



## Organisation of Pharmaceutical Producers of India

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## 48th Annual Report 2013-14





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# Executive Committee

## PRESIDENT

Dr Shailesh Ayyangar

Sanofi India Ltd

## VICE PRESIDENTS

Sudarshan Jain

Abbott Healthcare Pvt Ltd

Aijaz Tobaccowalla

Pfizer Ltd

Pheroze Khan\* (up to 31.5.2014)

Bristol-Myers Squibb India Pvt Ltd

Lawrence Ganti\* (up to 7.5.2014)

Merck Ltd

Sameer Savkur

Biogen Idec Biotech India Pvt Ltd

K.G. Ananthakrishnan

MSD Pharmaceuticals Pvt Ltd

## MEMBERS

Raghu Kumar

Allergan India Pvt Ltd

Sanjay Murdeshwar

AstraZeneca Pharma India Ltd

Angel-Michael Evangelista

Bayer Pharmaceuticals Pvt Ltd

Sharad Tyagi

Boehringer Ingelheim India Pvt Ltd

K. Shivkumar

Eisai Pharmaceuticals India Pvt Ltd

Edgard A. Olaizola

Eli Lilly & Company (India) Pvt Ltd

G. Sathya Narayanan

Galderma India Pvt Ltd

Dr Hasit B. Joshipura

GlaxoSmithKline Pharmaceuticals Ltd

Sanjiv Navangul

Johnson & Johnson Ltd

Dr Ramesh Panchagnula

Nektar Therapeutics (India) Pvt Ltd

Ranjit Shahani

Novartis India Ltd

Melvin D'Souza

Novo Nordisk India Pvt Ltd

Meeta Gulyani\* (up to 31.3.2014)

Roche Products (India) Pvt Ltd

Aman Bajaj

Takeda Pharmaceuticals India Pvt Ltd

Dr Safia Rizvi

UCB India Pvt Ltd

## SPECIAL INVITEES

Anish Bafna (w.e.f. 3.6.2014)

Baxter India Pvt Ltd

Jitendra Tyagi (w.e.f. 14.8.2014)

Bristol-Myers Squibb India Pvt Ltd

Maturin Tchoumi (w.e.f. 8.5.2014)

Roche Products (India) Pvt Ltd

## SECRETARIAT

### MUMBAI

Ranjana Smetacek

Director General

Rajiv Shukla

Director – Alliance Development

Vivek Padgaonkar

Director – Project & Policy

Dr Ajaykumar Sharma

Director – Research

Bhavna Singh (w.e.f. 23.6.2014)

Director – Communications

Ajit Bendre

Director – Finance, Admn. & Association Secretary

Ashvin Muchhala

Manager – Accounts & Administration

Cloti Baptista

Sr. Executive Secretary

### NEW DELHI

Tabrez Ahmad

Secretary General

Prem Singh Rawat

Manager – Government Affairs

\*Resigned

# Members

## ORDINARY MEMBERS:

• Abbott Healthcare Pvt Ltd • Allergan India Pvt Ltd • Amgen Technology Pvt Ltd • Astellas Pharma India Pvt Ltd • AstraZeneca Pharma India Ltd • Baxter India Pvt Ltd • Bayer Pharmaceuticals Pvt Ltd • Bilcare Ltd • Biogen Idec Biotech India Pvt Ltd • Boehringer Ingelheim India Pvt Ltd • Bristol-Myers Squibb India Pvt Ltd • Dey's Medical (U.P.) Pvt Ltd • Eisai Pharmaceuticals India Pvt Ltd • Eli Lilly and Company (India) Pvt Ltd • Fresenius Kabi India Pvt Ltd • Galderma India Pvt Ltd • GlaxoSmithKline Pharmaceuticals Ltd • Johnson & Johnson Ltd • Laboratories Griffon Ltd • Lundbeck India Pvt Ltd • Martin & Harris Pvt Ltd • Merck Ltd ( Merck Serono) • MSD Pharmaceuticals Pvt Ltd • Nektar Therapeutics (India) Pvt Ltd • Novartis India Ltd • Novo Nordisk India Pvt Ltd • Pfizer Ltd • Ranbaxy Laboratories Ltd • Roche Products (India) Pvt Ltd • Sanofi India Ltd • Serdia Pharmaceuticals (India) Pvt Ltd • Takeda Pharmaceuticals India Pvt Ltd • UCB India Pvt Ltd

## AFFILIATE MEMBERS:

• BMR & Associates LLP • Ernst & Young LLP • IMS Health information & Consulting Services India Pvt Ltd • KPMG in India • Quintiles Research (India) Ltd • Strategic Marketing Solutions and Research Centre Pvt Ltd • Wolters Kluwer Health India Pvt Ltd

## ASSOCIATE MEMBERS:

• ACG Associated Capsules Pvt Ltd • Colorcon Asia Pvt Ltd • SCHOTT Glass India Pvt Ltd

## ASSOCIATE MEMBER – MEDICAL DIAGNOSTICS & DEVICES:

• Johnson & Johnson - Medical

## OPPI'S MEMBERSHIP OF ASSOCIATIONS:

- ① The Associated Chambers of Commerce & Industry of India (ASSOCHAM), New Delhi
- ② Confederation of Indian Industry (CII), New Delhi
- ③ Employers' Federation of India (EFI), Mumbai
- ④ Federation of Indian Chambers of Commerce and Industry (FICCI), New Delhi
- ⑤ Indian Merchants' Chamber (IMC), Mumbai
- ⑥ International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), Geneva, Switzerland



**DR SHAILESH AYYANGAR**

President, OPPI

Since the last Annual General Meeting of the Organisation of Pharmaceutical Producers of India (OPPI), the political landscape of our country has taken a dramatic turn. In the world's largest election process, over 800 Million people demonstrated their collective power by electing a popular Government. The transition of power in India is hailed as being among the most transparent and peaceful. We now have a Government with a decisive mandate to fulfill its promises of good governance, transparency in policy making and a corruption-free pro-growth agenda. Prime Minister Shri Narendra Modi has ushered in an era of hope and development across India, and its 1.2 billion people look to the new Government, to foster all round economic prosperity and open new avenues for employment. On behalf of India's vibrant pharmaceutical industry, I can say that we are ready and eager to join hands with the new Government to address the complex challenge of access to quality and affordable healthcare for all the people of our country.

In 2013-14, the OPPI members identified three areas of focus:

- Partnering with stakeholders to advance the Government's agenda of improving access to healthcare for all sections of society
- Raising quality standards in the Indian pharmaceutical industry to make it best in class, competitive and relevant in an increasingly global environment. OPPI member companies voluntarily adhere to the stringent 'OPPI Code of Pharmaceutical Practices 2012'
- Promoting a culture of innovation to meet our numerous healthcare challenges, with an eco-system that rewards innovation and is supported by the required infrastructure

OPPI's Working Groups and Committees tried to deliver upon our articulated objectives and made significant contribution and progress during the year. You will read about these in the pages of this Annual Report. I take this opportunity to thank all my colleagues who have been actively involved in this process. With the direction clearly laid out, we must now accomplish all that needs be done.

Over the years, OPPI member companies have contributed significantly to making high quality medicines available in adequate quantities, at affordable prices. We have individually and collaboratively participated in various capacity building activities, access programmes and humanitarian initiatives. Since 2012, individual

employees of member companies have volunteered their personal time to support the efforts of local doctors and complement Government facilities, to address maternal mortality challenges in Jawhar (Maharashtra). Till today over 4100 women have received systematic care so that the birth weight of their babies improves and they themselves stand a better chance of survival.

Member companies have also forged important partnerships with domestic pharmaceutical and healthcare companies, as well as the Government, to introduce new technology and foreign direct investment. I can proudly say that OPPI continues to play its role as India's foremost industry body - *keeping the patients of our country at the centre of all our actions.*

**Price Control:** OPPI is committed to supporting Government's endeavour to provide quality medicines at affordable prices. However, we expect consistency in Government policies – especially relating to price control. The DPCO 2013 is endorsed by most stakeholders and has been operational for the past year. The industry has complied fully with all its provisions and patients are deriving the benefit of some of the lowest prices anywhere in the world, for essential medicines. At the same time, the Government had incentivised manufacturers, allowing competitive pricing for drugs outside the National List of Essential Medicines (NLEM 2011). This was done with the express intent to balance the need for making essential medicines available with the need for investment in quality systems and industry growth through reasonable returns from products outside of price control. The recent July 2014 order from the National Pharmaceutical Pricing Authority (NPPA) has brought several drugs, outside the NLEM, under price control and severely dented Industry confidence. The pharmaceutical industry has always sought a stable and predictable policy framework which would help all stakeholders. Decisions like these can impair the growth of our industry and be harmful for patients.

**Innovation and the Protection of Intellectual Property Rights:** Innovation must be protected through a robust IPR regime that is in harmony with healthcare access. OPPI member companies sincerely believe that patients must have access to the fruits of innovation, irrespective of their paying capacity. For that to happen in a sustainable manner, all healthcare stakeholders must make a contribution. It cannot be expected that only innovators will carry the burden of affordable access to innovative products. The enforcement of IPR laws and respect for genuine innovation is everyone's responsibility. This is the only way to create an eco-system where a steady flow of new ideas and new products continues to help defeat the diseases that afflict mankind.

**Consistent Healthcare Policies:** There are several policy issues that can be smoothed to bring about rapid and responsible growth for our industry and benefits to Indian patients. The new drug approval process, the clinical development policy and many other issues remain ambiguous and delay development in our industry. OPPI urges the new Government to resolve these long-pending issues that discourage investment and stand in the path of progress. Removing these hurdles will help industry to realise its true potential and make a more meaningful contribution. Furthermore, a predictable regulatory environment for clinical trials can help bring newer drugs earlier to India

I thank all OPPI member companies and all stakeholders for their active support and collaboration. All members have truly contributed to India with the diverse capacity building initiatives each has undertaken. OPPI remains committed to its strategic objectives and we will continue to participate enthusiastically in addressing the healthcare challenges facing our country.

**Dr Shailesh Ayyangar**  
President, OPPI  
September 27, 2014  
Mumbai





**RANJANA SMETACEH**  
Director General, OPPI

Ranked third in volume globally and employing almost 400,000 people, the pharmaceutical industry contributes significantly to India's GDP. Alongside the Indian Government, we carry our share of responsibility towards improving the health of our nation. We had this in mind when we articulated our objectives one year ago: supporting Access to quality healthcare; striving for Intellectual Property (IP) protection; following and promoting a stringent code of Ethics & Compliance.

This past year has been a year of change at OPPI and our new dispensation resulted in a restructured, revitalised and better resourced OPPI. The year brought its set of challenges, along with some opportunities. We have witnessed a historic election resulting in significant political developments, with short and long term implications for business in general and the pharmaceutical industry in specific. Encouraged by positive statements of ambitious health insurance plans and consolidated procurement systems, we hoped the new Government would act quickly on major healthcare reform and announce more support for this sector in the new budget. However, we saw little budget consideration and I think we still have a long way to go.

On the positive side, the formation of a National Health Assurance Mission to bridge gaps in healthcare access is a welcome move. We also welcome the commitment to address the issue of unethical marketing practices in the healthcare sector. All OPPI member companies follow OPPI's stringent code of conduct and we continue to urge Government to make the UCPMP (Uniform Code of Pharmaceutical Marketing Practices) a statutory code. This will serve to ensure that prescriptions are based entirely on clinical judgment and that patients are protected and benefitted.

We have yet to see a real commitment to a robust IP rights environment in India. While there is more balance in the public discourse on IP protection, with engagement from multiple stakeholders, much still needs to be done and Government needs to engage with industry in finding sustainable solutions that balance the need for innovation and affordable medicines, within a meaningful IP regime.

Most recently, the industry has been shaken by a surprise decision from the National Pharmaceutical Pricing Authority (NPPA) to bring several non-essential medicines under price control. These actions can only be viewed as major deterrents to the overall growth of the Indian pharmaceutical industry, without conferring the required benefits to the nation. NPPA's actions call for a unified industry response to demand the assurance that important decisions will be taken only after consultation with all stakeholders.

OPPI's knowledge platform, the Healthcare Access Summit, has become an annual calendar event. At our third summit, eminent panelists representing diverse stakeholder groups arrived at the consensus that Universal Healthcare Access can only be achieved through collaboration between all stakeholders, and that Government will have to lead the way. IMS findings have established that access to quality healthcare depends on four dimensions: the physical proximity of a healthcare facility, the availability and functionality of adequate infrastructure, the quality of services, and finally the affordability relative to the income of the patient. Government must look at the issue of healthcare access in a holistic manner and ensure improvement across all dimensions. On affordability, the focus should shift beyond controlling prices toward improving ability to pay, for a big part of our population.

We have some successful examples to learn from, internationally and at home. The drug procurement policy followed in some states demonstrates how state governments can play a meaningful and effective part in this endeavor. In the meantime, our member companies continue to make world-class medicines available to patients across the country - through tiered pricing schemes, public-private partnership models and patient access programs.

The Indian pharmaceutical industry has been and remains a willing and committed partner to the Indian Government, as our country advances towards its dream of quality healthcare for all. To achieve this vision, all stakeholders will have to collaborate and play their roles to support the Indian Government. The continued health of the pharmaceutical industry is also in the best interests of our patients and our country. The need of the hour is a supportive ecosystem that will allow this industry to flourish.

In the year ahead, OPPI will continue to engage with the Government and other stakeholders on these and other issues to ensure progress towards the shared vision of a healthier India. I thank all of you, my colleagues, our members and our well-wishers, for your ongoing support.

**Ranjana Smetacek**  
Director General, OPPI  
September 27, 2014  
Mumbai.

# The Pharmaceutical Landscape

## Indian Pharmaceutical Market

India represents one of the fastest growing markets in global healthcare with a market size of USD 28 bn in 2010, which is expected to grow to USD 31 bn by 2015. The Indian Pharmaceutical Market (IPM) is ranked third largest in volume contributing to 10% of the global market. By value, it occupies the 14th position, accounting for 1.4% of the total global market. The share of the emerging market in the global pharmaceutical industry is expected to increase from 18% to 28% by 2015. India constitutes 8% of this segment currently (1.44% of the total market) and is projected to grow to 10% (2.8% of the total) by 2015. (Source: DoP - E&Y Report).

## Domestic Formulation Market

The domestic pharmaceutical formulation market has grown from USD 10.3 bn in 2010 to close to USD 14.7 bn in 2013 registering a growth of 10% and is expected to record a CAGR of 11.6% for the period 2013-2018, according to the IMS Prognosis Report 2014. Historically, the IPM has grown annually by twice the GDP growth percentage. It is now expected that IPM turnover will touch around USD 55 bn by 2020. (Source: IMS).

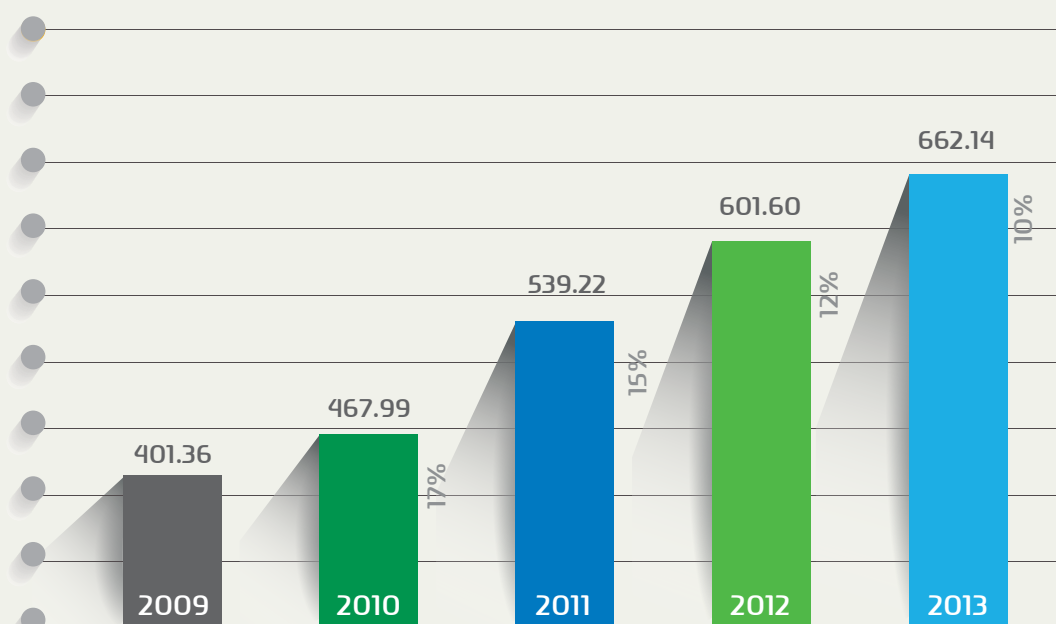
## Pharmaceutical Retail Sector

In 2013, the Indian pharmaceutical retail market recorded a turnover of USD 10.9 bn, growing at 13% CAGR over the last five years. (Source: IMS TSA, MAT Dec 2013).

