Changes to International Nonproprietary Names for antibody therapeutics 2017 and beyond: of mice, men and more.

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Abstract:
Active pharmaceutical substances require an International Nonproprietary Name (INN) assigned by the World Health Organization (WHO) to obtain market authorization as a medicinal product. INNs are selected to represent a unique, generic name for a drug enabling unambiguous identification by stakeholders worldwide. INNs may be requested after initiating clinical development of an investigational drug. Pharmaceutical classes are indicated by a common stem or suffix. Currently, INNs for monoclonal antibody-based drugs are recognized by the suffix, -mab, preceded by a source infix such as -xi- (chimeric), -zu- (humanized) or -u- (human) designating the species from which the antibody was derived. However, many technological advances have made it increasingly difficult to accurately capture an antibody’s source in its name. In 2014, the WHO and the United States Adopted Names (USAN) Council approached this challenge by implementing changes to antibody source infix definitions. Unfortunately, gaps and ambiguities in the definitions and procedures resulted in inconsistent source category assignments and widespread confusion. The Antibody Society, extensively supported by academic and industry scientists, voiced concerns leading to constructive dialog during scheduled consultations with WHO and USAN Council representatives. In June 2017, the WHO announced that use of the source infix will be discontinued for new antibody INNs effective immediately. We fully support this change as it better aligns antibody INNs with current and foreseeable future innovations in antibody therapeutics. Here we review the changes implemented. Additionally, we analyzed antibody INNs recently assigned under the previous 2014 definitions and provide recommendations for further alignment.

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