ORGANISATION OF PHARMACEUTICAL PRODUCERS OF INDIA
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INDIA

Area:	2 973 193 km^2
Inhabitants (2010):	1,173,108,018
Population density (2010):	363 inhabitants per km^2
Gross Domestic Product (2010) (e):	INR 64350 billion = $ 1430 billion
General government expenditure on health as a % of total expenditure on health (2009)	17%
General government expenditure on health as a % of total government expenditure (2009):	3.9%
Public healthcare expenditure (2010):	0.9%
Private healthcare expenditure (2010):	4.3%
Total healthcare expenditure as a % of GDP (2010):	5.2%

Sources: PricewaterhouseCoopers (CIA World Factbook, Indiastat.com, International monetary fund, WHO, Business Monitor International, 2010)

1. CLASSIFICATION

In India, the import, manufacture, distribution and sale of drugs and cosmetics are regulated by the *Drugs and Cosmetics Act, 1940* (DCA), the *Drugs and Cosmetics Rules, 1945* (DCR)[1]

OTC Drugs

The phrase 'OTC' has no legal recognition in India, all the drugs not included in the list of 'prescription-only drugs' are considered to be non-prescription drugs (or OTC drugs). Hence 'OTC Drugs' means drugs legally allowed to be sold 'Over The Counter' by pharmacists, i.e. without the prescription of a Registered Medical Practitioner.

Prescription-only drugs are those medicines that are listed in *Schedules H and X* of the Drug and Cosmetics Rules. Drugs listed in *Schedule G* (mostly antihistamines) do not need prescription to purchase but require the following mandatory text on the label: "Caution: It is dangerous to take this preparation except under medical supervision".

Currently, non drug-licensed stores (e.g. non-pharmacists) can sell a few medicines classified as 'Household Remedies' listed in *Schedule K* of the D&C Rules in villages whose population is below 1 000 subject to certain other conditions.

Ayurvedic Medicines

OTC drugs registered as 'Ayurvedic Medicines' (i.e. traditional Indian system of medicines containing natural / herbal ingredients) are also regulated by the DCA and DCR. Ayurvedic drugs are manufactured under a manufacturing licence issued by the Ayurvedic State Licensing Authorities. However, they do not require a drug sale licence and can be sold freely by non-chemists. Some of the largest OTC brands in India are registered as 'Ayurvedic Medicines' because of their plant-based natural active ingredients (e.g. Vicks VapoRub, Amrutanjan Pain Balm, Zandu Pain Balm, Iodex Pain Balm, Moov Pain Cream, Itch Guard Cream, Eno Fruit Salt antacid, Vicks Cough Drops, Halls Lozenges, Dabur's Pudina Hara, Calcium Sandoz etc.).

[1] http://cdsco.nic.in/html/Drugs&CosmeticAct.pdf

Considering the above framework, key categories with OTC potential in India would be: vitamins and minerals; health tonics, cough and cold; gastrointestinals; analgesics; dermatologicals; herbal / ayurvedic medicines, among others, which do not contain any substance listed in Schedules G, H or X. There is also a provision under schedule G and H which exempts Topical or external use (except ophthalmic and ear / nose preparations containing antibiotics and / or steroids) applications of the ingredients from these schedules e.g. while Diclofenac is listed in Schedule H but Topical form of the same is excluded. Some of the vitamin supplements come under price control, which can be addressed by making dosage / formulation combination modification. Some of the non-scheduled drugs like Aspirin also come under price control, through Drug Price Control Order (DPCO)

Additionally, there is also The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules, 1955. This Act controls the advertisements for certain category of drugs with a view to prevent people from self medication under the influence of misleading and exaggerated advertisements. There are 54 ailments covered under this action, of which Fever is one of them.

2. MARKETING AUTHORISATION

The major legislation for pharmaceutical regulation is the *Drugs and Cosmetics Act, 1940* (DCA) and its subordinate legislation, the *Drugs and Cosmetics Rules,1945* (DCR)[1]. Drug (Prices Control) Order, 1995, Drugs (Magic Remedies) Objectionable Advertisement Act, 1954 and Pharmacy Act, 1948 are other regulations which have a bearing on the pharmaceutical business in India.