## Performance of IPM (Retail) over last five years

The key growth drivers were a large number of new introductions, price revisions, increased demand for

Performance of IPM (Retail)



Source: TSA MAT DEC 2013

Rupees Billions

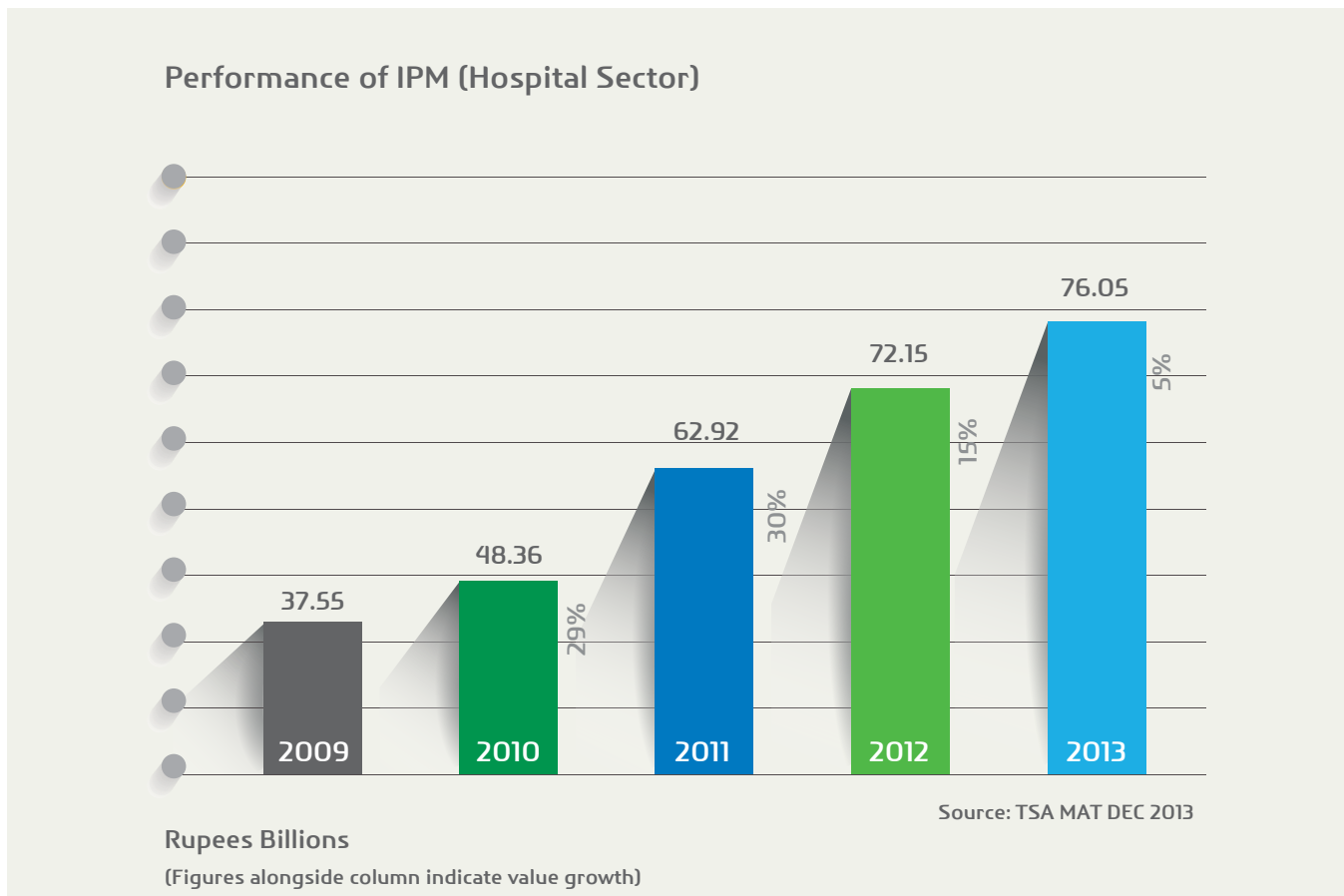
Figures alongside column indicate value growth)

existing products and expansion of the market beyond traditional core markets. The value contribution from companies with turnover of more than USD 166 mn increased from 58% to 69%, while the value contribution from companies with turnover between USD 49.8 mn - 166 mn decreased to 14% in 2013 from 20% in 2010. The extension of price control to all products on the National List of Essential Medicines (NLEM 2011), implemented in 2013, limited revenue growth.

### Performance of IPM (Hospital Sector) over last five years

In 2013, the Indian hospital market for pharmaceuticals registered a turnover of USD 1.26 bn.

Growth is expected to continue, but at a rate slower than in previous years.



Leading corporate hospital groups have announced expansion plans, firstly focusing on broadening their geographical presence and setting up hospitals in smaller cities and secondly extending their businesses beyond hospitals and foraying into specialist primary care provision. Increase in private health insurance coverage, which remains largely focused on in-patient coverage, will be another growth driver. Overall, the market is estimated to grow at ~14% over the next five years to reach - USD 2.49 bn in 2017.

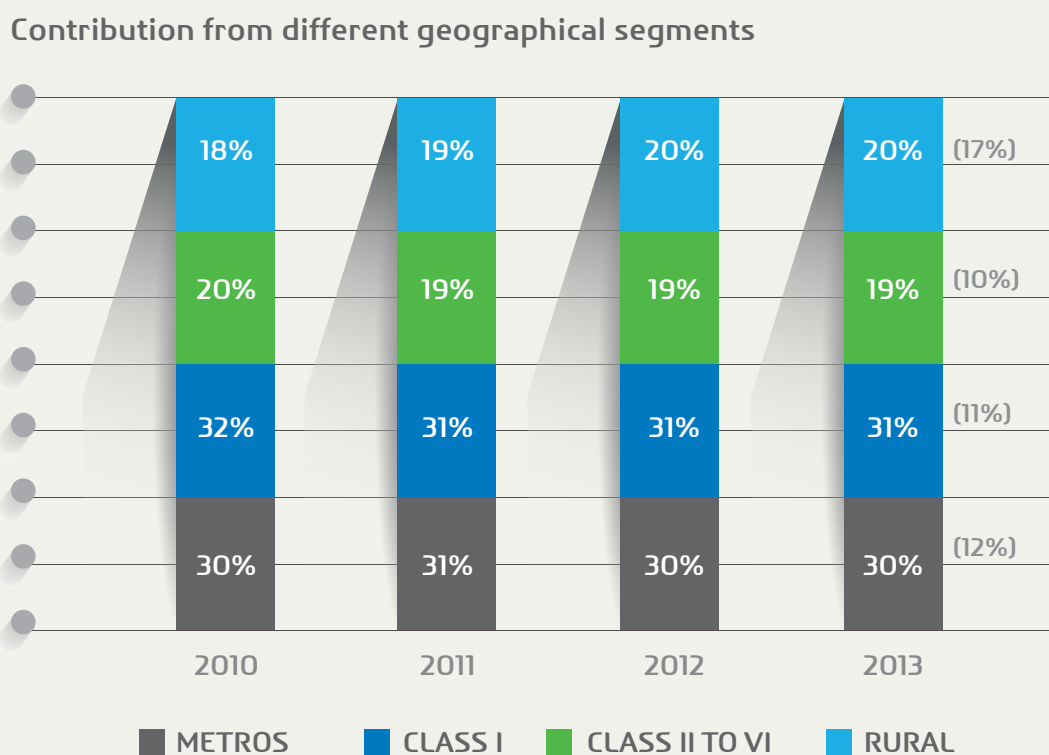
### Extra-urban Markets

Local manufacturers have spearheaded moves to broaden geographical coverage of the market, targeting extra-urban and rural areas over the past five years.

The pharmaceutical industry has begun to clock gains from the extra-urban markets and this appears to be catalysing the next wave of growth for pharmaceutical companies. The markets beyond the metros offer a vast untapped potential.

These markets are expected to contribute significantly with increasing government spend on National Rural

## Contribution from different geographical segments over last four years



Source: SSA MAT DEC 2013- Share in IPM (CAGR in bracket)

Health Management, *Rashtriya Swasthya Bima Yojna* (National Health Insurance Programme) and the thrust on *Jan Aushadhi* (Generic Medicine initiative)

### Formulations Export

India's pharmaceutical exports stood at USD 14.84 bn in FY 2013-14.

As per the report by India Ratings & Research, pharma exports from the country will amount to more than the domestic sales by FY 2015. Indian exports are expected to grow at a healthy 12-14% CAGR over the next five years. The Government has planned a 'Pharma India' brand promotion campaign spanning over three years to provide an impetus to generic exports. Indian companies export off-patent generic drugs to over 200 countries and India is often referred to as 'The Pharmacy of the World'.

### Bulk Drugs (Active Pharmaceutical Ingredients)

High growth trend of the international generic drug industry continues to fuel the growth of the bulk drugs industry, worldwide. Domestic formulation growth will continue to have a direct impact on the API sales in India. Bulk drugs export from India is expected to reach around USD 12.5 bn by 2015 (Source: OPPI-Yes Bank Report).

### Research and Development Landscape

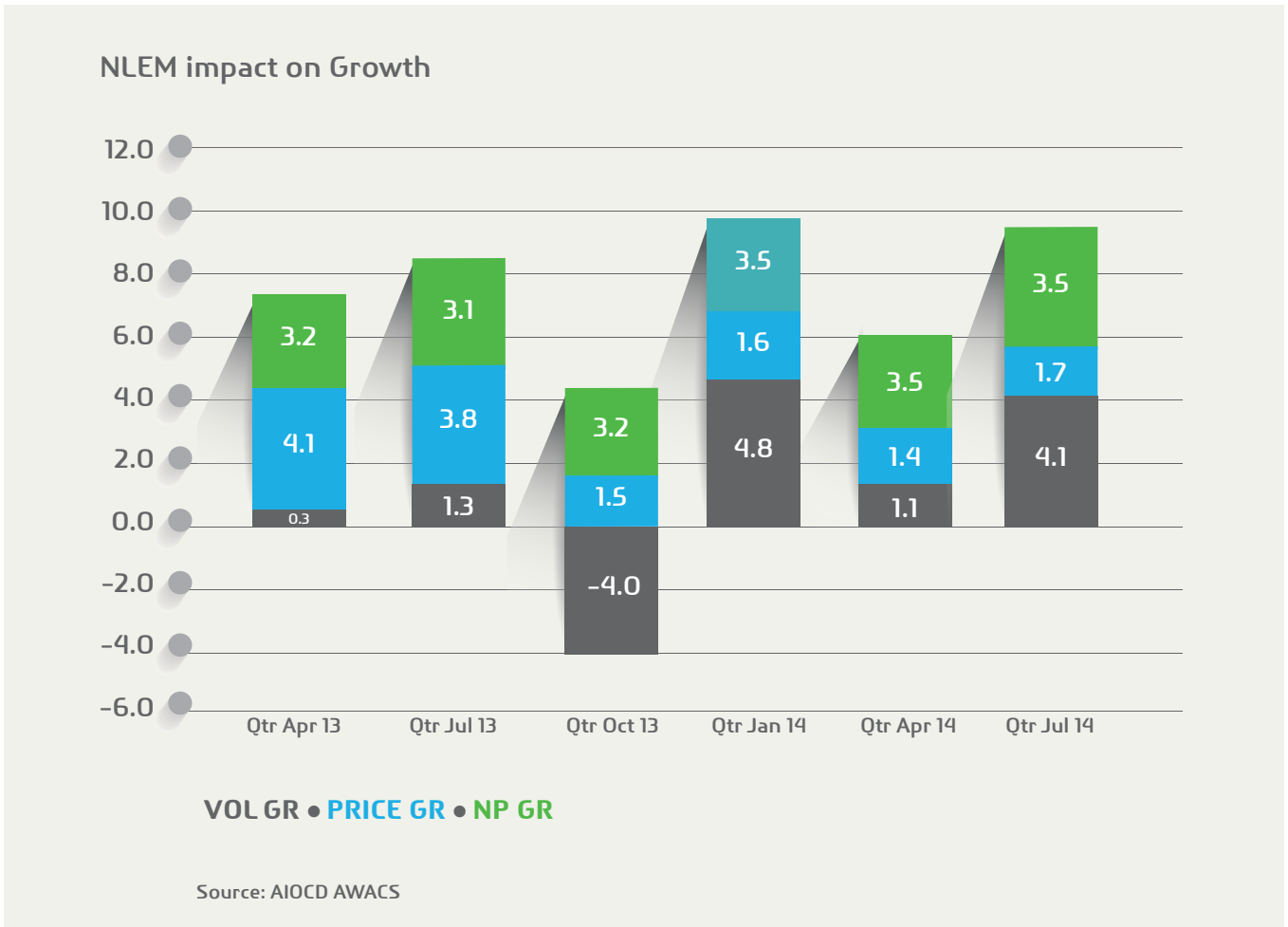
The Government's objective is to develop India as a Drug Discovery and Pharma Innovation hub by 2020 for which certain milestones have been set:

- Capturing 15-20% of the world's R&D pipeline
- Investments worth USD 1-2 bn annually for five years up to 2015, leading to a GDP contribution of USD15-20 bn

- Reaching a level of USD 100 bn pharma production
- Creating five million jobs, including 500,000 high pay jobs

### DPCO 2013 Impact

The pharmaceutical industry has been significantly impacted by the DPCO 2013.



The DPCO rolled out in May 2013 negatively impacted the growth of the pharmaceutical Industry in the October 2013 quarter, as seen in the chart. The industry did show some signs of recovery in the January 2014 Quarter, with growth again slowing down in April 2014 quarter but picking up in the July 2014 quarter.

Jul-14	Value (in billions INR)		Units in 000's	
	Val	GR	Unit	GR
IPM	7161	7.2	1628472	-1.7
NLEM	1188	-0.7	314251	3.2
NON NLEM	5973	8.9	1314221	-2.8

Source: AIOCD AWACS

July 2014 data indicates that the Non NLEM portfolio has been the growth driver.

## Political Landscape

The country is optimistic that the newly elected Government will bring in favourable policies and improve the business environment

The Government has promised to prioritise healthcare and is exploring ways to make it accessible and affordable. The recently announced Union Budget has highlighted some initiatives for healthcare:

- The Finance Minister (FM) has stated the intent of 'Health for All', especially 'Free Drug Service' and 'Free Diagnosis'. It has proposed to set up two National Institutes in New Delhi and Chennai for early diagnosis and treatment of Tuberculosis.
- Funds have been allocated for setting up of four more All India Institute of Medical Sciences in Andhra Pradesh, West Bengal, Vidarbha and Poorvanchal.
- It has also proposed to add 12 more Government medical colleges.
- Central Government will provide assistance to States' Drug Regulatory and Food Regulatory Systems by creating new drug testing laboratories and strengthening the 13 existing state laboratories.
- It has proposed to set up 15 Model Rural Health Research facilities, in various states, to undertake research on health issues concerning the rural population.
- It has proposed to strengthen at least five research centres of the Department of Science & Technology, to make them more effective in innovation through Private Public Partnerships (PPPs).

## Some actions from the new Government that impact the Pharmaceutical Sector:

- Ministry of Health & Family Welfare

Post the announcement of providing free medicines for all at public health facilities, the Government is planning to bring about a 'complete transformation' of the health sector and is working on the blueprint of the world's largest universal health insurance programme

- Department of Pharmaceuticals (DoP), Ministry of Chemicals & Fertilizers

NPPA has fixed the prices of 108 non-scheduled drugs, leading to a price-cut of almost 35%. It is now looking at expanding price control to other therapeutic areas

- Department of Industrial Policy & Promotion (DIPP), Ministry of Commerce & Industry

DIPP has proposed a composite foreign investment cap on certain sectors including the Pharmaceuticals sector

- Department of Legal Affairs, Ministry of Law & Telecom

Broadband connectivity to villages is a priority for the new Government

- Ministry of Finance, Corporate, Defence

The provisions made in the budget enhance both financial and physical access to healthcare. Through broadband in rural areas, telemedicine will increase access to qualified doctors. The hike in insurance investment limit to 49 per cent is expected to increase financial access

- Ministry of Science & Technology

Efforts will be made to make India strong in the field of science and technology and acquire the No. 1 position in the world by 2020. R&D growth will be encouraged in multifarious directions.

## Objectives 2013–14: Making a Difference, with focus on

- Intellectual Property Protection

We will promote innovation for the good of India, shifting away from the MNC Vs. domestic debate

- Access to Healthcare

We will continue to partner with stakeholders to make a difference in three access areas - physical reach, quality and affordability

- Ethics and Compliance

We will reinvent ourselves as an industry, be open to innovative solutions and commit to high ethical standards and compliance to attract the best talent to build careers in the healthcare industry

In order to better serve OPPI objectives, we structured ourselves into four Working Groups (each chaired by an Office bearer) and five Committees (each chaired by an Executive Committee member). Additionally, we created a Government Affairs Forum to connect our Delhi-based Corporate Affairs heads. This forum meets periodically, to share intelligence on industry issues and listen to valuable insights from knowledgeable guest speakers.



# Working Groups (WG)

## Access and Affordability

### Objectives:

To support advocacy to improve healthcare access and proactively engage in policy development leading to increased investment in healthcare infrastructure and capacity building.

- Define OPPI's charter for supporting the Government in enhancing access to healthcare. Hold seminars to bring diverse stakeholders together for a comprehensive dialogue on access issues
- Develop a participative model for OPPI to engage with the Public Health Foundation of India (PHFI) and the Health Ministry at the centre and in the states
- Get buy-in from industry associations to join in the industry-wide solidarity with the Government and NGOs in addressing at least one of the most pressing healthcare access issues

The Third Healthcare Access Summit was held on August 8, 2014 at Hotel Palladium, Mumbai. Key speakers represented industry associations like IPA, IDMA, ASSOCHAM, EFPIA and PhRMA. Voices were also present from NGO's, patient groups, industry and academia. With more than 300 attendees, the summit proved to be an engaging platform discussing challenges and presenting solutions towards making healthcare accessible.

