CHAPTER-7

ORGANIZATIONS OF INDIAN PHARMACEUTICAL INDUSTRY & OVERSEAS
ORGANIZATION OF PHARMACEUTICAL PRODUCERS OF INDIA (OPPI)

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ORGANIZATION CHART (OPPI)

PRESIDENT
↓
VICE PRESIDENTS
↓
ELECTED MEMBERS
↓
SPECIAL INVITEES
↓
CHAIRMEN OF SPECIAL COMMITTEES
↓
Industrial
Pricing &
Policy & Legal
Taxation
Human Resource
Development

Technical
Medical
Communications

Marketing
Animal Health
Finance & Administration

Export & Material Mgmt

OTC

products

products

Secretariat
↓
Director General
↓
Secretary General
↓
Delhi Director


The Organization of Pharmaceutical Producers of India (OPPI) is headed by its President and is assisted by Vice Presidents, elected members, special invitees and various chairmen of special committees on – Industrial
policy and legal matters, pricing and taxation, human resource development, technical, medical, marketing, animal health products (sub-committee), communications, OTC products, Finance & Administration, Export & Materials Management. The organization also has a secretariat comprising of – Director General, Secretary General and a Delhi Director.

**ORGANIZATION OF PHARMACEUTICAL PRODUCERS OF INDIA (OPPI)**

"The OPPI, established in 1965, is a premier organization of Pharmaceutical manufacturers in India."¹ Its membership consists of companies with international collaboration and large Indian companies. It represents primarily research based companies in India.

OPPI, members account for a substantial share of the industry's total investment, export and R&D. "The market share of its Member-firms in total pharmaceutical market in India is around 60%. OPPI members currently manufacture over 200 bulk drugs and account for 50% of the industry's export of drugs and pharmaceuticals."²

OPPI is not only an industry association but also a scientific and professional body. It organises national and international seminars and workshops relating to key issues of the Pharmaceutical industry and healthcare. It supports scientific research by professionals and academic institutes. It has brought out a number of technical publications. "These include Quality Assurance Guide and Environment, Health & Safety Guide."³

OPPI members adhere to the code of Pharmaceutical Marketing Practices of International Federation of Pharmaceutical Manufacturers (IFPMA). OPPI has developed operational guidelines for its members, for

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² Ibid, pp. 11-12
³ Ibid, p. 13
interpretation and implementation of this code of Ethical Marketing Practices. "OPPI is an active member of IFPMA. OPPI is also a member of the World Self-Medication Industry (WSMI), France".4

OPPI is actively engaged in designing and conducting training programmes for managers working in the pharmaceutical industry to equip them for competing in the global setting.

OPPI identifies itself with the country's national objectives in health and encourages its members to amplify substantial contributions to social concerns. It also coordinates its Members' efforts in national calamities like epidemics, floods, earthquakes and cyclone.

**OPPI Initiatives and Activities**

"OPPI members met with Union Minister of Health and Family Welfare on 7\textsuperscript{th} Sept., 2002, for the removal of excessive controls, strengthening of regulatory framework and reduction of taxes on medicines. It also held an Interactive Consultative Meeting with the Ministry of Chemicals & Fertilizers in Delhi on 8\textsuperscript{th} Nov., 2002, to accelerate the legal process in the context of the writ petition and notify the much awaited DPCO. Members met with Dr Vijay Kelkar, Advisor to the Union Finance Minister on 22\textsuperscript{nd} Nov., 2002 and suggested for a single rate of customs duty, integrating all other duties like special additional duty and the basic customs duty. OPPI participated in Round Table on IPR and Emerging Knowledge Economy in India organized by PHD Chamber of Commerce & Industry in New Delhi on Jan. 29, 2003. Members met with Prof. Trevor Jones, CBE, Director General, Association of the British Pharmaceutical Industry (ABPI) who made a presentation to OPPI members on "Pharmaceutical Industry in Europe 2003 : Challenges & Opportunities" on Jan. 23, 2003. The members also met with Mr Bruno Grele, Area Director,