The legislations apply to the whole of India and to all categories of medicines (e.g., allopathic, ayurvedic, siddha, unani and homeopathy.), whether imported or manufactured in India. The legislation is regulated by the Central Government (*Ministry of Health & Family Welfare*[2]) in New Delhi, which is responsible for its overall supervision and enforced by State Government through its *Food and Drug Administration* (FDA).

The office of the Drugs *Controller General of India* (DCGI) has the primary responsibility for approving new drugs, molecules and standards, Vaccines & Sera, new usage and claims, new method of administration, clinical research and trials, introductions of a new unique formulation and granting import and export licences. It oversees the activities of the *Central Drugs Standard Control Organization* (CDSCO)[3]. The DCGI also exercises control over medical devices imported or manufactured in India.

However, power to provide manufacturing and selling licences - which are the two main stages required to manufacture and sell a drug - belongs to each individual State Government through its *Food and Drug Administration* (FDA). These Food and Drug Administrations (FDAs) also carry out enforcement of the DCA and the DCR.

The DCGI office is established in modern premises in Delhi:
Central Drugs Standard Control Organization
Directorate General of Health Services
Ministry of Health and Family Welfare
Government of India
FDA Bhavan, ITO, Kotla Road, New Delhi - 110002
Phone: +91-11-23 23 69 68
Fax: +91-11-23 23 69 73

1 http://cdsco.nic.in/html/Drugs&CosmeticAct.pdf
2 http://mohfw.nic.in/
3 http://cdsco.nic.in/index.html

3. PATIENT INFORMATION

Rule 96 of the DCR ('Manner of Labelling') mandates the minimum information which needs to be put on the label of all medicines other than ISM medicines (ayurveda, siddha, unani). This includes:

a) proper (generic) and trade (brand) name
b) net contents and content of active ingredients,
c) name and address of manufacturer including manufacturing licence number,
d) distinctive batch number, manufacturing and expiry date etc.
e) Maximum Retail Price (inclusive of all taxes)

Rule 97 requires on-label caution statements for the different drug schedules. For example, drugs falling under Schedule G require "Caution: it is dangerous to take this preparation except under medical supervision". Schedule H drugs need the symbol 'Rx' as well as "Schedule H – Warning: To be sold by retail on the prescription of a Registered Medical Practitioner only".

There are no separate labelling requirements for 'OTC drugs'. Under *The Standards of Weights & Measures (Packaged Commodities) Rules*, most packaged consumer products including ISM drugs are required to have the Maximum Retail Price (MRP) printed on the label. The maximum retail sale price of scheduled and non-scheduled drugs is as per the provisions of DPCO 1995. The trade margins (wholesale and retail) are also restricted under DPCO. The selling of any product at a price higher than the MRP is not permitted.

The labelling provisions of ISM medicines are covered by Rule 161.

4. ADVERTISING TO THE GENERAL PUBLIC

The *Drug & Magic Remedies (Objectionable Advertisement) Act & Rules* mentions a list of ailments for which no advertising is permitted. It also prohibits false or misleading advertisements which, directly or indirectly, give false impressions regarding the true character of the drug, make false claims, or are otherwise false or misleading in any particular respect. There is an *OPPI Code of Pharmaceutical Marketing Practices, 2010*[1], based on the IFPMA code. Currently, there is no specific law which prohibits the advertising of prescription drugs. The following OTC medicines advertising can be seen on TV in India:

- digestives
- antacids
- antiflatulents
- cold rubs and analgesic balms/creams
- vitamins/tonics/health supplements (especially herbals and Ayurvedic-registered)
- medicated skin treatment
- analgesic /cold tablets
- antiseptic creams/liquids
- glucose powders
- cough liquids
- throat lozenges
- medicated dressings (band-aids)
- baby gripe water
- Ayurvedic medicines and preparations.

[1] http://www.indiaoppi.com/OPPI%20Code%20of%20Marketing%202007.pdf

5. TRADE NAMES

Trade names are regulated by the *Trade and Merchandise Marks Act* (TMMA). The TMMA provides for registration of trademarks for a period of seven years at a time, renewable after each period. For any item, trademarks should not be objectionable from a religious or social point of view. They should not contravene the *Emblems and Names (Prevention of Improper Use) Act*, 1950. They should also not yet be registered or applied to be registered in India. The trademark can be registered even if the item is not produced or sold in India at present.

