

47TH ANNUAL REPORT – 2007-08

DRAFT NATIONAL PHARMACEUTICAL POLICY 2006

IDMA had submitted various representations to the concerned departments including the GoM on the adverse implications of the Drug Policy and also highlighted the dangers of cost based price control and the benefits of price monitoring.

The fourth meeting of the GoM was held on 30th April 2008 to consider the National Pharmaceutical Policy 2006. However, the GoM has not been able to arrive at any decision due to major differences among the stake-holders on several proposals especially on the issue of bringing more medicines under price control. The Law Ministry has asked the Group of Ministers (GoM) on Pharmaceutical Policy to approach the Supreme Court (SC) again to ascertain if the 354 drugs identified by the Chemicals Ministry as essential medicines actually qualify as such and need to be subjected to price control by Government.

Department of Pharmaceuticals formed

The Government of India has set up a new Department – '**Department of Pharmaceuticals**' under the Ministry of Fertilizers, Chemicals and Petrochemicals to solely look after Pharmaceutical Sector. It will be the administrative authority for the National Pharmaceutical Pricing Authority (NPPA) for all matters relating to price control of essential drugs and monitoring of markets. All matters relating to drugs and pharmaceuticals, except those specifically allotted to other departments would come under the purview of the new department. Mr. Ashok Kumar (Former Chairman of NPPA) has taken over as the Secretary of the new Department of Pharmaceuticals. We have congratulated him and have invited him to Mumbai for an interactive meeting with our members.

Department of Pharmaceuticals wants DCG(I)'s & NPPA office under its ambit

The newly-formed Department of Pharmaceuticals which feels that if the DCG(I)'s office presently under the Ministry of Health and NPPA under the Ministry of Chemicals and Fertilizers is brought under one roof it would result in better compliance with price-control norms. The Association feels that status quo would be in the best interest of the country and the industry.

Working Group on Branded Generic Drugs constituted by Department of Pharmaceuticals

The Department of Pharmaceuticals informed us that a Working Group on Branded Generic Drugs has been constituted to popularize the Generic Drugs in the country. The Working Group will also make recommendations regarding reasonable trade margins for Branded Generic Drugs. The Working Group would comprise of the following representatives:

Joint Secretary (Pharma)	Chairman
DCG(I)	Member
Representative from M/o H&FW	Member
Representative from NPPA and NIPER	Member
One representative from each Industry Associations (viz. IPA/IDMA/CIPI/SPIC)	Member
Dy. Secretary (Pharma)	Convener

Department of Pharmaceuticals scheme for opening Retail Outlets for sale of unbranded Generic Drugs in various Districts

The Department of Pharmaceuticals proposed to open generic drug stores in each district of the country to ensure affordable medicines to the poor section of the Society. The Department has decided to constitute a joint forum comprising of various public sector companies, NGOs and manufacturers' Associations to implement this scheme. Mr. N.I. Gandhi, Past President and Chairman of IDMA Pricing Sub-Committee has been nominated to represent IDMA at this forum. The Government has identified over 300 drugs in 16 therapeutic areas to be sold through the proposed generic stores. 25% of the drugs will be sourced from the pharma companies in the public sector and the remaining from the private sector.

Competition Law

The Competition Act (yet to be notified) has recently been amended (2007) introducing more 'teeth' in the Act. Mr. Vinod Dhall, Acting Chairman, Competition Commission of India (CCI) had called a meeting of IDMA, OPPI, and IPA on 8th April 2008 to brief the amendments. The salient features of the briefing are:

1. The Competition Act as amended is far more effective than the MRTP Act, which will be superseded. The MRTP Commission will be given time (about 2 years) to decide pending cases. No new cases will be sent to them. Instead the CCI will deal with all new cases.
2. The CCI is not a regulator, i.e. it does not fix 'prices of services'. It is a sort of reference with punishment powers; and act when things go wrong.
3. The CCI will deal with anything that goes against competition and free trade. It will act whenever there is an 'abuse of dominant position' and will regulate 'combinations' (mergers and amalgamations), and both horizontal as well as vertical arrangements wherein competition is affected.
4. Trade Associations have a special responsibility in that it should see that its members are fully conversant with the provisions of the Competition Act. Special briefing can be requested from the Commission.
5. Trade Associations should guard against any 'collusive' activity by the Association or its members. For example they should not discuss or encourage matters such as price fixing,

collusive deals, production restrictions, or anything that goes against competition and fair trade.

6. Associations should draft a Code of Conduct and advise members to adhere to it with the goal of promoting competition and fair trade.

A note on the amendments had been published in IDMA Bulletin for members' information.

Central Drugs Authority (CDA)

The Parliamentary Standing Committee on Health and Family Welfare, which has been examining the Drugs and Cosmetics (Amendment) Bill 2007 seeking to set up the Central Drugs Authority (CDA), has rejected the proposal as per newspaper reports. The Committee has recommended that instead of entrusting entire powers of the State licensing authorities with the CDA, four zonal officers of the CDSCO should also be made licensing authorities for the respective regions.

PRICING

Mr. A.K. Banerjee, New Chairman of NPPA

Mr. A.K. Banerjee has taken over as the New Chairman of NPPA in place of Mr. Ashok Kumar during the year. As per usual practice we have congratulated him and also informed him that IDMA has always worked very closely with NPPA in the interest of the patients as well as the National sector Pharmaceutical Industry.

CC, PC & PL Norms and Packing Material Costs

We have been informed by NPPA that the Pharma manufacturing units & companies are to furnish the information / data to NPPA (as per the questionnaire provided by NPPA) in a soft copy on a Compact Disk (CD) along with duly signed hard copy as also the copy of the Annual Report of the company for the last 2 years i.e. 2005-06 and 2006-07. The last date for submission was 31st January 2008. On the basis of our request the date was extended to 28th February 2008. Finally the NPPA has fixed/revised the norms for Conversion Cost, Packing Charges, Process Loss and Packing Material on 13th August 2008. The same was published in IDMA Bulletin for information of all members.

33 Bulk Drug prices reduced on suo-moto basis –

NPPA had revised the ceiling prices of 33 bulk drugs vide their order No. PN/99/2008/NPPA dated 20th March 2008. In this regard we had submitted a representation to the Chairman, NPPA on 14th May 2008 drawing his attention to the suo-moto price reduction for 33 bulk drugs due to revision in the excise duty/CVD and weakening of the US dollar. In response to our representation we received a reply from NPPA informing us that while carrying out the price revision they had

taken into consideration the changes in the rate of excise duty/CVD and various other factors like strengthening of US dollar, etc. However, they had invited IDMA President for a meeting with Mr. G.S. Sandhu, Jt. Secretary, C&PC on 26th June 2008 at Delhi and also requested to inform our member-companies that those who are affected by the price reduction in respect of the 33 bulk drugs and desirous of seeking price increase, should furnish necessary data and justification in support of the claim. Accordingly IDMA requested all members to furnish the necessary data. In this regard a preparatory meeting was also held on 20th June 2008 in IDMA conference room to discuss the points to be raised at the meeting with Mr. Sandhu at Delhi on 26th June 2008.

The President led a delegation comprising senior members viz., Mr. N.I. Gandhi, Mr. D.B. Mody, and Mr. P.C. Godha assisted by our Delhi office for a meeting with Mr. G.S. Sandhu, Joint Secretary (PI), Dept. of C&PC on 26th June 2008 at Delhi. Mr. Paresh Johari and Mr. S.K. Sharma, Deputy Secretaries from C&PC and from NPPA Mr. Arun Jha Member-Secretary, Mr. A.K. Singhal Advisor, Mr. B.K. Pandey, Director and Dy. Directors Mr. Jagdish Kumar and Mr. Manish Goswami were also present. Mr. N.I. Gandhi made a detailed presentation requesting an *ad hoc* price increase of 25% on all APIs (Active Pharmaceutical Ingredients) falling under the scheduled category and at least 20% increase in all scheduled formulations to tide over the crisis arising out of the unprecedented rise in prices of raw materials and input costs such as APIs, Excipients, packing materials, etc. A detailed representation containing the above facts was also submitted to him.

We also requested for an increase of 10% on notified prices of bulk drugs as the present system of price revision by NPPA is bureaucratic and needs to be discontinued; and an automatic system linked to inflation as well as increase in prices of important materials and utility items should be introduced.

So far no response has been received from the Government. However, Department of Pharmaceuticals has indicated to the Industry to file individual applications for an upward price revision of products and assured such applications will be disposed off immediately. NPPA has subsequently been revising prices of Bulk drugs and formulations periodically. The same have been published in IDMA Bulletin from time to time for information of members.

Undue increase in prices of Basic Chemicals by PSUs

Prices of some of the basic chemicals viz., formic acid, sodium nitrite, acetic acid, etc. manufactured by PSUs i.e. Rashtriya Chemicals and Fertilizers Ltd. (RCF) and Gujarat Narmada Valley Fertilizers Corporation (GNFC) have gone up substantially. This has led to considerable additional burden on the bulk drug manufacturers, many of whose products are under price control under DPCO 1995. In this regard we had submitted a representation to the Hon'ble Minister of C&F, Mr. Ram Vilas Paswan and Mr. Narendra Mody, Chief Minister of Gujarat State on 15th and 17th July respectively, requesting them to take up the matter with the concerned PSUs.

Representation requesting increase in prices of formulations due to increase in prices of raw materials across the board

We had submitted a representation dated 4th July addressed to Mr. Paresh Johari Dept. of C&PC requesting him to increase prices of formulations due to increase in prices of raw materials across the board. As documental support to our request, we obtained data from the *Chemical weekly* issues of different months showing the steep hike of APIs between April and June 2008 and submitted with our representation for his ready reference.

