



Guidance on the establishment of new INN stems

Programme on International Nonproprietary Names (INN)

Quality Assurance and Safety: Medicines (QSM) Medicines Policy and Standards (PSM) World Health Organization Geneva

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Guidance for INN applicants with regard to the establishment of new INN stems

In recent years a trend has been observed whereby manufacturers applying for an INN¹ increasingly request the establishment of a new INN stem for substances for which they claim a novel mode of action or a new therapeutic approach. This issue has been extensively discussed among the INN Expert Group at various consultations and, at the 44th INN Consultation held in May 2007, it has been decided to provide manufacturers and national nomenclature authorities with a guidance paper concerning the establishment of new INN stems.

The INN stem system is operating according to the WHO Executive Board resolution EB15.R7 (as amended by the resolution EB115.R4), which requests that "*a group relationship of pharmacologically related substances should, if possible, be shown in the name by using a common stem.*" A stem is a syllable (or 2-3 syllables) inserted to the new INN, in most cases as a suffix, to indicate the pharmacological relationship. The INN Programme publishes every two years² a document containing extensive information about the INN stem system and the complete INN stem lists: "*The use of stems in the Selection of International Nonproprietary Names for Pharmaceutical Substances*", which is complemented twice a year, after each INN Consultation, by an Addendum³ listing newly selected pre-stems and former pre-stems promoted to stems.

During the 44th INN Consultation, the INN Expert Group agreed that an excessive number of new stems would limit considerably the ability of creating new distinctive INNs, and thus endanger basic aims of any nomenclature system by diminishing its usefulness to healthcare practitioners. Distinctive INNs contribute to the safety of drug prescription and dispensation by excluding any confusion that may arise among INNs and with other well-established drug names, especially T/M names.

Moreover, as the World Health Assembly requested Member States in its resolution WHA 46.19 "*to discourage the use of trade names derived from or including established INN stems*", an undue proliferation of INN stems would also impact adversely on the ability to coin future T/Ms.

Therefore, the INN Programme confirms its present policy of using existing stems whenever possible and of establishing new INN stems only in those cases where a group of at least several new substances shows a confirmed novel mode of action.

For a new stem to be established, the INN applicant will have to submit substantial clinical and preclinical data documenting that the new substances do not fit at all into existing nomenclature schemes and that such a new stem is warranted. The same documentation needs shall apply for the informal pre-stem list, an existing intermediate stage of the INN stem establishment process, containing syllables included in new INNs for which a specific mode of action is claimed.

¹ either directly or through institutions involved in the establishment of national nonproprietary names for pharmaceutical substances collaborating closely with the INN Programme, such as the United States Adopted Names Council

² hardcopy and website <http://www.who.int/medicines/services/inn/publication/en/index.html>

³ website only <http://www.who.int/medicines/services/inn/publication/en/index.html>