CHAPTER-3
REGULATORY ASPECTS
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CENTRAL DRUG STANDARD CONTROL ORGANIZATION (CDSCO)

Historical Perspective

In the beginning of the current century drug industry was practically non-existent in India and Pharmaceuticals were being imported from abroad. The First World War changed the situation and not only were finished and cheap drugs imported in increasing volume, the demand for indigenous products also was voiced from all sides. With the clamour for swadeshi goods manufacturing concerns, both Indian and Foreign, sprang up to produce pharmaceuticals at cheaper rates to compete with imported products. Naturally some of these were of inferior quality and harmful for public health. The Government was, therefore, called upon to take notice of the situation and consider the matter of introducing legislation to control the manufacture, distribution and sale of drugs and medicines.

"Two of the laws, the poisons Act and the Dangerous Drugs Act were passed in 1919 and 1930 respectively. The Opium Act was quite old having being adopted as early as 1878. But to have a comprehensive legislation, with rapid expansion of the pharmaceutical production and drug market required by the end of the second decade for its control, the Indian Government appointed, a Drug Enquiry Committee in 1931 under the chairmanship of Lt. Col. R.N. Chopra"¹, which was asked to make sifting enquiries into the whole matter of drug production, distribution and sale by inviting opinions and meeting concerned people. The committee was asked to make recommendations about the ways and means of controlling the production and sale of drugs and medicines.

¹ Law Relating to Drugs and Cosmetics. CDSCO website, (cdSCO.nic.in) accessed on 28.9.2006
pharmaceuticals in the interest of public health. The Chopra Committee toured all over the country and after carefully examining the data placed before it, submitted a voluminous report to Government suggesting creation of drug control machinery at the centre with branches in all provinces. For an efficient and speedy working of the controlling department the committee also recommended the establishment of a well-equipped central drug laboratory with competent staff and experts in various branches for data standardization work. Under the guidance of the Central Laboratory, it was suggested, small laboratories would work, in the provinces. For the training of young men and women, the committee recommended the permission of Central Pharmacy Council, and the provincial pharmacy councils, with registrars who would maintain the lists containing names and addresses of the licensed pharmacists.

The outbreak of the second world war in 1939 delayed the introduction of legislation on the lines suggested by the Chopra Committee which the Indian government contemplated and considered as urgent. However, "the Drugs Act was passed in 1940, partly implementing the Chopra recommendations. With the achievement of independence in 1947 the rest of the required laws were put on the Statute Book. In 1985, the Narcotic Drugs and Psychotropic substances Act was enacted repealing the Dangerous Drugs Act 1930 and the opium Act of 1878."²

Presently, the following Acts and Rules made there under govern the manufacture, sale, import, export and clinical research of drugs and cosmetics in India:- "The Drugs and Cosmetics Act, 1940, the Pharmacy Act, 1948, the Drugs and Magic Remedies (Objectionable Advertisement) Act, 1954, the Narcotic Drugs and Psychotropic substances Act, 1985, the Medicinal and Toilet Preparations (Excise Duties) Act, 1956, the Drugs (Prices Control) order, 1995 (under the Essential Commodities Act)."³

² Law Relating to Drugs and Cosmetics, CDSCO website, (cdsco.nic.in) accessed on 28.9.2006.
³ Ibid.
CHART-A: ORGANISATION CHART (CDSCO)
Directorate General of Health Services/ Central Drug Standard Control Organization
Drug Controller General (India)

Headquarter
- Jt. Drugs Controller (I)
- Dy. Drugs Controller (I)
- Asst. Drugs Controller (I)
- Technical Officer
- Sr. Technical Asst.
- Supporting Staff

Zonal Officers (4)
- Dy. Drugs Controller (I)
- Asst. Drugs Controller (I)
- Drugs Inspector
- Sr. Technical Asst.
- Supporting Staff

Sub-zonal Officer (2)
- Asst. Drugs Controller (I)
- Technical Officer
- Sr. Technical Asst.
- Supporting Staff

Port/Airport Office (7)
- Asst. Drugs Controller (I)
- Technical Officer
- Sr. Technical Asst.
- Supporting Staff

