AHIP Board of Directors Statement on Improving the Availability and Affordability of Generic Biopharmaceuticals for Patients

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INTRODUCTION

Biopharmaceuticals or "biologics", such as proteins used for treatment of anemia and rheumatoid arthritis, are available to treat an increasing array of conditions. These products, unlike traditional prescription drugs, are derived from living sources and are manufactured using complex biotechnology. Biologics typically cost tens of thousands of dollars annually for a single patient and health insurance plans are working to meet the challenge of making affordable, clinically sound coverage of these products available to patients.

As in the case of traditional prescription drugs, generic forms of biologics offer the potential for increasing access to these potentially life-saving treatments by making them less costly. An expedited process for the Food and Drug Administration (FDA) approval of generic "drugs" that are equivalent to brand name drugs has resulted in the increased availability of these generics. However, currently there is no similar expedited pathway for regulatory approval of generic biologics. While comparisons of brand-name biologics and proposed generic alternatives present more challenges than comparisons of drugs, scientific analyses that reliably evaluate safety, quality, and effectiveness are available and provide the foundation needed for an expedited FDA approval process. To promote more affordable access to biologics, AHIP supports enactment of legislation that would provide an expedited means of bringing safe and effective generic biologics to market based upon the following principles.

PRINCIPLES FOR IMPROVING THE AVAILABILITY AND AFFORDABILITY OF GENERIC BIOLOGICS

AHIP supports the establishment at the FDA of a means for manufacturers to make use of an abbreviated regulatory pathway to receive approval of generic biologics through a process that is consistent with the following principles:

- **Promotion of timely market entry of generic biologics** – The process should provide manufacturers with the incentive to develop generic versions of brand-name innovator biologics by eliminating, to the extent possible, the need to perform extensive, costly, and

duplicative clinical testing while still requiring documentation that demonstrates safety and effectiveness.

The widespread availability of lower-cost generic drugs is largely attributable to the FDA's implementation of an abbreviated regulatory approval pathway authorized by statute in 1984. These generic drugs have become one of the most effective tools health insurance plans have for controlling prescription drug costs, while providing patients with significant savings on high quality, effective drug therapies. The increasing availability and use of biologics and their contribution to the rising health care costs make it important to establish an abbreviated pathway for FDA approval of generic biologics that achieves the same goals as the abbreviated approval pathway for generic drugs.

- **Ensuring that generic biologics are comparable to brand-name products in safety, quality, and effectiveness** – FDA approval should be based on a finding that the generic product is comparable in safety, quality, and effectiveness to the brand-name product based upon comparative analyses that are capable of assessing the unique characteristics of the type of biologic being evaluated. Patients and physicians should have confidence that the generic biologics meet standards that ensure they will be as safe and clinically effective as the brand-name product.

  A critical element of the abbreviated approval pathway for generic drugs is the demonstration that the generic version is bioequivalent to the brand drug. The complexity of biologics and the effect that the manufacturing process can have on their effectiveness and safety make the bioequivalent comparison used for generic drugs insufficient. However, more sophisticated scientific methods are available to compare brand and generic biologics; methods, for example, that manufacturers of innovator brand-name biologics have already relied on for comparing their own products following changes in manufacturing processes or locations. These methods can be utilized to ensure the comparability of safety and effectiveness of generic biologics without the need to automatically repeat the extensive clinical testing required for brand name biologics.

- **Providing a mechanism to allow the review criteria to keep pace with innovation in biologics** – The abbreviated FDA approval pathway should foster the use of new scientific methods of analysis that respond to the characteristics of new products and should not be designed as a one-size-fits all approach for the review and approval of all generic biologics. The complexity and variation in the composition of available biologics and their manufacturing processes means that not all generic biologics can be compared using the same scientific methods, and some may merit more extensive evaluation than others. Therefore, an abbreviated FDA approval pathway will need to be adaptable to ensure the safety and effectiveness of generic biologics. As the range of biologic products continues to grow, evolution of the FDA approval pathway will be essential to facilitate ongoing efforts to make new generic biologics available to patients.