International Journal of Psychosocial Rehabilitation, Vol. 20, Issue 02, 2016
ISSN:1475-7192

Drug Menace in India: A status report of law and loopholes in the implementation

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Abstract

India is recognized as one of the leading global players in the manufacture of pharmaceuticals as it is fourth in terms of volume and thirteenth in terms of value of production. It is also recognized that the cost of drugs produced in India is amongst the lowest in the world. It is estimated that industry has the potential to achieve Rs 1,000,000 million in formulations with bulk drug production going up from Rs 80000 million to Rs 250,000 million by the year 2010. The pharmaceuticals sector has witnessed tremendous growth over the past few years – from a turnover of Rs 50000 million in 1990 to over Rs 500,000 million during 2004-2005. Exports also grew very significantly during this period to over Rs 167000 million.

Indian exports supply more than 200 countries around the globe including the highly regulated markets of US, Europe, Japan and Australia. The value of exports of drugs and pharmaceuticals increased to over Rs. 21,000 crore or US$ 4.7 billion in 2005-06 from around Rs. 78578 million in 2004-05, while their imports has been around 999.97 million US$ in the year 2005-06[2]. It is estimated that the industry has the potential to achieve over Rs. 1,000,000 million in formulations and bulk drug production by the year 2010.[3] This article delineates the concerned law and infra structure in place in this country and how the present system is unable to deal with the counterfeit drug menace properly.

Key Words : *Drugs, Pharmaceutical Companies, Laws, Right to Health, Counterfeit*

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[2] Data retrieved from website http://www.business-standard.com/india/news/pharma-ecports-to-cross-rs-21000-cr-in2005-06/227129/ on 22.2.2008.

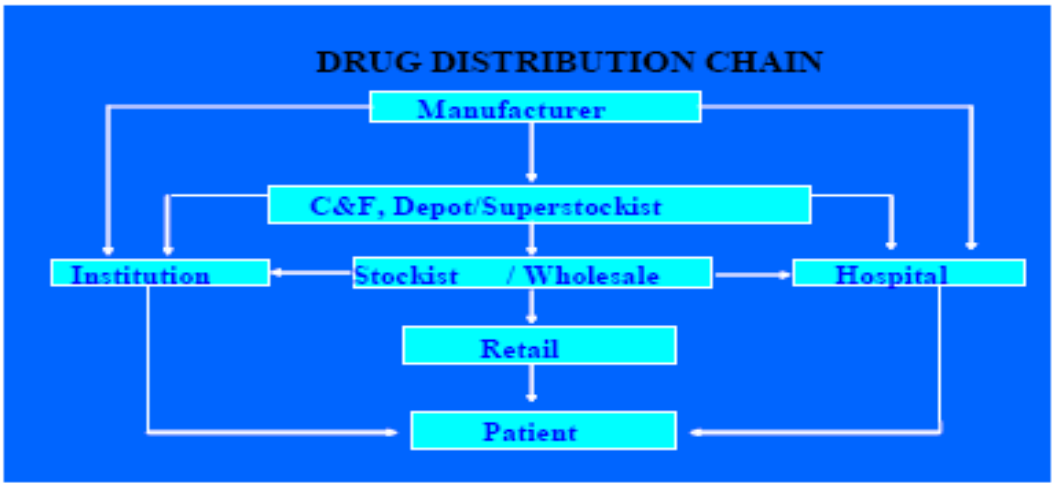
[3] http://business.gov.in/Industry_services/drugs.php (22.1.2008)

DOI: https://doi.org/10.53555/V20I2/400067

1.Introduction

In India the pharmaceutical industry includes manufacture of basic drugs, formulations, intravenous fluids and pharmaceutical aids such as hospital disposables, kits, capsules etc. Currently, the Indian pharmaceuticals market is serviced by over 25,000 manufacturing units, large and small pharmaceuticals. Over 15,000 units fall in the small-scale sector. Nearly 20% of manufacturing units, say 5,000, are involved in the manufacturing of bulk drugs. The average growth of the drug industry was of the order of 10% during the last decade, which was higher than the overall growth of the industry of the country in general. The overall turnover in the pharmaceutical industry during the year 2000 increased to the tune of Rs 200 Billion from Rs 3 billion in 1970[4].

(Legal) Distribution Chain:



a) Traditional System

Drugs transportation chain starts from the manufacturer to wholesale distributors. Generally each state will have one or more distributors who in turn distribute drugs to retailers who are called chemists and druggists. Wholesale dealers need not have any special qualification but chemists or druggists or shop keepers must at least possess the minimum qualification of Diploma in Pharmacy from a Pharmacy College recognized by the Pharmacy Council. The chain is depicted in the above diagram.[5]

[4] The data is collected from various sources such as news papers, Ministry of Health and Family welfare Department of the Central Government.

[5] *Mashelkar Report*, p. 70.

b) Sale of Drugs through the Internet:

The spread of the Internet has also contributed to its increasing use as a distribution channel for drugs. Drugs from a host of Indian companies, such as *Ranbaxy, Dr Reddy's, Cipla, Cadila, Lupin Laboratories* and several others, are available to consumers via the Internet.[6] They can be ordered online and are delivered to the customer's doorstep. Some other companies such as Cadila Pharmaceuticals are planning to start this mode of sale.

Strictly speaking sale of drugs by means of the internet is not allowed in India. Indian Drug Manufacturers are not permitted to sell drugs via the internet. The reason behind this is that a drug shall not be sold without prescription from a medical practitioner of course this rules is not applicable to OTC Drugs (Over the Counter Drugs).[7] 'OTC Drugs' in common parlance means drugs which are legally allowed to be sold Over the Counter without the prescription of a Registered Medical Practitioner. These preparations have no legal recognition and could be called as 'non-prescription drugs' and/or as 'household remedies' ".[8] But the problem is that there is no law regulating or prohibiting the sale of drugs through the internet and therefore it is not correct to say that the sale of drugs via the internet is illegal.

The Indian pharmaceutical industry is also worried about fake drugs sale through the internet. If web sites sell counterfeit drugs, they may harm the reputation of the Indian drug manufacturing companies. Another reason for concern is that it is extremely difficult for the drug manufacturing companies to keep track of websites selling drugs. The profits of the drug manufacturing companies would also be affected if a drug loses its credibility in the market because of its low therapeutic value.

2. Protection of intellectual property

Intellectual property rights relating to drugs are protected through three Acts, the Copy Right Act 1957 (a), the Trade and Merchandise Marks Act 1958, amended by

6 Subramanian, Nithya, 'Pharmacos in a spot as Web sites hawk drugs', Business Line, April 15th 2004, retrieved from the website : http://www.thehindubusinessline.com/2004/04/15/stories/2004041501390200.htm (10th.July 2008).

7 Interviewed Mr. R.Ranga Rao, Director, Drugs Control Admn. Drugs, Shri Momin, Commissioner, Food and Drugs, on 5.01.2009 at Hyderabad and Delhi. These over the counter (OTC) drugs (vitamin tablets etc are called as OTC Drugs) are generally sold in all medical shops without medical prescription.

8 (M.R. Shastri, Director (Retired), Drugs Control Administration, Gujarat *OTC Drugs some legal aspects*, Bulletin of the Society for Rational Therapy, July 1991; retrieved ffrom the website http://www.locostindia.com/CHAPTER_1/About_Drugs_3.htm, 3.01.2010.

The Trade Marks Act 1999 (b), and the Indian Patent Act 1970 (c). IPC does not contain any provision with regards this matter.

a) The Copyright Act, 1957

As mentioned earlier, whenever a drug is launched in the market, it is often accompanied by literature informing about the contents (salt), use, and manner of consumption, effects and side effects of the product. Most of the times, the fake drug manufacturers also copy this literature. The Copyright Act 1957 protects original literary, dramatic, musical and artistic works and cinematograph films and sound recordings from unauthorized use.[9] It provides for remedies, both civil and criminal, to drug manufacturers.

Drug manufacturers can protect literature published by them such as manuals, patient package inserts and brochures explaining the merits of the drug and the method of using the drug, any promotional materials used for the drugs including those on websites. As the Act protects dramatic and cinematographic works, CDs prepared by the drug manufacturer to promote the drug or to explain to the customer as to how to use the drug are also protected. Any diagrams printed on the brochures of the drug can be protected as artistic works, such as for example Cartoons published on the brochures for syrups used by children.

