June 10, 2014

Jeremy Sharp
Counselor to the Secretary for Science and Public Health
United States Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201
Via email: jeremy.sharp@hhs.gov

Dear Mr. Sharp:

We understand that the Food and Drug Administration (FDA) has submitted recommendations to the Secretary outlining the agency's proposed policy for the naming of biosimilar products. In light of this development, the American Pharmacists Association (APhA), the National Association of Chain Drug Stores (NACDS) and the National Community Pharmacists Association (NCPA) would like to convey our perspectives on behalf of the community pharmacy profession to the Department of Health and Human Services (HHS) regarding this topic.

APhA founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services.

NACDS represents traditional drug stores and supermarkets and mass merchants with pharmacies. Chains operate more than 40,000 pharmacies, and NACDS' 125 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ more than 3.8 million individuals, including 175,000 pharmacists. They fill over 2.7 billion prescriptions yearly.

NCPA represents the interests of America's community pharmacists, including the owners of more than 23,000 independent community pharmacies, pharmacy franchises, and chains. Together, they represent a $93 billion health-care marketplace, employ over 300,000 employees including 62,400 pharmacists, and dispense over 40% of all retail prescriptions.

Together, our organizations support a naming policy of assigning the same individual nonproprietary name ("INN") to a biosimilar product that is assigned to the reference biologic counterpart. This approach is consistent with the naming conventions for brand and generic small molecule drugs, and is familiar to healthcare providers and patients alike. Applying unique INNs to biosimilars deviates from traditional naming practices and could lead to general confusion

relative to the appropriate use, safety, and efficacy of biologic products, as well as therapeutic duplication that would be detrimental to patients' health.

Unique INNs for common active ingredients may generally increase confusion, leading to increased safety concerns and possibly medication errors. Physicians are already pressed for time, and therefore it is imperative that there are no additional and unnecessary obstacles that hinder them from timely decision-making, especially in cases of urgent care. The use of different INNs would increase the burden of being able to distinguish which products are biosimilar and interchangeable with a particular reference drug and may pose difficulties in recognizing the best alternative drug for therapeutic use in a timely manner. Such confusion may lead to medication errors such as therapeutic duplication. Furthermore, unique INNs would be contrary to the World Health Organization (WHO) naming system that is accepted globally, causing confusion within the global marketplace.

We are further concerned that unique INNs could undermine physician and patient confidence in biosimilars in general. Given that brand and generic versions of small molecule drugs share the same INN, physicians and patients have come to understand that a shared INN denotes that a generic product is at least comparable to the brand. However, if FDA were to deviate from this naming convention and apply unique INNs to biosimilars, this move could serve to perpetuate the notion that biosimilars are not comparable to the innovator biologic.

We acknowledge that the ability to uniquely identify which biological product a patient is taking is important, especially in cases of adverse events and quality issues. However, the use of INNs is not warranted and may interfere with current pharmacy safety alert systems and complicate the collection of global safety information. Using examples of successful biopharmaceuticals marketed under the same INN, such as human growth hormone and insulin, the FDA can apply the same concept for naming biosimilars. The same INN will not necessarily denote interchangeability, but rather be used to categorize a similar therapeutic drug.

In 2006, the FDA concluded to its global regulatory peers that "INNs should not be used to differentiate products with the same active ingredient(s) when credible scientific data demonstrate that no pharmacologically relevant differences exist."[1] Our organizations continue to support and find relevance in this stance as it applies today to biosimilars.

We thank HHS for the opportunity to communicate our perspectives regarding how FDA should approach nonproprietary names to biosimilar products. We appreciate HHS considering our comments on this important issue.

Sincerely,

American Pharmacists Association
National Association of Chain Drug Stores
National Community Pharmacists Association

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[1] WHO Informal Consultation on International Nonproprietary Names (INN) Policy for Biosimillar Products. Presentation from FDA. September 2006. http://www.who.int/medicines/services/inn/BiosimilarsINN_Report.pdf.

For additional information, please contact:

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