South-East Asia, Sanofi Synthelabo, who visited OPPI on 20th Feb., 2003. The discussion focussed on interesting issues relating to partnership in the form of co-marketing, co-licensing and joint ventures. Area Vice President (South Asia), IMS Health India Pvt. Ltd. made a presentation on pharmaceutical industry review 2002, on June 19, 2003. Also met with Mr Stefan Vranckx, Director, External Relations, International, GSK and Ms. Jin Montesano, Corporate and Government Affairs Director, Asia Pacific, GSK on 23rd June, 2003. The main theme of discussion related to Trade issues, regulatory and pricing issues and European perspective on IPR.5

Besides the association provided specific comments and suggestions to the Ministry of Commerce & Industry.

On giving advance intimation to the holder of the patent or Exclusive Marketing Rights (EMR) when the application is made by another party for compulsory licensing or for revocation of EMR.

- Defining clearly the term National Emergency.
- Setting a suitable time limit for giving notice of opposition.
- Need for one time payment of fees for the duration of the patent rather than yearly payment.

A number of special meetings, jointly with experts of Management Consultancy Agencies like Ernst & Young were also organized for the Members to deal with intricate issues in the context of value added tax (VAT).

The technical committee focussed on: OPPI Scientist Award; Harmonisation of Licensing requirements; Compiling the list of anti-counterfeit measures; GMP Audit Checklist and Seminar on Environment, Health & Safety.

Animal Health Products (AHP) Sub Committee

Aims to pursue the objective of marketing data; renumeration survey of employees; interface with key-customers and rural penetration development programme.

Human Resource Development (HRD) Committee has undertaken activities for talent utilization and talent management.

The medical committee aimed to resolve issues arising out of registration requirements for Imported drugs; duty exemption on imported life saving drugs; assisting regulatory authorities in implementation of GCP guidelines and analysing issues related to data exclusivity.

**OPPIs Representations on Various Committees**

"Customs Advisory Committee, Mumbai; Regional Advisory Committee Organized Sector, Central Excise Mumbai II; State Advisory Committee on Contract Labour, Government of Maharashtra, Mumbai; Tripartite Industrial Committee on Chemical Industry, Ministry of Labour, New Delhi; Zonal Special Advance Licensing Committee, Joint Director General of Foreign Trade, Ministry of Commerce, Government of India, Mumbai; Joint Committee of the Indian Pharmaceutical Association (Maharashtra State Branch), Mumbai; Bureau of Indian Standards (Technical Committee), New Delhi; State Level Security Guards Advisory Council, Mumbai."

**Seminars/Workshops/Symposia organized by OPPI**

"OTC Seminar on 'Unlocking the OTC Future' on 19th Nov.'02 at Mumbai; Seminar/Training Programme on 'Negotiation Skills' on 14th March'03 at Mumbai; Seminar on 'Talent Management : Winning the War for

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"Talents" on 4th July'03 at Mumbai; Workshop on 'Code of Marketing Practices' on 8th Aug.'03 at Mumbai; Asian Symposium on Healthcare Industry: Regulatory Policies and Growth Constraints on 10th Feb'03 at Hyderabad; Seminar on Spurious Drugs: Its Magnitude and what needs to be done on 5th Apr'03 at Mumbai; Round Table meeting on R&D Data Exclusivity on 29th Apr'03 at Mumbai; Symposium on All that you should know about IPR and Patent Act Amendment on 15th Jul'03 at Mumbai; Infra Medica: International Exhibition & Conference on 'Creating Infrastructure for Healthy India' on 28th to 30th Aug'03 at New Delhi".7

OPPI Publications8

- OPPI President's Speech at the 36th Annual General Meeting (September 2002).
- Biotechnology Research in the Pharmaceutical Sector. Keynote address by Dr (Mrs) Manju Sharma, Secretary, Department of Biotechnology, Government of India (September 2000).
- Contribution to Drug Discovery (October, 2000).
- OPPI Directory (November, 2000)
- The Menace of Spurious Drugs (December, 2000).
- Gateway to Knowledge Economy – A Brochure on OPPI's Multifarious Activities and Organisation Structure.

