**NLEM & Pricing**

- It is learnt that Dr V M Katoch has been reinstated as the Chairman of the NLEM Core Committee. In its meeting, the Core Committee opined that specific strengths and dosages must be clarified in the NLEM as every dosage/strength may not be essential. On the inclusion of combinations of NLEM drugs, it was of the opinion that all combinations are not essential merely for the reason that one of the constituents is a NLEM drugs. Combinations may be included only on the ground of essentiality and/or if such combination forms a part of some National Health Programme. The Committee is expected to finish its deliberations by end of May 2015 and by mid of June 2015, the recommendations may be submitted to Ministry of Health. OPPI sent a representation to the PMO, Ministry of Finance and Ministry of Health & Family Welfare on the concerns on the revision of the NLEM 2011, along with a note on the impact of NLEM and price control.
- Patented Product Pricing Policy: The OPPI position paper is ready

**Healthcare Access**

- After the news of the Government pressing the brakes on the National health Assurance Mission, there was another setback with the news of a quiet burial for the announced Free Drugs Plan ([The Times of India](https://timesofindia.indiatimes.com)).
- On World Health Day, the government reiterated the dream of a health India and access to affordable medicines ([The Economic Times](http://www.economictimes.indiatimes.com)). The current state of healthcare in India was amplified in the social media through the OPPI Blog ([http://www.indiaoppi.com/blog/](http://www.indiaoppi.com/blog/)), Twitter ([https://twitter.com/OPPIIndia](https://twitter.com/OPPIIndia)) and Face Book([https://www.facebook.com/INDIAOPPI](https://www.facebook.com/INDIAOPPI)).
- OPPI partnered with EFPIA, for the India-EU Health Conference in New Delhi, on April 29, 2015. The theme was strengthening health systems. The conference shared the learnings from the EU on how best to adapt them to the Indian set up.
- The Health Minister said that the [national health policy](http://www.indiaoppi.com/blog/) to make quality healthcare accessible and affordable to all, would be announced soon.
- The OPPI Access WG is working on a paper on viable financial models (with support from IMS) for universal healthcare.

**IPR**

- On April 24, 2015, Prime Minister Modi stated, at a public forum, that [India’s patent laws should be brought on par with global standards](https://en.wikipedia.org/wiki/India%E2%80%99s_patent_laws), which was seen by some as a weakening in Government’s stance on IPR. Combined with the [May, 2015 US Trade Representative report](https://ustr.gov), which places India (along with China and 11 other countries) on the ‘Priority Watch List’ for a poor record of protecting IPR, this has stirred up a storm. On May 4, 2025, India’s Commerce Minister has been quick to defend India’s IP laws and explain what the PM really meant. She declared that India is fully aligned with international IPR standards and ‘there is no need for anyone to question us’. This issue also received attention from Scrip and continues to find play in national and international media, as well as on NGO blogs.
- On World IP Day (April 26), OPPI’s message on the need for a robust IPR regime was voiced in the feature on the [need for the National IPR policy](https://www.indiaoppi.com/blog/). Few more articles were carried in the media on the need for research and development to boost the ‘Make in India’ initiative ([Business Standard](https://www.businessstandard.in), [The Hindu Business Line](https://www.thehindubusinessline.com/)). An opinion piece from Ranjana Smetacek on how Innovation can support the Make in India initiative, appeared in [The Hindu Business Line](https://www.thehindubusinessline.com/).
Reiterating the theme of Innovation in India, OPPI promoted another op-ed from Lalit Bhasin, President, Society of India Law Firms (Business Standard)

- On the National IPR Policy: the Think Tank has submitted its final report to the Commerce Minister, on April 18, 2015. Currently the DIPP is consulting with different Ministries and, following inter-ministerial deliberations, will submit a formal note to the Cabinet. The National IPR Policy will become final after Cabinet approval.

Medical & Regulatory

- FICCI in association with Strategy &, a Global consulting firm and Price Water House Coopers today released a study titled “Why Banning Plastics Packaging is Not a Viable Option”. According to the study, ban on plastic packaging will directly impact plastic industry sales of INR 53,000 Crores. Additionally, 13 lakh personnel across 10,000 firms (mostly SMEs) engaged in plastic packaging for FMCG will be left jobless.
  - A question was raised in the Rajya Sabha on the adverse effects of PET bottles on public health. The Health Minister responded that In order to assess the health and environmental impact of use of PET bottles for packaging drugs, it has been decided to constitute a High Level Committee.
- To promote the ‘Make in India’ initiative in pharmaceutical sector, the Government had constituted a Committee to study the whole issue of APIs of critical importance. These recommendations are being examined for formulation of a Policy for Promotion of Manufacturing of Bulk Drugs. (PIB)

