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To be completed by the Office of the Secretary of the House of Delegates

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American Pharmacists Association
House of Delegates – Baltimore, MD
March 4 - 7, 2016

NEW BUSINESS

(To be submitted and introduced by Delegates only)

Introduced by: Elise Barry for the New Jersey Pharmacists Association
(Name)

01/21/16 **(Date)**

New Jersey Pharmacists Association **(Organization)**

Subject: Biotechnology

Motion: Move to adopt the following policy statement:

APhA supports legislation or regulation that requires all phases of clinical data on biosimilar and small molecule generics to be made available on clinicaltrials.gov and published in peer reviewed and retrievable literature.

Background:

Biologics are complex, biotechnology-derived drugs that originate from living sources. These biologics are often difficult to replicate due to their complex nature. "A biosimilar product is a biological product that is approved based on a showing that it is highly similar to a Food and Drug Administration (FDA) approved biological product, known as a reference product, and has no clinically meaningful differences in terms of safety and effectiveness from the reference product. Only minor differences in clinically inactive components are allowable in biosimilar products.[1]" It is also important to note that biosimilars may not carry all of the indications that the reference biologic does. Biologics differ from small molecule drugs in size and complexity. Generic versions of small molecule drugs are identical in structure to the reference drug, whereas biosimilars are not identical in structure to reference products.

An interchangeable product is biosimilar to a reference product and can be expected to produce the same clinical effect as the reference product.[1] Interchangeable products may be substituted at the pharmacy if the FDA has determined the product interchangeable and the appropriate state law allows such rights to the pharmacist. The topic of interchangeability and substitution is left to state pharmacy laws regarding biosimilars. "FDA must find a biosimilar to be interchangeable with its reference product if the information submitted by the biosimilar applicant demonstrates that:
The applicant's product is biosimilar to the reference product (under the law's standard for biosimilarity)
The applicant's product can be expected to produce the same clinical result as the reference product in any given patient.[2]"
Access to clinical trial data in regards to biosimilars and interchangeable products would be imperative in formulating these substitution decisions.

Clincaltrials.gov is one of the largest public registries for clinical research studies. It was established in 2009 in order for clinical trials to publish their basic results. It allows public access to data including participants and their characteristics, overall limitations, outcome measures, adverse events, and more. The results summary is made available no later than 1 year after the trial completion date.

It is important for health care providers to have access to biosimilar clinical trials for a variety of reasons. "The "Purple Book" lists biological products, including any biosimilar and interchangeable biological products licensed by FDA under the Public Health Service Act (PHS). The lists include the date a biological product was licensed under the PHS Act and whether FDA evaluated the biological product to the reference product. The Purple Book will also enable a user to see whether a biological product licensed has been determined by FDA to be biosimilar to or interchangeable with a reference biological product. Biosimilar and interchangeable biological products licensed under the PHS Act will be listed under the reference product to which biosimilarity or interchangeability was demonstrated.[3]" If the information needed is not provided within the purple book, pharmacists and other health care providers need a reliable resource. The information on biosimilar safety, efficacy, pharmacokinetic, and pharmacodynamic data contained in clinical trials can be advantageous in the decisions regarding interchanging products. It is inappropriate to assume similar adverse events with biosimilars and their reference product as you may have been able to with small molecule drugs and their generics.

The significance in obtaining clinical trial data for biosimilars is the concern in efficacy and safety in the products dependent on small changes in the development. "Examples of changes include alterations in the product's isoforms, three-dimensional protein structure, quantity of acid-base variants, and glycosylation profile. Changes such as these, which often are due to variability in source materials, cell line used, extraction and purification processes, and scale changes, may result in alterations in clinical efficacy and safety.[4]" Since biosimilars are not identical to the reference product, more information is needed on their efficacy, safety, and overall clinical trial data.

Currently, Section 801 of the Food and Drug Administration Amendments Act mandates the registration with ClinicalTrials.gov of certain clinical trials including those of biological products.[6] Transparency of clinical trials and registry to clinicaltrials.gov is important because it allows others to determine whether the study is appropriate according to their concern, if the integrity of the trial was maintained based on their protocol, and it allows efficient allocation of resources. Therefore, it would be appropriate to include biosimilar clinical trial data onto clinicaltrials.gov database.

References

1. "Biosimilars" *U.S. Food and Drug Administration.* 2015
2. Bogaert, P., Lietzan, E., Sim, L. "Biosimilar Regulation: Important Considerations and Global Developments" *Life Sciences Handbook.* 2011
3. "Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations" *U.S. Food and Drug Administration.* http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm. Accessed 01/21/2016.
4. Alten, R., Cronstein, B. "Clinical Trial Development for Biosimilars" *Seminars in Arthritis and Rheumatism.* 2015; 44 (52-58).
5. "Information on Registering and Reporting Results of Clinical Trials" *Protocol Registration and Results System.* https://prsinfo.clinicaltrials.gov/. Accessed 01/09/2016.
6. "Understanding Key Differences Between Biosimilars and Small Molecule Generics" *Pharmacy Practice News.* 2013.
7. http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/ucm411418.htm

Current APhA Policy & Bylaws:

2012, 2007 Biologic Drug Products

1. APhA encourages the development of safe, effective, and affordable therapeutically equivalent generic/biosimilar versions of biologic drug products, including clinical trials that assess safety.

2. APhA encourages the FDA to develop a scientifically based process to approve therapeutically equivalent generic/biosimilar versions of biologic drug products.

3. APhA should actively support legislation to hasten the development of an efficient regulatory process to approve therapeutically equivalent generic versions of biologic drug products.

4. APhA should initiate educational programs for pharmacists and other health care professionals concerning the determination of therapeutic equivalence of generic/biosimilar versions of biologic drugs products.

(JAPhA NS45 (5):580 September-October 2007)) (JAPhA NS52(4) 458 July/August 2012)

2005 Public Access to Clinical Trials Data

APhA supports access by healthcare professionals and the public to all clinical trial data derived from scientifically valid studies. APhA supports the establishment of a single, independent, publicly accessible clinical trials database that includes but is not limited to the following components: (a) includes all studies, pre and post drug approval, throughout the research period (whether completed, in-progress or discontinued) (b) clearly states the size, demographics, limitations and citations, if published, of each study listed (c) includes an interpretative statement by an independent review body regarding the purpose of the study, methodology and outcomes to assist the public in understanding the posted information in a timely manner (d) includes warnings to the public regarding inappropriate or incomplete use of the data in making clinical decisions in absence of an interpretive statement (e) the sponsor and any supporting company, organization, or partnered institution of each clinical trial listed shall be clearly identified. (This includes Clinical Research Organizations, Academic Research Organizations, Site Management Organizations or any other group that is responsible other than the investigator's research site.)

(JAPhA NS45(5):554-555 September/October 2005) (Reviewed 2009)(Reviewed 2014)

New Business Items are due to the Speaker of the House by **February 3, 2016** (30 days prior to the start of the first House session). Consideration of urgent items can be presented with a suspension of the House Rules at the session where New Business will be acted upon. Please submit New Business Items to the Speaker of the House via email at hod@aphanet.org.