As far as civil remedies are concerned, the owner of the copyrighted material has such remedies as injunction, damages, accounts etc.[10] Moreover, if the author has any specific information about the presence of the infringing material in any premises, he can obtain an *Anton Pillar* order from the court and visit the premises and take the possession of the infringing material found the premises. The infringing material is considered to be the property of the owner of the copyrighted original material.[11]

Copyright infringement is also an offence under the Copyright Act 1957. Any person who knowingly infringes or abets the infringement of the copyright in any

[9] Sec. 13 Copyright Act.

[10] Sec. 55 Copyright Act – *Civil remedies for infringement of copyright*. – (1) Where copyright in any work has been infringed, the owner of the copyright shall, except as otherwise provided by this Act, be entitled to all such remedies by way of injunction, damages, accounts and otherwise as are or may be conferred by law for the infringement of a right.

[11] Sec. 58 Copyright Act – *Rights of owner against persons possessing or dealing with infringing copies.* – All infringing copies of any work in which copyright subsists, and all plates used or intended to be used for the production of such infringing copies, shall be deemed to be the property of the owner of the copyright, who accordingly may take proceedings for the recovery of possession thereof or in respect of the conversion thereof:
Provided that the owner of the copyright shall not be entitled to any remedy in respect of the conversion of any infringing copies, if the opponent proves
(a) that he was not aware and had no reasonable ground to believe that copyright subsisted in the work of which such copies are alleged to be infringing copies; or
(b) that he had reasonable grounds for believing that such copies or plates do not involve infringement of the copyright in any work.

work commits criminal offence under Sec. 63 of the Copyright Act.[12] The minimum punishment for infringement of copyright is imprisonment for six months with the minimum fine of fifty thousand rupees. In the case of a second and subsequent conviction the minimum punishment is imprisonment for one year and fine of one lakh rupees (0.1 million).[13]

Any police officer, of not below the rank of sub inspector, may, if he is satisfied that an offence in respect of the infringement of copyright in any work has been, is being, or is likely to be committed, seize without warrant[14], all copies of the work and all plates used for the purpose of making infringing copies of the work, wherever found. All copies and plates so seized have to be produced before a magistrate as soon as practicable. No court inferior to that of a Metropolitan Magistrate or a Judicial Magistrate of the first class shall may try any offence under the Copyright:[15]

[12] Sec. 63 Copyright Act – *Offence of infringement of copyright or other rights conferred by this Act.* Any person who knowingly infringes or abets the infringement of

(a) the copyright in a work, or

(b) any other right conferred by this Act, except the right conferred by section 53A

shall be punishable with imprisonment for a term which shall not be less than six months but which may extend to three years and with fine which shall not be less than fifty thousand rupees but which may extend to two lakh rupees: Provided that where the infringement has not been made for gain in the course of trade or business the court may, for adequate and special reasons to be mentioned in the judgement, impose a sentence of imprisonment for a term of less than six months or a fine of less than fifty thousand rupees.

Explanation (…).

[13] Sec. 63A Copyright Act. *Enhanced penalty on second and subsequent convictions.* – Whoever having already been convicted of an offence under section 63 is again convicted of any such offence shall be punishable for the second and for every subsequent offence, with imprisonment for a term which shall not be less than one year but which may extend to three years and with fine which shall not be less than one lakh rupees but which may extend to two lakh rupees :
Provided ……

[14] Sec. 64 Copyright Act: *Power of police to seize infringing copies:* – (1) Where a magistrate has taken cognizance of any offence under section 63 in respect of the infringement of copyright in any work, it shall be lawful for any police officer, not below the rank of sub-inspector, to seize without any warrant from the magistrate, all copies of the work wherever found, which appear to him to be infringing copies of the work and all copies so seized shall, as soon as practicable, be produced before the magistrate.

(2) Any person having an interest in any copies of a work seized under sub-section (1) may, within fifteen days of such seizure, make an application to the magistrate for such copies being restored to him and the magistrate, after hearing the applicant and the complainant and making such further inquiry as may be necessary, shall make such order on the application as he may deed fit.

[15] Sec. 70 Copyright Act: *Cognizance of offences:* – No court inferior to that of a presidency magistrate or a magistrate of the first class shall try any offence under this Act.

b) Trade and Merchandise Marks Act 1958, amended by The Trade Marks Act 1999

The Indian law of trademarks was enshrined in the Trade and Merchandise Marks Act, 1958. However, in order to bring the Indian law into compliance with the requirements of the TRIPS agreement a new law called Trade Mark Act, 1999 was developed.

According to the Trade Mark Act, a trademark is a mark used in relation to goods so as to indicate a connection in the course of trade between the goods and some person having the right as proprietor to use the mark. A 'mark` may consist of a word or invented word, signature, device, letter, numeral, brand, heading, label, name written in a particular style, the shape of goods other than those for which a mark is proposed to be used, or any combination thereof or a combination of colours and so forth.[16] Any mark which is capable of graphic representation and which is capable of distinguishing goods/services of one company from those of another can be registered as a trademark.[17]

As far as drugs are concerned, the name of the drug or the company of the drug can be trade marked, for example a tablet for cough and cold "Escold" manufactured by NATCO Pharmaceuticals could be trademarked under the same name. The signature of any person on the bottle cover is protected under this Act. For example the shape of the tablet, the shape of the container, or the shape of the bottle for example the bottle shape of Sandoz company's calcium tablets are protected under this Act.

For the purpose of registration, chosen marks may not be deceptively similar to an existing mark of another person[18] nor expressly prohibited under the Act. The marks devoid of any distinctive character, or which are only indicative of the kind, quality,

16 Sec. 2(m) Trade Marks Act: "mark" includes a device, brand, heading, label, ticket, name, signature, word, letter, numeral, shape of goods, packaging or combination of colours or any combination thereof.

17 Sec. 2(zb) Trade Marks Act: "trade mark" means a mark capable of being represented graphically and which is capable of distinguishing the goods or services of one person from those of others and may include shape of goods, their packaging and combination of colours (…).

18 Sec. 11 Trade Marks Act: Relative grounds for refusal of registration

(1) Save as provided in section l2, a trade mark shall not be registered if, because of

(a) its identity with an earlier trade mark and similarity of goods or services covered by the trade mark; or

(b) its similarity to an earlier trade mark and the identity or similarity of the goods or services covered by the trade mark, there exists a likelihood of confusion on the part of the public, which includes the likelihood of association with the earlier trade mark.

(2) A trade mark which

(a) is identical with or similar to an earlier trade mark; and

(b) is to be registered for goods or services which are not similar to those for which the earlier trade mark is registered in the name of a different proprietor, shall not be registered if or to the extent the earlier trade mark is a well-known trade mark in India and the use of the later mark without due course would take unfair advantage of or be detrimental to the distinctive character or repute of the earlier trade mark.

quantity, purpose, value or geographical origin of the goods, or which are marks already in vogue in the trade due to their customary use may not be registered.[19] But these disqualifications do not apply to marks, which have already acquired distinction due to their popularity and consistent use. The present term of registration of a trademark is ten years, which may be renewed on payment of prescribed renewal fees.[20]

Two types of remedies are available to the owner of a trademark for unauthorized use of his or her mark or its imitation by a third party. These remedies are:

- an action for infringement in case of a registered trademark; and
- an action for passing off in the case of an unregistered trademark.

While the former is a statutory remedy, the latter is a common law remedy. In an action involving infringement or passing off, a court may grant relief of injunction and/or monetary compensation for damages for loss of business and/or confiscation/destruction of infringing labels and tags etc.[21]

The Act also makes falsifying or falsely applying the trademarks an offence.[22] The act further provides that any person who sells, lets for hire or exposes for sale, or hires

19 Sec. 9 Trade Marks Act: *Absolute grounds for refusal of registration*
(1) The trade marks -
(a) which are devoid of any distinctive character, that is to say, not capable of distinguishing the goods or services of one person from those of another person;
(b) 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 rendering of the service or other characteristics of the goods or service;
(c) which consist exclusively of marks or indications which have become customary in the current language or in the bona fide and established practices of the trade, shall not be registered:
PROVIDED that a trade mark shall not be refused registration if before the date of application for registration it has acquired a distinctive character as a result of the use made of it or is a well-known trade mark.