Retrospective fixing of prices of bulk drugs and formulations by NPPA

A practice of recent origin of making prices fixed under the DPCO 95 of bulk drugs and formulations to be retrospectively applicable by NPPA had been brought to our notice by some of our members affected by this exercise.

In this regard we made a representation to the Chairman, NPPA on 23rd May 2008 informing him that the true and correct interpretation of the provisions of the DPCO particularly Para 14 which deals precisely with the subject of giving effect to the prices fixed in the official Gazette of bulk drugs or formulations.

Excise Duty reduced on Drugs and Pharmaceuticals from 8% to 4%

In order to mitigate the impact of world-wide economic turmoil and recession, the Prime Minister announced certain incentives and measures to lessen the impact on the Indian economy. As a part of these measures, the Central Excise Duty on Drugs and Pharmaceuticals was reduced from 8% to 4% and on Bulk Drugs from 14% to 10% (vide Notfn. No. 58/2008 CE dated 7 December 2008). (*Highlights of other measures/incentives are covered in Taxation Section*).

NPPA issues Advisories

Following the reduction in Excise Duty, NPPA issued an advisory (vide S. O. 2856 dated 10th December 2008) to reduce the MRP (inclusive of Excise Duty & all taxes) of all scheduled formulation packs by 2.84%.

This reduction was not applicable to those formulation packs for which no excise duty was paid.

NPPA also issued a Guideline for non-scheduled formulation packs (vide Guideline No. 5 dated 10th Dec. 2008) to reduce (inclusive of Excise Duty & all taxes) of all non-scheduled formulation packs by 2.84%. This was not applicable to those categories of non-scheduled formulation packs where no excise duty was actually paid to the Government.

Guidelines for complete Information in Form III

Internal Guideline No.3 dated 7th April 2008

As per Para 8(1) of DPCO, 1995, “the Government may from time to time fix the price of a scheduled formulation in accordance with the formula laid down in Para 7. Further, where the Government fixes or revises the price of any bulk drug under the provisions of this order and the manufacturer utilizes such bulk drug in the scheduled formulation he shall, within 30 days of such fixation or revision, make an application to the Govt. in Form – III for price revision of all such formulations and the Government may, if considered necessary, fix or revise the price of such formulations.”

The Form-III lays down the specific details which companies are required to submit while making an application for approval or revision of prices of the scheduled formulations. With reference to note-2 in Form-III of DPCO, relevant extracts of which are reproduced below:-

- (a) A statement indicating the purchases made during the last three months with copies of invoices certified by Cost Accountant / Chartered Accountant shall be enclosed.
- (b) Certified copies of recent batch production records or, in case production has not commenced, other documents maintained under Drugs and Cosmetics Act and the Rules made thereunder, in support of the quantities of raw materials claimed.

Further, as per para 8(4) of DPCO, the Government is required to fix a revised price of such formulation or reject the application for revision for reasons to be recorded in writing, within a period of two months from the date of receipt of complete information.

It is clarified that in the absence of complete information regarding purchase of bulk drug and major raw materials during the last three months alongwith the copies of invoices certified by Cost Accountant/Chartered Accountant alongwith all other information required under the DPCO, 1995, the application submitted for revision of the price shall necessarily have to be considered as incomplete. NPPA shall have no option but to reject such incomplete applications in Form-III as not being in conformity with the relevant provisions of DPCO 1995.

REGULATORY AND TECHNICAL

New DCG(I) – Dr. Surinder Singh

Dr. Surinder Singh took charge as New Drugs Controller India w.e.f 1st February 2008. We have congratulated him and also informed him that IDMA has always worked very closely with his office in the interest of the patients as well as the National sector of Pharmaceutical companies. We had a number of meetings with him on various vital issues in Mumbai, Delhi, etc.

DCG(I)'s new office

Office of the Drugs Controller General (India), the headquarters of the Food and Drug Administration (FDA), Government of India is now housed in a new Building 'FDA Bhavan' at Kotla Road, New Delhi.

IDMA Interactive Meeting with Dr. Venugopal Somani, Deputy Drugs Controller (India) West Zone held on 18th April 2008 in IDMA Office

IDMA had organized an interactive meeting with Dr. Venugopal Somani, Dy. Drugs Controller (India), West Zone on 18th April 2008 in IDMA office. A number of important issues were discussed and various industry problems regarding regulatory affairs were brought to his notice. Dr. Somani gave a patient hearing and appreciated the good work done by the Industry and promised support wherever possible.

DCG (I) Time Limits

Following our members' continued concern about the long delays in processing various documents and licenses with the Central Drug Control administration, we held meetings with the new DCG(I) and represented our case to him. The DCG (I) was very positive and has worked out time limits for various approvals as below, which considerably shortened the waiting periods.

<u>Description</u>	<u>Time Frame</u>
Form 10	: 4 weeks
Test Licence	: 4 weeks
Export NOC	: 2 weeks
Registration	: 12 weeks
Endorsement of additional product on registration	: 8 weeks
First response to new drug	: 6 weeks
Additional indication, etc.	: 4 weeks
FDC first response	: 6 weeks
BE Exports	: 6 weeks
Dual use – Rule 37 & Neutral code	: 3 weeks

Stamping/Affixing Stickers on the Labels of Medicines in certain circumstances

A representation was submitted to the DCG(I) on 31st December 2007 reminding him about our pending request in regard to guidelines to be issued for stamping/affixing stickers on the labels of medicines in certain circumstances in response to our representation of 24.10.2007 and a subsequent reminder on 5 June 2008. DCGI has categorically informed that although it is in the purview of the licensing authority to grant permission in such cases, it may not be possible for him to accept such a request where he has to confront the other government departments, i.e. NPPA, Deptt. of Revenue, etc. In very special cases, he may consider the proposal if request is made to him but he cannot issue any guidelines across the board.

Spurious Drugs Amendment Bill Passed

The Drugs and Cosmetics (Amendment) Act 2008 regarding enhancement of punishments for manufacture, or sale of spurious drugs had been passed in the Rajya Sabha on 21st October and in Lok Sabha on 23rd October 2008.

We made a detailed representation to the DCG(I) dated 14th November 2008 to rectify and clarify certain aspects in the amendments carefully while framing the Rules. In this connection a meeting was also organized by CIPI and FOPE in New Delhi with the DCG(I) on 15th November 2008. The DCG(I) exclaimed that the Industry did not take up the issue strongly though the Amendment Bill was pending for the last 3 years. He agreed to look into the genuine problems of the industry and assured that the genuine manufacturers will not be harassed. He requested IDMA to prepare a brief representation giving details of important provisions – implications and Industry suggestions. He also appreciated IDMA suggestions in preparing a manual giving guidelines for Drug Control officers throughout the country.

The Act received the President Smt. Pratibha Devisingh Patil's assent on 5th December 2008. As requested by DCG(I), IDMA made a representation on 22nd December 2008 with suggestions for providing safeguards for bonafide manufacturers.

Medical Devices - Framing Rules and Regulations

Joint Secretary Ministry of Health, Shri Debashish Panda held a meeting of different associations, lawyers and other stakeholders to consider framing of rules and regulations for medical devices on 11th Feb. 2008 at New Delhi. At present, there are no separate regulations for 'medical devices', as they are covered under the definition of word "drug" under Section 3 (b). However, since medical devices are more technology oriented than drugs (being a machine or apparatus) rules and regulations relating to drugs do not fully cover them. For example, while schedule M applies to pharmaceutical plants, there is no standardized regulations for medical devices. Ministry of Health & Family Welfare now wants to fill this gap. In this meeting several ideas were discussed. This is now under consideration of the Ministry and the DCGI's office.

Workshop Recommendations of the National Campaign on Quality Assurance of AYUSH Drugs – Reg.

We had received the workshop recommendations of the National Campaign on Quality Assurance of AYUSH Drugs held on 10th -11th June 2008 at Delhi. The Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy (AYUSH), Govt. of India, Ministry of Health and Family Welfare had requested us to send comments/suggestions, if any. The same was published in *IDMA Bulletin* for members to respond.

Indian Pharmacopoeia Commission – Autonomous status

Government of India has granted autonomous status to the Indian Pharmacopoeia Commission and the Central Indian Pharmacopoeia Laboratory (CIPL) merged with IPC.

Indian Pharmacopoeia 2007

The IP 2007 was released on December 2007 which was originally planned to be made effective from April 1, 2008.

We made a representation dated 25th February 2008 addressed to Dr. Nitya Anand Chairman and Dr. G.N. Singh, Secretary Cum Scientific Director, IPC Ghaziabad and to Dr. Surinder Singh, DCG(I) on 28th February 2008 requesting them to extend the effective date of implementation from 1-4-2008 to 1-7-2008 due to valid reasons. **As per our request, the implementation date was extended to 1-7-2008.**

We had received certain queries and comments on Indian Pharmacopoeia 2007 monographs from our members requiring clarifications and inputs. The same was forwarded to the Scientific Body of Indian Pharmacopoeia Commission on 6th February 2008 and also published in IDMA Bulletin for information of all members. Subsequently IPC has sent us a list of amendments incorporating our suggestions for consideration for inclusion in IP 2007.

We have also received the following lists from CIPL/IP Commission:

1. Proposed amendment list for IP 2007
2. List of New Monographs available for addendum (2nd draft)

These lists had been e-mailed to all members (and also published with an explanatory note in IDMA Bulletin dated 29th February 2008) with a request to send their suggestions / comments at the earliest to IP Commission with a copy to IDMA Secretariat.

Indian Pharmacopoeia Addendum 2008

Comments and Suggestions have been updated as on 26-5-2008 / revised as on 3-7-2008 by Indian Pharmacopoeia Commission. The monographs are available at the IPC website: www.ipc.gov.in

under “Monographs for Comments”. To finalize the IP Addendum 2008 and IP amendments 2007, a special meeting of interested parties under the chairmanship of Dr. R.S. Iyer was held in IDMA office on 1st and 2nd August 2008.