8 Ibid, p. 76.
The IDMA is headed by its President who is assisted by members of Executive Committee, Secretariat and State Boards. The Executive Committee has several sub-committees on International Trade, IPR, Pricing & Consumer affairs, regulatory & technical, quality management & assurance, trade &
employee relation, bulk drug, SSI, taxation/excise and customs, medical, finance & administration, publications, membership & constitution, biotechnology and R&D and public relations. Besides there are immediate Past President, Vice Presidents of Western, Eastern, Northern & Southern Region, Hony. Gen. Secretary, Jt. Secretary and Hony. Treasurer. The Secretariat comprises of Secretary General, Asstt. Secretary General (Accounts & Administration/Publication & Public Relations) and front office personnel. Besides, the Delhi Office which has an Executive Director and a Jt. Director. The State Boards in turn have – Chairman and Hony. Secretary, to discharge their respective duties for the smooth running and functioning of the association.

INDIAN DRUG MANUFACTURERS' ASSOCIATION (IDMA)

The Voice of the National Sector

At the time of Independence, the pharmaceutical business activity in India was dominated by the foreign pharmaceutical companies. It was at this critical time that a group of small manufacturers, wholly Indian and mainly consisting of technocrat entrepreneurs, got together with the clear objective of collectively supporting and bringing up indigenous production of pharmaceutical preparations. And thus was born the Indian Drug Manufacturers' Association (IDMA). To help manufacturers and to protect the interest of the Indian Consumer, "IDMA was formed in 1961".9

IDMA represents the national sector of the Indian manufacturers engaged in producing and providing high quality essential bulk activities and pharmaceuticals to the nation and to the world at very reasonable prices. "The growth which the Indian pharmaceutical Industry has achieved is mainly due to the Indian Patents Act, 1970 which was one of the achievements of IDMA in

strengthening the national sector."\textsuperscript{10} This vital piece of legislation was a landmark in giving the national sector the much needed impetus in manufacturing bulk actives from the basic stage and formulations thereof, thus enabling the country to attain the national objectives of self-sufficiency and self-reliance in the vital sector of Healthcare of the people.

"IDMA has a membership of over 600 wholly Indian large, medium and small companies, spread over the length and breadth of the country."\textsuperscript{11} The association plays a vital role in the growth and development of the industry by taking up with the Government major issues such as Price Control, Patents and Trademarks Laws, Quality & GMP, R&D, Exports, etc. and promoting better understanding with consumer organizations, the press and other media on the problems faced by the industry.

In order to promote and help the growth of the national Pharmaceutical Industry, IDMA has instituted various awards: "IDMA Best Patent Award, IDMA G.P. Nair Awards, IDMA Research Awards, IDMA Gold, Silver and Merit Quality Excellence Awards, IDMA APA Eminent Analyst Award, IDMA APA Young Analyst Award."\textsuperscript{12}

**ACTIVITIES AND ACHIEVEMENTS**

Various issues of policy or operational nature relating to the structure and implementation of the Drugs Cosmetics Rules at Central or State Level are taken up with the authorities through representations and follow-up meetings. Some of the important issues which have been taken up with the authorities in recent times are: "Extension of validity of WHO-GMP certificates to five years, Six months grace period needed for implementation of Overseas

\textsuperscript{10} IDMA, 44\textsuperscript{th} Annual Report, Mumbai, 2006, pp. 31-33
\textsuperscript{11} Ibid, pp. 31-33.
\textsuperscript{12} Ibid, pp. 45-47.
Pharmacopoeia; Decentralization of work regarding registration for import of drugs; Delay in testing of drugs; Licence/inspection fees for SSI sector; Menace of Spurious Drugs etc.\(^\text{13}\)

The Association has submitted its observations/suggestions on the provisions of the revised schedule drawing authority's attention to the clauses which need amendments, the clauses in which inadvertent contradictions were noticed and clauses on which guidelines/clarifications were required.

