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INTERNATIONAL NONPROPRIETARY NAMES FOR PHARMACEUTICAL SUBSTANCES

prepared by the International Bureau

I. BACKGROUND

1. The World Health Organization (WHO) has the constitutional mandate to develop, establish and promote international standards with respect to biological, pharmaceutical and similar products. In accordance with World Health Assembly (WHA) resolution 3.11 on Nonproprietary Names for Pharmaceutical Substances (adopted in May 1950 by the Third World Health Assembly), WHO collaborates closely with national nomenclature committees to select a single, nonproprietary name of worldwide acceptability for each active substance used in pharmaceutical preparations. Under the procedure for the selection of recommended INNs, proposals for recommended INNs are submitted to WHO and discussed by an expert panel (the WHO Expert Panel on the International Pharmacopoeia and Pharmaceutical Preparations) of which secretaries or representatives of all the major national nomenclature committees are members. If all members of that Panel agree to a given name, it is published as a proposed INN. In addition to the publication in the *WHO Chronicle*, lists with proposed INNs are sent to WHO member States and to national pharmacopoeia commissions or other bodies designated by member States. Within four months of the publications of a proposed INN, objections against a proposed name may be filed by any interested person. Where there is a formal objection, WHO may either reconsider the proposed name or use its good offices to attempt to obtain withdrawal of the objection. A name is not selected as a recommended INN while there exists a formal objection thereto which has not been withdrawn. Where no objection was made or all objections were withdrawn, the Director General of WHO gives notice that the name has been selected as a recommended INN. In forwarding a

recommended INN to the WHO member States, the Director General of the WHO requests that such name be recognized as the nonproprietary name for the substance and 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 a trademark or a trade name. In 1997, the list of recommended INNs contained some than 7000 names.¹

II. CONTACTS BETWEEN WIPO AND WHO

2. The underlying reason for ensuring that proprietary rights, including trademarks, cannot be claimed in INNs is to protect the safety of patients by allowing them to identify a specific pharmaceutical substance under one single, globally available name. In this context, WHO has approached WIPO to explore possible ways of cooperation between the two Organizations in order to ensure that INNs are not misused or appropriated through registration as trademarks. Subsequently, the subject of INNs was put on the Agenda of the first meeting of the Standing Committee on the Law of Trademarks, Industrial Designs and Geographical Indications (SCT), which met in Geneva from July 13 to 17, 1998.²

3. The SCT agreed at that meeting that the International Bureau would conduct a survey among its Member States concerning trademark office practice as regards the examination of applications for trademark registrations as to conflicts with proposed or recommended INN(s), and that it would present the results of that survey to the Standing Committee at its third session (SCT/1/6, paragraph 34).

III. THE WIPO QUESTIONNAIRE

4. Following the above-mentioned decision by the SCT, the International Bureau prepared a questionnaire which was sent to all States party to the Paris Convention and/or member of the World Intellectual Property Organization. As of September 30, 1999, replies had been received from the following States: Albania, Argentina, Armenia, Australia, Austria, Belarus, Belgium, Bhutan, Bosnia and Herzegovina, Brazil, Brunei Darussalam, Bulgaria, Cambodia, Canada, China, Colombia, Croatia, Cyprus, Czech Republic, Denmark, Dominica, El Salvador, Estonia, Finland, France, Georgia, Germany, Ghana, Greece, Guatemala, Guinea, Hungary, Iceland, India, Ireland, Israel, Jamaica, Japan, Kazakhstan, Kyrgyzstan, Latvia, Lebanon, Liechtenstein, Lithuania, Mali, Malta, Mauritius, New Zealand, Nicaragua, Norway, Panama, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Romania, Russian Federation, Singapore, Slovakia, Slovenia, Spain, Sri Lanka, Sweden, Switzerland, Tajikistan, The former Yugoslav Republic of Macedonia, Tunisia, Turkmenistan, Ukraine, United Kingdom, United States of America, Uruguay, Viet Nam (74). The Benelux Trademark Office also replied to the questionnaire.

