WHO/EMP/RHT/TSN/2016.1

International Nonproprietary Names (INN) for biological and biotechnological substances

(a review)

2016

World Health Organization

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International Nonproprietary Names (INN) Programme

Technologies Standards and Norms (TSN)
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INTRODUCTION

More than 50 years ago, WHO established the International Nonproprietary Name (INN) Expert Group/WHO Expert Committee on Specifications for Pharmaceutical Preparations, to assign nonproprietary names to medicinal substances, so that each substance would be recognized globally by a unique name. These INNs do not give proprietary rights, unlike a trade mark, and can be used freely as they are public property.

INNs have been assigned to biological products since the early days of the INN Programme. As well as many names for individual substances, animal insulin preparations were given an INN in Recommended list 3 in 1959. In the period up to 1980, names were assigned to antibiotics, synthetic peptides, hormones and other proteins. In names of compounds related by structure and/or function, specific letter groups, called stems, are included to aid recognition by health professionals. The *-actid*e for synthetic polypeptides with a corticotrophin-like action is an early example.

In 1982, the name *insulin human* was proposed for the recombinant protein identical to natural human insulin, and since then names have been assigned to a growing number of recombinant products. Within the INN Programme, names have not been assigned to natural human blood products or vaccines. For those groups of biological products, the WHO Expert Committee on Biological Standardization (ECBS) has been adopting the scientific names of the biological products within the definitions of respective requirements.

Since the time when *insulin human* became the first recommended INN (rINN) for a recombinant product, the range of biological/biotechnological products has increased in size and complexity. For example, new stems have been introduced for tissue plasminogen activators (*-plase*) among other groups. Recombinant glycosylated proteins with the same protein sequence but produced in different cell systems have been classified using Greek letters as indicators in the sequence of submission for an INN, for example erythropoietin gives *epoetin alfa*, *epoetin beta* and so on. In the 1990s, a systematic scheme for naming monoclonal antibodies was implemented, based on the stem *-mab*, which indicates the origin (human, mouse etc) of the antibody and its intended use: for example tumour, immunomodulator and so on.

As a result of the scientific and technical developments over the past few years and continuing now, new products of biotechnology and other biological products have been developed and approved for clinical use and more products can be expected for the treatment or prevention of disease. Examples include recombinant blood products, transgenic products (human proteins expressed in animals or plants), products for gene and cell therapy and novel vaccines.

As this area became more and more complex and challenging, the INN Expert Group requested the WHO-INN Secretariat to prepare a working document intended to summarize and review the past and present INN situation activities and policies in this field.

This document, first published on the website of the INN Programme in 2006, presents an inventory of the policy decisions taken by the INN Expert Group during all these years of

change, and of the names assigned to biological and biotechnological substances. Considering the potential for further developments in the field of biologicals, this review is intended to be a *living document* which is updated regularly to include new policies, and INNs that have been assigned. The current version has been revised fully to reflect discussions and decisions taken by the INN Expert Group following a comprehensive review undertaken by many experts in the field, the INN Expert Group and Secretariat.

Comments and suggestions from all interested parties are always welcome and will be presented to the INN Expert Group for their consideration and for possible incorporation in future updates of this review.

You are reading the current updated version, also available as pdf-copy at:

http://www.who.int/medicines/services/inn/publication/en/index.html.