20 Sec. 25 Trade Marks Act: *Duration, renewal, removal and restoration of registration*
(1) The registration of a trade mark, after the commencement of this Act, shall be for a period of ten years, but may be renewed from time to time in accordance with the provisions of this section.
(2) The Registrar shall, on application made by the registered proprietor of a trade mark in the prescribed manner and within the prescribed period and subject to payment of the prescribed fee, renew the registration of the trade mark for a period of ten years from the date of expiration of the original registration or of the last renewal of registration, as the case may be (which date is in this section referred to as the expiration of the last registration).

21 Sec. 29 Trade Marks Act: *Infringement of registered trade marks*
(1) A registered trade mark is infringed by a person who, not being a registered proprietor or a person using by way of permitted use, uses in the course of trade, a mark which is identical with, or deceptively similar to, the trade mark in relation to goods or services in respect of which the trade mark is registered and in such manner as to render the use of the mark likely to be taken as being used as a trade mark. (…)

22 Sec. 103 Trade Marks Act: *Penalty for applying false trade marks, trade descriptions, etc.* Any person who
(a) falsifies any trade mark; or
(b) falsely applies to goods or services any trade mark; or

or has in his possession for sale, goods or things, or provides or hires services, to which any false trade mark or false trade description is applied be punishable with imprisonment for a term no less than six months, which may extend to three years and with fine which no less than 50,000 Rupees or (1000 $), which may be extended to 2 lakhs rupees or (4000$).[23] Hence this section can be of special importance to those drug manufacturers fighting a war against spurious drugs.

c) The Indian Patent Act, 1970

A patent can be defined as a grant of exclusive rights to an inventor over his invention for a limited period of time. The exclusive rights conferred include the right to make, use, exercise, sell or distribute the invention in India.

The Indian Patent Act, 1970 came into force on 20th April 1972 along with Patent Rules 1972. The Indian parliament has ratified drastic changes to the Patents Act, 1970. The changes are in line with the commitments made by India before the WTO. India is committed to harmonize its intellectual property laws with the members of WTO. The WTO agreement enables a signatory to take advantage of a transition

(c) makes, disposes of, or has in his possession, any die, block, machine, plate or other instrument for the purpose of falsifying or of being used for falsifying, a trade mark; or
(d) applies any false trade description to goods or services; or
(e) applies to any goods to which an indication of the country or place in which they were made or produced or the name and address of the manufacturer or person for whom the goods are manufactured is required to be applied under section 139, a false indication of such country, place, name or address; or
(f) tampers with, alters or effaces an indication of origin which has been applied to any goods to which it is required to be applied under section 139; or
(g) causes any of things above-mentioned in this section to be done, shall, unless he proves that he acted, without intent to defraud, be punishable with imprisonment for a term which shall not be less than six months but which may extend to three years and with fine which shall not be less than fifty thousand rupees but which may extend to two lakh rupees:
PROVIDED that the court may, for adequate and special reasons to be mentioned in the judgement, impose a sentence of imprisonment for a term of less than six months or a fine of less than fifty thousand rupees.

23 104. Penalty for selling goods or providing services to which false trade mark or false trade description is applied Any person who sells, lets for hire or exposes for sale, or hires or has in his possession for sale, goods or things, or provides or hires services, to which any false trade mark or false trade description is applied or which, being required under section 139 to have applied to them an indication of the country or place in which they were made or produced or the name and address of the manufacturer, or person for whom the goods are manufactured or services provided, as the case may be, are without the indications so required, shall, unless he proves,-
(a) that, having taken all reasonable precautions against committing an offence against this section, he had at the time of commission of the alleged offence no reason to suspect the genuineness of the trade mark or trade description or that any offence had been committed in respect of the goods or services; or
(b) that, on demand by or on behalf of the prosecutor, he gave all the information in his power with respect to the person from whom he obtained such goods or things or services; or
(c) that otherwise he had acted innocently, be punishable with imprisonment for a term which shall not be less than six months but which may extend to three years and with fine which shall not be less than fifty thousand rupees but which may extend to two lakh rupees:
PROVIDED that the court may, for adequate and special reasons to be mentioned in the judgement, impose a sentence of imprisonment for a term of less than six months or a fine of less than 1060$.

period of ten years to implement its commitments. India made use of the full transition period of ten years up to 2005 in order to formulate and amend its patent laws.[24]

As a condition of the GATT negotiations which paved the way for entry into the WTO, India was put under the contractual obligation to amend its Patents Act in compliance with the provisions of TRIPS. India had to meet the first set of requirements by 01. 01.1995. The amendment came into force on 26th March 1999 retrospective from 1st January, 1995. It lays down the provisions for filing of application for product patent in the field of drugs or medicines with effect from 1st January, 1995 and grant of exclusive marketing rights on those products.[25]

India amended its Patents Act again in 2002 to meet with the second set of obligations (term of patent etc.), which had to be effected from 1st January, 2000. This amendment, which provides for a 20 years term for the patent, reversal of burden of proof etc. came into force on 20th May, 2003. The third amendment of the Patents Act 1970, by way of the Patents (Amendment) Ordinance 2004 came into force on 1st January, 2005, incorporating the provisions for granting product patents in all fields of technology including chemicals, food, drugs & agrochemicals. The Ordinance has been replaced by the Patents (Amendment) Act 2005 which is now in force since 1st January, 2005.[26]

The Patent Act acts against the generic drugs and not against the fake drugs. A generic drug may violate someone's patent but may not be a fake drug at all. It may be become fake if it uses the trademark of the original proprietor of the patent. But in most of the cases companies producing the generics use their own trademark. A fake drug may not violate the patent right of any one as it may not be the same product but just a fake. Hence patent law may not help much in counterfeit drugs.

The patent holder has the right to make, use, exercise, sell or distribute the invention in India.[27] The civil remedies under the Act are *Injunctions* which act as a preventive relief to the patentees. The patent owner at the start of a trial can request for an interim injunction in order to restrain the infringer from continuing the

24 *Elizabeth Verkey*, "Pharmaceuticals and Patents", Drugs & Cosmetics Act, 1940, p. A-39.

25 Ibid.

26 S. 23, 92A of The Patents (Amendment) Act, 2005, No.15 of 2005.

27 Sec. 48 Patents Act: *Rights of patentees* (1) Subject to the other provisions contained in this Act, a patent granted before the commencement of this Act, shall confer on the patentee the exclusive right by himself, his agents or licensees to make, use, exercise, sell or distribute the invention in India.

(2) Subject to the other provisions contained in this Act and the conditions specified in section 47, a patent granted after the commencement of this Act shall confer upon the patentee -

where the patent is for an article or substance, the exclusive right by himself, his agents or licensees to make, use, exercise, sell or distribute such article or substance in India;

where a patent is for a method or process of manufacturing an article or substance, the exclusive right by himself, his agents or licensees to use or exercise the method or process in India.

infringement in order to prevent further losses. Permanent injunction is given based on the merits of the case at the end of the trial. Along with the injunction a patent owner is also entitled to the *relief of damages* as compensation to the patentee yet not to punishment of infringer.[28]

Chapter XX of the Act deals with *penalties* to be imposed. For the violation of any of the rights of the patentee as described in Sec. 118 to 124[29] imprisonment and also fine is imposed on the offender. . It is difficult to say whether this improvement is the result of the availability of quality drugs, but it can more appropriately attributed to the availability of drugs. Earlier i.e. before independence (before 1947) people were not aware of allopathic drugs and used to suffer from these chronic diseases.

3.Damages to property/assets

It is difficult to asses the exact damage suffered by the manufacturers, because no empirical study was done in India. Following the *Mashelkar*-Report, the figures quoted in the media and by different sources about the extent of spurious drugs in the country varied anywhere from 0.5% to 35 %. Based on the samples tested by the state authorities, data were analysed for the period 1995-2003. According to this data, the extent of substandard drugs varied from 8.19 to 10.64% and that of spurious drugs varied between 0.24 % and 0.47%.[30] Representatives of the Confederation of Indian Industry (CII) estimated the loss of revenue to the Indian industry at over Rs. 40000 million *per annum*, but were unable to substantiate this estimate, despite being requested to supply this information by the *Mashelkar* Committee.[31]

4. Damages to health and health risks to consumers

The following are the few incidents which show the gravity of the menace of counterfeit drugs. Actually very few cases are registered and many go unreported.

