

A Study on the Use of International Nonproprietary Names in India

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FOREWORD

International Nonproprietary Names (INNs) are internationally recognized names for pharmaceutical substances recommended by the World Health Organization (WHO) and provide a standardized system of nomenclature. INNs replace long, unwieldy chemical names for pharmaceutical substances with short names that are easy to recall and developed in a standardized manner. INNs are universally applicable generic names for drugs and thus help to reduce confusion in drug nomenclature. The generic name allows an understanding of the drug even when that individual drug is not known, and is a vital piece of information that is compulsory on a medicine label. INNs are nonproprietary in nature, which implies that the same INN can be used by all manufacturers of that pharmaceutical substance, irrespective of the brand name under which the drug is marketed by each manufacturer. Since brand names are proprietary in nature and are protected from appropriation by other sellers of the same generic product, in principle INNs should not be used to coin brand names. However, many pharmaceutical companies use brand names coined from INNs. This practice dilutes the INN system and hampers the creation of new INNs since brand names are protected as proprietary names under trademark laws. To address this issue, in 1993 the World Health Assembly of WHO adopted Resolution 46.19 exhorting Member States to devise appropriate policies and regulations for the use of INNs.

In India, the trademark registration of words that are declared as INNs or those that are deceptively similar to INNs is prohibited under Section 13 (b) of the Trade Marks Act, 1999. Nevertheless, there are instances of brand names derived from INNs being used as trademarks in India. In view of the requirements of WHA Resolution 46.19 of 1993, WHO has requested the Drugs Controller General of India (DCGI) to take appropriate measures to address the situation. However, little progress has been made in implementing this Resolution.

The use of INNs to coin brand names can have important public health implications. It is argued that INNs can be a useful tool for promoting generic prescription in India, enabling consumers to access medicines at lower prices on the basis of their freedom to choose. In the absence of any comprehensive law or policy on promotion of generic prescriptions and price control of drugs, the use of INNs for coining brand names may be helpful in identifying the active ingredient of a drug as well as in reducing the branding cost of such drugs.

This study examines the legal and policy regime for the use of INNs in India in the context of these diverse implications. It provides a legal interpretation of WHA Resolution 46.19 and the institutional mechanisms of the WHO-INN Programme. It also examines the Indian trademark and drug regulatory laws and policies in view of the requirements of WHA Resolution 46.19. The study identifies gaps in these international and domestic regimes pertaining to the use of INNs, and makes suggestions for the progressive reform of these regimes.

It is hoped that the analysis in this paper will be useful for policy-makers, researchers and civil society. It is also hoped that it will help take forward India's law and policy on the subject in accordance with international best practices. Suggestions and feedback would be welcome.

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ABBREVIATIONS AND ACRONYMS

AMA	American Medical Association
APA	American Pharmacists Association
BAN	British Approved Name
CDER	Center for Drug Evaluation and Research
CDSCO	Central Drugs Standard Control Organization
CPMP	Committee for Proprietary Medicinal Products
DCGI	Drugs Controller General of India
EMA	European Medicines Evaluation Agency
EU	the European Union
FDA	Food and Drug Administration
FDC	Fixed-Dose combination
HAI	Health Action International
INN	International Nonproprietary Name
INNM	Modified International Nonproprietary Name
IPLR	Industrial Property Law Reports
LNC	Labelling and Nomenclature Committee
MAH	Marketing Authorization Holder
NFI	National Formulary of India
PTC	Patents and Trademarks Cases
UDRP	Uniform Domain Name Dispute Resolution Policy
UK	The United Kingdom
USA	The United States of America
USAN	United States Adopted Name
USPC	United States Pharmacopeial Convention
WHA	World Health Assembly
WHO	World Health Organization
WIPO	World Intellectual Property Organization

EXECUTIVE SUMMARY

From a public health perspective, it is desirable for drugs to be marketed by their generic names. However, drugs are generally marketed by their brand names though there is a legal requirement to mention generic names in the labels. Countries have their own systems of generic nomenclature for pharmaceutical substances. However, owing to the various languages used by different national nomenclature systems, there is a need to have a uniform, standardized system of generic names that are accepted worldwide; this would help in identifying the composition of a pharmaceutical substance. The World Health Organization (WHO) administers an international generic nomenclature system called International Nonproprietary Names (INNs).

INN facilitates the identification of a pharmaceutical substance or active pharmaceutical ingredient. Each INN is a unique name that is globally recognized and is public property. Thus, INNs help in the easy identification of a drug thereby reducing confusion in drug nomenclature, which is an essential element of drug safety for better patient care. Since INNs are unique identifiers that are available in the public domain, any use of INNs as private property must be discouraged. However, in reality many pharmaceutical companies indulge in the practice of coining brand names from INNs and registering them as trademarks. Since they get proprietary rights over such trademarks they can legally oppose the coining of new INNs in the future if they are similar to the trademark. Moreover, such a practice may also lead to confusion in drug nomenclature and thereby expose patients to the risk of improper medication.

The use of INNs as trademarks constitutes a problem in two ways: use of parts of INNs in trademarks can dilute the INN system by creating confusion in drug nomenclature. Second, unlike INNs, since trademarks enjoy legal protection the use of INN stems in trademarks may thwart the coining of new INNs in the future using the common stem if a trademark owner opposes the INN. This is because in the selection of INNs it is ensured that the rights of trademark owners are not affected through INNs.

To address this problem, in 1993 the World Health Assembly (WHA) adopted Resolution 46.19 requesting Member States to take appropriate action to devise policy guidelines on the use of INNs and to discourage the registration of names derived from INNs, particularly INN stems, as trademarks. In accordance with this resolution, Section

13 (b) of the Trade Marks Act of India specifically prohibits the trademark registration of words that are INNs or that are deceptively similar to such names.

The Indian pharmaceutical industry is generally of the view that the practice of deriving brand names from parts of generic names is common throughout the world. The practice of using parts of INN stems is not specifically prohibited under Indian law; moreover, this does not cause confusion since the Indian regulations require the generic name to be shown more prominently than the brand name. Further, the use of stems in the brand name may help in easy identification of the brand with the generic substance. It may also be cost-effective for small companies to use a brand name that contains a part of an INN without having to invest substantially on developing unique brand names. Large companies want to have unique brand names identifying the name with the company, since they want to build the loyalty of the customer to the company and all its brands. Small companies, with a smaller range of products, need to develop loyalty to particular brands. It is easier to create names using parts of generic names, as they are easy to recall and identify. Some stakeholders also hold the view that while it may be ideal to have generic names for drug promotion, it may not be a practical policy in India where most drugs are marketed by the private sector. However, the practice of using INN stems in brand names may lead to confusion due to the availability of drugs that sound alike and look alike.

The Indian Law

Section 13 (b) of the Trade Marks Act, 1999 states that no word that is declared as an INN by WHO and is notified by the Registrar of Trade Marks, or which is deceptively similar to such names, can be registered as trademarks. However, no INN has been notified by the Trade Marks Registrar. There is also no requirement under the Trade Marks Rules for conducting a search of INNs while examining new trademark applications in class 5 (pharmaceutical substances come under class 5). Moreover, there is no mandatory requirement of registering a trademark in India. Even without a registration a mark may be protected as an unregistered trademark. Hence, the scrutiny of Section 13 (b) may be bypassed by not registering a mark as a trademark.

In spite of the provision in Section 13 (b), there are instances in India of drugs bearing names that have been derived from INNs and registered as trademarks. In this respect, WHO has issued INN protection letters to the Drugs Controller General of India (DCGI) requesting the DCGI to take an appropriate action to discourage the trademark registration of such names. However, so far no remedial action has been taken in this regard by any of the concerned authorities.

There is also no mandatory requirement for registration of brand names in India.

The drug regulatory system in India is highly decentralized with a limited role being played by the Central Drug Regulatory Authority. The State Drug Regulatory Authorities do not have the capacity to control this effectively in a decentralized system. Hence there is need for a specific policy guideline on the use of INNs in India. Although the Drugs and Cosmetics Rules requires that generic names including INNs be printed more prominently than brand names on drug labels, this requirement is often bypassed by printing the brand name in bold font than the generic name. In order to control such practices, it is desirable to develop a centralized database of brands that are approved by State Drug Regulatory Authorities by simply posting them on the internet. However, there is no centralized database of brands approved for marketing in India.

This suggests that there are major gaps in the legal and policy regime in India on the use of INNs. This study examines some of these gaps and advances the following suggestions:

Suggestions

WHO

- 1 For the effective and transparent implementation of WHA Resolution 46.19 a reporting and monitoring mechanism should be established.
- 2 Since Resolution 46.19 is non-binding, it would be appropriate to work towards the development of an international convention on the use and protection of international nonproprietary names for pharmaceutical substances. Since there is no authoritative interpretation of WHA Resolution 46.19, development of an international convention may help to codify the international legal regime for the use of INNs. At present, there is little transparency in the compliance mechanism of the INN Programme. The proposed convention should also have a mandatory requirement for all Member States to send periodic reports to WHO informing it about the steps taken to ensure compliance with the international legal regime.
- 3 The issue regarding the use of INNs should be treated as a brand registration rather than a trademark issue. Thus, the INN Programme should focus on the use of brand names derived from INNs rather than focusing only on trademark registrations.
- 4 The communications from WHO to the DCGI do not state the importance of INNs. There is a lack of clarity on the rules relating to the use of INN stems. The leaflet prepared by WHO for trademark offices does not make any mention of discouraging the use of INN stems. Therefore, there is a necessity for clear and

effective communication from WHO to the responsible national authorities for creating awareness about all issues pertaining to the use of INNs.

- 5 It would be appropriate for WHO to informally coordinate with the trademark offices in India on this issue.

Trade Marks Registry

- 1 The Registrar of Trade Marks should notify INNs recommended by WHO in the *Trade Marks Journal*.
- 2 The Trade Marks Rules should specifically require an examination of new applications under class 5 to determine whether they are derived from INNs.
- 3 All class 5 applications for registration of trademarks should disclose the generic name of the mark applied for.
- 4 The examiners should be imparted training on INNs, especially on its public health implications.
- 5 The trademarks offices must respond to communications from the DCGI on the protection of INNs.
- 6 The *Manual for examiners* should be rectified to make it reflect the spirit of Section 13.
- 7 The *Manual for examiners* should be made accessible to the general public.

DCGI

- 1 Guidelines on the use of INNs in brand names should be developed in accordance with requirements of WHA Resolution 46.19.
- 2 A database of brand names registered throughout the country should be maintained on the internet.
- 3 There should be effective coordination with WHO. Action taken by the DCGI in response to WHO letters should be communicated to WHO.
- 4 There should be better coordination between the DCGI, state drug regulators and the trade marks offices on the use and protection of INNs.
- 5 There should be capacity building at the level of state drug regulatory authorities.

Other stakeholders

- 1 There is a need to generate awareness within the pharmaceutical industry on the use of INNs.
- 2 Pharmaceutical associations should develop guidelines for the use of INNs.
- 3 Medical and legal professionals should be sensitized to this issue.
- 4 INNs should be made a part of the syllabus for medical students.

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I. INTRODUCTION

Drugs are generally marketed and prescribed under brand names. However, for purposes such as international trade in drugs, or in international expert committee lists such as the World Health Organization (WHO) List of Essential Medicines, and for all pharmaceutical exchanges and scientific research methods, reference to drugs is made by their generic names.¹ Civil society organizations and individuals engaged in public health issues are lobbying vigorously for the use of only generic names for the sale of drugs. They have urged the government to abolish the widespread use of brand names and instead promote the use of generic names to describe the drug along with the name of the manufacturer.² This will enable consumers to choose from multiple sources of the same pharmaceutical substance, which is also cost-effective.

WHO administers an international generic nomenclature system called International Nonproprietary Names commonly referred to as INNs. The World Health Assembly (WHA), through its Resolution 46.19 calls upon Member States to take necessary measures to regulate the use of INNs and to discourage the use of names derived from INN stems as trademarks. This study attempts to understand and examine the legal and policy measures relating to the use of INNs in India for the marketing of drugs. This analysis has been conducted in the context of the current discourse on the use of generic names for marketing of pharmaceutical products. A detailed analysis of these issues is undertaken in the light of the international legal framework for the protection of INNs. It also discusses the implementation of safeguards against the misappropriation of INNs in India and, based on the findings, suggests options to improve the existing regime.

The analysis comprises a review of both primary and secondary materials. Primary materials include relevant resolutions of WHO regarding the protection of INNs, reports of other international organizations and national authorities, the Trade Marks Act, 1999 of India and various decisions of courts and other bodies. The study also draws upon responses obtained on the basis of interviews with various stakeholders. The interviews were conducted with the objective of receiving inputs from people with varied perspectives on the issue, and they included trademark officials, responsible

¹ Anant Phadke, "Profiteering in the Pharmaceutical Sector", *InfoChange News & Features*, July 2005 [online], available at <http://www.infochangeindia.org/analysis78.jsp>, visited on 28th February 2006.

² *Ibid.*

government authorities, trademark lawyers, pharmaceutical companies, associations of the pharmaceutical industry, officials of WHO, public health activists and consumer groups. It was also designed to test the awareness of stakeholders about INNs.

The study is divided into six parts. The second part gives a brief account of the functioning of the INN system. This part also briefly explains the efforts made to harmonize the different national systems of generic nomenclature, with particular reference to the American and British systems. The third part examines the main issues relating to the use of INNs and the implementation of the WHA resolutions on INN, particularly in USA and Europe.

The fourth part discusses the legal and policy regime in India relating to drug nomenclature-the Drugs and Cosmetic Act, 1940 and the Trade Marks Act, 1999. The fifth part analyses how far the legal and policy framework in India succeeds in preventing misappropriation of INNs. It also identifies the gaps and loopholes in the implementation of the legal and policy regime relating to the use of INNs in India. It discusses the gaps at the level of the WHO, the Trademark Registry and the DCGI. It also portrays the opinions and views on this issue of various stakeholders.

The sixth part presents the conclusions and suggestions based on the findings of the study.

II. INNs AND OTHER NOMENCLATURE SYSTEMS

Till World War II, most drugs were extracts of natural products. After the War, however, synthetic drugs became more common. As the chemical names of these drugs were too lengthy and complex, they became incomprehensible for general use. It was necessary, therefore, to develop simple names that would help to identify the chemical composition of drugs. To address this need, the United Kingdom (UK) established the system of British Approved Names (BANs) in 1948 to provide convenient generic names by which the increasingly complex compounds for pharmaceutical substances could be identified.³ Following this step, other countries including the USA, France, Italy and Japan developed similar systems. The British and American nomenclature systems are briefly discussed below.

BAN is the official nonproprietary name or generic name given to a pharmaceutical substance, as defined in the British Pharmacopoeia. BAN is also used as the official name of pharmaceutical substances in many other countries throughout the world, especially in countries belonging to the British Commonwealth. BANs are assigned for combination as well as single-drug preparations. BANs are approved on the basis of applications made by the inventor or manufacturer of the pharmaceutical substance. All national nomenclature systems as well as the WHO-INN Programme follow this procedure.

The American system of nomenclature is called the United States Adopted Names (USAN). This system is administered by the USAN Council to serve American health professionals by selecting simple, informative and unique nonproprietary names for drugs by establishing logical nomenclature classifications based on pharmacological or chemical relationships. Three entities, the American Medical Association (AMA), the United States Pharmacopoeial Convention (USPC) and the American Pharmacists Association (APA) sponsor the USAN Council. The USAN Council works closely with the WHO-INN Programme and various national nomenclature groups, and aims at global standardization and unification of drug nomenclature and related rules for ensuring that drug information is communicated accurately and unambiguously to the WHO-INN Programme.

³ Frances Thompson, "Where do generic and brand names come from?", *The Pharmaceutical Journal*, vol.267, no.7161, 2001, pp.223-224 [online], available at http://www.pjonline.com/Editorial/20010818/news/news_brandnames.html, visited on 10th March 2006.

Need for an international system of nomenclature

The most important criterion relating to the use of names for a pharmaceutical substance is to avoid those that create confusion about the ingredients and usage of the drug. Hence, generic names are selected with the objective of enabling easy identification of the pharmaceutical active substances contained in a medicinal product. As a result, there is a need to ensure that the same substance does not carry different generic names in different countries. For example, a person consuming a drug having a particular generic name in country A may be confused when buying the same drug bearing a different generic name in country B. In a world with very few national generic nomenclature systems, it would not be difficult to ensure that the same substance does not have different generic names. However, with the existence of different national nomenclature systems, the need for an international standardized system assumed greater significance. Hence, it became necessary to develop an international system to coordinate different national nomenclature systems for achieving international standardization and harmonization. The WHO-INN Programme was developed to address this need.

The purpose of the INN system is to identify pharmaceutical substances or active pharmaceutical ingredients. The system aims to provide a unique and universally available designated name to identify each pharmaceutical substance. Clear identification on the basis of INN helps in ensuring safe prescription and dispensing of medicines to patients. INNs also facilitate communication and exchange of information among health professionals, scientists and other interested people throughout the world. Since INNs are unique names, they should be distinctive and not liable to confusion with other names in common use. As the word “nonproprietary” suggests, WHO has formally placed these names in the public domain.⁴ Hence, an INN is open to being used by all manufacturers of the pharmaceutical substance to which it relates. While such names can also be used for commercial purposes, no private proprietary interest may be acquired over these names. In other words, nobody can claim exclusive rights to an INN or any part thereof through intellectual property protection.

