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

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Recommendations:

Very Good 07 Mar 2018

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GOOD FOR TEACHING | REVIEW / COMMENTARY

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Giving generic names to drugs (in this case antibody-based drugs) may seem a dry topic. However, it is hugely important that appropriate names are selected that are sufficiently distinct and memorable to avoid prescribing errors while also avoiding commercial advantages (such as clear clinical indications) or disadvantages (such as being difficult to pronounce, or rude, in some languages). Antibodies are estimated to make up approximately 33% of drugs in development and about 25% of all drugs that get as far as being issued an International Nonproprietary Name (INN). The paper describes the problems of the naming scheme used up until 2017 and its challenges given the huge number of antibodies for which names are required. One component of the name (the 'source infix') described in just one or two letters how the antibody was produced (with the implication that this may have some relevance to immunogenicity). As the paper describes, the way this was assigned led to increasing controversy as well as difficulty in the light of complex methods used in therapeutic antibody creation, leading to this component of the name being dropped. This has opened up the available name space for new antibody names.

Disclosures

I am a member of the WHO International Nonproprietary Name (INN) committee which allocates names to biologics including antibodies.

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Abstract:

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,... more »

-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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Comments: