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Janssen Pharmaceutical Companies of Johnson & Johnson Submit Citizen Petition to the U.S. FDA Regarding Naming of Biosimilars

Ask Agency to require that biosimilars bear distinguishable names to enhance patient safety

Washington, D.C. (January 8, 2014) – The Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen) today submitted a Citizen Petition to the U.S. Food and Drug Administration (FDA) asking the agency to require biosimilars to bear nonproprietary names that are similar to, but not the same as, those of their reference products or of other biosimilars. The Petition states that distinguishable names are essential for enhancing patient safety and to ensure effective pharmacovigilance.

"Ensuring biosimilars bear distinguishable names is of critical importance for patient safety," said Jay P. Siegel, M.D., Chief Biotechnology Officer and Head, Scientific Strategy and Policy, Johnson & Johnson. "Names that are similar but not the same will appropriately reflect the legal and scientific reality that biosimilars are similar to but not the same as their reference products or other biosimilars."

As FDA continues to implement the Biologics Price Competition and Innovation Act, the question of how biosimilars will be named must be addressed. This question is currently being evaluated and will be addressed by the World Health Organization (WHO) and health authorities around the world. Janssen submitted its Citizen Petition to communicate the company's position that requiring distinguishable names for biosimilars is critical for the safety of patients globally.

According to the Janssen Citizen Petition, the naming of biosimilars could have important patient safety implications beyond the name itself, including pharmacovigilance, product switching and extrapolation of indications. Patients, their physicians and regulatory authorities such as the FDA need to know precisely which biological product has been used to distinguish it from other similar products and ensure effective pharmacovigilance. Additionally, some biosimilars will likely not be approved for all approved uses of the reference product so shared names will increase the probability that patients are treated with a drug that is neither approved nor scientifically demonstrated to be safe and effective for the intended use.

"Our own experience with EPREX®/ERYPO® (epoetin alfa) has informed our views and highlights important considerations concerning the naming of biosimilars," said Dr. Siegel. "These considerations include the need for reliable pharmacovigilance mechanisms for detection and investigation of postmarketing safety signals, the importance of the ability to identify precisely which product a patient has received and the risks associated with inadvertent switching between products," he said.

"We have a long history of supporting efforts to establish an approval pathway for biosimilars that is in the best interest of patient safety," said Dr. Siegel. "While we fully appreciate efforts to address the need to expand access to safe and affordable medicines – including therapeutic biologics - the standards and policies applied to biosimilars must place a high priority on assuring patient safety and welfare," he added.

About Janssen
At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people with serious diseases throughout the world. Beyond its innovative medicines, Janssen is at the forefront of developing education and public policy initiatives to ensure patients and their families, caregivers, advocates and healthcare professionals have access to the latest treatment information, support services and quality care.

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