

REPORT 4 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (A-14)  
Biosimilar Product Approval and Marketing  
(Reference Committee E)

EXECUTIVE SUMMARY

Objective. To revisit the topic of biosimilars, study emerging issues that are relevant for such products under the current abbreviated pathway for approval, and recommend changes to relevant AMA policy.

Methods. English-language reports were selected from a PubMed and Google Scholar search from 2010 to April 1, 2014 using the MeSH terms “biological products/\*economics/therapeutic use,” “therapeutic equivalency,” and “drug approval/\*legislation,” and the text terms “biosimilar(s),” or “follow-on biologics.” Additional articles were identified by manual review of the references cited in these publications. Further information was obtained from the Internet sites of the FDA, the United States Adopted Names (USAN) Council, the World Health Organization (WHO), and the European Medicines Agency (EMA). Additionally, some verbiage in this report is extracted from comments submitted by our AMA in response to an FDA public hearing on the approval pathway for biosimilar and interchangeable biological products held on November 2, 2010, and a recent public workshop held by the Federal Trade Commission (FTC) on the impact of legislative and naming proposals on competition in the, as yet, still emerging U.S. market for biosimilars.

Results. The European Union has made significant progress in developing a viable biosimilar market. Despite the existence of an abbreviated pathway for the approval of biosimilar products, no such products are yet available in the United States. Despite the lack of available biosimilar products, several states have enacted changes in state pharmacy practice acts to govern the substitution of biosimilar products. Some of these changes involve new notification or record keeping requirements for pharmacists and/or prescribers that may serve as barriers to the uptake of biosimilar products. In addition, no consensus has emerged on a naming convention for biosimilar products, which also has the potential to affect uptake.

Conclusion. The abbreviated approval pathway for biosimilars is intended to lower costs and increase patient access by increasing market competition through the introduction of multisource highly similar biologic products. Several uncertainties remain with regard to establishing a viable biosimilar market in the United States, including lack of a uniform nomenclature/naming convention, variable state requirements regarding substitution practices, and educational gaps for prescribers.

## CONCLUSION

Our AMA remains mindful of the unique safety challenges posed by the manufacture of complex biologicals and the corresponding challenges for biosimilars, but is committed to the overall goal of developing policies that recognize physician autonomy, promote patient access, and protect patient safety in a manner that preserves market competition and innovation. This is especially important given the anticipated growth in health care costs associated with biologics and the emergence of biosimilar products in the United States as a market-forming event characterized by substantial uncertainty. Several uncertainties remain with regard to establishing a viable biosimilar market in the United States, including lack of a uniform nomenclature/naming convention, variable state requirements regarding substitution practices that have the potential to serve as barriers to biosimilar uptake, and educational gaps for prescribers. Additional issues exist that are likely to influence competition in the emerging biosimilar market such as the extent to which extrapolation of clinical data is allowed, potential patent/legal challenges, and the potential need for distinctive product labeling for biosimilars, to name a few.

## RECOMMENDATIONS

The Council on Science and Public Health recommends that the following statements be adopted and the remainder of the report filed.

1. That Policy H-125.980, “Abbreviated Pathway for Biosimilar Approval,” be amended by addition and deletion to read as follows:

~~AMA policy is that pharmaceutical companies should be allowed to make biosimilar medications available to physicians and their patients in a reasonable period of time with a reasonably predictable pathway to bring them to market. Our AMA supports will advocate for appropriate FDA Guidance and implementation of the Biologics Price and Competition and Innovation Act of 2009 in a manner that: 1) includes a straightforward regulatory process for an abbreviated approval pathway for biosimilars; 2) places appropriate emphasis on the promoting patient access, protecting of patient safety, and preserving market competition and innovation in both the original branded products and all biosimilar products that are brought to market; and 3) includes planning by the FDA and the allocation of sufficient resources to ensure that physicians understand the distinctions between biosimilar products that are considered highly similar, and those that are deemed interchangeable. Focused educational activities must precede and accompany the entry of biosimilars into the U.S. market, both for physicians and patients; 3) includes compiling and maintaining an official compendium of biosimilar products, biologic reference products, and their related interchangeable biosimilars as they are developed and approved for marketing by the FDA.~~ (Res. 220, A-09; Reaffirmation A-11; Modified: CSAPH Rep. 1, I-11) (Modify HOD Policy)

2. That Policy D-125.989, “Substitution of Biosimilar Medicines and Related Medical Products,” be amended by addition and deletion to read as follows:

Our AMA urges that State Pharmacy Practice Acts and substitution practices for biosimilars in the outpatient arena: (1) ~~mirror the current practices for A-rated generic drugs by preserving physician autonomy the right of physicians and other prescribers to designate which biologic or biosimilar product is dispensed to their patients;~~ (2) allow substitution when physicians expressly authorize substitution of an interchangeable product (3) limits the authority of pharmacists to automatically substitute only those biosimilar products that are deemed interchangeable by the FDA. (Res. 918, I-08; Modified: CSAPH Rep. 1, I-11) (Modify HOD Policy)

3. That our AMA urges the FDA to finalize Guidance on the naming and labeling conventions to be used for biosimilar products, including those that are deemed interchangeable. Any change in current nomenclature rules or standards should be informed by a better and more complete understanding of how such changes, including requiring a unique identifier for biologic USANs would impact prescriber attitudes and patient access, and affect post marketing surveillance. Actions that solely enhance product identification during surveillance but act as barriers to clinical uptake are counterproductive. However, because of unique product attributes, a relatively simple way to identify and track which biosimilar products have been dispensed to individual patients must be established. If unique identifiers for biosimilar USANs are required to support pharmacovigilance, they should be simple and the resulting names should reinforce similarities by using the same root name following standards for nonproprietary names established by the USAN Council. (New HOD Policy)
4. That Policy D-125.988, “Updating AMA Policy on Biosimilars,” be rescinded. (Rescind HOD Policy)

Fiscal Note: Less than \$500