- In February 2002, fake drugs worth Rs 10 million were seized from Jagatpuri in East Delhi. The drugs included 10,000 vials of Netromycin, a very expensive antibiotic used for life saving purposes.[32]

28 Sec. 108 Patents Act *Reliefs in suits for infringement:* The reliefs which a court may grant in any suit for infringement include an injunction (subject to such terms, if any, as the court thinks fit) and, at the option of the plaintiff, either damages or an account of profits.

29 Sec. 118 - Contravention of secrecy provisions relating to certain inventions; Sec. 119 - Falsification of entries in register, etc.; Sec. 120 - Unauthorised claim of patent rights; Sec. 121 - Wrongful use of words "patent office"; Sec. 122 - Refusal or failure to supply information; Sec. 123 - Practice by non-registered patent agents; Section 124 - Offences by companies.

30 *Mashelkar*-Report, No. 8.4.1 and 8.4.2 (p. 75).

31 *Mashelkar*-Report, No. 8.4.3 and 8.4.4 (p. 75).

32 *World Health Organisation*, Essential drugs and medicines policy; retrieved from the website: www.who.int/medicines/organization/qsm/activities/qualityassurance/counterfeit/counterfeit_info

– In July 2001 drug inspectors and members of the Delhi Medical Association (DMA) collected 53 samples from different locations in and around Bhagirath Place. It is a wholesale market notorious for its second hand drugs and scrap market in Delhi. Most of these samples belonged to well-known companies such as Pfizer, Novartis, Lupin, Dabur, and Glaxo. At least nine samples had no medical ingredient and four had only negligible amounts[33]. The accused were arrested while the drugs were stored in the shop before sale.
– Cough expectorant manufactured by a company in Gurgaon was found to be contaminated with diethylene glycol; 36 children aged from two months to six years who were admitted to two hospitals in Delhi between 1 April and 9 June 1998 developed high fever and kidney failure and 33 children died in three days.[34]

Occasionally certain cases involving damages to health, which occurred in conjunction with the use of a drug, are reported indicating the presence of a spurious drug. Some of the instances are given as follows:

- A lady had a long history of epilepsy. She was under medical treatment and free of seizures for four years. She then suffered one after taking medicine from a new source.[35]
- A lady was admitted to a private hospital in Chennai for a minor surgical procedure. The surgery went off well until an injection of Ceftazidine, to prevent infection was given, when the patient suddenly developed complications. On testing the seized vials, no active ingredient was found therein.[36]
- the US Food and Drug Administration has blacklisted about 30 generic drugs of Ranbaxy Pharmaceuticals Ltd, being manufactured by the company at its Dewas and Paonta Sahib plants in India on September 17th , 2008.
- Medicines manufactured in China and Nigeria are marketed in India (August 10th, 2009)[37]

-facts.html; (22.05.2008); *N.N.*, Enough to make you sick, in: health & environment newsletter july-aug & sept-oct 2002, pp. 8-13, 9; retrieved from the website http://www.cseindia.org/html/healthnews/2002sept_oct/death.pdf (1.12.2009).

33 *Srivastava, R.D.*, Fake drugs thrive in city marts, Hindustan Times (New Delhi), 20 February 2002, p. 4; retrieved from the website: www.expresshealthcaremgmt.com/20021115/insignia2.htm (20.02.2008) .

34 *Srivastava*, ibid. (Fn. 33); *N.N.*, Enough to make you sick, in: health & environment newsletter july-aug & sept-oct 2002, 8-13, 9; *Singh, Jagvir*, et al.: Diethylene glycol poisoning in Gurgaon, India 1998, Bulletin of the World Health Organisation 79 (2001), pp. 88-95.

35 *Prasad, R.*: Spurious drugs – consumer's health at stake, The Hindu, July 31, 2003; retrieved from the website www.hinduonnet.com/thehindu/seta/2003/07/31 (17.06.2008).

36 India Today, Sept 30, 2000, retrieved from the website http:///www.indiatoday.com/webexclusive/dispatch/20000930/sayantan.html (16.07.2008).

37 http://www.zeenews.com/news554326.html retrieved on 4.01.2010

Mashelkar-Committee mentioned in their report that revenue losses to the Indian Drug Industry may be around 40 billions.[38] Actual data as to loss in terms of taxes such as income tax, customs etc is not available. It seems the Indian government has not made efforts in this direction since the committee report was published.

5. Organization of police and prosecution authorities and spurious drugs

Prosecution can be instituted in three ways according to DCA, i.e., the Drug Inspector, the person aggrieved or any consumer association irrespective of the fact that whether the person aggrieved is the member of the association or not.[39]Ordinary police does not have the power to arrest the offender according to DCA except under the offences recognized by the Indian Penal Code. The police is a state subject i.e., controlled by the state. The powers of the police while conducting the investigation (Sec. 154-174 CrPC) is laid down in the Code of Criminal Procedure, 1973. Under the DCA, the drug inspector can also be appointed by the centre and state. He only has the power to arrest the accused and initiate the proceeding.[40] Drug inspectors who are appointed according to Sec. 3(e) DCA[41] can conduct the investigation and seize the drug.[42] They are given special training in the field of drugs.

38 *Mashelkar*-Report, p. 76. The data was collected on 7th July, 2003 by the comittee members. Thereafter some newspapers such as the *Financial Express* gave various figures which are approximate estimates of various drug companies and not based on any scientific study.

39 Sec 32. *Cognizance of offence.* —(1) No prosecution under this Chapter shall be instituted except by an Inspector or by the person aggrieved or by a recognised consumer association whether such person is a member of that association or not.
(2) No court inferior to that of a Metropolitan Magistrate or of a Judicial Magistrate of the first class shall try an offence punishable under this Chapter.
(3) Nothing contained in this Chapter shall be deemed to prevent any person from being prosecuted under any other law for any act or omission which constitutes an offence against this Chapter.

40 Drug inspectors have the power to seize the drug but some state governments also have given them the power of Arrest, for example the state of Andhra Pradesh.

41 Sec. 3 (e) DCA: "Inspector" means—
in relation to Ayurvedic, Siddha or Unani drug, an Inspector appointed by the Central Government or a State government under section 33G; and
in relation to any other drug or cosmetic, an Inspector appointed by the Central Government or a State Government under section 21;

42 S. **22. Powers of Inspectors**.—*(1)* Subject to the provisions of section 23 and of any rules made by the Central Government in this behalf, an Inspector may, within the local limits of the area for which he is appointed,—

4[*(a)* inspect,—

(*i*) any premises wherein any drug or cosmetic is being manufactured and the means employed for standardising and testing the drug or cosmetic;

(*ii*) any premises wherein any drug or cosmetic is being sold, or stocked or exhibited or offered for sale, or distributed;

(b) take samples of any drug or cosmetic,—

(*i*) which is being manufactured or being sold or is stocked or exhibited or offered for sale, or is being distributed;

The state takes the responsibility to prosecute offenders on behalf of victims. It represents the people in their collective responsibility and participates in a criminal trial as party against the person accused of crime. Infact the victim doesn't have any role to play in the criminal trial. There is no special prosecution system to prosecute the offences relating to drug counterfeiting. General prosecutors who deal with general offences also deal with the offences relating to drug counterfeiting. However the problem is they do not have the required technical expertise to deal with the cases regarding drugs Act. The hierarchy of prosecution is as follows:

The Public Prosecutor (P.P.) or the Assistant Public Prosecutor (A.P.P.) is the counsel for the state in such trials. His duties mainly consist of conducting prosecutions on behalf of the state. The Public Prosecutor also appears as state counsel in criminal appeals, revisions and such other matters in the Sessions Courts and the High Courts. The Prosecutor has authority to appear and plead before any court in any case entrusted to him. He can give advice to the police or other government departments with regard to the prosecution of any person if his advice is so sought. He cannot however, appear on behalf of the accused. The entire system of prosecutors in a state work under the supervision of DPP, Directorate of Public prosecution.[43] Prosecutors are appointed by both central and state governments. After completing the investigation the drug inspector submits the final report (chargesheet) to the court. Then the court would allot the case to a prosecutor for prosecution.

