INTERNATIONAL NONPROPRIETARY NAMES (INN) FOR PHARMACEUTICAL SUBSTANCES

Lists 1-105
of Proposed INN
and
Lists 1-66
of Recommended INN
Cumulative List N°14

DENOMINATIONS COMMUNES INTERNATIONALES (DCI) POUR LES SUBSTANCES PHARMACEUTIQUES

Listes 1-105
de DCI proposées
et
Listes 1-66
de DCI recommandées
Liste récapitulative N°14

World Health Organization
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Contents

Introduction…….....i
Use of INN……...ii
Compilation of Cumulative List No. 14…….iii
Layout of information…….....v
Explanatory notes on layout…….....vi
Abbreviations……ix
Selection of INN……xi
General principles for devising INN……xvii
Names for radicals and groups……xviii
Modified INN (INNM)…….. xix
Protection of INN……... xix
List of INN in Latin, English, French, Spanish, Arabic, Chinese, and Russian (in alphabetical order of the Latin name), with supplementary information……..1
Annex 1. Names for radicals and groups……..1191
Annex 2. Molecular formula index with reference to the INN……..1207
Annex 3. Chemical Abstracts Service registry number index with reference to the INN……...1281
Annex 4. World Health Assembly resolution WHA46.19: Nonproprietary names for pharmaceutical substances……. 1357
Annex 5. Standardization of the Spanish version of INN…….. 1363

Table des matières

Introduction……...xxi
Utilisation des DCI……..xxii
Etablissement de la Liste récapitulative no 13……...xxiii
Présentation de l'information…….. xxv
Notes explicatives sur la présentation de l'information……...xxvi
Abréviations……... xxx
Choix des DCI……xxxii
Principes généraux applicables à la formation des DCI……. xxxviii
Dénominations applicables aux radicaux et aux groupes…….....xl
DCI modifiées (DCIM)…… xli
Protection des DCI……xli
Liste de DCI en latin, anglais, espagnol, français, arabe, chinois et russe (dans l'ordre alphabétique des dénominations latines), avec des informations complémentaires……..1
Annexe 1. Dénominations applicables aux radicaux et aux groupes……... 1191
Annexe 2. Index des formules brutes des substances et DCI correspondantes……1207
Annexe 3. Index des numéros dans le registre du Chemical Abstracts Service et DCI correspondantes……1281
Annexe 4. Résolution WHA46.19 de l'Assemblée mondiale de la Santé: Dénominations communes pour les substances pharmaceutiques……1357
Annexe 5. Uniformisation de la version espagnole des DCI……..1363

Introduction

International Nonproprietary Names (INN) identify pharmaceutical substances or active pharmaceutical ingredients. Each INN is a unique name that is globally recognized and is public property. A nonproprietary name is also known as a generic name.

The INN system as it exists today was initiated in 1950 by a World Health Assembly resolution WHA3.11 and began operating in 1953, when the first list of International Nonproprietary Names for pharmaceutical substances was published. The cumulative list of INN now stands at some 8500 names designated since that time, and this number is growing every year by some 120-150 new INN.

Since its inception, the aim of the INN system has been to provide health professionals with a unique and universally available designated name to identify each pharmaceutical substance. The existence of an international nomenclature for pharmaceutical substances, in the form of INN, is important for the clear identification, safe prescription and dispensing of medicines to patients, and for communication and exchange of information among health professionals and scientists worldwide.

As unique names, INN have to be distinctive in sound and spelling, and should not be liable to confusion with other names in common use. To make INN universally available they are formally placed by WHO in the public domain, hence their designation as "nonproprietary". They can be used without any restriction whatsoever to identify pharmaceutical substances.

Another important feature of the INN system is that the names of pharmacologically-related substances demonstrate their relationship by using a common "stem". By the use of common stems the medical practitioner, the pharmacist, or anyone dealing with pharmaceutical products can recognize that the substance belongs to a group of substances having similar pharmacological activity.

The extent of INN utilization is expanding with the increase in the number of names. Its wide application and global recognition are also due to close collaboration in the process of INN selection with numerous national drug nomenclature bodies. The increasing coverage of the drug-name area by INN has led to the situation whereby the majority of pharmaceutical substances used today in medical practice are designated by an INN. The use of INN is already common in research and clinical documentation, while their importance is growing further due to expanding use of generic names for pharmaceutical products.

Use of INN

Nonproprietary names are intended for use in pharmacopoeias, labelling, product information, advertising and other promotional material, drug regulation and scientific literature, and as a basis for product names, e.g. for generics. Their use is normally required by national or, as in the case of the European Community, by international legislation. As a result of ongoing collaboration, national names such as British Approved Names (BAN), Dénominations communes françaises (DCF), Japanese Adopted Names (JAN) and United States Accepted Names (USAN) are nowadays, with rare exceptions, identical to the INN.

Some countries have defined the minimum size of characters in which the generic nonproprietary name must be printed under the trade-mark labelling and advertising. In several countries the generic name must appear prominently in type at least half the size of that used for the proprietary or brand-name. In some countries it has to appear larger than the trade-mark name. Certain countries have even gone so far as to abolish trade-marks within the public sector.

To avoid confusion, which could jeopardize the safety of patients, trade-marks should not be derived from INN and, in particular, must not include their common stems. As already mentioned the selection of further names within a series will be seriously hindered by the use of a common stem in a brand-name.

Compilation of Cumulative List No. 14

This edition consolidates the International Nonproprietary Names (INN) for pharmaceutical substances, published in Cumulative List No. 13, 2009 and Lists 102 to 105 of proposed INN published since that time. It incorporates 8493 INN for individual pharmaceutical substances.

Up to the end of 1986 lists of INN were published in the *WHO Chronicle*. From the beginning of 1987 they have been published in *WHO Drug Information*.

The Cumulative List groups together all INN in Latin, English, French, Spanish, Arabic, Chinese and Russian published up to November 2011, together with references to the lists of proposed and recommended INN in which they have been published. It also includes references to other generic names such as national nonproprietary names and names used by the International Organization for Standardization (ISO), pharmacopoeial monographs, the List of Narcotic Drugs under International Control, and other sources (see page ix). National nonproprietary names differing from the INN are cross-referenced to the corresponding INN. In addition, the list contains molecular formulae and the Chemical Abstracts Service (CAS) registry numbers. Since the publication of Cumulative List No.13, some 297 INN have been selected as proposed INN and 286 have been published as recommended INN.