A foreign trademark can be used without any restriction. Foreign companies can license their trade mark to their local subsidiaries or joint ventures. The *Indian Copyright Act, 1957*[1] also provides protection for unique logos and designs on packaging.

"Infringement" and/or "Pass-off" or look-alike copies, counterfeits and spurious products of popular OTC drugs are a major issue because the licence to manufacture and sell drugs is issued by state-level FDAs who do not independently verify whether they issue a manufacturing and selling licence to a pass-off drug. However, the Indian courts are known to provide quick and corrective action against such violators, although the burden of searching and taking the pass-off manufacturer to court falls on the individual affected company.

6. DISTRIBUTION

India is geographically a very large country, with the population spread over urban (33%) and rural (67%) areas. There is at present no system of national chains of supermarkets or drugstores / pharmacies, and retailing is dominated by small independent shops. However, a few chains such as Apollo Pharmacy, Medicine Shoppe, Good Health etc., are entering the market and are expected to make inroads all over India in the near future. However, chain pharmacies haven't been able to make any significant gains in garnering share of market. Simultaneously, AIOCD (the trade body) has corporatised itself and has now become, AIOCD Ltd. It will have all the chemists across India as its members. The estimates of total number of pharmacies in India vary from 750,000 to 10,00,000. Typically however, less than 5% of sales of FMCG manufacturers in 2006 went through organised retailers. A manufacturer or importer has to make his proper arrangements for distribution to the retail level. However, for the pharmacies, close to 30% of their revenue comes from non-pharma products, large part of which is FMCG products.

Due to interstate Central Sales Tax (CST), operating a warehouse or stockist in each state and distributing within the state from there is a common practice. Further, there are very few national distribution agencies that distribute third-party products throughout the country.

The method of distribution is therefore from the manufacturer's location to a company's own state depots for stocking before making a sale. This avoids the 2% Central Sales Tax. These depots are either run by the company or outsourced to Clearing and Forwarding agents (C&F) who operate the depots on the company's behalf but employ their own staff and premises.

Each warehouse is required to take out a drug-selling licence. The C&F is under the supervision of the company's regional office (usually located at the four metropolitan areas of Mumbai, New Delhi, Kolkata and Chennai, representing the West, North, East and South regions). Each regional office looks after sales in five or six states.

[1] http://www.education.nic.in/CprAct.pdf

The dispatch of goods takes place from the manufacturer's location to the C&F locations, but without invoicing at that stage as it is only a transfer of goods and not a sale. The C&F invoices goods to stockists or distributors who have town or area-wide stocking points. The responsibility of stockists is to resell and distribute goods to wholesalers and retailers in their defined area of operations. In some cases stockists provide sales personnel to cover retail stores as well. The company's sales / medical representatives co-ordinate with the C&F agent as well as the stockists to support retail sales and avoid shortages.

Buying and selling of allopathic drugs is regulated through a licensing system either by the central authority and/or by state drug control authorities. It is an offence to manufacture, store, sell or distribute drugs without a valid drug licence.

7. DISTANCE SELLING

Distance selling and teleshopping of non-prescription medicines is not permitted in India as the sale of drug products can only take place through licensed stores. However, multi-level-marketing (MLM) for food supplements is allowed. For example, Nutrilite by Amway is a very big brand in India, marketed directly to consumers by direct sales agents.

8. PRICING

Price controls are exercised on certain drugs by virtue of the *Drugs (Prices Control) Order 1995* (DPCO)[1], in the framework of the *Essential Commodities Act* (ECA). The DPCO is the responsibility of the *Ministry of Chemicals and Fertilisers*[2] and is supervised by the *National Pharmaceutical Pricing Authority* (NPPA)[3]. It outlines the classification of price-controlled products and methods of price fixation and revision. The NPPA monitors drug prices by fixing and revising them. The 347 price-controlled drugs under the *Drugs (Prices Control) Order 1979* were brought down to 143 in the *Drugs (Prices Control) Order 1987*. Under the DPCO-1995, there are 74 bulk drugs and their formulations under price control (known as scheduled drugs) covering significant percentage of the total pharmaceutical market in India. Only a few OTC actives, e.g. acetylsalicylic acid and ephedrine and its salts, fall under the current DPCO price control.

