



USAN Program and Biosimilar Nomenclature

The USAN Council supports the policy that innovator biological drugs should share the same USAN and INN with the follow-on biological product (biosimilar drugs). We trust that the regulatory authorities in the United States will be able to accurately determine the efficacy and quality of the biosimilar drugs and will be able to provide pharmacovigilance of all biologic and similar biologic drugs prescribed. However, we understand that in some markets, pharmacovigilance activities may not be robust and we would support the INN Biological Qualifier (BQ) proposal, and in particular the principle that the BQ should apply to all biologics and be kept in a database and not published as part of the nonproprietary name.

The USAN Council pledges to work with its partners, the AMA, USP and APhA and with the FDA and the INN to continue to develop a global approach to the naming of all biologicals not just biosimilars that is built on and consistent with existing, accepted scientific principles critical to supporting a globally relevant approach to the quality assessment of biological drugs.