The OPPI Healthcare Access Award supported by Abbott Healthcare and Johnson & Johnson, was introduced for the first time this year. The award recognised the highest contribution by an individual or institution on Access to Healthcare with consideration for patient safety and adherence to quality. The jury comprised of Dr Srinath Reddy (PHFI), Amit Backliwal (IMS), Ranga Iyer (Consultant), Palash Mitra (McKinsey) and Dr Rajendra Gupta. Jaipur Foot was declared the winner of the OPPI Healthcare Access Award. Padma Bhushan, Devendra Raj Mehta, Founder and Chief patron, BMVSS received the award.

The OPPI project on 'Reduction of Maternal Mortality in India', in collaboration with the Government of Maharashtra, Rotary Club, Mumbai, Indian Medical Association and NGO Pragati Pratishtan, continued for the second year at Jawhar, Palghar District, Maharashtra. Around 4000 patients benefitted from this initiative. This year, OPPI partnered with HCL to introduce a platform for sharing real time information to achieve 100% access to care for antenatal check-ups. Currently, a feasibility study is being undertaken with HCL to consider scaling up this project. More on this initiative on the Project Jawahar page

To increase awareness on healthcare access, OPPI co-sponsored events organised by Partnership to Fight Chronic Diseases (PFCD) on 'Facing Our Future: Countering Non-Communicable Diseases (NCDs) in India through Investments in Innovation in Delhi and Mumbai. This two-city discussion highlighted the challenges faced by developing countries on NCDs and access to healthcare and attempted to provide a few solutions in connecting these challenges.

The WG championed research papers on critical access issues and promoted their use for policy discussions:

A paper on 'Collaborating to improve healthcare access in Rural India- Challenges and Opportunities' developed jointly by Imperial College (London), Innoplexus, Merck Serono and OPPI advocated a larger role of Public Private Partnerships (PPP) in rural areas for strengthening the healthcare delivery infrastructure. The Healthcare Access study by IMS on 'Understanding Healthcare Access in India: What is the current status?' was commissioned by the industry last year. The findings of the study were disseminated to relevant stakeholders across the country. Meetings were conducted with Government bodies (Planning commission,

DoP, Ministry of Health & Family Welfare, NPPA, etc.), industry associations (IPA, IDMA, CII, FICCI, etc.), NGO's and patient groups to share this report. Phase II of the study on deciphering Out of Pocket expenses across primary, secondary and tertiary level of care is planned.

A position paper on e-prescription has been created for use by member companies.

WG members initiated policy discussions and shared OPPI's views on Access to Healthcare at various public platforms hosted by Bangalore Bio, CII, IPA, FICCI, IDMA and other industry associations.

**CHAIRMAN:** Sudarshan Jain (Abbott)

**CO-CHAIRMAN:** Sanjiv Navangul (Johnson & Johnson)

**MEMBERS:** Shirish Ghoge (Abbott) • Amitabh Baxi (Abbott) • Krishnanand Atreya\* (AstraZeneca) • Sanjeev Panchal (AstraZeneca) • Navin Sharma (Baxter) • Pooja Vatsyayan (Biogen Idec) • Radhika Bhalla\* (Boehringer Ingelheim) • Meenal Gauri (Bristol-Myers Squibb) • Jitendra Tyagi (Bristol-Myers Squibb) • P.M. Srikanth (Eisai) • Vineet Gupta\* (Eli Lilly) • Sudheendra Kulkarni (Johnson & Johnson) • Shilpa Arora (Merck Serono) • K.G. Ananthakrishnan (MSD Pharmaceuticals) • Sanchit Nanda (Novartis) • Sundeep Kumar (Novartis) • Vinay Ransiwala (Novo Nordisk) • Partha Ghosh (Pfizer) • Umang Chaturvedi (Ranbaxy) • Oliver Jarrett (Roche) • Sangita Topiwala (Sanofi) • M.K. Narayanaswamy (Sanofi) • Dr Asmita Nimkar (Serdia) • K. Venkatesh (UCB) • Saameer Khedkar\* (UCB) • Sudip Chakraborty (UCB)

**SPECIAL INVITEE:** Amit Backliwal (IMS Health)

\*Resigned

# Ethics and Compliance

## Objectives:

To strengthen efforts to implement an ethical code of business practice. Provide appropriate training on the industry code of ethics and monitor adherence to it by member companies.

- To decide ways to make the Code of Ethical Practices in pharmaceutical marketing more visible to internal and external stakeholders
- To bring together multiple stakeholders – doctors, thought leaders, patient groups, NGOs and industry leaders to address the ethical aspects of pharmaceutical marketing
- To explore ‘An OPPI Company’ label on each detailing aid, to remind every doctor that the representative carrying such a detailing aid is fully trained in the code of ethical practices
- To develop a common training toolkit for OPPI member companies and get a buy-in from internal stakeholders
- Prepare a status report every six months on Compliance Matters. Along with Communications Committee, create opportunities to speak about the actions taken by OPPI and its member companies in transforming the industry by adhering to the highest standards of ethical and compliant practices

OPPI supported IFPMA Code Workshops in Mumbai and Dubai. The aim of these workshops was to provide international case studies and relevant industry exposure to those responsible for promotional material of products.

The WG revisited the OPPI Code of Pharmaceutical Practices 2012 based on the IFPMA Code governing ethical behaviour in pharmaceutical marketing. The Group discussed OPPI Code Clauses 7.1.5; 7.5.1; 7.5.3 and elements such as consultant agreements, promotional aids, brand reminders, patient assistance programmes, third party sponsorship, etc. The WG designed FAQs to facilitate uniform interpretation of the Code among internal stakeholders.

The Task Force (TF) met with the Secretary, Department of Consumer Affairs for a discussion on the OPPI Code.

In its bid to transform the industry’s approach towards ethical practices, the WG studied country-specific pharmaceutical industry codes of various countries including Britain, Italy, Hong Kong, Australia and Canada on aspects of complaints and sanctions. Recommendations were made based on this studies on the actions to be taken against those who violate the Code.

**CHAIRMAN:** Melvin D’Souza (Novo Nordisk) • Lawrence Ganti\*(upto 07.05.2014) (Merck Serono)

**CO-CHAIRMAN:** Edgard A. Olaizola (Eli Lilly)

**MEMBERS:** Swati Dalal (Abbott) • Vijayaprakash Devulapalli (Abbott) • Ramesh Varadarajan (AstraZeneca) • Rajiv Wani (Bayer) • Raelene Antao Banerjee (Bayer) • Neha Kshirsagar (Bayer) • Rajiv Malhotra (Biogen Idec) • Dr Viraj Suvarna (Boehringer Ingelheim) • Santhosh Mane (Boehringer Ingelheim) • Anuradha Gupta\* (Boehringer Ingelheim) • Bratin Bag (Bristol-Myers Squibb) • Ashish Srivastav (Bristol-Myers Squibb) • P. Achuthan\* (Eisai) • Dr Simrat Sohal (Eli Lilly) • S. Raghavendra (Galderma) • Jayashree Shetty (Johnson & Johnson) • Dr Rajesh Chitre (Merck Serono) • Sandeep Seth (MSD Pharmaceuticals) • Girish Tekchandani (Novartis) • Dr Raman Shetty\* (Novo Nordisk) • Dr Ramesh Jagannathan (Novo Nordisk) • Samir Kazi (Pfizer) • Dr Jejeeo KaranKumar (Ranbaxy) • Ravindra Jain (Roche) • Parichay Mittal (Sanofi) • Dr Asmita Nimkar (Serdia) • Ashok Kumar Bhattacharya (Takeda) • Dr Safia Rizvi (UCB)

\*Resigned

# Innovation and Intellectual Property Rights (IPR)

## Objectives:

To create a positive environment for the implementation of Intellectual Property Rights (IPR) and to encourage research and innovation

- To bring about a balanced tone in discussions around Innovation and Intellectual Property (IP)
- To foster a perception among key stakeholders that Innovation and IP are good for the country
- To develop a blue print for an eco-system in India for the effective enforcement of IPR

The WG developed a coordinated approach with stakeholders and aligned with PhRMA and EFPIA to build stronger advocacy.

The WG created a presentation and position paper, which were presented to a group of nine foreign missions in a meeting in Delhi.

The group provided updates to position papers - The Position Paper on Compulsory Licensing (CL) described CL and patent infringements in India comparing these globally and analysed the impact of CL on Access to Healthcare. The paper also suggested alternative solutions to increase healthcare access.

The group worked on a case study and other reference material for members to use, while presenting the case for strong IPR in academic institutions or at public debates.

The WG addressed various major issues:

Disclosure of International Non-proprietary Names (INNs) in a Patent Specification - The Indian Patent Office (IPO) decided to mandate disclosure of INNs for all patent applications, to establish patentability. This, it was felt would facilitate patent examiners in scrutinising patent applications and researchers in identifying patent applications in respect of a particular INN. OPPI opposed this move as it impedes innovation and may lead to pre-grant opposition. OPPI made representations to the Government seeking a non-partisan approach to discourage additional burden on innovators, which in turn would reduce domestic patent filings.

IPO Guidelines for examination of Patent Applications in the field of pharmaceuticals - IPO introduced guidelines for patent examination in areas covering pharmaceutical, biotechnology and traditional knowledge. These guidelines were set with a view to improve examination standards by introducing harmonious practices among examiners. OPPI submitted representations highlighting discrepancies in the draft manual.

Patent infringements through state Food and Drug Administration (FDA) by exploiting provisions of Drugs & Cosmetics Rules- Under the Drugs and Cosmetics Act 1940, only new drugs need clinical trials and approval from the Drug Controller General of India (DCGI) before launch for human consumption. A pharmaceutical manufacturer can apply for license to market a drug from state FDAs, if the chemical entity has been in the market for four or more years. This results in potential conflict and infringement.

The Group met the Secretary, Department of Industrial Policy and Promotion (DIPP) and suggested:

- DIPP shares the list of patented medicines with DCGI and further on with state FDA
- DIPP issue an inter-departmental order to DCGI and State FDAs/ drug controllers to inform the patent holder if they receive any application for manufacture of formulations from the 'list of patented medicines'
- The matter be referred to central FDA by the state FDAs

**CHAIRMAN:** Aijaz Tobaccowalla (Pfizer)

**CO-CHAIRPERSONS:** Angel-Michael Evangelista (Bayer) • Dr Safia Rizvi (UCB)

**MEMBERS:** Dr Shripad Jathar (Abbott) • Shyamakant Giri (Abbott) • Pawan Singhal (AstraZeneca) • Dr Ashish Gawde (Bayer) • Nilesh Limaye (Bayer) • Kedar Suvarnapathaki (Boehringer Ingelheim) • Bhavik Desai (Bristol-Myers Squibb) • Suresh Gupta (Bristol-Myers Squibb) • K. Shivkumar (Eisai) • Edgard A. Olaizola (Eli Lilly) • Dr Gaurav Arya (Eli Lilly) • Priya Hingorani (Johnson & Johnson) • Nishant Berlia (Martin & Harris) • Prashant Laghate (Merck Serono) • Dinesh Charak (Novartis) • Vinay Ransiwal (Novo Nordisk) • Shivprasad Laud (Roche) • Sujatha Subramaniam (Roche) • Yasmin J. Cama (Sanofi) • Dr Asmita Nimkar (Serdia) • Milind Kulkarni (UCB)

## Medical and Regulatory

### Objectives:

To provide input for changes in policies affecting Medical, Biotech and Vaccines. Support the development of healthcare regulatory policy by sharing global best practices and standards.

- Address issues and concerns relating to Prof. Ranjit Roy Chaudhury Expert Committee Report on Clinical Trials and New Drug Approvals. Obtain positive outcomes in the shortest time through broad coalition with associations
- Create a joint workshop on regulatory challenges bringing together the DCGI staff, regulatory experts from our parent companies, representatives from FDA, WHO, etc. and build a knowledge sharing platform
- Engage with DCGI or Health Ministry experts on Dr C.K. Kokate Expert Committee Report on Fixed Dose Drug Combinations (FDCs)
- Advocate for adherence of Biosimilar Guidelines and addressal of ongoing regulatory issues

India needs policies and regulations that build confidence among scientists and innovator companies in carrying out clinical research. Therefore, a robust and transparent process for conducting clinical trials is urgently needed. Several industry associations like IPA, IDMA, CII, FICCI, ASSOCHAM are working together to resolve issues on clinical trials.

Clinical trial waiver for New Drugs- As per Indian regulations, under Rule 122E, Phase III clinical trials need to be conducted before registration of 'new' drugs. While in most situations these trials are conducted as per regulatory requirements, there are some exceptions. Orphan drugs, national emergencies and life-saving products need to be registered quickly in order to allow immediate access. OPPI is collaborating with the regulators to achieve clear criteria on grant of waivers of Phase III trial.

In order to develop a balanced regulatory environment and share global best practices and standards, OPPI along with Indian Society for Clinical Research (ISCR) has planned a two-day work shop for Central Drugs Standard Control Organization (CDSCO) on 'Drug Development and Good Clinical Practices'.

OPPI made representations for effective implementation of the Guidelines on Similar Biologics to the CDSCO to ensure high quality and safe biosimilar products.

### Ongoing regulatory issues:

Registration of Site of Manufacture - India has strict rules and regulations governing import of drug product and drug substance. One such measure is registration of the overseas manufacturing site. In addition to extensive documentation this requires possible inspection of the overseas site. OPPI members are in dialogue with the regulators to register the key site responsible for the product quality. This will ease the burden on member companies and meet the objective of the regulators.

India-specific Imported Packs - Earlier this year, CDSCO decided to allow imports only in India-specific packaging with no stickers on the pack. OPPI made requests to the drug authorities to grant adequate time for the switch over. Following this request, DCGI agreed to a time-line of June 2014 for the switch over.

Indian Pharmacopoeia - Due to demanding compliance timelines and the task of validating monographs, OPPI requested an extension of the implementation date of Indian Pharmacopoeia 2014. The Indian Pharmacopoeia

Commission granted an extension of four months for the effective implementation of the new edition of Indian Pharmacopoeia from December 01, 2013 to April 01, 2014.

Schedule H1- On OPPI's request, a clarification note was issued from DCGI office on Gazette Notification (GSR 588(E) dated August 30, 2013), which directed that only stocks of Scheduled H1 drugs manufactured after the deadline would need to be labelled as per the new requirements and that stocks manufactured prior to March 01, 2014 could be manufactured and sold as per the earlier norms.

DCGI issued circulars (dated January 15, 2013 and July 05, 2013) to all States and UTs directing the manufacturers of FDCs to regularise the State-approved FDCs. OPPI and IDMA made a joint representation in this regard to the Government.

**CHAIRMAN:** Sameer Savkur (Biogen Idec) • Pheroze Khan\* (up to 31.5.2014) (Bristol-Myers Squibb)

**MEMBERS:** Dr Balagopal Nair (Abbott) • Dr Paramjit Singh (Allergan) • Dr Thirumalai Velu (Allergan) • Dr Veena Jaguste (Amgen) • Dr Shashwati Pramanik (Amgen) • Dr Pratik Shah (Astellas) • Dr Bhavesh Kotak (AstraZeneca) • Dr Premnath Shenoy (AstraZeneca) • Dr Ashok Mohrana (Baxter) • Dr Ashish Gawde (Bayer) • Dr Girish Parhate (Bayer) • Dr Anjali Nagpal (Biogen Idec) • Meenu Batolar (Biogen Idec) • Dr Viraj Suvarna (Boehringer Ingelheim) • Dr Vinod Mattoo (Bristol-Myers Squibb) • Dr Ramakrishnan Sundaram (Bristol-Myers Squibb) • Dr Chandrashekhar Chavan (Eisai) • Jitendra Patel (Eisai) • Dr Anurita Majumdar (Eli Lilly) • Rahul Chauhan (Eli Lilly) • Dr Rahul Sawakhande (Galderma) • Dr Prashant Desai (Johnson & Johnson) • Dr Qayum Mukaddam (Merck Serono) • Dr Priya Chatterjee (Merck Serono) • Dr Amit Arora (Merck Serono) • Swarnaraj Jacob (MSD Pharmaceuticals) • Dr Viraj Salgaonkar (MSD Pharmaceuticals) • Dr Suresh Menon (Novartis) • Amita Bhave (Novartis) • Dr Raman Shetty\* (Novo Nordisk) • Dr Ramesh Jagannathan (Novo Nordisk) • Dr Chandrashekhar Potkar (Pfizer) • Rajgopal Bhutada (Ranbaxy) • Dr Anil Kukreja (Roche) • Seema Shimpi (Roche) • Dr Mubarak Naqvi (Sanofi) • Yasmin Shenoy (Sanofi) • Dr Asmita Nimkar (Serdia) • Dr Santosh Jha (Takeda) • Dr Manishchandra Hathial\* (UCB) • Dr Sangeeta Madhok (UCB)

**SPECIAL INVITEE:** Suneela Thatte (Quintiles)

\*Resigned

# Committees

## Communications and Stakeholder Engagement

### Objectives:

To develop and implement communication strategies to improve the image of member companies and the industry

- To drive internal and external communication
- Define areas of focus for OPPI Communications Strategy in 2014
- Define expectations from PR Agency. Formulate key communications calendar for 2014 including planned press meets and public announcements
- Showcase the excellent work done by member companies on CSR and access programmes to external and internal stakeholders
- Create a toolkit for members to use in communicating key messages to the Government and other stakeholders
- Showcase the research based industry's contribution in improving healthcare standards in our country
- Timely response to critical issues/crisis

The OPPI Communication strategy identified and prioritised stakeholders for effective engagement. The three areas of focus were defined as Innovation, Access to Healthcare and Ethics & Compliance. Based on these thrust areas, key messages were constructed for consistent and uniform messaging.