Mandate of WHO on INNs

The mandate for the INN Programme can be traced to the constitutional objectives of WHO, which was established in 1948. One of the constitutional objectives of WHO is the “... attainment by all peoples of the highest possible level of health”.⁵ In accordance

⁴ WHO, *Guidance on INN* [online], available at <http://www.who.int/medicines/services/inn/innquidance/en/index.html> , visited on 28th February 2006.

⁵ WHO, *Constitution of the World Health Organization*, Article 1, [online] available at < http://policy.who.int/cgi-bin/omisapi.dll?hitsperheading=on&infobase=basicdoc&jump=Constitution&softpage=Document42#JUMPDEST_Constitution >, visited on 11th March 2006. The constitution was adopted by the International Health Conference in New York on 22nd July 1946.

with this objective, WHO is mandated to

- 1 act as the directing and coordinating authority on international health work; and
- 2 develop, establish and promote international standards with respect to food, biological, pharmaceutical and similar products.⁶

By virtue of this mandate, WHO sought to coordinate the activities of the national nomenclature commissions to achieve international standardization in drug nomenclature. In 1948, the first WHA Resolution 1.27 requested WHO to work towards the unification of pharmacopoeias and the preparation of an International Pharmacopoeia. As an extension of this programme, WHO developed a programme on the selection of INNs. In 1949, the WHO Expert Committee on Unification of Pharmacopoeias drew up a plan for preparing general rules of nomenclature. This was adopted in 1950 by Resolution 3.11 of the WHA. In 1953, the first list of INNs was published, which formally established the INN Programme of the WHO.⁷ The INN Programme is administered by the WHO Secretariat located in Geneva, Switzerland. Members of the WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations, Nomenclature Section select nonproprietary names bi-annually. This advisory panel comprises representatives from national nomenclature groups and experts in various fields (i.e. medicinal nomenclature, chemistry, pharmacology, pharmaceutical chemistry, biology, etc).⁸

Selection of INNs

The selection process is initiated through an application proposing an INN for a new pharmaceutical substance by its manufacturer or inventor. Generally, the applicant has to suggest three possible names to be recommended as an INN. Proposals of INNs are to be submitted by the Director-General of WHO to the INN Expert Group. Experts from the WHO Expert Advisory Panel on the International Pharmacopoeia and Pharmaceutical Preparations then review the application. The selection process has the following stages:

1. First, an application for an INN is submitted by the manufacturer or inventor of a pharmaceutical substance;
2. Second, a review of the application is followed by the selection of a proposed INN and its publication for comments;

⁶ Ibid, Article 2(a) and (u).

⁷ WHO, *Guidelines on the Use of International Nonproprietary Names (INNs) for Pharmaceutical Substances* (Geneva: World Health Organization, 1997), p.13.

⁸ AMA, *International Nonproprietary Names*, [online] available at www.ama-assn.org/ama1/pub/upload/mm/365/timeprocessrqrd_0902.doc, visited on 13th march 2006.

3. After a period of time allowed for opposing the proposed INN, the name obtains the status of recommended INN and is published as such.⁹

The proposals are considered in accordance with the “General principles for guidance in devising international nonproprietary names for pharmaceutical substances”. In principle, 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.¹⁰ Where the name suggested does not seem to be appropriate there may be consultations between WHO and the manufacturer/inventor. Following this examination, the proposed INN will be notified in the *WHO Chronicle* and communicated to all Member States, the national pharmacopoeia commissions or other designated bodies. Following the publication of a proposed INN, an interested person who considers that the proposed INN is in conflict with an existing trademark may file a formal objection or give comments on the proposed INN within four months from the date of publication. Thus, during the process of selecting an INN, the rights of trademark owners are respected and protected. In case of objections, WHO tries to arrange for the withdrawal of the objection or it reconsiders the proposed INN. Once the objection is withdrawn, the proposed INN is published as a recommended INN.¹¹ This is also communicated to the national authorities requesting them to recognize the INN and take necessary measures to prevent the acquisition of proprietary rights over the INN, including the registration of the name as a trademark or trade name.¹²

Components of INNs

Usually, an INN consists of two parts—a randomly selected, fancy term and a stem. Stems are those parts of a group of pharmacologically related INNs that indicate the relationship between two pharmaceutical substances using a common element or compound. For instance, the INN *clopidogrel* comprises the stem *-grel* and the fancy term *clopido*. Table 2 provides further examples of the use of stems and fancy terms in INNs.

In the initial years, many countries used shortened chemical names as generic names. This system was found to be very limited, as many molecules contain similar elements and groups such as phenol, chlor, methyl or benzene rings in their chemical structures.¹³ Hence, it seemed to be reasonable to develop names that helped to identify such common elements and groups. This rationale led to the use of common stems in the selection of INNs.

⁹ WHO, *supra* n.7 p.2.

¹⁰ WHO, *Procedure for the Selection of Recommended International Nonproprietary Names for Pharmaceutical Substances*, text adopted by Executive Board of WHO in Resolution EB 15.R7, 1955 and amended by Resolution EB 43.R9, 1969, Article 2, reprinted in *WHO Drug Information*, vol.19, no.2, 2005, pp.189-90.

¹¹ *Ibid*, Articles 3 –7.

¹² *Ibid*, Article 8.

¹³ *Ibid*, p.6.

The purpose of having common stems in INNs is to identify the common elements that are present in different molecules. Hence, INNs of different drugs that are pharmacologically related have a common stem. There is no authoritative interpretation on what constitutes a common stem. However, each stem has its own technical definition that explains its function. A list of some INN stems and their definitions is given in Table 1.

TABLE 1. INN stems and their definitions

INN stem	Definition
gli	Antihyperglycaemics
-grel	Platelet aggregation inhibitors
-azepam	Diazepam derivatives
-aldrate	Antacids

Source: The use of stems in the selection of International Nonproprietary Names (INN) for pharmaceutical substances Geneva, WHO, 2004.

For instance, beta-adrenoreceptor blocking drugs (beta-blockers) block the beta-adrenoreceptors in the heart, peripheral vasculature, bronchi, pancreas and liver. While many varieties of beta-blockers are available, there are differences between them that may affect choice in treating particular diseases. Hence, there is a necessity for such substances to have distinct names with stems that help to identify them as beta-blockers. This is where the system of using common INN stems is helpful. The stem for beta-blockers is 'lol'. Different beta-blockers contain this stem in their INN e.g. *propranolol*, *acebutolol*, *atenolol*, etc. An INN is generally designated for the active part of the substance. Where an active ingredient is used with a combination of some other salt, ester, etc. the user has to create a modified INN (INNM) on their own (e.g. *mepyramine maleate* is an INNM that comprises a salt of mepyramine with maleic acid). When this procedure leads to the use of long and inconvenient names for the radical part of the INNM, the INN Programme selects a short name for the radical (e.g. *mesilate* for *methanesulfate*).¹⁴

Generally, stems are used as suffixes but sometimes they are used as prefixes. Combinations of infixes and suffixes are used. Table 2 illustrates the use of stems. Stems are thus the most important component of INNs. The basic functions of INNs are served through the use of stems to avoid confusion in drug nomenclature.

¹⁴ See WHO, supra n.7, p.4.

TABLE 2. The use of stems in INNs

INN	Fancy term	Stem
Clopidogrel	Clovido	grel
Ramipril	Rami	pril
Lisinopril	Lisino	pril
glimepiride	Mepiride	gli
Glicazide	Cazide	gli
escitalopram	es-(stem)-opram	-cital-

Source: <http://mednet.who.int>

INNs and fixed-dose combinations (FDCs)

INNs are assigned to well-defined pharmaceutical substances and not to mixtures or combinations. The rules for the use of INNs in relation to fixed-dose combination (FDC) drugs are not clear. Manufacturers of generic drugs can develop FDCs of different generic drugs more easily than manufacturers of branded drugs. Thus, generic companies can market FDCs under brand names. For instance, Ranbaxy markets an FDC of lamivudine 150 mg + stavudine 30 mg + nevirapine 200 mg, under the brand name Virolans/Triviro. However, in coining such brand names, companies sometimes use parts of INNs. For instance, the brand Zidovex-L of Aurobindo Pharma Ltd. is an FDC of zidovudine 300 mg + lamivudine 150 mg. This brand name uses the first part of the INN zidovudine in the brand name. Both USAN and BAN have attempted to name FDCs, but the idea was abandoned for various reasons. At present, there is no nomenclature system for FDCs and this is cited as a lacuna of the INN system.

Harmonization of nomenclatures

Nomenclature systems vary in different parts of the world and there is a necessity to harmonize these systems with the INN system. For instance, under the European Union (EU) legislation, the British Pharmacopoeia has to be harmonized with the European Pharmacopoeia. Since INNs have been adopted across the EU, BANs are now the same as INNs in all cases. However, the guiding principles for the adoption of BAN still state that a recommended INN will be adopted as the BAN when necessary.¹⁵ The USAN Council's rules for coining names states that a USAN should be free from conflict with other nonproprietary names.¹⁶ The reference to other nonproprietary names includes INNs. Thus, when a tentatively adopted USAN has been selected, the USAN

¹⁵ See BAN, *British Approved Names: Guiding Principles*, [online] available at <http://www.pharmacopoeia.org.uk/guiding.cfm>, visited on 13th March 2006.

¹⁶ See AMA, *Rules for Coining Names*, paragraph 4, [online] available at <http://www.ama-assn.org/ama/pub/cat-egory/print/4769.html>, visited on 13th March 2006.

Secretariat forwards this name and appropriate background information to the WHO INN Committee Secretariat. The INN Committee then undertakes an evaluative procedure not unlike that conducted by the USAN Council, and this process takes approximately five months, but may extend longer. A formal negotiation is initiated to accept the tentative USAN or to consider an INN counterproposal if there is a problem with the use of the original name in other countries. Only when it becomes apparent that the tentative name is acceptable to the USAN Council, to the submitting manufacturer, and to the INN Committee, will it be formally adopted as a USAN and published as an INN.¹⁷

Since generic names help to identify the chemical composition of a drug, it is necessary to ensure that such names devised in different national systems do not cause confusion. Hence, there is a need to create an international nomenclature system. The selection process of an INN seeks to ensure that a new INN does not conflict with an existing one or at trademark. Whenever an INN is proposed or recommended by WHO, national authorities are also informed to ensure adequate protection for the INN. An important aspect of INNs is the use of common stems to help identify pharmacologically related elements or groups in the molecule of a pharmaceutical substance. However, stems are determined on the basis of technical considerations and there is no general rule for determining which part of an INN constitutes a stem. Therefore, it would be pertinent to examine how INNs have been actually used for commercial purposes by pharmaceutical companies.

¹⁷ AMA, *USAN Negotiation Process*, [online] available at www.ama-assn.org/ama1/pub/upload/mm/365/timeprocessrqrd_0902.doc, visited on 13th March 2006.

III. INNs AND BRAND NAMES

The commercial success of pharmaceutical products depends not only on their therapeutic efficacy but also on their popularity through marketing. To increase the popularity of a product, companies use different marketing strategies. The most important strategy is to market the drug under a brand name in order to build the brand loyalty of the consumer. As a result, drugs that have the same generic name may have different brand names. For instance, Crocin and Calpol are two different brand names for the same generic substance paracetamol.

Brand names and generic names differ in their legal status. Brand names are proprietary in nature, conferring upon the owner the exclusive right to use the name. Hence, the owner can restrain others from using the brand name or part of it, if the proposed name is deceptively or confusingly similar to the brand name. On the other hand, proprietary rights over generic names are not recognized, since such names are always kept in the public domain, their purpose being to enable identification of the pharmacological properties of the product. Hence, all manufacturers of the same generic product can freely use the same generic name, since generic names are nonproprietary in nature. Therefore, generic names are also called nonproprietary names.

Choosing and registering a brand name is a long and expensive process. Often, companies utilize the services of advertising and other name creation agencies to source some good ideas for a brand name that is both distinctive and will remain in the consumer's mind. Sometimes, the selection of brand names is an internal process, wherein the marketing department of the company develops a branding strategy for each product. The primary criteria for choosing brand names are the following:

- The name should be memorable, easy to pronounce and different.
- It may reflect the mode of action, the therapeutic area or part of the body for which the medicine will be used.¹⁸

In the pharmaceutical industry, it is believed that a brand name is in some sense the very identity of the product and hence a great brand name can salvage a mediocre product while a poor name can hamper an excellent product. Most pharmaceutical companies spend considerable time and resources in selecting the right brand name

¹⁸ See Frances Thompson, *supra* n.3.

and have definite philosophies on how a brand name should be developed. A distinctive proprietary name confers the following benefits on the owner of the brand:

- It helps in distinguishing the owner's product from competing products.
- It has a greater recall value due to its uniqueness.
- It indicates the quality of the product through the brand name.
- It creates brand loyalty thereby increasing the sale of the product.¹⁹

Once the marketing department chooses a brand name on the basis of its branding strategy, the legal department looks into the availability of the name and the permissibility of using it. Thereafter, companies may register the brand name as a trademark, or they may introduce the brand in the market without registering the same as a trademark.

However, from a public health perspective, this practice of promotion and marketing of pharmaceutical products, especially drugs, is viewed with much scepticism. The reasons for this scepticism can be summed up as follows:

- First, brand loyalty may often lead doctors to prescribe drugs according to their brand names instead of generic names. Consequently, consumers cannot choose the lowest priced generic drug available in the market.
- Second, brand promotion requires substantial investments in advertising and marketing, which in turn increases the price of the drug.
- Third, aggressive brand building suppresses the competition by seizing a substantial share of the market and thus creates a monopoly. This again reduces the consumer's choice.

On the other hand, the use of generic names enables consumers to choose a drug from different companies based on its cost-effectiveness. This may help to bring down the cost of medicines and promote peoples' access to medicines at affordable rates. Therefore, many countries have taken various measures to promote generic names ranging from banning the use of brand names, to discouraging the use of such names through various disincentives. For instance, Bangladesh had banned the use of brand names for marketing of pharmaceutical products, but this was later withdrawn . France gives a higher margin for generic products. In South Africa and Sri Lanka, doctors have the legal obligation to prescribe by generic name. In some countries, consumers have the right to ask for a generic or a brand name prescription. Moreover, health insurance companies generally do not support brand name prescriptions to the

¹⁹ Dan Boring, "The Development and Adoption of Nonproprietary, Established, and Proprietary Names for Pharmaceuticals", *Drug Information Journal*, vol.31, 1997, p.627.

same extent as generic prescriptions. It is also interesting to note that in India, the *Report of the Committee on the drugs and pharmaceutical industry, 1975* (the Hathi Committee) had recommended the abolition of brand names in India in a phased manner.²⁰ Recently, the Proneb Sen Committee has also recommended that all public health facilities should be encouraged to prescribe and dispense drugs under the generic names.²¹ The Committee also recommended that public procurement and distribution of drugs through the public health system should preferably be on the basis of generic names.²² However, at present, there is no law or policy guideline making it mandatory to procure and distribute drugs by their generic names.

Companies have different strategies for selecting brand names. Brand names are derived from syllables of nonproprietary names, or by using words that help to identify the therapeutic action, the name of the company, the route of administration, the dosage schedule or the dosage form. Sometimes brand names are developed as completely unique, eye-catching words including palindromes (Table 3).²³ Generally, brand building is not required in a market where the product is protected by product patents, because during the patent period there is sufficient time to build the brand name without any competition. However, when the brand becomes off-patent, other companies may find it difficult to cut into the monopoly of the established brand without using parts of the generic name in their brand name.²⁴ Therefore, as a new entrant in the market, companies may use two techniques to establish their own brands. First, they may take a part of an already successful brand (the patented drug). For instance, “Penagra” and “Kamagra” are two brand names for sildenafil citrate derived from the original brand “Viagra”. Second, companies also select brand names that help to relate the name with the molecule used in the drug. In the process, companies may follow the INN nomenclature in selecting brand names. However, companies also use INNs in coining their brand names. For instance, the brand name “Lipitor” may have been derived from the INN atorvastatin (Table 4). The brand names “Trizivir” and “Zestril” are derived from the INNs abacavir and lisinopril, respectively.

²⁰ See *Report of the Committee on the Drugs and Pharmaceutical Industry, 1975*, p.254.

²¹ See *Recommendations of the Task Force constituted under the Chairmanship of Dr.Proneb Sen to explore issues other than Price Control to make available Life-saving Drugs at Reasonable Prices*, paragraph 1.10.

²² *Ibid*, paragraph 8.1.

²³ Boring, *supra* n.19 p.628

²⁴ Interview with Dr. G. Wakankar, Indian Drug Manufacturers Association, conducted on 23rd February 2006, on file with the authors

TABLE 3. Derivation of brand names

Method	Proprietary name	Derivation
Nonproprietary name syllables	Alzolam	alprazolam
Therapeutic action	Azmatrol	Asthma control
Completely unrelated	Xanax	Palindrome
Company name + INN stem	Sandostatin	Sandoz Pharmaceuticals + INN stem -stat-

Source: Boring D. The development and adoption of nonproprietary, established, and proprietary names for pharmaceuticals. *Drug Information Journal* 1997,.31:621-634.

