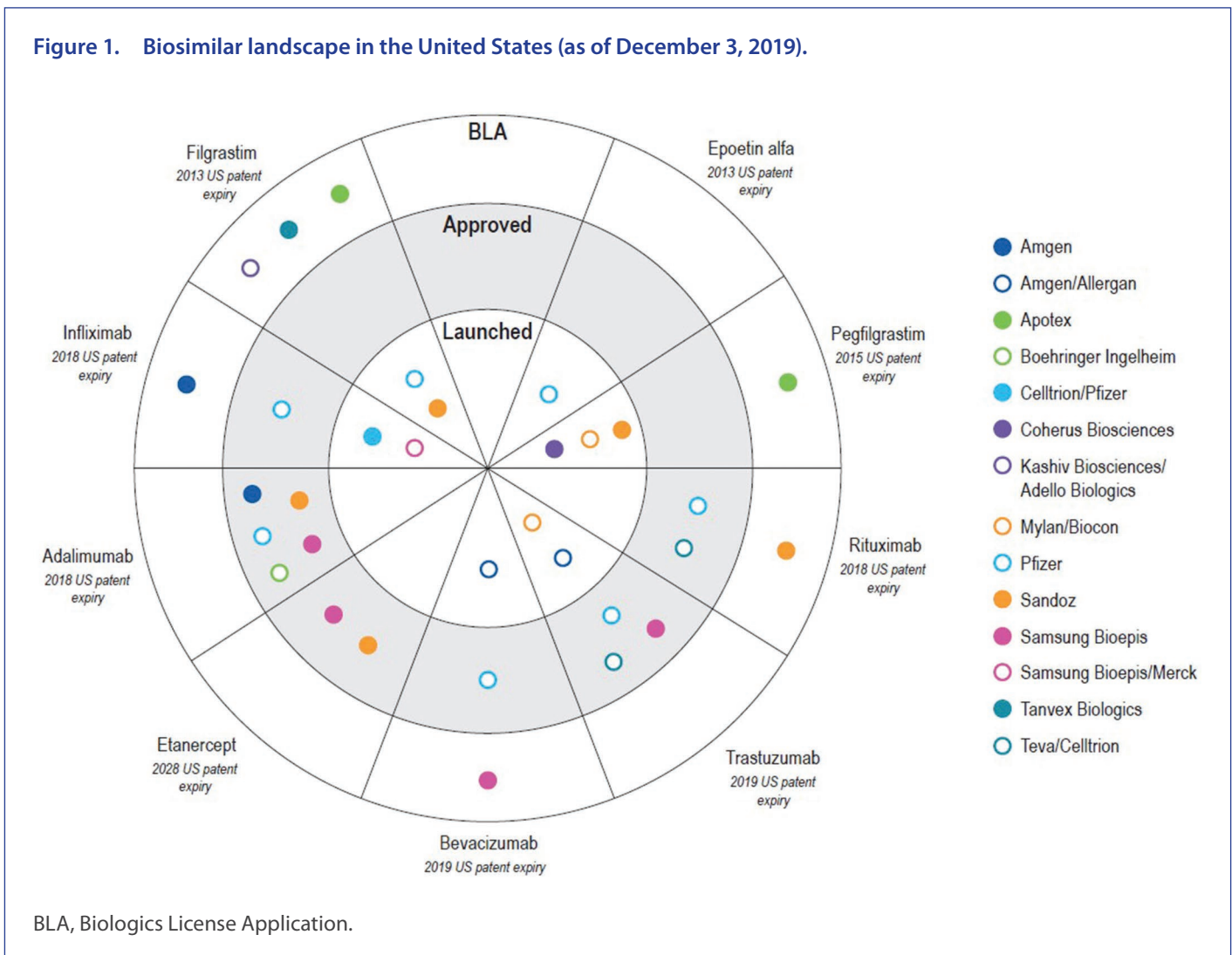
More than 50 biosimilars have been approved in the European Union (EU) since 2006.⁴ Despite the BPCIA of 2009, the first biosimilar (filgrastim-sndz) was not approved by the US Food and Drug Administration (FDA) until 2015.^{5,6} Since filgrastim-

sndz, 24 additional biosimilars have been approved,⁷ 11 of which have been launched; others are currently under FDA review⁸ (Figure 1). Thus, relative to the EU, the United States has less experience in managing the challenges and complexities posed by biosimilars. This article seeks to provide an overview of how the US health-system landscape has been shaped by the entry of biosimilars, with a focus on the health-system pharmacist.