The IPC has already issued 4 drafts of the Amendments list and the final amendment list will be made available shortly. The IP Addendum 2008 is being planned to be released as early as possible and made applicable by January 2009.

The IPC has thanked the President, Secretary-General and IDMA’s Technical Sub-committee members for their assistance and support to IP Commission.

The Sub-committee had organized a meeting with Dr. G.N. Singh, Secretary-cum-Scientific Director, IP Commission, Ghaziabad, in IDMA Conference Room on 13th March 2008.

IDMA-APA PAC 2008

The eleventh IDMA-APA PAC 2008 was held on 10th and 11th October 2008 at Hyatt Regency, Mumbai. The theme of the year was “**New Product Development – From Conceptualization to Commercialization**”. Various important topics were also covered.

Mr. Habil Khorakiwala, Chairman, Wockhardt Ltd. was the Chief Guest. He inaugurated the Convention, released the Souvenir of PAC 2008, ***IDMA-APA Forum News Letter***, *Technical Monograph No. 3 “Investigation of Out of Specification (OOS) Test Results”* and *Technical Monograph No. 4 “Pharmaceutical Preformulation Analytical Studies”* were published and released at the PAC 2008.

A large number of enthusiastic participants representing Pharma Units from all over the country and over 50 invitees from regulatory, academic and industry fields participated.

The Guest of Honour Dr. Surinder Singh, DCG(I) and Mr. Debasish Panda Joint Secretary, Department of Health, Ministry of Health and Family Welfare graced the function and appreciated IDMA for organizing the 11th IDMA APA PAC 2008. They had a round of the exhibit area where a large number of sponsors had participated and displayed their equipments and services. The Guests and all the delegates were very appreciative of the equipments displayed.

Various Awards were presented to eminent scientists at the Convention as follows:-

Sl. No.	Name of Award	Recipient
1.	IDMA-APA Young Pharmaceutical Analyst Award	Dr. Ravishankara M.N. Assistant Manager, Analytical Development Dept., Sun Pharma Advanced Research Centre

2.	IDMA-APA Eminent Pharmaceutical Analyst Award	Dr. Saranjit Singh Dean, NIPER SAS Nagar
3.	IDMA-APA Outstanding Pharmaceutical Analyst Award	Dr. Vishwanath Balkrishna Malkar Head-Regulatory, Reliance Pharms. Pvt. Ltd.

The Convention was a stupendous success as in previous years. The proceedings were published in IDMA Bulletin for information of members.

INTERNATIONAL TRADE (Including Customs)

During the year a number of Open House meetings were held with the Chief Commissioners of Customs I, II and III. Various representatives from Industry and Trade participated in the meetings. Our representatives regularly attended the Regional Advisory Committee meetings for Organized Sector and Small Scale Sector.

Annual Supplement to Foreign Trade Policy 2008-09

IDMA had made few suggestions on Annual Supplement to the Foreign Trade Policy 2008-09 on 14th March 2008 to the Hon'ble Minister of Commerce and Industry drawing his attention to the suggestions made by IDMA regarding extension/withdrawal of the DEPB Scheme. In the representation we suggested that DEPB scheme is to be phased out only after a new substitute scheme is prepared and discussed with all the Councils.

Also, the 'Export Oriented Unit sunset clause' was to expire on 31st March 2009 and there was no sufficient time to the exporters to switch over to SEZ. If the exporters are not able to take timely decision, then the profits accrued on exports would have attracted income Tax @ 34%.

In response to our request the Government issued a communication vide Public Notice No. 133(RE-2007)/2004-2009 dated 29th March 2008 informing the following:

- **DEPB Scheme has since been extended beyond 31.3.2008 upto 31.5.2009**
- **Income Tax benefits to EOUs under Section 10B of Income Tax Act is being extended for one more year beyond 31.3.2009**

Expert Committee for Permission of Patents and Proprietary products - AYUSH reg.

IDMA, as a responsible industry association looking after the interests of Indian pharma industry strongly felt that this additional step will cause delay in granting permission to Patent & Proprietary Ayurvedic products and which will have adverse impact on the promotion of AYUSH products from India. The Government of India through all its Ministries encourages exports of AYUSH products,

and at the same time, such bureaucratic procedures were being added which would cause delay and in turn loss of business for AYUSH products. In this regard we had made representation to Mr. Shiv Basant, Jt. Secretary, Ministry of Health and Family Welfare, Mr. Rajiv Kher, Jt. Secretary, Ministry of Commerce and Mr. G.S. Sandhu, Jt. Secretary, Ministry of Chemicals and Fertilizers on 7th March 2008.

Hindrance faced by Members in respect of Import Clearance

An order issued by the Chief Commissioner of Customs, Mumbai I, to stop LUT registration of fresh Advance Licences, had been creating problems for our members at the JNPT in getting clearance of their imported goods lying with them. In this regard we had made a representation dated 26th February 2008 addressed to the Chief Commissioner of Customs, Mumbai-I requesting him to issue necessary instructions to their concerned departments to avoid any further inconvenience to our exporter-members.

Review of condition no. 6 of the registration certificate – Drugs and Cosmetics Act, 1940 and Rules 1945

Our members are facing a lot of problems due to cancellation of registration as per Rule 41, Para 6. This had been conveyed to the DCG(I) on 3rd January 2008. In this connection the Association had a meeting with the DCG(I) on 24th March '08 on the above subject. The DCG(I) agreed to look into the matter. He suggested to submit a representation containing problems in making registrations and delays faced by the manufacturers and suggestions if any. Accordingly we have submitted a representation dated 24th March 2008 with various suggestions as follows:

1. Samples tested at CDTL take more than 6 months delay in the process of registration. Further, CDTL sometimes do not have necessary testing instruments and the reagents to test the samples. Private approved laboratories should be recognized to test samples. Many times samples are tested after 3-6 months time. The industry is not aware of the storage conditions of samples at CDTL. Abnormal delay in testing the samples and inadequate storage conditions may result in samples failing in the moisture tests. In such cases companies have to resend the samples, which further delays the approval of the product. This can be avoided if samples are tested on time.
2. Registration of the product should be cleared within 9-12 months. In many case the query or requirement of samples comes from DCGI's office after 7-8 months. We request laying down of proper lead time norms for approval of samples.
3. DCGI's office has also cancelled the registration where a foreign manufacturer has more than one agent. This decision is arbitrary as no where such clarification was mentioned in the registration rule, as it is the prerogative of the overseas manufacturer to appoint one or more agent for their company's products.

Heavy shortfall in supply of Erythromycin Thiocyanate

There was heavy shortfall in supply of Erythromycin Thiocyanate. This raw material has been basically used as an intermediate for the manufacture of Erythromycin Salts, and higher macrolides like Azithromycin, Clarithromycin and Roxythromycin, which are front line antibiotics. The above raw material is being imported from various countries like USA, Poland, China, etc. The estimated total demand for Erythromycin Thiocyanate is 2700 / 2800 MT annually. However, the estimated supplies for 2008-09 is 1240 MT, i.e., a shortfall of 1500 MT. In this regard we made a detailed representation to the Drugs Controller General (India) on 13th June 2008 informing him that the quantities being supplied from the registered sources are limited in respect to the local demand. This will result in an acute shortage of Macrolides for domestic markets during the impending monsoon season. Hence, we have requested him to allow the clearance of all consignments of Erythromycin Thiocyanate on fast track basis of 7 working days as a special case till December 2008, with NOCs for all imports from Manufacturers whose registration is pending.

Sudden Stoppage of Supply from China

A few months prior to the Beijing Olympics, the supply of APIs and other raw materials from China dried up all of a sudden, as:

1. Many units in China closed down due to environmental reasons
2. Some of the units were manufacturing APIs without valid permissions
3. Much higher effluent discharge than permitted levels by the Government
4. Steep increase in prices of petroleum based items like Phenol, Benzene, Toluene etc., which are starting solvents and feedstock chemicals for production of most of the APIs.
5. Revaluation of Chinese currency vis-à-vis US\$ to the extent of nearly 15%
6. Increased cost of electricity in China

The stoppage in supply led to our manufacturers facing many hardships, as some products were being imported from China in large quantities and led to sudden and steep increase in prices of these APIs and chemicals, over and above the shortage.

Import of bulk drugs for 'Dual Purpose Use'

IDMA had submitted a representation dated 28th July 2008 to the DCG(I) requesting to clear import of bulk drugs for 'Dual Purpose Use'. In the representation we have included various suggestions to simplify the procedure of issuing the import permit for the bulk drugs used for manufacturing other bulk drugs, viz.,

- (A) If Applications made for import of bulk drugs for manufacturing other bulk drug had no formulations in India, these bulk drugs should automatically be removed from the dual purpose procedure.

- (B) When Applicant furnishes details along with flowchart, and if the chemical structure of the final product is changed, his office should immediately give clearance for the import permit for the bulk drugs for the purpose of manufacturing other bulk drugs.

We have also requested him to consider the following suggestions to stop importing bulk drugs from unregistered sources:

- (A) Importer should furnish to the Assistant Drug Controller at the customs, Registered Manufacturer Agent's Indent for clearing the import of bulk drugs for which Drug Controller General of India's office has given the permission in Form 41, where the agent's name is mentioned.
- (B) The above stipulation should also be applicable, if the shipment is made by Export agent of Registered Product as Agent of Registered Manufacturer is responsible for all the acts in India.

If the Drug Controller General's office implements these suggestions, it will ensure stoppage of import of bulk drugs from unregistered sources while paving the way for faster and smoother clearance of bulk drugs for import.

In this regard our Past President Mr. Anant Thakore had a fruitful meeting with the DCG(I) at Delhi on 8th August 2008. Accordingly, the DCG(I) has worked out a time frame for clearance of various applications. The same was published in IDMA Bulletin for information of all members.