Laboratories (6)
- Director
- Dy. Director
- Sr. Scientific Officer (I)
- Sr. Scientific Officer (II)
- Research Officer
- Sr. Scientific Asst.
- Jr. Scientific Asst.
- Supporting Staff

North Zone: Ghaziabad
- Ahmedabad
- Hyderabad

South Zone: Chennai

East Zone: Kolkata

West Zone: Mumbai

Source: www.cdsco.nic.in (website of CDSCO)

Abbreviation: CDL: Central Drug Laboratory; CIPL: Central Indian Pharmacopoeia Laboratory; CDTL: Central Drug Testing Laboratory; RDTL: Regional Drug Testing Laboratory; Website: www.cdsco.nic.in (accessed on 16.9.2006).

*Not under CDSCO **To start shortly

*CDL: Kasauli
*IVRI: Izzatnagar
*NIV: Noida
**RDTL: Chandigarh
Central drugs standard control organization (CDSCO) functions under the Directorate General of Health Services with Drugs Controller General as its head. There are various divisions and sub-divisions within CDSCO to carry out the smooth functioning of its activities. It is divided into Headquarters, four zonal offices at Ghaziabad (North Zone), Chennai (South Zone), East Zone (Kolkata) and West Zone (Mumbai), two sub zonal office's at Ahmedabad and Hyderabad, seven Port/Airport office's at Ahmedabad, Chennai, Kolkata, Delhi, Kochi, Naraseva and Mumbai and six laboratories at Kolkata, Ghaziabad, Mumbai, Chennai, Guwahati and Chandigarh. All these divisions and sub-divisions comprises of various officials such as Joint Drugs Controller, Deputy Drugs Controller, Asst. Drugs Controller, Technical Officer, Sr. Technical Assistant, Supporting Staff, Drug Inspector, Director, Deputy Director, Sr. Scientific officer, Research Officer, Sr. Scientific Asst. and Jr. Scientific Asst., who carry out the day to day functioning of the organization.

SOME OTHER LAWS

There are some other laws which have a bearing on pharmaceutical manufacture, distribution and sale in India. The important ones being:

"The industries (Development and Regulation) Act, 1951, the Trade and Merchandise Marks Act, 1958, the Indian Patent and Design Act, 1970, Factories Act." 4

CENTRAL DRUGS CONTROL ADMINISTRATION

Under the Drug and Cosmetics Act, the regulation of manufacture, sale and distribution of Drugs is primarily the concern of the state authorities while the central authorities are responsible for approval of New Drugs, Clinical Trials in the country, laying down the standards for Drugs, Control over the quality of imported Drugs, coordination of the activities of State Drug Control

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4 Law Relating to Drugs and Cosmetics CDSCO website, (cdsco.nic.in) accessed on 28.9.2006
Organizations and providing expert advice with a view of bringing about uniformity in the enforcement of the Drugs and Cosmetics Act.

Drug Controller General of India is responsible for approval of licenses of specified categories of Drugs such as blood and blood products, I.V fluids, vaccine and sera. To regulate Indian Pharma industry different apex organization's have been formed. Some of them are as- Central Drug Standard Control Organization (CDSCO).

Central Drug Standard Control Organization (CDSCO) is located at New Delhi and functions under the Directorate General of Health Services.

Its senior officers include:– Drugs Controller General of India, Deputy Drugs Controllers, Asst. Drugs Controllers, Technical Officers.

DRUGS CONTROL ADMINISTRATION

Functions Undertaken by Central Government
(Statutory Functions)

"Laying down standards of drugs, cosmetics, diagnostics and devices, laying down regulatory measures, amendments to act and rules, to regulate market authorization of new drugs, to regulate clinical research in India, to approve licenses to manufacture certain categories of drugs as Central License Approving Authority i.e. for Blood Banks, large volume parenterals and vaccines and sera, to regulate the standards of imported drugs, work relating to the drugs technical advisory board (DTAB) and Drugs Consultative Committee (DCC), testing of drugs by central drugs Labs, Publication of Indian Pharmacopoeia, coordinating the activities of the state drugs control organizations to achieve uniform administration of the Act; and Policy guidance, Guidance on Technical matters, participation in the WHO GMP Certification Scheme, Monitoring adverse drug reactions (ADR), conducting training programmes for regulatory officials and Govt. Analysis, Distribution of quotas of narcotic drugs for use in medicinal formulations, Screening of drug formulations available in Indian Market, Evaluation/Screening of
applications for granting No objection certificates for export of unapproved/banned drugs". 5