Health-system pharmacists face unique challenges

Much of the concern over biosimilars for health-system pharmacists stems from the complexity of the biologics themselves and the regulations pertaining to labeling, naming, substitution, and interchangeability. First, these pharmacists should carefully review the product labels of the biosimilar(s) and its RP to discern differences that may impact clinical practice and formulary decisions. For example, in contrast to innovator infliximab,⁹ neither biosimilar infliximab-dyyb¹⁰ nor infliximab-abda¹¹ was granted a pediatric ulcerative colitis indication at initial approval (although both have since been approved for this indication).^{10,11} Moreover, it is unclear whether post-marketing safety concerns attributable to one product (biosimilar or RP) will result in updates to the labels of all related products (biosimilar[s] and RP).¹² In addition to indications, storage conditions for the biosimilar(s) and its RP can vary. Unopened

Figure 1. Biosimilar landscape in the United States (as of December 3, 2019).



vials of innovator infliximab can be stored at temperatures up to 30°C,⁹ but unopened vials of infliximab-dyyb and infliximab-abda must be refrigerated (2–8°C).^{10,11} Consequently, pharmacy or nursing staff could inadvertently mishandle these products if not properly trained. In another example, innovator filgrastim offers a single-dose vial,¹³ which may be important to neonatal units that prepare small, customized doses, whereas biosimilar filgrastim-sndz is only supplied in standard, prefilled syringes¹⁴ that are not amenable to dose adjustments. It is also possible that new claims, formulations and/or routes of administration could emerge over time.¹⁵ Therefore, to avoid errors, biosimilars and RPs should be stored in separate, clearly marked bins to ensure that they are prescribed, dosed, stored, dispensed, and handled according to their respective labels.¹⁶ As multiple biosimilars for a given RP enter the market, these activities will become progressively more challenging.

Second, a new naming convention for biologics may cause additional confusion and implementation challenges for pharmacy, finance, and nursing staff. The familiar format of trade and nonproprietary names (i.e., Trade [nonproprietary]) is changing to a convention applicable not only to biosimilars but also to RPs, including those with no approved biosimilars.¹⁷

This new format, which appends a unique, arbitrary, four-letter suffix to the nonproprietary name (i.e., Trade [nonproprietary-xxxx]), is intended to enhance pharmacovigilance and traceability. Biosimilars and newly approved RPs now use this naming convention, but previously approved RPs need not do so.¹⁷ Electronic medical record systems should be updated to accommodate this new format to ensure the accurate identification of biologic products. Errors in the transition to nonproprietary biologic names could have consequences concerning inventory management, billing, reimbursement, pharmacovigilance, and most importantly, patient safety (e.g., inadvertent switching from one product to another). Prescribing and dispensing practices may become more challenging, as multiple biosimilars for a single RP become available.

Another unique feature of the biosimilar landscape is interchangeability, which generates many operational challenges for health-system pharmacists. In contrast to generic products that are regarded as therapeutically equivalent (interchangeable) and can, by law, be automatically substituted for an RP upon approval,^{18,19} in the United States an ‘interchangeability’ designation is achieved independently from the initial biosimilar approval process. Consequently, biosimilars

enter the market only with a 'biosimilar' designation and may never seek or achieve interchangeability.²⁰ In the absence of an 'interchangeability' designation, substitution may still occur but only with the documented prescriber, and possibly patient, notification and/or consent, as stipulated by state-level laws. Furthermore, there may be issues with switching among biosimilars. From a regulatory perspective, biosimilars are only considered to be biosimilar to the RP, not to other biosimilars, and there are no requirements for biosimilar manufacturers to demonstrate biosimilarity to other biosimilar products.²¹ Currently, no biosimilar has been designated by the FDA as interchangeable. Until such time, pharmacists should establish procedures to comply with notification and/or consent requirements when switching among biosimilar and RPs.²⁰

Health-system pharmacists lead formulary assessment

The health-system pharmacist will shoulder much of the responsibility for guiding the formulary committee's assessment of biosimilars. This assessment provides recommendations on the number and types of biosimilars that should be placed on the formulary, to which patients biosimilars can be dispensed (i.e., those initiating therapy *versus* those switching between treatments), and switching (i.e., between an RP and its biosimilar and among biosimilars, if multiple agents are available).^{22,23} To do this successfully, the pharmacist will need to consider all available clinical and economic data (Table 1).

Beyond formulary review, pharmacists may also be challenged to generate proposals that support switching patients who are currently stable on an RP to a biosimilar, as they face increasing institutional pressures to contain costs. However, there will likely be limited data available on single or multiple switches, and little or no evidence on switching among biosimilars. Notably, undesirable clinical outcomes, including disease worsening and increases in adverse event occurrence, have been reported after switching.^{24–26} In fact, low patient expectations of treatment or a reluctance to switch from effective therapy can negatively affect clinical outcomes. This phenomenon, known as the nocebo effect, has been observed in the context of nonmedical switching to biosimilars. Therefore, developing recommendations based on a systematic failure mode and effects analysis (FMEA) of switching scenarios may be onerous and may include guidance on restarting therapy with the RP, switching to a different product within the same therapeutic class, or switching to a product with a different mechanism of action. Screening and education may be warranted to mitigate potential 'nocebo effects' and to ensure patient comfort with any switch in medication.