Certificate of Pharmaceutical Product (COPP) registration to 5 years

We made a representation to Dr. Surinder Singh, Drugs Controller General (India) on 15th May 2008 that when the State FDA issues COPP after a joint inspection of the manufacturing facility by inspectors from CDSCO and State FDA, the validity of this COPP is for 2 years only. Re-inspection is required to get the new COPP, but many a times re-inspection is not possible in time (due to various constraints such as limited number of staff available, etc.) and hence an extension of COPP is sought.

Regulatory authorities in most of the countries do not accept COPP with a remaining validity of 6 months. This means that COPP is effectively valid only for 18 months. An extension of 6 months is given, but only after the completion of 2 years validity which is of no significant value and the registration process gets held up.

We have hence requested him to help the industry by way of considering to grant the COPP also for a period of 5 years (with a provision for inspection after every 2.5 years, if required). This will help to expedite the registration of Products and in-turn will help in boosting the nation's Pharmaceutical Exports.

It was also informed him that the product registration offered by majority of countries is valid for 5 years. The drug manufacturing license in India is also valid for 5 years.

IPR

Patent Linkage with Marketing Approval

The MNCs put tremendous pressure on the Government to link patent registration with marketing approval through out the year. The multinational companies wanted the Health Ministry to make it compulsory for the Drug Regulator to check the patent status before accepting applications for marketing approval. We in the IDMA expressed our grave concern to the Government. IDMA is totally opposed to this idea because this step can easily delay the Indian manufacturers' genuine application for marketing approval with no benefit either to the country or to the consumer. In this connection we have submitted a representation to DCGI.

The matter was pursued during a meeting organized by IDMA on 1st August 2008 at Mumbai with Joint Secretary Health Mr. Debashish Panda and the Drugs Controller General (India) Dr. Surinder Singh, who were visiting Mumbai during the period. The meeting discussed three matters, namely, (1) Patent linkage with marketing approval; (2) Data Protection and (3) Data Exclusivity.

On Patent linkage issue, Mr. Debashish Panda categorically stated that they had no plan to make grant of marketing approval dependent upon the patent status. He however wanted that the patent status should be indicated in the application for marketing approval. The Joint Secretary and the DCGI gave two weeks time for IDMA to write their position. Accordingly, we reexamined the issue and wrote a letter to DCGI on 19.8.2008. The main points were:

As required by item 1 (8) of Form 44, we have no objection for the applicants for marketing approval to write the patent status of the drug against this entry in the form. However, we opposed to putting the application on the web. Why should the whole world know that an application had been made on a particular molecule? We would like to make it clear that we were not opposed to the patent holder knowing that the application had been made; our concern was that the competitor in the market should not know it.

Since we did not approve of putting this information on the web, the question whether there should be a waiting period of one month or 15 days does not arise. There should be a fixed time limit of 30 days for the issuance of marketing approval.

Data Exclusivity

There was no further development on the Satwant Reddy Committee report. For all practical purposes the report has been filed at least for the time being.

Patents Manual

The Government (Controller General of Patents) prepared and circulated a draft Patent Manual in April 2008 and asked for suggestions from the stakeholders. IDMA submitted its detailed comments

to the Government on April 24, 2008. The suggestions were in areas (1) Patentability; (2) Pre-grant Opposition; (3) Compulsory Licences; and (4) Indian traditional knowledge. The DIPP and Controller Generals Office organized 4 separate workshops (In Delhi workshop we had furnished our comments) in Delhi, Mumbai etc. They have consolidated the suggestions and it is expected that the manual will be finalized by January 2009.

Meeting on Pharma pricing and regulatory frameworks for affordable medicines

The Department of Chemicals & Petrochemicals, the NPPA and the Department of International Development of UK held a one day seminar on 12th April 2008 on '**Pharmaceutical Pricing and Regulatory Frameworks for Affordable Medicines**'. As a preparation to this Seminar, a Round Table was also held a day earlier on 11 April 2008 in which only the Government participants and foreign experts participated (about 50 participants). IDMA and others were invited only to the Seminar. The most important thing was that the presence of President IDMA in the seminar was recognized by Chairman NPPA as well as the Minister. Joint Secretary Mr G.S. Sandhu invited the President to join the Minister for lunch at the head table. The Minister also appreciated his attending the seminar. There were some 200 invitees including people from foreign countries.

Chairman NPPA and Joint Secretary Mr Sandhu gave detailed presentations justifying price control by the Government. However, some of the important presentations from other countries did not support this concept. Mr. Charles Chift an expert invited by NPPA stated: "Cost plus system" does not encourage efficient production. This system also does not encourage R&D. Taking the specific case of India, he said the Cost plus price control was a "blunt instrument". The pricing policy is not only important for the common man but also because of the signals that it sends to the industry".

In UK there is pricing freedom except that the government possesses power to fix the upper ceiling. In France, there is a reference price mechanism and upper ceiling is fixed by the regulators on the basis of prices fixed across the country. In Turkey, pricing is based on competition and comparison. In the case of patented medicines, Turkey compares its prices with prices in France and UK.

It seemed that the Ministry had wanted to elicit expert opinion in favour of price control. But that did not succeed. This seminar was inconclusive.

Working Group on Patents, Designs and Trade Marks

The Consultative Working Group on Patents, Designs and Trade Marks has been functioning in FICCI for more than a year. This group was formed from among stakeholders with active participation by Department of Industrial Policy & Promotion (DIPP). Most meetings were chaired by Shri N N Prasad, Joint Secretary DIPP. On patent applications and on the working of the patent office, some important decisions were taken in several meetings of the Group during the year:-

- Digitization of patent application has been accepted and the patent applications can now be e-filed;
- A digital library is being set up for this purpose by the Controller General of Patents. All patent offices will have access to this digital library. At a suitable time, this access will be given to public also.
- Electronic transfer of patent records from one office to another has been agreed to.

The Consultative Working Group on Patents, Designs and Trade Marks asked for feedback on Patent and Trade Marks matters in June 2008, for being discussed and submitted to DIPP. IDMA participated and gave a detailed feedback to FICCI.

Efforts to bring in Bio-diversity and Traditional Knowledge elements in TRIPS:

The TRIPS agreement does not require a Patent Applicant to disclose the geographical origin of any biological matter used in that invention. Although there are some regulations on this subject in Convention on Biological Diversity (CBD-1992), they are not effective against somebody who uses 'biological material' or 'traditional knowledge' of some country to obtain a patent on that information.. The result is that people from advanced countries have been systematically stealing 'bio-diversity' or 'traditional knowledge' and then converting it into patents for commercial gain. The original country has no way of stopping such theft. India, on its own, has made it compulsory under the Indian Patents Act (Section 10 and 25) to make such disclosure in the patent application. If such disclosure is not made and if it is found that some bio material had been used, the patent can be annulled. However, since TRIPS does not require it, things are different in other countries. For example USA and the European countries do not require this information to be a part of the patent application. Similarly, this information is not required in a PCT (international patent) or PLT Application. Since the developing countries want to protect their bio-diversity and traditional knowledge from being stolen; India and other developing countries want an amendment in the TRIPs agreement for this purpose. Efforts were made during the year to sensitize people on this matter so that this item is incorporated in TRIPS.

Toxicity Data

There was a move from the office of Drugs Controller General (India) regarding the Toxicity Data to be furnished by second and subsequent applicant during Marketing Approval. Form No. 44 [Part B (b)] does require that toxicity data should be provide by every applicant. However, this has not been insisted upon by successive drugs controllers because it involves unnecessary duplication of effort and avoidable expenditure. (Toxicity data require Rs.40 to Rs.50 lakhs and 4 to 6 months time). Why should the Government insist upon it? Therefore, IDMA is opposing it. No decision so far.

Issue regarding Definition of Counterfeit Medicines

A meeting was held at WHO-IMPACT in Geneva on this issue. Dr. Praful Naik, Chief Scientific Officer and Executive Director of M/s. Bilcare Research, Pune, (An Associate Company Member of IDMA) represented IDMA & OPPI. He had a meeting with Dr. Valerio Reggi, Executive Secretary of WHO-IMPACT.

At the General Meeting of IMPACT held in December 2007, the Committee endorsed an updated definition on counterfeit medical product as below:-

“A **medical product** is counterfeit when there is a false representation in relation to its **identity, history or source**. This applies to the product, its container or other packaging or labeling information. However, quality defects or non-compliance with Good Manufacturing Practices/Good Distribution Practices (GMP/GDP) in legitimate, authorized medical products should not be confused with counterfeiting. For example,

- Any misleading statement with respect to name, composition, strength, or other elements
- Any misleading statement with respect to manufacturer, country of manufacturing, country of origin, marketing authorization holder
- (This refers to) ingredients or any other component of a medical product.

The revision aims at:

- a) Encompassing all medical products and not just medicines
- b) Forgery of documents
- c) Correcting an imprecision in the old definition which did not mention the case of active ingredients in excess of the amount declared.
- d) Declare explicitly that quality defects in authorized products is not counterfeiting

Mr. Ram Chander, Under Secretary, Department of Pharmaceuticals, solicited our views / comments. We submitted a representation with our views and suggestions to the DCG(I) on 5th September 2008.

Our main objection to the inclusion of the word ‘history’ in the definition of counterfeit medicine as proposed by WHO IMPACT was supported by DCG(I) and other NGOs and taken up strongly by Indian Government. This has now been accepted by WHO-IMPACT at its meeting on 5-7 December 2008 with 24 attending countries including the US, the UK, Canada, countries from the European Union, Brazil, Tanzania and Ghana, and WHO representatives. The Committee agreed to redefine the definition of ‘Counterfeit medicine’ after omitting the word ‘history’ in the definition and adopted a revised definition.

