Memorandum of Meeting
Amgen and Actavis
November 18, 2014
3:00pm to 3:30pm, CR 415-F/Humphrey Bldg.

SUBJECT: Meeting with Amgen and Actavis to listen to their comments and views regarding biosimilars, including nonproprietary names of biological products.

ATTENDEES:

Amgen and Actavis
Dr. Steven Galson, Senior Vice President, Global Regulatory Affairs and Safety, Amgen
Dr. James Fenton, Vice President, U.S. Government Affairs, Actavis
Dr. Philip Ball, Director, Biologics Alliance Management and Government Affairs, Actavis
Kimberly Greco, Director of R&D Policy, Amgen
Dr. Gustavo Grampp, Director of R&D Policy, Amgen

HHS and FDA
Dr. Richard Frank, Assistant Secretary for Planning and Evaluation (ASPE), HHS
Laina Bush, Associate Deputy Assistant Secretary, HHS/ASPE/Office of Science and Data Policy
Amber Jessup, Senior Economist, HHS/ASPE
Teresa Manocchio, Special Assistant, HHS/ASPE
Janice Weiner, Senior Regulatory Counsel, FDA/CDER/Office of Regulatory Policy

BACKGROUND:

A meeting with Dr. Frank was requested on behalf of scientists and policy advisors from Amgen and Actavis to discuss their partnership on biosimilars and their thoughts on the biosimilars marketplace.

To the extent that this discussion involves issues raised by citizen petitions pending with FDA related to biosimilars nomenclature, HHS/FDA stated that it was open to meeting with Amgen and Actavis, but it would be a "listening session" (i.e., HHS/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answer questions or expand on any issues beyond what is in the public domain and what we have stated in the published draft guidance documents).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 a summary of this meeting will be posted in the public dockets for pending citizen petitions related to biosimilars nomenclature.[1]

DISCUSSION SUMMARY:

Amgen discussed its view that biologic medicines require product-specific pharmacovigilance, and that distinguishable nonproprietary names are the simplest solution, because they are the only shared data element in all records.

Amgen explained that product-specific pharmacovigilance is necessary to identify the company that manufactured the product at issue, and then the company can investigate (e.g., determine the manufacturing site that produced the specific product) and work to address any concerns.

[1] See Docket Nos. FDA-2013-P-1153, FDA-2013-P-1398, and FDA-2014-P-0077.

Amgen stated that the nonproprietary name is least likely to fail as an identifier because it exists everywhere. Other identifiers (e.g., bar codes) would need technology in each health care system and pharmacy, which may be challenging. In addition, immune reactions from biological products can take time to develop, and a patient or healthcare provider may no longer have the biological product packaging at the time of reporting the adverse reaction. Actavis further noted that multiple identifiers associated with a biological product provide redundancy, which may reduce incorrect assignment of an adverse reaction to the suspected product.

Amgen also discussed its view that distinguishable nonproprietary names do not deter uptake, as evidenced by data from Australia and Japan. Actavis further noted that different interpretations of the same data reflect the various factors that may affect uptake of biosimilars, and it would be difficult to show a direct impact due to nonproprietary naming. Amgen explained that uptake of biosimilar products in the United States is expected to be driven by formulary placement and factors other than the nonproprietary name.

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