¹ See WHO Publication WHO/PHARM S/NOM 1570 (*Guidelines on the Use of International Nonproprietary Names (INNs) for Pharmaceutical Substances*).

² WHO also submitted a comment to WIPO within the framework of the WIPO Domain Name Process, concerning the unauthorized registration of INNs as Internet domain names (see WIPO Publication No. 439(E) or "<http://wipo2.wipo.int>", *Report of the WIPO Internet Domain Name Process*, paragraphs 296 to 303).

5. The text of the questionnaire showing the number of replies given to the various questions is reproduced in the Annex.

IV. INTERPRETATION OF THE REPLIES AND PROPOSED FURTHER ACTION

6. Concerning potential conflicts between applications for trademark registration and INNs, the survey shows that, among those offices who replied to it, there is great awareness concerning that problem. Out of 75 replies, 54 offices (72%) stated that they examine applications for the registration of trademarks as to conflicts with INNs and/or equivalent nonproprietary names adopted by a national or regional authority (as opposed to 21 negative replies (28%)). Sixty-four offices (~ 85%) replied that they would refuse the registration of a trademark because of a conflict with an INN (as opposed to 8 negative replies (~10%)).³

7. As regards the source from which offices obtain the lists on the basis of which applications for trademark registrations are examined, the majority of offices (36 out of 75, or 48%) indicated that this information was obtained directly from WHO. Furthermore, it appears to be significant that 68 offices (~ 90%) stated that they had an interest in receiving lists with proposed or recommended INNs in an electronic format, whereas only 4 out of 75 replies (~5%) were negative in that respect.³

8. In a general sense, it can be said that the majority of the offices that replied to the questionnaire examine applications for the registration of trademarks against any conflicting nonproprietary name for pharmaceutical substances or refuse the registration of such a trademark. Furthermore, a high interest in obtaining relevant information in electronic format was manifested.

9. At this time, if the SCT so desires, the International Bureau could hold direct discussions with the WHO Secretariat in order to find ways of making available the lists of INNs adopted and compiled by WHO in an electronic format to those States party to the Paris Convention and/or members of WIPO which wish to obtain such information. Once information is received as to the form in which those lists can be made available to interested WIPO and/or Paris Member States, that information will be submitted to the SCT.

[Annex follows]

³ In a number of questionnaires, a reply was not given to that question

**Questionnaire Concerning Trademarks and International Nonproprietary Names for
Pharmaceutical Substances (INNs)**

1. Does your Office examine applications for the registration of trademarks as to conflicts with INNs and/or equivalent nonproprietary names adopted by a national or regional authority?

Yes	No
54	21

2. If your Office does not carry out such an examination, is it possible to invalidate or cancel registered trademarks which conflict with such names?

Yes	No
35	7

3. If your Office carries out such an examination, from what source does it obtain the lists on the basis of which applications for trademark registrations are examined?

World Health Organization	Other (Please specify)
36	14

Problems with updating (2)

National Health Administration
17

4. If your Office carries out such an examination, does your Office carry out a manual or an automated search in order to determine possible conflicts between applications for trademark registrations and INNs?

Manual Search	Automated Search
40	14

5. Would you be interested in receiving the lists with proposed or recommended INNs in an electronic format? If yes, what format(s) would you prefer?

Yes (Please specify format)	No
68	4
Excel (5)	
Word (10)	
PDF (6)	
Oracle (1)	
TXT (4)	
HTM (3)	
ASCII (3)	
Access (2)	
Magnetic Tape (1)	
CD-ROM (25)	

6. Would your Office refuse the registration of a trademark because of a conflict with an INN? If yes, under what condition?

Yes (Please specify condition)	No
64¹	8

[End annex and of document]

¹ Replies containing an affirmative response to that question generally indicated that a registration of a trademark would be refused because of a conflict with an INN, since such a trademark would be regarded to be either descriptive (if the trademark was constituted by or contained the INN proposed or adopted for the substance for which the trademark is used), or deceptive (if the trademark was constituted by or contained an INN proposed or adopted for a substance other than the one for which the trademark is used).