AMCP Is Disappointed in FDA's Draft Guidance and Proposed Rule Calling for Suffix on Nonproprietary Names of Biological Products

ALEXANDRIA, Va., Aug. 27, 2015 /PRNewswire-USNewswire/ -- The Academy of Managed Care Pharmacy (AMCP) is disappointed in the Food and Drug Administration's (FDA's) draft guidance and proposed rule that calls for biologics, including reference products and biosimilars, to bear a nonproprietary name with an FDA-designated suffix. For several years, AMCP has been seeking a decision from the FDA on the naming issue and recently joined 18 diverse health care stakeholders urging the agency to use the same nonproprietary names for both biologics and biosimilars.

According to the FDA guidance and proposed rule, both issued Aug. 27, "There is a need to clearly identify biological products to improve pharmacovigilance and, for the purposes of safe use, to clearly differentiate among biological products that have not been determined to be interchangeable. Accordingly, for all biological products, FDA intends to designate a nonproprietary name that includes a suffix composed of four lowercase letters."

AMCP CEO Edith A. Rosato, RPh, IOM, issued the following statement in response:

The current naming convention using the same nonproprietary name has proven safe and effective globally for small molecule drugs and for biological products in Europe, and therefore it should be the standard in the United States.

AMCP is concerned that any departure from the currently accepted nonproprietary naming system will create confusion amongst healthcare practitioners and patients, have negative effects on the ability to ensure safe dispensing and tracking, and result in lower market adoption and cost-savings.

AMCP agrees with the FDA that performing diligent pharmacovigilance for biological products post-marketing is vital. However, AMCP believes this can be accomplished through the continued use of existing mechanisms, including utilizing identifying factors such as manufacturer name, national drug code, and lot numbers. AMCP has taken a proactive approach to pharmacovigilance and will soon launch a significant nationwide initiative to proactively monitor both biologics and biosimilars using data from millions of de-identified patients.

AMCP will submit comments on the draft guidance and proposed rule, and will continue to work with the FDA and other stakeholders to ensure biologics and biosimilars are safe, effective and widely accepted by patients and providers.

About AMCP
The Academy of Managed Care Pharmacy (AMCP) is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's 7,000 members develop and provide a diversified range of clinical, educational and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit. www.amcp.org.

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