BIOSIMILARS LABELING

U.S. Food and Drug Administration (FDA)-approved prescription drug labeling is the most authoritative mechanism for communicating information about a medicine's safety and effectiveness to health care providers. The approved labeling summarizes key scientific information about a medicine that health care providers need to assess its benefit-risk profile and determine if the medicine is appropriate for use in treating a particular patient.

PhRMA's Support of the Biologics Price Competition and Innovation Act (BPCIA)

In 2010, Congress approved the BPCIA which created an abbreviated approval pathway for biosimilars and provided 12 years of data protection for biologics. The legislative intent was to balance increased competition from biosimilar products with the need to provide biopharmaceutical researchers with certainty to make long-term research and development decisions and support future medical innovation.

PhRMA supported the enactment of the BPCIA and has actively participated in FDA's ongoing efforts to implement the statute. PhRMA's consideration of biosimilar policies is guided by our support for:

- **Science-based implementation** of the BPCIA and regulatory decision-making;
- **Patient safety** through effective identification of biologics and robust pharmacovigilance;
- **Health care provider and patient choice** in prescribing;
- **Regulatory transparency** that enables stakeholders to understand the basis for FDA's decisions; and;
- **Long-term stability of the biosimilar user fee program** through financial transparency, efficiency and accountability.

PhRMA believes that FDA Should Adopt an Approach to Biosimilar Labeling that Provides Regulatory Transparency to Facilitate Informed Choices by Health Care Professionals and Patients

In order to facilitate patient-centric prescribing and choice, PhRMA believes that biosimilar labeling should provide appropriate regulatory transparency, including a statement of biosimilarity, a description of the nonclinical and clinical data supporting the biosimilar's approval, a description of the basis of approval for each indication, and a statement regarding whether or not FDA has made a determination of interchangeability with the reference product and the result of that finding. FDA-approved biosimilar labeling that includes these approaches will facilitate informed prescribing and protect against inadvertent substitution.

PhRMA's Recommendations for FDA-approved Biosimilar Labeling Should do the Following:

- State that the product has been approved as a biosimilar for stated indications and routes of administration and identify the reference product;
- Describe the basis of approval for each indication by identifying the relevant data for the reference product and biosimilar that support a finding of biosimilarity; and
- State whether or not FDA has made a determination of interchangeability with the reference product and include any such FDA finding.

PhRMA believes that, from a patient and health care professional perspective, this proposed approach to biosimilar labeling is best given the fact that biosimilars are similar to, but not the same as, their reference products.