(*ii*) from any person who is in the course of conveying, delivering or preparing to deliver such drug or cosmetic to a purchaser or a consignee;

(*c*) at all reasonable times, with such assistance, if any, as he considers necessary,--

(*i*) search any person, who, he has reason to believe, has secreted about his person, any drug or cosmetic in respect of which an offence under this Chapter has been, or is being, committed; or

(*ii*) enter and search any place in which he has reason to believe that an offence under this Chapter has been, or is being, committed; or

(*iii*) stop and search any vehicle, vessel or other conveyance which, he has reason to believe, is being used for carrying any drug or cosmetic in respect of which an offence under this Chapter has been, or is being, committed,

and order in writing the person in possession of the drug or cosmetic in respect of which the offence has been, or is being, committed, not to dispose of any stock of such drug or cosmetic for a specified period not exceeding twenty days, or, unless the alleged offence is such that the defect may be removed by the possessor of the drug or cosmetic, seize the stock of such drug or cosmetic and any substance or article by means of which the offence has been, or is being, committed or which may be employed for the commission of such offence;]

(*cc*) examine any record, register, document or any other material object found 4[with any person, or in any place, vehicle, vessel or other conveyance referred to in clause (*c*)], and seize the same if he has reason to believe that it may furnish evidence of the commission of an offence punishable under this Act or the rules made thereunder;]

(*cca*) require any person to produce any record, register, or other document relating to the manufacture for sale or for distribution, stocking, exhibition for sale, offer for sale or distribution of any drug or cosmetic in respect of which he has reason to believe that an offence under this Chapter has been, or is being, committed;]

(d) exercise such other powers as may be necessary for carrying out the purposes of this Chapter or any rules made thereunder.

43 According to the New Amendment made in the year 2005.

6. Prosecution practices and problems:

6.1. Measures taken to detect counterfeits

a) Police

Drug inspectors have the power to investigate any complaint on counterfeit drug.

The drug inspectors play a particularly important role in the detection of counterfeits. As envisaged in Sec. 22 DCA, drug inspectors have the following powers:

- to inspect the premises where any spurious or adulterated or misbranded drug is being manufactured or sold or exhibited, offered for sale or distributed;
- to take samples of any such drug from any person who is delivering or preparing to deliver to a purchaser;
- to search any person bodily if there is reason to believe that the accused has any drug on his person with an intention to commit an offence which is recognized by the Act;
- to search the premises if there is reason to believe that any offence recognized by the act is committed;
- to stop the vehicle or vessel or any other conveyance if there is reason to believe that the particular vehicle is used to commit any offence recognized by the Act;
- to order the person in possession of the spurious drug to not to dispose of the stock for a period of not exceeding 20 days;
- to seize the instruments which were used to prepare counterfeit drugs and also the stock if the defect in the drugs is not removable;
- to examine the document if it contains the material evidence to prosecute the offender;
- to summon any person to produce any record or document or register relating to the manufacture, sale or distribution of counterfeit drugs;
- to break open the house if the offender is not cooperating and not allowing the inspector to search the premises.[44]
- Persons who are in charge of the premises are under a duty to inform the Drug Inspector about the place of manufacture or sale of drugs.[45]
- As per the provisions of the statute DCA, drugs inspectors cooperate with the government analysts appointed by the state or the central government (Sec. 20 DCA) for testing token samples of drugs. After testing the drug the government analyst has to prepare a report in triplicate and submit it to the drug inspector. The document given by the government analyst is of great importance because it acts as conclusive evidence as far as the facts

44 Sec. 22 (2) DCA along with Sec. 100 Cr.P.C. (Persons in charge of closed place to allow search).

45 Sec. 24 DCA.

of the case are concerned. If the person from whom the drug was seized disputes the authenticity of the report of the government analyst the Court sends the sample to the Central Drugs Laboratory and will get it tested. The result obtained thereof is conclusive evidence.

b) Initiatives by the government to protect the consumer

The department of Consumer Affairs prepared a bill to create "National Consumer Protection Authority" at the national level which was supposed to hear all the cases of aggrieved consumers. But the bill is yet to get the approval of the Indian parliament. If the Act is enacted by the parliament, unregistered advertisers such as those offering health supplements and spurious drugs will come under the scrutiny of the law.[46]

c) Private Initiatives

French drugmaker *Sanofi-Aventis*, along with two other multinational pharmaceutical companies, is planning to team up with the *World Customs Organisation* (WCO) and regulatory authorities of India and four other Asian countries to weed out spurious and counterfeit drugs originating from the region. The initiative will include special training for customs and drug regulatory officials to identify spurious drugs, their origin, distribution chain and follow-up action to raid premises and book culprits, in coordination with regulatory and police officials of various countries. The joint exercises will also involve agencies such as the *International Criminal Police Organization* (ICPO), popularly known as *Interpol*[47].

6.2 Measures taken to investigate criminal offences and criminal offenders: national prosecution

Drug inspectors take a sample of the suspected counterfeit drug (Sec 22 DCA) and send it to the government laboratory. If the seized drug is found to be spurious, on the basis of the report given by the laboratory, the central drug control authority will cancel the license granted and the case is then sent to the court. The DCA does not create special courts to try these offences. Ordinary criminal courts only deal with these cases on the condition that judges below the rank of metropolitan magistrate and judicial magistrate of first class should not deal with the case (Sec 32 DCA). These judges constitute the second rung in the hierarchy of judges. The trial is conducted according to the procedure envisaged in Code of Criminal Procedure, 1973 which is the general criminal procedural law of India. Judges depend on the report given by the laboratories in deciding the case. The cases are allotted to the criminal prosecutors by the court who are permanently recruited.

46 http://www.business-standard.com/india/news/ministry-moves-cabinet-note-to-setncpa/347216/ (20.01.2010)

47 http://www.searpharmforum.org/LinkFiles/SEARPharm_Forum_Home_Page_CFM-incidents-2009.pdf (15.3.2008)

6.3 . Private investigations (esp. by the manufacturers of the original products), cooperation with prosecuting agencies

The *Organisation of Pharmaceutical Producers of India (OPPI)* along with the IFPMA and the *Pharmaceutical Security Institute* (Geneva, Switzerland) had plans to set up an intelligence network to counter the counterfeit drugs trade but so far nothing happened. *Glaxo* is going in for holograms, special ink, printed/locked capsules, biocodes and embossing of tablets with a logo. Many drug manufacturers are also seeking the help of private detective agencies or using marketing staff to monitor the trade. Major Indian pharmaceutical companies such as Alembic, Cipla, Dr Reddy's Labs, Lupin, Nicholas Piramal, Ranbaxy, Sun Pharmaceutical and Wockhardt have joined hands to form the *Indian Pharmaceutical Alliance (IPA)* to look into the counterfeit trade[48].

6.4 Civil law proceedings by pharmaceutical companies against counterfeiters/ distributors of counterfeit products

The law dealing with the drug regulation in India is only criminal in nature. There is no provision to file a civil suit in counterfeit drug related cases.

6.5 Contribution to international cooperation

India is a signatory to Rome Declaration (2006) on *'Combating Counterfeit Drugs: Building Effective International Collaboration*',[49] which pledges to fight against the menace of counterfeit drugs. India is trying to comply with the standards set by WHO in the matters of quality standards for drugs.

6.6. Self-protection by affected companies and consumers – Measures taken to educate the consumer

Affected consumers or manufacturers can resort to following remedies available under the Consumer Protection Act and the Drugs and Cosmetics Rules:

There is legislation in India enacted with the sole objective of helping the aggrieved consumers called as *Consumer Protection Act*, 1986. According to it the consumer can file a petition in the district consumer forum and can claim damages from the manufacturer in case he suffers any injury to his body, mind, property or reputation.

Moreover, any person or any recognized consumer association, whether such person is a member of that association or not, is, on application in the prescribed

48 *Asthana, S.,* Eight drug firms come together, float association, in: The Financial Express, 11-26-1999.

49 www.who.int/entity/medicines/services/counterfeit/RomeDeclaration.pdf (2.12.2009).

manner and on payment of the prescribed fee, entitled to submit any drug or cosmetic purchased by him or it for test or analysis to a government analysts and to receive a report of such test or analysis signed by the government analyst.[50] The procedure laid down in the consumer protection Act is easier than procedure mentioned in DCA. However, so far not many cases of counterfeit drug complaints have been registered under this Act. It seems consumers have not yet taken the advantage of this law.