Edelman PR was appointed as OPPI's Communications and PR Agency to help enhance the image of OPPI and raise its profile. A planned and exhaustive communication calendar was drawn up and a TF created to engage with the media, along with the agency.

The committee undertook the task of creating a bank of 'good stories'. The good stories bank captured the commendable socially relevant work of member companies in identified disease areas along with the initiatives which have benefitted patients. The TF put together inspiring stories of affected individuals, capturing their struggle and the focused role of the member companies in helping them re-build their lives.

The committee is working on a toolkit containing the key messages. The toolkit includes presentations, position papers and case studies which could be used by each member while engaging with stakeholders.

By engaging with the media and through effective outreach programmes, the committee made attempts to showcase the pharma industry's contribution in improving the overall health standards in India.

**CHAIRMAN:** K.G. Ananthkrishnan (MSD Pharmaceuticals)

**CO-CHAIRPERSON:** Meeta Gulyani\* (up to 31.03.2014) (Roche)

**MEMBERS:** Varsha Chainani (Abbott) • Sridhar Ranganathan (Allergan) • Rajesh Mehra (AstraZeneca) • Aloke Pradhan (Bayer) • Justin D'sa (Bristol-Myers Squibb) • Dr Gaurav Arya (Eli Lilly) • Ransom D'Souza (Johnson & Johnson) • Rimmi Harindran (Merck Serono) • Jyotsna Ghoshal (MSD Pharmaceuticals) • Neelima Dwivedi (MSD Pharmaceuticals) • Svetlana Pinto (Novartis) • Sundeep Kumar (Novartis) • Sarita Bahl\* (Pfizer) • Amitabha Gangopadhyay (Ranbaxy) • G. K. Raman (Roche) • Aparna Thomas (Sanofi)

\*Resigned



## Finance and Taxation

### Objectives:

To review and provide input into finance and taxation matters impacting the industry

To provide oversight and review of internal OPPI accounts and administration issues

- Create position papers on impact of DPCO 2013
- Brainstorm and develop a position paper on the implementation of DPCO 2013
- Provide inputs for OPPI representations on Patented Product Pricing and other policy issues
- Work closely with IDMA & IPA on industry issues and articulating the industry response to the Union Budget 2013-14
- Oversee OPPI Accounts & Administration in terms of statutory compliance as well as benchmarking against industry standards

OPPI along with its member companies focused on the operational issues relating to the effective implementation of DPCO 2013, through several meaningful meetings and representations to NPPA and DoP. In addition to this, trade and prescription audits were undertaken on a regular basis to ascertain the impact of this new policy on access to medicines in the country.

A Cross Functional TF with members from Medical and Regulatory Working Group, Finance & Taxation Committee and Legal Committee was formed to measure the impact of DPCO 2013 / NLEM 2011 and to make recommendations for NLEM 2014. This TF is preparing a white paper providing suggestions for enhanced access to medicines.

In its representation to the newly formed Inter-Ministerial Committee on Patented Product Pricing, OPPI outlined criteria for successfully formulating a sustainable pricing and patient access policy, which:

- Supports innovation and a viable industry business environment
- Is technically and clinically appropriate, feasible and clearly defined
- Enhances access to healthcare
- Promotes an equitable approach

A pre-budget memorandum, prepared with inputs from our affiliate members E&Y and KPMG was submitted to DoP, DoR, Ministry of Finance and other relevant departments. This memorandum was prepared in consultation with other associations like IDMA, IPA, CII, FICCI, & ASSOCHAM. The TF made several presentations to DoP on direct taxes, indirect taxes and transfer pricing elements impacting the industry. Subsequently, post-budget recommendations with inputs from the industry bodies have been submitted to the Government.

The committee provided inputs on statutory compliances and other financial matters to augment OPPI's Accounts and Administration.

The Companies Act, 2013, has recently become the new legislation for corporate India. Although the Act is now final, the rules are still at a draft stage, inviting improvements and suggestions. The committee partnered

with E&Y in organising an interactive session covering accounting, audit, legal, corporate social responsibility, mergers & acquisitions and tax related aspects of the Companies Act 2013.

A post-budget interactive discussion was arranged for OPPI Members. E&Y made a presentation on 'Key Features of India's Union Budget 2014-15' pertaining to the Life Science Industry.

A knowledge-sharing session was organised with KPMG on the Regulatory and Monetary Policy with reference to limited liability partnership, foreign investments, dividend distribution tax, market acceptable pricing from RBI perspective.

**CHAIRMAN:** Aman Bajaj (Takeda)

**CO-CHAIRMAN:** Melvin D'Souza (Novo Nordisk)

**MEMBERS:** Sachin Dharap (Abbott) • Shirish Ghoge (Abbott) • Rajesh Sharma (Allergan) • Abhay Kulkarni (Astellas) • Sandeep Devgon (Baxter) • N.V. Chalapathi Rao (Bayer) • Davendra Singhvi (Biogen Idec) • Thomas Wilmesmeier (Boehringer Ingelheim) • Mukesh Agarwal (Bristol-Myers Squibb) • Girish Hingorani (Eisai) • Vikram Arora (Eli Lilly) • Dewang Smart (Galderma) • Manish Vora (Johnson & Johnson) • Kalpana Umakanth (Martin & Harris) • Chinmaya Parekh (Merck Serono) • Giri Giridhar (MSD Pharmaceuticals) • Milind Patil (Novartis) • Suhas Karambelkar (Novo Nordisk) • S. Sridhar (Pfizer) • Sundeep Mehta (Ranbaxy) • Patrick Watkins (Roche) • M.K. Narayanaswamy (Sanofi) • Vaibhav Karandikar (Sanofi) • Geeta Karnik (Serdia) • Vinay Potdar (Takeda) • Satish Joshi (UCB)

**SPECIAL INVITEES:** Hitesh Sharma (Ernst & Young) • Hitesh Gajaria (KPMG)

# Governance and Human Resources Management

## Objectives:

To conduct an industry benchmarking study for member companies

- Conduct an outreach program for academic Institutions in consultation with the Communications team. Develop a toolkit for highly impactful presentations on the healthcare industry
- Leverage relationships with other industry associations and jointly address Industrial Relations (IR) issues of pharmaceutical industry
- Raise the profile of medical representatives and area managers – OPPI seminar on creating the pharma industry as a career choice for Gen Y. Strengthen focus on Talent Attraction in the pharmaceutical Industry

To provide governance support to the OPPI Secretariat to ensure effective implementation of the organisation's goals

- Review and recommend HR practices for OPPI Secretariat
- Put in place developmental agenda for OPPI staff in collaboration with EFPIA, PhRMA, etc.

To develop a comprehensive strategy for attracting the best young talent to the pharmaceutical industry, the committee is in talks with leading consulting firms for instituting a benchmarking study on talent attraction.

OPPI has been engaging with the students and faculty of top management institutes through the OPPI Academia Programme. This is designed to initiate dialogue between the industry, the future workforce and academia. As a part of this initiative, the committee visited some management institutes across the country - NIPER Mohali and Hyderabad, IIM Trichy, GIM Goa and NMIMS and Welingkar, Mumbai, to name a few. The objective was to gauge levels of interest among students towards the pharmaceutical industry and help make it an industry of choice for young employees.

The Sales Promotion Employees (Conditions of Service) Act, 1976, was enacted by the Parliament to have a special legislation for regulating the services of Sales Promotion Employees- Medical representatives (MRs). In view of the nature of the work for MRs, the authorities while promulgating the said Act have not prescribed work timing for them.

OPPI along with IDMA took up IR issues related to the fixed working hours of MRs in the following states -

- Rajasthan and Punjab – The Labour Courts of Rajasthan and Punjab have decided in favour of the industry and have not allowed requests from the Union of MRs for fixed working hours in these states.
- Karnataka – A writ petition at Karnataka High Court seeking stay on the fixed hour working of MRs Notification (issued by the State Labour Department of Karnataka) was jointly filed by OPPI and IDMA. The Hon'ble High Court is considering the industry plea and has stayed the order of the State Labour Commissioner.
- Maharashtra – The OPPI President met with Shri Jayant Patil, Maharashtra Cabinet Minister to revoke the fixed hour working notification of MRs. At the same time, the matter has been represented to the State Labour Minister for consideration.

OPPI HR Summit 'Attracting, Developing & Retaining Talent' was held on September 10, 2014 in Mumbai. The event saw global and domestic healthcare experts share their views on addressing the future challenges of Human Resources Management.

The committee, along with the members of the OPPI Secretariat set up HR driven systems and processes to ensure higher levels of efficiency and productivity, internally.

**CHAIRMAN:** K. Shivkumar (Eisai)

**CO-CHAIRMAN:** Sharad Tyagi (Boehringer Ingelheim)

**MEMBERS:** Ajay Bhatt (Abbott) • Debashish Chatterjee (Allergan) • Kinnari Joshi (Astellas) • Smita Saha (AstraZeneca) • K.S.Harish (Bayer) • Prachi Sharma (Biogen Idec) • Shraddha Pradhan (Bristol-Myers Squibb) • Vikram Arora (Eli Lilly) • Tejashree Talpade (Eisai) • Vishal Vadakeri\* (Galderma) • Abhigyan Ghosh (Galderma) • Anupam Shrihari (Johnson & Johnson) • Nishant Berlia (Martin & Harris) • Cecilia M. Azavedo (Merck Serono) • Milind Thatte (Merck Serono) • Sameer Tamhane (MSD Pharmaceuticals) • Meenakshi Priyam (Novartis) • Malapaka SRKV Murthy (Novo Nordisk) • Dr Lakshmi Nadkarni (Pfizer) • Vikram Duggal (Ranbaxy) • Nilesh Kulkarni (Roche) • Gaurav Bahadur (Sanofi) • Mehernosh Mehta\* (Sanofi) • Jui Dabir (Serdia) • Deepa Misra (Takeda) • Ashish Ranjan (UCB)

**SPECIAL INVITEE:** Ryan Lowe (Ernst & Young)

\*Resigned

# Legal

## Objectives:

To monitor and review changes in laws and policies in the pharma industry

To act as an advisory and consultant for legal issues

- Review all IPR related cases impacting member companies and help to vigorously defend the member companies' rights
- Ensure that members are kept fully aware of the changes relating to Company law, Patent law, Pricing/ Competition law, etc.
- Identify key business issues facing member companies from the legal perspective and develop a common understanding and approach to bring about changes
- React in any emergency situation to defend the legal rights of the member companies to do business in India under the Indian laws
- Support on AIDAN case
- Continue supporting - all WGs and Committees as needed, with ongoing monitoring and review of changes in relevant laws and policies-

NPPA's use of Para 19, under DPCO 2013, extends price control to non-scheduled medicines in the cardiovascular and diabetes therapy area. OPPI challenged the constitutional validity of NPPA's arbitrary action in the Delhi High Court.

In the hearing of the All Indian Organisation of Chemists and Druggists (AIOCD) case at Competition Appellate Tribunal Board (COMPAT), OPPI through its counsel is filing a prayer for removal of its name from the array of parties since there are no findings against OPPI in the three orders passed by the Competition Commission of India (CCI) against which the AIOCD has filed appeals.

The committee provided inputs on NPPA's notices on overcharging of old batches of drugs, without establishing the manufacturer's role. Members met the Ministry of Health on this issue. The committee also contributed suggestions to address the anomaly of price-fixation of injections.

A new regulation for certain categories of Prescription Drugs (Schedule H1) was introduced effective March 01, 2014. The drugs covered were formulations containing psychotropic and narcotic substances like Codeine, Diazepam, etc. The regulation requires new warning labels and a record of sale to be maintained by the retailer or pharmacist. Both these requirements have posed challenges towards implementation. The committee has been in talks with the local state authorities to gather clarification on this issue.

The issue of vitamin supplements marketed as 'Dietary Supplements' was taken up by the committee. With no law governing vitamin supplements till 2010, the drug authorities raised this issue and many legal actions unfolded. The writ petitions before Kerala High Court have been dealt with. The Food Authority has issued adhoc advisories directing product approvals for dietary supplements, applying Recommended Dietary Allowance norms. Meanwhile, the product approval advisory stay continues.

The committee tracked a few cases throughout the year which would have an impact on business.

The High Court directed constitution of an expert body to look into the issues under Drugs & Cosmetics Act and Food Safety & Standards Authority of India.

There has been no definition issued on segregating gifts from brand reminder products. Till such a clarification is issued, OPPI members will continue with brand reminders.

The DCGI has constituted various New Drug Advisory Committees to consider applications filed for approval. Meanwhile, stay orders continue for:

- Haryana Pharmaceuticals Manufacturer Association Vs. Union of India and others – Punjab & Haryana High Court ‘not to take coercive action against the petitioner for compliance of the impugned letters, till the next date of hearing’
- Sirmour Pharma Manufacturers Association Vs. Union of India and Others – Simla High Court
- ‘Interim stay’ of the circular dated July 01, 2013 directing filing of applications by August 31, 2013.

The committee has been providing relevant data to the Government authorities and continues to provide regular inputs to the Medical and Regulatory committee for action items on relevant cases.

**CHAIRMAN:** G. Sathya Narayanan (Galderma)

**CO-CHAIRMAN:** Sanjay Murdeshwar (AstraZeneca)

**MEMBERS:** Ravi Kiran (Abbott) • Pawan Singhal\* (AstraZeneca) • Pankaj Jain (AstraZeneca) • Anuranjan Prasad (Baxter) • Rajiv Wani (Bayer) • Neha Kshirsagar (Bayer) • Santosh Mane (Boehringer Ingelheim) • Bhavik Desai (Bristol-Myers Squibb) • Dr Simrat Sohal (Eli Lilly) • Sharmistha Basu (Johnson & Johnson) • Vikas Gupta (Merck Serono) • Jaspreet Sing Chandhok\* (MSD Pharmaceuticals) • Raman Akella (Nektar) • Durganand Singh (Novartis) • Kavary Madappa (Novo Nordisk) • Samir Kazi (Pfizer) • Akhilesh Nand (Ranbaxy) • Shivprasad Laud (Roche) • Yasmin Cama (Sanofi) • Partha Sil (Sanofi) • Dr Yanick Girard (Serdia) • Satish Joshi (UCB)

\*Resigned

## Technical and Supply Chain

### Objectives:

To help shape the regulatory environment for improving the quality of medicines and for better compliance  
To facilitate efficient supply chain management, including the creation of 'Pharmazones' and improvement of the cold chain for pharmaceutical products.

- Share knowledge on good practices and ensure compliance
- Collaborate for the creation of 'Pharmazones'

The committee provided inputs to relevant ministries on the implementation of IP 2014, challenges faced in clearing consignments of imported finished formulations in Universal/International packs and Regulation of Controlled Substances (Preparations of Ephedrine and Pseudoephedrine).

The committee organised interactive sessions on:

Counterfeiting Pharmaceuticals - Schott Kaisha and Sovereign Pharma made a presentation on 'A crime against humanity - Importance of Primary Packaging' (case: Trends in Injectables). The comparison of manufacturing facilities on 'How it is produced Vs. How it should be produced' engaged the audience. The importance of primary packaging, trends in injectables with focus on Chinese and Indian Lyophilisation technology and patient safety were part of the discussion.

Members actively participated in a workshop on Harmonisation of Effective Recall and Good Distribution Practices at Chennai by CDSCO, South Zone.

The committee prepared 'Guidelines on Good Distribution Practices for Pharmaceutical Products', a document covering receipt of goods, storage, issuance and return, as well as queries on customer service, breakage, expiry and claims and instructions for Good Selling Practices, Good Warehousing Practices and Good Distribution Practices across 20 elements of good warehousing practices.

A research paper identifying key infrastructure issues in Life Science (LS) logistics was created inviting life sciences and logistics professionals, Government authorities, infrastructure developers and private logistics players to share insights on how India can achieve a world-class LS logistics set up. The committee undertook a SWOT analysis of India's current LS logistics and benchmarked these with good practices in China (a similar emerging economy, facing comparable economic challenges) and the European Union (a more advanced, best practice market). The recommendations in this paper aim to help India emerge more competitive, with world-class LS Logistics. The committee thanks DHL for providing significant inputs and allowing access to their data.

Good Distribution Practices: LBW Consultants shared insights on the challenges faced by supply chain managers and Carrying & Forwarding Agents (CFAs) and current warehousing practices in India.

DoP is preparing a draft paper for promoting the domestic manufacture of critical bulk drugs and creating an eco-system to make the domestic bulk drug industry more attractive and cost competitive. Committee members provided valuable inputs to the paper.

A TF visited the Goa plants of Abbott, Merck Serono, Pfizer and Sanofi. Issues concerning FDA, DCGI, DGFT and implementation of IP 2014 as well as concerns about the Indian Pharmacopoeia Commission were discussed. Subsequently, representations were made to relevant Government authorities.

A TF led a site visit to Mezies Air Cargo Pvt Ltd, Air Cargo Terminal, Hyderabad and discussed issues

like customs working, life-saving drugs, NOC (from Logistic Promotion Board, Bulk Drugs), cold storage facilities, indirect taxes, shipping issues (clearance of part consignment), testing of samples, interpretation of Government orders, documentation, etc. It was decided to make a joint representation to the relevant Government departments on the industry's concerns.

