June 2, 2015

Dr. Raffaella G. Balocco Mattavelli, Group Lead INN,
International Nonproprietary Name (INN) Programme,
HIS/EMP/RHT/TSN,
World Health Organization,
20, Avenue Appia, CH-1211 Geneva 27, Switzerland

RE: Front Page Meeting with INN Stakeholders
Biologics Qualifier Comments Review

Dear Dr. Balocco Mattavelli,

The Lupus and Allied Diseases Association, Inc., is a passion driven, all-volunteer patient advocacy organization based in the United States. We are dedicated to improving quality of life for those impacted by lupus and allied diseases and conditions of unmet need by fostering collaboration among all stakeholders and promoting innovative advocacy, awareness and biomedical research program initiatives. We thank you for inviting input from the patient advocacy community and greatly appreciate the opportunity to provide remarks concerning the naming of biologics as part of the June 16th Front Page meeting with INN Stakeholders to review Biologics Qualifier comments.

Unlike small molecules, biologics are extremely complex large molecules patterned after human tissue and cells that have the ability to target the underlying cause of some diseases. They have advanced with each generation; evolving from proteins that are naturally-occurring to monoclonal, and eventually to polyclonal and fusion proteins. Biosimilar drugs hold tremendous promise and therapeutic advantages for lupus and autoimmune patients just as biologic medicines have for millions of individuals living with life-threatening and life-diminishing diseases. As biosimilars become available in the United States we want to ensure they are safe, efficacious, accessible, and affordable. We must remain vigilant in protecting patient safety while promoting unfettered access to vital and effective treatments.

Our organization is a proud member of Patients for Biologics Safety and Access (PBSA), a patient-driven collaboration comprised of 21 leading U.S. patient advocacy organizations dedicated to protecting patient access to safe and effective biologic medicines. As biosimilar drug regulation standards are finalized in the United States and throughout the world, we want to ensure that patient safety is the utmost priority and critical protections are put in place that include a robust system for reporting and tracking adverse events. We have urged the U.S. Food and Drug Administration (FDA) to issue a clear policy requiring distinguishable non-proprietary names for all biologic medicines, including biosimilars. Therefore, we ask the World Health Organization to ensure that its Biologics Qualifier assignment system provides for clearly identifiable distinct non-proprietary naming for all biologics, including biosimilars.

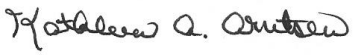
Utilizing discernible non-proprietary names provides much-needed transparency by enabling better safety monitoring via tracking the therapy and tracing the product, promoting timeliness in addressing potential adverse events, and providing physicians with more information to recognize which products are likely to be safer or more effective in a specific patient. Given the vast differences between chemical compounds and biologics, we request that all biologics, including biosimilars, carry distinguishable non-proprietary names. This will avoid confusion with the original reference product and ensure accurate physician-patient communication, as well as reliability in the prescribing, dispensing and compliance processes of specific therapies and better guarantee accurate post-marketing surveillance.

Furthermore, having distinguishable non-proprietary names is paramount in identifying exactly which medicine was received if an adverse event occurs since biologics and biosimilars in reality will be administered to patients suffering from serious, life-threatening diseases who take many concomitant medications and are not in a controlled clinical study.

We strongly believe that applying unique non-proprietary names will create clarity, facilitate prompt and accurate association between adverse events and specific products, and thereby maintain drug manufacturer accountability for their product and enable the healthcare community to better address any potential adverse events. We implore adoption of a final WHO policy that requires distinguishable names for all biological medications thus ensuring accurate tracking of medication utilization and adverse events, and facilitating transparency.

In closing, we would like to thank you for the opportunity to share our patient perspective as you evaluate the naming of biologics and applaud you for recognizing the importance of the patient voice, especially since we are the sole stakeholders who will be taking and experiencing the benefits/risks of these new drugs. Please contact Kathleen Arntsen at 315-264-9101 or lupuskaa@aol.com if you have any questions.

Respectfully submitted,



Kathleen A. Arntsen
President/CEO