Biosimilar Drug Therapies

The Academy of Managed Care Pharmacy (AMCP) supports an abbreviated licensure pathway for the approval of biosimilar biologic drug therapies[1] by the U.S. Food and Drug Administration (FDA). Biological products[2] are certain to play an increasingly important role in the country's health care system – both in terms of scientific improvements in the treatment of disease and increased drug costs. An expedited approval process for biosimilar and interchangeable products provides a needed incentive for the development of new therapeutic products that hold the promise of preventing, treating or curing otherwise inevitable, untreatable and incurable diseases. Such a process will help ensure greater access to new therapies at costs expected to be below those of a FDA- approved biological product (a "reference product").

It is important for the approval process to support an appropriate balance between bringing safe and effective drugs to market and maximizing patient access to affordable drugs. The regulatory process must be designed to rigorously examine the safety and efficacy of a biosimilar applicant, but not prove too burdensome in either the length of time required for review or in added costs for the manufacturer seeking the biosimilar or interchangeable license. To this end, the FDA should determine on a case-by-case basis whether to require additional clinical studies prior to approval, as well as any post-marketing studies.

Manufacturers of approved biosimilars should be allowed to use the same government-approved name/international nonproprietary name as the reference product (e.g. epoetin alpha for Procrit®). This will limit confusion among prescribers and patients, and help to encourage substitution of biosimilar products where appropriate. It is also important to continue to use current mechanisms such as manufacturer name, national drug code (NDC) numbers and lot numbers to effectively differentiate batches for safety monitoring purposes.

Product labels for biosimilars should contain the same content found in the label for the reference product. We believe that clinical data supporting the reference product is the basis of safety and efficacy of a biosimilar and should be included in the label. Additionally, we believe including a statement describing that the product was approved as a biosimilar to a reference product may discourage use and confidence in biosimilar products, and do not support its inclusion. We also believe that the use of multiple product identifiers (reference product name, biosimilar product name, core name or a combination of these names) throughout the label will cause unnecessary confusion for health care providers and patients.

In addition to an approval pathway for biosimilar products, the FDA has provided clear rules for the designation of a biosimilar product as interchangeable with a reference product, similar to the current "AB" ratings used for small-molecule chemical drugs.[3] AMCP supports the FDA two-step process, with the first step determining biosimilarity and the second step determining the interchangeability with the reference product. A determination of interchangeability should not be a requirement as a condition for approval of a biosimilar product. AMCP believes that the states should follow the FDA's determination of interchangeability with regards to granting substitution authority to pharmacists. Therefore, AMCP opposes unnecessary requirements for recordkeeping and prescriber notification of the product dispensed when the FDA has designated a product as interchangeable.

In addition to actions by the FDA, AMCP encourages manufacturers of biosimilar products to seek approval for all of the same FDA-approved indications as the reference product when appropriate, recognizing that special populations, such as children and adolescents, may require additional safety and benefit evaluation. The foundation of biosimilar development is the demonstration that chemical, physical and biological parameters are highly similar to the reference product. Any clinical studies confirm functional sameness rather than establish efficacy and safety *de novo*, which has already been established with the reference product. Based on this, we support approval of biosimilars for all the clinical indications of the reference product based on the totality of the evidence.

AMCP supports biosimilar competition with reference biologic products and therefore opposes any delays in this competition. This includes utilizing the FDA's Risk Evaluation and Mitigation Strategies (REMS) program to block the development of biosimilars, additional patents to prevent biosimilar competition beyond the 12 year market exclusivity and the requirement that a biosimilar manufacturer must provide a 180 day notice to the reference product sponsor from the date of FDA approval before a commercial launch.

AMCP understands the importance of educating pharmacists, physicians, nurses and other health care providers on biosimilars in order to improve understanding and confidence in their safety and effectiveness. To help address this need, AMCP launched a Biosimilars Resource Center (BRC), an unbiased, policy-neutral repository of educational resources and information on biosimilars. The site was developed in partnership with leading national pharmacy organizations and can be accessed at www.biosimilarsresourcecenter.org.

AMCP *Where We Stand* series: www.amcp.org/positionstatements.

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[1] As defined by the FDA: "A biosimilar is a biological product that is highly similar to a U.S.-licensed reference biological product notwithstanding minor differences in clinically inactive components, and for which there are no clinically meaningful differences in between the biological product and the reference product in terms of the safety, purity and potency of the product."

[2] As defined by the FDA: "Biological products can include a wide range of products including vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and proteins. Unlike most traditional, small-molecule prescription drugs that are made through chemical processes, biological products are generally made from human and/or animal materials. Biological products are usually larger than and have a more complex structure than small-molecule prescription drugs. Such products may be manufactured through biotechnology, derived from natural sources, or, in some cases, produced synthetically."

[3] A product receives an AB rating if the FDA has determined that it contains identical active ingredient(s), dosage form, and route(s) of administration and has the same strength as the brand-name product.