The price of scheduled drug fixed by NPPA is revised from time to time. The manufacturer is not allowed to increase retail price of scheduled drugs without approval of NPPA. However, prices of non-scheduled drugs are fixed by the manufacturer subject to a maximum increase of 10% on the prevailing price over a 12-month period.

There are no price controls on 'Ayurvedic Medicines'.

Under the *National Pharmaceutical Policy 2006*, the government intended to:

- Strengthen the Patent office infrastructure,
- Focus on Research & Development strategies to increase access to anti-cancer and anti-HIV drugs,
- Rationalise the Excise Duty schemes in order to promote access to drugs for the poor,
- Set up a Drugs Price Monitoring Awareness and Accessibility Fund
- Create a Pharma Advisory Forum and
- Increase the range of price controls.

1 http://nppaindia.nic.in/drug_price95/txt8.html

2 http://chemicals.nic.in/

3 http://nppaindia.nic.in/index1.html

However, at the beginning of 2010 the Policy was still under review by a government-appointed high level committee of cabinet ministers.

9. PRICE BUILD-UP

The stockist / wholesale and retail margins on OTC medicinal products are fixed by an agreement of Industry Associations including OPPI and the All India Organisation of Chemists & Druggists (AIOCD) whereby a 10% margin on the Maximum Retail Price (MRP exclusive of all taxes & duties) is provided for the stockist/wholesaler and 20% for retailers for non-price-controlled drug products. For price controlled products 16% margin for Retailers is mandated by the DPCO. Generally, Stockists retain between 5-6% of margin while passing on the balance 3-4% margin to sub-wholesaler or bulk retail buyer. The consumer price or Maximum Retail Price (MRP) build-up for a typical* non-price-controlled medicine is as follows:

	%	%
Manufacturer's selling or ex-factory price (MSP)	100.0	60.4
Central VAT (16% of 57.5% of the MRP)	115.2	69.7
State VAT (4% of the MRP)	121.8	73.7
Stockist / Wholesale price (margin = 10% of the MRP[1])	136.6.	82.6
Maximum Retail Price (MRP) (margin = 20% of MRP[1])	165.3	100.0

[1] Excluding taxes.

* Stockist and retailer margins may very for Ayurvedic and Food/Nutrition related products

10. MARKET DATA

The value of the pharmaceutical market in India as on October MAT (Moving Average Total) 2010 was Rs. 50,000 Crore ($ 11.1 billion, assuming $ 1 = Rs. 45 conversion rate, euro 8.32 billion) which represented a growth of 17.6%. India's pharmaceutical market represents 1.8% of the global pharmaceutical market in terms of value and 8% in terms of volume. Globally, India ranks 4th in volume and 14th in value terms. The exports of bulk drugs and formulations represented USD 6 billion (euro 4.378 billion) in 2007.

OTC medicines

India currently ranks 11th in the global OTC market size. It is estimated that it will reach 9th position within five years.

Currently the Indian OTC market (including frank OTC medicines which are advertised and deemed OTC brands, and ones that are non-advertised or Rx marketed but with large OTC sales component) is estimated to represent approximately USD 1,813 million (euro 1362 million) with an annual growth rate of 10.7% at the end of calendar year 2009

Main self-medication product groups

Category	2005	2006	2007	2008	2009
(Sales in US$ Million)					
OTC sales - India	1243.4	1371.4	1491.0	1638.9	1813.4
Analgesics	178.8	192.9	201.7	223.4	258.6
Cough, Cold & Allergy	227.2	250.7	269.7	295.1	318.1
Gastrointestinals	231.4	256.7	281.0	301.2	332.6
Vitamins, Minerals & Supplements	447.1	494.3	538.6	583.0	634.5
Dermatologicals	144.1	160.3	181.9	212.4	236.5
Lifestyle OTCs	14.8	16.4	18.1	23.9	33.1