Companies follow different strategies for using INNs in the brand name. Brand names may be coined by using different parts of INNs or other generic names. Some names are coined by combining only the first and last parts of a generic name and deleting the middle part, while others use the first, middle or last part of the generic name along with a prefix that may identify the name of the company or the therapeutic area of the drug. By following this strategy, brand names are derived not only from INNs, but also from other national nomenclature systems. Table 4 illustrates how some brand names have used INNs. For instance, the brands “Virosine”, “Gliride” and “Alzolam” use the first and last parts of the INN vinleurosine, glimepiride and alprazolam, respectively. The brand names “Zestril” and “Trizivir” use the last three letters of their INNs lisinopril and abacavir, respectively. Moreover, -tril is also the stem for endopeptidase inhibitors. “Alrubicin” takes the suffix -rubicin from the INN epirubicin and uses the prefix “Al” from the company name Alembic. “Virosine DR” uses the stem -osine of the INN vinleurosine.

The illustrations given in Table 7 shows further the use of INN stems, either in part or full, for coining brand names.

TABLE 4. Use of INNs to coin brand names

INN	Stem	Brand name	Company	Country
<u>vinleurosine</u>	-osine	<u>Virosine</u> DR	Ranbaxy	India
<u>lisinopril</u>	-pril	<u>Zestril</u>	AstraZeneca	UK
<u>abacavir</u>	-cavir	<u>Trizivir</u>	GSK	UK, USA
<u>glimepiride</u>	gli-	<u>Gliride</u>	Varun Continental	India
<u>alprazolam</u>	-zolam	<u>Alzolam</u>	Sun Pharmaceuticals	India
<u>epirubicin</u>	-rubicin	<u>Alrubicin</u>	<u>Alembic</u>	India

Source: Websites of respective companies.

Besides using INNs and INN stems for coining brand names, some companies also resort to the use of names derived from INNs as internet domain names. In respect of domain name registrations that are similar to INNs, the World Intellectual Property

Organization (WIPO) has proposed a set of recommendations which seek to prohibit and exclude the registration of domain names that are similar to INNs, with retrospective effect.²⁵ WHO has also pointed out to WIPO that the use of INNs in domain names could easily lead to a disruption in the consistent association of an INN with scientifically established characteristics and the misinformation and confusion in prescribing and dispensing of medicines.²⁶ In *Teva Pharmaceuticals Industries Limited v. BLTC Research*, the WIPO Administrative Panel concluded that INNs are not trademarks and they fall outside the scope of WIPO's Uniform Domain Name Dispute Resolution Policy (UDRP).²⁷ The Second WIPO Domain Name Registration Process, 2001 addressed this issue and recommended that there should be a prohibition against the registration of exact INNs as domain names in deference to the integrity of INNs. Though it did not recommend the prohibition of registration of domain names using parts of INNs because of the lack of convincing evidence of damage caused by such use, it did not rule out the possibility of re-visiting the issue in future.²⁸

The practice of coining brand names by using INNs threatens the principle that INNs are public property and may create confusion in drug nomenclature by virtue of the fact that brands attract the minds of customers. Hence, a popular brand name that is using an INN might eventually push the INN into oblivion. This is evident from the example of the brand "Xerox", which is today synonymous with a photocopying machine. Similarly, the brand name "aspirin" has become a de facto generic name for acetylsalicylic acid. Moreover, since INNs do not become popular in the market unless they are used for a long time, they tend to become less attractive compared to brand names that are aggressively marketed and become popular in a shorter time. Further, when a new INN is to be created, the existence of a brand name that uses a part of the stem to be used in the new INN may threaten the creation of the new INN by enabling the owner of the brand name to oppose the new INN by virtue of his proprietary right over the brand name coined from a nonproprietary name. Thus, the use of stems as trademarks can frustrate the rational selection of further INNs for future substances. The use of INNs or parts thereof as brand names results in their appropriation by companies/ individuals and tends to dilute the status of INNs as names that are in the public domain. Hence, this practice threatens the public domain status of INNs and it may compromise the safety of patients by creating confusion in drug nomenclature. Moreover, confusion created by use of INNs, especially INN stems in brand names, may lead to medication

²⁵ WIPO, *Proposed Recommendations in Regard of INNs* [online], available at <http://www.arbiter.wipo.int/processes/process2/rfc/rfc3/comments/docs/Appendix1.doc> , visited on 28th February 2006.

²⁶ WIPO, *Standing Committee on the Law of Trademarks, Industrial designs and Geographical Indications: Second Special Session on the Report of the Second WIPO Internet Domain Name Process*, Geneva: 2004, p.3.

²⁷ See WIPO Arbitration and Mediation Center, *Teva Pharmaceuticals Industries Limited v. BLTCResearch*, Case No.D2005-0113.

²⁸ WIPO, *Report of the Second WIPO Internet Domain Name Process, 2001*, available at <http://arbiter.wipo.int/processes/process2/report/html/report.html> , visited on 2nd June 2006.

errors where the doctors may be misled about the true nature of the drug. This would not only threaten the life of the patients but also expose the doctors to claims for damages due to medical negligence.

WHA Resolution on INNs

WHO's concern pertains to the use of INNs as trademarks in general as well as the use of INN stems as trademarks in particular. The WHO Expert Committee on the Use of Essential Drugs took note of this and observed that instead of marketing pharmaceutical products under generic names, many companies apply for a trademark derived from an INN and, in particular, including an INN common stem.²⁹ Further, the Committee states that "trademark applications are disallowed 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". Therefore, the Committee has taken a stand that "...it would be appreciated if trade-marks were not derived from INNs and if INN stems were not used in trade-marks".³⁰

On the basis of the recommendations of the Committee in 1991, the WHA unanimously adopted Resolution 46.19 on "Nonproprietary Names for Pharmaceutical Substances" in 1993. The Resolution contains a preamble and two operative paragraphs. In its preamble, the Resolution noted the current trend of marketing products with the same active ingredient as a product currently on the market, under trademarks or brand names derived from stems or other parts of INNs. It pointed out that such a practice, particularly in respect of single-ingredient prescription drugs, may compromise the safety of patients by creating confusion in prescribing or dispensing medicines and by interfering with the development of nomenclature for INNs. Paragraph 1 of the Resolution states that the WHA requests Member States:

1. to enact rules or regulations, as necessary, to ensure that INNs (or the equivalent nationally approved generic names) used in the labelling and advertising of pharmaceutical products are always displayed prominently;
2. to encourage manufacturers to rely on their corporate name and INNs, rather than on trademarks, to promote and market multi-source products introduced after patent expiration;
3. to develop policy guidelines on the use and protection of INNs, and to discourage the use of names derived from INNs, and particularly names including established INN stems as trademarks;³¹

²⁹ WHO, n.7 p.7.

³⁰ WHO, *The Use of Stems in the Selection of International Nonproprietary Names (INN) for Pharmaceutical Substances*, 2004, WHO/EDM/ QSM/2004.5, p.6. Emphasis added.

³¹ WHA 46.19, *Nonproprietary Names for Pharmaceutical Substances*, 12 May 1993, paragraph 1. (emphasis added).

A close perusal of all the three clauses of paragraph 1 of the Resolution shows that the resolution does not request Member States to prohibit the use of INNs or INN stems as part of brand names. The Resolution in fact promotes the basic objective of the INN system, viz. that for the purpose of ensuring safety in drug consumption, it is imperative to use such names in the pharmaceutical industry that do not cause confusion in the mind of the average consumer. In furtherance of this objective, clause (1) of paragraph 1, of the Resolution exhorts Member States to enact appropriate rules and regulations for ensuring that INNs are always displayed prominently in drug labelling and advertising. Clause (2) calls upon States to encourage manufacturers to use INNs along with their corporate name, rather than using trademarks. For instance, a Canadian company called Apotex markets its products under names that use the whole generic name along with the acronym “Apo” for the company Apotex as prefix. Therefore, instead of developing a brand using part of the INN acebutolol, for example, “X-olol”, the company uses the name “Apo-acebutolol”. Clause (3) requests Member States of WHO “... to develop policy guidelines on the use and protection of INNs, and to discourage the use of names derived from INNs ... *particularly names including established INN stems as trade marks*”.³² Thus, WHA Resolution 46.19, shifted the focus from the need to develop and harmonize the INN system with national nomenclature systems, to the more pressing issue of ensuring the sustainability of the INN system through better protection of INNs from misappropriation.

Paragraph 1(3) of the Resolution requests Member States to take two kinds of actions. In the first place, it calls upon Member States to develop policy guidelines relating to the use of INNs and their protection. It should be noted here that Member States are called upon to develop only *policy guidelines* and not a legal regime for the use and protection of INNs. Further, the word *use* may have two meanings: first, it may be a policy guideline explaining how INNs may be used for coining the brand name. This interpretation is supported by the fact that the Resolution does not request Member States to prevent the use of INNs in brand names. Second, the word *use* may imply only the permissible use of INNs, for instance, as branded generics, as mentioned in paragraph 1 (2) of the Resolution.³³ This interpretation would suggest that while INNs may be legitimately used for commercial purposes, the use of INNs as proprietary marks needs to be discouraged. The second part of paragraph 1 (3) of the Resolution supports this argument.

The second part of this paragraph addresses two specific concerns in respect of INNs, i.e. discouraging the use of names derived from INNs, and particularly registration of names including established INN stems, as trademarks. The use of the word

³² Ibid.

³³ The term branded generic here means products that have brand names using a part of the company's name along with the generic name or INN.

discourage suggests that any use of INNs in contradiction to the basic objectives of the INN system should be restrained. Even though the word *discourage* does not per se prohibit the use of INNs as brand names, it gives some flexibility to countries to determine ways and means of regulating the use of INNs, including prohibiting the use of INNs in brand names. However, as mentioned earlier, the nonproprietary commercial use of INNs is not discouraged.

In some legal systems, such as common law systems, a trademark can be used with or without registration. The word *use* in this provision implies all kinds of trademark use, including the use of brand names as registered or unregistered trademarks. In some legal systems there is a distinction between trade names and trademarks. The Resolution covers both types of uses. In order to implement the requirements of the Resolution, it would be necessary to regulate all use of INN-derived names. The word *particularly* in the second part of the paragraph conveys that while any kind of use of names derived from INNs is to be discouraged, the use of such names that include established INN stems as trademarks should be restrained on an urgent basis. The broader objective of discouraging the practice of deriving brand names from INNs is to be achieved in a progressive manner. Since WHO cannot force the issue with Member States, it has to adopt a flexible approach. Therefore, in general terms, Member States are called upon to discourage the use of names derived from INNs. Nevertheless, the increasing use of INN stems threatens the future development of the INN system. This challenge needs immediate attention.

One of the major challenges identified by the Expert Committee was the registration of trademarks using names derived from INNs. The Committee observed that ...“ trademark applications are disallowed ... 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 names, many companies apply for a trademark derived from an INN and, in particular, including an INN common stem”.³⁴ However, the Resolution does not use the words *derived from an INN* while discouraging its use as a trademark. As a result, a trademark office can still continue with the practice of disallowing registration of only those names that are *identical* to INNs.

The Resolution also calls upon States to discourage the use of *established* INN stems. Therefore, it conveys the meaning that there is a distinction among INN stems. It is not clear as to what constitutes an *established* INN stem. How does an INN stem become established? Does a stem become established by virtue of its publication by WHO? Or does it become established by long usage? WHO officials hold that a stem

³⁴ See WHO, *Guidelines on the Use of International Nonproprietary Names (INNs) for Pharmaceutical Substances*, 1997, p.7. (emphasis added).

becomes established by virtue of its publication after official approval of the INN Expert Group.³⁵ However, there is no authoritative interpretation of this point and further elaboration and explanation of this aspect of the Resolution are required through explanatory guidelines.

Resolution 46.19 of the WHA is a unanimously adopted resolution of an international organization and it reflects the collective will of the community of nations on the issue of the use and protection of INNs. Being merely a resolution of an international organization, it does not create an obligation similar to that under an international treaty, though it may mark a process towards the development of an international treaty law on the subject. Therefore, WHA Resolution 46.19 creates an international responsibility for all Member States, not amounting to an international obligation, to endeavour to implement the mandate of the Resolution. However, resolutions of international organizations are not binding upon the States. At best they are only soft law obligations that a State endeavours to respect. Nevertheless, the collective action of States in international organizations, repeated and acquiesced to by sufficient members with sufficient frequency, eventually attains the status of customary international law.

There is a view that the resolutions of international organizations such as WHO are often regarded by States as being as important as traditional sources of international law. In areas such as health and employment, where customary law is scarce, recommendations are as important as treaties. Hence, it may be inappropriate to dismiss such resolutions as simply a source of State practice when examining customary international law. They can in themselves be independent sources of law, albeit with a weak structure. Indeed, the resolutions and recommendations of the UN Human Rights Commission are not mandatory in nature. Nevertheless, the Commission has compliance mechanisms such as monitoring and periodic review of reports from States on the implementation of its resolutions and recommendations.

The system of reporting and monitoring makes States aware that while they cannot be compelled to implement international soft law obligations, they would be required to give plausible reasons for non-compliance. Though slow, such mechanisms have proved effective. It should be noted that WHA Resolution 46.19 does not create any reporting and monitoring mechanism for ensuring compliance. It would be pertinent to examine whether the WHO-INN Programme has a mechanism for ensuring compliance with the requirements of WHA Resolution 46.19.

As pointed out earlier, whenever WHO recommends an INN, the national authorities designated to WHO by respective governments are informed about this,

³⁵ E-mail from Rafaella Balocco Matavelli, INN Programme Manager, WHO, dated 24th April 2006.

through letters issued by WHO calling upon them to ensure that the INN is not misappropriated. The INN Programme does not provide any reporting mechanism for ensuring compliance with WHA resolutions on INNs, since it has only an advisory role. Nevertheless, all action taken by the country and notified to WHO is recorded and treated confidentially.³⁶ WHO's INN Programme collaborates with different groups and organizations such as the European Medicines Agency, also known as the European Medicines Evaluation Agency (EMA), WIPO, national authorities and trademark offices for monitoring the implementation of WHA resolutions on protection of INNs.³⁷

INNs in the UK, USA and EU

In principle, countries should defer to INNs in the process of trademark registration of brand names for pharmaceutical products. As mentioned earlier, WHA Resolution 46.19 requested Member States to develop policy guidelines on the use and protection of INNs and to discourage the use of names derived from INNs, particularly names that included established INN stems, as trademarks.³⁸ This resolution has been implemented in many countries including India. The legal and policy regime for the use of INNs in India is discussed in the next part of the study.

In the UK, the BAN guidelines for the construction of pharmaceutical trademarks states that the requirements of WHA Resolution 46.19 should be observed while creating trademarks for pharmaceutical products.³⁹ The UK trademark office has a policy of rejecting applications for pharmaceuticals and related substances for names that are internationally recognized as nonproprietary names. Such names are called “reserved words” and registration of trademarks that use these words are objected to.⁴⁰ In the USA, the Trademark Act, 1946 states that a petition to cancel the registration of a mark may be filed at any time if the registered mark becomes the generic name for the goods or services, or a portion thereof, for which it is registered.⁴¹ The US Food and Drug Administration (FDA) also plays a role when a manufacturer seeks to register a trademark (proprietary name) for a drug entity that has been assigned a nonproprietary name. Within the Center for Drug Evaluation and Research (CDER)⁴² of the FDA, the Labelling and Nomenclature Committee (LNC) provides recommendations on the acceptability of proposed proprietary names. One of the criteria for rejection is the use

³⁶ Interview with Rafaella Balocco Matavelli, INN Programme Manager, WHO, conducted on 25th January 2006, on file with the authors.

³⁷ Ibid.

³⁸ See WHA, supra n.30.

³⁹ See BAN, *Guidelines for the Construction of Pharmaceutical Trademarks*, [online] available at <http://www.pharmacopoeia.org.uk/trade.cfm>, visited on 13th March 2006.

⁴⁰ UK Trade Marks, *International Nonproprietary Names for Pharmaceutical Substances (INNs)*, [online] available at <http://www.patent.gov.uk/tm/reference/inn.htm>, visited on 13th March 2006.

⁴¹ See 15 U.S.C. § 1064.

⁴² The CDER is responsible for ensuring the availability of safe and effective drugs in America.

of USAN syllables or stems in the proposed trademark.⁴³

One can obtain a marketing authorization for a medicinal product throughout the European Union. Such authorization is granted on the basis of the invented name of the medicinal product. If applicants submitting applications under the centralized procedure do not wish to use the invented name, common name or scientific name, under Article 1.2 of the EC Directive 92/27/EEC, a marketing authorization application can be submitted using such a name together with a trade name or the name of the manufacturer. In terms of Article 1(20) of the EC Directive 2001/83/EC, the name of the medicinal product may be either an invented name, or a common or scientific name accompanied by the trade name or the name of the marketing authorization holder (MAH).⁴⁴ The common name of a medicinal product is the INN, or where the INN does not exist, the usual common name of the substance.⁴⁵ Article 1 (20) also states that the invented name should not be liable to confusion with the common name. Thus, while proposing an invented name, applicants/MAHs are advised to take into consideration the provisions of WHA Resolution 46.19. The applicant/MAH has to identify whether the proposed name has any similarity with an INN or an INN stem. Where there is any similarity between an INN or INN stem and the proposed name, the applicant/MAH has to justify its use. In case the proposed name is similar to an existing INN, the following criteria may be considered for justifying its use:

- The closeness of the INN and proposed name in speech or in writing,
- The general use, indications, etc. of the medicinal product,
- The conditions of use of the product, i.e. whether restricted to hospitals, specialists, etc.,
- The routes of administration of the product and, where possible, the concerned pharmaceutical form.⁴⁶

Where the applicant/MAH identifies that its proposed invented brand name includes an INN stem, justification should be provided addressing the following criteria:

- Whether the INN stem and the medicinal product are from the same pharmacological class,
- Whether the INN stem is in accordance with the location of the WHO-INN stems, i.e. whether they are used as prefixes or suffixes as they are used in the INN nomenclature,

⁴³ AMA, *Liaison Relationship with the US Food and Drug Administration*, [online] available at www.ama-assn.org/ama1/pub/upload/mm/365/timeprocessrqrd_0902.doc, visited on 13th March 2006.