FUNCTIONS UNDERTAKEN BY STATE GOVERNMENTS

Statutory Functions

"Licensing of drug manufacturing and sales establishments, Licensing of drug testing laboratories, Approval of drug formulations for manufacture, Monitoring of quality of drugs and cosmetics manufactured by respective state units and those marketed in the state, Investigation and prosecution in respect of contravention of legal provisions, administrative actions, pre and post licensing actions, recall of sub-standard drugs". 6

ACTIVITIES OF CDSCO

National Good Clinical Practice (GCP) Workshops

"To meet this requirement Drugs Controller General of India (DCGI) under the WHO-Biennium 2004-2005 [coordinated by Mr. Sunil Nandraj, (WHO- India Office) awarded the Department of Clinical Pharmacology, TN Medical College & BYL Nair Hospital, Mumbai, (under the guidance of Dr. Urmila Thatte, Professor & Head)] the task of preparing GCP training modules for the various stakeholders involved in the conduct of clinical trials and pilot testing these modules. Workshops were held in the month of April 2005, with the primary aim of developing and validating the training materials."7

Following the successful testing of the training modules, the department was requested by the Drugs Controller General of India (DCGI) to coordinate the conduct of 9 different workshops for the various stakeholders across the country. These workshops were held in different cities having local coordinators who organized the workshops.

Table-7: Budget Allocation Directorate General of Health Services (DGHS)

(Value in Rs. Crore)

<table>
<thead>
<tr>
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<tr>
<td></td>
<td>Plan</td>
<td>Non-plan</td>
<td>Total</td>
<td>Plan</td>
<td>Non-plan</td>
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<tr>
<td>2210</td>
<td>1.26</td>
<td>14.68</td>
<td>15.94</td>
<td>2.0</td>
<td>15.0</td>
</tr>
</tbody>
</table>

BUDGET ALLOCATION

The budgetary allocation of Directorate General of Health Services (DGHS) in 2002-03 was Rs. 1.26 crore plan expenditure and Rs. 14.68 non-plan expenditure with total plan outlay for the year at Rs. 15.94 crore. In 2002-03, the plan expenditure rose to Rs. 2.0 crore as against Rs. 1.26 crore in the previous year and for the non-plan expenditure it rose marginally to Rs. 15.0 crore as against Rs. 14.68 crore in prior year and a total budget outlay for the year 2003-04 stood at Rs. 17.0 crore. In 2004-05 there was a decline in plan expenditure to Rs. 1.60 crore from Rs. 2.0 crore in previous year. But, the non-plan expenditure went up sharply to Rs. 17.10 crore as against Rs 15.0 crore in the previous year and the total outlay also increased by 1.70 crore as against previous year and went upto Rs. 18.70 crore. However, in 2005-06, there was no change in budget outlay for the year as compared to prior year. In 2006-07, the plan outlay declined to Rs. 1.30 crore as against Rs. 1.60 crore in 2005-06. However, non-plan expenditure went up to Rs. 19.16 crore as against Rs. 17.10 crore compared to previous year, with total outlay for the year going up to Rs. 20.46 crore as against Rs. 18.70 crore compared to previous year.

Indian Drug Policy – A Backdrop

"The development of Indian Pharmaceutical industry during the protected regime from seventies to nineties is much due to the drug policy in which the report of the Hathi Committee (1975) is an important landmark". The Hathi Committee in particular emphasized the need for achieving self-sufficiency in medicines and ensuring abundant availability of essential medicines at reasonable prices. "Since 1975, the Indian Pharmaceutical Industry has grown to be the most diversified and vertically integrated

pharmaceutical Industry in the entire third world". The country has achieved self-sufficiency in formulations and also in a large number of bulk drugs.

