

**The National Coalition of Autoimmune Patient Groups (NCAPG) represents AD patients at the United Nations World Health Organization (WHO) conference**

United Nations World Health Organization (WHO) held a meeting at its Geneva, Switzerland, headquarters, June 16, 2015, on International Nonproprietary Names (INN) Biological Qualifiers (BQ) to continue its development of a worldwide accepted naming convention for biologic and biosimilar drugs.

The National Coalition of Autoimmune Patient Groups (NCAPG) was represented at the meeting by Richard Hodge, member of the American Autoimmune Related Disease Association (AARDA) board of directors. Other healthcare organizations, provider groups, the media, and various regional and national organizations also attended the meeting.

The National Coalition of Autoimmune Patient Groups has the mission to consolidate the voice of autoimmune disease patients and to promote increased education, awareness, and research into all aspects of autoimmune diseases through a collaborative approach. NCAPG is supported and facilitated by AARDA and is composed of 37 autoimmune disease patient groups.

In March the NCAPG sponsored a congressional briefing on biosimilars.

AARDA submitted comments to the WHO INN BQ Expert Group earlier this year emphasizing major patient safety concerns that endanger AD patients—given the complexity of biologic medicines, their potential for causing serious adverse reactions and the long-term potential consequences for patients. AARDA’s comments continued, that biologics are not identical to one another and shared non-proprietary names create the potential for ambiguity that could lead to inadvertent and inappropriate substitutions. AARDA concluded addressing biosimilar pharmaceuticals, “distinguishable product identification is essential.”

The new generation of biologic pharmaceuticals and biosimilars now coming to market offer autoimmune disease patients the best hope yet. Biologics are complicated drugs developed from living tissue. Biologics are comprised of complex molecules that are very complicated to replicate and difficult to compare. The characteristics of biologics and biosimilars, similar to generic versions of simpler inorganic compounds, are highly dependent upon the manufacturing process in addition to the ingredients. Because of the complexity and the importance of the manufacturing process, it's critically important to be able to identify and track the manufacturer and the manufacturing site of biosimilars.

The purpose of the WHO meeting was to explain the INN BQ Expert Group proposal process, the proposal development thus far, discuss the latest round of comments received, and explain the rationale for the current proposal. The meeting was attended by approximately 45 in person and many more on the WebEx. The BQ Expert Group has published a new Biological Qualifier Proposal draft based on the numerous comments received.

Representatives of the WHO Secretariat and INN BQ Expert Group explained in detail the reason for and history of the proposed INN BQ, and the status of the proposal. In accordance with the current WHO proposal, the assignment of an INN BQ to a "biological active substance" would be done by the WHO upon application and the BQ would not have any impact on the INN itself or be a part of the INN itself but a suffix. BQs, as currently proposed, would apply to all biologics not just biosimilars. The current Expert Group proposal is to include after the biosimilar's name a four digit alpha code (with no vowels or numbers) indicating the BQ applicant and site of manufacture. Also being considered is a fifth digit verification digit. BQs could include manufacturer, chemical variants, trade names, etc. BQ could track variations in amino acid sequence. The BQ once assigned would remain the same for the life of the product. The BQ applicant would be the same worldwide.

WHO itself has no regulatory authority in the individual countries to enforce the final INN BQ proposal. National compliance with the final proposal will be voluntary based on decisions of the many national regulatory agencies around the world to embrace the final WHO proposal. At this point, the national regulatory agencies have not committed to using the BQs but it is anticipated that they will when the final proposal is released.

The WHO INN BQ Expert Group is being extremely collaborative and inclusive to ensure optimal acceptance and adoption of the final proposal by as many national regulatory agencies around the world as possible. The universal adoption of the BQ for all biologics and biosimilars is essential to protection of patients around the world.

The next step is for the WHO BQ Expert Group to publish yet another draft proposal incorporating the latest round of comments and proposals and to hold additional discussions most likely in October 2015 and the National Coalition of Autoimmune Patient Groups and AARDA will continue carefully monitoring the developing proposal on behalf of all AD patients.