⁴⁴ EC, *Directive 2001/83/EC*, Article 1 (20).

⁴⁵ *Ibid*, Article 1 (21).

⁴⁶ EMEA, *Guideline on the Acceptability of Invented Names for Human Medicinal Products Processed through the Centralised Procedure, 2005*, CPMP/328/98, Revision 4, paragraph 2.2.

- The general use, indications, etc. of the medicinal product,
- The conditions of use of the product, i.e. whether restricted to hospitals, specialists, etc.,
- The routes of administration of the product and, where possible, the concerned pharmaceutical form.⁴⁷

In 1998, the Committee for Proprietary Medicinal Products (CPMP) of the EMEA agreed to a guideline on the acceptability of trade names for human medicinal products. Paragraph 3 of the guideline strongly advises applicants to take into account the concerns of WHO in terms of WHA Resolution 46.19.⁴⁸

There is also evidence of countries protecting INNs even as far back as the 1980s. For instance, in a German case relating to Godecke A.G.'s application to register a trademark, the German patent office refused to register the trademark as it was very similar to an INN. In that case, trademark registration of a brand name Prazepam was refused on the ground of its similarity with the INN prazepam or prazepaum. It was held that not only INNs but also words that were apparently modifications of INNs must be refused registration. The German Supreme Court upheld the decision of the patent office and observed that modifications of INNs without any characterizing individuality are not liable to be registered because of the lack of distinctiveness where the INN is known among experts. Even where the INN is not well known, a modification of the INN is not to be registered because in case of new INNs, some time will naturally pass before a new substance is generally known. During this period, it is necessary to ensure that the name is not monopolized by a single party.⁴⁹

However, it should be noted that these countries have not legally prohibited the use of INNs or parts thereof in brand names. In spite of there being substantive provisions regarding the use of INNs and the prevention of trademark registration of names that are similar to INNs, there are instances of brand names being derived from INNs in these countries as well. A perusal of brand names used in the UK and the USA shows that there are instances of names that are similar to INNs (Table 5). Table 5 shows that even in countries with well-established regimes laying down policies for the use of nonproprietary names, brand names are derived from generic names.

⁴⁷ Ibid.

⁴⁸ EMEA, *Guideline on the Acceptability of Invented Names for Human Medicinal Products Processed through the Centralised Procedure, 2002*, CPMP/328/98, Revision 3, paragraph 3.

⁴⁹ IPLR, 1980, July, vol.5, no.2, p.64.

TABLE 5. Brand names similar to INNs

INN/BAN/USAN	Stem	Brand	Country
lisinopril	-pril	Zestril	UK
diltiazem	-azem	Dilzem XL	UK
streptokinase	-kinase	Streptase	UK
riluzole	-uzole	Rilutek	UK
abacavir	-cavir	Trizivir	UK
carboplatin	-oplatin	Paraplatin	USA
diltiazem	-azem	Cardizem	USA
glipizide	gli-	Metaglip	USA

Source: British National Formulary and USFDA.

WHA Resolution 46.19 requests Member States to discourage the practice of deriving brand names from INNs. It particularly calls upon them to discourage the use of such names or names using established INN stems as trademarks. Though Resolution 46.19 does not impose any binding obligation under international law upon Member States, they nevertheless have the responsibility to report steps taken by them to ensure compliance with the Resolution. However, the use of INNs as brand names has not been legally prohibited in the UK, USA and Europe. In this context, it will be pertinent to examine the regime for the use and protection of INNs in India.

IV. USE OF INNs IN INDIA

This section examines the legal and policy regime pertaining to the use of INNs in India in the context of the discussions in the preceding section. Specifically, the provisions of the Drugs and Cosmetics Act, 1940 and the National Pharmaceutical Policy and the Trade Marks Act, 1999 are analysed here.

The Drugs and Cosmetics Act, 1940

The Drugs and Cosmetics Act, 1940 and the Drugs and Cosmetics Rules, 1945 as amended from time to time, regulate the marketing approval, manufacture, and distribution and sale of drugs in India. Under Section 18 of the Drugs and Cosmetics Act, the manufacture or sale of any misbranded drug is prohibited.⁵⁰ The Act also states that a drug shall be deemed to be misbranded if it is not labelled in the prescribed manner.⁵¹ The Drugs and Cosmetics Rules, 1945 deal with the requirements of labelling of drugs in India. Under the Rules, no drug, whether proprietary or otherwise, can be sold or distributed in India unless it is labelled in accordance with these Rules.⁵² Rule 96 states that the name of the drug must appear conspicuously on the cover of the drug. This Rule also states that the proper name of the drug must be written or printed more conspicuously than the trade name. The trade name shall appear immediately after or under the proper name.⁵³ INNs are considered as the proper name of the drug only where the drug in question does not have any name under Schedule F, the official pharmacopoeia or the National Formulary of India (NFI).⁵⁴ Thus, the provisions of the Drugs and Cosmetics Act and the Drugs and Cosmetics Rules fulfil the basic requirements of paragraph 1 (1) of WHA Resolution 46.19, since they give greater emphasis on the generic name and require that it should be printed more prominently than the brand name (trademark).

India has a decentralized drug regulatory structure, with separation of powers at the federal and state levels. The DCGI heads the Central Drugs Standard Control Organization (CDSCO) and discharges the functions attributed to the Central Government. The DCGI is a statutory authority under the Act and has port offices, zonal

⁵⁰ The Drugs and Cosmetics Act, 1940, Section 18 (a) (i).

⁵¹ *Ibid*, section 17 (b).

⁵² *Drugs and Cosmetics Rules*, 1945, Rule 95.

⁵³ *Ibid*, Rule 96 (1) (i).

⁵⁴ *Ibid*, Rule 96 (1) (i) (a) – (d).

offices with drug inspectors and drug testing laboratories functioning under it.⁵⁵ The DCGI also has the responsibility of laying down regulatory measures and amendments of the Act and Rules, laying down standards for drugs, cosmetics, diagnostics and devices and updating the Indian pharmacopoeia, coordinating the activities of the states and advising them on matters relating to uniform administration of the Act and Rules in the country.⁵⁶ The state regulators are responsible for the licensing of manufacturing establishments and sales premises.⁵⁷ In the present situation, the DCGI only gives an initial marketing approval to a pharmaceutical substance, while manufacturing approval and subsequent marketing approvals fall within the domain of the state regulators.

The DCGI has the responsibility of approving new chemical entities introduced in the country. Generally, four years from the date of first approval by the DCGI, individual state drug regulatory authorities issue marketing approval and manufacturing licences. However, irrespective of the state where the marketing approval is obtained, the product can be marketed throughout India. The company has a choice to either market the drug by a brand or a generic name. If the company wants to market the drug under a brand name, it has to disclose the brand name along with the generic name. Hence, the various state drug regulatory authorities can regulate the use of INNs in coining brand names. However, there is no regulation or guideline on how INNs are to be used in drug nomenclature in India. The DCGI is of the opinion that his office has a limited mandate, with its role being restricted to ensuring the safety of the drugs that are given marketing approvals.⁵⁸ However, paragraph 1 (3) of the WHA resolution directs that Member States should develop policy guidelines on the use and protection of INNs and discourage the use of names derived from INNs. There is a necessity to develop clear guidelines on the use and protection of INNs in accordance with the WHA Resolution. Since trademark registration of brands is not compulsory in India, many brands may escape regulation in terms of INN compliance unless they are subjected to compulsory registration of the brand name with the drug regulatory authority.

The National Pharmaceutical Policy

The existing drug policy in India is silent on the use of nonproprietary names in drug nomenclature. The Draft National Pharmaceutical Policy points out that the present system of brand approval for pharmaceutical substances is inappropriate. The draft policy identifies two areas of concern. First, there are several brand names that are very similar. Second, in many instances the composition has been changed without any

⁵⁵ Ministry of Health and Family Welfare, Govt. of India, *The Interim Report of the Expert Committee on a Comprehensive Examination of Drug Regulatory Issues, including the Problem of Spurious Drugs, 2003*, (Mashelkar Committee) paragraph 3.2.1.

⁵⁶ *Ibid*, paragraph 3.2.2.

⁵⁷ *Ibid*, paragraph 3.2.3.

⁵⁸ Interview with Ashwini Kumar, the Drugs Controller General of India, conducted on 10th March 2006, on file with the authors.

change in the brand name. In the context of these two concerns, the draft policy holds the view that branding of drugs should be brought under a central drug regulatory system. The Drug Regulator must be required to maintain a database of brands and their compositions. All brand registrations must be compulsorily approved.⁵⁹ The Proneb Sen Committee recommends that the Government or its designated authority should have the power to approve a brand name for a specific product so as to determine the nomenclature under which the brand can be marketed.⁶⁰

The Trade Marks Act, 1999

Like any other legal regime in India, the trademark law in India follows the common law system. Under this system, both registered and unregistered trademarks are protected. Registered trademark owners have exclusive rights over the mark and can take legal action for infringement of the mark. On the other hand, owners of unregistered marks can also file a civil action against any person passing off the goods under the unregistered mark as his own.

The law relating to trademarks in India was contained in the Trade and Merchandise Marks Act, 1958. The Trade Marks Act, 1999, replaced that statute. Sections 9 and 11 of the Act lay down the absolute and relative grounds for refusal of registration of a mark as a trademark. Section 9 states that trademarks which do not have any distinctive character, or which are exclusively of a descriptive nature, or which have become exclusively customary in the current language or in the established practice of the trade, cannot be registered. Section 11 of the Act prohibits the registration of a mark if its use would be likely to deceive or cause confusion.

Section 13 of the Trade Marks Act, 1999 lays down specific provisions restraining trademark registration of words that are similar to INNs. Section 13 states that:

“No word -

- (a) “ which is the commonly used and accepted name of any single chemical element or any single chemical compound (as distinguished from a mixture) in respect of a chemical substance or preparation, or
- (b) “which is declared by the World Health Organization and notified in the prescribed manner by the Registrar from time to time, as an international nonproprietary name or which is deceptively similar to such name,

“shall be registered as a trade mark and any such registration shall be deemed for the purpose of Section 57 to be an entry made in the register without

⁵⁹ Draft National Pharmaceutical Policy, 2005, pp.23-24.

⁶⁰ *Proneb Sen Committee Report*, supra n.21 paragraph 2.6.

sufficient cause or an entry wrongly remaining on the register, as the circumstances may require.”

In terms of this provision, commonly used or accepted names of any single chemical substance, or any word which has been declared as an INN by the WHO cannot be registered as a trademark. Any such registration will be removed from the register as per the requirements of Section 57. Section 57 of the Act states that “Any person aggrieved by any entry made in the register without sufficient cause, or by any entry wrongly remaining on the register, or by any error or defect in any entry in the register, may apply in the prescribed manner to the Appellate Board or to the Registrar, and the tribunal may make such order for expunging or varying the entry, as it may think fit.”⁶¹ Section 57 (4) of the Act empowers the tribunal to remove such entries on its own.

Section 13 (b) of the Trade Marks Act, 1999 clearly states that no word that is an INN or deceptively similar to it shall be registered as a trademark, and any such entry will be deemed to be an entry wrongly made or wrongly remaining in the register. It is worth noting that the WHA Resolution does not call upon Member States to develop legal regimes for the protection of INNs from being used as trademarks. Rather, it only calls upon Member States to discourage such use. Section 13 (b) not only discourages the use of INNs as trademarks, it imposes a legal restraint on trademark registration of words derived from INNs. Thus, Section 13 (b) prohibits the use of INNs as trademarks, going beyond the requirements of the Resolution. Even though the Act does not make any mention of INN stems, the same may fall within the scope of Section 13 if such use is deceptively similar. This point is discussed at length later in this section.

Under the Trade and Merchandise Marks Act, 1958 use of common or generic names as trademarks was permissible when the word was used to denote the brand of the element or compound made by a person, in association with a suitable name or description open to public use. Under Section 13 of the Trade Marks Act of 1999, no registration of such common names for chemical substances is permissible. Though there was no provision for protecting INNs from appropriation through trademark registration under the Trademarks and Merchandise Act, 1958, there is a view that the prohibition of trademark registration words declared by WHO as INNs was being followed by the Registrar.⁶² The Trade Marks Act, 1999 introduced a specific provision for the protection of INNs from trademark registration. Thus, the Trade Marks Act of 1999 marks a definite improvement over the law of 1958 with regard to INNs.

⁶¹ The Trade Marks Act, Section 57 (2).

⁶² P. Narayanan, *Law of Trade Marks and Passing off*, (Kolkata: Eastern Law House, 2004) edn.6, p.253.

Scope of Section 13

Section 13 (a) of the Trade Marks Act, 1999 not only restrains the trademark registration of words that are derived from INNs, it also restrains the trademark registration of any word "...which is the commonly used and accepted name of any single chemical element or a single chemical compound for a chemical substance or preparation". As all synthetic pharmaceutical substances are essentially chemical substances, generic names that are not INNs are also covered within the scope of Section 13 of the Act.

The application of Section 13 (b) to INNs is qualified by two words - "declared" by WHO, and "notified" as such by the Registrar. WHO does not "declare" a word as an INN. It only recommends certain names found to be acceptable by it as INNs. Both proposed and recommended INNs are published and hence it may be said that WHO declares them as proposed or recommended INNs. Thus, it is not certain whether the term "declared INNs" under Section 13 (b) applies to both proposed as well as recommended INNs. Trademark lawyers are of the opinion that this phrase refers to only recommended INNs.⁶³

Even where WHO recommends a name as an INN, it does not come within the protection of Section 13 (b) unless it is notified as such by the Trade Marks Registrar. As informed by trademark lawyers and the trademark office, no INN has been notified by the Registrar.⁶⁴ Thus, in the absence of any notification, Section 13 (b) cannot become operational. The possible option of restraining the use of INNs as trademarks lies under Section 13 (a) under which the commonly used or accepted name of any single chemical entity cannot be registered. However, INNs are not chemical names in the strict sense, they are names that identify the chemical composition of the drug and help to replace long and unwieldy chemical names. Hence, it is not clear whether INNs come within the scope of Section 13 (a). Further, Section 13 (a) cannot prevent the registration of words derived from INNs including INN stems, on the ground of deceptive similarity to such names, because deceptive similarity is determined on the basis of the proprietary nature of another mark. Since INNs are nonproprietary, the test of deceptive similarity may not apply. Deceptive similarity has been interpreted by the courts in accordance with its definition under Section 9 of the Act. Thus, to determine what constitutes deceptive similarity under Section 13 of the Act, it may be relevant to study how the courts have interpreted this phrase.

Section 9 of the Trade Marks Act, 1999 lays down the absolute grounds for refusal

⁶³ Interview with Shailamanyu Singh Rathore, Attorney, Remfry & Sagar, conducted on 7th February 2006, on file with the authors.

⁶⁴ Ibid. Interview with Ruchika Sukh, Associate, K&S Partners, conducted on 19th February 2006, on file with the authors.

of registration of a trademark. This section states that the Registrar of Trade Marks shall refuse to register a trademark if it is of such nature as to deceive the public or cause confusion.⁶⁵ Thus, it would be pertinent to examine what constitutes deceptiveness under the trademark law. According to the Trade Marks Act, “A mark shall be deemed to be deceptively similar to another mark if it so nearly resembles another mark as is likely to deceive or cause confusion.”⁶⁶ Therefore, for deciding whether a trademark is deceptively similar to another mark, it has to be determined whether the mark is likely to deceive or cause confusion.

In the case of *F. Hoffman-la Roche & Co. Ltd. v. Geoffrey Manners & Co. Pvt. Ltd.*, the Supreme Court of India followed the explanation given by Lord Denning to these words in the case of *Parker Knoll Ltd. v. Knoll International Ltd.* (1962 RPC 265 at 274). According to Lord Denning, the basis of deceptiveness is the making of a false representation, intentional or otherwise, thereby causing a person to believe a thing to be true which is false. However, confusion may be caused without making any false representation, because of the lack of knowledge or ability of the people to whom such representation is made, to understand the difference between one mark and another similar mark.⁶⁷

In *SBL Ltd. v. Himalaya Drug Co.* the Delhi High Court held that a trademark is likely to deceive or cause confusion by its resemblance to another trademark already on the register. Two important issues for determining deceptive resemblance are as follows:

1. first, who are the persons whom the resemblance is likely to deceive or confuse, and
2. second, what rules of comparison are to be adopted in judging whether such resemblance exists.⁶⁸

The Court also observed that in the case of pharmaceutical preparations, where trading is governed by statutory rules or regulations, additional considerations are relevant. These include:

1. first, the manner in which the trade is carried on, such as sales being made only by authorized or licensed vendors with special knowledge of medicines and pharmacy, and
2. second, the class of persons who would be the purchasers, whether they would be accompanied by doctors’ prescriptions and also would in all probability remain in touch with the doctor while consuming the medicine.⁶⁹

⁶⁵ The Trade Marks Act, 1999, Section 9 (2) (a).

