Occasional Information Note July 2010

Dear ECONMED participants:

Within ECONMED's occasional information initiative we are pleased to transmit the most recent developments in the field of regulation of biological products in the US resulting from the health reform finally approved last march.

We encourage ECONMED participants to share the status of regulation of biological and biotechnological products in their respective national realities. We will be distributing shortly the summary and conclusions of the first session of working group on biological/biotechnological products of the Pan American Network on Drug Regulatory Harmonization (PANDRH) held in Punta Cana, DOR between June 15th-17th

US: Biologics Price Competition and Innovation (BPCI) Act of 2009

The Patient Protection and Affordable Care Act (PPAC Act), signed into law by President Obama on March 23, 2010, amends the Public Health Service Act (PHS Act) to create an abbreviated approval pathway for biological products that are demonstrated to be "highly similar" (biosimilar) to or "interchangeable" with an FDA-approved biological product. These new statutory provisions also may be referred to as the Biologics Price Competition and Innovation Act of 2009 (BPCI Act).

Immediately after the new statute was enacted, FDA formed a working group, the Biosimilar Implementation Committee, to plan the agency's approach to implementing the statute in order to ensure that the process of evaluation, review and approval of products within this newly-defined product category, will be achieved in a consistent, efficient and scientifically sound manner.

The Biosimilar Implementation Committee (BIC) will be co-chaired by the director of the Center for Drug Research and Evaluation (CDER) and the acting director of the Center for Biologics Evaluation and Research (CBER). In addition to CDER and CBER staff, this cross-center group also has members from the Office of Chief Counsel and the Office of the Commissioner. Two review committees have also been chartered; the CDER Biosimilar Review Committee and the CBER Biosimilar Review Committee. Both groups will have members from both centers and will address product-specific review and issues relating to scientific methodology.

The BIC has been deeply engaged in the work of evaluating the statute and planning the necessary steps toward implementation. Among other things the scope of this work includes: budget planning, policy development, resource evaluation and needs assessment.

The committee intends to hold public meetings in order to solicit comment from stakeholders, experts, innovators, patients and all members of the public who wish to express their point of view. In addition, the committee is in the process of considering how best to provide clarification on the policies and processes which will be used in the evaluation and approval process.

The goal of the BPCI Act is similar, in concept, to that of the Drug Price Competition and Patent Term Restoration Act of 1984 (a.k.a the "Hatch-Waxman Act") which created abbreviated pathways for the approval of drug products under Federal Food, Drug, and Cosmetic Act (FFD&C Act). **The BPCI Act aligns with the FDA's longstanding policy of permitting appropriate reliance on what is already known about a drug, thereby saving time and resources and avoiding unnecessary duplication of human or animal testing.** Under the BPCI Act, a sponsor may seek approval of a "biosimilar" product under new section 351(k) of the PHS Act. A biological product may be demonstrated to be "biosimilar" if data show that the product is "highly similar" to the reference product notwithstanding minor differences in clinically inactive components and there are no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency.

In order to meet the higher standard of interchangeability, a sponsor must demonstrate that the biosimilar product can be expected to produce the same clinical result as the reference product in any given patient and, for a biological product that is administered more than once, that the risk of alternating or switching between use of the biosimilar product and the reference product is not greater than the risk of maintaining the patient on the reference product. **Interchangeable products may be substituted for the reference product by a pharmacist without the intervention of the prescribing health care provider**.

This Communications is a translated and edited (with hyperlinks to legal references and backgrounds) referred by Dr. Moises Mendez Mondragon to the listserv *dialogosfarmaops*, whom we would like to thank. Link to the original communication:

http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/ucm215089.htm