For the chemical names and graphic formulae, the individual lists of INN should be consulted. For the chemical names in English and French published in Lists 1-25 of proposed INN, the user should refer to *International Nonproprietary Names for pharmaceutical substances, Cumulative List No. 3, 1971* (Geneva, World Health Organization). Graphic formulae are contained in the lists published in the *WHO chronicle*, from List 18 onwards, and, from 1987, in *WHO drug information*. Annexes 2 and 3 provide, respectively, a molecular formula index and a CAS registry number index. For the 7th Cumulative List the Spanish versions of INN were standardized, and detailed information on this is provided in Annex 5. A general rule has been established for the gender of French INN: those ending in "-one" and "-ine" are considered to be of feminine gender, and all others masculine, e.g. "la difloxacine" and "le difétérol". INN are printed in lower-case letters, allowing for the use of accents in the French and Spanish names. INNs have been transliterated into Arabic, Chinese and Russian. To ensure the development and maintenance of a meaningful generic nomenclature system, it is vital that INN common stems (and particularly new stems for emerging groups of substances, such as biotechnological products) should be used exclusively in generic names and never in trade-marks. This has been emphasized in the World Health Assembly resolution WHA46.19 on nonproprietary names for pharmaceutical substances (see Annex 4).

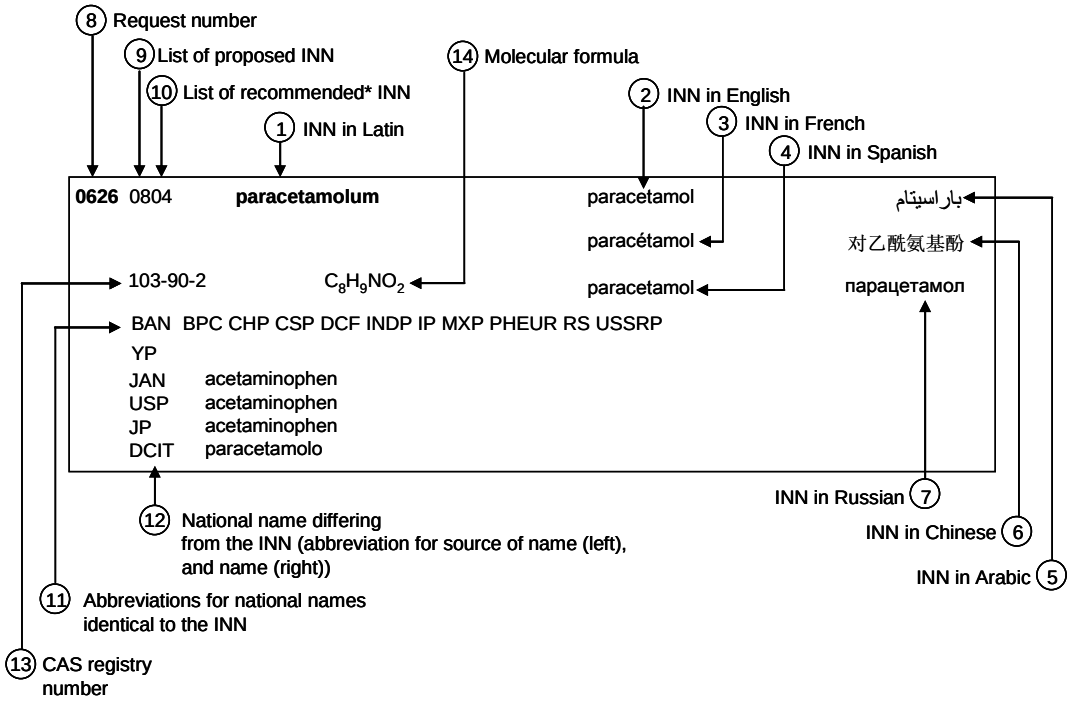
Comprehensive information on the INN programme can be found in: WHO Technical Report Series, No. 581, 1975 (*Nonproprietary names for pharmaceutical substances: twentieth report of the WHO Expert Committee*); in: "The selection and protection of International Nonproprietary Names for pharmaceutical substances", *WHO Chronicle*, 1981, 35(5), suppl. 172-175; and in: "International Nonproprietary Names (INN) for

pharmaceutical substances", *Bulletin of the World Health Organization*, 1995, 73(3), 275-279. Further documentation on selection of INN is available on request direct from: INN Programme Secretariat, Quality Assurance and Safety: Medicines, Department of Essential Medicines and Pharmaceutical Policies, World Health Organization, 1211 Geneva 27, Switzerland.

The inclusion of a name in the lists of proposed or recommended INN does not imply any recommendation for the use of the substance in medicine or pharmacy.

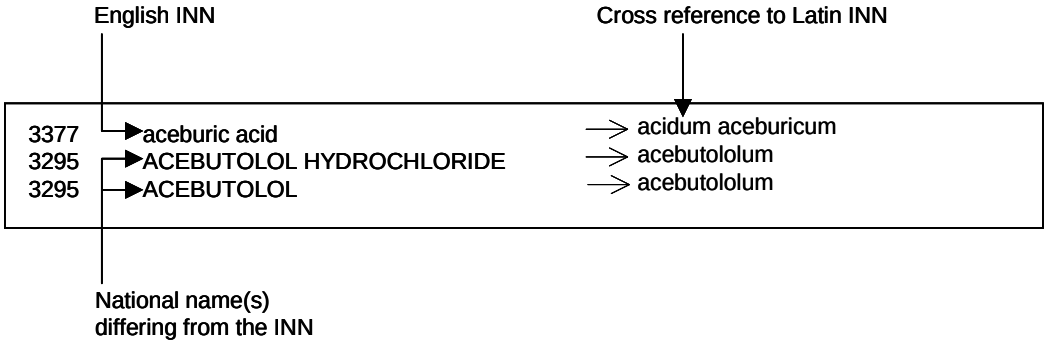
In order to make full use of the information in this book please consult the section on layout of information (page v) and the accompanying explanatory notes.

Layout of information



* An asterisk in place of a recommended list number signifies that an objection has been raised to the proposed name.

Note: Cross-references are provided for entries corresponding to (a) English, French and Spanish INN that appear in different alphabetical positions from the Latin INN and (b) national names that differ from the INN. Entries for (a) are printed in lower-case letters (as in the example of aceburic acid, below) while entries for (b) are printed in capitals (as in the examples of ACEBUTOLOL HYDROCHLORIDE and ACEBUTOLOLO).



Explanatory notes on layout

①-⑦. *International Nonproprietary Names* in Latin, English, French, Spanish, Arabic Chinese and Russian. Proposed nonproprietary names for radicals and groups are identified "(R)" after the Latin name.

