



# WORLD HEALTH ORGANIZATION

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## **International Nonproprietary Names: revised procedure**

### **Report by the Secretariat**

#### **BACKGROUND**

1. In order to select a single, nonproprietary name of worldwide acceptability for each active substance used in pharmaceutical preparations, WHO collaborates closely with the national nomenclature committees.<sup>1</sup> In this regard, WHO has been responsible for selecting and promoting the protection of recommended International Nonproprietary Names (INN) for pharmaceutical substances, in coordination with national authorities worldwide. Members of the Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations have been designated (“the INN Expert Group”) to assist WHO in this task, by considering and selecting proposed names.
2. INN are intended to be used globally for the identification of a specific pharmaceutical substance. So as to ensure the universal availability of INN for their intended purpose, they should be free from any protection by proprietary rights – hence, the designation nonproprietary. The existence of an international nomenclature for pharmaceutical substances, in the form of INN, is important for the clear and unambiguous 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.
3. The current procedure guiding the selection of recommended INN was adopted by the Executive Board in 1955 in resolution EB15.R7. Since then, only one amendment has been made to this procedure, namely in resolution EB43.R9, adopted in 1969, which changed the term “pharmaceutical preparations” to “pharmaceutical substances”.
4. During the past 50 years, it has become increasingly difficult to deal with objections to published proposed INN and to substitute previously recommended INN. Under the current procedure, if an objection is not withdrawn, the selection of a proposed INN as a recommended INN is effectively blocked. In addition, the number of requests for substitution of a previously recommended INN has

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<sup>1</sup> See resolution WHA3.11 on Nonproprietary Names for Pharmaceutical Substances, adopted in 1950 by the Third World Health Assembly.

increased over the past few years. Such requests often result from confusion with a registered trademark or another commonly used name, leading to possible errors in prescription practices.

## **REVISION PROCESS**

5. The proposed amendments to the procedure and working process were drawn up in consultation with the INN Expert Group. They were mailed for comments to more than 240 national authorities, as well as the International Federation of Pharmaceutical Manufacturers Associations. Feedback was positive and supportive, and, where feasible, suggestions were taken into account in finalizing the text.

## **THE REVISED PROCEDURE**

6. In addition to some corrections and clarifications to reflect the current state of affairs, the proposed amendments are aimed at establishing (1) a procedure for the acceptance or rejection of an objection raised against a proposed INN, and (2) rules for a possible substitution of a previously recommended INN.

7. The proposed revised procedure is attached (Annex 1). It is further proposed to include the text of a working process as an appendix to the procedure. This working process (Annex 2) is intended to serve as a guide for the INN Expert Group in the implementation of the procedure. The General principles for guidance in devising International Nonproprietary Names for pharmaceutical substances are attached at Annex 3.

## **ACTION BY THE EXECUTIVE BOARD**

8. The Executive Board is invited to consider adopting the revised procedure for the selection of recommended International Nonproprietary Names for pharmaceutical substances and the above-mentioned working process as a new appendix to the procedure.

## ANNEX 1

**PROCEDURE FOR THE SELECTION OF  
RECOMMENDED INTERNATIONAL NONPROPRIETARY NAMES  
FOR PHARMACEUTICAL SUBSTANCES<sup>1</sup>**

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 the World Health Assembly resolution WHA3.11, **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 the World Health Organization on the form provided therefor. **The consideration of such proposals shall be subject to the payment of an administrative fee designed to cover the corresponding costs of the Secretariat of the World Health Organization (“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”, appended 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***<sup>2</sup> and by letter to Member States and to national **and regional** pharmacopoeia commissions or other bodies designated by Member States.

(i) Notice may also be sent to specific persons known to be concerned with a name under consideration.

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<sup>1</sup> See Annex 1 in WHO Technical Report Series, No. 581, 1975; proposed amendments are shown in bold-face type. The original text was adopted by the Executive Board in resolution EB15.R7 and amended in resolution EB43.R9.