Enforcement of IP Rules by Customs Authorities by WCO

The World Customs Organization has formed a Working Group called 'Standards Employed by Customs for Uniform Rights Enforcement' [SECURE] to examine how to introduce uniform standards for enforcement of Intellectual Property rules by customs authorities. We along with other developing countries like Brazil, Argentina have been opposing IPR matters to be included in investigation powers to be given to customs authorities. This is a TRIPS Plus proposal and is aimed at discouraging competition from the developing countries. IDMA has sent a note to DIPP and Joint Secretary in Department of Revenue which deals with this matter in World Customs Union.

MEDICAL

Issue re Fixed Dose Combinations (294)

Dr. R.K. Sanghavi, Chairman of Medical Sub-Committee was selected as Chairman of the Screening Committee to represent the Industry, at the Industry Associations meeting with the DCG(I) on 10th June 2008. The meeting decided to examine the FDCs in question based on the scientific data and the Industry was asked to prepare the data to support its demand to manufacture and market these products. Another meeting was held on 14th July 2008 at the DCG(I)'s office. The Sub-committee Chairman, Dr. Sanghavi along with his team comprising of Dr V V Joshi, USV Ltd, Dr Jaideep Gogtay, Cipla Ltd Dr Aziz Keshwani, Alkem Ltd represented the Industry.

In this regard various meetings were held from time to time. The meeting on 1st October 2008 was attended by Dr Sanghavi and his team, senior officials and experts including Dr. Y.K. Gupta (HOD Pharmacology – AIIMS), FDA officials from Gujarat & Delhi and Consultant Physician from RML Hospital (Delhi) on the government side and representatives of all major organizations including IDMA, OPPI, SPIC, FOPE and CIPI.

At the meeting the 294 FDCs were re-classified as under:

<i>FDCs that are not to be discussed</i>	:	98
- Banned FDCs	:	17
- Grossly irrational FDCs that are to be discontinued	:	26
- Duplicated FDCs	:	32
- Already approved FDCs	:	23
<i>FDCs that are to be discussed</i>	:	190
- Similar FDCs already approved (SFAA)	:	48
- FDCs that need further examination	:	142
<i>Pre-1988 approved FDCs</i>	:	6

The Sub-committee presented the modus operandi of how to go about discussing the FDCs that need to be rationalized. At the meeting it was agreed upon by all present that six meetings are to be arranged at 2-monthly intervals starting the last week of November 2008. At each meeting about 25-30 FDCs will be deliberated. The entire process would be completed by August 2009. A final list of FDCs will be referred to DTAB for clearance.

Spurious Drugs

The Drugs and Cosmetics (Amendment) Act 2008 regarding enhancement of punishments for manufacture, or sale of spurious drugs was passed in the Rajya Sabha on 21st October and in Lok Sabha on 23rd October 2008. *(for more details please see under Regulatory and Technical)*

Constitution of Working Group on Branded Generic Drugs

The Department of Pharmaceuticals constituted a Working Group on Branded Generic Drugs. This Group will also make recommendations regarding a reasonable level of trade margins for Branded Generic Drugs.

Amendments to Schedule Y of the D&C Rules

We received the proposed amendments to be made to Schedule Y under D&C Rules from the DCG(I) broadly covering:-

- To make provision under the Schedule Y for concurrent Phase I clinical trials and microdosing studies in the country for new drug substances discovered outside India.
- Rationalizing requirements of Toxicology studies for new drugs by making them at par with international norms.
- To introduce separate "Appendix" for application for clinical trials as conduct of clinical trials may or may not be linked to the permission for marketing the drug in the country.
- Other minor changes pertaining to special studies in population follow up of adverse reactions etc.

In this regard a meeting of the Expert Group was held on 16th July 2008. Medical Sub-committee members Dr. Kiran Marthak and Dr. Arun Bhatt represented IDMA.

Most of the proposed amendments are desirable to bring Indian Regulatory requirements in line with the international regulations and guidelines. The proposed amendment will help the Indian companies to conduct cost effective studies in India and to gain valuable experience in clinical trials. The amendment will avoid unnecessary exposure of Indian subjects in a separate phase III trials and will allow rapid introduction of the drug in the Indian market. This will be a positive feature for overseas companies looking at India for clinical trials and marketing.

An Expert Group meeting was held at DCG(I)'s office, Delhi on 12th August 2008 to finalize the amendments to Schedule Y of the Drugs & Cosmetics Rules. In this regard we had submitted a detailed representation dated 8th August 2008 to the DCG(I) informing him among other things, that the rider on the IPR for the new drug substance to be 'owned by or assigned to an Indian company' or 'a valid agreement of the applicant with the holder of IPR for conducting Phase I studies....' etc., complicates matters unnecessarily. It was also informed to him that such a policy was not warranted and would not be of national interest. Dr. Dhananjay Bakhle, Medical Sub-committee member represented IDMA at the meeting.

In response to our suggestions they decided to drop the clause in question at the meeting held on 12th August 2008. It was also decided to provide for phase I trials, allowing global clinical trials data as part of study for registration in India, provision for microdosing studies etc.

We have thanked the DCG(I) on the proposed move vide our letter dated 1st September 2008 and also pointed out certain other requirements/ amendments.

The Medical Sub-committee had organized the following Congress / Workshops during the year:

- **'Coping With Patent Writing : Expand Your Intellectual Property'** on 9th and 10th May 2008 at Institute of Chemical Technology (UIC), Matunga, Mumbai
- **2nd Asia-Pacific Clinical Trials Congress - 2008 (2nd APCTC Conference)** successfully organized on 20th, 21st and 22nd November 2008 at Hotel Hyatt Regency, Mumbai. This is for the first time IDMA was organizing a 3-day event. The conference covered Phase I Studies: HIV/Oncologists, Vaccines, interpretation of Preclinical data for Clinical Development, Pharmaceutical Medicine as a subspecialty in Asia, Accelerating Clinical Research by newer methodologies, Issues in Clinical Trials in Complementary & Alternative Medicine, Biomarkers, Drug Safety Trials, etc.

MSME

IDMA's efforts for revival of CLCS Scheme for SMEs

The most popular scheme of CLCS scheme for SMEs for technological upgradation up to Rupees One Crore was earlier withdrawn by the Planning Commission. IDMA made suitable representation to the concerned authorities and has got the CLCS Scheme revived for the benefit of SMEs. Now under the scheme, SIDBI has started disbursing the funds.

Export Credit for SSIs

The Under Secretary, Mr. Ram Chander, Department of C&PC requested for our views on Lok Sabha Starred question No. 164 of 9.3.97 regarding Export Credit for SSIs. In this regard we submitted our views on 11th March 2008 as below:

Export orders from any SME enterprise to be treated differently, i.e.,

- a) Single window clearance of loans against export orders
- b) Separate consolidated loan facility to be available to any SMEs after confirming that enterprise's past twelve months' export performance.
- c) Separate terminology in banking such as 'CASH CREDIT ACCOUNT FOR EXPORTS ONLY' to be introduced with separate pass books. The interest rates on the said loan to be at par with PLR
- d) Any past or present NPA's must not hinder the SME from getting loan facility.
- e) Loan disbursement to be expedited and have a time element of not more than a fortnight.
- f) Any institution or Bank to confirm the genuineness of export order by faster means of communication like e-mail or telephonic conversation in the light of the present day upgraded facilities of telecommunications.
- g) The strength of any SME enterprise in the domestic arena to be appreciated. Institutions like SIDBI and Development Commissioner of SISI to play a major role even in sanctioning the domestic loans, subsequent to cancellation of CLCSS. (This was pointed out in last parliamentary members meeting in Mumbai by our executive committee member).

PTUF Scheme

The objective of the PTUF scheme is to assist the SSI units for the technological upgradation of their manufacturing facilities in compliance with the Good Manufacturing Practices (GMP) as per standards fixed by Union Health Ministry in Schedule M of Drugs and Cosmetics Rules, 1945. Under the scheme, the Government proposes to provide soft loans to the SSIs to upgrade their facilities.

The scheme assists the SME sector of pharmaceutical industry in upgradation of their Plants as per requirement of Schedule M and is applicable only to the projects with new machinery. The Government had been approached by various SSI Associations in a concerted move to request that the scheme should be extended to the entire purchase cost including plant and machinery.

We wrote on 14th November 2008 to the Development Officer, Central MSME Ministry requesting to provide the MSMEs, especially the SSI units, loan facilities under CLCSS and PTUF for upgradation of machineries, equipments, tools etc., as required under Schedule M. A list of such items was identified and forwarded along with the letter to the DO for urgent action.

Definition of small scale industries to be changed to MSMEs : Request to grant exemption from DPCO to Micro & Small Enterprises

As per SO No. 134(E) dated 2nd March 2008, certain exemptions were granted to SSI Units (subject to certain conditions) under para 25 of the Drugs Price Control Order (DPCO). One of the conditions is that a copy of the Registration Certificate - as a small scale industry - is to be submitted

to the Government within 60 days from the date of the notification in case of existing units and sixty days from the date of commencement of production in case of new units. Some of the units are not aware of this notification and have not availed of the exemption facility under para 8 of DPCO. The above notification requires a revision as the definition of small scale industries has been changed to MSME (Micro, Small & Medium Enterprises). As such, IDMA is making a representation to the newly formed Department of Pharmaceuticals to revise the above notification and request them to grant exemption from DPCO to all Micro & Small Enterprises, excluding the Medium sector.

Qualifying criteria for procurement of drugs and medicines through tenders by Government / Semi-Government bodies / PSUs

Indian Railways – Tender Application criteria

Indian Railways had been limiting applications for tenders from Pharma Companies having turnover of minimum Rs. 50 crores and above only. In this regard we had made a detailed representation to the Chairman, Indian Railways and the Hon'ble Minister of Railways on 23-7-2008, requesting that turnover should not be a criterion for procuring quality medicines and such limiting factors hinder the development and growth of our SMEs. It was also emphasized that all our SME members strictly adhere to revised GMP norms in producing quality affordable medicines.