The main objectives of the Drug Policy of 1986 which was titled as measures for rationalization, Quality control and growth of drugs pharmaceuticals Industry in India were:

Ensuring abundant availability, at reasonable prices of essential and life saving and prophylactic medicines of good quality, strengthening the system of quality control over drug production and promoting the rational use of drugs in the country, creating an environment conducive to channelising new investments into the pharmaceutical industry with a view to encourage cost-effective production with economic sizes and introducing new technologies and new drugs, and strengthening the indigenous capability for production of drugs.

**History of Drug (Prices Control) Order (DPCO)**

"Drug prices have been under government control since 1970 under the drug (Price control) order 1970. Successive orders have been issued in 1979, 1987 and 1995 with more liberalized and industry oriented view". While issuing these orders, it was also kept in the mind that the Indian pharmaceutical industry undergoes transformation from process to patent era. "On this date, only 74 drugs are covered under DPCO".

DPCO controls the domestic prices of major bulk drugs and their formulations with an aim to provide patients with medicines at affordable prices. It is applicable only to allopathic drugs where DPCO ascertains the bulk drugs (and their formulations) to be kept under price control.

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11 NPPA website accessed on 28.9.2006 http://www.nppaindia.nic.in
DPCO came into being for the first time in 1970. At that time, the Indian pharmaceutical industry predominantly comprised of multinational (MNC) affiliates and subsidiaries. In its introductory form, DPCO was more of a control on the profitability of a pharmaceutical business, and thereby it directly sought to control the prices of pharmaceuticals. Also, with individual product prices not requiring approval from the government, bureaucratic hurdles were relatively low. The Indian Patents Act 1970 gave an impetus of local players to reverse engineer drugs and foray into various therapeutic segments. "Overall, the Indian Pharmaceutical industry prospered from 1970 to the next DPCO in 1979".12

In its 1979 - revised version, the DPCO stipulated ceiling prices for controlled categories of bulk drugs and their formulation. In fixing the price, the Government continued to advocate profitability ceiling. In the case of bulk drugs, this was through a limit on the company's return on net worth or capital employed.

"The drugs price control order, 1995 is an order issued by the Government of India Act, 1955 to regulate the prices of drug."13 Its basic structure remains same as that under the prior two orders of '79 and '87, but it did liberalize the span of control considerably. For the purpose of implementing provisions of DPCO, powers of the government have been vested in the National Pharmaceutical Pricing Authority (NPPA).

13 Ibid, p. 68.
"National pharmaceutical pricing authority (NPPA) was established on 29th August, 1997, as an independent body of experts as per the decision taken by the cabinet committee in September 1994 while reviewing Drug Policy. The NPPA is governed by the provisions of Drug Policy, 1994, and DPCO, 1995."\textsuperscript{14}

The authority, inter alia, has been entrusted with the task of fixation/revision of prices of pharmaceutical products (bulk drugs and formulations), enforcement of provisions of the drugs (price control) order and monitoring of the prices of controlled and decontrolled drugs in the country. The organization is also entrusted with the task of recovering the amounts overcharged by the manufacturers for the controlled drugs.

The main functions of NPPA are to:

"Implement and enforce the provisions of the drugs (price control) order in accordance with the power delegated to it; Deal with all legal matters arising out of the decisions of the authority; Monitor the availability of drugs, identify shortages, if any, and to take remedial steps; collect/maintain data on production, exports and imports, market share of individual companies, profitability of companies etc., for bulk drugs and formulations; undertake and/or sponsor relevant studies in respect of pricing of drugs/pharmaceuticals; Recruit/appoint the officers and other staff members of the Authority, as per rules and procedures laid down by the government; Render advice to the central government on changes/revisions in the drug policy; and render assistance to the central government in the parliamentary matters relating to the drug pricing, to fix/revise prices of bulk drugs and related formulations. The NPPA is empowered to take final decisions, but subject to review by the government, as and when considered necessary, to update the list under price

\textsuperscript{14} NPPA website accessed on 28.9.2006, http://www.nppaindia.nic.in
control by inclusion and exclusion of drugs on the basis of the established criteria/ guidelines, to monitor the prices of decontrolled drugs and formulations".\textsuperscript{15}

**Specific division wise duties and powers of officers are as follows:**

**Bulk Drug Division:** Bulk drug division handles the work relating to collection and compilation of data relating to bulk drug and fixation/revision of bulk drug prices.