⑧. *Request number* (sequential number given to INN requests).

⑨. *List of proposed INN* in which the name has been published. Where an INN has been published in several lists owing to the need for amendments, the number refers to the last proposed list in which the name was mentioned.

The references to the various lists are as follows:

List no. and reference

1 *Chron. Wld Hlth Org*. 7: 299 (1953)
2 *Chron. Wld Hlth Org*. 8: 216 (1954)
3 *Chron. Wld Hlth Org.* 8: 313 (1954)
4 *Chron. Wld Hlth Org* 10: 28 (1956)
5 *Chron. Wld Hlth Org.* 11: 231 (1957)
6 *Chron. Wld Hlth Org*. 12: 102 (1958)
7 *WHO Chronicle* 13: 105 (1959)
8 *WHO Chronicle* 13: 152 (1959)
9 *WHO Chronicle* 14: 168 (1960)
10 *WHO Chronicle* 14: 244 (1960)
11 *WHO Chronicle* 15: 314 (1961)
12 *WHO Chronicle* 16: 385 (1962)
13 *WHO Chronicle* 17: 389 (1963)

List no. and reference

14 *WHO Chronicle 18*: 433 (1963)
15 *WHO Chronicle* 19: 446 (1963)
16 *WHO Chronicle* 20: 216 (1963)
17 *WHO Chronicle* 21: 70 (1963)
18 *WHO Chronicle 21*: 478 (1963)
19 *WHO Chronicle* 22: 112 (1963)
20 *WHO Chronicle* 22: 407 (1963)
21 *WHO Chronicle* 23: 183 (1963)
22 *WHO Chronicle* 23: 418 (1963)
23 *WHO Chronicle* 24: 119 (1963)
24 *WHO Chronicle* 24: 413 (1963)
25 *WHO Chronicle* 25: 123 (1963)

Lists 1-25 of proposed INN are included in *International Nonproprietary Names for pharmaceutical substances*, *Cumulative List No. 3*, 1971 (Geneva, World Health Organization), which is the last cumulative list containing chemical names or descriptions.

26 *WHO Chronicle* 25: 415 (1971)
27 *WHO Chronicle* 26: 415 (1972)
28 *WHO Chronicle* 26: 415 (1972)
29 *WHO Chronicle* 27: 415 (1973)
30 *WHO Chronicle* 27: 415 (1973)
31 *WHO Chronicle* 28: 415 (1974)
32 *WHO Chronicle* 28: No. 9, suppl. (1974)
33 *WHO Chronicle* 29: No. 3, suppl. (1975)
34 *WHO Chronicle* 29: No. 9, suppl. (1975)
35 *WHO Chronicle* 30: No. 3, suppl. (1976)
36 *WHO Chronicle* 30: No. 9, suppl. (1976)
37 *WHO Chronicle* 31: No. 3, suppl. (1977)
38 *WHO Chronicle* 31: No. 9, suppl. (1977)
39 *WHO Chronicle* 32: No. 3, suppl. (1978)
40 *WHO Chronicle* 32: No. 9, suppl. (1978)
41 *WHO Chronicle* 33: No. 3, suppl. (1979)
42 *WHO Chronicle* 33: No. 9, suppl. (1979)
43 *WHO Chronicle* 34: No. 3, suppl. (1980)
44 *WHO Chronicle* 34: No. 9, suppl. (1980)
45 *WHO Chronicle* 35: No. 3, suppl. (1981)
46 *WHO Chronicle* 35: No. 5, suppl. (1981)
47 *WHO Chronicle* 36: No. 2, suppl. (1982)
48 *WHO Chronicle* 36: No. 5, suppl. (1982)
49 *WHO Chronicle* 37: No. 2, suppl. (1983)
50 *WHO Chronicle* 37: No. 5, suppl. (1983)
51 *WHO Chronicle* 38: No. 2, suppl. (1984)
52 *WHO Chronicle* 38: No. 2, suppl. (1984)
53 *WHO Chronicle* 39: No. 1, suppl. (1985)
54 *WHO Chronicle* 39: No. 4, suppl. (1985)
55 *WHO Chronicle* 40: No. 1, suppl. (1986)

56 *WHO Chronicle* 40: No. 5, suppl. (1986)
57 *WHO Drug Information* 1: No. 2 (1987)
58 *WHO Drug Information* 1: No. 3 (1987)
59 *WHO Drug Information* 2: No. 2 (1988)
60 *WHO Drug Information* 2: No. 4 (1988)
61 *WHO Drug Information* 3: No. 2 (1989)
62 *WHO Drug Information* 3: No. 4 (1989)
63 *WHO Drug Information* 4: No. 2 (1990)
64 *WHO Drug Information* 4: No. 4 (1990)
65 *WHO Drug Information* 5: No. 2 (1991)
66 *WHO Drug Information* 5: No. 4 (1991)
67 *WHO Drug Information* 6: No. 2 (1992)
68 *WHO Drug Information* 6: No. 4 (1992)
69 *WHO Drug Information* 7: No. 2 (1993)
70 *WHO Drug Information* 7: No. 4 (1993)
71 *WHO Drug Information* 8: No. 2 (1994)
72 *WHO Drug Information* 8: No. 4 (1994)
73 *WHO Drug Information* 9: No. 2 (1995)
74 *WHO Drug Information* 9: No. 4 (1995)
75 *WHO Drug Information* 10: No. 2 (1996)
76 *WHO Drug Information* 10: No. 4 (1996)
77 *WHO Drug Information* 11: No. 2 (1997)
78 *WHO Drug Information* 11: No. 4 (1997)
79 *WHO Drug Information* 12: No. 2 (1998)
80 *WHO Drug Information* 12: No. 4 (1998)
81 *WHO Drug Information* 13: No. 2 (1999)
82 *WHO Drug Information* 13: No. 4 (1999)
83 *WHO Drug Information* 14: No. 2 (2000)
84 *WHO Drug Information* 14: No. 4 (2000)
85 *WHO Drug Information* 15: No. 2 (2001)
86 *WHO Drug Information* 16: No. 1 (2002)
87 *WHO Drug Information* 16: No. 2 (2002)
88 *WHO Drug Information* 17: No. 1 (2003)
89 *WHO Drug Information* 17: No. 3 (2003)
90 *WHO Drug Information* 18: No. 1 (2004)
91 *WHO Drug Information* 18: No. 2 (2004)
92 *WHO Drug Information* 18: No. 4 (2004)
93 *WHO Drug Information* 19: No. 2 (2005)
94 *WHO Drug Information* 19: No. 4 (2005)
95 *WHO Drug Information* 20: No. 2 (2006)
96 *WHO Drug Information* 20: No. 4 (2006)
97 *WHO Drug Information* 21: No. 2 (2007)
98 *WHO Drug Information* 21: No. 4 (2007)
99 *WHO Drug Information* 22: No. 2 (2008)
100 *WHO Drug Information* 22: No. 4 (2008)
101 *WHO Drug Information* 23: No. 2 (2009)
102 *WHO Drug Information* 23: No. 4 (2009)
103 *WHO Drug Information* 24: No. 2 (2010)
104 *WHO Drug Information* 24: No. 4 (2010)
105 *WHO Drug Information* 25: No. 2 (2011)