"9\(^{\text{th}}\) Pharmaceutical Analysts Convention, IDMA APA PAC, 2006, was held on 23\(^{\text{rd}}\) & 24\(^{\text{th}}\) January, 2006, at Mumbai. Attended by 300 participants and over 100 invitees from regulatory, academic and industry fields. Main agenda of convention was issued related to EDQM and European Pharmacopoeia 5\(^{\text{th}}\) Edition."\(^{14}\)

Seminars/Workshops are organized on regular basis at various pharma growth centres in the country on topics of interest to the pharma analysts:

"One day workshop on Achieving Expertise in Pharmaceutical HPLC Analysis, was held on Fri. 13\(^{\text{th}}\) Oct.'06 at Mumbai; Two days workshop on GCP-Practicing what is preached, was held on Fri.-Sat. 24-25 Nov'06 at Mumbai."\(^{15}\)

Besides submitting suggestions for improvement/modification in the EXIM Policy, the Association regularly takes up with the authorities various strategic issues relating to the constraints faced by the member companies in implementation of the EXIM policy provisions. The difficulties faced by the member companies at the customs on operational side are also presented to the authorities. Association's representatives on the Chief Commissioner of

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\(^{13}\) IDMA, 44\(^{\text{th}}\) Annual Report, Mumbai, 2006, p. 53.

\(^{14}\) Ibid, p. 55

\(^{15}\) IDMA, 44\(^{\text{th}}\) Annual Report, Mumbai, 2006, p. 59.
Custom's Open House Meeting also take-up operational issues for their necessary redressal.

**Export Data Bank**

The association has collected data/reports of various countries. The copies of these reports/data would be made available to the member companies on request and written requisition.

Pre-budget and Post-budget submissions on issues relating to direct (Income Tax, Corporate Tax) and indirect taxes (Customs & Excise duties) are made to the authorities on regular basis.

**Publications**

IDMA publishes two periodicals – one, a monthly Scientific and Technical Journal – *Indian Drugs* and a weekly communication medium IDMA Bulletin and various other prestigious publications such as the Annual Publication, Indian Herbal Pharmacopoeia, etc.

**INDIAN PHARMACEUTICAL ALLIANCE (IPA)**

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**ORGANIZATION CHART (IPA)**

Secretary General
\[ \downarrow \]
President
\[ \downarrow \]
Vice President
\[ \downarrow \]
Members
\[ \downarrow \]
Office Staff

Source: IPA Mumbai, 11th Oct.'06
The Indian pharmaceutical alliance is headed by the Secretary-General of the alliance. Besides it also has President, Vice President and office staff to support the functioning of the alliance.

"IPA was formed in November, 1999 with eight leading domestic pharmaceutical companies as members"\(^\text{16}\), has emerged as a credible, representative industrial body in the short span of its functioning, working closely with the government on policy matters and in unshackling the industry from redundant regulatory grips.

**ABOUT IPA**

The Indian Pharmaceutical Alliance (IPA) represents research based national pharmaceutical companies. It consists of the following members:

"Alembic Ltd.; Cadila Healthcare Ltd.; Dr Reddy's Laboratories Ltd.; Emcure Pharmaceuticals Ltd.; Glenmark Pharmaceuticals Ltd.; Lupin Limited; Matrix Laboratories Ltd.; Ranbaxy Laboratories Ltd.; Sun Pharmaceutical Industries Ltd.; Torrent Pharmaceuticals Ltd.; Unichem Laboratories Ltd.; USV Limited; Wockhardt Limited"\(^\text{17}\).

"Collectively, their R&D spend at over Rs 1,500 crores in the year ended March 2005, accounted for 90% of the total private sector spending in pharmaceutical research and development. These national companies exports of drugs and pharmaceuticals are estimated at Rs 5,600 crores, that is more than one-third of the country's exports of drugs and pharmaceuticals, and they service over 30 percent of the domestic market."\(^\text{18}\)

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\(^{16}\) Information accessed through mail, dgshah@vision_india.com on 11\(^{th}\) Oct.'06 (Ms Fernandes, Office Staff).

