Bio
BIOTECHNOLOGY
INDUSTRY ORGANIZATION

PhRMA

June 25, 2012

Margaret A. Hamburg, M.D.
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg,

The Biotechnology Industry Organization (BIO) and Pharmaceutical Research and Manufacturers of America (PhRMA) appreciate the opportunities that the Food and Drug Administration (FDA) has provided this year for stakeholders to give input on a regulatory pathway for biosimilar and interchangeable biological products. Together, our associations represent hundreds of members involved in the research and development of biological products, with decades of experience that is crucial to understanding both innovative biological products and biosimilars. BIO and PhRMA believe it is important to emphasize one drug safety issue now facing FDA that is integral to the protection of patients who will be treated with biosimilar medicines.

Because a biosimilar or interchangeable biological product is highly similar to, but not the same as, its respective reference product, it would be inappropriate, from a patient safety perspective, to permit use of the same name for biological products that are not the same. Unique names will be necessary to ensure appropriate pharmacovigilance. Thus, it is essential that each biological medicine have a unique non-proprietary name.

Some stakeholders have recently raised concerns about the ability of existing pharmacy information technology systems to accommodate the use of unique names for biosimilars.[1] These concerns are misplaced and would jeopardize patient safety. First, existing systems should have the capability to accommodate the use of unique non-proprietary names for biologics. Second, if there are valid concerns that specific existing pharmacy systems lack the ability to capture the complete name of a product, then those systems need to be updated. Inadequacies of pharmacy IT systems should not be used as an excuse to jeopardize patient safety.

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[1] APhA, NACDS, and NCPA submission to Docket No. FDA-2011-D-0618, May 25, 2012.

When considering naming policies for biosimilar products, it is essential that the solution be viable in the long-term. Given that the determination of interchangeability is likely to occur as the second step of a two-step process (*i.e.*, following an initial approval as a biosimilar), a system that assigns unique names to all biologics at the time of market entry is the most straightforward approach that ensures that patient safety is protected, particularly as the market becomes more complex.

In the event that both biosimilar and interchangeable products are available for a single reference product, the need for unique names for all biological products becomes even more important. Interchangeability will only have been designated between one interchangeable biological product and one reference product – not any other product. Therefore, it will always be necessary to distinguish any biosimilar or interchangeable biological product from any other biological product by unique name such that regulatory determinations are respected and patient safety is protected.

We believe that FDA adoption of a system that assigns the same name to products that are similar, but not the same, would create confusion for physicians and patients and risk patient safety by hindering effective pharmacovigilance. We urge the FDA to consider these points as the Agency develops guidance on this issue.

Please let us know if you would like to discuss this important patient safety issue further.

Sincerely,

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