**Formulation Division:** Formulation division handles the work relating to collection and compilation of data relating to formulation and fixation/revision of formulation prices.

**Monitoring & Enforcement Division (M&E):** M&E division handles the work relating to collection and compilation of data relating to monitoring of schedule and non-schedule formulations based on ORG IMS retail store audit report and based on price list in form V. This division also examine overcharging cases based on reference received from state drug controllers, NGO or complaint received from VIPs.

**Legal & Overcharging Division:** Legal division handles the work relating to court cases, legal matters arising out of decisions of NPPA. The recovery of overcharged amount along with interest as per the provision of drug price control order 1995 and essential commodities act 1955.

\textsuperscript{15} NPPA website accessed on 28.9.2006, http://www.nppaindia.nic.in
National pharmaceutical pricing authority (NPPA) is headed by its Chairman and has various other functionaries to discharge the duties such as member secretary, advisor (pricing). Besides there are several Director's – Administration division and monitoring and enforcement division, legal and overcharging division, formulation division and establishment division. There are also two Deputy Director's – technical and cost, one under secretary (administration) and section officer. All decisions relating to price fixation/price revision of bulk drugs and formulations are taken in the meeting of the authority which comprises – Chairman and member secretary (NPPA),
Ex-Officio members, Drug Controller General of India, Chief Advisor (Cost), besides Advisor (Department of Economic Affairs).

**ACTIVITIES AND ACHIEVEMENTS**

"The NPPA has fixed/revised the prices of scheduled drugs in 315 cases which includes 170 bulk drugs and 145 derivatives of scheduled bulk drugs and 4692 formulation since its inception. In the year 1999, NPPA fixed ceiling/non-ceiling prices of some drug formulations. It also notified the bulk drug prices of 15 bulk drugs. In the year 2000, retail prices of 68 formulation packs including ceiling prices was fixed/revised. During the year NPPA fixed/revised prices of 295 formulation packs. It also revised the price of 20 bulk drugs. NPPA brought out frequently asked questions (FAQ's) relating to drug pricing matters for information of general public. In 2001, NPPA revised drug price of 22 bulk drug. It also revised/fixed prices of 447 formulations. During the year NPPA prepared consolidated list of ceiling prices of scheduled formulations. In 2002, NPPA revised the price of 10 bulk drug. It also fixed/revised prices of 189 formulations. Govt. of India, Department of chemical and Petrochemicals announced pharmaceutical policy 2002. During the year NPPA sponsored a study on availability and prices of medicines in India to a NGO, namely, Voluntary Organization in interest of consumer education (VOICE), which was conducted in U.P. and Karnataka. In 2003, prices of 35 scheduled bulk drug was revised. NPPA also fixed/revised price of 391 formulations. In 2004, NPPA fixed/revised prices of 45 bulk drugs and 213 formulation packs. It also notified norms of Packing Material Cost under DPCO. During the year NPPA also notified norms for conversion cost, packing charges and process loss and also notified non-ceiling packs in imported formulations. In 2005 NPPA revised prices of 18 scheduled bulk drugs. It also revised/fixed prices of 720 formulations. Prices of 47 bulk drugs was also fixed/revised. During the year grievance cell was also set up and information relating to right to information act, 2005. NPPA also revised the norms for conversion cost, packing charges,
process loss and packing material cost. In 2006, prices of 78 bulk drugs and 1018 formulations packs was fixed/revise’d. \(^{16}\)

### Table-8: Budget Allocation (NPPA)

**Head wise Breakup of NPPA (2005-06)**

<table>
<thead>
<tr>
<th>Head</th>
<th>Amount (Rs. Lakhs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salaries</td>
<td>154.35</td>
</tr>
<tr>
<td>Wages</td>
<td>6.50</td>
</tr>
<tr>
<td>O.T.A.</td>
<td>1.35</td>
</tr>
<tr>
<td>Medical Treatment</td>
<td>10.00</td>
</tr>
<tr>
<td>Domestic Travel expenses</td>
<td>11.00</td>
</tr>
<tr>
<td>Foreign Travel expenses</td>
<td>6.30</td>
</tr>
<tr>
<td>Office expenses</td>
<td>260.00</td>
</tr>
<tr>
<td>Rent, Rate and Taxes</td>
<td>91.00</td>
</tr>
<tr>
<td>Other administrative expenses</td>
<td>4.50</td>
</tr>
<tr>
<td>Professional services</td>
<td>40.00</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>585.00</strong></td>
</tr>
</tbody>
</table>