<sup>2</sup> Before 1987, lists of INN were published in the *Chronicle of the World Health Organization*.

- B. Such notice shall:
- (i) set forth the name under consideration;
  - (ii) identify the person who submitted a proposal for naming the substance, if so requested by such person;
  - (iii) identify the substance for which a name is being considered;
  - (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 the World Health Organization 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 the World Health Organization.

#### Article 4

Comments on the proposed name may be forwarded by any person to the World Health Organization 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***.

[A.] 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.

**Before proceeding to the submission of such an objection to the INN Expert Group in accordance with article 6, the Secretariat shall either use its good offices to obtain a withdrawal of the objection, or, if in the opinion of the Secretariat there seem to be compelling reasons to reconsider a proposed name, directly proceed with the submission of this objection to the INN Expert Group.**

#### Article 6

**Where there is a formal objection under article 5, and this objection has not been withdrawn within two (2) months of the Secretariat's written request to that effect (if any), the objection shall be submitted to the INN Expert Group for consideration. An objection shall be**

considered in accordance with the General principles referred to in article 2 and take account of:

- (a) a possible confusion of the proposed international nonproprietary name with:
  - a trademark for a pharmaceutical drug product; or
  - another international nonproprietary name (confusion could arise, for instance, in prescription practices or due to language-related issues); or
  - a commonly used name in pharmaceutical and/or prescription practices, other than a trademark or an international nonproprietary name;
- (b) substantial risk to the safety of patients, arising out of a possible confusion as set forth under (a) above;
- (c) the extent to which the trademark, other international nonproprietary name or commonly used name referred to in (a) above is actually in use and takes priority over the selection of the proposed international nonproprietary name;
- (d) any comments provided under article 4 above; and
- (e) any other relevant nomenclature issue.

In the event that, after consideration of an objection, the INN Expert Group concludes that a proposed international nonproprietary name needs to be reconsidered, this name shall be substituted in accordance with the General principles referred to in article 2 and the procedure set forth in articles 3 to 8 inclusive.

In the event that, after consideration of an objection, the INN Expert Group concludes that there are no compelling reasons to reconsider a proposed international nonproprietary name, this name shall be selected as a recommended international nonproprietary name. In such event, the letter to Member States and to national and regional pharmacopoeia commissions or other bodies designated by Member States, referred to in article 3A, shall include a notice that the nonproprietary name is being recommended despite one or more objections (with a short description of the objection(s) in question and the reason(s) why those objections were not considered sufficiently compelling to reconsider the recommended international nonproprietary name).

Any person having filed an objection shall be notified by the Secretariat as to whether or not the proposed international nonproprietary name has been, or will be, reconsidered.

#### Article 7

Where no objection has been filed under article 5, or all objections previously filed have **either** been withdrawn **under article 5**, or been considered **insufficiently compelling under article 6**, the **Secretariat** shall give notice in accordance with subsection A of article 3 that the name has been selected by the World Health Organization 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, including prohibiting registration of the name as trademark or tradename.

**Article 9 [new]**

- A. **Proposals for substitution of a previously recommended international nonproprietary name may be filed by any interested person. Such proposals shall be submitted on the form provided therefor 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.**

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

**In the event that there seems to be no compelling reason for substitution, in the opinion of the Secretariat, the Secretariat shall use its good offices to obtain a withdrawal of the proposal before proceeding to submit this proposal to the INN Expert Group. Where there is a formal proposal for substitution, and this proposal has not been withdrawn within two (2) months of the Secretariat's written request to that effect (if any), the Secretariat shall submit the proposal to the INN Expert Group for consideration. However, the Secretariat may directly proceed with the submission of the proposal to the INN Expert Group, if, in the opinion of the Secretariat, there seem to be compelling reasons for substitution.**