⑩. *List of recommended INN* in which the name has been published. Where an INN has been published in several lists owing to the need for amendments, the number refers to the last recommended list in which the name was mentioned. An asterisk in place of a recommended list number signifies that an objection has been raised to the proposed name in at least one Member State, in accordance with the "Procedure for the selection of recommended International Nonproprietary Names for pharmaceutical substances" (see page xiii). Before such a name is taken into use in a given country, it should be ascertained that there is no objection to it in the country concerned. Nonproprietary names for radicals and groups are not generally published in the lists of recommended INN.

The references to the various lists are as follows:

List no. and reference

1 *Chron. Wld Hlth Org.* 9: 185 (1955)
2 *WHO Chronicle* 13: 106 (1959)
3 *WHO Chronicle* 13: 463 (1959)
4 *WHO Chronicle* 16: 101 (1962)
5 *WHO Chronicle* 19: 165, 206, 249 (1965)
6 *WHO Chronicle* 20: 421 (1966)
7 *WHO Chronicle* 21: 538 (1967)
8 *WHO Chronicle* 22: 463 (1968)
9 *WHO Chronicle* 23: 490 (1969)
10 *WHO Chronicle* 24: 526 (1970)
11 *WHO Chronicle* 25: 476 (1971)

Lists 1-11 of recommended INN are included in *International Nonproprietary Names for pharmaceutical substances, Cumulative List No. 3*, 1971 (Geneva, World Health Organization).

List no. and reference	List no. and reference
12 *WHO Chronicle* 26: 476 (1972)	40 *WHO Drug Information* 12: No.3 (1998)
13 *WHO Chronicle* 27: 453 (1973)	41 *WHO Drug Information* 13: No.1 (1999)
14 *WHO Chronicle* 28: No. 10, suppl. (1974)	42 *WHO Drug Information* 13: No.3 (1999)
15 *WHO Chronicle* 29: No. 10, suppl. (1975)	43 *WHO Drug Information* 14: No.1 (2000)
16 *WHO Chronicle* 30: No. 10, suppl. (1976)	44 *WHO Drug Information* 14: No.3 (2000)
17 *WHO Chronicle* 31: No. 10, suppl. (1977)	45 *WHO Drug Information* 15: No.1 (2001)
18 *WHO Chronicle* 32: No. 10, suppl. (1978)	46 *WHO Drug Information* 15: No.3-4 (2001)
19 *WHO Chronicle* 33: No. 10, suppl. (1979)	47 *WHO Drug Information* 16: No.1 (2002)
20 *WHO Chronicle* 34: No. 10, suppl. (1980)	48 *WHO Drug Information* 16: No.3 (2002)
21 *WHO Chronicle* 35: No. 5, suppl. (1981)	49 *WHO Drug Information* 17: No.2 (2003)
22 *WHO Chronicle* 36: No. 6, suppl. (1982)	50 *WHO Drug Information* 17: No.4 (2003)
23 *WHO Chronicle* 37: No. 6, suppl. (1983)	51 *WHO Drug Information* 18: No.1 (2004)
24 *WHO Chronicle* 38: No. 6, suppl. (1984)	52 *WHO Drug Information* 18: No.3 (2004)
25 *WHO Chronicle* 39: No. 5, suppl. (1985)	53 *WHO Drug Information* 19: No.1 (2005)
26 *WHO Chronicle* 40: No. 6, suppl. (1986)	54 *WHO Drug Information* 19: No.3 (2005)
27 *WHO Drug Information* 1: No.4 (1987)	55 *WHO Drug Information* 20: No.1 (2006)
28 *WHO Drug Information* 2: No.3 (1988)	56 *WHO Drug Information* 20: No.3 (2006)
29 *WHO Drug Information* 3: No.3 (1989)	57 *WHO Drug Information* 21: No.1 (2007)
30 *WHO Drug Information* 4: No.3 (1990)	58 *WHO Drug Information* 21: No.3 (2007)
31 *WHO Drug Information* 5: No.3 (1991)	59 *WHO Drug Information* 22: No.1 (2008)
32 *WHO Drug Information* 6: No.3 (1992)	60 *WHO Drug Information* 22: No.3 (2008)
33 *WHO Drug Information* 7: No.3 (1993)	61 *WHO Drug Information* 23: No.1 (2009)
34 *WHO Drug Information* 8: No.3 (1994)	62 *WHO Drug Information* 23: No.3 (2009)
35 *WHO Drug Information* 9: No.3 (1995)	63 *WHO Drug Information* 24: No.1 (2010)
36 *WHO Drug Information* 10: No.3 (1996)	64 *WHO Drug Information* 24: No.3 (2010)
37 *WHO Drug Information* 11: No.1 (1997)	65 *WHO Drug Information* 25: No.1 (2011)
38 *WHO Drug Information* 11: No.3 (1997)	66 *WHO Drug Information* 25: No.3 (2011)
39 *WHO Drug Information* 12: No.1 (1998)	

⑪. *Abbreviations for national generic names identical to the INN* (for meaning of codes, see Abbreviations, page ix).

⑫. *National generic name differing from the INN* (for meaning of codes, see Abbreviations). When national names differing from the INN have been published for a salt or ester, they are given in full under this category. Thus, the equivalent to the USAN "acepromazine maleate" is not the INN "acepromazine" but the INN Modified or INNM[1] "acepromazine maleate". When the INN designation is assigned to a particular salt or ester (e.g. *levothyroxine sodium*) the name of the acid or base, or of a different salt or ester, may be identified as an INNM (e.g. *levothyroxine*) derived from the published INN. (The INNM are not published separately.) When more than one national name has been published for the same substance (e.g. for different salts of the same compound), these are identified as USAN and so on.

⑬. *CAS registry number*. This number applies to the substance identified by the INN (e.g. "acepromazine") and not to the INNM (e.g. "acepromazine maleate") (see Note 12).

⑭. *Molecular formula*.