## Annual Awards

The Committee managed the annual OPPI Excellence Awards in the fields of research, sales & marketing and supply chain. The awards are covered on the Awards page

**CHAIRMAN:** Raghu Kumar (Allergan)

**CO-CHAIRMAN:** Dr Ramesh Panchagnula (Nektar)

**MEMBERS:** Shailendra Bobhate (Abbott) • K.T. Rajan (Allergan) • Robert Haxton (AstraZeneca) • Dr Premnath Shenoy (AstraZeneca) • Vinay Phatak (Bayer) • Sanjay Manjarekar (Bayer) • Santosh Chandgadkar (Bristol-Myers Squibb) • Raghavendra Agarwal (Bristol-Myers Squibb) • P. Thiyagarajan (Eli Lilly) • Dr Anand Dixit (Galderma) • Riju Verma (Johnson & Johnson) • Aditya Berlia (Martin & Harris) • Rakesh Shah (Merck Serono) • Sanjay Bhatkhande (MSD Pharmaceuticals) • Dharmesh Kharwar (MSD Pharmaceuticals) • Saurabh Garg (Nektar) S.G. Rao (Novartis) • Suhas Karambelkar (Novo Nordisk) • Vivek Dhariwal (Pfizer) • Sailesh Tekriwal (Ranbaxy) • Arun Manjeshwar (Roche) • Krishna Parab (Sanofi) • Sadhana Mogre (Sanofi) • Santhosh Menon (Serdia) • Milind Kulkarni (UCB)

**SPECIAL INVITEES:** Ajit Singh (ACG) • Mohan Joshi (Consultant)



# Project Jawhar

27 year old Rama Devi, a resident of Jawhar felt constantly weak and tired. Her haemoglobin (HB) read a dangerously low 3.5. In her fourth month of pregnancy, she was fighting for her life and the life of her yet to be born baby. It was a blessing that she visited one of the medical camps organised at Jawhar. Today, she has a healthy baby and is doing fine herself.

Close your eyes for a second and picture a happy Rama Devi with her new- born. Doesn't it bring a smile to your face? Today, there are over 4000 smiles in Jawhar, a remote district in Palghar, Maharashtra. Around 4000 healthy nursing mothers with their babies motivate us at Project Jawhar, which is in its second year.

Project Jawhar aims at making a positive difference in bringing down the Maternal Mortality Rate (MMR). Socio-economic and demographic factors contribute in a big way, to the poor MMR in India. When we take a look at the lack of facilities across the country, it is not surprising to note that India fares badly in this area.

Jawhar draws on the Three Delays Model which recognises the barriers women face in achieving the timely and effective medical care needed to prevent deaths occurring in pregnancy and childbirth. *Delay one:* in decision to seek care stems from socio economic factors like the financial burden, a poor understanding of risk factors in pregnancy and a previous poor experience of healthcare. *Delay two:* in reaching care due to the non-availability of proper transportation and distance to healthcare centres and hospitals and a poor road network and *Delay three:* in receiving adequate healthcare due to the lack of medical supplies, inadequately trained medical staff and inadequate referral systems. With women in rural areas still subject to all these delays, their health issues remain unattended. A lack of awareness and knowledge pose an additional challenge.

OPPI's Project Jawhar, a joint initiative with the Government of Maharashtra, the Rotary Club, Mumbai, the Indian Medical Association and NGO Pragati Pratishthan, aims to promote awareness around the importance of reducing delays in emergency treatment and encourages local women's groups to understand and accept the principles of antenatal care, postnatal care, spacing children and child immunisation.

In addition, project workers have to deal with the social issues of repeated pregnancies till the birth of a boy child, a practice still rampant in rural India. They have to counsel women about the physical and emotional trauma of repeated pregnancies and their long-term effects on health. Focus is maintained on the concepts of family planning and the importance of the right diet during pregnancy and lactation.

Many women participate in the antenatal and postnatal camps, which are held periodically. The women are educated on the importance of good health and given tips on leading a healthy life. All participants in the project receive regular health checks and their newborns receive paediatric care as well.

Today, Project Jawhar has helped make a real difference in the lives of the women in Jawhar. Like Rama Devi, many women who initially registered in the camps recorded threatening low HB levels. However, Jawhar has registered a rise in HB levels amongst women from 5 to 9 and proudly recorded a zero mortality rate. OPPI member companies have stepped in with free supplies of iron and calcium tablets and injectables for 100 days of pregnancy. This helps provide cover for good health among expectant mothers during the critical period of pregnancy.

Sadly, women in rural India are denied basic access to healthcare. Through Jawhar, our endeavour is to slowly build the health literacy levels among sections of such women and provide the support and care women need during this phase. Saving a life is as critical as giving birth to one! Through Jawhar we aim at doing both.



- The world has just one more year to achieve the Millennium Development Goals (MDGs)
- The MDGs address multi-dimensional issues and manifestations of the extreme poverty prevailing in the world
- Eight MDGs are specified with 18 quantifiable targets and these will be evaluated by 48 indicators
- The fifth MDG is to improve the Maternal Mortality Ratio (MMR)
- Though the MMR in India has declined from 398 to 178 per 100,000 live births, the objective is to reduce this figure to 109 by 2015

# OPPI AWARDS



Winner of Marketing Award - New Products  
*Boehringer Ingelheim India Pvt Ltd*



Winner of Marketing Award - Existing Products  
*Novartis India Ltd*



Winner of Scientist Award  
*Dr Prabhu Dutt Mishra, Piramal Enterprises Ltd*



Winner of Scientist Award  
*Dr Gangadhar J. Sanjayan, CSIR, Pune*

OPPI has instituted Annual Awards for excellence in Research, Sales, Marketing and Supply Chain. These awards recognise outstanding work which becomes part of the good practices followed in the Indian pharmaceutical industry. These Awards have now become the gold standard of the industry.



Winner of Sales Force Excellence Award  
*Eli Lilly & Company (India) Pvt Ltd*



Winner of Best Vendor Award - Carrying & Forwarding Agents  
Leo Enterprises



Winner of Best Vendor Award - Contract Manufacturing  
Medreich Ltd



The OPPI Healthcare Access Award was introduced for the first time this year. The award recognised the highest contribution by an individual or institution on Access to Healthcare with consideration for patient safety and adherence to quality. JAIPUR FOOT was declared the winner and the award was received by Padma Bhushan Devendra Raj Mehta, Founder and Chief patron of the Bhagwan Mahaveer Viklang Sahayata Samiti (BMVSS) for the exemplary work done for the rehabilitation of the physically disabled



# Meetings with Policy Makers and Government Authorities

w.e.f September 16, 2013

Date	Ministers / Officials	Delegation	Purpose
1 27.09.2013	<ul style="list-style-type: none"> <li>Dr Krishnarajan Bangarurajan Deputy Drugs Controller (India), CDSCO</li> </ul>	<ul style="list-style-type: none"> <li>Dr S. Thirumalai Velu, Allergan</li> <li>Rahul Chauhan, Eli Lilly</li> <li>Girish Parhate, Bayer</li> <li>Ketan Kotadiya, Roche</li> <li>Anil Puri, Sanofi</li> <li>Tabrez Ahmad, OPPI</li> <li>Prem Singh Rawat, OPPI</li> </ul>	Discussion on Guidance Document on common submission format for import & registration of bulk drugs & finished formulations in India
2 04.10.2013	<ul style="list-style-type: none"> <li>Shri D.S. Kalha Secretary, Department of Pharmaceuticals (DoP)</li> <li>Shri C.P. Singh Chairman, NPPA</li> </ul>	<ul style="list-style-type: none"> <li>Aijaz Tobaccowalla, Pfizer &amp; Vice President, OPPI</li> <li>Sachin Dharap, Abbott</li> <li>Amitabh Baxi, Abbott</li> <li>S. Sridhar, Pfizer</li> <li>Tabrez Ahmad, OPPI</li> <li>Prem Singh Rawat, OPPI</li> </ul>	<ul style="list-style-type: none"> <li>Trade margins on DPCO 2013</li> <li>NLEM drugs</li> </ul>
3 09.10.2013	<ul style="list-style-type: none"> <li>Dr K.S. Kardam Joint Controller of Patents &amp; Designs, Patent Office</li> <li>Shri Hardev Karar Deputy Controller of Patents &amp; Designs, Patent Office</li> <li>Dr S.S. Singh Assistant Controller of Patents &amp; Designs, Patent Office</li> </ul>	<ul style="list-style-type: none"> <li>Suresh Gupta, BMS</li> <li>Dr Gaurav Arya, Eli Lilly</li> <li>Lakshmi Balasubhramaniam, CLG</li> <li>Tabrez Ahmad, OPPI</li> </ul>	International Non-proprietary Names (INN) at Patent Office
4 18.10.2014	<ul style="list-style-type: none"> <li>Shri Pankaj Agrawala Secretary, Dept. of Consumer Affairs</li> </ul>	<ul style="list-style-type: none"> <li>Tabrez Ahmad, OPPI</li> </ul>	OPPI Code of Pharmaceutical Practices 2012
5 22.10.2013	<ul style="list-style-type: none"> <li>Shri Pankaj Agrawala Secretary Department of Consumer Affairs</li> </ul>	<ul style="list-style-type: none"> <li>Pheroze Khan, BMS &amp; Vice President, OPPI</li> <li>Dr Simrat Sohal, Eli Lilly</li> <li>Rajiv Malhotra, Biogene Idec</li> <li>Tabrez Ahmad, OPPI</li> <li>Vivek Padgaonkar, OPPI</li> <li>Prem Singh Rawat, OPPI</li> </ul>	OPPI Code of Pharmaceutical Practices 2012
6 25.10.2013	<ul style="list-style-type: none"> <li>Shri D.S. Kalha Secretary, DoP</li> </ul>	<ul style="list-style-type: none"> <li>Dr Shailesh Ayyangar, Sanofi &amp; President, OPPI</li> </ul>	Trade Margins on NLEM 2011

			<ul style="list-style-type: none"> <li>• Sudarshan Jain, Abbott &amp; Vice President, OPPI</li> <li>• Aijaz Tobaccowalla, Pfizer &amp; Vice President, OPPI</li> <li>• Shirish Ghoge, Abbott</li> <li>• Tabrez Ahmad, OPPI</li> </ul>	
7	07.11.2013	<ul style="list-style-type: none"> <li>• Dr Syeda Hameed Member, Planning Commission</li> </ul>	<ul style="list-style-type: none"> <li>• Tabrez Ahmad, OPPI</li> </ul>	<ul style="list-style-type: none"> <li>• Access to Healthcare</li> <li>• CSR and PAP</li> </ul>
8	11.11.2013	<ul style="list-style-type: none"> <li>• DoP Meeting under the Chairmanship of Shri Shambhu Kallolikar Joint Secretary, DoP</li> </ul>	<ul style="list-style-type: none"> <li>• Shirish Ghoge, Abbott</li> <li>• M.K. Narayanaswamy, Sanofi</li> <li>• Hitesh Gajaria, KPMG</li> </ul>	Proposals for the Union Budget – 2014-15
9	11.11.2013	<ul style="list-style-type: none"> <li>• Dr K.S. Kardam Joint Controller of Patents &amp; Designs, Patent Office</li> </ul>	<ul style="list-style-type: none"> <li>• Members of the Government Affairs Forum</li> </ul>	Issues related to Pharmaceutical Patents
10	25.11.2013	<ul style="list-style-type: none"> <li>• Dr Vijay Raghavan Secretary Department of Biotechnology</li> </ul>	<ul style="list-style-type: none"> <li>• Tabrez Ahmad, OPPI</li> </ul>	Innovations in biotechnology
11	26.11.2013	<ul style="list-style-type: none"> <li>• Ms D. Purandeswari Minister of State for Commerce &amp; Industry</li> </ul>	<ul style="list-style-type: none"> <li>• Tabrez Ahmad, OPPI</li> </ul>	FDI in Pharmaceuticals
12	29.11.2013	<ul style="list-style-type: none"> <li>• Interactive Session of NPPA with Industry Associations</li> </ul>	<ul style="list-style-type: none"> <li>• Shirish Ghoge, Abbott</li> <li>• M.K. Narayanaswamy, Sanofi</li> <li>• Ranjana Smetacek, OPPI</li> <li>• Tabrez Ahmad, OPPI</li> <li>• Prem Singh Rawat, OPPI</li> </ul>	Issues related to pricing and implementation of various provisions of DPCO 2013
13	09.12.2013	<ul style="list-style-type: none"> <li>• Shri Keshav Desiraju Secretary, Ministry of Health &amp; Family Welfare (MoHFW)</li> <li>• Arun Maira, Member Planning Commission</li> <li>• Dr Syeda Hameed, Member Planning Commission</li> </ul>	<ul style="list-style-type: none"> <li>• Dr Shailesh Ayyangar, Sanofi &amp; President, OPPI</li> <li>• Ranjana Smetacek, OPPI</li> <li>• Tabrez Ahmad, OPPI</li> </ul>	Industry's role in building its image as a health provider
14	11.12.2013	<ul style="list-style-type: none"> <li>• Shri Arun Maira Member, Planning Commission</li> </ul>	<ul style="list-style-type: none"> <li>• Tabrez Ahmad, OPPI</li> </ul>	Business Regulations and Corporate Conduct
15	14.12.2013	<ul style="list-style-type: none"> <li>• Dr G.N. Singh Drugs Controller General (India)</li> </ul>	<ul style="list-style-type: none"> <li>• Tabrez Ahmad, OPPI</li> </ul>	<ul style="list-style-type: none"> <li>• Study on Counterfeits</li> <li>• Quality medicines for safety of patients</li> </ul>

16	04.01.2014	<ul style="list-style-type: none"> <li>• Dr Y.K. Gupta, Chairman, Sub-Committee of DTAB on FDCs and his team of officials</li> <li>• Shri A.K. Pradhan Deputy Drugs Controller and officials from CDSCO</li> </ul>	<ul style="list-style-type: none"> <li>• Girish Parhate, Bayer</li> <li>• Rajgopal H. Bhutada, Ranbaxy</li> <li>• Dr Jejee KaranKumar, Ranbaxy</li> <li>• Yasmin Shenoy, Sanofi</li> <li>• Tabrez Ahmad, OPPI</li> </ul>	Meeting of Sub-Committee of DTAB on FDCs
17	21.01.2014	<ul style="list-style-type: none"> <li>• Ms Aradhana Johri Secretary, DoP</li> </ul>	<ul style="list-style-type: none"> <li>• Aman Bajaaj, Takeda</li> <li>• Shirish Ghoge, Abbott</li> <li>• Ranjana Smetacek, OPPI</li> <li>• Tabrez Ahmad, OPPI</li> <li>• Prem Singh Rawat, OPPI</li> </ul>	<ul style="list-style-type: none"> <li>• DPCO issues - pricing of innovative ER/SR drugs</li> <li>• Corporate Social Responsibility (CSR)</li> </ul>
18	21.01.2014	<ul style="list-style-type: none"> <li>• Shri R.K. Jain Additional Secretary, MoHFW &amp; Director General, CGHS</li> </ul>	<ul style="list-style-type: none"> <li>• Aman Bajaaj, Takeda</li> <li>• Shirish Ghoge, Abbott</li> <li>• Ranjana Smetacek, OPPI</li> <li>• Tabrez Ahmad, OPPI</li> <li>• Prem Singh Rawat, OPPI</li> </ul>	<ul style="list-style-type: none"> <li>• Clinical Trials</li> <li>• CSR</li> <li>• Ethical Code of Pharmaceutical Marketing Practices</li> <li>• Drugs &amp; Cosmetics (Amendment) Bill, 2013</li> </ul>
19	21.01.2014	<ul style="list-style-type: none"> <li>• Dr A.K. Panda Joint Secretary, MoHFW</li> </ul>	<ul style="list-style-type: none"> <li>• Aman Bajaaj, Takeda</li> <li>• Shirish Ghoge, Abbott</li> <li>• Ranjana Smetacek, OPPI</li> <li>• Tabrez Ahmad, OPPI</li> <li>• Prem Singh Rawat, OPPI</li> </ul>	<ul style="list-style-type: none"> <li>• Clinical trials</li> <li>• Regulatory delays</li> </ul>
20	24.01.2014	<ul style="list-style-type: none"> <li>• Dr G.N. Singh, DCGL &amp; CDSCO Officials</li> </ul>	<ul style="list-style-type: none"> <li>• Sameer Savkur, Biogen</li> <li>• Edgard A. Olaizola, Eli Lilly</li> <li>• Dr Suresh Menon, Novartis</li> </ul>	Meeting with Industry Associations to streamline the process of regulatory approval and enforcement through transparent and accountable mechanism
21	28.01.2014	<ul style="list-style-type: none"> <li>• Dr Y.K. Gupta Head, Department of Pharmacology, AIIMS</li> </ul>	<ul style="list-style-type: none"> <li>• Dr Gaurav Arya, Eli Lilly</li> <li>• Khomba Singh, Pfizer</li> <li>• Ranjita Sood, Roche</li> <li>• Tabrez Ahmad, OPPI</li> <li>• Prem Singh Rawat, OPPI</li> </ul>	<ul style="list-style-type: none"> <li>• Partnership with stakeholders in healthcare</li> <li>• Clinical Trials</li> <li>• NLEM</li> <li>• Trade margins</li> </ul>
22	03.02.2014	<ul style="list-style-type: none"> <li>• Shri C.P. Singh Chairman, NPPA</li> </ul>	<ul style="list-style-type: none"> <li>• Ratnesh Lal, MSD</li> <li>• Tarun Bhatnagar, Sanofi</li> <li>• Tabrez Ahmad, OPPI</li> <li>• Prem Singh Rawat, OPPI</li> </ul>	Issues relating to implementation of DPCO, Pricing of ER/SR versions of NLEM drugs and trade margins
23	05.02.2014	<ul style="list-style-type: none"> <li>• Shri Shailendra Kumar Director, Department of Health, Ministry of Health and Family Welfare (MoHFW)</li> </ul>	<ul style="list-style-type: none"> <li>• Tabrez Ahmad, OPPI</li> <li>• Prem Singh Rawat, OPPI</li> </ul>	<ul style="list-style-type: none"> <li>• Clinical Trials</li> <li>• NLEM</li> <li>• Compulsory Licensing</li> </ul>

