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International Nonproprietary Names (INN) for biological and biotechnological substances

(a review)

Programme on International Nonproprietary Names (INN)
Quality Assurance and Safety: Medicines
Essential Medicines and Pharmaceutical Policies (EMP)

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CONTENTS

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 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. Analogues of recombinant glycosylated proteins produced in different cell systems have been classified using Greek letters as indicators in the sequence of product introduction: erythropoietin (*epoetin alfa*, *beta* and so on) and glycoprotein hormones (*follitropin*) are examples. In the 1990s, a systematic scheme for naming monoclonal antibodies was implemented, based on the stem *-mab*, which indicates the origin (mouse, human, etc) of the antibody and its intended use: tumour, immunomodulator and so on.

As a result of the scientific and technical developments currently taking place, new products of biotechnology and other biological products are being introduced and more products can be expected for the treatment or prevention of disease. Examples of such new products include recombinant blood products, transgenic products (human proteins expressed in animals or plants), products for gene therapy and novel vaccines.

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

This document, first published on the website of the INN Programme in 2006, therefore 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 will be regularly updated to include new policies, and future INNs assigned.

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

1. PHARMACOLOGICAL CLASSIFICATION OF BIOLOGICAL AND BIOTECHNOLOGICAL SUBSTANCES [1]

Alimentary tract and metabolism

insulins (see item 4.17).

Anti-infectives

antimicrobial, bactericidal permeability increasing polypeptides (see item 4.1)

human papilloma virus (see item 4.16).

Antineoplastics

peptide vaccines / recombinant vaccines (see item 4.24)

toxins (see item 4.30).

Blood and agents acting on the haemopoietic system

antithrombins (see item 4.3)

blood coagulation cascade inhibitors (see item 4.4)

blood coagulation factors (see item 4.5)

erythropoietin type blood factors (see item 4.8)