In institutions that support clinical trials, pharmacists should also assess how investigational drug programs would be affected by formulary decisions. Clinical study protocols may prohibit the substitution of one or more biosimilar products for the RP, and a complete formulary switch to a biosimilar may

not be feasible. Input from investigational drug support teams regarding biosimilar formulary proposals may help in avoiding protocol deviations and clinical errors.

In addition to evaluating biosimilars from a clinical perspective, health-system pharmacists should also review economic analyses that include cost comparisons with the RP and/or other biosimilars, reimbursement assessments, payor coverage reviews, and access evaluations. Estimates should not only reflect differences in individual drug costs but also portfolio-wide discounts provided by manufacturers that supply multiple products. Moreover, each new biosimilar of a single RP that enters the market has the potential to drive costs down, as evidenced by the price reductions for innovator infliximab following the introduction of biosimilar infliximab-dyyb and infliximab-abda. Therefore, health-system pharmacists should routinely re-evaluate the economic impact of changes in average selling price (ASP) and the commensurate adjustments to reimbursement, which will be based on the ASP for each product.

The effects of nondrug costs should be included in any economic analysis of a biosimilar. For example, formulary assessments should examine differences in distribution channels. When the biosimilar filgrastim-sndz was initially launched, it was supplied through a specialty pharmacy distribution channel, and health systems were unable to realize the discounts typically achieved through wholesale channels. Thus, pharmacists should also consider the nondrug costs associated with switching. These nondrug costs include the following: (1) the additional time that healthcare professionals spend educating patients on biosimilars, such as the reason(s) leading to the treatment switch, the safety and efficacy of the biosimilar, and any differences in storage and/or handling relative to the RP; (2) laboratory testing associated with monitoring the safety of the patient following the switch, such as assays that detect antidrug antibodies; and (3) staff training on reimbursement and preauthorization requirements.^{27,28}

The patient cannot be forgotten as a critical stakeholder when evaluating biosimilars, as patient-related concerns can also impact formulary assessments. In situations where the switch from an RP to a biosimilar is mandated, there is likely to be anxiety associated with the loss of autonomy.²⁹ Patient fears of adverse events, reduced efficacy, and loss of insurance coverage or other financial support should also be considered.³⁰ Although biosimilar products are purported to save money, these savings may not be transferred to patients, as pharmacy benefit managers may be incentivized to prioritize high-priced drugs to receive greater reimbursements on the rebates obtained.³¹ Beyond drug costs, formulary assessments should consider factors that impact patient satisfaction and personal economics, such as the resources that support benefit verification, product replacement policies, starter kit support, comfort and familiarity with the drug-delivery device, and financial support services. Differences in these programs may fuel anxiety in patients who feel forced to switch products based solely on formulary policies. 'Biosimilar first' policies may

Table 1. Considerations for formulary assessment and implementation of biosimilars.**Clinical**

1. Number of products to maintain on formulary for each mechanism of action
2. Decision to endorse initiation of treatment with each biosimilar product
3. Limited/no clinical data regarding efficacy or safety of switching or alternating among products; if available, switching studies for each biosimilar may be conducted in different populations
4. Decision to endorse switching or alternating from RP to each biosimilar and/or among biosimilars
5. Development of treatment algorithms for potential post-switch sequelae
6. Differences in:
 - a. Approved indications
 - b. Interchangeability designations and pharmacy substitution procedures
 - c. Approved dosage and supplied volumes
 - d. Storage, administration, and handling procedures
 - e. Availability of supply from various distribution channels
7. Ability to execute clinical trials with RP and/or biosimilars without deviation
8. Patient considerations, including differences in out-of-pocket costs, manufacturers' programs and services (e.g., financial support), and confidence in drug shelf supply to ensure treatment continuity

Economic

1. Downward fluctuation of pricing, reimbursement, and total revenue
2. Savings, if any, related to portfolio-wide contracts with manufacturers
3. The extent to which varied distribution channels impact discounts
4. Costs to continually update and validate information technology systems
5. Costs to develop, maintain, and deliver educational content

Implementation

1. Frequent information technology system updates following the addition of new products and updated product identifiers, such as Healthcare Common Procedure Coding System codes and nonproprietary names
2. Tracking procedures to ensure accuracy of benefit investigations, billing, reimbursement, prescribing, dispensing, administration, and drug utilization
3. Management of multiple product inventories, particularly in space-constrained facilities
4. Frequent stock rotation

Education

1. Cost, time, and effort to develop, maintain, and deliver new educational content for various stakeholders, including formulary committee members, prescribers, pharmacists, nurses, other staff, and patients

also restrict access to newer or better products. Therefore, the formulary analysis for each biosimilar should seek to evaluate the net impact on patients.