SAIL's Policy to purchase Medicines based on ORG top ranking companies

Steel Authority of India (SAIL) had restricted their purchase of medicines (in tablet form) to the top 100 companies featuring in ORG's rankings and also restricted the tender applications for injectables to the top 200 companies. In this regard we made a representation to the Chairman of SAIL informing him that the above policy was highly discriminatory to many of our SSI members who comply with the strictest GMPs as per latest Schedule M guidelines and other quality norms. SSI manufacturers are the very life breath of our economy and hence should be given adequate and fair opportunity to compete and participate in the purchase of the tenders.

We requested the Competition Commission by representation dated 30th December 2008 to take notice of such anti-competitive practices by Railways, SAIL, etc. and take appropriate action as deemed fit.

Seminar on Export Opportunities

The Sub-committee jointly with Pharmexcil and IDMA TNSB organized a seminar on “**Export Opportunities for Pharma SMEs**” on 11th October 2008 in Chennai. The topics such as Export Marketing, Pricing, Audits, Registration, Banking and Incentives were covered. The seminar was well attended and appreciated.

EXCISE AND TAXATION

Union Budget 2008-09 announced on 28th February 2008

Reduction in Excise Duty from 16% to 8%

Our continued requests to reduce Excise Duty from 16% to 8% was accepted by the Finance Minister, Mr. P. Chidambaram in the Union Budget 2008-09. Members were requested to pass on whatever benefits available to the consumers. A downward revision in abatement from 42.5% to 35.5% was also announced. This would reduce the benefit of reduction in Excise Duty. NPPA worked out the actual reduction in ED to be 4.58%

CST reduced from 3% to 2% with effect from 1st June 2008

The Ministry of Finance had proposed in the Union Budget to reduce the rate of CST from 3% to 2% from 1st April 2008. We had requested the Finance Minister, P. Chidambaram to instruct his concerned officers to notify the reduction by way of a notification at the earliest. On the basis of our representation the Ministry of Finance issued a notification vide S.O.No. 1277 dated 30th May 2008 informing that CST has been reduced from 3% to 2% with effect from 1st June 2008.

Reduction in the rate of excise duty on medicinal and toilet preparations containing alcohol

Medicinal preparations containing alcohol are subject to excise duty under the Medicinal and Toilet Preparations (Excise Duties) Act, 1955. Such medicinal preparations are also subject to ad valorem duties. The rate of excise duty on such preparations was fixed at 16% ad valorem by issue of notification No. 1/2003-M&TP (F. No. 334/1/2003-TRU) dated 1.3.2003. The Finance Minister had announced in the current year Budget 2008-09 a reduction in the general rate of CENVAT from 16% to 14% and excise duty on medicines from 16% to 8%. The rate of excise duty on medicinal preparations containing alcohol was fixed at par with CENVAT rate of 16% ad valorem applicable to medicines not containing alcohol and the rate of CENVAT on pharmaceuticals, falling under Chapter 30 of the Central Excise Tariff had been reduced to 8% ad valorem. In this regard a representation on 17th June 2008 was made to the Chairman, CBEC requesting him to fix the rate of excise duty at 8% ad valorem on medicinal preparations containing alcohol to maintain the objective of parity.

The Central Government, in its drive to boost our economy further reduced the excise duty across the board by 4%. This effectively meant reduction from 8% to 4% on formulations and 14% to 10% on bulk drugs. This further complicated matters for M&TP manufacturers as M&TP was not covered in this exercise as it is a State subject. We sent an urgent appeal on 30th December 2008 to the Ministries of Finance and Commerce requesting for relief from the accumulated CENVAT credit as also to ensure that the prices of medicines under M&TP do not shoot up instead of coming down.

Our Consultant Mr. Shailesh Sheth made a presentation on the proposals regarding '**Indirect Taxation with greater emphasis on Service Tax – Budget 2008**' immediately after the EC meeting on 27th June 2008.

Section 10A

Section 10A of the Income Tax Act provides for deduction of such profit and gain upto 90% as are derived from an Undertaking established in a Free Trade Zone from the Export of Articles or Things or Computer Software for a period of 10 consecutive Assessment Years. Subsequently, the Govt. truncated this deduction and instead of allowing for deduction for 10 consecutive years, it has been decided to discontinue the deduction after the F.Y. ending 31st March 2010.

Special Incentives announced by Central Government

The Government of India unveiled a Rs. 300,000-crore fiscal package with specific measures for various sectors along with duty cuts on 7th December 2008 to boost the economy.

Some of the highlights are:

- A 4% cut in CENVAT to help corporate India in general and sops for exporters to stimulate growth.
- The measures for exporters, who saw a decline in shipments in October for the first time in five years, include interest support of two percent for labour intensive sectors.
- Additional allocation made towards various incentives for exporters, guarantee of export credit, full refund of service tax to foreign agents and refund of service tax under the duty drawback scheme.
- Instructions given to state-run banks to unveil a scheme under which borrowers for houses under two categories - up to Rs, 500,000 and up to Rs.2 million - will get special incentives.
- For small and micro enterprises, the limits under the credit guarantee scheme which gives access to working capital and other financial needs was doubled to Rs.10 million.
- The lock-in period for loans covered under the existing credit guarantee scheme reduced from 24 to 18 months to encourage banks to extend more loans under the scheme.
- Interest rate on post shipment export credit upto 180 days not to exceed BPLR minus 2.5%

TRADE EMPLOYEE RELATIONS

Trade Margins on Pharmaceuticals

The first meeting of Trade Margins on Pharmaceuticals was held at Delhi on 12th February 2008. IDMA was represented by President Mr. B.N. Singh, Vice-President (NR) Mr. N.R. Munjal assisted by Mr. G. Wakankar and Mr. S.K. Arya. The meeting was also attended by representatives

from AIOCD, CIPI and Small Scale Manufacturers Association. The meeting was inconclusive, but it was felt that price control on generic-generic drugs was inevitable.

FMRAI issues

The Federation of Medical and Sales Representatives' Associations (FMRAI) have been very active and becoming more aggressive. They are restricting the working hours of the Sales Promotion employees to 8 hours a day. This is hampering industry's business expansion plans. They have sought central Government's intervention in settling various issues, including amendment of section 2(j) of Industrial Disputes Act to accord workmen status to the sales representatives and also to make sales promotion joint responsibility of the employers and the employees. The FMRAI delegation has met Union Minister of Labour and Employment, Shri Oscar Fernandes.

Moreover, the FMRAI is planning to begin nationwide stir against the increase in prices of essential medicines and other issues related to the Pharmaceutical Industry. Their major demands are:

- To reduce the prices of all essential medicine and keep them under strict price control
- To revive all public sector medicines and vaccine producing companies
- To withdraw excise duty from all essential medicine
- To withdraw all irrational and harmful medicine
- To enforce Drugs and Cosmetics Act
- To withdraw amendment Bill on Drugs and Cosmetics Act 1940
- To develop ethical code for marketing of medicine, etc..

It is necessary that every member company should counsel their MRs and brief them about the exact situation regarding prices & availability of medicines. They should be told to act responsibly and not get carried away by FMRAI.

Request to remove Medical Representatives classification as Workmen from Sales Promotion Employees Act.

We submitted a representation to the Hon'ble Minister of Labour and Employment Mr. Oscar Fernandes requesting him to remove MRs classification as Workmen from Sales Promotion Employees Act as the duties and responsibilities of the MRs job clearly show that it is managerial in nature with a high level of responsibility and accountability, hence they should not be given additional protection through special legislative or Government intervention. We also requested him to grant us an appointment to explain the problem in detail.

Jointly with other Industry Associations we sought a meeting with the Union Labour Minister to impress upon him the need to remove Medical Representatives classification as Workmen from Sales Promotion Employees Act. We have also sought legal opinion on the above issue.

Trade related issues :

AIOCD affiliated associations are bypassing the MoUs between Trade and Industry and instead are following their own system of collecting PIS charges, NOC charges, Trade Margin, etc. In this regard we have requested vide our letter dated 19th May 2008 to the Hon. General Secretary to instruct their affiliated associations to strictly follow the MoUs.

AIOCD vide their letter no. AIOCD/SVD/08/Gen/1698 dated 28th June 2008 had requested us to inform them the problems faced by Industry on trade related matters. Accordingly, we had informed them the various issues which are adversely affecting our members due to unilateral decisions taken by State level AIOCD affiliated associations viz., PIS charges (Collecting PIS charges and not giving any publicity in their Bulletin), Trade Margins (some companies have been calculating trade margins inclusive of excise duty) Settlement of claims within 30 days, to absorb/ reimbursement of CST, demand for NOC money, etc. In this regard they promised to have a meeting with Office Bearers of AIOCD shortly to settle these issues.

New President and other Office-bearers of AIOCD

The new President and other Office-bearers elected for AIOCD for the period 2008-2011 are Mr. J.S. Shinde President, Mr. Parsan K. Singh (Patna) Hon. General Secretary, Mr. Gautam Chand Dhing (Ujjain) Organising Secretary, Mr. Bipin Mehta (Calcutta) Joint Secretary and the Mr. Vinay Shroff (Nandurbar) Treasurer. We congratulated the New President and the other Office-bearers of AIOCD.

QUALITY MANAGEMENT

IDMA Quality Excellence Awards 2007

IDMA Quality Excellence Awards were instituted in 1984, to assist, encourage, recognize, appreciate and nurture the quality excellence achievement among IDMA members. The awards were categorized as Gold and Silver. The units were also categorized as follows:-

Category: A) Formulations –

- (1) Annual Turnover between Rs. 25 & Rs. 100 crores
- (2) Annual Turnover above Rs.100 crores

B) Bulk Drugs – Annual Turnover above Rs. 100 crores

The assessment for the Awards was made with consensus among the visiting experts, using the transparent point rating system, points being assigned for various aspects like product development, GMP, GLP, Personnel, Environment, Stores, Manufacture, Quality assurance, etc. A total of 22 units had participated this year.