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[1] For further information on the INNM, see: WHO Technical Report Series, No. 581, 1975 (*Nonproprietary names for pharmaceutical substances*: twentieth report of the WHO Expert Committee), p. 8. and the INN Working Document 05.167/3: International Nonproprietary Names Modified, 2005 http://www.who.int/medicines/services/inn/publication/en/index.html

Abbreviations

Official names and other references[1]

BAN	British Approved Name (English) British Approved Names booklet 2007 (Supplement No.4, Effective date: 1 January 2011)
BS	International Biological Standard or Reference Preparation[2] (English, French)
BS-P	International Biological Standard - preparation under investigation (English, French)[2]
DCF	Dénomination commune française (French) Pharmacopée française, 10th Ed. Section IV. 4. Add. 2002
DCIT	Denominazione comune italiana (English) Denominazione comune italiana dei principi attivi contenuti nei medicamenti, Lista 1988, Suppl. November 1990 and January-February 1991
FDA	Official names of drugs published by the United States Food and Drug Administration (English). (Federal Register 37, 18, 2 January 1972)
ISO	Pesticides and other agrochemicals - common names (published by the International Organization for Standardization; ISO) (English, French) ISO Ref.: 1750 Addendum 1 (1983), Addendum 2 (1983)
JAN	Japanese Accepted Names for Pharmaceuticals (English) Cumulative List 2011
NC 1961	Drug included in List of Narcotic Drugs under International Control (English, French) (UN List, 49th edition, December 2010)
NC 1971	Drug mentioned in Schedules I-IV under the 1971 Convention on Psychotropic Substances (English, French) (UN List, 24th edition, May 2010)
NC 1988	List of Precursors and Chemicals frequently used in the Illicit Manufacture of Narcotic Drugs and Psychotropic Substances under International Control, 12th edition, January 2011

[1] The language indicated in parentheses refers to the language in which comparison with the INN was made.

[2] *Biological substances: International Standards and Reference Reagents, 1990.* Geneva, World Health, Organization, 1991.

RS	International Chemical Reference Substance (English, French)
USAN	United States Adopted Name (English) USAN 1961-2011, Cumulative List
(R)	Names for Radicals and Groups, see Annex 1

Pharmacopoeias

The list of pharmacopoeias mentioned below has traditionally been referred to in the INN database and cumulative lists in the connection with the official names used as monograph titles.

The pharmacopoeias highlighted in bold are updated on a regular basis by WHO. Pharmacopoeias and other references not highlighted are no longer updated but kept at the current state as a matter of information.

BP	British Pharmacopoeia 2001 (English)
BPC	British Pharmaceutical Codex, 12th ed., 1994 (English)
ChP	Pharmacopoeia of the People's Republic of China, V, 1995 (Latin), English edition, 1997
CSL	Ceskoslovensky Lékopis, Pharmacopoea Bohemoslovenica, 5th ed., 1989 (Latin), Addendum 1, 1991
24EC	Monographs included in the twenty-fourth report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series, No. 487, 1972) (English, French)
25EC	Monographs included in twenty-fifth report of the WHO Expert Committee on Specifications for Pharmaceutical Preparations (WHO Technical Report Series, No. 567, 1975) (English, French)
Ph. Eur.	European Pharmacopoeia, 4th ed., 2002; suppl. 4.1-4.2, 2002; suppl. 4.3-4.5, 2003m (Latin)
Ph. fr.	Pharmacopée française, 10th ed., 1982-1996 (French)
DAB	Deutsches Arzneibuch, 1999 (Latin)
Ph. Hg.	Pharmacopoea Hungarica, 7th ed., 1986 (Latin)
IP	Indian Pharmacopoeia, 1996 (English)

Ph. Int.	**The International Pharmacopoeia, Pharmacopoea Internationalis, 4th ed., First and Second supplements, 2011**
JP	The Japanese Pharmacopoeia, 13th ed., 1996; suppl. 1, 1998 (English)
JRA	Minimum requirements for antibiotic products of Japan, 1993 (English)
FEUM	Farmacopea de los Estados Unidos Mexicanos, 6th ed., 1994; suppl. 1, 1995 (Spanish)
Ph. Helv.	Pharmacopoea Helvetica, 8th ed., 1987-1997, suppl. 1999 (Latin)
USP	The United States Pharmacopeia, 25th ed., 2002; suppl. 1-2, 2002 (English)
USSRP	State Pharmacopoeia of the Union of Soviet Socialist Republics, XI ed., vol. 1, 1987, vol. 2, 1990 (Latin)
YP	Pharmacopea Jugoslavica, 4th ed., 1984 (Latin)

Selection of INN

The names which are given the status of an INN are selected by the World Health Organization on the advice of experts from the WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations. The process of INN selection follows three main steps:

- a request/application is made by the manufacturer or inventor;
- after a review of the request a proposed INN is selected and published for comments;
- after a time-period for objections has lapsed, the name will obtain the status of a recommended INN and will be published as such if no objection has been raised.

INN are selected in principle only for single, well-defined substances that can be unequivocally characterized by a chemical name (or formula). It is the policy of the INN Programme not to select names for mixtures of substances, while substances that are not fully characterized are included in the INN system in exceptional cases only. INN are not selected for herbal substances (vegetable drugs) or for homoeopathic products. It is also the policy of the INN Programme not to select names for those substances that have a long history of use for medical purposes under well-established names such as those of alkaloids (e.g. morphine, codeine), or trivial chemical names (e.g. acetic acid).

An INN is usually designated for the active part of the molecule only, to avoid the multiplication of entries in cases where several salts, esters, etc. are actually used. In such cases, the user of the INN has to create a modified INN (INNM) himself; *mepyramine maleate* (a salt of *mepyramine* with *maleic acid* is an example of an INNM)

When the creation of an INNM would require the use of a long or inconvenient name for the radical part of the INNM, the INN Programme will select a short name for such a radical (for example, *mesilate* for *methanesulfonate*).[1]

In the process of INN selection, the rights of existing trade-mark owners are fully protected. If in the period of four months following the publication of a proposed INN, a formal objection is filed by an interested person who considers that the proposed INN is in conflict with an existing trade-mark, WHO will actively pursue an arrangement to obtain a withdrawal of such an objection or will reconsider the proposed name. As long as the objection exists, WHO will not publish it as a recommended INN.

The selection of a new INN relies on a strict procedure. Upon receipt of an INN request form, the WHO Secretariat examines the suggested names for conformity with the general rules, for similarities with published INN and potential conflicts with existing names, including published INN and trade-marks. A note summarizing the result of these checks is added and the request is subsequently forwarded to the INN experts for comments. Once all experts agree upon one name, the applicant is informed of the selected name.