⁶⁶ The Trade Marks Act, Section 2 (1) (d).

⁶⁷ *F.Hoffman-la Roche & Co. Ltd. v. Geoffrey Manner & Co. Pvt. Ltd.*, MANU/SC/0302/1969, paragraph 7.

⁶⁸ *SBL Ltd. v. Himalaya Drug Co.*, 1997 PTC (17) (DB), p.558.

⁶⁹ *Ibid*, p. 555.

Even in the case of *F. Hoffman-la Roche & Co. Ltd.* the Supreme Court observed that the question of deceptive similarity must be decided on the basis of the class of goods to which the trademarks apply.⁷⁰ Therefore, in the case of trademarks for pharmaceutical products, the issue of likelihood of deception or confusion between two marks is relative to the determination of who is the consumer of the product. Generally, pharmaceutical companies market their products to the doctors who prescribe them to their patients. Thus, from the perspective of the companies, the doctor is the consumer and hence, the likelihood of deception or confusion is to be determined in the context of the knowledge that can be reasonably expected of a doctor. However, this may not be reflective of the ground reality where many prescription drugs are directly sold over the counter to the end users.

In this context, it is important to examine whether proprietary rights can be acquired through trademarks over names that are in the public domain. The legal position in India, as it has evolved through judicial interpretations, is that no one can claim an exclusive right over a generic name. This consequently allows everybody to use parts of generic names in their trademarks even if there is an existing trademark using part of the generic name, provided it satisfies other requirements of the Trade Marks Act, 1999. In the *SBL Ltd.* case the Court observed that "...In the trade of drugs it is common practice to name a drug by ... the main ingredients of the drug. Such ingredient ... being generic cannot be owned by anyone as a trademark".⁷¹ In *Griffon Laboratories (P) Ltd. v. Indian National Drug Co. P. Ltd.*, there was a dispute on using the trademarks "Sorbiline" and "Sorbitone", by two rival companies, both names being derived from the generic "sorbitol". The Calcutta High Court held that as several medicines were being manufactured with the prefix "sorbi", it was a common practice in the medical world. Therefore, it cannot be said that the objective of using "sorbi" is to cause confusion.⁷²

Relying upon this decision, the Delhi High Court in *Panacea Biotech Ltd. v. Recon Ltd.*, held that it is well settled that no person can claim the exclusive use of generic terms. Hence, a trademark on Nimulid derived from nimesulide cannot prevent a trademark on Remulide, also derived from nimesulide.⁷³ Subsequent trademarks using parts of generic names cannot be prevented on the ground of deceptive similarity with an existing trademark. However, this interpretation will not help in preventing the misuse of INNs. It only prevents the acquisition of proprietary rights over INNs. Therefore, to prevent the misappropriation of INNs through trademarks, it is necessary to pre-empt the registration of such names. This is where the implementation of Section 13 (b) of the Trade Marks Act, 1999 assumes critical importance.

⁷⁰ In re *F.Hoffman-la Roche & Co. Ltd.*, n.53 paragraph 9.

⁷¹ *SBL Ltd. V. Himalaya Drug Co.* supra n.66.

⁷² IPLR 1989, vol.14, p.14.

⁷³ 1996 PTC (16), p.583.

Section 13 of the Trade Marks Act, 1999 specifically restrains the trademark registration of words that are derived from INNs. Even though the registration of common names of chemical substances is prohibited under Section 13 (a), the registration of names using INNs is dependent on the INN concerned being notified by the Trade Marks Registrar under Section 13 (b). In the absence of such notification, the only remedy that is partially available is under Section 13 (a). However, Section 13 (a) cannot comprehensively prevent the registration of names derived from INNs. The judicial interpretation of the use of terms in the public domain especially in relation to pharmaceutical products shows that no person can claim an exclusive right to commonly accepted public names by registering words having elements of the same as trademarks. However, this *per se* does not restrain any person from registering a trademark derived from a generic name. By allowing names in the public domain to be used by all, the legal position in India prevents the appropriation of INNs through intellectual property. However, this does not address the issue of removal of confusion in drug nomenclature.

It has been suggested that a possible way of preventing trademark registration of names using INNs or parts thereof may be found under Section 9 of the Trade Marks Act, 1999. Section 9 lays down the absolute grounds for refusal of registration of a mark. Among other grounds, it specifically states that trademarks which consist exclusively of marks or indications which may serve in trade to designate the kind, quality, quantity, intended purpose, values, geographical origin or the time of production of the goods or other characteristics of the goods shall not be registered.⁷⁴ If this provision is read with Section 13 (b) of the Act, it may be interpreted that since INNs are names that designate the kind of chemical substance used in the drug, registration of such names must be absolutely refused. However, the provision in Section 9 is qualified by the use of the word “exclusively” implying that words that use only a part of INNs including INN stems, along with some unique prefix, suffix or infix, may not come under the ambit of Section 9. Hence, it has been suggested that the word “exclusively” be removed from Section 9 and the provision of Section 13 (b) may be appended as an explanation to Section 9 in relation to INNs.⁷⁵

Moreover, the proviso to Section 9 (1) states that a mark cannot be refused registration if before the date of application of the registration the mark acquires a distinctive character as a result of the use of the mark, or it acquires the status of a well-known trademark. This provision is in consonance with the general principle that a well-established mark or a mark that becomes distinct by long usage can be regarded as a unique trademark. Therefore, even if a mark is wrongly registered its removal from

⁷⁴ Section 9 (1) (b), *The Trade Marks Act, 1999*.

⁷⁵ Presentation by Tahir Amin, Alternative Law Forum, Bangalore, at the workshop organised to present the preliminary report, on 29th March 006.

the register under Section 57 does not prevent it from acquiring a distinctive character by long use as an unregistered mark.

Section 57 of the Act empowers the Registrar or the Appellate Board, established under Section 83 of the Act, to pass appropriate orders for cancelling or varying the registration of a trademark on the ground of any contravention or failure to observe any condition entered in the register in relation to the mark. The Appellate Board or the Registrar discharges this function working as a tribunal. Any aggrieved person can complain to them that a mark has been registered without sufficient cause, or has been entered wrongly in the register. Section 13 states that any entry made in the register in contravention of the provisions of that section shall be deemed to be an entry wrongly remaining in the register or an entry made without sufficient cause. Therefore, if a complaint is made to the Registrar or the Appellate Board in relation to registration of a trademark coined from INNs, the entry in the register may be expunged or varied. Moreover, under Section 57 (4), the tribunal may decide such issues on its own motion. According to Section 2 (ze) the tribunal means the Registrar or, as the case may be, the Appellate Board, before which the concerned proceeding is pending. Thus, the Registrar is empowered to remove such marks from the Register even without any complaint from any person, and can rectify any violation of Section 13 even after the registration of such marks. However, the tribunal has the discretion to initiate such action.

V. IMPLEMENTATION

In spite of the fact that the trademark law explicitly prohibits the registration of words derived from INNs as trademarks, there are instances in India of brand names being derived from INNs. The pharmaceutical industry in India ranks fourth in the world in terms of volume. In terms of value, it is ranked thirteenth. The pharmaceutical market in India is highly fragmented with about 20 000 to 25 000 entities spread across small, medium and large scale companies..⁷⁶ In such a vast and fragmented market, brand names are widely used for the marketing of drugs. Indeed, there are a large number of brands for a single pharmaceutical substance(Table 6).

TABLE 6. Number of brands associated with a single generic name

Generic name	No. of brands
amoxicillin	86
amoxicillin + other substances	102
glimepiride	32
clopidogrel	45
atorvastatin	69
betamethasone	66

Source: Indian Drug Review, Nov-Dec 2005.

There are instances where pharmaceutical substances in India have been marketed under brand names that are very similar to INNssome of which use INN stems. A list of certain brand names that are apparently derived from INNs is attached as Annexure B. The list contains examples of names using both stems as well as other parts of INNs. The list also shows that both big and small companies, including multinational companies, follow this practice. In some specific cases, WHO has issued INN protection letters to the DCGI, requesting that steps be taken to ensure that such names are not registered as trademarks. Table 7 contains an illustrative list of instances where WHO has issued INN protection letters to the DCGI. A complete list of INN protection letters issued by WHO to the DCGI is attached as Annexure C of this study.

⁷⁶ Piribo, Indian Pharmaceutical Industry. Issues and Opportunities, [online] available at http://www.piribo.com/publications/country/indian_pharma_issues.html, visited on 14th March 2006.

TABLE 7. INN protection letters issued by WHO to the DCGI

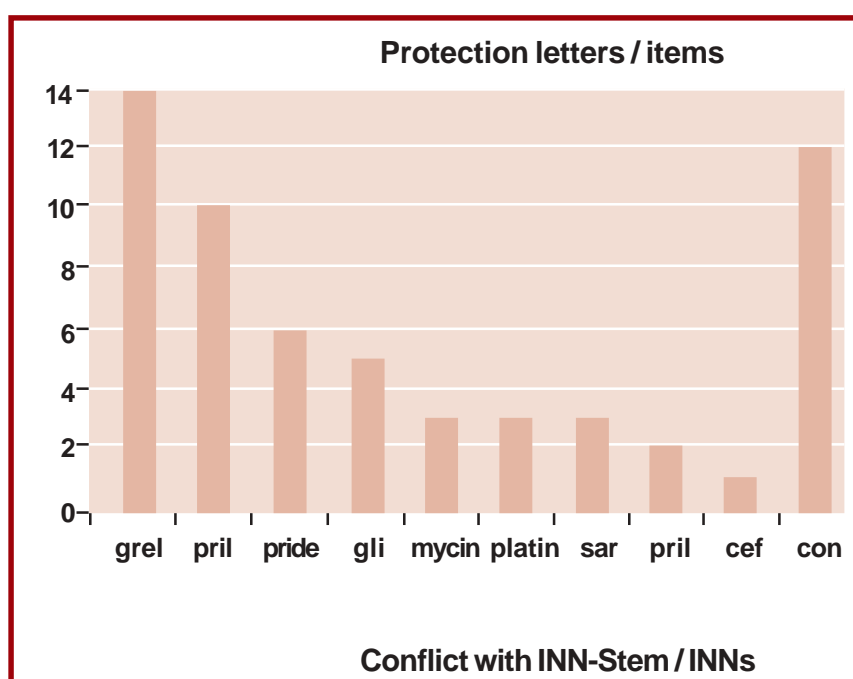
INN	Stem	TM	TM number	Firm	Date of WHO letter
NA*	cef	Cef	B1096796	Mica Labs Pvt Ltd, Ranchi	08/03/2004
glimepiride	gli	Gliride	B1027541	Varun Continental, Mumbai	02/02/2004
glimepiride	gli	Glimeride	B965893	Medley Pharms, Mumbai	08/03/2004
glimepiride	gli	Glime	987850	Biochem Pharms. Industries, Mumbai	08/03/2004
glimepiride	gli	Glimerit	B1056868	Aviat Chemical Private Ltd, Navi Mumbai	12/05/2004
	gli	Gliride	955139	Nicholas Piramal India, Mumbai	06/04/2005
clopidogrel	grel	Pidogrel	937874	Aviat Chem., Mumbai	12/08/2003
clopidogrel	grel	Clogrel	905979	Cadila Health Care, Ahmedabad	11/11/2003
clopidogrel	grel	Clopigrel	1095907	USV, Mumbai	11/11/2003
	grel	C-Grel	1085860	Medisearch Pharm., Chennai	22/09/2003
	grel	Idogrel	1136886	Rajvi Vipul Bhagat, Mumbai	22/03/2004
lovastatin	vastatin	Lostatin 10	696848	DrReddy's Laboratories	22/09/2003
roxithromycin	mycin	Roxymycin	906506	Apex Laboratories, Chennai	02/10/2002
roxithromycin	mycin	Roxthromycin	913105	Indian Drugs & Pharm. Ltd, Gurgaon	13/08/2003
roxithromycin	mycin	Roxithro	613577	Gufic Chem. Private. Ltd, Bombay	13/08/2003
oxaliplatin	platin	Oplatin	B1182221	Rajvi Vipul Bhagat, Mumbai	25/05/2004
	platin	Oxiplatin	1231144	Rajvi Vipul Bhagat, Mumbai	23/03/2005
	platin	Oxiplatin	1231144	Rajvi Vipul Bhagat, Mumbai	23/03/2005
pantoprazole	prazole	Panprazol	1149412	Ramji Jaiswal Vardan, Mumbai	08/03/2004
	prazole	Prazole	B1134569	Syncom Healthcare Ltd, Indore	22/03/2004
	prazole	Oprazole	1119112	Glenmark Laboratories, Mumbai	09/03/2005
amisulpride	pride	Moprid	773021	Cadila Healthcare Ahmedabad	21/03/2001
	pride	Guapride	1018517	Ajanta Pharma, Mumbai	06/04/2005
	pride	Guapride	1018517	Ajanta Pharma, Mumbai	10/05/2005
	pride	Tripride	1301205	Micro Labs, Bangalore	08/06/2005
	pride	Amipride	1214276	A.N. Pharmacia Labs. Pvt Ltd, Kolkata	19/07/2005
ramipril	pril	Lomipril	898800	Basilco India Ltd, New Delhi	08/03/2004
	pril	Rampril	1128934	Protech Biosystems PVT LTD New Delhi	03/11/2005
	pril	Rampri	1330831	Rajvi Vipul Bhagat Mumbai	07/12/2005
NA	sartan	Alsartan	738837	Aristo Pharm., Mumbai	22/09/2003
	sartan	Sartan	748135	Cipla Limited	22/03/2004
	sartan	Sartan	825986	Lupin Laboratories	25/05/2004

Source: WHO-INN Programme

*INN protection letters does not mention the INN and only refers to the stem

From a perusal of the list of INN protection letters issued by WHO, it is evident that most of the alleged cases involve misappropriation of INN stems. Figure 1 shows the INN stems that have been exploited the most as trademarks. The INN stem in respect of which most INN protection letters have been issued by WHO is “-grel”, followed by “-prazole”, “-pride” and “gli-”. While “-grel” and “-sartan” are stems for cardiovascular drugs, “-prazole” is a stem for drugs used to treat gastroesophageal diseases, “-pride” is a stem for antidepressants, “gli-” is a stem for antidiabetic drugs, while “-platin” and “-cef-” are stems for oncology drugs. This shows that a large number of cases of alleged misappropriation of INNs in India involve drugs for heart diseases, diabetes and cancer. There are also brands in respect of which INN protection letters have not been issued for several other brands.

Figure-1



Source: WHO-INN Programme

Table 8 gives a list of some of such brands. Some brands with similarity to INNs are among the top selling brands in India (see Box 1).

TABLE 8 : Brands derived form INN stems

INN	Stem	Brand name	Company
vinleurosine	-osine	Virosine DR	Ranbaxy
piracetam	-acetam	Alcetam	Alkem
epirubicin	-rubicin	Alrubicin	Alembic
lovastatin	-vastatin	Lostatin	DrReddy's Laboratories
alprazolam	-zolam	Alzolam	Sun Pharmaceuticals
ramipril	-pril	Codiopril	Dr.Reddy's Laboratories

Source: Websites of surveyed companies

Figure 1. INN stems that have been misappropriated

BOX 1

The brand Lostatin of Dr Reddy's Laboratories is ranked no. 1 and Alzolam of Sun Pharmaceuticals is ranked no. 4 in their respective categories based on their value. These brand names are derived from the INNs *lovastatin* and *alprazolam*, respectively.

Source: SEAR Pharm Forum[Au: Incomplete]

INN protection letters issued by the WHO-INN Programme to the DCGI show that brand names have been coined from INNs primarily by small pharmaceutical companies. However, a survey conducted among the leading pharmaceutical companies in India shows that even these companies have coined about 10% of their brands from INNs (Table 9). Leading companies have largely concentrated on deriving brand names from INNs in therapeutic areas such as diabetes, and cardiovascular and antihypertensive drugs. The benefits and disadvantages of this practice from a public health perspective need to be examined in detail.

TABLE 9. Number of brand names and therapeutic areas coined from INNs by large pharmaceutical companies

Company	No. of brands Surveyed	No. of brands derived from INNs	Therapeutic areas where names have been coined from INN
Ranbaxy	184	8	Anti-infectives, cardiovascular, diabetes, anti-retroviral
Cipla	97	17	-do-
Dr Reddy's Labs.	189	15	Antihypertensive, cardiovascular, diabetes
Sun Pharmaceuticals	400	90	Diabetes, anti-infectives, cardiology, oncology, anti-histaminic
Nicholas Piramal	156	56	Cardiovascular, central nervous system, diabetes
Lupin Ltd.	150	20	Antihypertensive, antiretroviral
Aurobindo	116	10	Antihypertensive, diabetes, anti-infective
Cadila Healthcare	78	24	Antihypertensive, diabetes, cardiovascular

Source: Websites of surveyed companies

Gaps in implementation

The gaps in implementation of the legal and policy regime are given below and possible deficiencies at the various levels that enable this situation to flourish identified. The views of the major stakeholders such as industry, legal practitioners, health professionals and public health groups are also presented.