For the year 2007, the following firms were the recipients of the Awards:-

I CATEGORY FORMULATIONS

Annual Turnover between Rs. 25 & Rs. 100 crores

GOLD: Astral Pharmaceutical Industries, Vadodara

SILVER : 1. Charak Pharma Pvt. Ltd., Silvassa
2. Indchemie Health Specialties Pvt. Ltd., Daman

II Annual Turnover more than Rs. 100 crores

SILVER : Ajanta Pharma Ltd., Aurangabad
Alkem Laboratories Ltd., Daman
Micro Labs Ltd. (Ophthalmics) , Bommasandra
Micro Labs Ltd., Goa

Bulk Drugs Annual Turnover above Rs. 100 crores

SILVER: Calyx Chemicals & Pharmaceuticals Ltd., Tarapur

The Quality Management Sub-committee successfully organized a One day seminar on '**How Quality Pays**' on 23rd May 2008 at Mumbai. Dr. Surinder Singh, DCG(I) inaugurated the seminar and delivered the keynote address. A large number of delegates participated. The complete proceedings were made available on CD and were available at IDMA Secretariat. The seminar was a stupendous success.

BULK DRUGS

Sudden Stoppage of Supply from China

A few months prior to the Beijing Olympics, the supply of APIs and other raw materials from China dried up all of a sudden, as:

- Many units in China closed down due to environmental reasons
- Some of the units were manufacturing APIs without valid permissions
- Much higher effluent discharge than permitted levels by the Government
- Steep increase in prices of petroleum based items like Phenol, Benzene, Toluene etc., which are starting solvents and feedstock chemicals for production of most of the APIs.
- Revaluation of Chinese currency vis-à-vis US\$ to the extent of nearly 15%
- Increased cost of electricity in China

The stoppage in supply led to our manufacturers facing many hardships, as some products were being imported from China in large quantities and led to sudden and steep increase in prices of these APIs and chemicals, over and above the shortage.

Heavy shortfall in supply of Erythromycin Thiocyanate

There was heavy shortfall in supply of Erythromycin Thiocyanate. This raw material has been basically used as an intermediate for the manufacture of Erythromycin Salts, and higher macrolides like Azithromycin, Clarithromycin and Roxithromycin, which are front line antibiotics. The above raw material was being imported from various countries like USA, Poland, China, etc. The estimated total demand for Erythromycin Thiocyanate was 2700 / 2800 MT annually. However, the estimated supplies for 2008-09 was 1240 MT, i.e., a shortfall of 1500 MT. (*Further details under International Trade section*)

Import of bulk drugs for 'Dual Purpose Use'

IDMA submitted a representation dated 28th July 2008 to the DCG(I) requesting to clear import of bulk drugs for 'Dual Purpose Use'. In the representation we included various suggestions to simplify the procedure of issuing import permit for the bulk drugs used for manufacturing other bulk drugs. (*Further details under International Trade section*)

PUBLICATIONS

IDMA BULLETIN

IDMA Bulletin was published every week on time. Through this publication up-to-date information and data was disseminated on developments in the drug industry, Government regulations on pricing, customs duty, excise, import, export and all other aspects concerned with the drug industry including Parliament question and answers to all our members. Also the activities of the Association, representations made, new members inducted and all other developments were regularly reported.

INDIAN DRUGS

The technical and scientific journal of the Association; '*Indian Drugs*', a monthly publication, covering original research articles and review articles of current scientific interest to the drug industry was also published regularly on time.

ANNUAL PUBLICATION

The 46th Annual Publication 2008 was published with the theme "Indian Pharmaceutical Industry: Exciting Times Ahead". This compendium containing data on exports, imports, new drugs approved for marketing, patent expirations and various other useful data and information such as pharmaceutical trade statistics of all countries, alphabetical list of bulk drugs & formulations registered with DCG(I) for import into India, etc. was published on the occasion of the 46th Annual celebrations of the Association held on 11th January 2008 and was well received by all as a useful reference book.

OTHER IDMA AWARDS

IDMA RESEARCH PAPER AWARDS – 2007

In order to encourage R&D in the country, IDMA instituted "Research Awards" for the Best Original Research Articles published in the Association's scientific journal "*Indian Drugs*" every year, from the year 1981-82, in the following disciplines:

1. Pharmaceutical Chemistry
2. Pharmacognosy and Phytochemistry
3. Pharmaceutics
4. Pharmaceutical Analysis
5. Pharmacology

The Award is in the form of a Citation and a Cash Award of Rs. 2500/- in each Discipline.

Discipline	Title of the Article	Authors
PHARMACEUTICAL CHEMISTRY	Studies on Inclusion Complexes of Ziprasidone Hydrochloride with β Cyclodextrin and Hydroxypropyl β Cyclodextrin	Potnis V.V Deshmukh S.S Shelar D.B Mahaparale P.R
PHARMACOGNOSY AND PHYTOCHEMISTRY	Physico-chemical Evaluation of Lauha Bhasma and Mandura Bhasma	Sarkar P.K Prajapati P.K Choudhary A.K De S
PHARMACEUTICS	Release Characteristics of gentamycin from collagen – poly (ϵ -caprolactone) composite matrix	Ramesh D.V Sehgal P.K
PHARMACEUTICAL ANALYSIS	Simultaneous quantitation of estradiol and estrone in human plasma by LC-TMS with electrospray ionization	Dr. Shivprakash Shruti P Dasandi B Panchal A Jansari P Prasahanthkumar V
PHARMACOLOGY	The Role of Patient Education on the Quality of Life of Asthma Patients – A controlled study	Shabaraya A.R Vishnusharma M Rajendran S.D Suresh B

Review Article

Paper : Track-Etch Membranes (TEMs): Applications in Medicine and Pharmaceutical Technology
Author : Iyer R.H.

BEST PATENT AWARDS

The Association introduced this Award in 2001-02 with the following objectives:-

- a) To appreciate the talent of the large community of research scientists in the country
- b) To take note of the need for greater emphasis on innovative research for developing new drugs in India.

The winners of the **PATENT APPRECIATION AWARD 2007** were:

Natco Pharma Limited, Hyderabad

APL Research Centre, Hyderabad

IDMA G.P. NAIR AWARDS

Since 1970, our Association has been presenting every year the IDMA G.P. Nair Award to University students to encourage excellence in the Pharmaceutical profession.

25 candidates from 24 Universities listed here received the IDMA G.P. Nair Awards for having secured the first rank in their respective Universities.

SR. NO.	UNIVERSITY	CANDIDATE'S NAME
1.	Amravati University	Mr. Kamlesh Vilas Katkar
2.	Andhra University	Ms. Suparna Sarkar
3.	Annamalai University	Mr. D. Satheeshkumar
4.	Banaras Hindu University	Mr. Nitin Rai
5.	Berhampur University	Ms. Saraswati Panigrahi
6.	Birla Institute of Technology	Ms. Nidhi Sinha
7.	Devi Ahilya Vishwavidyalaya	Ms. Pooja Bhatia
8.	Dibrugarh University	Mr. Bhriagu Kumar Sarma
9.	Dr Harisingh Gour Vishwavidyalaya	Ms. Himanshu Mishra
10.	Gujarat University	Mr. Dhaval V. Madat
11.	Guru Ghasidas University	Mr. Ashish Jawalkar
12.	Jadavpur University	Mr. Sayantan Chattoraj

13.	North Maharashtra University	Mr. Harun M. Patel
14.	Panjab University , Chandigarh	Ms. Divya Pathania
15.	Punjabi University, Patiala	Ms. Amanpreet Kaur
16.	Rajiv Gandhi University of Health Sciences	Mr. Munjal J. Patel
17.	S.N.D.T. Women's University	Ms. Anjali Singh M.H.
18.	Sardar Patel University	Mr. Jigarkumar R. Patel
19.	Shivaji University	Ms. Farhat Shaikh
20.	The Maharaja Sayajirao University of Baroda	Mr. Sunil Patel
21.	The Tamil Nadu Dr. M G R Medical University	Dr. Ms. Roshini P.
22.	University of Kerala	Ms. Mahalakshmy R.
23.	University of Mumbai (B.Tech)	Ms. Sharddha Sadekar
24.	(B.Pharm)	Ms. Shabnam M, Golwala
25.	University of Pune	Ms. Nazneen Z Ratlamwala

MEMBERSHIP AND CONSTITUTION

During the year our Association has been very pro-active in enrolling new members. This year **19** ordinary and **9** Associate Company members were inducted. The total number of members at present stands at **591** as on date.

We are trying to find out ways and means to increase our membership strength by way of inducting bigger companies. We would organize periodical informal meetings of prospective members and discuss with them the latest issues affecting the Pharma Industry.

The President, assisted by the Secretary-General made a presentation on the achievements and initiatives of IDMA at the Haryana State Board on 26th September 2008. The presentation was well received by the State Board members and many of them have been eager to take membership with IDMA.

An interactive meeting was also held at IDMA Gujarat State Board members at Ahmedabad on 19th December 2008.

IDMA State Boards

As in previous years, all the four State Boards of IDMA viz., Gujarat, Haryana, Tamil Nadu and West Bengal functioned efficiently and in co-ordination with the Head Office.