Source: RTI act 2005, NPPA website accessed on 29.6.2007

**Budget Allocation (Summary)**

The budgetary allocation of National Pharmaceutical pricing authority (NPPA) is divided under the following heads- salaries constitute Rs. 154.35 lac which is 26.38% of the total budget and is the second highest head after office expenses. Wages constitute Rs 6.50 lac which is 1.11% of the total budget other traveling allowance (OTA) is Rs. 1.35 lac which is 0.23% of the total budget. Medical treatment constitute Rs. 10.0 lac which is 1.71% of the total budgets. Domestic and foreign travel expenses constitute Rs. 11.00 lac and Rs. 6.30 lac respectively, which is 1.9% and 1.07%, of the total budget. Office expenses constitute the largest head of Rs. 260.0 lac which is 44.4% of the total

\(^{16}\) NPPA website archive year 1999-2006, (accessed on 21.9.2006) http://www.nppaindia.nic.in
budget. Besides rent, rate and taxes constitute Rs. 91.0 lac which is 15.5% of the total budget. Other administrative expenses and professional services constitute Rs. 4.50 lac and Rs. 40.0 lac, respectively which is 0.76% and 6.8% of the total budget.

**Publication**

NPPA compendium has been brought out by NPPA in 2006 and its second edition in 2007. Attempt has been made to compile the prices of scheduled bulk drugs and formulations based on Gazette notification and price orders relating to fixation/revision of prices.

**Pharma Export Promotion Council (Pharmexcil):** "The pharma export promotion council (Pharmexcil) having its HQ’s at Hyderabad and Regional Offices at Mumbai and Delhi, was set up by the Ministry of Commerce and Industry, Govt. of India, on 12th May 2004"\(^\text{17}\), with the objective of:-

a. Facilitation of export of drugs, pharmaceutical, biotechnology product, herbal medicines, diagnostics.

b. Export thrust to various products through workshops, conferences and seminars and delegate visits.

The pharmexcil will represent the pharma industry in the Board of trade under the ministry of commerce and industry and will regularly address the emerging issues. "The board of pharmexcil constitute 25 Govt. officials and 23 members from trade councils which may include the chairman"\(^\text{18}\).

Pharmexcil is supposed to take care of drugs and pharmaceuticals including intermediaries, herbal, ayurvedic, unani and biological products, diagnostics, surgicals, nutraceuticals, pharma industry related services,

\(^{17}\) ITP division, Ministry of External Affairs, Govt. of India, 11 Nov., '07.

collaborative research, contract manufacturing, clinical trials and consultancy operations.

In order to make the pharma exports competitive, the council has urged the union commerce ministry to include expenses incurred on patent registration in the market access initiative (MAI) fund, in view of the TRIPS compliance regime in the country and most of the other prospective markets. The council organized a foreign trade officials – industry meet and took feedback from the exporters on various schemes under the MAI and market Development Assistance (MDA) for further enhancing the scope of these export incentives.

"In 2004 the government announced to pump in nearly Rs. 450 crore in the medium term for export marketing and sales promotion activities for various export sectors". According to the council, the revamped MAI scheme will focus on sustained export promotion efforts, rather than one-time projects like participation in an overseas trade fair. Individual exporters could access the scheme of registration of pharmaceuticals, bio-tech. products in select markets, whereas the rules for MDA have been tightened to get a better value for money. "The MDA is meant for small exporters with a turnover upto Rs. 5 crore per annum, will now fund only promotion efforts aimed at Latin America, African, CIS and Asean markets".

The Netherlands based KLM Cargo in alliance with European drugs distribution major OPG group has launched their integrated export services solution for Indian pharmaceutical exporters recently. With the tie-up, KLM Pharma Cargo would offer the members of pharmexcil cost effective and value added services.