The Trade Marks Office

The basic requirement of Section 13 (b) of the Trade Marks Act, 1999 is that INNs must be notified by the Registrar. However, as mentioned earlier, no such notification has been issued. During informal interactions, senior trademark officials informed us that although INNs are not notified, the computerized database of the Registry contains INNs that are fed in from time to time. However, this does not satisfy the legal requirements since INNs must be formally notified under Section 13 (b).

There is no specific provision either in the Trade Marks Act, 1999 or in the Trade Marks Rules, 2001 relating to the procedure for examining whether an application for a trademark for a pharmaceutical substance has any similarity with an INN. The Trade Marks Rules merely state “that the Registrar shall publish from time to time in the Trade

Marks Journal, the words which are declared by the WHO as INNs referred to under Section 13 (b)".⁷⁷ Hence, while Section 13 of the Act speaks of words that are declared by WHO as INNs and are notified as such by the Registrar, the Trade Marks Rules state that such notification has to take place from time to time by publication of INNs in the *Trade Marks Journal*. However, till date no such notification has been made. In the absence of formal notification of INNs, Section 13 (b) is not in force and therefore not applicable.

A formal notification may render marks derived from INNs as violative of Section 13. Though INNs are not notified formally at present, either the government or the court may start this at any time, because the formal notification of INNs is a statutory requirement. In this event, INN-derived marks that are currently registered would be exposed to the threat of legal challenge by any public interest group or other interested person or the Registrar under Section 57 of the Trade Marks Act, 1999. This would lead to litigation costs for pharmaceutical companies and might damage their business including their brand equity. Hence, it is in the interest of all parties that the Trade Marks Registry should discourage such registration and notify INNs at the earliest.

With regard to the procedure for registration of trademark applications, the Trade Marks Rules state that the application should, with sufficient precision, give a description of the trademark in words, if necessary, to determine the right of the applicant.⁷⁸ On receipt of a trademark application, the Registrar shall cause a search to be made to ascertain whether there is on record any identical or deceptively similar mark. Such a search shall be carried out among registered trademarks and pending trademark applications.⁷⁹ Thus, there is no requirement under the Trade Marks Rules, 2001 to conduct a search among INNs that may be notified in the journal.

However, Chapter 6 of the *Practice and procedure manual for the administration of the Trade Marks Act, 1999* lays down certain guidelines to be followed by trademark examiners in respect of Section 13 (b) of the Act. It states the grounds for refusal to register a trademark under Section 13 (b); if a trademark to be used in relation to a pharmaceutical substance is the same or confusingly similar to a notified INN or other generic drug name. For the purpose of examination, the examiners shall refer to the INNs maintained in the Trade Marks Registry.⁸⁰

The *Manual* also states that a ground for refusal under Section 13 (b) exists where the trademark and INN are identical or deceptively similar.⁸¹ It states that if such a mark were applied to the substance which has an INN, the mark would not be capable of

⁷⁷ *The Trade Marks Rules, 2001*, Rule 121.

⁷⁸ *Ibid*, Rule 25 (12) (a).

⁷⁹ *Ibid*, Rule 37 (2).

⁸⁰ *Practice and Procedure Manual for the Administration of the Marks Act, 1999*, paragraph 21.

⁸¹ *Ibid*

distinguishing between the goods of the proprietor and similar substances identified as INNs. Moreover, if such a mark were used on goods with different constituents, it would be deceptive.⁸²

With regard to the use of INN stems, the *Manual* states that it would be appropriate to impose some restrictions on the use of the mark to ensure that its use accords with the descriptive significance of the stem used.⁸³ Thus, the *Manual* does not specifically instruct examiners to refuse the registration of marks using INN stems. Consequently, this dilutes the prohibition of trademark registration of any word that is deceptively similar to INNs in terms of Section 13 (b) of the Act.

Nevertheless, the existence of a large number of trademarks that are similar to INNs points to the fact that a close scrutiny rarely takes place of trademark applications in terms of Section 13 (b) of the Act. On the basis of informal interactions with trademark examiners, it is learnt that all names applied for are checked with the computerized database of the Registry. In view of the existing state of affairs, therefore, it seems that there is no mention of INNs in the database. It is also learnt that, in spite of there being a manual for examiners, most examiners are unaware of the requirements of Section 13 (b) and are not imparted any training in this matter. The few instances of rejection of trademark applications on the ground of deceptive similarity with INNs may be because the examiner who dealt with the matter was aware of INNs, or because some other person raised an objection. A few instances of rejection of trademark applications occurred in the early 1980s. In *ICI v. Cipla*, the Trade Marks Registry refused to register the mark *Atenolar* on the ground of the mark being similar to the generic name *atenolol*.⁸⁴ A possible reason for this could be that before 1981, Rule 96 of the Drugs and Cosmetics Rules, 1945 required that the label of drugs only carry the generic name of the drug or the INN and not the trade name. For this reason, the Trade Marks Registry as a rule included a requirement for filing an affidavit for marks in class 5, under which pharmaceutical products are registered, stating that the application is not for any notified generic drug. However, in the case of *Hoechst Pharmaceuticals Ltd. and others v. Government of India and others*,⁸⁵ the decision of the High Court of Delhi prohibiting the use of trade names under the power conferred by Sections 12 and 33 brings the impugned portion of Rule 96 in conflict with the provisions of the Trade Marks Act, 1999. In view of this, the requirement for filing an affidavit with the Trade Marks Registry has also been done away with.⁸⁶ Thus, it may be appropriate to make it mandatory for all applications in class 5 to disclose the generic name of the substance for which a mark is sought to be registered. This will make it easier for the examiners to

⁸² *Ibid.*

⁸³ *Ibid.*, paragraph 29.

⁸⁴ IPLR 1980, vol.5, p.90.

⁸⁵ IPLR 1982, vol.7, p.1.

⁸⁶ *Interview with Shailamanyu Singh Rathore and Ruchika Sukh*, n.61, 62.

ascertain whether the name has been derived from a generic name or an INN. This is more significant as the majority of trademark applications fall under class 5, i.e. for pharmaceutical substances.

BOX 2

The *Annual report 2002-03*, of the Trade Marks Registry states that most of the applications for the preceding year have been received in class 5 for pharmaceutical, veterinary and sanitary substances (23.86%, a total of 22 462 applications).⁸⁷ As per the *Annual report 2001-02*, the largest number of applications for registration of trademarks was received in respect of goods in class 5 (24.42%, a total of 22 036 out of 90 236 applications).

Source: Annual report, 2002-2003, of the Controller General of Patents, Designs, Trade Marks and Geographical Indications, pp.58, 63.

The format of the trademark examination report contains a column to record objections under Section 13. However, the examiners revealed that to their knowledge no such objection has been raised. According to them, the use of a part of the generic name may be permissible. To ascertain whether the examination of applications for trademark registration of pharmaceutical substances includes an examination of the marks under Section 13, a trademark search was conducted with 19 names including new INNs and some INN stems. The search report revealed that while objections were raised in all cases on the ground of existence of similar marks, no objection was raised under Section 13. For instance, the report states that the INNs apixaban and dapliclermine cannot be registered as trademarks because of the existence of similar marks such as Apix, and Dap-AC and Dapco, respectively. The search report also reveals that many marks have been derived from INN stems. For instance, the report states that the stem “cef” cannot be registered because of the existence of similar marks such as Cefdor, Cefex, Cefin, etc. This clearly establishes that there is a general lack of awareness among examiners about the requirements of Section 13, as well as on the public health implications of INNs. This indicates a lack of specialization of examiners on INN-related issues.

Gaps in the drug regulatory system

There is no specific mandate of the DCGI for regulating the use of INNs in India. However, such a mandate may be accorded by implication, since the DCGI is the nodal agency representing India before WHO and because the DCGI has a specific mandate to lay down regulatory measures and standards for drugs. In this context, the Drugs and

⁸⁷ *Annual Report, 2002-2003, of the Controller General of Patents, Designs, Trade Marks and Geographical Indications*, pp.58, 63.

Cosmetics Rules, 1945 requires that generic names should be printed prominently (usually double the font size of brand names). However, this requirement is often overlooked and the brand name is printed in bold letters and attractive colours. The laws regarding labelling ought to be implemented more stringently. .

At present, there is no specific policy guideline on the use and protection of INNs in India. As there is no mandatory requirement to register brand names as trademarks, prevention of trademark registration by itself will not curb the practice of using brand names derived from INNs. In many cases, pharmaceutical brands are launched in the market even before their trademark registration either to avoid delay in trademark registration or to bypass objections under the trademark law. Therefore, it is essential to develop a detailed policy guideline on the use of INNs as well as disincentives for brands using parts of INNs.

There is no centralized mechanism for the registration of brand names of drugs in India. Currently, drug companies register their brand names with the respective state regulators. Interactions with the DCGI revealed that the DCGI's office does not maintain a database of all the brand names registered in the country. Thus, without changing the brand registration system, introduction of INNs alone will not be effective. A centralized directory should be developed of brand names approved by state regulatory authorities. With the availability of the internet, state regulators can be asked by the DCGI to post all drugs approved by them on the website which can serve as a centralized database. The draft National Pharmaceutical Policy has suggested that "...branding of drugs ... should be brought under the Central drug regulatory system. The drug regulator must be required to maintain a data base on brands and their compositions, and all brand registration of drugs must compulsorily be approved by the drug regulator".⁸⁸

State drug regulatory authorities have a predominant role in granting manufacturing and marketing approvals for pharmaceutical substances. Hence, state drug regulators should ensure that drugs with brand names coined from INNs are not marketed. However, state drug regulatory authorities hardly have the technical capability to deal with this situation. Therefore, it is imperative to devise a policy guideline for state regulators to ensure that marketing approvals are not given for such brands.

During personal interviews, it was conveyed by the DCGI that though there is no legal obligation, the DCGI's office respects the spirit of WHA Resolution 46.19 and hence, the DCGI does not have any role in the approval of any brand name. This falls within the domain of the state regulators. The primary concern of the DCGI's office is the safety of drugs. When an application is made for the approval of a new drug, the DCGI decides

⁸⁸ Draft National Pharmaceutical Policy, supra n.57 pp.23-24.

this on the basis of the generic name. It is also learnt that whenever WHO issues an INN protection letter to the DCGI, it is communicated to the state drug regulators, the Trade Mark Registry and pharmaceutical companies and pharmaceutical associations.⁸⁹ Our field study showed that state regulators also forward such communications to the pharmaceutical companies. As mentioned by the DCGI, no response has been received on these communications. Hence, there is little information on what specific action has been taken by the concerned authorities with regard to the use of INNs in brand names. There is no formal coordination mechanism between the DCGI and the trademark office with regard to INNs. An administrative mechanism for better coordination between these offices should be devised.

The DCGI also urged state regulators to take into account the issue of INNs. INN was a specific item on the agenda of the 36th Drug Consultative Committee, 2005 meeting between the DCGI and state regulators. No other organization besides WHO has sent any communication regarding the misappropriation of an INN to the DCGI. The DCGI has not received any reply to its communications in this connection to the Trade Marks Registry. Apart from the action it has taken, the DCGI can do little in view of the inadequate infrastructure and lack of a specific mandate.⁹⁰

The WHO-INN Programme

WHA Resolution 46.19 has not been authoritatively interpreted. Hence, there is a lack of awareness about the meaning and content of the Resolution, leading to a lack of consistency in the regime for the use and protection of INNs in Member States. As the Resolution does not have any legal binding under international law it would be appropriate in the long run to develop an international convention on the use and protection of INNs.

As WHA Resolution 46.19 does not establish a reporting and monitoring mechanism in relation to INNs, WHO does not have a mandate for establishing a reporting and monitoring mechanism in relation to INNs. As a result, WHO receives reports of misappropriation of INNs from a variety of sources such as trademark offices, national drug regulators and pharmaceutical companies. Where a trademark office notifies WHO, the WHO-INN Programme informs the trademark department that appropriate action has been taken with the responsible national authorities. WHO gets information about the use of trademarks derived from INNs in India from similar sources.⁹¹ However, WHO is unable to state the specific sources from which it gets information as

⁸⁹ Interview with Rita Teatia, Joint Secretary, Ministry of Health and Family Welfare, Govt. of India, conducted on 2nd March 2006, on file with the authors.

⁹⁰ Interview with Ashwini Kumar, supra n.56.

⁹¹ Ibid.

this is confidential.⁹² There is a possibility that in many cases WHO might have received such reports from pharmaceutical companies, since authorities in countries that do not have strong substantive or procedural legal regimes for preventing misappropriation of INNs can hardly be expected to report cases of misappropriation, which they themselves could not detect.

The WHO-INN Programme issues INN protection letters to the DCGI. The DCGI has not responded to any communication from WHO.⁹³ Under the present circumstances, the DCGI is reactive rather than being proactive. Hence, it would be more useful for WHO to write about INN misappropriation to the Trade Marks Registry rather than the DCGI.⁹⁴ However, the WHO-INN Programme Manager is of the view that WHO can issue protection letters only to the national information officer designated by the national authority and it is their responsibility to decide whether they want to take action with the persons responsible at the national level.⁹⁵ WHO can only work with the trademark office if requested by the national authorities responsible to WHO. It may be pertinent to mark a copy of INN protection letters to the trademark offices.

Though WHA Resolution 46.19 specifically calls for the protection of INN stems, it is not clear as to how a stem is defined for determining which part of the INN constitutes the stem. WHO publishes a list of INN stems⁹⁶ from time to time, but trademark officials would be largely unaware of this. The Information leaflet for trademark departments issued by the INN Programme does not mention that the use of INN stems should be discouraged.

Perspectives of major stakeholders

A questionnaire-based field survey was conducted, and formal and informal interactions were held with the pharmaceutical industry, trademark attorneys, civil society organizations and pharmacologists to ascertain the perspectives of major stakeholders on this issue. While most respondents were aware of the objectives of the INN Programme and that the trademark use of names derived from INNs was undesirable, they revealed a general lack of understanding about what constitutes legitimate use of INNs and INN stems. The respondents had different opinions on the desirability of using INNs in brand names.

People associated with the pharmaceutical industry believe that deriving brand

⁹² E-mail from Rafaella Balocco Matavelli, INN Programme Manager, WHO, dated 13th February 2006

⁹³ Interview with Rafaella Balocco Matavelli, INN Programme Manager, WHO, conducted on 25th January 2006, on file with the authors.

⁹⁴ See HAI News: The Newsletter of Health Action International, no.130, July-September 2004, p.15.

⁹⁵ E-mail from Rafaella Balocco Matavelli, supra n.91.

⁹⁶ The list of official stems are published in the WHO website http://whqlibdoc.who.int/hq/2004/WHO_EDM_QSM_2004.5.pdf.

names from INNs is a worldwide practice.⁹⁷ In India, a mark is coined from the pharmacopoeial name to provide the doctor an indication of the use of the drug. This strategy is based on the industry's perception of the doctor as the customer. Since in India a single pharmaceutical substance has many brand names, it is easier and less expensive to develop brand names derived from INNs.⁹⁸ An initial entrant in the market usually indulges in this practice to enable doctors to easily recall the drug and subsequent entrants follow suit. However, the prevalence of a large number of brand names derived from INNs may discourage a new entrant from using such names and they may wish to develop unique, stand-alone names.⁹⁹ Unlike large companies, small pharmaceutical companies do not have the capacity to push a unique brand name in the market.¹⁰⁰ Most INN protection letters have been issued for brands of small pharmaceutical companies.

It may be easier to make inroads into the monopoly of a brand as soon as it becomes off-patent by using a part of the generic name in the brand name.¹⁰¹ In a product patent regime, the patent holder is enabled to build up the brand loyalty using the patent monopoly. As a result, the new entrant may find it difficult to break the brand loyalty of the customer after expiry of the patent. This assumes relevance in the future because of the introduction of product patents in India. To avoid such a situation the patent holder should be required to market the patented product using only the generic name for the duration of patent protection.

Responding to the specific question of whether the practice of using INNs in the brand name can retard the creation of new INNs using the same stem in future, some health professionals were of the view that though this can discourage the creation of new INNs in future, clinically it may not make any significant impact. If a unique brand name is pushed aggressively in the market, it can have better sales than another brand name that uses part of the INN. In such an event, subsequent companies launching the same molecule may not bother about selecting names that are similar to INNs.¹⁰²

Under the Drugs and Cosmetics Rules, 1945, INNs are required to be written in bolder letters than the brand name. Hence, there could be no confusion even if the brand name is derived from a generic name. Moreover, WHO requests Member States to only prevent trademark registration of INNs. It does not say that a trade name should not be derived from a generic name. As long as the brand name is not the *exact* reproduction of the INN, there should be no objection to it.¹⁰³ The industry holds that by

⁹⁷ Interview with Dr. G. Wakankar, *supra* n.24.

⁹⁸ Interview with Homi Bhaba, Director, Organization of Pharmaceutical Producers of India, conducted on 1st March 2006, on file with the authors.