\(^{17}\) Information accessed through mail, dgshah@vision_india.com on 11\(^{th}\) Oct.'06 (Ms Fernandes, Office Staff).

\(^{18}\) Ibid.
The main aims of the Indian Pharmaceutical Alliance are: Partnering the
government in the evolution of a patent regime that will on the one hand meet
the TRIPs obligations and on the other serve national interest; Engaging the
government in constructive dialogue to move to price management from price
control regime for the benefit of the consumer; Working with the government
in progressively upgrading regulatory provisions, procedures and standards for
harmonization with those of the developed markets.

The Indian Pharmaceutical Alliance, works closely with Government on
policy related matters and seek to imbibe the experiences of the generic
pharmaceutical industry internationally. "It is affiliated to the International
Generic Pharmaceutical Alliance (IGPA) located at Brussels which collectively
represents a significant cross-section of the global pharmaceutical industry".\(^\text{19}\)
The main objective of IGPA is to promote international pharmaceutical
harmonization and regulatory decisions in a way that will benefit the public
and strengthen the industry.

\(^{19}\) Ibid.
The working of IFPMA is divided among the council, the ICH Secretariat and the Secretariat. The Council consist of President, Vice-Presidents and members. The ICH secretariat has – Secretary (part time) and Coordinator (GCG & Med. DRA affairs). The secretariat is the principal body which takes all policy decisions of the IFPMA. It is headed by the Director General, who in turn is assisted upon by various Directors – Regulatory & Scientific Affairs, International trade and market policy, Communications, Biological & Vaccines, Administration & Finance, Japan Liaison Executive...
and Health Care Systems. Besides this, the Secretariat has various support staff – Personal assistant to Director General & Meetings, Receptionist & Secretariat, Policy Analysts, Administrative Assistant, Communications Manager, Research Analyst for International trade and market policy.

**International Federation of Pharmaceutical Manufacturers Association (IFPMA)**

"Created in 1968"\(^{20}\), The International Federation of Pharmaceutical Manufacturers Association, is a non-profit, non-governmental Organization (NGO) representing national industry associations and companies from both developed and developing countries. Member companies of the IFPMA are research based pharmaceutical, biotech and vaccine companies.

"In the research and development pipe-line, the pharmaceutical industry is working on more than 700 new medicines and vaccines"\(^{21}\), for infectious diseases including HIV/AIDS, cancer, heart disease and stroke, and diseases that disproportionately affect women, such as osteoporosis.

The Main Objectives of IFPMA are: "to encourage a global policy environment that is conducive to innovation in medicine, both therapeutic and preventative, for the benefit of patients around the world; to promote and support principles of ethical conduct and practices voluntarily agreed upon as exemplified by the IFPMA code of pharmaceutical marketing practices; to promote and support the adoption of high standards of manufacturing practices and quality assurance for pharmaceutical products; to contribute industry expertise and foster collaborative relationships and partnerships and non-governmental organizations, national institutions, government's and NGOs that are dedicated to the improvement of public health, especially in developing and emerging countries; and to assure regular contact and experience-sharing and

\(^{20}\) IFPMA website http://www.ifpma.org, accessed on 10\(^{th}\) Nov.'06.

\(^{21}\) Ibid.
coordinate the efforts of its members towards the realization of its objectives.\textsuperscript{22}

The pharmaceutical industry, represented by IFPMA, is committed to the research and development and quality manufacturing of innovative therapeutic medicines that save lives, reduce overall health care costs and improve the quality of life of people around the world.

The industry strives to create a global environment that fosters: innovation in preventing and curing diseases; drug regulation that expedites approvals of new chemical and biological treatments for patients and assures the availability of genuine quality medicines; patient access to innovative therapies and protection from substandard and counterfeit products; market based competition in the health care sector; and, the dissemination of drug information and ethical promotion of drugs to medical professionals and to patients.

\textbf{Activities and Achievements}

- Fact-gathering and analysis of the policy issues of major importance to industry

- Advocating policies supporting intellectual property protection, market competition, drug regulation and access to information about new therapies

- Encouraging measures consistent with the objectives of industry and patients stated above;

- Co-ordinating and leading member association and industry efforts to achieve an environment conducive to therapeutic innovation and competition.

