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CURRENT OPINION

Similar Names for Similar Biologics

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Abstract Approval of the first biosimilar in the USA may occur by the end of 2014, yet a naming approach for biosimilars has not been determined. Biosimilars are highly similar to their biologic reference product but are not identical to it, because of their structural complexity and variations in manufacturing processes among companies. There is a need for a naming approach that can distinguish a biosimilar from its reference product and other biosimilars and ensure accurate tracing of adverse events (AEs) to the administered product. In contrast, generic small-molecule drugs are identical to their reference product and, therefore, share the same nonproprietary name. Clinical trials required to demonstrate biosimilarity for approval may not detect rare AEs or those occurring after prolonged use, and the incidence of such events may differ between a biosimilar and its reference product. The need for precise biologic identification is further underscored by the possibility of biosimilar interchangeability, a US designation that will allow substitution without prescriber intervention. For several biologics, the US Food and Drug Administration (FDA) has used a naming approach that adds a prefix to a common root nonproprietary name, enabling healthcare providers to distinguish between products, avoid medication errors, and facilitate pharmacovigilance. We recommend that the FDA implement a biosimilars naming policy that likewise would add a distinguishable prefix or suffix to the root nonproprietary name of the reference product. This approach would ensure that a biosimilar could be distinguished from its reference product and other biosimilars in patient records and pharmacovigilance databases/reports, facilitating accurate attribution of AEs.

Key Points

Biosimilars are highly similar to their biologic reference product but are not identical to them, because of their structural complexity as biologics and because production processes vary among manufacturers.

There is a need for a standardized naming approach to distinguish a biosimilar from its reference product and other biosimilars, and to ensure accurate tracing of adverse events.

To facilitate accurate adverse event reporting, we recommend adding a distinguishable prefix or suffix to the root nonproprietary name of the reference product for biosimilars.

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1 Introduction

The introduction of biosimilars is intended to lower costs and further increase patient access to important biologics [1, 2]. There are nine biosimilars marketed in the European Union (EU) under 16 brand names (Table 1), including recently approved biosimilars of infliximab (marketed under two brand names), follitropin alfa, and filgrastim [3]. The first approval of a biosimilar in the USA may occur by the end of 2014 [4], and, according to the US Food and Drug Administration (FDA), biosimilars of 13 different reference products are currently under development. Despite the growing number of biosimilars worldwide, there is considerable debate on whether to assign distinguishable nonproprietary names to biosimilars to maintain the ability to readily identify each biologic [5–8]. Currently, biosimilars naming policies differ among individual regulatory bodies [9, 10]; however, the World Health Organization (WHO) is evaluating potential biosimilars naming conventions that could address the naming of biologics globally [5]. The naming convention that is ultimately implemented will directly affect the accuracy and efficiency with which biosimilars can be identified for postapproval safety monitoring (also known as pharmacovigilance) [11].

The legal foundation for biosimilars in the USA was established by the Biologics Price Competition and Innovations Act of 2009 [1]. According to this law, a biosimilar is highly similar to its reference product and has no clinically meaningful differences from it in terms of safety, purity, and potency [1]. However, because of the complexity of biologics and their manufacturing processes, which inevitably vary among manufacturers, it is widely accepted that a biosimilar may have slight structural variations and will not be identical to its reference product or to other biosimilars of the same reference product [6, 12]. In contrast, generic small-molecule drugs are identical to their reference product, and consequently they receive the same nonproprietary name [8].