⁹⁹ Interview with Abhay Gandhi, Sun Pharmaceuticals, conducted on 2nd March 2006, on file with the authors.

¹⁰⁰ Interview with Dr.C.M.Gulhati, Editor, MIMS-India, conducted on 12th February 2006, on file with the authors.

¹⁰¹ Interview with Dr. G. Wakankar, *supra* n.24.

¹⁰² *Interview with Dr. Sampada Patvardhan*, conducted on March 3rd 2006, on file with the authors.

¹⁰³ *Submissions of Indoco Remedies Ltd. to the Commissioner, Food & Drug Administration, Maharashtra, 14th June 2005*, on file with the authors.

using generic names to coin brand names instead of a stand-alone one, it actually promotes the use of generic names, especially because these are more prominently printed on the label.¹⁰⁴

Some representatives of civil society organizations working on health issues have pointed out that the issue of INNs is at best a peripheral issue in India. If the objective of INNs is to ensure that there is no confusion regarding the names of pharmaceutical substances, the use of INN stems may be promoting that objective rather than violating it.¹⁰⁵ The use of common stems may be a half-way house to the ultimate goal of marketing and identifying drugs only by their generic names. Using brand names that are totally unrelated to the INN (e.g. AZ-1 for azithromycin and AZ for albendazole) can create further confusion in a country such as India, where anarchy prevails in the medicines market due to the proliferation of brand name drugs, many of which are irrational combination drugs. Using totally unrelated brand names would help only big pharmaceutical companies with marketing clout to induce brand name recall among prescribers and end users. Small- and medium-scale companies will have to spend more money to build up a unique brand name, which will be reflected in even higher prices and probably eventually wipe them out.¹⁰⁶ The practice of deriving brand names from INNs is resorted to because companies can avoid substantial expenses in selecting brand names. Therefore, rather than discouraging the use of INNs, it would be wiser to discourage the use of brand names as such.

On the one hand, it may be argued that deriving brand names from INNs helps in easily identifying the drug with its molecule and avoids confusion. On the other hand, the use of INN stems in brand names can lead to confusion within brand names, particularly in cases where the brand names become more popular than the generic names. This increases the danger of pharmacists giving the wrong medicine to patients as two brands derived from the same INN stem may sound and look alike. It is suggested that if doctors have a brand preference they should write the brand name in brackets along with the generic name.¹⁰⁷

The legal fraternity is aware of the law relating to drug nomenclature in India, and should be proactive in instilling in their clients a sense of awareness about the need to respect INNs. Since doctors are regarded by the pharmaceutical industry as the customers of pharmaceutical products, awareness needs to be generated among doctors regarding the public health implications of using INNs. Doctors should also be discouraged from prescribing only by brand name. Medication errors due to confusion created by INN-derived brand names can make doctors liable for damages. Thus, there

¹⁰⁴ Interview with Dr. Gopakumar Nair, former President, IDMA, conducted on 27th March 2006.

¹⁰⁵ Interview with Dr. Amit Sengupta, conducted on 14th February 2006, on file with the authors.

¹⁰⁶ E-mail from S. Srinivasan dated 2nd April 2006.

¹⁰⁷ Interview with Dr. B. Ekbal, conducted on 7th February 2006, on file with the authors.

is a necessity to sensitize doctors and medical students regarding INNs .

Hence, both trademark attorneys and doctors need to be engaged in the discourse on INNs. Civil society organizations can also help in ensuring effective implementation of the law and policy relating to the use of generic names including INNs.

VI. CONCLUSIONS AND SUGGESTIONS

International nonproprietary names are unique names that help to identify the complex chemical compositions of pharmaceutical substances. Common elements in pharmacologically related substances are reflected in INNs through the use of words called stems, which are mostly suffixes to randomly selected prefixes. Thus, the most important part of an INN is its stem because this helps in establishing a pharmacological relationship between two substances and in naming new pharmacologically related substances in the future. While selecting INNs it is ensured that these are not similar to trademarks. Hence, there is a reciprocal necessity for national trademark authorities to ensure that trademarks approved in their country are not derived from INNs. WHA Resolution 46.19 of 1993 exhorts Member States to develop legal and policy regimes to address this need.

Though WHA Resolution 46.19 is non-binding in nature, India has substantially implemented its requirements under Section 13 (b) of the Trade Marks Act, 1999. Nevertheless, no INN has been notified by the Trade Marks Registry in the *Trade Marks Journal*. Presently, an objection to a mark on the ground of its similarity with an INN can be raised only if the individual examiner is aware of what INNs are. Very few, if any, examiners are aware of INNs. Even at the substantive level, the use of INN stems is not prohibited in India.

The INN protection letters issued by WHO show that the Organization is singularly concerned with trademark registration of names derived from INNs. However, it is not clear whether a part of the INN stem may be used in the brand name. The WHO-INN Programme does not have an effective monitoring and reporting mechanism for INNs.

The national drug regulatory authority in India, the DCGI, does not have any specific mandate to ensure that brand names are not derived from INNs. Except for the initial marketing approval, approval for manufacturing and subsequent marketing approvals fall within the domain of state regulators. With its insufficient infrastructure, the DCGI is unable to play more than a persuasive role in this matter.

The pharmaceutical industry in India is of the view that deriving brand names from parts of generic names is common practice throughout the world. It has been reasoned that using parts of INN stems does not cause confusion since the Indian regulations

require the generic name to be shown more prominently than the brand name. It has been argued from a public health perspective that the use of stems in brand names may help in easy identification of the brand with the generic substance. It may also be cost-effective for small companies to use a brand name having a part of an INN without having to invest substantially on developing unique brand names. However, the practice of using INN stems in brand names may lead to confusion as different drugs with parts of the same INN stem may sound and look alike.

Suggestions

There are gaps in the legal and policy regime on the use and protection of INNs in India. These gaps are present at various levels - WHO, the Trade Marks Registry, the DCGI and others. On the basis of the findings of the study, we offer the following suggestions to address these gaps.

World Health Organization

- For the effective and transparent implementation of WHA Resolution 46.19, a reporting and monitoring mechanism should be established.
- Since Resolution 46.19 is non-binding, it would be appropriate to work towards the development of an international convention on the use and protection of INNs for pharmaceutical substances. Since there is no authoritative interpretation of WHA Resolution 46.19, the development of an international convention may help to codify the international legal regime for the use of INNs and make it mandatory in nature. At present, there is little transparency in the compliance mechanism of the INN Programme. The proposed convention should also have a mandatory requirement for all Member States to send periodic reports to WHO informing it about the steps they have taken to ensure compliance with the international legal regime.
- The use of INNs should be treated as an issue of brand registration rather than the one concerning trademark registration. Thus, the INN Programme should focus on the use of brand names derived from INNs rather than focusing only on trademark registration.
- The rules for the use of INNs in relation to FDCs should be clarified.
- The communications from WHO to the DCGI do not state the importance of INNs. Further, there is a lack of clarity on rules relating to the use of INN stems. The leaflet prepared by WHO for trademark offices does not make any mention of discouraging the use of INN stems. Therefore, clear and effective

communication is needed from WHO to the responsible national authorities for creating awareness about all issues pertaining to the use of INNs.

- WHO should informally coordinate with the trademark offices in India on this issue.

The Trade Marks Registry

- The Registrar of Trade Marks should notify INNs recommended by WHO in the *Trade Marks Journal*.
- The Trade Marks Rules should specifically require an examination of new applications in class 5 to determine whether they are derived from INNs.
- All class 5 applications for registration of trademarks should disclose the generic name of the mark applied for.
- The examiners should be imparted training on INNs, especially on its public health implications.
- The trademarks offices must respond to communications from the DCGI on the protection of INNs.
- The *Manual* for examiners should be rectified to make it reflective of the spirit of Section 13.
- The *Manual* for examiners should be made accessible to the general public.

Drugs Controller General of India (DCGI)

- Guidelines on the use of INNs should be developed in accordance with the requirements of WHA Resolution 46.19 and communicated to the state drug regulatory authorities.
- A database of brand names registered throughout the country should be maintained on the internet.
- There should be effective coordination with WHO. Action taken by the DCGI in response to WHO letters should be communicated to WHO.
- There should be better coordination between the DCGI, the state drug regulators and the trademarks offices on the use and protection of INNs.
- There should be capacity building at the level of state drug regulatory authorities.

Other stakeholders

- There is a need to generate awareness in the pharmaceutical industry on the use of INNs.
- Pharmaceutical associations should develop guidelines for the use of INNs.
- Medical and legal professionals should be sensitized on this issue.
- INNs should be made a part of the syllabus for medical students.

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ANNEXURE A

WHA 46.19 Nonproprietary names for pharmaceutical substances

The Forty-sixth World Health Assembly,
Recalling Resolution [WHA31.32](#) on the importance of using nonproprietary names in establishing national drug formularies;

Acknowledging with satisfaction the increasing contribution of generic products to national drug markets in both developed and developing countries;

Noting the current trend to market products with the same active ingredient as, and intended to be clinically interchangeable with, a product currently on the market (multisource products) under trade-marks or brand names derived from stems or other descriptors used in international nonproprietary names;

Recognizing that such a practice, particularly in respect of single-ingredient prescription drugs, may compromise the safety of patients by creating confusion in prescribing and dispensing medicines and by interfering with the orderly development of the nomenclature for international nonproprietary names; Aware of the concern expressed by the Sixth International Conference of Drug Regulatory Authorities (1991) about the increasing use of pharmaceutical brand names that are very similar to or derived from international nonproprietary names;

Noting the recommendation made by the WHO Expert Committee on the Use of Essential Drugs, in its fifth report, on the need to discourage, as a matter of urgency, the use of trade-marks that are derived from international nonproprietary names,

1. REQUESTS Member States:

- (1) 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;
- (2) to 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;
- (3) to 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;

2. CALLS ON the Director-General to intensify his consultations with governments and representatives of the pharmaceutical industry on ways of reducing to a minimum the problems arising from drug nomenclatures that may create confusion and jeopardize the safety of patients.

ANNEXURE B

Examples of names coined from INNs

INN	Stem	Brand	Company
vinleurosine	-osine	Virosine DR	Ranbaxy
efavirenz		Aviranz	_____
nevirapine	-virapine	Nevipan	_____
chloroquine	-quine	Uquine Injection	Alkem
atorvastatin	-vastatin	Atvas	_____
indapamide	-amide	Atemide	_____
pantoprazole	-prazole	PAN	_____
piracetam	-cetam	Alcetam	_____
cefuroxime	cef-	Zocef	_____
cefadroxyl	cef-	Cefkem	_____
levetiracetam	-acetam	Levesam	Nicholas Piramal
escitalopram	-cital-	Szetalo	_____
citalopram	_____	Citalo	_____
glimepiride	gli-	Glimer	_____
metformin	-formin	Gluformin	_____
pioglitazone	-azone	Piozone	_____
tizanidine	-nidine	Tizan	Sun Pharmaceuticals
glimepiride	-gli	Glypride	_____
pioglitazone	-azone	Pioglit	_____
lovastatin	-vastatin	Aztatin	_____
baclofen	-ofen	Liofen	_____
clonazepam	-azepam	Lonazep	_____
alprazolam	-azolam	Alzolam	_____
ramipril	-pril	Codiopril	Dr.Reddy's
carboprost	-prost	Deviprost	_____
glimepiride	gli-	Glimy-P	_____
lovastatin	-vastatin	Lostatin	_____
sertraline	Sert-	Xsert	Cadila Pharmaceuticals
daunorubicin	-rubicin	Norubin	_____
zidovudine	-vudine	Zidovir	Cipla
lamivudine	-vudine	Lamivir	_____
stavudine	-vudine	Stavir	_____
abacavir	-cavir	Abamune	_____
NA*	-sartan	Sartan	_____
NA	cef-	Sefpirome	Novartis AG
NA	-sartan	Sartan	Lupin
clopidogrel	-grel	Clodogrel	Rajvi Vipul Bhagat
NA	-oplatin	Oplatin	_____
NA	-oprazole	Oprazole	Glenmark

*Used common stems of INNs without using othe pats of INN

ANNEXURE C

INN	stem	TM	TM number	Firm	Date of WHO letter	Source of information
artesunate	arte	Artesunate	B1120701	Unigrass Remedies, Mumbai	19/04/2005	Trademark dept./ Pharmaceutical Company
NA*	cef	Cef	B1096796	Mica Labs Pvt Ltd, Ranchi	08/03/2004	Trademark dept./ Pharmaceutical Company
cefotaxime	cef	Cefotaxim	708698	Ajanta Pharma, Mumbai	30/01/2006	Trademark dept./ Pharmaceutical Company
rofecoxib	coxib	Rofecox	905280	Biochem Pharms. Industries, Mumbai	26/09/2002	Trademark dept./ Pharmaceutical Company
rofecoxib	coxib	Rocoxib	905285	Biochem Pharms. Industries, Mumbai	26/09/2002	Trademark dept./ Pharmaceutical Company
glimepiride	gli	Glimiride	695661	Themis Chemicals, Mumbai	31/03/2003	Trademark dept./ Pharmaceutical Company
glimepiride	gli	Gliride	B1027541	Varun Continental, Mumbai	02/02/2004	Trademark dept./ Pharmaceutical Company
glimepiride	gli	Glimeride	B965893	Medley Pharms, Mumbai	08/03/2004	Trademark dept./ Pharmaceutical Company
glimepiride	gli	Glime	987850	Biochem Pharms. Industries, Mumbai	08/03/2004	Trademark dept./ Pharmaceutical Company
glimepiride	gli	Glimerit	B1056868	Aviat Chemical Private Ltd, Navi Mumbai	12/05/2004	Trademark dept./ Pharmaceutical Company
	gli	Gliride	955139	Nicholas Piramal India, Mumbai	06/04/2005	Trademark dept./ Pharmaceutical Company
clopidogrel	grel	Pidogrel	937874	Aviat Chem., Mumbai	12/08/2003	Trademark dept./ Pharmaceutical Company
clopidogrel	grel	Clogrel	905979	Cadila Health Care, Ahmedabad	11/11/2003	Trademark dept./ Pharmaceutical Company
clopidogrel	grel	Clopigrel	1095907	USV, Mumbai	11/11/2003	Trademark dept./ Pharmaceutical Company
	grel	C-Grel	1085860	Medisearch Pharm., Chennai	22/09/2003	Trademark dept./ Pharmaceutical Company
	grel	Idogrel	1136886	Rajvi Vipul Bhagat, Mumbai	22/03/2004	Trademark dept./ Pharmaceutical Company
	grel	Opigrel	1136885	Rajvi Vipul Bhagat	22/03/2004	Trademark dept./ Pharmaceutical Company
clopidogrel	grel	Clodogrel	B1160761	Rajvi Vipul Bhagat, Mumbai	21/04/2004	Trademark dept./ Pharmaceutical Company
	grel	C Grel	B1130564	Triton Health Care, Chennai	25/05/2004	Trademark dept./ Pharmaceutical Company

	grel	Logrel	1132917	Rajvi Vipul Bhagat, Mumbai	25/05/2004	Trademark dept./ Pharmaceutical Company
	grel	Logrel	1132918	Rajvi Vipul Bhagat	04/06/2004	Trademark dept./ Pharmaceutical Company
clopidogrel	grel	Clogrel	851477	Cadila Health Care Ltd	08/06/2005	Trademark dept./ Pharmaceutical Company
	grel	Dogrel	1270677	Genom Biotec Pvt	09/08/2005	Trademark dept./ Pharmaceutical Company
	grel	Zogrel	130195	Rajvi Vipul Bhagat	09/08/2005	Trademark dept./ Pharmaceutical Company
	grel	Grel	1249383	Shreya Life Sciences, Mumbai	09/08/2005	Trademark dept./ Pharmaceutical Company
roxithromycin	mycin	Roxymycin	906506	Apex Laboratories Chennai	02/10/2002	Trademark dept./ Pharmaceutical Company
roxithromycin	mycin	Roxthromycin	913105	Indian Drugs & Pharm. Ltd, Gurgaon	13/08/2003	Trademark dept./ Pharmaceutical Company
roxithromycin	mycin	Roxithro	613577	Gufic Chem. Private. Ltd, Bombay	13/08/2003	Trademark dept./ Pharmaceutical Company
	mycin	Mycin	B580739	Syntho Pharm., Lucknow	28/11/2003	Trademark dept./ Pharmaceutical Company
	platin	Tevaplatin	736843	TevaPharmaceuticals Industries LTD, Jerusalem, Israel	14/05/2003	Trademark dept./ Pharmaceutical Company
	platin	Platin	845812	Wockhardt, Mumbai	28/11/2003	Trademark dept./ Pharmaceutical Company
oxaliplatin	platin	Oplatin	B1182221	Rajvi Vipul Bhagat, Mumbai	25/05/2004	Trademark dept./ Pharmaceutical Company
	platin	Oxiplatin	1231144	Rajvi Vipul Bhagat, Mumbai	23/03/2005	Trademark dept./ Pharmaceutical Company
	prazole	Prazol	883060	Prashi Pharma, Mumbai	17/11/2003	Trademark dept./ Pharmaceutical Company
pantoprazole	prazole	Panprazol	1149412	Ramji Jaiswal Vardan, Mumbai	08/03/2004	Trademark dept./ Pharmaceutical Company
	prazole	Prazolec	2479950	IvaxArgentina S.A.	08/03/2004	Trademark dept./ Pharmaceutical Company
	prazole	Prazole	B1134569	Syncom Healthcare Ltd, Indore	22/03/2004	Trademark dept./ Pharmaceutical Company
	prazole	Toprazol	1050780	Karnataka Antibiotics & Pharms. Ltd, Bangalore	01/04/2004	Trademark dept./ Pharmaceutical Company
	prazole	Prazole	1055339	Syncom Healthcare Ltd, Mumbai	01/04/2004	Trademark dept./ Pharmaceutical Company