24	24.02.2014	<ul style="list-style-type: none"> <li>Shri C.P. Singh Chairman, NPPA and Sr. NPPA Officials</li> </ul>	<ul style="list-style-type: none"> <li>Shirish Ghoge, Abbott</li> <li>Amol Kulkarni, Fresenius Kabi</li> <li>S. Sridhar, Pfizer</li> <li>Prem Singh Rawat, OPPI</li> </ul>	Issues related to Implementation of DPCO 2013
25	24.02.2014	<ul style="list-style-type: none"> <li>Dr A.K. Panda Joint Secretary - Health MoHFW</li> </ul>	<ul style="list-style-type: none"> <li>Sameer Savkur, Biogen</li> <li>Shirish Ghoge, Abbott</li> <li>Swarnaraj Jacob, MSD</li> <li>S. Sridhar, Pfizer</li> </ul>	Clarification on implementation of Schedule H1
26	04.03.2014	<ul style="list-style-type: none"> <li>Meeting convened by the Department of Revenue, Ministry of Finance, chaired by the Additional Secretary (Revenue)</li> </ul>	<ul style="list-style-type: none"> <li>Shirish Ghoge, Abbott</li> <li>Tabrez Ahmad, OPPI</li> </ul>	Regulation of Preparations of Ephedrine and Pseudoephedrine
27	04.03.2014	<ul style="list-style-type: none"> <li>Dr Jagdish Prasad, Director General - Health Services</li> <li>Dr G.N. Singh, DCGI</li> </ul>	<ul style="list-style-type: none"> <li>Pheroze Khan, BMS &amp; Vice President, OPPI</li> <li>Rahul Chauhan, Eli Lilly</li> <li>Dr Chandrashekhar Potkar, Pfizer</li> <li>Dr Sanjay Sharma, Ranbaxy</li> <li>Tabrez Ahmad, OPPI</li> </ul>	Brainstorming with stakeholders to discuss issues related to Clinical Trials
28	04.03.2014	<ul style="list-style-type: none"> <li>Dr Jagdish Prasad Director General Directorate General of Health Services (DGHS) MoHFW</li> </ul>	<ul style="list-style-type: none"> <li>Pheroze Khan, BMS</li> <li>Rahul Chauhan, Eli Lilly</li> <li>Dr Suresh Menon, Novartis</li> <li>Dr Chandrashekhar Potkar, Pfizer</li> <li>Yasmin Shenoy, Sanofi</li> <li>Tabrez Ahmad, OPPI</li> </ul>	Key regulatory issues concerning the Pharmaceutical Industry
29	07.03.2014 & 08.03.2014	<ul style="list-style-type: none"> <li>Dr S. Manivannan Deputy Drugs Controller(India) CDSCO, South Zone</li> </ul>	<ul style="list-style-type: none"> <li>Vivek Dhariwal, Pfizer</li> </ul>	Workshop on Harmonisation of Effective Recall and Good Distribution Practices (GDP) at Chennai
30	13.03.2014	<ul style="list-style-type: none"> <li>Dr Sharat Chauhan PS to Minister for Health &amp; Family Welfare</li> </ul>	<ul style="list-style-type: none"> <li>Tabrez Ahmad, OPPI</li> <li>Khomba Singh, Pfizer</li> <li>Prem Singh Rawat, OPPI</li> </ul>	Clarification on implementation of Schedule H1
31	13.03.2014	<ul style="list-style-type: none"> <li>Dr A K Panda Joint Secretary, Health MoHFW</li> </ul>	<ul style="list-style-type: none"> <li>Tabrez Ahmad, OPPI</li> <li>Khomba Singh, Pfizer</li> <li>Prem Singh Rawat, OPPI</li> </ul>	<ul style="list-style-type: none"> <li>Clarification on implementation of Schedule H1</li> <li>Roger Bates issue</li> <li>India specific labeling on imported medicines</li> <li>Clinical Trial case in Supreme Court</li> </ul>



32	24.03.2014	<ul style="list-style-type: none"> <li>Shri Rajeev Kher Secretary - Commerce</li> </ul>	<ul style="list-style-type: none"> <li>Tabrez Ahmad, OPPI</li> </ul>	FDI and IPR issues
33	24.03.2014	<ul style="list-style-type: none"> <li>Shri D.V. Prasad Joint Secretary, DIPP</li> </ul>	<ul style="list-style-type: none"> <li>Tabrez Ahmad, OPPI</li> </ul>	IPR issues
34	24.03.2014	<ul style="list-style-type: none"> <li>Shri Lov Verma Secretary - Health MoHFW</li> <li>Dr A.K. Panda Joint Secretary - Health MoHFW</li> </ul>	<ul style="list-style-type: none"> <li>Tabrez Ahmad, OPPI</li> <li>Prem Singh Rawat, OPPI</li> </ul>	Innovation and Healthcare
35	26.03.2014	<ul style="list-style-type: none"> <li>Dr G.N. Singh, DCGI</li> <li>Dr V.G. Somani, Joint DCGI</li> <li>Shri A.K. Pradhan, Dy. DCI</li> <li>Officials from CDSCO</li> </ul>	<ul style="list-style-type: none"> <li>Dr Suresh Menon, Novartis</li> <li>Dr S. Thirumalai Velu, Allergan</li> <li>Shripal Sharma, Bayer</li> <li>Rahul Chauhan, Eli Lilly</li> <li>Riju Verma, Johnson &amp; Johnson</li> <li>Swarnaraj Jacob, MSD</li> <li>Dr Manish Paliwal, Pfizer</li> <li>Sonika Shah, Sanofi</li> <li>Daisy Sharma, Boehringer Ingelheim</li> <li>Tabrez Ahmad, OPPI</li> <li>Prem Singh Rawat, OPPI</li> </ul>	India specific labeling on imported finished formulations
36	31.03.2014	<ul style="list-style-type: none"> <li>Shri Amitabh Kant Secretary, DIPP</li> </ul>	<ul style="list-style-type: none"> <li>Dhritiman Biswas, Abbott</li> <li>Dr Gaurav Arya, Eli Lilly</li> <li>Neelima Dwivedi, MSD</li> <li>Sundeeep Kumar, Novartis</li> <li>Khomba Singh, Pfizer</li> <li>Tabrez Ahmad, OPPI</li> <li>Prem Singh Rawat, OPPI</li> </ul>	IPR related issues
37	14.04.2014 &15.04.2014	<ul style="list-style-type: none"> <li>Shri B.K. Singh, Director, DoP</li> </ul>	<ul style="list-style-type: none"> <li>Sangita Topiwala, Sanofi</li> <li>Dr Ajay Sharma, OPPI</li> </ul>	DPCO 2013 and pricing issues
38	15.04.2014	<ul style="list-style-type: none"> <li>Dr Rakesh Sarwal Advisor - Health Planning Commission</li> </ul>	<ul style="list-style-type: none"> <li>Sangita Topiwala, Sanofi</li> <li>Dr Ajay Sharma, OPPI</li> </ul>	<ul style="list-style-type: none"> <li>Access to medicines and healthcare</li> <li>Out-of-pocket expenses</li> </ul>
39	15.04.2014	<ul style="list-style-type: none"> <li>Ms Renu Parmar Advisor - Industry &amp; VSE Planning Commission</li> </ul>	<ul style="list-style-type: none"> <li>Sangita Topiwala, Sanofi</li> <li>Dr Ajay Sharma, OPPI</li> </ul>	<ul style="list-style-type: none"> <li>Access to healthcare</li> <li>PPP</li> <li>Pricing models</li> </ul>
40	24.04.2014	<ul style="list-style-type: none"> <li>Shri Keshav Desiraju Secretary Department of Consumer Affairs</li> </ul>	<ul style="list-style-type: none"> <li>Dr Shailesh Ayyangar, Sanofi &amp; President, OPPI</li> <li>Tabrez Ahmad, OPPI</li> </ul>	OPPI Code of Pharmaceutical Marketing Practices

41	24.04.2014	<ul style="list-style-type: none"> <li>Ms Aradhana Johri Secretary, DoP</li> </ul>	<ul style="list-style-type: none"> <li>Dr Shailesh Ayyangar, Sanofi &amp; President, OPPI</li> <li>Tabrez Ahmad, OPPI</li> </ul>	Issues facing the industry
42	24.04.2014	<ul style="list-style-type: none"> <li>Shri Lov Varma Secretary - Health MoHFW</li> </ul>	<ul style="list-style-type: none"> <li>Dr Shailesh Ayyangar, Sanofi &amp; President, OPPI</li> <li>Tabrez Ahmad, OPPI</li> </ul>	Regulatory issues facing the industry
43	26.04.2014	<ul style="list-style-type: none"> <li>Shri Amitabh Kant Secretary, DIPP</li> <li>Shri Chaitanya Prasad Controller General of Patents, Designs &amp; Trade Marks</li> <li>Shri D.V. Prasad Joint Secretary, DIPP</li> </ul>	<ul style="list-style-type: none"> <li>Tabrez Ahmad, OPPI</li> </ul>	<ul style="list-style-type: none"> <li>IP related issues: Government's and domestic industry's views</li> <li>Judiciary's perspective</li> </ul>
44	08.05.2014	<ul style="list-style-type: none"> <li>Shri Mahesh Zagade Commissioner, Food &amp; Drug Administration Maharashtra State</li> </ul>	<ul style="list-style-type: none"> <li>OPPI Executive Committee Members</li> </ul>	Issues related to the Pharmaceutical Industry
45	19.05.2014	<ul style="list-style-type: none"> <li>Dr G.N. Singh, DCGI</li> <li>Ms Annam Visala Deputy Drugs Controller (India)</li> </ul>	<ul style="list-style-type: none"> <li>Meenu Batolar, Biogen Idec</li> <li>Rishi Kapur, BMS</li> <li>Lakhvinder Singh, Johnson &amp; Johnson</li> <li>Tabrez Ahmad, OPPI</li> </ul>	Checklists for devices, cosmetics, GCTs, etc.
46	29.05.2014	<ul style="list-style-type: none"> <li>Dr G.N. Singh, DCGI</li> <li>Shri Aseem Sahu, Dy. DCI</li> <li>CDSCO Officials</li> </ul>	<ul style="list-style-type: none"> <li>Sameer Savkur, Biogen &amp; Vice President, OPPI</li> <li>Rahul Chauhan, Eli Lilly</li> <li>Lakhvinder Singh, Johnson &amp; Johnson</li> <li>Amita Bhave, Novartis</li> <li>Smriti Bhat, Sanofi</li> </ul>	<ul style="list-style-type: none"> <li>Site registration</li> <li>Package insert approval issues</li> <li>Clinical trials / compensation formula</li> <li>Status of NDAC / MDAC</li> <li>OPPI-ISCR workshop</li> </ul>
47	09.06.2014	<ul style="list-style-type: none"> <li>Department of Revenue Ministry of Finance</li> </ul>	<ul style="list-style-type: none"> <li>Shirish Ghoge, Abbott</li> <li>Renu Kulshreshta, Abbott</li> <li>Rohit Khandelwal, Eli Lilly</li> <li>Abhishek Jain, E&amp;Y</li> </ul>	<ul style="list-style-type: none"> <li>Pre-Budget meeting</li> </ul>
48	16.06.2014	<ul style="list-style-type: none"> <li>Shri B.K. Singh Director, DoP</li> </ul>	<ul style="list-style-type: none"> <li>Dr Ratnesh Lal, MSD</li> <li>Khomba Singh, Pfizer</li> <li>Prem Singh Rawat, OPPI</li> </ul>	<ul style="list-style-type: none"> <li>Internal Guidelines May 29, 2014 under Para 19 of the DPCO issued by NPPA</li> <li>UCPMP</li> <li>Excise duty exemption for stickering / relabeling</li> </ul>
49	19.06.2014	<ul style="list-style-type: none"> <li>Shri Injeti Srinivas Chairman, NPPA</li> </ul>	<ul style="list-style-type: none"> <li>Dr Gaurav Arya, Eli Lilly</li> <li>Dr Ratnesh Lal, MSD</li> </ul>	<ul style="list-style-type: none"> <li>Internal Guidelines May 29, 2014 under</li> </ul>

		<ul style="list-style-type: none"> <li>• Khomba Singh, Pfizer</li> <li>• Ranjita Sood, Roche</li> <li>• Tabrez Ahmad, OPPI</li> <li>• Prem Singh Rawat, OPPI</li> </ul>	<ul style="list-style-type: none"> <li>• Para 19 of the DPCO issued by NPPA</li> <li>• Pricing of ER/SR versions of NLEM drugs</li> </ul>	
50	26.06.2014	<ul style="list-style-type: none"> <li>• Mrs Aradhana Johri Secretary, DoP</li> </ul>	<ul style="list-style-type: none"> <li>• Vivek Dhariwal, Pfizer</li> <li>• Dr Sadanand Joglekar, Sanofi</li> <li>• Prem Singh Rawat, OPPI</li> </ul>	Draft paper for promoting domestic manufacturing of certain critical bulk drugs
51	04.07.2014	<ul style="list-style-type: none"> <li>• Shri Ananth Kumar Hon'ble Minister of Chemicals &amp; Fertilizers</li> </ul>	<ul style="list-style-type: none"> <li>• Ranjit Shahani, Novartis &amp; Immediate Past President, OPPI</li> <li>• Sudarshan Jain, Abbott &amp; Vice President, OPPI</li> <li>• Sameer Savkur, Biogen &amp; Vice President, OPPI</li> <li>• K.G. Ananthakrishnan, MSD &amp; Vice President, OPPI</li> <li>• Ranjana Smetacek, OPPI</li> </ul>	Discussion on critical issues of the Pharmaceutical Industry
52	04.07.2014	<ul style="list-style-type: none"> <li>• Shri Shambhu Kallolikar Joint Secretary, DoP</li> <li>• Shri B.K. Singh Director, DoP</li> </ul>	<ul style="list-style-type: none"> <li>• Amitabh Baxi, Abbott</li> <li>• Navin Sharma, Baxter</li> <li>• Khomba Singh, Pfizer</li> <li>• Ranjita Sood, Roche</li> <li>• Tabrez Ahmad, OPPI</li> <li>• Prem Singh Rawat, OPPI</li> </ul>	<ul style="list-style-type: none"> <li>• NPPA Internal Guidelines under Para 19 of DPCO 2013 dated May 29, 2014</li> <li>• NLEM</li> <li>• Pricing of ER/SR versions of NLEM drugs</li> </ul>
53	07.07.2014	<ul style="list-style-type: none"> <li>• Dr G.N. Singh, DCGI</li> </ul>	<ul style="list-style-type: none"> <li>• Tabrez Ahmad, OPPI</li> </ul>	Regulatory issues
54	11.07.2014	<ul style="list-style-type: none"> <li>• Dr G.N. Singh, DCGI</li> </ul>	<ul style="list-style-type: none"> <li>• Meenu Batolar, Biogen</li> <li>• Amita Bhave, Novartis</li> <li>• Sofi Joseph, Pfizer</li> <li>• Yasmin Shenoy, Sanofi</li> <li>• Tabrez Ahmad, OPPI</li> </ul>	<ul style="list-style-type: none"> <li>• Criteria for local CT data waiver for New Drug Approvals / Additional Indications</li> <li>• Site registration / renewal issues</li> </ul>
55	11.07.2014	<ul style="list-style-type: none"> <li>• Shri Injeti Srinivas Chairman, NPPA</li> </ul>	<ul style="list-style-type: none"> <li>• Tabrez Ahmad, OPPI</li> </ul>	NPPA Internal Guidelines under Para 19 of DPCO 2013 dated May 29, 2014
56	15.07.2014	<ul style="list-style-type: none"> <li>• Ms Aradhana Johri Secretary, DoP</li> </ul>	<ul style="list-style-type: none"> <li>• Ranjit Shahani, Novartis &amp; Immediate Past President, OPPI</li> <li>• K.G. Ananthakrishnan, MSD &amp; Vice President, OPPI</li> <li>• Shirish Ghoge, Abbott</li> <li>• Amitabh Baxi, Abbott</li> <li>• Ranjana Smetacek, OPPI</li> <li>• Tabrez Ahmad, OPPI</li> </ul>	Price fixation of Anti-diabetic and Cardiovascular Drugs en masse under Para 19 of DPCO 2013 - ref. NPPA Notification dated July 10, 2014