Table 1 Biosimilar products with European Union marketing authorization

Manufacturer	Brand name (active substance)
Erythropoietin	
Rentschler Biotechnologie GmbH; Lek Pharmaceuticals	Abseamed (epoetin alfa)
	Binocrit (epoetin alfa)
	Epoetin Alfa Hexal (epoetin alfa)
Norbitec GmbH	Retacrit (epoetin zeta)
	Silapo (epoetin zeta)
Granulocyte colony-stimulating factor	
SICOR Biotech UAB	Biograstim (filgrastim)
	Ratiograstim (filgrastim)
	Tevagrastim (filgrastim)
Sandoz GmbH	Filgrastim Hexal (filgrastim)
	Zarzio (filgrastim)
Intas Biopharmaceuticals Ltd.; Apotex Nederland BV	Grastofil (filgrastim)
Hospira Zagreb	Nivestim (filgrastim)
Human growth hormone	
Sandoz GmbH	Omnitrope (somatropin)
Human follicle-stimulating hormone	
Merckle Biotec GmbH; Teva Pharmaceuticals Europe BV	Ovaleap (follitropin alfa)
Anti-human tumor necrosis factor alpha-2 monoclonal antibodies	
Celltrion Inc.	Inflectra (infliximab)
	Remsima (infliximab)

2 Regulatory Approval and Pharmacovigilance of Biosimilars

Because of the greater complexity of biologics compared with small-molecule drugs and the potential for differences between biosimilars and their reference products [8], regulatory agencies worldwide, including the FDA, have developed separate regulatory pathways to approve biosimilars [12–17]. These biosimilar pathways are distinct from those used to approve generic small-molecule drugs, which rely on demonstration of pharmaceutical and pharmacokinetic equivalence to the small-molecule reference product [18–20]. The FDA 351(k) regulatory pathway for biosimilars evaluates the similarity of a proposed biosimilar and its reference product on the basis of analytic, preclinical, and clinical studies that are designed to compare product characteristics, pharmacokinetics and/or pharmacodynamics, safety, and efficacy [12, 13]. The FDA recommends comparative analytic studies to assess the similarity of the proposed biosimilar and its reference product with respect to molecular structure, the nature and extent of protein modifications (e.g., glycosylation), biological activity, and purity [13]. Preclinical studies of the proposed biosimilar and its reference product are recommended for comparison of toxicity profiles in animal models, followed by comparative clinical studies to evaluate the similarity of the pharmacokinetics, pharmacodynamics, and immunogenicity [13]. If biosimilarity remains uncertain after these studies, additional head-to-head clinical trials of the proposed biosimilar and its reference product are recommended for comparison of their safety and effectiveness [12]. A biologic that is similar to a previously approved biologic but is approved through a

standard 351(a) biologics license application and not through the FDA biosimilar approval pathway, such as tbo-filgrastim, is not considered a biosimilar in the USA.

Clinical trials that are required to demonstrate biosimilarity for approval may not detect rare adverse events (AEs) or events that may emerge after prolonged use, which may differ between a biosimilar and its reference product [12, 15, 17]. For example, potential differences in immunogenicity could occur on the basis of variations in molecular structure (e.g., glycosylation) or administration, or as manufacturing processes for the biosimilar and reference product evolve. Such differences, as well as differences in pharmacology-related AEs between a biosimilar and its reference product, may be detected only after a biosimilar is approved. In addition, as some indications for the biosimilar may be approved on the basis of extrapolation from clinical studies in other conditions of use, it may be relevant to confirm the risk–benefit profile of the biosimilar in the extrapolated indications. Potential postapproval measures could include passive or enhanced safety surveillance in the extrapolated indications [21]. The FDA and the European Medicines Agency have emphasized the importance of rigorous pharmacovigilance for all biologics, including biosimilars [12, 15, 17]. Pharmacovigilance encompasses the procedures and systems designed to monitor the safety of medicines after their approval [8]. Successful pharmacovigilance systems rely on accurate identification of drugs in safety reports and in electronic health records to ensure that suspected AEs can be accurately traced to the correct product. Consequently, distinguishable and recognizable names are needed for all biologics, including biosimilars [8].