Health-system pharmacists lead implementation

Health systems within large, integrated delivery networks will likely face unexpected challenges with the implementation of multiple biosimilars. Many of these challenges will revolve around product traceability and inventory control. If an RP and one or more biosimilars remain on the formulary, health-system pharmacists should develop comprehensive plans to update and validate systems and processes with unique product

identifiers (e.g., both trade and nonproprietary names, National Drug Code numbers, lot numbers). These measures would help address possible stock-outs, ensure inventory control, enable accurate pharmacovigilance, generate data for drug utilization reviews, and reduce the risk of inadvertent switching during a transition in care or the admission/discharge of patients. Accuracy in drug identification improves efficiency during health benefit investigations, as well as prior authorization and claims processes, and ensures correct reimbursement and patient assistance. As multiple biosimilars are added to pharmacy systems inventory, it must be possible to easily verify that drug orders match administration notes, which, in turn, match the actual product prepared, administered, removed from inventory, and billed. Billing systems will also need to be

updated to include new Healthcare Common Procedure Coding System codes for each product. Storage capacity and inventory management are other concerns when stocking RPs and multiple biosimilars, especially within small pharmacies and outpatient clinics. Therefore, close management of drug stock rotation and turnover of biosimilar inventory is recommended.

Health-system pharmacists lead education

Because of the unique nature of biosimilar regulation, formulary assessment, and challenges concerning the implementation of biosimilars in clinical practice, health-system pharmacists are uniquely positioned to lead educational programs. Physicians, nurses, pharmacists, and, most notably, patients are in need of education regarding biosimilars. To help formulary committee members and prescribers critically evaluate biosimilars, pharmacists can draw upon resources from the FDA³² and reputable organizations, such as the Academy of Managed Care Pharmacy (AMCP)³³ and American Society of Health-System Pharmacists (ASHP),³⁴ which explain the regulatory approval pathway for biosimilars and criteria for biosimilarity, extrapolation of data for multiple indications, and interchangeability.

Competency programs on biosimilars may be added to the training curricula of pharmacy and nursing staff to provide general education, as well as specific instruction on the handling, dispensing, documentation, and administration policies and procedures for their institution. Pharmacists may also direct healthcare professionals to accredited continuing education programs offered by the ASHP,³⁵ American Pharmacists Association,³⁶ AMCP,³⁷ and other professional organizations. Specific educational modules may also need to be developed for coding experts and personnel who manage prior authorization, claims, and reimbursement.

Finally, in collaboration with physician and nursing colleagues, it is our recommendation that pharmacists develop educational materials addressing patient-focused aspects of treatment with biosimilars. Recent reports have suggested that the lack of patient education surrounding biosimilars is correlated with unsuccessful outcomes, including greater and earlier drug discontinuation rates.^{29,38} These reports underscore the

need for appropriate patient-friendly language to address common questions, such as 'What are biosimilars and how are they different from RPs or generics?', 'Are biosimilars safe and effective?', 'Do biosimilars cost less?', and 'What questions should I ask my doctor about switching?' Through pharmacy leadership in educational endeavors, stakeholders across the healthcare system can gain the fluency necessary to adopt and implement biosimilars in a safe, efficient, and successful manner.

Summary

Health-system pharmacists in the United States face unique challenges related to the adoption and implementation of biosimilars into clinical practice. Although the FDA provides some guidance, numerous real-world scenarios that health-system pharmacists are likely to face are not addressed. Regarding formulary assessments, it is clear that the clinical data typically used to support proposals and FMEA may not be available for biosimilars, and little regulatory direction or clinical data are available to guide pharmacists and prescribers as they face cost pressures to switch to biosimilars. Additionally, economic analyses can be complicated by frequent ASP and reimbursement changes, portfolio-level contracts, and differences in patient costs and services between the RP and its biosimilars. Evaluation of patient perspectives during formulary selection should consider the anxiety associated with mandated switching from an effective therapy, potential interruption in therapy, access to holistic support services, and possible cost increases. Implementation of one or more biosimilars into an institutional formulary may result in myriad operational considerations, including the need to develop processes for accurate traceability, inventory control, billing, reimbursement, and adverse event reporting, as well as prescribing, dispensing, and administering the correct product to each patient. Pharmacists are ideally placed to advance education efforts aimed at prescribers, formulary committee members, other pharmacists, nurses, administrative staff, and patients to foster the informed adoption of biosimilars into health systems, but moving rapidly into a healthcare environment crowded with multiple biosimilars for a single RP will likely present unusual and unforeseen challenges. Education and preparedness will be key to the success of health-system pharmacists.

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