Memorandum of Meeting
GPhA
January 30, 2015
2:00pm to 2:30pm, CR 1215/White Oak Bldg. 51

SUBJECT: Meeting with GPhA to listen to their comments and views regarding the World Health Organization (WHO) biologic qualifier proposal

ATTENDEES:

GPhA
David Gaugh, Senior Vice President for Sciences and Regulatory Affairs

FDA
Robert Ball, Deputy Director, Office of Surveillance and Epidemiology, CDER
Sandra Benton, Senior Policy Analyst, Office of Medical Policy
Steven Kozlowski, Director, Office of Biotechnology Products, CDER
Diane Maloney, Associate Director for Policy, CBER
Christopher Pruitt, Associate Chief Counsel for Drugs, Office of Chief Counsel
Kellie Taylor, Deputy Director, Office of Medication Error Prevention & Risk Management
Maryll Toufanian, Associate Chief Counsel for Drugs, Office of Chief Counsel
Janice Weiner, Senior Regulatory Counsel, Office of Regulatory Policy, CDER

BACKGROUND:

GPhA requested this meeting to discuss a dialogue held at the October 14, 2014 World Health Organization (WHO) meeting regarding the WHO's biological qualifier proposal.[1] These issues relate to a citizen petition[2] submitted by GPhA, which is pending with FDA as of the date of the meeting. FDA stated that it was open to meeting with GPhA, but it would be a "listening session" (i.e., FDA would be unable to answer questions or expand on any issues beyond what is in the public domain and what we have stated in the published draft guidance documents). FDA also stated that the summary for this meeting will be posted in the public dockets for pending citizen petitions related to biosimilars nomenclature.[3]

DISCUSSION SUMMARY:

GPhA asked to meet with FDA to present its views on WHO's biological qualifier proposal and shared a copy of the presentation it presented at the October 14, 2014 WHO meeting.

[1] See http://www.who.int/medicines/services/inn/bq_innproposal201407.pdf
[2] See Docket No. FDA-2013-P-1153.
[3] See also Docket No. FDA-2013-P-1398 and FDA-2014-P-0077.

Highlights:

- GPhA has concerns that using a variation on the INN would frame biosimilars as a different product and could impact competition. GPhA noted that some healthcare payers are currently not allowing access to some biologics due to affordability (slide 3).
- GPhA noted that there are several factors that will influence a competitive biosimilar marketplace and naming is one of those factors (slide 4). It is understood that companies will need to market biosimilars to healthcare providers to encourage acceptance of these products.
- GPhA understands concerns regarding pharmacovigilance, just not why pharmacovigilance is such a priority for this one subset of products. Pharmacovigilance and patient safety are concerns for any medical product.
- GPhA re-emphasized the 5 identifiers for product recognition: brand name, company name, lot number, national drug code (NDC) in the U.S., and international nonproprietary name (INN) (slide 5).
- GPhA understands that many biosimilars will have brand names. However, for those products that currently have identifiers as part of the nonproprietary name, such as tbo-filgrastim and ado-trastuzumab emtansine, the databank systems are inconsistent in including these identifiers with the INN in the database file.
- GPhA is not in favor of the BQ, as the code system is not immediately recognizable. If one is going to use a qualifier, it should be an immediate qualifier (e.g., manufacturer name), rather than a code that needs to be looked up. Further, GPhA is concerned that identifiers may not be included in the database system entry. Most systems allow 28-32 characters in the nonproprietary name field. A technician, not a healthcare practitioner, would be expected to make the decision of how much of the nonproprietary name with the identifier to include in the field.
- GPHA expressed concern with the WHO proposal to have a qualifier to the INN for each drug substance manufacturing site. It is unclear which qualifier would take precedence or if multiple qualifiers were to be included with the INN.
- GPhA noted that biologic products are typically dispensed in a very controlled manner, and have detailed dispensing records, and that they could provide data to FDA on this point (Slide 8).
- GPhA ended by stating that several biological products on the market share the same INN, but concern has only been expressed regarding biosimilar products. Pharmacovigilance is important for all products.

WHO has scheduled a meeting on April 13, 2015 to discuss the biological qualifier proposal further and GPhA plans to attend.

Attachment