3 Differences in Indications and the Potential for Interchangeability: Implications for Naming of Biosimilars

It is possible that some biosimilars in the USA could be approved for use in some, but not all, indications that are approved for the reference product [14, 22, 23]. Potentially, multiple biosimilars of a single reference product could enter the market, each with a different subset of approved indications. This possibility underscores the need for a naming approach that clearly distinguishes each biosimilar product. If such products had the same name, medication/prescription errors could occur [8]. Biosimilar manufacturers in the USA will also have the opportunity to pursue an interchangeability designation for a biosimilar, with submission of additional data [1]. The interchangeable biosimilar designation will allow pharmacists to substitute without prescriber intervention. This potential for interchangeability, which could lead to multiple switches between an interchangeable biosimilar and the reference product, also highlights the need for a naming approach that clearly distinguishes all biologics [8].

A recent survey of 376 US prescribers demonstrated that physicians generally believed that drugs that have the same nonproprietary name are interchangeable [24]. More than 76 % of prescribers assumed that drugs with the same nonproprietary name were structurally identical, and 64 % assumed that such products could be safely switched during treatment with the same expected results. Although this survey did not distinguish between small-molecule and biologic drugs, the findings were applied to biologics [6]. Whereas US law establishes two tiers of biosimilars (biosimilars and interchangeable biosimilars), the FDA deems that only interchangeable biosimilars are appropriate for substitution [1, 2]. Yet, if a noninterchangeable biosimilar shared the same nonproprietary name as its reference product, mistaken assumptions could result in inappropriate substitution, potentially exposing patients to risks [6]. It should be noted, however, that there is no regulatory pathway for interchangeability of biosimilars in the EU, and that regulations for substitution of biologics differ among EU member states [25]. For example, the French Parliament recently passed a law that allows pharmacy-level substitutions of biosimilars for patients initiating a course of treatment if the prescribing physician has not indicated that the prescription is nonsubstitutable [26]. The law does not allow for pharmacy-level biosimilar substitutions for patients who have already initiated treatment with a biologic, nor does it confer interchangeability status to biosimilars [27].

A review evaluating potential safety concerns associated with switching between originator biologics and biosimilars approved in the EU (erythropoietins, filgrastims, and growth hormone products) did not identify direct safety risks associated with substituting biologics; however, most of the included trials were underpowered to identify AEs associated with switching [28]. In the EU, no major safety concerns have been identified for biosimilars that are used in approved indications and according to approved routes of administration. Notably, a postmarketing clinical trial of a biosimilar epoetin was terminated early following unexpected immunogenicity in two patients [29]. As more biosimilars are approved, there likewise is a growing need for a naming approach that allows all biologics, including biosimilars, to be distinguished and specifically tracked following substitution, to facilitate pharmacovigilance. The encouraging experience with biosimilar safety in the EU does not preclude the possibility of problems in the future.

4 Biosimilar Product Identifiers: Limitations and Recommendations

In a study that evaluated the traceability of biologics in the FDA Adverse Event Reporting System (FAERS) and EudraVigilance databases, product names were considered

identifiable in reports that included either the brand name or the international nonproprietary name (INN) combined with the name of the marketing authorization holder [30]. The use of brand names to identify biosimilars has been suggested as a means to address pharmacovigilance concerns. This approach has been favored in the EU, where brand names are required and "unbranded" biologics may receive a quasi brand name comprising the INN in conjunction with the name of the manufacturer/marketing authorization holder (e.g., filgrastim Hexal) [25]. To facilitate traceability of biologics in the EU, the new Pharmacovigilance Directive requires that all biologics, including biosimilars, are clearly identified [31]. Accordingly, brand names are required in suspected adverse reaction reports in the EU, together with the INN and batch number [31, 32]. In contrast with the EU, brand names are not mandatory in the USA and therefore cannot be relied on to ensure precise identification of products for accurate AE tracing in the pharmacovigilance system.