57	16.07.2014	<ul style="list-style-type: none"> <li>Shri Injeti Srinivas Chairman, NPPA</li> </ul>	<ul style="list-style-type: none"> <li>Ranjit Shahani, Novartis &amp; Immediate Past President, OPPI</li> <li>K.G. Ananthkrishnan, MSD &amp; Vice President, OPPI</li> <li>Shirish Ghoge, Abbott</li> <li>Ranjana Smetacek, OPPI</li> <li>Tabrez Ahmad, OPPI</li> </ul>	Price fixation of Anti-diabetic and Cardiovascular Drugs en masse under Para 19 of DPCO 2013 - ref. NPPA Notification dated July 10, 2014
58	16.07.2014	<ul style="list-style-type: none"> <li>Shri Ananth Kumar Hon'ble Minister of Chemicals &amp; Fertilizers</li> </ul>	<ul style="list-style-type: none"> <li>Ranjit Shahani, Novartis &amp; Immediate Past President, OPPI</li> <li>K.G. Ananthkrishnan, MSD &amp; Vice President, OPPI</li> <li>Shirish Ghoge, Abbott</li> <li>Ranjana Smetacek, OPPI</li> <li>Tabrez Ahmad, OPPI</li> </ul>	Price fixation of Anti-diabetic and Cardiovascular Drugs en masse under Para 19 of DPCO 2013 - ref. NPPA Notification dated July 10, 2014
59	17.07.2014	<ul style="list-style-type: none"> <li>Dr Jagdish Prasad Director General, DGHS</li> <li>Dr B.D. Athani, Special DGHS</li> <li>Dr G.N. Singh, DCGI</li> <li>Dr V.G. Somani, Joint DCGI</li> <li>Shri A.K. Pradhan, Deputy DCI</li> <li>Officials from CDSCO</li> </ul>	<ul style="list-style-type: none"> <li>Chirag Trivedi, Sanofi</li> <li>Prem Singh Rawat, OPPI</li> </ul>	Stakeholders' meeting called by DGHS, to deliberate on the Draft Rules published vide notification GSR 364(E) dated June 07, 2013, for audio/video recording of informed consent process
60	28.07.2014	<ul style="list-style-type: none"> <li>Workshop organised by Ministry of Finance</li> </ul>	<ul style="list-style-type: none"> <li>Khomba Singh, Pfizer</li> <li>Tabrez Ahmad, OPPI</li> </ul>	National Workshop on NDPS (Essential Narcotics Drugs) Rules, 2014
61	30.07.2014	<ul style="list-style-type: none"> <li>Shri Lov Verma, Secretary - Health MoHFW</li> </ul>	<ul style="list-style-type: none"> <li>Sameer Savkur, Biogen &amp; Vice President, OPPI</li> <li>Dr Suresh Menon, Novartis</li> <li>Chandrashekhkar Potkar, Pfizer</li> <li>Tabrez Ahmad, OPPI</li> </ul>	<ul style="list-style-type: none"> <li>Criteria for local CT data waiver for New Drug Approvals / Additional Indications</li> <li>Amendments to Rule 122 DAB G.S.R. 292(E) of April 24, 2014</li> <li>Inordinate delays in the overall review / approval process for New Drugs and Clinical Trial applications</li> </ul>
62	30.07.2014	<ul style="list-style-type: none"> <li>Shri K.L. Sharma, Joint Secretary - Health MoHFW</li> </ul>	<ul style="list-style-type: none"> <li>Sameer Savkur, Biogen &amp; Vice President, OPPI</li> <li>Dr Suresh Menon, Novartis</li> <li>Dr Chandrashekhkar Potkar, Pfizer</li> <li>Tabrez Ahmad, OPPI</li> </ul>	<ul style="list-style-type: none"> <li>Visit</li> </ul>

63	31.07.2014 • Indian Patent Office	<ul style="list-style-type: none"> <li>• Dr Gaurav Arya, Eli Lilly</li> <li>• Tabrez Ahmad, OPPI</li> </ul>	<ul style="list-style-type: none"> <li>• Guidelines for examination of patent applications in the field of pharmaceuticals</li> </ul>
64	01.08.2014 • Shri Sumanta Chaudhuri Joint Secretary (Commerce) Ministry of Commerce & Industry	<ul style="list-style-type: none"> <li>• Tabrez Ahmad, OPPI</li> </ul>	<ul style="list-style-type: none"> <li>• Multilateral Trade Agreements (China &amp; Asia Pacific)</li> </ul>
65	14.08.2014 • Shri Chaitanya Prasad Controller General of Patents, Designs & Trade Marks Ministry of Commerce & Industry  <ul style="list-style-type: none"> <li>• Dr Amitava Chakraborti Deputy Controller of Patents &amp; Designs Ministry of Commerce &amp; Industry</li> </ul>	<ul style="list-style-type: none"> <li>• OPPI Executive Committee Members</li> </ul>	<ul style="list-style-type: none"> <li>• IP and patent related issues of the pharmaceutical industry</li> </ul>

# Representations 2013-14

w.e.f. September 01, 2013

## Summary:

	Ministry	Representations
1	Ministry of Chemicals & Fertilizers (DoP, NPPA)	21
2	Ministry of Health & Family Welfare / CDSCO / IPC / FDA	29
3	Ministry of Commerce & Industry	04
4	Ministry of Finance	10
5	Ministry of Labour & Employment	05
6	Others	07
	Total	76

## MINISTRY OF CHEMICALS & FERTILIZERS (Department of Pharmaceuticals – DoP and National Pharmaceutical Pricing Authority – NPPA)

	Date	Subject	Addressed to
1	19.09.2013	OPPI Pre-Budget Memorandum 2014-15	<ul style="list-style-type: none"><li>Shri Dilsher Singh Kalha Secretary, Department of Pharmaceuticals (DoP)</li><li>Ms Barnali Kshtagir Under Secretary, DoP</li></ul>
2	01.10.2013 / 22.10.2013	Benefit of Excise Notification to be extended	<ul style="list-style-type: none"><li>Shri Dilsher Singh Kalha Secretary, DoP</li></ul>
3	06.12.2013	Price Fixation of New Drug as per the provisions of Para 5 of DPCO 2013 – suggestion for expert in Pharmacoeconomics	<ul style="list-style-type: none"><li>Shri A.K. Gautam Advisor (Cost), NPPA</li></ul>
4	16.01.2014	OPPI Pre-Budget Memorandum 2014-15 - with financial impact	<ul style="list-style-type: none"><li>Shri B.K. Singh Director, DoP</li></ul>
5	10.02.2014	CL as a tool to improve Access to Medicines in India	<ul style="list-style-type: none"><li>Shri Srikant Jena Hon'ble Minister of State for Chemicals &amp; Fertilizers</li><li>Ms Aradhana Johri Secretary, DoP</li></ul>
6	25.02.2014	Additional / revised comments on the Report of the Committee on Price Negotiation of Patented Drugs	<ul style="list-style-type: none"><li>Shri Shambhu Kallollikar Chairman, Inter-Ministerial Committee on Prices of Patented Drugs &amp; Joint Secretary, DoP</li></ul>

			<ul style="list-style-type: none"> <li>Ms Barnali Khastgir Under Secretary, DoP</li> </ul>
7	28.02.2014	Follow up on the interactive discussion with Industry Associations on issues related to Implementation of DPCO 2014	<ul style="list-style-type: none"> <li>Shri C.P. Singh Chairman, NPPA</li> </ul>
8	25.02.2014	Response to the Inter-Ministerial Committee request dated February 17, 2014 for additional / revised comments on the 'Report of the Committee on Price Negotiation of Patented Drugs'	<ul style="list-style-type: none"> <li>Shri Shambhu Kallolikar Chairman Inter-Ministerial Committee on Prices of Patented Drugs &amp; Joint Secretary, DoP</li> <li>Ms Barnali Khastgir Under Secretary, DoP</li> </ul>
9	28.02.2014	Follow up on Implementation of DPCO 2013 – interactive discussion by NPPA with Industry Associations held on February 24, 2014	<ul style="list-style-type: none"> <li>Shri C.P. Singh Chairman, NPPA</li> <li>Shri A.K. Gautam, Advisor Cost, NPPA</li> <li>Shri A.K. Saha Director (Overcharging), NPPA</li> <li>Shri Jagdish Kumar Director (M &amp; E), NPPA</li> </ul>
10	11.03.2014	Constitution of Pharmaceutical Advisory Forum	<ul style="list-style-type: none"> <li>Ms Aradhana Johri Secretary, DoP</li> </ul>
11	28.04.2014	Follow up of meeting (April 24, 2014 ) with OPPI President and Secretary General	<ul style="list-style-type: none"> <li>Ms Aradhana Johri Secretary, DoP</li> </ul>
12	12.05.2014	OPPI comments on National List of Essential Medical Devices	<ul style="list-style-type: none"> <li>Ms Barnali Khastgir Under Secretary, DoP</li> </ul>
13	28.05.2014	Rational of fixing ceiling prices on single - dose and multi-dose vials of essential medicines	<ul style="list-style-type: none"> <li>Shri C.P. Singh Chairman, NPPA</li> <li>Ms Aradhana Johri Secretary, DoP</li> </ul>
14	29.05.2014	Notices on overcharging raised by NPPA	<ul style="list-style-type: none"> <li>Shri C.P. Singh Chairman, NPPA</li> <li>Ms Aradhana Johri Secretary, DoP</li> </ul>
15	03.06.2014	Notification on Benefit of Excise	<ul style="list-style-type: none"> <li>Ms Aradhana Johri Secretary, DoP</li> </ul>
16	25.06.2014	Priorities to support the healthcare objectives and revitalise the Indian pharmaceutical industry	<ul style="list-style-type: none"> <li>Shri Ananth Kumar Hon'ble Minister of Chemicals &amp; Fertilizers</li> </ul>
17	11.07.2014	Arbitrary price fixation of Anti-diabetic and Cardiovascular Drugs en masse under Para 19 of DPCO 2013	<ul style="list-style-type: none"> <li>Ms Aradhana Johri Secretary, DoP</li> </ul>

18	11.07.2014	NPPA's unilateral decision to extend price control on products outside NLEM 2012	<ul style="list-style-type: none"> <li>Shri Ananth Kumar Hon'ble Minister of Chemicals &amp; Fertilizers</li> </ul>
19	14.07.2014	New Drug Delivery Systems (NDDS) such as Sustained Release / Extended Release preparations	<ul style="list-style-type: none"> <li>Ms Aradhana Johri Secretary, DoP</li> <li>Shri Shambhu Kallolikar Joint Secretary, DoP</li> <li>Shri Injeti Srinivas Chairman, NPPA</li> </ul>
20	21.07.2014	Price fixation of Non-Essential Anti-diabetic and Cardiovascular drugs under Para 19 of DPCO 2013	<ul style="list-style-type: none"> <li>Shri Injeti Srinivas Chairman, NPPA</li> <li>Shri Ananth Kumar Hon'ble Minister of Chemicals &amp; Fertilizers</li> <li>Ms Aradhana Johri Secretary, DoP</li> </ul>
21	31.07.2014	Post-Budget recommendations – 2014-15	<ul style="list-style-type: none"> <li>Ms Aradhana Johri Secretary, DoP</li> </ul>

## Ministry of Health & Family Welfare (MoHFW) / CDSCO

Date	Subject	Addressed to	
1	03.09.2013	GSR 364(E) dated June 07, 2013 – Draft Rules to amend Drugs & Cosmetics Rules 1945 in Schedule Y pertaining to Clinical Trials	<ul style="list-style-type: none"> <li>Dr A.K. Panda Joint Secretary, MoHFW</li> <li>Shri Keshav Desiraju Secretary, MoHFW</li> <li>Dr G.N. Singh Drugs Controller General (India), CDSCO</li> </ul>
2	03.09.2013	GSR 520(E) dated July 31, 2013 Regarding package insert and promotional literature in bold red letters for preparation containing Pioglitazone	<ul style="list-style-type: none"> <li>Dr A.K. Panda Joint Secretary, MoHFW</li> <li>Shri Keshav Desiraju Secretary, MoHFW</li> <li>Dr G.N. Singh, DCGI</li> </ul>
3	07.10.2013	Guidance Document on Common Submission Format for Import and Registration of Bulk Drugs & Finished	<ul style="list-style-type: none"> <li>Dr Krishnarajan Bangarurajan Deputy Drugs Controller (India), CDSCO</li> </ul>
4	18.10.2013	Draft Report of Dr C.K. Kokate Expert Committee to formulate policy guidelines	<ul style="list-style-type: none"> <li>Shri Keshav Desiraju Secretary, MoHFW</li> </ul>



and procedures for approval of FDCs

- Dr C.K. Kokate  
Chairman, Expert Committee  
on FDCs
- Dr G.N. Singh,  
DCGI

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5	18.10.2013	Report of Prof Ranjit Roy Chaudhury Expert Committee to Formulate Policy Guidelines and SOPs for Approval of New Drugs, Clinical Trials, Banning of Drugs	<ul style="list-style-type: none"><li>• Shri Keshav Desiraju Secretary, MoHFW</li><li>• Prof Ranjit Roy Chaudhury Chairman, Expert Committee</li><li>• Dr G.N. Singh, DCGI</li></ul>
6	29.11.2013	Implementation of Indian Pharmacopoeia 2014	<ul style="list-style-type: none"><li>• Dr G. N. Singh DCGI &amp; Secretary-cum- Scientific Director, Indian Pharmacopoeia Commission</li></ul>
7	18.12.2013	Agenda No.2 of Minutes of 65th Meeting of DTAB held on November 25, 2013 – regarding issue of PET bottles	<ul style="list-style-type: none"><li>• Dr G.N. Singh, DCGI</li></ul>
8	21.01.2014	OPPI suggestions on the action taken on Recommendations of the Prof Ranjit Roy Chaudhury Expert Committee Report	<ul style="list-style-type: none"><li>• Shri Keshav Desiraju Secretary, MoHFW</li><li>• Dr G.N. Singh, DCGI</li><li>• Prof Ranjit Roy Chaudhury Chairman, Expert Committee</li></ul>
9	21.01.2014	OPPI recommendations / suggestions on CDSCO's Draft Guidelines on Audio-Visual recording of the informed consent process in Clinical Trial, dated January 09, 2014	<ul style="list-style-type: none"><li>• Dr G.N. Singh, DCGI</li></ul>
10	27.01.2014	India's Polio Eradication Program	<ul style="list-style-type: none"><li>• Shri Ghulam Nabi Azad Hon'ble Minister of Health &amp; Family Welfare</li></ul>
11	07.02.2014	Inputs for visit of USFDA Commissioner	<ul style="list-style-type: none"><li>• Dr G.N. Singh, DCGI</li></ul>
12	10.02.2014	CL as a tool to improve Access to Medicines in India	<ul style="list-style-type: none"><li>• Shri Ghulam Nabi Azad Hon'ble Minister of Health &amp; Family Welfare</li><li>• Shri K. Desiraju Secretary, MoHFW</li></ul>

13	12.02.2014	G.S.R. 588(E) dated August 30, 2013: Request for clarification on implementation of Schedule H1 labelling requirements under Rule 96 of the Drugs & Cosmetics Rules, 1945	<ul style="list-style-type: none"> <li>• Dr G.N. Singh, DCGI</li> </ul>
14	21.02.2014	Agenda No.2 – Minutes of the 65th meeting of DTAB held on November 25, 2013: Regarding PET Bottles	<ul style="list-style-type: none"> <li>• Dr A.K. Panda Secretary, MoHFW</li> <li>• Dr Jagdish Prasad Director General of Health Services (DGHS)</li> </ul>
15	12.03.2014	Request regarding challenges faced in clearing consignments of imported finished formulations in universal / international packs	<ul style="list-style-type: none"> <li>• Dr A.K. Panda Joint Secretary, MoHFW</li> <li>• Dr Jagdish Prasad Director General, DGHS</li> <li>• Dr G.N. Singh, DCGI</li> </ul>
16	01.04.2014	Request for extension of effective date of Indian Pharmacopoeia 2014	<ul style="list-style-type: none"> <li>• Dr G.N. Singh, DCGI &amp; Secretary-cum-Scientific Director Indian Pharmacopoeia Commission</li> </ul>
17	10.04.2014	Key issues of the Pharmaceutical Industry	<ul style="list-style-type: none"> <li>• Dr G.N. Singh, DCGI</li> </ul>
18	15.04.2014	Schedule H1 (Tramadol and Tapentadol)	<ul style="list-style-type: none"> <li>• Dr G.N. Singh, DCGI</li> </ul>
19	28.04.2014	System of pre-screening for submission of reports of SAEs to CDSCO	<ul style="list-style-type: none"> <li>• Dr G.N. Singh, DCGI</li> </ul>
20	28.04.2014	Follow up of meeting (April 24, 2014) with OPPI President and Secretary General	<ul style="list-style-type: none"> <li>• Shri Lov Verma Secretary - Health MoHFW</li> </ul>
21	06.08.2014	Follow up of meeting with OPPI delegation on: New drug applications and additional indications, manufacturing site registration and the permission of Rule 37	<ul style="list-style-type: none"> <li>• Dr G.N. Singh, DCGI</li> </ul>
22	12.05.2014	Request for clarification on the current status of New Drug Advisory Committee(NDAC) and Medical Devices Advisory Committee (MDAC)	<ul style="list-style-type: none"> <li>• Dr G.N. Singh, DCGI</li> </ul>
23	21.05.2014	CDSCO document: Draft formula to determine the quantum of compensation in case of Clinical Trial related injury (other than death)	<ul style="list-style-type: none"> <li>• Dr G.N. Singh, DCGI</li> </ul>