Category (growth %)	06/05	07/06	08/07	09/08
OTC sales - India	*10.3*	*8.7*	*9.9*	*10.7*
Analgesics	7.9	4.6	10.7	15.8
Cough, Cold & Allergy	10.3	7.6	9.4	7.8
Gastrointestinals	10.9	9.5	7.2	10.4
Vitamins, Minerals & Supplements	10.6	8.9	8.2	8.8
Dermatologicals	11.3	13.5	16.8	11.3
Lifestyle OTCs	11.0	10.1	31.9	38.9

Source: Nicholas Hall & Company, India, DB6 2010 – 1US$ = INR.46.54

11. RESTRICTIONS CONCERNING IMPORTS

Imports of formulations into India are negligible given the price disadvantage arising from import tariffs and local manufacturing cost advantages. Further, the product approval process for new molecules can be difficult and time-consuming. Price controls are also an added negative factor.

The *Ministry of Health and Family Welfare* has published a Gazette Notification GSR no. 604 (E) dated 24.08.2001 amending the various provisions of the *Drugs & Cosmetics Rules*, thereby introducing a new provision for the registration of the manufacturing premises of foreign drug manufacturers and individual drugs prior to their import into the country. The notification also introduced a few other provisions, e.g. enhanced import licence fees, increased validity period of licence, deletion of exemption from requirement of import licence for bulk drugs for actual users, requirement of minimum 60% of residual shelf life for imported drugs and provisions for import of small quantities of new drugs by Government hospitals for the treatment of their patients, etc.

Under these provisions, foreign manufacturers have to apply for a registration certificate for their manufacturing premises and the individual drugs they want to export to India. Authorised agents of foreign firms in India can make the applications. The documents required for registration certificates are clearly specified in the amendments. The validity of registration certificates is three years from the date they are issued.

According to the modified rules, an import licence is required for all types of drugs instead of the previous import licence requirements for Schedule C & C (1) and Schedule X drugs only.

12. SWITCH CLIMATE

Currently, aches/pains, cough, colds, hyperacidity, minor topical infections and indigestion are major OTC categories. Emerging categories include cuts, wounds and burns, muscle pains and sprains, diarrhoea and constipation. There are many products in the Rx sector which could be revitalised through OTC switches. An analytical interpretation of various data places the focus on vitamins, cough & cold, antacids, antipyretics and NSAIDs as opportunity areas for switch in India. India does not have a well documented process or a specific regulation on switching Rx to OTC products and this is becoming need of the hour. Globally many countries have a formal process of transferring prescription (Rx) drugs to over-the-counter (OTC) status, known as "Rx-to-OTC switch. In these markets Rx to OTC switch is also seen as an efficient way of reducing healthcare costs by expanding the most inexpensive form of health care which is self-medication with OTC medicines. Regulators in India will sooner or latter need to very clearly define OTC formally as a

category because at the end this will help promote access to market and will empower consumers who want to take a more active role in their own health care. In fact, in the near future, switching would be one of the most used strategies to enter OTC by new players.

The reason why "switch" so far was not a big issue in OTC marketing is because currently even drugs which do not require a prescription are promoted via the doctor because:

a) Marketing through medical representatives is less expensive than mass media advertised marketing. This makes that OTC medicines are higher priced than the equivalent medicines promoted ethically.
b) Practically all Rx drugs can be purchased without a prescription.
c) Doctor influence is strong in patients' purchase behaviour.
d) Distribution of allopathic OTC medicines is limited to drug licensed stores (mainly pharmacies).

13. PHARMACY TRAINING AND ATTITUDES

OTC drugs require no pharmacists' consultation for selling. However, an active role and responsibility of pharmacists in promoting self-medication is important.

14. DOCTORS TRAINING AND ATTITUDES

A survey among doctors on OTC medicines[1] brought out the following interesting responses:

- 72% of doctors were willing to give an opinion on the OTC medicine
- 21% of doctors were willing to recommend / prescribe an alternative
- Only 7% of doctors found it against their medical ethics to give advice on advertised brands.