Newly selected, proposed INN are then published in *WHO Drug Information*, which indicates a deadline of a 4-month objection period. This period is allowed for comments and/or objections to the published names to be raised. The reasons for any objection must be stated clearly and these will be evaluated by the experts for further action. Users are invited to refrain from using the proposed name until it becomes a recommended INN, in order to avoid confusion should the name be modified. Two lists of proposed INN are published yearly.

The final stage of the selection process is the recommended INN. Once a name has been published as a recommended INN it will not normally be modified further and is ready for use in labelling, publications, on drug information. It will serve to identify the active pharmaceutical substance during its life-time worldwide. Since the name is available in the public domain it may be used freely. However, it should not be registered as a trade-mark since this would prevent its use by other parties.

Recommended INN are published in the *WHO Drug Information* as a consequence of the objection procedure applied to proposed INN. As from 1997, two lists of proposed INN are published yearly and as from list 37 of recommended INN, graphic formulae are also included for better identification of the substances.

The procedure for selecting recommended INN is carried out in accordance with a text adopted by the WHO Executive Board.

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[1] For further information on the INNM, see: WHO Technical Report Series, No. 581, 1975 (*Nonproprietary names for pharmaceutical substances*: twentieth report of the WHO Expert Committee), p. 8. and the INN Working Document 05.167/3: International Nonproprietary Names Modified, 2005 http://www.who.int/medicines/services/inn/publication/en/index.html

Procedure for the selection of recommended International Nonproprietary Names for Pharmaceutical substances[1]

The following procedure shall be followed by the World Health Organization (hereinafter also referred to as "WHO") in the selection of recommended international nonproprietary names for pharmaceutical substances, in accordance with resolution WHA3.11 of the World Health Assembly, and in the substitution of such names.

Article 1 - Proposals for recommended international nonproprietary names and proposals for substitution of such names shall be submitted to WHO on the form provided therefore. The consideration of such proposals shall be subject to the payment of an administrative fee designed only to cover the corresponding costs of the Secretariat of WHO ("the Secretariat"). The amount of this fee shall be determined by the Secretariat and may, from time to time, be adjusted.

Article 2 - Such proposals shall be submitted by the Secretariat to the members of the Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations designated for this purpose, such designated members hereinafter referred to as "the INN Expert Group", for consideration in accordance with the "General principles for guidance in devising International Nonproprietary Names for Pharmaceutical Substances", annexed to this procedure. The name used by the person discovering or first developing and marketing a pharmaceutical substance shall be accepted, unless there are compelling reasons to the contrary.

Article 3 - Subsequent to the examination provided for in article 2, the Secretariat shall give notice that a proposed international nonproprietary name is being considered.

a) Such notice shall be given by publication in *WHO Drug Information*[2] and by letter to Member States and to national and regional pharmacopoeia commissions or other bodies designated by Member States.

> i) Notice shall also be sent to the person who submitted the proposal ("the original applicant") and other persons known to be concerned with a name under consideration.

b) Such notice shall:

> i) set forth the name under consideration;
> ii) identify the person who submitted the proposal for naming the substance, if so requested by such person;
> iii) identify the substance for which a name is being considered;

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[1] Text adopted by the Executive Board of WHO in resolution EB15.R7 and amended by the Board in resolution EB43.R9. First published in WHO Technical Report Series, No. 581, 1975 (Nonproprietary names for pharmaceutical substances: twentieth report of the WHO Expert Committee), pages 16-18.

[2] The title of this publication was changed to *WHO Chronicle* in January 1959. From 1987 onwards, lists of INN have been published in *WHO Drug Information*.

iv) set forth the time within which comments and objections will be received and the person and place to whom they should be directed;

v) state the authority under which WHO is acting and refer to these rules of procedure.

c) In forwarding the notice, the Secretariat shall request that Member States take such steps as are necessary to prevent the acquisition of proprietary rights in the proposed name during the period it is under consideration by WHO.

Article 4 - Comments on the proposed name may be forwarded by any person to WHO within four months of the date of publication, under article 3, of the name in *WHO Drug Information*.

Article 5 - A formal objection to a proposed name may be filed by any interested person within four months of the date of publication, under article 3, of the name in *WHO Drug Information.*

Such objection shall:

i) identify the person objecting;
ii) state his or her interest in the name;
iii) set forth the reasons for his or her objection to the name proposed.

Article 6 - Where there is a formal objection under article 5, WHO may either reconsider the proposed name or use its good offices to attempt to obtain withdrawal of the objection. Without prejudice to the consideration by WHO of a substitute name or names, a name shall not be selected by WHO as a recommended international nonproprietary name while there exists a formal objection thereto filed under article 5 which has not been withdrawn.

Article 7 - Where no objection has been filed under article 5, or all objections previously filed have been withdrawn, the Secretariat shall give notice in accordance with subsection (a) of article 3 that the name has been selected by WHO as a recommended international nonproprietary name.

Article 8 - In forwarding a recommended international nonproprietary name to Member States under article 7, the Secretariat shall:

a) request that it be recognized as the nonproprietary name for the substance; and

b) request that Member States take such steps as are necessary to prevent the acquisition of proprietary rights in the name and to prohibit registration of the name as a trademark or trade name.

Article 9

a) In the extraordinary circumstance that a previously recommended international nonproprietary name gives rise to errors in medication, prescription or distribution, or a demonstrable risk thereof, because of similarity with another name in pharmaceutical and/or prescription practices, and it appears that such errors or potential errors cannot readily be resolved through other interventions than a possible

substitution of a previously recommended international nonproprietary name, or in the event that a previously recommended international nonproprietary name differs substantially from the nonproprietary name approved in a significant number of Member States, or in other such extraordinary circumstances that justify a substitution of a recommended international nonproprietary name, proposals to that effect may be filed by any interested person. Such proposals shall be submitted on the form provided therefore and shall:

i) identify the person making the proposal;
ii) state his or her interest in the proposed substitution; and
iii) set forth the reasons for the proposal; and
iv) describe, and provide documentary evidence regarding the other interventions undertaken in an effort to resolve the situation, and the reasons why these other interventions were inadequate.

Such proposals may include a proposal for a new substitute international nonproprietary name, devised in accordance with the General principles, which takes into account the pharmaceutical substance for which the new substitute international nonproprietary name is being proposed.