MEMBERSHIP OF OTHER ORGANISATIONS

The Association is a member of following Organizations:

1. All India Organization of Employers
2. Employers' Federation of India
3. Confederation of Indian Industry
4. Federation of Associations of Small Scale Industries of India
5. Federation of Indian Chambers of Commerce and Industry
6. Indian Merchants' Chamber
7. Indian Pharmaceutical Association
8. Maharashtra Economic Development Council
9. Centre for Advancement of Philanthropy

REPRESENTATION ON GOVERNMENT COMMITTEES

1. It was a privilege for the Association to have interaction with a number of Government Committees directly concerned with the Pharmaceutical Industry. Members of the Association served on several such Committees, the important amongst which were:-
2. PMO's Task Force on Pharmaceutical & Knowledge based Industries
3. Expert Committee for comprehensive examination of drug regulatory issues including problems of spurious Drugs (Dr. Mashelkar Committee)
4. I.P. Working Group
5. Sandhu Committee constituted by the Department of Chemicals & Petrochemicals
6. Pharmaceutical Advisory Forum constituted by the Department of C&PC, Ministry of C&F.
7. Department of Pharmaceuticals scheme for opening Retail Outlets for sale of unbranded Generic Drugs
8. DoP Working Group on Branded Generic Drugs
9. DCG(I)'s Screening Committee to examine the contentious Fixed Dose Combinations
10. International Medical Products Anti-Counterfeiting Task force (IMPACT) - a WHO- WHA initiative
11. Working Group on Drugs and Pharmaceuticals for Eleventh Five Year Plan
12. Joint Committee to suggest proposals for National Pharmaceutical Policy 2006 constituted by the Minister of C&F and Steel

13. National Manufacturing Competitiveness Council (NMCC) –
14. Evaluation Committee formed by Dept. of Scientific and Industrial Research, Ministry of Science and Technology.
15. ECGC - Western Regional Advisory Committee, Mumbai.
16. Watchdog Committee of Customs, Mumbai
17. Open House Meet of Chief Commissioner of Customs, Mumbai
18. RAC meetings of the Chief Commissioner of Central Excise, Mumbai IV.
19. “Help Centre” Constituted by Central Excise Mumbai IV (For SSI members particularly for Excise related matters)
20. Ministry of Health’s Committee to suggest remedial measures to combat menace of spurious drugs.

We are also represented in other Committees such as:

21. FICCI’s Foreign Trade Committee
22. FICCI’s Health Services Committee
23. FICCI’s Pharmaceutical Committee
24. Confederation of Indian Industry’s - Pharmaceutical Committee

PUBLIC RELATIONS

Senior correspondents of various newspapers, financial journals and TV channels were briefed on a regular basis about the developments in the Industry. Background notes, Representations, comments and view points were also made available. Press Releases were also issued on important industry related matters. The same was duly published / covered by the media.

Special attention was paid to strengthen internal communications with member-firms through the medium of IDMA Bulletin, circulars, e-mails, website, informal get-togethers, etc.

At the 46th Annual General Meeting, the members present suggested that IDMA should make efforts to enhance the image of the Association as well as of the Pharmaceutical industry. There are misconceptions about the Indian Pharma Industry created by vested interests. To promote goodwill between IDMA and the public, media, NGOs, etc., we engaged a professional agency M/s. Newsmen Media Consultants, to publish rejoinders in news papers whenever an adverse comment is made against the Industry by NGO or Government Department/Minister/NPPA. The quotes / opinions of the President as well as the Secretary-General were given sufficient exposure in the media.

SOCIAL RESPONSIBILITIES

Bihar Flood Relief Work

This year also, many of the areas of Bihar and neighbouring States suffered tremendous hardship due to the havoc caused by floods due to the Kosi river changing course. As in the past, IDMA members spontaneously rose to the occasion by providing medicines through Indian Red Cross Society, Bihar, FDA Maharashtra, FDA Gujarat, etc.

SECRETARIAT

The Secretariat provided assistance to the Special Committees set up for specific purposes and to members in general. It also assisted actively in organizing conferences, seminars, workshops and training programmes. The Secretariat successfully co-ordinated members' efforts in making contributions towards social causes.

Delhi office

The Delhi office provided regular feedback on developments affecting the Pharmaceutical Industry and organized meetings for the President, Executive Committee members and members of various delegations. It also followed up on various matters concerning the National Pharma Industry with the various concerned Ministries, Members of Parliament, NPPA, DCG(I), DGFT, FICCI, CII, *WHO*, etc. apart from briefing them through periodical presentations.

EXECUTIVE COMMITTEE MEETINGS

The Executive Committee met 12 times during the period from 11th January 2008 to 19th December 2008 (November ECM was not held due to uncertainty in the aftermath of the terrorists attack in Mumbai) including One Emergency Executive Committee meeting to discuss about the likely implications of the New Drug Policy and IDMA's action plan.

An Informal get-together and dinner meeting was held on 25th July 2008 at Mumbai. An informative presentation was made on “**Addressing Business Challenges & Generating more Profits**” by Mr. Uday Shankar, Director (Sales & Marketing) of SpectraSoft Technologies Ltd., Bangalore & Mr. Uday Wagle (Channels Director – Medium Enterprises) of SAP India and IBM Ltd.

IDMA SEMINARS / WORKSHOPS

Date	Topic /Sub-committee /Place
4-4-2008	Generic Drugs : Opportunities, Challenges and Trends, Mumbai
9th&10th May 2008	Coping with Patent Writing: Expand your intellectual Property - UICT Mumbai – IDMA Medical and IPR Sub-committees in collaboration with UICT.
23-5-08	One day seminar – How Quality Pays - Mumbai – IDMA Quality Management Sub-committee
10-11th October'08	11th IDMA-APA PAC 2008
25-7-08	Informal Get-Together , Mumbai
26-9-08	Interactive Meeting - Chandigarh
11-10-2008	Export Opportunities for Pharma SMEs – Tamilnadu - IDMA TNSB jointly with Pharmexcil
20,21,22 Nov. 2008	2nd Asia-Pacific Clinical Trials Congress – 2008 – Mumbai IDMA Medical Sub-committee
19-12-2008	Interactive Meeting, Ahmedabad

MEETINGS

Date	Meetings / Subject
21-1-2008	Mr. V.S. Sampath, New Secretary Dept. of C&PC – Pharmaceutical Policy
11-2-2008	Mr. Debashish Panda, Jt. Secretary, Ministry of Health – To consider framing of Rules and Regulations for medical devices
12-2-2008	Mr.G.S. Sandhu, Joint Secretary (PI), Shri Ashok Kumar, Chairman, NPPA - First Meeting of Trade Margins, Pharma Policy, CC PC Norms, etc.
13-3-208	Dr. G.N. Singh, Secretary-cum Scientific Director, IP Commission – Effective Date of IP 2007
24-3-2008	Dr. Surinder Singh, DCG(I) – Review of condition no. 6 of the Registration certificate – Drugs and Cosmetics Act, 1940 and Rules 1945

25-3-2008	Mr. G.S. Sandhu, Jt. Secretary (PI) and Dr. Surinder Singh, DCG(I) – Pharma Policy 2006, Enhancement in abatement vis-a-vis Reduction in Excise Duty, Re-labeling of packs where excise duty has been reduced, FDCs etc.
8-4-2008	Mr. Vinod Dhall, Acting Chairman, Competition Commission of India – Competition Law amendment
18-4-2008	IDMA Interactive meeting with Dr. Venugopal Somani, Dy. DCI, West Zone – IDMA office
18-4-2008	Dr. Venugopal, Deputy Drugs Controller (India) West Zone – Interactive Meeting in IDMA office – Various regulatory issues.
15-5-2008	Dr. Surinder Singh, DCG(I) – Re the efforts of MNCs linking up patent status with marketing approvals. Shri G.S. Sandhu Joint Secretary (PI), to discuss various
10-6-2008	Dr. Surinder Singh, DCG(I) - Technicalities of the 294 FDCs
26-6-2008	Mr. G.S. Sandhu, Jt. Secretary, Dept of C&PC ,Mr. Paresh Johari and Shri S.K. Sharma Dy. Secretaries from C&PC – From NPPA Mr. Arun Jha Member-Secretary, Mr. A.K. Singhal Advisor, Mr. B.K. Pandey, Director and Dy. Directors Mr. Jagdish Kumar and Mr. Manish Goswami. Need to increase the price – Steep hike in all the input costs, CCPC & PL Norms etc.
14-7-2008	Dr. Surinder Singh, DCG(I) - Technicalities of the 294 FDCs
16-7-2008	Dr. Surinder Singh, DCG(I) - Schedule Y – Amendment – Clinical Trial
1-8-2008	Mr. Panda, Joint Secretary Dr. Surinder Singh, DCG(I) - - IPR issues- Patent Linkage with Marketing Approval, Data Protection and Data Exclusivity
8-8-2008	Dr. Surinder Singh, DCG(I) - Clear import permission for number of applications of bulk drugs “Dual Purpose Use’
12-8-2008	Dr. Surinder Singh, DCG(I) - Linkage to IPR
3-9-2008	Dr. Surinder Singh, DCG(I) - New definition to counterfeit drugs
23-10-2008	Meeting with Shri Ram Vilas Paswan – at Indiacem 2008: Various issues viz., R&D, initiatives required by NPPA, Pricing etc.
15-11-2008	Dr. Surinder Singh, DCG(I) - Drugs and Cosmetics (Amendment) Act 2008 - Spurious Drugs

16-12-2008	<p>Shri Ashok Kumar, Secretary, DoP Shri A.K. Banerjee, Chairman, NPPA</p> <ul style="list-style-type: none"> - Govt. proposal for Sale and Distribution of Generics - Revision of CC, PC and PL Norms - Industry's request for urgent suo-moto price increase
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CONSULTANTS

Ramu & Associates	Patents
Shailesh Sheth	Taxation
S W Deshpande	Regulatory Affairs
Kasim K Master	DPCO
V. D. Deshmukh	FDA Matters
K Srivathsan	Excise & Customs
Chetan Doshi	Accounts/Finance
K T Rai	Labour