7. Prosecution measures and instruments

7.1. Traditional criminal procedural law, permissibility and application of special investigatory measures

Traditionally the investigation is conducted by the general police according to the Code of Criminal Procedure, 1973 (CrPC). The provisions from Sec. 154 to Sec. 176 of CrPC deal with the procedure for investigation, which includes drawing of First Information Report, going to the place of occurrence, collecting the evidence (material and documentary), taking the statements from the witnesses if there are any, then interrogating the witness and the accused in the police station and then submitting the final report to the Judicial Magistrate who has the jurisdiction to take cognizance of the offence.

The object of a criminal trial is to find out the truth and to determine the guilt or innocence of the accused. The duty of the public prosecutor as the counsel for the state in such a trial is not merely to secure conviction at all costs but to place before the court whatever evidence is possessed by the prosecutor, whether it be in favour of or against the accused, and to leave the court to decide upon all such evidence – whether the accused was or was not guilty of the offence alleged.[51] A prosecutor should be personally indifferent to the result of the case. The Prosecutor has the authority to appear and plead before any court in any case entrusted to him. He can give advice to the police or other government departments with regard to the prosecution of any person if his advice is so sought. There is no special prosecution system to prosecute the offences relating to Drug Counterfeiting. All prosecutors work under the supervision of the DPP, Directorate of Public prosecution.[52]

India follows the adversarial method of criminal justice system where judge is passive and does not take active part in the trial. As far as the offences against IPC and/or DCA [committed by the offenders under DCA] are concerned, the trials are conducted in general courts and no special courts are constituted. In pursuing the recommendation of *Mashelkar*-committee to establish special courts under the Drugs

50 Sec. 26 DCA as amended by Act 21 of 1962, Act 68 of 1982 and Act 71 of 1986.

51 this opinion is given by the Supreme Court in many cases, some of them are **Shakila Abdul Gafar Khan vs. Vasant Raghunath Dhobale**, (2003) 7 SCC 749 **Hitendra Vishnu Thakur v. State of Maharashtra** (1994) 4 SCC 602.

52 According to the New Amendment made in the year 2005 the Directorate of Public Prosecution is established in all states, however it is left to the discretion of the states and not a mandatory provision. But as of now all most all states have this system in place.

and Cosmetics Act,[53] *The Drugs and Cosmetics (Amendment) Act, 2008/9* allows designation of one or more Court of Session as Special Court for trial of offences related to adulterated or spurious drugs.[54]

Pursuing another recommendation of *Mashelkar*-Committee,[55] The Drugs and Cosmetics (Amendment) Act 2008/9 includes the provision to make offences relating to adulterated or spurious drugs as cognizable.[56] Furthermore, the *Mashelkar*-Committee recommended making the offences non-bailable,[57] but in The Drugs and Cosmetics (Amendment) Act 2008/9 the legislator was satisfied with tightening the preconditions under which bail may be granted.**[58]**

While *Mashelkar*-report recommended, in addition to the Drugs Inspector, authorizing the police also to file prosecutions related to offences against the Drugs and Cosmetics Act,[59] under The Drugs and Cosmetics (Amendment) Act 2008/9 powers were conferred upon the police officers not below the rank of sub-inspector of police and other officers of the central government or state government authorised by it to institute the prosecution under the Drugs and Cosmetics Act.[60]

The DCA has special police who are called drug inspectors. They are given special powers and procedures.[61]

Section 21 DCA contemplate the appointment of drug inspectors by the central and state government, respectively, to execute the purposes of the Act. Inspectors have various powers including that of inspection, taking samples of any drug and cosmetic, examination of any records, registers or documents et al, and search and seizure[62].

According to S. 32 DCA, prosecution can be instituted by three persons, i.e., the Drug Inspector, the person aggrieved or any recognised consumer association

53 *Mashelkar*-Report, recommendation 4.9.d) and 10.8 (p. 19 and p. 87).

54 See Sec. 36 AB The Drugs and Cosmetics (Amendment) Act, 2008/9.

55 *Mashelkar*-Report, Recommendation 4.9.b and 10.3.1 (p. 19 and p. 86).

56 See Sec. 36AC (1) (a) The Drugs and Cosmetics (Amendment) Act 2008/9. – As in Sec. 2(c) CrPC defined, "cognizable offence" means an offence for which a police officer may, in accordance with the First Schedule or under any other law for the time being in force, arrest without warrant.

57 *Mashelkar*-Report, Recommendation 4.9.b and 10.3.1 (p. 19 and p. 86). According to Sec. 2(a) CrPC means "bailable offence" an offence which is shown as bailable in the First Schedule, or which is made bailable by any other law for the time being in force; and "non bailable offence" means any other offence. – An arrested person who is accused of a bailable offence is entitled to be released on bail as a matter of right (Sec. 436 CrPC), while to a person accused of a non-bailable offence bail can be granted at the discretion of the court (Sec. 437 CrPC).

58 See Sec. 36AC (1)(b) The Drugs and Cosmetics (Amendment) Act, 2008/9.

59 *Mashelkar*-Report, Recommendation 10.10., p. 87.

60 See Amendment of. Sec. 32 by The Drugs and Cosmetics (Amendment) Act, 2008/9.

61 Sec. 22 DCA.

62 Drug Inspectors cooperate with the general police in nabbing the accused and sharing the information about the hide outs of the accused.

irrespective of the fact that whether the person aggrieved is a member of that association or not. Ordinarily police can initiate the prosecution of crimes contained in the IPC Sec. 274-276, 284. Any offence relating to counterfeit drugs is only prosecuted under DCA. Provisions of IPC are also added by way of abundant caution while framing charges. But the prosecution would prefer DCA because of the stringent punishment prescribed.

The special investigative measures used by the drug inspectors are not known to any one. The Act specifically does not recognise any special investigative mechanism such as under cover agents or telephone tapping.

7.2. Precautionary measures for customs / seizure at borders

The Drugs and Cosmetics Act helps to seize the articles on borders and search the containers, vessels etc. Sec. 10, Sec. 10A and Sec. 11[63] of the Drugs and Cosmetics Act have to be referred to for this purpose. The central government, by notification of official gazette, will prohibit the import of certain drugs, which are of inferior quality or spurious or adulterated[64]. The government can prohibit the import of any drug if it is satisfied that the drug is injurious to the health of human beings or animals.[65]

63 Sec. 11 DCA *Application of law relating to sea customs and powers of Customs Officers.* (1) The law for the time being in force relating to sea customs and to goods, the import of which is prohibited by section 18 of the Sea Customs Act, 1878 (8 of 1878) shall, subject to the provisions of section 13 of this Act, apply in respect of drugs and cosmetics the import of which is prohibited under this Chapter, and officers of Customs and officers empowered under that Act to perform the duties imposed thereby on a Customs Collector and other officers of Customs, shall have the same powers in respect of such drugs and cosmetics as they have for the time being in respect of such goods as aforesaid.

(2) Without prejudice to the provisions of sub-sections *(1)*, the Customs Collector or any other officer of the Government authorized by the Central Government in this behalf, may detain any imported package which he suspects to contain any drug or cosmetic the import of which is prohibited under this Chapter and shall forthwith report such detention to the Drugs Controller, India, and, if necessary, forward the package or sample of any suspected drug or cosmetic found therein to the Central Drugs Laboratory.

64 Sec. 10 DCA *Prohibition of import of certain drugs or cosmetics.* … no person shall import —

(a) any drug or cosmetic which is not of standard quality;

(*b*) any misbranded drug or misbranded or spurious cosmetic;

(*bb*) any adulterated or spurious drug;

(*c*) any drug or cosmetic for the import of which a licence is prescribed, otherwise than under, and in accordance with, such licence;

(*d*) any patent or proprietary medicine, unless there is displayed in the prescribed manner on the label or container thereof the true formula or list of active ingredients contained in it, together with the quantities thereof;

(*e*) any drug which by means of any statement, design or device accompanying it or by any other means, purports or claims to cure or mitigate any such disease or ailment, or to have any such other effect, as may be prescribed;

(*ee*) any cosmetic containing any ingredient which may render it unsafe or harmful for use under the directions indicated or recommended;

(*f*) any drug or cosmetic the import of which is prohibited by rule made under this Chapter:

Provided that nothing in this section shall apply to the import, subject to prescribed conditions, of small quantities of any drug for the purpose of examination, test or analysis or for personal use:

Sec 11 give powers to the customs officers to seize the drugs and also extends all the powers possessed by the drug inspectors according to the Act. Thereby not only government customs officers are empowered to appoint any government official to perform this duty.