Although National Drug Codes (NDCs) provide detailed information about products, they have limited utility for identifying products for pharmacovigilance and are rarely used in AE reporting [24, 33]. Physicians and patients are typically unfamiliar with NDCs, and as 10-digit numeric codes, they are often transcribed incorrectly [34]. Not all US states require NDCs in drug labeling, and NDCs are not captured in all provider/payer databases [35]. Moreover, the primary packaging, which may contain the NDC, may be discarded before an AE is reported. Lot numbers specifically identify the drug and production batch if the manufacturer is known, but, like NDCs, they are infrequently used in AE reports and are likewise susceptible to errors, which can limit their usefulness in product identification for tracing AEs [30, 34].

Some countries require that the nonproprietary name of a biosimilar include a code identifying it as different from the reference product. For example, in Australia, a biosimilar includes the Australian Biologic Name of the reference product plus the term "sim" and a three-letter code issued by the WHO INN Committee [9]. In Japan, the suffix "BS" is added to the reference product nonproprietary name to denote a biosimilar [36]. On the basis of WHO policy, glycosylated biosimilars are identified by a Greek letter suffix added to the reference product INN to indicate differences in glycosylation [36]. This naming policy, however, has not been applied consistently, as seen with the infliximab biosimilars recently approved in the EU with an INN identical to the reference product INN.

The FDA has recently used an approach of adding a prefix to a common root nonproprietary name for several biologics [e.g., tbo-filgrastim, ziv-aflibercept, ado-trastuzumab emtansine (not biosimilars)] [37–39]. This naming approach allows related biologics to be easily distinguished and thereby avoids medication errors and facilitates pharmacovigilance [37, 39]. We recommend that the FDA implement a biosimilars naming policy that likewise requires addition of a distinguishable prefix or suffix to the root nonproprietary name of the reference product to ensure that the biosimilar can be distinguished from its reference product and from other biosimilars. Such a biosimilars naming approach would help ensure that patient records and pharmacovigilance databases/reports correctly identify the specific biologic a patient received, and would support accurate attribution of AEs associated with biologics. This approach would also help separate class-level data, facilitating comparisons among approved biosimilars. This will be important because no data will exist to compare outcomes among approved biosimilars. The inclusion of a common root is essential for recognition of the product; therefore, we do not recommend a biosimilars naming convention that would use unique, unrecognizable nonproprietary names. To facilitate accurate and unambiguous identification in AE reports of any and all administered biologics, the FDA needs to develop and communicate a biosimilars naming policy before the first biosimilar is approved in the USA.

The WHO has noted that the use of the same nonproprietary name for a biosimilar and its reference product could lead to inadvertent switching of products, and has indicated that the naming of biosimilars needs to be addressed globally [5, 36]. Our recommendation aligns with a proposed biosimilars naming approach that was recently presented at the WHO and would use a distinguishable modifier of the root INN to identify the product as a specific biosimilar [36]. This proposed naming convention could help regulators worldwide identify a substance as a biosimilar [36]. Accordingly, we support collaboration between the FDA and the WHO to develop a naming policy that would bring additional consistency to naming of biosimilars worldwide and would facilitate precise identification of all biologics. As with all medical advances that are intended to increase therapeutic options, education of the healthcare community on the appropriate use of biosimilars will be necessary, particularly regarding naming of biosimilars and pharmacovigilance.

5 Conclusion

Given the expectation that the first US biosimilar may be approved in 2014, there is a need for a standardized biosimilars naming approach to ensure that all biosimilars can be easily distinguished from their reference products and from other biosimilars to facilitate accurate tracing of AEs. Product identifiers currently used in AE reports in the USA may not efficiently and unambiguously identify biologics

with the same INN. Therefore, we recommend a US biosimilars naming policy that adds a distinguishable prefix or suffix to the root nonproprietary name of the reference product. This proposed biosimilars naming convention is consistent with previous biologics naming approaches applied by the FDA and under consideration by the WHO. To ensure accurate AE reporting, the FDA should, ideally, establish and communicate its biosimilars naming policy before US approval of the first biosimilar.

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