The Secretariat shall forward a copy of the proposal, for consideration in accordance with the procedure described in subsection (b) below, to the INN Expert Group and the original applicant or its successor (if different from the person bringing the proposal for substitution and provided that the original applicant or its successor is known or can be found through diligent effort, including contacts with industry associations).

In addition, the Secretariat shall request comments on the proposal from:

i) Member States and national and regional pharmacopoeia commissions or other bodies designated by Member States (by including a notice to that effect in the letter referred to in article 3(a), and
ii) any other persons known to be concerned by the proposed substitution.

The request for comments shall:

i) state the recommended international nonproprietary name that is being proposed for substitution (and the proposed substitute name, if provided);
ii) identify the person who submitted the proposal for substitution (if so requested by such person);
iii) identify the substance to which the proposed substitution relates and reasons put forward for substitution;
iv) set forth the time within which comments will be received and the person and place to whom they should be directed; and
v) state the authority under which WHO is acting and refer to these rules of procedure.

Comments on the proposed substitution may be forwarded by any person to WHO within four months of the date of the request for comments.

b) After the time period for comments referred to above has elapsed, the Secretariat shall forward any comments received to the INN Expert Group, the original applicant or its successor and the person bringing the proposal for substitution. If, after consideration of the proposal for substitution and the comments received, the INN Expert Group, the person bringing the proposal for substitution and the original applicant or its successor all agree that there is a need to substitute the previously recommended international nonproprietary name, the Secretariat shall submit the proposal for substitution to the INN Expert Group for further processing. Notwithstanding the foregoing, the original applicant or its successor shall not be entitled to withhold agreement to a proposal for substitution in the event the original applicant or its successor has no demonstrable continuing interest in the recommended international nonproprietary name proposed for substitution.

In the event that a proposal for substitution shall be submitted to the INN Expert Group for further processing, the INN Expert Group will select a new international nonproprietary name in accordance with the General principles referred to in article 2 and the procedure set forth in articles 3 to 8 inclusive. The notices to be given by the Secretariat under article 3 and article 7, respectively, including to the original applicant or its successor (if not the same as the person proposing the substitution, and provided that the original applicant or its successor is known or can be found through diligent effort, including contacts with industry associations), shall in such event indicate that the new name is a substitute for a previously recommended international nonproprietary name and that Member States may wish to make transitional arrangements in order to accommodate existing products that use the previously recommended international nonproprietary name on their label in accordance with national legislation.

If, after consideration of the proposal for substitution and the comments received in accordance with the procedure described above, the INN Expert Group, the original applicant or its successor and the person bringing the proposal for substitution do not agree that there are compelling reasons for substitution of a previously recommended international nonproprietary name, this name shall be retained (provided always that the original applicant or its successor shall not be entitled to withhold agreement to a proposal for substitution in the event that the original applicant or its successor has no demonstrable continuing interest in the recommended international nonproprietary name proposed to be substituted). In such an event, the Secretariat shall advise the person having proposed the substitution, as well as the original applicant or its successor (if not the same as the person proposing the substitution, and provided that the original applicant or its successor is known or can be found through diligent effort, including contacts with industry associations), Member States, national and regional pharmacopoeia commissions, other bodies designated by Member States, and any other persons known to be concerned by the proposed substitution that, despite a proposal for substitution, it has been decided to retain the previously recommended international nonproprietary name (with a description of the reason(s) why the proposal for substitution was not considered sufficiently compelling).

General principles for devising INN[1]

1. International Nonproprietary Names (INN) should be distinctive in sound and spelling. They should not be inconveniently long and should not be liable to confusion with names in common use.
2. The INN for a substance belonging to a group of pharmacologically related substances should, where appropriate, show this relationship. Names that are likely to convey to a patient an anatomical, physiological, pathological or therapeutic suggestion should be avoided.

These primary principles are to be implemented by using the following secondary principles:

3. In devising the INN of the first substance in a new pharmacological group, consideration should be given to the possibility of devising suitable INN for related substances, belonging to the new group.
4. In devising INN for acids, one-word names are preferred; their salts should be named without modifying the acid name, e.g. "oxacillin" and "oxacillin sodium", "ibufenac" and "ibufenac sodium".
5. INN for substances used as salts should in general apply to the active base or the active acid. Names for different salts or esters of the same active substance should differ only in respect of the name of the inactive acid or the inactive base.
   For quaternary ammonium substances, the cation and anion should be named appropriately as separate components of a quaternary substance and not in the amine-salt style.
6. The use of an isolated letter or number should be avoided; hyphenated construction is also undesirable.
7. To facilitate the translation and pronunciation of INN, "f" should be used instead of "ph", "t" instead of "th", "e" instead of "ae" or "oe", and "i" instead of "y"; the use of the letters "h" and "k" should be avoided.
8. Provided that the names suggested are in accordance with these principles, names proposed by the person discovering or first developing and marketing a pharmaceutical preparation, or names already officially in use in any country, should receive preferential consideration.
9. Group relationship in INN (see General Principle 2) should if possible be shown by using a common stem. The following list contains examples of stems for groups of substances, particularly for new groups. There are many other stems in active use.[2]
   Where a stem is shown without any hyphens it may be used anywhere in the name.
   Subsidiary group relationships should be shown by devising INN that show similarities to and are analogous with a previously named substance.

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[1] These principles were published, in their original version, in the twentieth report (WHO Technical Report Series, No. 581, 1975) of the WHO Expert Committee on Nonproprietary Names for Pharmaceutical Substances, which reviewed the general principles for devising, and the procedure for selecting INN, in the light of developments in pharmaceutical compounds in recent years.

[2] A more extensive listing of stems is contained in the working document WHO/EMP/QSM/2011.3 which is regularly updated and can be requested from INN Programme Secretariat, Quality Assurance & Safety: Medicines, Department of Essential Medicines and Pharmaceutical Policies, World Health Organization, 1211 Geneva 27, Switzerland, or from the INN webpage:
http://www.who.int/medicines/services/inn/publication/en/index.html

