INN Working Document 09.251 Revised
Distr.: PUBLIC
ENGLISH ONLY
18/12/2009

General policies for monoclonal antibodies

The International Nonproprietary Names (INN) Programme is a core activity embedded in the normative functions of the World Health Organization (WHO) and has served the global public health and medicines community for over fifty years. The biotechnology market is expanding throughout many regions of the world with many new and innovative medicinal products reaching the clinical trials stage of development. Among these are monoclonal antibodies (mAbs).

In October 2008, International Nonproprietary Names (INN) Working Group Meeting on Nomenclature for Monoclonal Antibodies (mAb) was convened by WHO to review the mAb group and to streamline the mAb nomenclature scheme. The meeting involved participation of experts in nomenclature as well as those in biologicals, biotechnology and regulators. The meeting report was published.

Based on the recommendations of this meeting, a revised version of "General policies for monoclonal antibodies", containing the updated mAb nomenclature scheme, was prepared and made publicly available for comments (deadline 30.9.2009). No negative comments were received, hence the INN Expert Group adopted the revised version of "General policies for monoclonal antibodies" during the 49th INN Consultation (17-19 November 2009, Geneva).

Programme on International Nonproprietary Names (INN)
Quality Assurance and Safety: Medicines (QSM)
Essential Medicines and Pharmaceutical Policies (EMP)
World Health Organization (WHO), Geneva

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General policies for monoclonal antibodies

- INN for monoclonal antibodies (mAbs) are composed of a prefix, a substem A, a substem B and a suffix.
- The common stem for mAbs is *-mab,* placed as a suffix.
- The stem *-mab* is to be used for all products containing an immunoglobulin variable domain which binds to a defined target.
- Substem B indicates the species on which the immunoglobulin sequence of the mAb is based:

a	rat
axo (pre-sub-stem)	rat/mouse
e	hamster
i	primate
o	mouse
u	human
xi	chimeric
-xizu- (under discussion)	chimeric/humanized
zu	humanized

The distinction between chimeric and humanized antibodies is as follows:

A chimeric antibody is one that contains contiguous foreign-derived amino acids comprising the entire variable domain of both heavy and light chains linked to heavy and light constant regions of human origin.

A humanized antibody has segments of foreign-derived amino acids interspersed among variable domain segments of human-derived amino acid residues and the humanized variable heavy and variable light domains are linked to heavy and light constant regions of human origin.

The *–xizu-* infix is used for an antibody having both chimeric and humanized chains.
The *-axo-* infix is used for an antibody having both rat and mouse chains.

- Substem A indicates the target (molecule, cell, organ) class:

-b(a)-	bacterial
-c(i)-	cardiovascular
-f(u)-	fungal
-k(i)-	interleukin
-l(i)-	immunomodulating
-n(e)- (under discussion	neural
-s(o)-	bone
-tox(a)	toxin
t(u)	tumour
-v(i)-	viral

In principle, a single letter, e.g. *-b-* for bacterial is used as substem A. Whenever substem B starts with a consonant (e.g. x or z), to avoid problems in pronunciation, an additional vowel indicated in the table, e.g. *-ba-* is inserted.

Prefix

The prefix should be random, e.g. the only requirement is to contribute to a euphonious and distinctive name.

Second word

If the product is radiolabelled or conjugated to another chemical, identification of this conjugate is accomplished by use of a separate, second word or acceptable chemical designation. For instance, for mAbs conjugated to a toxin, the suffix *-tox* can be used in the second word.

If the monoclonal antibody is used as a carrier for a radioisotope, the latter will be listed first in the INN, e.g. *technetium (99mTc) nofetumomab merpentan (81)*.

The prefix *peg-* can be used for pegylated mAbs, but this should be avoided if it leads to over-long INN. In most cases, it is best to adopt two-word INN for pegylated mAbs, with the first word describing the mAb and the second being pegol or a related designation.

References

1. World Health Organization. International Nonproprietary Names (INN) Working Group Meeting on Nomenclature for Monoclonal Antibodies (mAb), Geneva, October 2008, Meeting report, INN Working Document 08.242 *

2. World Health Organization. International Nonproprietary Names (INN) for biological and biotechnological substances (a review), INN Working Document 05.179, update November 2009*

3. World Health Organization. The use of stems in the selection of International Nonproprietary Names (INN) for pharmaceutical substances, 2009, *WHO/PSM/QSM/2009.3**

** These documents are available on the INN Programme Website at: http://www.who.int/medicines/services/inn/en/index.html*