	prazole	Adaprazole	1044383	Ajay Batra (trading as Admac Pharma. Ltd)	21/04/2004	Trademark dept./ Pharmaceutical Company
	prazole	Prozol	1010319	CFL Pharms. Ltd, Panjim, Goa	12/05/2004	Trademark dept./ Pharmaceutical Company
	prazole	Pazole	1044385 B	Ajay Batra, Panchkula (Haryana)	12/05/2004	Trademark dept./ Pharmaceutical Company
	prazole	Oprazole	1119112	Glenmark Laboratories, Mumbai	09/03/2005	Trademark dept./ Pharmaceutical Company
NA	pride	Moprid	773021	Cadila Healthcare Ahmedabad	21/03/2001	Trademark dept./ Pharmaceutical Company
	pride	Prid-40	688186	Samarth Pharmaceuticals	21/03/2001	Trademark dept./ Pharmaceutical Company
NA	pride	Prideten	619995	Clover Pharmaceuticals PVT LTD	21/03/2001	Trademark dept./ Pharmaceutical Company
	pride	Guapride	1018517	Ajanta Pharma, Mumbai	06/04/2005	Trademark dept./ Pharmaceutical Company
	pride	Guapride	1018517	Ajanta Pharma, Mumbai	10/05/2005	Trademark dept./ Pharmaceutical Company
	pride	Dipride	1216239	Divus Laboratories, New Delhi	10/05/2005	Trademark dept./ Pharmaceutical Company
	pride	Pride	1213997	First Care Pharma, Jind	10.05/2005	Trademark dept./ Pharmaceutical Company
	pride	Tripride	1301205	Micro Labs, Bangalore	08/06/2005	Trademark dept./ Pharmaceutical Company
amisulpride	pride	Amipride	1214276	A.N. Pharmacia Labs. Pvt Ltd, Kolkata	19/07/2005	Trademark dept./ Pharmaceutical Company
tiapride	pride	Betapride	1234098	Avinash Health Products, Chennai	16/09/2005	Trademark dept./ Pharmaceutical Company
NA	pril	Antisapril	829133	Amuchina Genova [Au: ?place]	26/06/2002	Trademark dept./ Pharmaceutical Company
NA	pril	Lomipril	898800	Basilco India Ltd, New Delhi	08/03/2004	Trademark dept./ Pharmaceutical Company
ramipril	pril	Sunij Rx Ramipril Tablets RL-5	1305467	Sunij Pharma, Ahmedabad	27/07/2005	Trademark dept./ Pharmaceutical Company
ramipril	pril	Rampril	1128934	Protech Biosystems Pvt Ltd New Delhi	03/11/2005	Trademark dept./ Pharmaceutical Company
ramipril	pril	Rampri	1330831	Rajvi Vipul Bhagat, Mumbai	07/12/2005	Trademark dept./ Pharmaceutical Company
ramipril	pril	R-Amipil	1330832		07/12/2005	Trademark dept./ Pharmaceutical Company
NA	sartan	Alsartan	738837	Aristo Pharm., Mumbai	22/09/2003	Trademark dept./ Pharmaceutical Company
	sartan	Sartan	748135	Cipla Limited	22/03/2004	Trademark dept./ Pharmaceutical Company

	sartan	Sartan	825986	Lupin Laboratories	25/05/2004	Trademark dept./ Pharmaceutical Company
valsartan	sartan	Cansartan	B1027464	Medley Pharmaceuticals Ltd, Mumbai	17/08/2005	Trademark dept./ Pharmaceutical Company
valsartan	sartan	Ramsartan	1330830	Rajvi Vipul Bhagat Royla Status, Mumbai	04/01/2006	Trademark dept./ Pharmaceutical Company
lovastatin	vastatin	Lostatin-10	696848	Dr Reddy's Laboratories Stangen Pharmaceutic, Hyderabad	22/09/2003	Trademark dept./ Pharmaceutical Company
lovastatin	vastatin	Lostatin-20	696849	Dr Reddy's Laboratories Stangen Pharmaceutic, Hyderabad	28/11/2003	Trademark dept./ Pharmaceutical Company
lovastatin	vastatin	Vastatin	1322835	Citadel Aurobindo Biotech, Chennai	13/01/2004	Trademark dept./ Pharmaceutical Company
ceftriaxone	cef-	Triaxone	581207	Wockhardt Ltd	21/06/2001	Trademark dept./ Pharmaceutical Company
ezetimibe	-imibe	Exemibe	1160444	Ajanta Pharma, Mumbai	09/03/2004	Trademark dept./ Pharmaceutical Company
clozapine	-apine	Cozapine	921781	Magnet Labs, New Delhi	21/04/2004	Trademark dept./ Pharmaceutical Company
adenosine phosphate	NA	Adenosin	983654	Swiss Pharma Pvt Ltd, Ahmedabad	21/04/2004	Trademark dept./ Pharmaceutical Company
irbesartan	-sartan	Irbetan	920515	Cadila Pharmaceuticals	21/04/2004	Trademark dept./ Pharmaceutical Company
retinol	-inol	Retinol	1078869B	Psycoremedies, Punjab	10/05/2005	Trademark dept./ Pharmaceutical Company
cefpirome	cef-	Sefpirome	1085248	Novartis AG, Basel, Switzerland	08/06/2005	Trademark dept./ Pharmaceutical Company
riluzole	-uzole	Riluzole	91289791	Rajvi Vipul Bhagat, Mumbai	23/06/2005	Trademark dept./ Pharmaceutical Company
tiotropium bromide	NA	Tiotrop	1230390	Sun Pharm. Inds. Ltd, Mumbai	23/06/2005	Trademark dept./ Pharmaceutical Company
valsartan	-sartan	Valsar	1287345	Micro Labs, Bangalore	17/08/2005	Trademark dept./ Pharmaceutical Company
amiodarone	-darone	Amiodar	852474	Micro Labs, Bangalore	31/08/2005	Trademark dept./ Pharmaceutical Company
ramipril	-pril	Ramiril	1055353	Micro Labs, Bangalore	11/10/2002	Trademark dept./ Pharmaceutical Company
diltiazem	-azem	Diltiaz-30	1278035	Plethico Pharmaceuticals, Mumbai	04/01/2006	Trademark dept./ Pharmaceutical Company

* WHO protection letter does not mention either INN or INN stem

ANNEXURE D

Report of the Workshop on Protection of International Non-proprietary in India 29th March 2006

Non-Proprietary Names in India

The Centre for Trade and Development (Centad) organised a workshop on March 29, 2006, with the objective of inviting various stakeholders to contribute inputs for a study carried out by Centad on the use of International Non-Proprietary Names (INNs) for pharmaceutical substances in India.

The event was attended by many experts such as officials from the World Health Organisation (WHO), the Drug Controller General of India (DCGI), trademark attorneys, representatives from pharmaceutical companies, public health activists, doctors, etc.

The presentation by Centad highlighted various aspects of the study, beginning with a definition of the term 'INN'. The study examined the legal regime on INNs, both at the national as well as international level. However, the emphasis was on the World Health Assembly (WHA) Resolution 46.19 (hereinafter resolution), which calls for discouraging the use of INNs, particularly INN stems in drug brand names. The presentation also covered implementation of the resolution in India through various legal instruments and policy. It clearly explained lacunae in implementation. The presentation ended with an enumeration of suggestions to reform the regime.

The law and policy on INNs

INNs are internationally acceptable generic names for pharmaceutical substances that are proposed or recommended by the WHO with the aim of avoiding confusion in drug nomenclature and ensuring safety in drug use for the public. INNs are comprised of a unique fancy term along with a common stem. Common stems are the part of the INN that establishes the relationship between substances that have the same element in drugs. The uniqueness of an INN lies in its non-proprietary nature; therefore, the use of INNs in brand names would result in the appropriation of that name by the drug manufacturing company through a trademark.

This practice, it was argued, would create confusion in drug nomenclature thereby diluting the purpose of INNs. It was also pointed out that using stems in brand names impedes the creation of new INNs using the stem, as it enables a trademark owner to challenge the new INN .

WHA Resolution 46.19 encourages the use of INNs along with corporate names, to implement the objectives of the resolution. At the same time, the resolution is non-binding in nature (soft law) and does not create any monitoring or reporting mechanism to ensure compliance. The practice of issuing INN protection letters to national authorities is the only existing compliance mechanism available under the WHO-INN programme. Participants raised some questions on the effectiveness and exact nature of this mechanism.

With regard to domestic law and policy on the subject, the study explicated two relevant legislations — the Drugs and Cosmetics Act and the Trade Marks Act 1999, as well as the National Pharmaceutical Policy. The relevance of Rule 96 of the Drugs and Cosmetic Act, and Section 13 of the Trade Marks Act in India , in relation to the use of generic names, was pointed out. While Rule 96 insists that the proper name of the drug (including the INN) be prominently printed on the label, the Trade Marks Act provides that the single name of a chemical element or compound shall not be registered as a trademark, and also that the words that the WHO has declared as an INN and is notified by the trademarks registrar shall not be registered as a trademark.

Despite the existence of substantive legal provisions prohibiting the registration of INNs as trademarks, the presentation pointed out that there are instances where trademark registration of names derived from INNs has occurred. Speakers highlighted instances of the WHO sending INN protection letters to the DCGI. They also said that their interaction with the DCGI had revealed that the DCGI normally sends a copy of the letter to the State Drugs Controller (SDC), the trademarks office, and pharmaceutical companies, to which the DCGI has received no response. It was also noted that instances of changing INN-based brand names have occurred in rare cases.

A list of instances where brand names have been derived from generic names, in India , was cited. It was felt that the frequency of using generic names in brand names depends on markets.

It was suggested that though the legal position on the use of generic names in India is clearly defined, there is fragmentation in the domestic regulatory regime. Instances of violation or misuse of the law in the Indian context were substantially enumerated.

Major gaps in implementation of law on INNs

- The non-binding nature of the WHA resolution, the absence of a compliance mechanism and lack of authoritative interpretation of the resolution.
- Lack of notification of the INN by the trademarks registrar, under Section 13 (b) of the 1999 Act.
- Lack of specific policy guidelines from the DCGI on the use of INNs in India .
- Lack of awareness about the public health implications among major stakeholders like industry, medical and legal professionals as well as trademark examiners in India .
- Lack of any requirement under the trademarks law to disclose the generic name of the pharmaceutical substance when applying for a trademark for the same.
- Lack of any notification of INNs by the trademarks registrar, as required under Section 13 (b) of the Trade Marks Act.

Suggestions

- There is the need for an international convention on the use of INNs.
- An effective mechanism for compliance with the requirements of Resolution 46.19 must be established.
- There is scope for better and informal coordination between the WHO and the trademarks office on the one hand, and between the Drug Controller General and the trademark office on the other.
- The DCGI should develop a system for national registration of all brand names under which drugs are marketed.
- The DCGI should develop policy guidelines on the use of INNs.
- Trademark applications for pharmaceutical substances should be accompanied by a disclosure of the generic name of the substance.
- INNs should be regularly notified, as required by Section 13 (b) of the Trade Marks Act.
- Trademark examiners should be sensitised to the public health aspects of INNs.
- The pharmaceutical industry, medical and legal professionals and other stakeholders should be sensitised to issues relating to the use of INNs.

Reviews of the study

Following the presentation of the study, a panel of experts presented their views on it. It was pointed out that from a consumer's point of view, the problem of proliferation of brand names and its impact on drug prices had not been examined in the report. The role of the WHO in giving generic names was also stressed as a point that needed more consideration in the report. Apprehensions were expressed regarding an instance where the INN is considered as an option and the innovator is given a chance to bypass the whole process of INN and get the brand name registered. It was also feared that in the present scenario, the WHO could not do anything if the manufacturer opts for a generic name that is unpronounceable or outrageous. The reviewers also dealt with consumer interest in the case of fixed-dose combination drugs, and said that the report had failed to look into the issue. It was pointed out that in the name of protecting the INN the basics of generic prescription should not be violated.

From a legal standpoint, the study's failure to address Section 9 of the Trade Marks Act was highlighted. There was a suggestion that the word 'exclusively' be removed from Section 9, which talks about absolute grounds for registration that requires a distinctive character. It was also suggested that Section 13 be incorporated into Section 9 through a parliamentary amendment, for the resolution of existing questions on this Act. The review concluded by expressing a desire to change the trademark registration system altogether, as the present Act provides ample opportunity for trademark attorneys to register any generic name, even a name like 'antiflu', which is highly descriptive.

From a regulatory perspective, the review discussed in detail the coining of brand names, their supposed utility and the increasing problem of using brand names. Creating awareness among consumers was suggested as one way of solving the problem of confusing brand names. As regards misbranding, the need to check the safety profile of drugs was emphasised. There was also the view that brand identities were getting lost nowadays.

The comments that followed the review session suggested the following:

- The need for an international treaty for uniformity, in spite of the intricacies that are involved in evolving an international convention.
- The report should include the implication of combination drugs and prescription practices by doctors.
- The legal consequences of the use of stems in brand names should be studied in greater detail.

Group discussions

The reviews were followed by informal group discussions. For this, the participants were divided into three groups.

Group I discussed the integrity of INNs and their importance in public health. It agreed on the following:

- To wholeheartedly support the use of INNs (generic names).
- The need to come up with rules regarding stem use, for the rational use of drugs.

Group II discussed the WHO resolution, its nature and suggestions. It agreed on:

- The need for a treaty in the long run that would help to consider country-specific problems.
- The need for informal coordination between the trademarks registry, the DCGI and the WHO.
- The need to take coherent steps to promote INNs and to stop pharmaceutical companies from sidestepping the emerging product patent regime.

Group III debated the law and policy of INNs in India , and arrived at the following conclusions:

- INNs are absolutely relevant to identify products and the diseases for which they are used/prescribed anywhere in the world.
- Stems can be used as part of a brand name because they will help identify the disease for which they are used or prescribed. Use of stems in brand names can be helpful for small companies.
- A centralised database may be maintained in the drug controller's office to verify whether a licence had already been granted under the same name to a third party.
- The trademarks registrar should periodically be provided with a list of INNs to prevent their registration thereof as brand names.

The discussion concluded that INNs are extremely relevant in India. Their use should be encouraged, although there is the possibility of deception or confusion. The DCGI has a role to play in this regard, apart from the trademarks office. The need of the hour is better coordination between the DCGI's office and the trademarks office.

Concluding remarks and observations

The concluding session of the workshop consolidated the views on INNs, with interesting observations on the use of INN stems from a panel including the DCGI, WHO officials and legal experts representing the major agencies involved in the debate on INNs.

The DCGI complemented the WHO and Centad for initiating a serious discussion on INNs on a wider platform whereby all parties concerned could be sensitised to the issue. Despite constraints in the regulatory environment, the drug controller's office is engaged in promoting the use of generic names and has instructed the trademarks office to prevent the use of INN stems in trademarks.

The DCGI pointed out that there were several constraints in the regulation of brand names in India . This problem is further complicated by the large number of pharmaceutical companies in the country. Brand names cannot be restricted legally. However, the use of a stem or a part of it while coining a brand name gives an indication of the generic name of the drug thereby indirectly promoting its generic use.

It was observed that the attribution of a stem to a brand increases the substitution value of the drug and reduces its brand value, indirectly deferring the benefit of using INN stems in the industry. Setting aside commercial interests, one of the major concerns about permitting the use of stems would be to facilitate consumer awareness through a common stem.

In view of the diverse views held by participants on the use of INNs, particularly the views of some civil society organisations that there could be benefits for consumers if the use of INN stems was allowed with some caveats for coining brand names, it was acknowledged, on behalf of the WHO, that this concern may be given appropriate consideration. The participants did not reach any definite conclusion on this point but agreed that there was a need to examine the issue further.

The open forum that followed came up with the proposition that immediate action from all the concerned authorities was necessary. It concluded the discussion with the following suggestions:

- At the international level, there is a need to devise an international convention on INNs.
- There is a need for the WHO to devise a mechanism to monitor the implementation of the resolution in relation to INNs.
- At the national level, better coordination and an organic relationship between the DCGI and the trademarks office is needed.

- The issue of brand approval has to be resolved through a new policy drawn up by a Central Drug Control Authority.
- The trademarks office should maintain a list of INNs and crosscheck with the list before granting trademarks.
- Specialised examiners should be placed at the trademarks registry to deal with pharmaceutical trademarks.
- Adequate representation from medical professionals in the debate on INNs is called for.
- A national policy guideline on the use of INNs is urgently needed.
- The trademarks office should regularly notify INNs in the prescribed manner.
- Applications for trademark registration with respect to pharmaceutical substances should disclose the generic name of the substance.

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