**The Secretariat may request Member States and national and regional pharmacopoeia commissions or other bodies designated by Member States to comment on the proposed substitution. Such a request for comments shall be made by including a notice to that effect in the letter referred to in article 3A. In addition, a request for comments may be sent to specific persons known to be concerned by the proposed substitution.**

**The request for comments shall:**

- (a) **state the recommended name which is being proposed for substitution (and the proposed substitute name, if provided);**
- (b) **identify the person who submitted the proposal for substitution (if so requested by such person);**

- (c) identify the substance to which the proposed substitution relates and reasons put forward for substitution;
- (d) set forth the time within which comments should be received and the person and place to whom they should be directed; and
- (e) state the authority under which the World Health Organization is acting and refer to these rules of procedure.
- B. A proposal for substitution of a recommended international nonproprietary name shall be considered in accordance with the General principles referred to in article 2 and take account of the following:**
- (a) a possible confusion with:
- a registered trademark for a pharmaceutical drug product; or
  - another international nonproprietary name (confusion arises, for instance, in prescription practices or due to language-related issues); or
  - a commonly used name in pharmaceutical and/or prescription practices, other than a trademark or an international nonproprietary name;
- (b) substantial risk to the safety of patients, arising out of a possible confusion as set forth under (a) above;
- (c) the extent to which the recommended international nonproprietary name (proposed for substitution) on the one hand and the trademark, other international nonproprietary name or commonly used name as referred to under (a) above on the other hand, are actually in use;
- (d) any comments provided under article 9A by Member States, national and regional pharmacopoeia commissions, other bodies designated by Member States and/or other persons known to be concerned by the proposed substitution; and
- (e) any other relevant nomenclature issue.

In the event that, after consideration of a proposal for substitution, the INN Expert Group concludes that a recommended name needs to be substituted, a new international nonproprietary name shall be selected 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, shall in such event indicate that the new name is a substitute for a previously recommended name and that Member States may wish to make transitional arrangements, in order to accommodate existing products that use the substituted international nonproprietary name on their label in accordance with national legislation.

In the event that, after consideration of a proposal for substitution, the INN Expert Group concludes that there are no compelling reasons to substitute a previously recommended name, this name shall be retained. In such event, the Secretariat shall advise Member States, national

and regional pharmacopoeia commissions, other bodies designated by Member States that, despite a proposal for substitution, it has been decided to retain the previously recommended name (with a short description of the reason(s) why the proposal for substitution was not considered sufficiently compelling).

Any person having proposed a substitution shall be notified by the Secretariat as to whether or not the previously recommended international nonproprietary name will be substituted.

**Article 10 [new]**

A working process, intended to serve as a guide for the INN Expert Group in the implementation of these rules of procedure, is attached hereto as an appendix.<sup>1</sup>

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<sup>1</sup> See Annex 2.

## ANNEX 2

## APPENDIX

**Working process for the INN Expert Group<sup>1</sup>**

1. This document serves as a guide for the INN Expert Group in the implementation of the procedure for the selection of recommended international nonproprietary names for pharmaceutical substances (“the procedure”).<sup>2</sup>
2. The process of selecting an INN for a pharmaceutical substance is described in the procedure. The General principles for guidance in devising International Nonproprietary Names for pharmaceutical substances specify the criteria to be applied when selecting new INN.
3. The INN Expert Group is composed of specialists representing a broad range of expertise in the pharmaceutical, chemical, biochemical and pharmacological sciences pertinent to the selection of INN. The Group also aims to represent the widest possible geographical distribution. The INN Expert Group may invite coopted experts in the field of pharmaceutical trademarks and linguists to advise it on issues within the sphere of their competence.
4. The decisions on the selection of new INN are taken as a result of consultations and ensuing correspondence, if necessary (see paragraph 11 below). The consultations take place twice a year.
5. The members of the INN Expert Group may formulate their views in the following manner:
  - (a) unconditional acceptance of a suggested name;
  - (b) a negative opinion with a proposal to modify the suggested name;
  - (c) a conditional opinion (e.g. asking for further information from the originator of the request on the mode of action of the substance);
  - (d) abstention.
6. New INN requests and proposals for the resolution of outstanding, pending issues are regularly mailed by the Secretariat to the INN Expert Group. During the preliminary consultation phase, the Secretariat provides members of that Group with copies of each completed INN request form, together with the accompanying documentation submitted by the originator of each such request. The experts are usually also provided with an analysis in light of the guiding principles, previously recommended INN and established trademarks from the Secretariat and related additional information. Experts are invited to provide comments in writing to the Secretariat before the forthcoming consultation, taking account of, in particular:

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<sup>1</sup> Designated members of the Expert Advisory Group on the International Pharmacopoeia and Pharmaceutical Preparations.

<sup>2</sup> See Annex 1.

- correctness of classification and stem;
- conflicts with existing INN or trademarks;
- linguistic aspects.

The experts' comments are synthesized and analysed by the Secretariat for discussion during the consultation.

7. For the purpose of the twice-yearly INN consultations, the INN Expert Group selects a moderator from among its members. The moderator summarizes the opinions expressed during the preliminary consultation phase, after which the INN experts discuss the request for a new INN, and either select a proposed INN or defer the matter in accordance with the provisions set out in paragraphs 11 and 14.

8. The Secretariat drafts a report of each meeting, in which all decisions are reflected.

9. Within about one month after the consultation, the Secretariat sends a draft of the report to all members of the INN Expert Group, inviting them to comment whether the report accurately reflects the discussions and opinions expressed during the consultation, within a deadline of six weeks. In the absence of any written comments within the aforesaid six-week period, the report is assumed to reflect accurately the discussions and opinions expressed during the consultation.

10. Experts who are unable to attend a consultation must express their opinion in writing. If no opinion is received, this will be considered as an abstention. No decision can be taken in the absence of a majority of the members of the INN Expert Group having expressed their opinion, either in person during a consultation or in writing before a consultation (quorum for decision). Decisions are taken by consensus of the INN Expert Group members expressing their opinion.

11. In the absence of a consensus, in accordance with the provision of paragraph 10 above, the matter will continue to be discussed by correspondence or at the next consultation, if necessary. If requested by the INN Expert Group, the Secretariat will provide additional information and/or alternative proposals to the INN Expert Group for such continued discussions. This process will continue until a decision on a proposed INN is confirmed in accordance with the provision of paragraph 10 above.

12. In the absence of any comments on the manner in which a decision is reflected in the draft report, the decision will be considered as finally adopted. In such an event, the Secretariat informs the originator of the new INN request about the name that has been selected as a proposed name. Simultaneously, the Secretariat proceeds to publish the selected name in the forthcoming proposed INN list (see Article 2 of the procedure).

13. The rules set out above in regard to new INN equally apply in regard of:

- the selection of new common stems;
- the consideration of objections raised to proposed INN;

- a decision not to propose an INN (paragraph 14 below);
- the consideration of substitution of previously recommended INN.

14. The INN Expert Group may decide not to propose an INN at all. Such a decision is usually taken when there is already a common name in general use for the pharmaceutical substance, and that name does not fit into the selection criteria for an INN or the selection of an INN would cause confusion. INN are also not proposed when the general principles for selecting an INN are not met, e.g. in the case of a combination of two pharmaceutical substances.

### **Information available through the Internet**

***INN request form:***

<http://www.who.int/medicines/organization/qsm/activities/qualityassurance/inn/innform2000.pdf>

***Procedure for the selection of recommended International  
Nonproprietary Names for pharmaceutical substances:***

<http://www.who.int/medicines/organization/qsm/activities/qualityassurance/inn/innproc.html>

***General principles for guidance in devising International  
Nonproprietary Names for pharmaceutical substances:***

<http://www.who.int/medicines/organization/qsm/activities/qualityassurance/inn/inngen.html>

***On-line access to published INN:***

<http://mednet.who.int>

## ANNEX 3

**GENERAL PRINCIPLES FOR GUIDANCE IN DEVISING  
INTERNATIONAL NONPROPRIETARY NAMES FOR  
PHARMACEUTICAL SUBSTANCES<sup>1</sup>**

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 which are 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.