24	03.06.2014	Priorities to support the healthcare objectives and revitalise the Indian pharmaceutical industry	<ul style="list-style-type: none"> <li>Dr Harsh Vardhan Hon'ble Minister of Health &amp; Family Welfare</li> </ul>
25	17.06.2014	OPPI comments on GSR 292(E) dated April 24, 2014 amending Rule 122 DAB, Schedule-Y of the Drugs & Cosmetics Rules 1945 regarding medical management, compensation, etc. in case of clinical trial	<ul style="list-style-type: none"> <li>Dr G.N. Singh, DCGI</li> </ul>
26	30.06.2014	Warning letters issued by DCGI to sponsors and investigators	<ul style="list-style-type: none"> <li>Dr G.N. Singh, DCGI</li> </ul>
27	14.08.2014	Current challenges faced by the pharmaceutical industry	<ul style="list-style-type: none"> <li>Shri Lov Verma Secretary – Health MoHFW</li> </ul>
28	14.08.2014	OPPI comments on the draft Pharmacovigilance Guidance Document for Biological Products	<ul style="list-style-type: none"> <li>Dr G.N. Singh, DCGI</li> </ul>

## Ministry of Commerce and Industry

Date	Subject	Addressed to	
1	10.12.2013	Amendment of AOA of PHARMEXCIL for effective functioning of Council	<ul style="list-style-type: none"> <li>Shri Anand Sharma Hon'ble Minister of Commerce &amp; Industry and Textiles</li> <li>Secretary Department of Commerce</li> <li>Deputy Secretary Department of Commerce</li> </ul>
2	15.01.2014	Consolidated FDI Policy Circular – Issue of Seventh Edition of the Circular	<ul style="list-style-type: none"> <li>Smt. Anjali Prasad Joint Secretary Department of Industrial Policy &amp; Promotion (DIPP)</li> <li>Shri Ishtiyaque Ahmed Director, DIPP</li> </ul>
3	10.02.2014	CL as a tool to improve Access to Medicines in India	<ul style="list-style-type: none"> <li>Shri Anand Sharma Hon'ble Minister of Commerce &amp; Industry and Textiles</li> <li>Shri Saurabh Chandra Secretary, DIPP</li> <li>Shri D.V. Prasad Joint Secretary, DIPP</li> </ul>
4	25.06.2014	Priorities to support the healthcare objectives and revitalise the Indian pharmaceutical industry	<ul style="list-style-type: none"> <li>Ms Nirmala Sitharaman Hon'ble Minister of State of Commerce and Industry</li> </ul>

## Ministry of Finance

Date	Subject	Addressed to
1 19.09.2013	OPPI Pre-Budget Memorandum 2014-15	<ul style="list-style-type: none"> <li>Secretary Department of Revenue</li> <li>Chairperson Central Board of Excise &amp; Customs</li> <li>Shri Sunil Gupta Joint Secretary - Tax Policy &amp; Legislation (TPL), Central Board of Direct Taxes</li> <li>Shri P.K. Mohanty Joint Secretary (TRU-1)</li> </ul>
2 15.11.2013	Regulation of controlled substances (preparations of Ephedrine and Pseudoephedrine) F.No.11021/3/2010-NC-II dated October 30, 2013	<ul style="list-style-type: none"> <li>Shri S.N. Dash Under Secretary Department of Revenue</li> </ul>
3 10.02.2014	CL as a tool to improve Access to Medicines in India	<ul style="list-style-type: none"> <li>Shri P. Chidambaram Hon'ble Finance Minister</li> <li>Shri Arvind Mayaram Secretary, Department of Economic Affairs</li> </ul>
4 10.04.2014	Key issues of the Pharmaceutical Industry	<ul style="list-style-type: none"> <li>Office of the Commissioner of Customs and Central Excise, Goa</li> </ul>
5 05.05.2014	Suggestions from the Industry and Trade Associations on direct and indirect taxes for Union Budget 2014-15	<ul style="list-style-type: none"> <li>Shri M. Vinod Kumar Joint Secretary (TRU-II)</li> </ul>
6 17.07.2014	Amendment of NDPS Rules for Narcotic Drugs, manufactured drugs and psychotropic substances	<ul style="list-style-type: none"> <li>Ms Rashmi Verma Additional Secretary, Dept. of Revenue Ministry of Finance</li> </ul>
7 22.07.2014	Recommendations on Draft NDPS (Essential Narcotic Drugs), 2014 Rules	<ul style="list-style-type: none"> <li>Shri Rajesh Nandan Srivastava Director (Narcotics), Dept. of Revenue Ministry of Finance</li> </ul>
8 22.07.2014	Voluntary Code of Conduct and proposed amendments to NDPS (Regulation of Controlled Substances) Order, 2013	<ul style="list-style-type: none"> <li>Shri Rajesh Nandan Srivastava Director (Narcotics) Dept. of Revenue Ministry of Finance</li> </ul>
9 25.07.2014	Issue of Expression of Interest (EOI) for private companies to manufacture 'natural' manufactured drugs, from raw material other than opium or CPS under the provisions of Rule 36(2A) of the NDPS Rules, 1985	<ul style="list-style-type: none"> <li>Shri Rajesh Nandan Srivastava Director (Narcotics) Dept. of Revenue Ministry of Finance</li> </ul>

●	31.07.2014	Post-Budget recommendations – 2014-15	<ul style="list-style-type: none"> <li>• Finance Secretary, Ministry of Finance</li> <li>• Secretary, Dept. Revenue Ministry of Finance</li> <li>• Joint Secretary (TRU-I), Ministry of Finance</li> <li>• Joint Secretary, Tax Policy &amp; Legislation (TPL), Central Board of Direct Taxes Ministry of Finance</li> <li>• Chairperson, Central Board of Excise &amp; Customs, Ministry of Finance</li> </ul>
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## Ministry of Labour and Employment

Date	Subject	Addressed to
1 02.12.2013	Joint IDMA-OPPI representation on objection to the Notification No.SCA/CR-13/2012-13 dated October 21, 2013 regarding fixed working hours for the Sales Promotion Employees	<ul style="list-style-type: none"> <li>• Shri K.R. Niranjana Commissioner of Labour Karnataka</li> <li>• Shri B.N. Bachegowda Hon'ble Minister of Labour Government of Karnataka</li> <li>• Shri G.S. Narayana Swamy Secretary Department of Labour Karnataka</li> </ul>
2 27.01.2014	Memorandum of eight hours working of MRs (Ref.No.21/12010/SPA/1369-79 dated January 16, 2014)	<ul style="list-style-type: none"> <li>• The Asst. Labour Commissioner, Punjab</li> </ul>
3 20.02.2014	Objection to (Ref.No.21/12010/SPA/1369-79 dated January 16, 2014) the issued by Labour Department, Maharashtra, fixing working hours for the Sales Promotion Employees	<ul style="list-style-type: none"> <li>• Shri Hassan Miyanlal Mushrif Hon'ble Minister of Labour and Special Assistance Government of Maharashtra</li> </ul>
4 07.03.2014	Memorandum of eight hours working of MRs (Ref. No.21/1/2010/SPA/1369-79 dated January 16, 2014)	<ul style="list-style-type: none"> <li>• The Asst. Labour Commissioner, Punjab Chandigarh (General Branch)</li> </ul>
5 20.03.2014	Objection to Notification No.G.N. No.SPE-2010/C.R. 143/Lab-3 dated January 15, 2014 issues by Labour Department, Maharashtra fixing working hours for the Sales Promotion Employees	<ul style="list-style-type: none"> <li>• Shri Hassan Miyanlal Mushrif Hon'ble Minister of Labour and Special Assistance Government of Maharashtra</li> <li>• Shri Jayant R. Patil Hon'ble Minister of Rural Development Government of Maharashtra</li> </ul>

## Others

Date	Subject	Addressed to
1 07.10.2013	Comments / suggestions on the Drugs and Cosmetics (Amendment) Bill, 2013	<ul style="list-style-type: none"> <li>Smt Arpana Mendiratta Joint Director, Rajya Sabha Secretariat</li> </ul>
2 06.11.2013	Issues and concerns on working of Medical Representatives in Punjab	<ul style="list-style-type: none"> <li>Shri Sukhbir Singh Badal Deputy Chief Minister Government of Punjab</li> </ul>
3 10.02.2014	CL as a tool to improve Access to Medicines in India	<ul style="list-style-type: none"> <li>Dr Manmohan Singh Hon'ble Prime Minister of India</li> <li>Shri Montek Singh Ahluwalia Deputy Chairman Planning Commission</li> <li>Shri T.K.A. Nair Advisor, Prime Minister's Office</li> <li>Dr C. Rangarajan Chairman Economic Advisory Council to the Prime Minister</li> <li>Shri B.V.R. Subrahmanyam Joint Secretary to the Prime Minister, PMO</li> <li>Shri Vikram Doraiswamy Joint Secretary (Americas) Ministry of External Affairs</li> </ul>
4 13.02.2014	Regarding GEAC review of Pharmaceutical Applications	<ul style="list-style-type: none"> <li>The Chairman Genetic Engineering Appraisal Committee Ministry of Environment &amp; Forests</li> </ul>
5 10.04.2014	Key issues of the Pharmaceutical Industry	<ul style="list-style-type: none"> <li>Shri Salim A. Veljee Director, Food &amp; Drugs Administration Goa</li> <li>Smt. Saroj P. Billava, FTDO Office of the Deputy Director General of Foreign Trade (DGFT), Goa</li> </ul>
6 28.04.2014	Follow up of meeting (April 24, 2014) with OPPI President and Secretary General	<ul style="list-style-type: none"> <li>Shri Keshav Desiraju Secretary - Dept. of Consumer Affairs Ministry of Consumer Affairs, Food &amp; Public Distribution</li> </ul>
7 11.08.2014	Seeking intervention on National Pharmaceutical Pricing Authority (NPPA) notification of July 10, 2014	<ul style="list-style-type: none"> <li>Shri Narendra Modi Hon'ble Prime Minister of India</li> </ul>

# Seminars and Knowledge / Academia Programmes

Organised by OPPI

## Seminars / Conferences

Date	Programme	Venue
27.11.2013	HR Conclave: Talent Attraction-Engaging Gen Y	Hotel Four Seasons, Mumbai
08.08.2014	Third Healthcare Access Summit	Palladium Hotel, Mumbai
10.09.2014	HR Summit 2014: Attracting, Developing & Retaining Talent	Palladium Hotel, Mumbai

## Knowledge Programmes

Date	Programme	Venue
13.01.2014	Presentation on 'Risk Free Human Capital: Collaborative Solutions to Mitigate Misrepresentation in CVs' by Nipa Modi, Head – HR Services, CRP Technologies (India) Ltd. made to Governance & Human Resource Management Committee.	OPPI, Mumbai
17.01.2014	Presentation on 'Insights into The Companies Act 2013' by Prachi Manekar, Corporate Legal Advisor and Arbitration Consultant to Members of the Legal Committee	OPPI, Mumbai
12.03.2014	Presentation on the 'Foreign Contribution (Regulation) Act 2010' by Varghese Thomas, Partner, J. Sagar Associates, Advocates & Solicitors, to Members of the Legal Committee	OPPI, Mumbai
14.03.2014	Presentation on 'Counterfeiting Pharmaceuticals: A Crime Against Humanity – Important of Primary Packaging (case: Trends in Injectables)' by Kairus Dadachanji, Managing Director, Schott Kaisha and Sovereign Pharma to Members of Technical & Supply Chain Committee	OPPI, Mumbai
10.04.2014	Presentation on the 'Impact of DPCO 2013 and NPPP 2012 on the Indian Pharma Industry' by Karishma Shah, Senior Manager - Business Intelligence, AIOCD Pharmasofttech AWACS Pvt. Ltd. to Members of the Finance & Taxation Committee	OPPI Mumbai

15.05.2014 & 16.05.2014	Members of Technical & Supply Chain Committee's interaction with Pharma Zone, Hyderabad; Pulse Pharma Research Centre, ISCT-CSIR; NIPER and PHARMEXCIL	Hyderabad
27.05.2014	Presentation on 'GDP Compliance in Pharma - Role of CFAs, Basic Elements, Challenges in GDP, Maintenance of Ware House as per GDP, and related aspects' by B. Raveendran, Chief Executive Officer, LBW Consulting Pvt. Ltd. (Leadership in Business Worldwide), to Members of the Technical & Supply Chain Committee	OPPI Mumbai
08.07.2014	Presentation on 'Pharma Sales Medical Reps. Accreditation Programme' by N. Ahmedali, Managing Director, H R Cornucopia Pvt. Ltd. to Members of the Governance & HR Management Committee and Sales & Marketing Heads of OPPI Member Companies	OPPI, Mumbai
14.07.2014	Presentation on 'Key Direct and Indirect Amendments Impacting the Life Science Sector' by Hitesh Sharma, Partner, Ernst & Young LLP and his team to OPPI Member Companies	Club Peninsula, Mumbai
7.07.2014	Interaction with V.P. Singh, Litigation Partner, Ashish Jejurkar, General Corporate Partner, and Anish Tripathi Director - Strategy & Special Projects, Amarchand & Mangaldas with members of Legal Committee and Medical & Regulatory Working Group, on the updates of the current ongoing Clinical Trial case in Supreme Court	OPPI, Mumbai
07.08.2014	Presentation on 'NLEM 2013 – Notifications Released for Cardiac and Diabetic Segment (July 10, 2014) – A PharmaTrac Perspective' by Karishma Shah, Senior Manager – Business Intelligence, AIOCD Pharmasofttech AWACS Pvt. Ltd. to Members of the Finance & Taxation Committee	OPPI, Mumbai

## Industry-Academia Interactions

Date	Programme	Venue
25.10.2013	Dr L.H. Hiranandani College of Pharmacy, Ulhasnagar	College Campus, Ulhasnagar
07.01.2014 & 08.01.2014	Interaction: B.L. Boolani, Founder Trustee, Vivekananda Education Society's College of Pharmacy, Prof Jharana Das, Co-ordinator and Dr Supriya Shidhaye with members of Governance & Human Resource Management Committee to develop relations and support activities of the Institute	College Campus, Mumbai



13.01.2014	Interaction: Welingkar Management Institute, Mumbai with members of Governance & Human Resource Management Committee to discuss issues related to recruitment of students	OPPI, Mumbai
11.03.2014	Interaction: NIPERs (Mohali and Hyderabad) with members of Governance & Human Resource Management Committee	OPPI, Mumbai
07.05.2014	Interaction: Dr Prafulla Agnihotri, Director, IIM Tiruchirappalli, India and Ajit Parulekar, Professor (Marketing) & Dean (Healthcare Management), Goa Institute of Management with members of Governance & Human Resource Management Committee	OPPI, Mumbai
08.07.2014	Interaction: S.P. Jain Institute of Management & Research with members of the Governance & Human Resource Management Committee	OPPI, Mumbai
27.08.2014	Interaction with the Director and faculty of Goa Institute of Management	Ribandner and Sankhali Campuses, Goa

## Events Supported by OPPI

Date	Programme	Venue
05.10.2013 & 06.10.2013	Conference on 'Healthcare in India : Opportunities, Challenges & Innovations' organised by Indian Institute of Health Management Research (IIHMR)	IIHMR Campus, Jaipur
31.10.2013	CII's 11th Pharma Summit - 2013	Hotel The Lalit, Mumbai
05.12.2013 & 06.12.2013	'Healthcare Brand Summit' organised by afaqs.com	Hilton Hotel, Mumbai
17.12.2013 & 18.12.2013	10th India Health Summit - 'A Transparent and Integrated Health System for the Next Decade'	Hotel The Lalit, New Delhi
17.01.2014	FICCI-HADSA 5th Annual Nutraceuticals Conference - 'Business Dynamics of Nutraceuticals in India'	Sci-Tech Centre, Mumbai
02.05.2014	IFPMA Code Workshop: Hands-on Compliance Training	Palladium Hotel, Mumbai
04.08.2014 & 06.08.2014	Multi-stakeholder Discussion on 'Facing our Future: Countering Non-Communicable Diseases in India through Investments in Innovation' organised by PFCD (Partnership to Fight Chronic Diseases and SPAG Asia)	India Habitat Centre, New Delhi & Taj Mahal Palace, Mumbai
15.09.2014	Official Launch of the Australian Innovation Showcase 2014 organised by the Australian Trade Commission (Austrade)	Grand Hyatt Hotel, Mumbai

# OPPI Past Presidents

Name	Member company	Year
Late Dr H.R. Nanji	Pharmed	1966
Keith C. Roy	Merck Sharp Dohme	1967 - 1969
Late Brig. B. S. Bhagat	Rallis	1970 - 1973
S.V. Pillai	Pfizer	1974 - 1975
Late Mr Sisir Mitra	Cyanamid	1976 - 1978
Late Mr H.N. Dutt Gupta	East India Pharmaceutical Works	1979
Late Dr S.K. Bhattacharya	Sandoz	1980 - 1981
Late Mr George Daniel	Hoechst	1982 - 1984
R.N. Langrana	Abbott	1985
C.M. Hattangdi	Parke - Davis	1986 - 1987
Dr S. Agarwala	Rallis	1988 - 1990
D.K. Bose	Burroughs Wellcome	1990 - 1992
H. Dhanrajgir	Glaxo	1992 - 1994
Dr Anil S. Mehta	Wyeth	1994 - 1996
D. Bhadury	Hoechst Marion Roussel	1996 - 1998
H.R. Khusrokhan	Glaxo	1998 - 2000
Late Mr P. Gupta	Infar	2000 - 2001
Tapan Ray	Abbott	Sept. - Nov. 2001
Ranjit Shahani	Novartis	2001 - 2007
Ranga Iyer	Wyeth	2007 - 2009
Ranjit Shahani	Novartis	2009 - 2013