- Providing timely information to its members; and

\textsuperscript{22} Ibid.
• Diligently overseeing the implementation of the IFPMA code of pharmaceutical marketing practices.

IFPMA has achieved consultative status with the United Nations and international organizations such as: "WHO, WIPO, WTO, UNCTAD, UNIDO, ECOSOC and UNICEF"\(^{23}\)

IFPMA has five working committees\(^{24}\):

• Innovation, intellectual property and trade committee (IIPT)
• Partnerships, public health & advocacy committee (PPHA)
• Health Care Systems Committee (HCS)
• Regulatory policy and Technical standards committee (RPTS)
• Biological and vaccines committee (B&V).

CORPORATE SOCIAL RESPONSIBILITY

Pharmaceutical industry, through its voluntary initiatives, has not only become a leading CSR performer but an emerging key player in the area of global health. Its combined contributions (monetary, in-kind donations, expertise, know-how etc.) make a real difference worldwide for millions of people in need and are comparable in scale with efforts led by the international organizations and governments.

The IFPMA also works in close partnership with the WHO to improve drug quality and fight counterfeiting around the world.

The IFPMA Secretariat handle complaints of alleged violations of the IFPMA code of pharmaceutical marketing practices. IFPMA continues to

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\(^{23}\) IFPMA website http://www.ifpma.org, accessed on 18\(^{th}\) Feb.,'07.

\(^{24}\) Ibid.
support self-regulation as the most appropriate mechanism for regulating marketing and promotional practices by companies.

IFPMA has commissioned studies regarding the possibilities of key developing countries to develop their own R&D based pharmaceutical industry. These studies have found that such countries can make a significant contribution to global pharmaceutical R&D, including for diseases which particularly affect developing countries.

IFPMA continues its dialogue with international partners, especially WIPO and WHO, concerning how pharmaceutical information can be distributed responsibly and appropriately via the Internet.

News and Publications

Geneva Forum: Towards global access to health. The forum brought together health related IGOs, NGOs and industry, to discuss access to health in poor countries.

Asia Conference: Intellectual Property, Innovation & Health, Singapore, 23-24 August. This IFPMA-sponsored event focused on how Asian Countries can promote and nurture a culture of innovation for pharma and biotech.

IFPMA Forum: IP & Innovation Beijing, China 16-17 Oct.'06. Innovation Pharma industry featuring IP enforcement and the pharma industry.

Publications

In 2003, IFPMA Published
1. HIV/AIDS. Combining Innovation and Access.
2. Neglected diseases and the pharmaceutical industry.

25 IFPMA website http://www.ifpma.org, accessed on 5th Dec'07
3. Joining forces for health and development by VFA the German Association of Research Based Pharmaceutical companies.

4. Value of vaccines

5. Biodiversity resources, traditional knowledge and innovation in health.


7. Encouraging Pharmaceutical R&D in developing countries.


9. TRIPS, Pharmaceuticals and developing countries. Implications for healthcare access, drug quality and drug development.

10. Encouragement of new clinical drug development, the role of data exclusivity

**In 2004, IFPMA Published**

1. PhRMA Global partnerships brochure.

2. Building Healthier Societies through partnership.


4. R&D for neglected diseases: Lessons learned and remaining challenges.

5. Joining forces for change: The pharmaceutical industry in fight against HIV/AIDS.


7. Myths and Realities on prices of AIDS drugs

**In 2005, IFPMA Published**

1. A review of existing data exclusivity legislation in selected countries.
2. Joint position on the disclosure of clinical trial: Information via clinical trial, registries and databases.

3. Building Healthier Societies through partnership.

*In 2006 IFPMA Published*

1. Partnership to build healthier societies in the developing world.

2. R&D for neglected diseases, lessons learned and remaining challenges.

3. Conclusions and recommendations of the WHO international conference on combating medicine, declaration of Rome.

4. Adaptive innovation, intellectual property and the public interest: How patent extension leads to more better and safer medicine.