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<sup>1</sup> In its Twentieth report (WHO Technical Report Series, No. 581, 1975), the WHO Expert Committee on Nonproprietary Names for Pharmaceutical Substances reviewed the general principles for devising, and the procedures for selecting, INN in the light of developments in pharmaceutical compounds in recent years. The most significant change has been the extension to the naming of synthetic chemical substances of the practice previously used for substances originating in or derived from natural products. This practice involves the use of a characteristic "stem" indicative of a common property of the members of a group. The reasons for, and the implications of, the change are fully discussed.

The guiding principles were updated during the 13th consultation on nonproprietary names for pharmaceutical substances (Geneva, 27-29 April 1983) (PHARMS/NON 928 13 May 1983, revised 18 August 1983).

9. Group relationship in INN (see Guiding 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.<sup>1</sup> Where a stem is shown without any hyphens it may be used anywhere in the name.

Latin	English	
-acum	-ac	anti-inflammatory agents of the ibufenac group
-actidum	-actide	synthetic polypeptides with a corticotropin-like action
-adolum	-adol	} analgetics
-adol-	-adol-	
-astum	-ast	antiasthmatic, antiallergic substances not acting primarily as antihistaminics
-astinum	-astine	antihistaminics
-azepamum	-azepam	diazepam derivatives
-bactamum	-bactam	$\beta$ -lactamase inhibitors
bol	bol	steroids, anabolic
-buzonum	-buzone	anti-inflammatory analgesics, phenylbutazone derivatives
-cain-	-cain-	antifibrillant substances with local anaesthetic activity
-cainum	-caine	local anaesthetics
cef-	cef-	antibiotics, cephalosporanic acid derivatives
-cillinum	-cillin	antibiotics, derivatives of 6-aminopenicillanic acid
-conazolium	-conazole	systemic antifungal agents, miconazole derivatives
cort	cort	corticosteroids, except prednisolone derivatives
-dipinum	-dipine	calcium channel blockers, nifedipine derivatives
-fibratum	-fibrate	clofibrate derivatives
gest	gest	steroids, progestogens
gli-	gli-	sulfonamide hypoglycaemics
io-	io-	iodine-containing contrast media
-ium	-ium	quaternary ammonium compounds
-metacinum	-metacin	anti-inflammatory substances, indometacin derivatives
-mycinum	-mycin	antibiotics, produced by <i>Streptomyces</i> strains

<sup>1</sup> A more extensive listing of stems is contained in the working document WHO/EDM/QSM/99.6 which is regularly updated and can be requested from the INN Programme, WHO, Geneva.

<b>Latin</b>	<b>English</b>	
-nidazolum	-nidazole	antiprotozoal substances, metronidazole derivatives
-ololum	-olol	$\beta$ -adrenoreceptor antagonists
-oxacinum	-oxacin	antibacterial agents, nalidixic acid derivatives
-pridum	-pride	sulpiride derivatives
-pril(at)um	pril(at)	angiotensin-converting enzyme inhibitors
-profenum	-profen	anti-inflammatory substances, ibuprofen derivatives
prost	prost	prostaglandins
-relinum	-relin	hypophyseal hormone release-stimulating peptides
-terolum	-terol	bronchodilators, phenethylamine derivatives
-tidinum	-tidine	histamine H <sub>2</sub> -receptor antagonists
-trexatum	-trexate	folic acid antagonists
-verinum	-verine	spasmolytics with a papaverine-like action
vin-	vin-	} vinca alkaloids
-vin-	-vin-	

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