Ethics & Compliance

- Questions were raised in the Rajya Sabha on the recommendations of the Dr. NK Ganguly Committee report on Medical Code of Ethics and whether Government proposes to amend the Medical Code of Ethics to legalise travel and hospitality sponsorship for doctors by pharmaceutical companies. The Health Minister responded that as on date, clause 6.8 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 prohibits sponsorship (including gifts, travel facilities, hospitality etc.) of medical doctors and professional association of doctors by pharmaceutical companies. The proposal for amending the said clause, as received from Department of Pharmaceuticals, is not notified. He also replied that it was decided to dissolve the Dr. NK Ganguly Committee.
- The Comptroller and Auditor General (CAG) has asked for the income tax department to show the tax assessments of the whole pharma sector in India. This is in light of a slew of tax avoidance practices for claiming exemptions for illegal freebies given to doctors, research work which was not taking place, and other tricks, undertaken by the Indian pharma industry. (The Times of India)

Others

- Union Minister for Science & Technology and Earth Sciences announced that the Indian pharmaceuticals sector would soon be showcasing ‘candidate drugs’ for malaria, osteoporosis and diabetes which are currently undergoing clinical trials. He also stated that simultaneously, CSIR-CDRI is carrying out Investigational New Drug (IND) studies on lead molecules for fracture-healing, cancers, thrombosis, malaria and hyperglycemia. (PIB)
- The Minister of Skill Development and Entrepreneurship launched the HR and Skill Requirement Reports for 24 Priority Sectors that included Pharmaceuticals and Healthcare.
The 82nd Report on Demands for Grants 2015-16 (Demand No. 48) of the Department of Health and Family Welfare was presented by Parliamentary Standing Committee in the Lok Sabha and Rajya Sabha on April 24, 2015.

The President of India, addressed the inaugural session of the National Summit on CSR on the theme ‘Boardroom and Beyond’ organized by the CII. In his address, he emphasised that the corporate sector must provide renewed impetus to CSR initiatives towards cleanliness, health and education and create large high impact programmes.

Implementation of GST in pharma: Along with E & Y, OPPI is administering a survey with 7 to 10 members for a AS IS assessment. Based on the survey, the critical issues that will impact the members will be identified and studied.

Notifications

- Notification G.S.R. 224(E) dated March 25, 2015 issued by Ministry of Finance, Department of Revenue, to amend the Narcotic Drugs and Psychotropic Substances Rules, 1985.
- The Health Ministry vide notification no. S O 873 (E) dated March 30, 2015 notified additional branches of Bank of Baroda, for payment of fees paid with applications submitted to the office of DCGI.
- Ministry of Health issued a fresh Press Release dtd March 16, 2015 on Concept Note on National E Health Authority, extending the date for submission of views/suggestions to May 10, 2015.
- Ministry of Health Notification GSR 107 (E) dtd 17 February 2015 amending the Schedule K of Drugs & Cosmetics Rules.
- DIPP constituted a Committee of Experts vide its OM dated 06 April 2015, to study and replace multiple prior permissions with pre-existing regulatory mechanism. The Committee will examine the possibility of replacing multiple prior permissions with pre-existing regulatory mechanism and prepare a draft regulation, within 30 days. The committee, headed by former DIPP, Secretary, consists of representatives from Airtel, KPMG, Accenture, CII, IFC, CPO and British High Commission.

Appointments/Promotions

- Bhanu Pratap Sharma continues as the Chairman, Food Safety and Standards Authority of India for three months in addition to his core responsibility of Secretary, MoH.
- J.S Deepak, Additional Secretary, Ministry of Commerce, responsible for the Trade Policy Division received an extension of 6 months.
- Debashri Mukherjee, IAS 1991 UT Cadre, has been appointed in PMO as Joint Secretary.
- Anu Garg, Joint Secretary, PMO, has been appointed as Joint Secretary in the Ministry of Textiles.
- Jitendra Kumar Dadoo, IAS 1983 UT cadre, has been promoted as Additional Secretary, Department of Commerce.
- Sanjay Chadha, IRSME, 1985, has been appointed as Joint Secretary, Department of Commerce, in place of Asit K Tripathy, IAS.
- Anita Praveen, IAS, 1989 Tamil Nadu cadre, has been appointed as Joint Secretary, Department of Commerce, in place of Shri Sumanta Chaudhuri, IAS (WB:85).
- Ravneet Kaur, IAS, 1988 Punjab cadre, has been appointed as Joint Secretary, Department of Industrial Policy & Promotion, vice Shri Taleen Kumar, IAS (WB:87) consequent on completion of his tenure on 18.05.2015.