As part of exploring global opportunities, the council leads delegations to various export markets. "The council now claims that the industry response to the new export promotion body has been encouraging and in few months time it has been able to secure the memberships of more than 800 members".  

In addition to this, Pharmexcil have action plans in different operational segments of the industry as:

- Technological upgradation, research and development, policy initiatives, promotion measures.

**PHARMACEUTICAL EXPORT PROMOTION CELL**

The export promotion cell in the pharmaceutical division acts as a nodal agency in matters related to export of pharmaceuticals. In order to give adequate attention to day-to-day problems faced by exporters, the cell interacts with various ministries/ departments and missions abroad. The cell also collects statistical data on export and import of pharmaceuticals in the country and provides useful information on developing and increasing drugs and pharmaceuticals export.

The cell also conducts seminars and workshops on standards, quality control requirements *etc.*, of important countries so as to prepare domestic companies for exporting their products. The cell communicates with Indian Missions abroad and collect information related to pharmaceutical industry in these countries, such as, status of the pharmaceutical industry, details of documentation, guidelines for licensing of pharmaceutical companies, as well as registration for medicines, details of healthcare system, health indicators and prevalent disease pattern, details of imports of pharmaceuticals of these countries, details of joint venture units for pharmaceuticals operating in these countries, *etc*. The information so collected is passed on to the industry/ exporters for boosting pharmaceutical exports.

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EXIM POLICY 2002-2007

The government of India has announced on 31\textsuperscript{st} March, 2003 the latest policy package relating to the Exim Policy. The salient features of this policy are enumerated in the table below:

- "The policy aims at minimizing procedural hassles to boost exports to take India's share in global exports to one percent level by 2007 from the present 0.67 percent. This calls for an annual export growth of 12 percent."\textsuperscript{22}

- "The new policy offers an incentive to pharmaceutical companies in the form of 50% reimbursement of fees for registering products abroad. This is a positive step in view of considerably high registration fees incurred by the companies for registration of products in different countries. This may enable companies to register more products and cover more countries."\textsuperscript{23}

- "The policy also provide duty free import facility to the extent of 10% of the average foreign exchange earned in the preceding three licensing years."\textsuperscript{24}

- "On duty entitled passbook (DEPB) scheme, the government would provide facility for provisional DEPB rate introduced to encourage diversification and promote export of new products."\textsuperscript{25}

- "Export oriented units (EOUs) have been exempted from specific export obligations and are now only required to be net foreign exchange earners, bringing them on par with special economic zones (SEZs)."\textsuperscript{26}

- "The export obligation under the export promotion capital goods (EPCG) scheme has been changed from five times the value of capital goods

\textsuperscript{22} P. Francis, Chronicle Pharmabiz, Mumbai, Dec. 2, 2004, p. 56.
\textsuperscript{23} 37\textsuperscript{th} Annual Report 2002-2003, OPPI, p. 32.
\textsuperscript{24} Ibid.
\textsuperscript{25} Exim Policy Calls on 12% export growth, Chronicle Pharmabiz, Mumbai, Dec. 2, 2004, p. 56.
\textsuperscript{26} 56\textsuperscript{th} Indian Pharmaceutical Congress, Chronicle Pharmabiz, Mumbai, Dec. 2, 2004, p. 56.
imported to eight times the duty saved, which is likely to reduce the export obligations. 27

- "Import of spares has been allowed as also import for pre-production facilities. Under the DEPB scheme, the sales from domestic area to a SEZ will be treated as exports and will entitle the supplier to export benefit such as exemption on central sales tax (CST) and service tax." 28

- "Domestic sales by SEZ units will be exempted from special additional duty (SAD). The incentives to EOUs would go a long way in boosting the pharma sector where the contribution from EOUs is significant." 29

- "Another highlight of the policy is developing a scheme for EOUs with features similar to the SEZ regime in selected sectors with capital investment in plant and machinery over Rs. 25 crore." 30

- "The focus on African and CIS countries for market development is a step in right direction. Focus programme would be another morale booster for the Indian pharma sector which is increasingly looking at tapping the unregulated markets in this region." 31

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28 Ibid.
29 Ibid.