In fact, if it is a well-known & trusted brand, then they have no problem if it moves into OTC domain and is directly marketed to consumers

15. CONSUMER ATTITUDES/RESEARCH

Indian consumers confidently self-treat a wide range of common ailments such as cough, cold, fever, pain and sprains, heartburn and diarrhoea. When suffering from an ailment, consumer behaviour is as follows;

- Go to the pharmacist: 45%
- Go to the doctor: 24%
- Self-medication: 23%
- Do nothing: 9%

With a strong heritage of Ayurveda and alternative medicines, the usage of home remedies is quite high in Indian households. In fact, more than 30% of the time Indian consumers use home remedies. Major usage of home remedies is found in cough, cold, heartburn and indigestion categories[6].

1 Source: "OTC-the final frontier" by Nicholas Hall, Sorento Communications and IMRS, 2006.

16. OTHER NATIONAL DEVELOPMENTS

Intellectual property rights

As a founder member of the World Trade Organization (WTO), India was obliged to introduce an Intellectual Property Rights (IPR) regime compliant with TRIPS (Trade Related Aspects of Intellectual Property Rights) in January 2005. India ushered in a product patents regime by introducing *The Patents (Amendment) Ordinance, 2004* on 26 December 2004. After debating the provisions of the Ordinance, Parliament later passed *The Patents (Amendment) Bill, 2005*. This signalled the start of a new era for the pharmaceutical industry in India.

The 2005 Act was expected to boost R&D, help bring in Foreign Direct Investment and contribute to improved healthcare. As of now, patents can only be granted to new chemical entities. However, a committee has been formed to study the patentability of Novel Drug Delivery System (NDDS), polymorphs, metabolites etc.

Foods Standard & Safety Act (FSSA)

This law was passed in 2006 by Indian Parliament, but guidelines were not in place. Food Standards & Safety Act will finally include guidelines that clearly state which supplements can be classed as foods instead of drugs, allowing mass market sale. These guidelines will remove ambiguities for VMS marketers and could encourage more pharma companies to move into OTC, food companies to move into functional foods and FMCG companies to shift to cosmeceuticals, all under the wellness umbrella.

Local manufacture

India not only produces pharmaceutical formulations but also manufactures over 400 Active Pharmaceutical Ingredients (APIs) from the basic stage. An ancillary industry is also fully developed, and a full range of pharmaceutical manufacturing equipment is locally produced.

The Pharmaceutical Industry in India has quality producers, and regulatory authorities in the United States and the United Kingdom have approved many products. Today, India has the highest number of U.S. FDA-approved manufacturing facilities outside the United States, and Indian companies filed the highest number of DMFs with the U.S. FDA in 2007. The country has a pool of personnel with high managerial and technical competence as a skilled workforce. Its track record, particularly in the area of cost-efficient chemical synthesis for various drug molecules, is excellent.

Other data

- R&D expenditure: USD 520 million, equivalent to 6.6% of pharmaceutical sales.
- Life expectancy during the period 1951-2008 has increased from 37 to 69 years. Infant mortality (per 1000 live births) during the same period has come down from 150 to 34. Also, the death and birth rates (per 1000 inhabitants) have come down from 25 to 6 and from 41 to 22 respectively during the same period.

Promotion of responsible self-medication

The OTC Committee of the *Organisation of Pharmaceutical Producers of India* (OPPI) is working towards the promotion of responsible self-medication with a view to grow the OTC sector. It is aiming to get regulatory support for issues such as the accessibility of household OTC remedies and increasing the awareness of the importance of responsible self-medication with the general public and the Government.

17. ELECTRONIC INFORMATION

OPPI has a website (www.indiaoppi.com) with information on its activities.

Electronic information about the Indian market can also be obtained from the following websites:

- Ministry of Health and Family Welfare: http://mohfw.nic.in/
- Drug Controller General (India): http://mohfw.nic.in/ph/tdghs.htm
- Central Drugs Standard Control Organization (CDSCO): http://cdsco.nic.in/index.html
- Medicines laws: http://cdsco.nic.in
- Department of Chemicals (Ministry of Chemical & Fertilizers): http://chemicals.nic.in/
- National Pharmaceutical Pricing Authority (NPPA): http://nppaindia.nic.in/index1.html

18. INFORMATION KINDLY COMPILED BY:

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