Apart from the drug inspectors, customs officers according to Customs Act, 1962[66] have powers to stop the delivery of goods and seize the goods, arrest the person who is in possession of the counterfeit drugs in the airports and sea ports during export or import. The arrested person is put on the trial according to the provisions of DCA. At the end of the investigation the inspector form an opinion and mention the charges against the accused. The charge sheet is submitted to the court. Then the court looks into the prima-facie evidence available and frames charges.[67]

7.3. Other Health protection law

With a certain parallel to DCA, *The Prevention of Food Adulteration Act, 1954* plays an important role in punishing the people who affect the general health of the citizens by adulterated food. The Act consists of some provisions which are aimed at the protection of the health of the people. The object of the Act is to protect the public from poisonous and harmful foods, prevent the sale of substandard foods and to protect the interests of the consumers by eliminating fraudulent practices. Food inspectors appointed by the central government or by a state government can seize the food item if it is injurious to health and can send it to the laboratory.[68] If the accused is found guilty he may be given the penalty of imprisonment for a term which shall

Provided further that the Central Government may, after consultation with the Board, by notification in the Official Gazette, permit, subject to any conditions specified in the notification, the import of any drug or class of drugs not being of standard quality.

65 Sec. 10A DCA *Power of Central Government to prohibit import of drugs and cosmetics in public interest:* Without prejudice to any other provision contained in this Chapter, if the Central Government is satisfied that the use of any drug or cosmetic is likely to involve any risk to human beings or animals or that any drug does not have the therapeutic value claimed for it or contains ingredients and in such quantity for which there is no therapeutic justification and that in the public interest it is necessary or expedient so to do then, that Government may, by notification in the Official Gazette, prohibit the import of such drug or cosmetic.

66 Sec. 100 Customs Act *Power to search suspected persons entering or leaving India, etc*.: (1) If the proper officer has reason to believe that any person to whom this section applies has secreted about his person, any goods liable to confiscation or any documents relating thereto, he may search that person.

(2) This section applies to the following persons, namely : -

(a) any person who has landed from or is about to board, or is on board any vessel within the Indian customs waters;

(b) any person who has landed from or is about to board, or is on board a foreign-going aircraft;

(c) any person who has got out of, or is about to get into, or is in, a vehicle, which has arrived from, or is to proceed to any place outside India;

(d) any person not included in clauses (a), (b) or (c) who has entered or is about to leave India;

(e) any person in a customs area.

67 Charges are framed according to the provisions Sec. 211-223 of CrPC.

68 See Ss. 9 and 10 Prevention of Food Adulteration Act, 1954.

not be less than six months and up to 3 years and with fine up to thousand rupees ($ 20).[69]

7.4.Responsibility/involvement of private persons

In India there is no such graduated plan where private persons are involved in the framework.

Offences by companies are dealt with under Sec.34 of DCA, which makes a person liable for the commission of crimes relating to counterfeit drugs, if he was acting as a director, partner, officer, secretary or holding any responsibility to the company for the conduct of the business and has given consent or connived with the accused or was negligent shall be punished.[70] Indian pharmaceutical manufacturers are not liable for the acts committed by any third party posing threat to life, limb through fake drugs.

8. **Reform Proposals**

8.1. Drug Law

In India, drug policy was and is a prominent health policy issue. At the centre of interest is the question of how to supply the population with "essential drugs" at acceptable prices; inevitably connected to the question of the extent to which the state should regulate the market, e.g., by means of price control or even state ownership of companies. These related questions were tackled by two important committees that were appointed by the Government of India, the *Hathi Committee* and the *Mashelkar Committee*. Their suggestions culminated, in part, in concrete legislative projects at the national level.

69 Which article of the Prevention of Food Adulteration Act, 1954 contains this crime?

70 Sec. 34 DCA *Offences by companies:* (1) Where an offence under this Act has been committed by a company, every person who at the time the offence was committed, was in charge of, and was responsible to the company for the conduct of the business of the company, as well as the company shall be deemed to be guilty of the offence and shall be liable to be proceeded against and punished accordingly:

Provided that nothing contained in this sub-section shall render any such person liable to any punishment provided in this Act if he proves that the offence was committed without his knowledge or that he exercised all due diligence to prevent the commission of such offence.

(2) Notwithstanding anything contained in sub-section (1), where an offence under this Act has been committed by a company and it is proved that the offence has been committed with the consent or connivance of, or is attributable to any neglect on the part of, any director, manager, secretary or other officer of the company, such director, manager, secretary or other officer shall also be deemed to be guilty of that offence and shall be liable to be proceeded against and punished accordingly:

Explanation.—For the purposes of this section—

(a) "company" means a body corporate, and includes a firm or other association of individuals; and

(b) "director" in relation to a firm means a partner in the firm.

The report of the *Hathi Committee*[71] was presented at April 1975. It recommended, inter alia, to set up a national drug regulatory authority. Aspects of counterfeiting were not dealt with explicitly in this report. In contrast, the *Mashelkar-Committee* put a special focus on the problem of spurious and substandard drugs, while also presenting detailed recommendations for improving the Drug Regulatory System in its report presented in November 2003.

The following proposals made by the Mashelker Committee are still under the consideration:

1. To set up a well equipped, empowered, independent, and professionally managed CDSCO and to give the same the status of Central Drug Administration(CDA) with 10 main divisions.

1. Division for Regulatory Affairs & Enforcement
2. Division for New Drugs & Clinical Trials
3. Division for Biological & Biotechnology Products*
4. Division for Pharmaco-vigilance
5. Division for Medical Devices and Diagnostics
6. Division for Imports
7. Division for Organizational Services
8. Division for Training and Empowerment
9. Division for Quality Control Affairs
10. Division for Legal and Consumer Affairs[72]

2. Strengthen the State Drug Control Organization with additional manpower, infrastructure, technical capabilities and financial sources.
3. Set up Intelligence cum legal cell under the supervision of trained senior nodal officers. The State Government should put in place efficient mechanism for timely police help to these officers.
4. Establish a proper surveillance system for keeping a watch over suspected persons. Watchers should be employed and secret funds may be made available for intelligence activities.
5. Set up efficient communication networking for sharing and exchanging information in cases involving inter-state movement of spurious drugs.
6. Request the government to identify designated courts for speedy trial of spurious drug cases[73].

[71] *Ministry of Petroleum and Chemicals, government of India* (ed.), Report of the Committee on Drugs and Pharmaceutical Industry, April 1975, 275 p.

[72] Mashelker Committee Report, P.6.

[73] Mashelker Committee report. P. 11 (2.12, b,c,d,e)

8.2. Extra-legal (especially technical) solutions

The dispensing chemists are the most important terminal points in the whole chain as the people are defrauded by them to buy the spurious drugs. The profession of the chemists should be modernised. The integrity of the owner should be checked before issuing the licence. A person with a criminal record should be debarred. The information regarding the stock with details of manufacturers, batch numbers and expiry dates etc and the selling should be computerized. The information regarding the supplier with address, gate pass number, date etc should be recorded in the computer. It is very important to establish the link of the whole chain. The use of computer should be made mandatory by a specified period. The chemist shops not issuing cash memo for the sale should be heavily fined. The cash memo should clearly show the manufacturer's name and the batch number.

Having sophisticated tools for investigating counterfeit medicines is required if any progress is to be made in curbing the menace of spurious drugs. The use of near-infrared spectroscopy (NIRS) for rapid, on-site and non-destructive identification of counterfeit pharmaceuticals has been well documented.[74]

To stop the proliferation of spurious drugs in government hospitals, dispensaries, areas of defence, etc, which happen to be the biggest buyers of these drugs, the following steps should be taken: purchase the medicines without calling the tenders, shortlist the reputed pharmaceutical companies and procure the latest price lists of these companies, and order the medicines directly from the companies or their authorized stockists after negotiating the % discount. An independent agency to draw random samples for testing immediately after receiving the consignment in the stores is required.[75] A separate intelligence wing, to handle spurious drugs threats, should be set up under Food and Drugs Control Department. The staff should be trained to detect and catch the spurious drug manufacturers, stockists, retailers[76].