Latin	*English*	
-acum	*-ac*	anti-inflammatory agents, ibufenac derivatives
-adolum	*-adol* }	analgesics
-adol-	*-adol-}*	
-astum	*-ast*	anti-asthmatic, anti-allergic substances not acting primarily as antihistaminics
-astinum	*-astine*	antihistaminics
-azepamum	*-azepam*	diazepam derivatives
bol	*bol*	steroids, anabolic
-cain-	*-cain-*	class I antiarrhythmics, procainamide and lidocaine derivatives
-cainum	*-caine*	local anaesthetics
cef-	*cef-*	antibiotics, cefalosporanic acid derivatives
-cillinum	*-cillin*	antibiotics, 6-aminopenicillanic acid derivatives
-conazolum	*-conazole*	systemic antifungal agents, miconazole derivatives
cort	*cort*	corticosteroids, except prednisolone derivatives
-coxibum	*-coxib*	selective cyclo-oxygenase inhibitors
-entanum	*-entan*	endothelin receptor antagonists
gab	*gab*	gabamimetic agents
gado-	*gado-*	diagnostic agents, gadolinium derivatives
-gatranum	*-gatran*	thrombin inhibitors, antithrombotic agents
gest	*gest*	steroids, progestogens
gli	*gli*	antihyperglycaemics
io-	*io-*	iodine-containing contrast media
-metacinum	*-metacin*	anti-inflammatory, indometacin derivatives
-mycinum	*-mycin*	antibiotics, produced by *Streptomyces* strains
-nidazolum	*-nidazole*	antiprotozoal and radiosensitizers, metronidazole derivatives
-ololum	*-olol*	β-adrenoreceptor antagonists
-oxacinum	*-oxacin*	antibacterial agents, nalidixic acid derivatives
-platinum	*-platin*	antineoplastic agents, platinum derivatives
-poetinum	*-poetin*	erythropoietin type blood factors
-pril(at)um	*-pril(at)*	angiotensin-converting enzyme inhibitors
-profenum	*-profen*	anti-inflammatory, ibuprofen derivatives
prost	*prost*	prostaglandins
-relinum	*-relin*	pituitary hormone release-stimulating peptides
-sartanum	*-sartan*	angiotensin II receptor antagonists, antihypertensive (non-peptidic)
-vaptanum	*-vaptan*	vasopressin receptor antagonists
vin-	*vin- }*	vinca-type alkaloids
-vin-	*-vin-}*	

Names for radicals and groups

During the 1975 meeting on Nonproprietary Names for Pharmaceutical Substances the experts discussed the issue of INN for salts and esters and noted that requests had frequently been received for INN for salts, esters, or combination products of substances for which INN already existed. At that time, the experts decided that INN for the simple

salt and esters should be devised from the INN in conformity with normal chemical practice.

Some of the radicals and groups involved are, however, of such complex composition that it makes it inconvenient to use the chemical nomenclature. It was thus decided that in such cases, shorter nonproprietary names are selected for these inactive moieties and published in proposed lists under the title "Names for Radicals and Groups". Separate names for salts and esters derived from this procedure are not published. If a "radical and group name" is used in conjunction with an INN, they are referred to as International Nonproprietary Name (Modified) or INNM.

A comprehensive list of radicals and groups may be obtained from WHO's Marketing and Dissemination unit or the INN Programme Secretariat (*INN: Names for radicals and groups and others, comprehensive list*. Document WHO/PSM/QSM/2010.3, updated regularly).

Modified INN (INNM)

In principle, INN are selected only for the active part of the molecule which is usually the base, acid or alcohol. In some cases, however, the active molecules need to be expanded for various reasons, such as formulation purposes, bioavailability or absorption rate. In 1975 the experts designated for the selection of INN decided to adopt a new policy for naming such molecules. In future, names for different salts or esters of the same active substance should differ only with regard to the inactive moiety of the molecule. For example, *oxacillin* and *ibufenac* are INN and their salts are named *oxacillin sodium* and *ibufenac sodium*. The latter are called modified INN (INNM).

Before the existence of this rule, some INN were published for salts. In such cases, the term "modified INN" may also be used for a base or acid. For example, *levothyroxine sodium* was published as an INN and *levothyroxine* may thus be referred to as an INNM. For more information on the subject, the INN Working Document 05.167/3 "*International Nonproprietary Names Modified*" (2005), can also be downloaded from the INN website:
http://www.who.int/medicines/services/inn/en/

Protection of INN

Lists of both proposed and recommended INN are sent by WHO, together with a *note verbale*, to the Organization's Member States, to national pharmacopoeia commissions and to other bodies designated by Member States. In her *note verbale*, the Director-General of the World Health Organization requests that Member States should take such steps as are necessary to prevent the acquisition of proprietary rights on the name, including prohibiting registration of the name as a trade name.

Over the years, the need to maintain the integrity of the INN system has become urgent. This is reflected in the following extract from the Fifth Report of the WHO Expert Committee on the Use of Essential Drugs which met in November 1991[1]:

[1]WHO Technical Report Series, No. 825, 1992.

"The procedure for selecting INNs allows manufacturers to contest names that are either identical or similar to their licensed trade-marks. In contrast, trade-mark applications are disallowed, in accordance with the present procedure, only when they are identical to an INN. A case for increased protection of INNS is now apparent as a result of competitive promotion of products no longer protected by patents. Rather than marketing these products under generic name, many companies apply for a trade-mark derived from an INN and, in particular, including the INN common stem. This practice endangers the principle that INNs are public property; it can frustrate the rational selection of further INNs for related substances, and it will ultimately compromise the safety of patients by promoting confusion in drug nomenclature."

These concerns were debated during the sixth International Conference of Drug Regulatory Authorities (ICDRA), in Ottawa, in October 1991. Based on recommendations made by the WHO Expert Committee on the use of Essential Drugs, the resolution WHA46.19 on *Nonproprietary names for pharmaceutical substances* was adopted by the Forty-sixth World Health Assembly in 1993, requesting Member States to:

- *"...enact rules or regulations, as necessary, to ensure that international nonproprietary names (or the equivalent nationally approved generic names) used in the labelling and advertising of pharmaceutical products are always displayed prominently;*
- *...encourage manufacturers to rely on their corporate name and the international nonproprietary names, rather than on trade-marks, to promote and market multisource products introduced after the expiry of a patent;*
- *... develop policy guidelines on the use and protection of international nonproprietary names, and to discourage the use of names derived from them, and particularly names including established stems, as trade-marks."*

In the *note verbale*, attention is drawn to this resolution concerning the use and protection of INN. The full text of the resolution is reproduced in Annex 4.

As a matter of principle, it may thus be recommended that trade-marks should not be derived from INN. In particular, the intentional incorporation of meaningful INN stems in trade-marks should be avoided.

Similarly, inclusion of elements from biochemical nomenclature (like *-feron* from interferon, or *-leukin* from interleukin) in trade marks in anticipation is discouraged since these elements are likely to be utilized as stems within the INN nomenclature. Their inclusion in trade-marks could pre-empt the logical development of the INN nomenclature.

In accordance with resolution WHA46.19, registration of an INN together with a firm's name is perfectly acceptable, as long as it does not prevent another manufacturer from using the same approach.