

The use of stems in the selection of International Nonproprietary Names (INN) for pharmaceutical substances

2011



**World Health
Organization**

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PREFACE

The document *"The Use of Common Stems in the Selection of INNs"* is intended primarily for persons and companies applying to the WHO INN Programme for the selection of an INN for a new pharmaceutical substance and has been designed to assist in the process of devising a suitable proposal. It will also be of assistance to institutions and specialists involved in the review of proposed INNs, including drug regulatory authorities, pharmaceutical manufacturers, patent offices and trade mark officers as well as for scientists, teachers, health professionals and other persons interested generally in drug nomenclature. The document is composed of four main parts and annexes.

Part I *"Introduction"* describes the WHO INN Programme, INN selection procedure, and criteria for name selection and gives general information on the INN stem system.

Part II contains the list of all INN stems. It is composed of two indexes, one entitled *"Alphabetical List of Common Stems"* which presents the list of stems, and another entitled *"Alphabetical List of Common Stems and their definitions"* which includes a definition for each stem.

Part III presents the stem classification system used by the INN Programme to categorize the main activity of pharmaceutical substances. Each category included in the list is given an appropriate code consisting of a capital letter and three digits. When INNs for substances belonging to a given category include a specific stem, appropriate information is included in the table.

Part IV of the document entitled *"Alphabetical List of Stems Together With Corresponding INNs"* serves as a listing of all proposed INNs (published in lists 1 - 105) containing INN stems. The list is organized in alphabetical order (as set out in Part II) and includes all INNs containing individual stems. In addition, under each stem heading information is given on INNs in which the preferred stem has been used but not in accordance with its definition as well as on INNs which belong to the same group of pharmaceutical substances but in which no preferred stem has been used. To facilitate the use of Part IV, the lay-out of information is presented as a diagram on page 6 and is complemented by additional information given at the end of part I *"Introduction"*.

Six annexes attached to the document are intended to be of assistance to users. Annex 1 reproduces the *Procedure for the Selection of Recommended International Nonproprietary Names for Pharmaceutical Substances* as approved by the WHO Executive Board in its resolution EB15.R7 as amended by resolution EB115.R4. Annex 2 reproduces *General Principles for Guidance in Devising International Nonproprietary Names for Pharmaceutical Substances* as approved by the WHO Executive Board in the above-mentioned resolution, as amended. Annex 3 explains the nomenclature scheme for monoclonal antibodies. Annex 4 explains the nomenclature scheme for Gene Therapy Products. Annex 5 gives reference to the volumes of the *WHO Drug Information* in which proposed lists of INNs have been published. Annex 6 *"Why INN?"* gives general information on the present situation of WHO INN Programme and its achievements.

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PART I

INTRODUCTION

WHO'S INN PROGRAMME

The World Health Organization (WHO) has a constitutional responsibility to "develop, establish and promote international standards with respect to biological, pharmaceutical and similar products". The International Nonproprietary Names (INN) Programme is a core activity embedded in the normative functions of WHO and has served the global public health and medicines community for over fifty years. The Programme was established to assign nonproprietary names to pharmaceutical substances so that each substance would be recognized by a unique name. Such names are needed for the clear identification, safe prescription and dispensing of medicines, and for communication and exchange of information among health professionals. INNs can be used freely because they are in the public domain. In addition to being a basic component of many WHO medicines activities and programmes, INNs are used in regulatory and administrative processes in many countries. They are also intended for use in pharmacopoeias, labelling, and product information and to provide standardized terminology for the international exchange of scientific information.

INN SELECTION PROCEDURE

Each name proposed for designation as an INN is examined and selected in accordance with a formal procedure. Requests for INNs can be submitted directly to WHO (application forms online at <http://www.who.int/medicines/services/inn/en/index.html>). In some countries where national nomenclature commissions exist, applications may also be made through the national nomenclature authority.

Members of the WHO Expert Panel on the International Pharmacopoeia and Pharmaceutical Preparations (or other Panel as appropriate) are officially designated to select nonproprietary names. Based on the information provided, an agreed name is selected and published as a **proposed** INN. During a four month period, any person can make comments or lodge a formal objection to the proposed name. If no objection is raised, this agreed name is published as the **recommended** INN.

In 1993, the World Health Assembly endorsed resolution WHA46.19 which states that trade marks should not be derived from INNs and INN stems should not be used in trade marks. The Assembly reasoned that such practice could frustrate the rational selection of INNs and ultimately compromise the safety of patients by promoting confusion in drug nomenclature. Above all, INNs are protected for use in the public domain.

CRITERIA FOR SELECTION

International Nonproprietary Names (INN) should be distinctive in sound and spelling. They should not be inconveniently long and not be liable to confusion with names in common use. Information on the selection procedure and general criteria in devising INNs is set out in Annexes 1 and 2.

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