8.3. Other (e.g., education of the consumer)

According to Indian experts, the battle against drug counterfeiting must take place on various, mutually cooperating levels. The following section will summarize the recommendations and expectations that are being addressed to the pharmaceutical industry, the pharmaceutical trade, and the consumers.

a) Pharmaceutical industry

74 *Scafi, S.H., Pasquini, C.*: Identification of counterfeit drugs using near-infrared spectroscopy, in: Analyst 126 (2001), pp. 2218-2224.

75 Interviewed Mr.*Asim Sahu*, technical Officer Central Drug Control Authority, on 20.08.2008.

76 Shishir Kant Jain, The Spurious Drugs and Remedy, *Health Administrator Vol : XIX Number 1: 29-40*

According to the insights of the *Mashelkar*-Committee, the pharmaceutical industry itself plays a significant role in the fight against drug counterfeiting. The following individual recommendations are specifically directed to the pharmaceutical industry:[77]

- The pharmaceutical industry should, use its well-developed marketing network to identify distribution channels and persons involved in spurious drug trade.
- Assist, through its associations, in the detection and unearthing of spurious/counterfeit drugs by cooperating with regulatory and/or police authorities.
- Prepare, through its associations, a checklist for the guidance of manufacturers, wholesalers and retail sellers to identify and distinguish between spurious and genuine products.
- Formulate its own spurious/counterfeit drugs policy and a surveillance strategy to tackle the problem of spurious drugs.
- Establish close interaction with regulatory authorities and engage in full cooperation to eliminate the threat of spurious drugs.
- Streamline its supply chain and distribution network.
- Ensure proper storage of products during transit as well as at places of distribution.

b) Pharmaceutical Trade

The Mashelkar-Committee noted "that the sale of spurious drugs invariably takes place through wholesalers and retailers."[78] In addition to the requirement that "state drug controllers should take a severe action against those, who are found indulging in this activity and are not able to produce valid purchase records",[79] the Committee recommends some actions for the Pharma Trade Association:

- Play a proactive and visible role to help contain the threat of spurious/counterfeit drugs;

77 *Mashelkar*-Report, p. 97 (13.5.2).

78 *Mashelkar*-Report, p. 97 (13.6.1).

79 *Mashelkar*-Report, p. 97 (13.6.1).

- Develop a mechanism for identifying the persons directly or indirectly involved in abetting the distribution of spurious and/or counterfeit drugs as well as drugs of questionable quality;
- Prepare a checklist for the guidance of members and widely publicize it for the information of all members;
- Sub Rule 3 of Rule 65 (4) of Drugs & Cosmetics Rules requires that the supply by retail of any drug shall be made against a cash/credit memo. This condition of license should be strictly adhered to by all retail licensees;
- Every chemist/pharmacist is to act as a watchdog to prevent the entry of any spurious drugs, those of dubious quality and/or those purchased from unauthorized sources or without proper bills in the supply chain.[80]

c) Consumers/patients

The Mashelkar Committee writes that the consumer also plays a key role in the fight against drug counterfeiting and, in fact, sees an urgent need for an awareness campaign to educate not only medical and paramedical professionals but also the consumers.[81] *S.K. Jain* has emphasized this call for public awareness and pinpointed it as follows:

"The government should educate people through electronic media regarding the circulation of spurious drugs and the danger they pose to the health. …

The consumers have to play an active role in protecting themselves and help nab the culprits. They are required to be vigilant and alert while purchasing and using the drugs. Some of the precautions they should observe are listed as follows:

Consumer should buy drugs from reputed and well-established chemists that issue cash memo for the purchases. Check whether the batch number of the medicine is clearly and correctly written on the cash memo and should restrain from buying unusual packed medicines.

1. The task of educating the patient falls on the physician, whom the patient trusts. Physicians should familiarize themselves with the drugs most likely to be counterfeited and their identification
2. Consumers should buy medicines from well reputed chemists and take a receipt, which must carry the batch code and advise destruction of label and container after use[82]. They should not buy loose medicines[83] and should avoid buying the over the counter drugs, without prescription.
3. Consumer should not go for a cheaper medicine.

80 *Mashelkar*-Report p. 97 f. (13.6.2).

81 *Mashelkar*-Report p. 98 (13.6.3).

82 *Jain*, Health administrator XIX (2006), No. 1, pp. 29-40.

83 Source: Interview of several drug inspectors.

4. Consumer shall be vigilant on the spelling of name of the medicine if it is different
5. Consumer should report to the physician immediately if there is any adverse reaction such as nausea, headache, dizziness, heart or stomach pain, etc. If the physician says that these reactions are not normal, then the medicine could be spurious. Save the unused medicine and cash memo and file a complaint with either the manufacturer or the Drug Control Department.
6. If there is a severe reaction or death after consuming the medicine at home or in hospital, the matter should be immediately reported to the authorities for investigation.

9. Concluding Remarks

The researcher would like to conclude that counterfeit drugs is a big menace in India and are badly affecting the health of the people, but the Indian government is not giving enough importance to curbing this menace. The major emphasis is laid on narcotic drugs and not on counterfeit drugs. Litigation in this area is almost minimal. The conviction rate is also too low and the punishments awarded in those cases also is neither very stringent nor deterrent.

In a country where nearly half the population is illiterate, poverty is still rampant and where consumer awareness is low, the spread of fake and substandard drugs is a cause for alarm. Consumers are not vigilant about the problem of counterfeit drugs most of the time. Another reason for the less than serious approach of the government is that approximately 40% of the population live in rural areas and are uneducated. Thereby they are the easy prey to this business. Because of their ignorance no one takes steps towards making a complaint to the law enforcement machinery. There is no pressure from the people. The only sector worried about this menace is the drug manufacturing sector as they are incurring heavy losses. A group of pharmaceutical manufacturers in India are raising their voices against the fact that a large portion of drugs (about 20%) in the Indian market are counterfeit. According to an unofficial survey, north and north-eastern states of India, along with pockets in north-western India are flooded with spurious drug products. This alliance of pharmaceutical companies is also thinking of appointing private agencies to determine the exact status of counterfeit medicines in the Indian market.

If we have a look at the law presently being implemented in India regarding counterfeit drugs the special legislation Drugs and Cosmetics Act, 1940 is eminent. This Act exhaustively deals with all aspects of counterfeit drugs. Central Drug Laboratories are established under the Act. Drug Consultative Committee is established to supervise the drug control policies. Drug control enforcement machinery is established and they are given vast powers to search and seize the suspected counterfeit drugs. This is central legislation and all states are having powers to amend the law according to their convenience but these amendments are functional only in that particular state.

In spite of the infrastructure in place and elaborate procedures in operation it is a fact that the Act and machinery have failed or cannot achieve the success at the rate expected and at par with other developed countries. There are so many reasons for its failure. Some of them are that until the 2008/9 amendment special courts were not established to try these cases which is highly necessary, as the judge needing the expertise to try the case require special training. It should have been made non bailable as observed by Mashelkar committee report. At the same time the enforcement machinery needs to be strengthened. Not enough drug inspectors are available to effectively deal with the menace all over the country. The system is lacking in respect to gathering intelligence about the *modus operandii* and the gangs operating in the preparation of spurious drugs. The committee recommended making the offence compoundable, which will water down the seriousness of the law.

Various aspects of combating counterfeit drugs have been delayed by various legislations, various machinery and many departments of the Indian government leading to lot of confusion. For example apart from the Drug and Cosmetics Act, Customs Act and Pharmacy Act, many more legislations are operating in the same area. Most of the time the central government departments do not work in coordination with each other and the biggest flaw is the lack of coordination in between the enforcement machinery of the central and state governments. Hence it is a dire necessity that the Indian government should bring the entire enforcement machinery under one roof and should centralize the system. CDSCO which is presently working as a central drug control authority should be strengthened by providing more man power and a higher number of testing labs in all metropolitan cities and capacity of drug testing laboratories must be established to help analyze drugs other than for statutory purpose. Legitimate drug manufacturers also should develop measures, such as securing their own stocks of medicines and packaging materials in order to prevent their diversion to illegal manufacturers and packagers.

The dissemination of information to health professionals, on the existence of counterfeit drugs in the national distribution channels, as fast as possible, is a necessary but neglected issue. Appropriate warnings should be issued through mass media. It is important to establish standard methods for reports by licensed / authorized drug manufacturers / distributors, prescribers, and consumers, if they observe or suspect the presence of counterfeit drugs in the distribution channels. Procedures for the recall and immediate removal of counterfeit drugs should also be formulated.