Dear Reader,

This newsletter presents a round-up of all the key issues that affect our industry.

Please feel free to share your feedback. We look forward to hearing from you!

Happy Reading!

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IP AND INNOVATION

- **Mixed Signals from the Government**: The Prime Minister Modi’s speech at the **Indo-German Summit** referenced his commitment to protecting IP and the forthcoming IPR policy. Recently, the Health Minister, J.P. Nadda said that India will ensure the Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities are fully harnessed to provide sustained and uninterrupted access to life-saving medicines to patients across the world. ([The Times of India](https://timesofindia.indiatimes.com))

  On the very same day, Commerce Minister Nirmala Sitharaman and US Trade Representative Mike Froman emphasised the role of robust and balanced intellectual property rights protection in fostering creativity, promoting innovation. They reiterated the goal of ensuring the poorest populations in India and the US have access to quality healthcare, and committed to identifying ways in which trade and innovation policies can enhance access to quality health and affordable medicines. ([Business Standard](https://business-standard.com))

- **Update on the draft National IPR Policy**: It is understood that Government may announce the proposed new IPR policy by end 2015.

- **Atal Innovation Mission (AIM)**: The AIM set up under the aegis of NITI Aayog, will be an innovation promotion platform involving academics, entrepreneurs and researchers drawing upon national and international experiences to foster a culture of innovation, research and development (R&D) and promote a network of world-class innovation hubs. NITI Aayog has invited comments on recommendations of the expert committee on innovation and entrepreneurship under the AIM by **November 28**.

- **Amendments to Patent Rules 2003**: The Department of Industrial Policy & Promotion issued a draft notification dated October 26, 2015 on the proposed amendments to the Patents Rules 2003 inviting objections / suggestions from the stakeholders, **within 30 days from the date it is made available to the public**.

- **Update on Trans-Pacific Partnership (TPP) Talks**: The US, Japan and 10 other Pacific Rim nations reached final agreement on the largest regional trade accord in history. The 13-nation Trans-Pacific Partnership (TPP) deal may pose new challenges to India like adopting 'TPP-type' rules in its trade policies as the country aims greater integration with the Asia-Pacific. ([The Economic Times](https://economictimes.indiatimes.com))
**Update on NLEM:** MoH may notify the NLEM by mid November 2015.

**Update on the AIDAN case:** OPPI to provide inputs to DoP.

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**HEALTHCARE ACCESS**

- British medical journal *The Lancet* is set to publish a report in December challenging the NDA government on service delivery and universal health care, one of Prime Minister Narendra Modi's poll promises. The Lancet's editor-in-chief Richard Horton has told The Times of India that health seemed to have "completely vanished" from the NDA's agenda. *(The Times of India)*

  The health ministry has rubbished Horton's comments and listed its latest schemes and missions *(The Times of India)*

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**MEDICAL & REGULATORY**

- Minister of Health & Family Welfare Shri J P Nadda spoke to the President of the All India Organisation of Chemists & Druggists, regarding their call for an All India strike on 14.10.2015 against the alleged efforts to allow sale of medicines through internet. The Union Minister clarified that no such decision has been taken by the Government. *(PIB)*

- The government is likely to commission a study soon to assess the impact of foreign direct investment in existing pharmaceutical companies in view of concerns expressed on the issue by a Parliamentary panel. There are apprehensions that takeovers by MNCs have impacted the generic medicine industry of the country. *(The Economic Times)*

- A new report on clinical trials by the Pugatch Consilium titled ‘Quantifying the Economic Gains of Strengthening India’s Clinical Research Policy Environment’ found that if India were to address outstanding concerns with clinical trials regulations, the country could see an increase in the number of new clinical trials per year to above 800 and add over $600 million in direct monetary transfers and indirect economic gains.

- Indian Council of Medical Research (ICMR) has invited comments/feedback on the draft National Ethics Guidelines for Biomedical Research involving children, by November 15. This document covers the ethical and legal issues that researchers need to consider when carrying out biomedical research in neonates and children.

- Meeting of the Task Force on Development of manufacturing capabilities in each Medical Vertical was held in October. OPPI the member Secretary of the sub-group on NCDs, submitted the report to the DoP.

- NPPA issued a price notification on October 30 under DPCO 2013, capping prices of 18 formulations packs, including anti-diabetic Metformin HCl tablets, antibacterial Ceftriaxone Sodium injection packs and devices among others. Prices have also been fixed/revised for hormone releasing IUD, ondansetron HCl orally disintegrating strip, Metformin HCl tablets, Cefaclass injection pack among others.

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**ETHICS & COMPLIANCE**

- **Update on the Uniform Code of Pharmaceutical Marketing Practices (UCPMP):** The industry associations along with PwC will draw a core working group to decide the modalities of regulation, and is in favour of a body similar to the Advertising Council of India which is not a statutory body, to regulate the code. A final proposal will be drawn up soon.
OPPI NEWS

• OPPI celebrated its 50th year with all healthcare stakeholders, looking back at a memorable half century and renewing its commitment to bringing quality medicines to patients across the nation. An eminent panel of OPPI’s Office Bearers decided to confer Special Golden Jubilee recognitions to mark its 50 years. Shri. Ch. Vidyasagar Rao, Hon’ble Governor of Maharashtra delivered the inaugural address. Dignitaries including Dr V K Subbaraj, Secretary, Department of Pharmaceuticals and Dr Jagdish Prasad, Director General of Health Services were present on the occasion celebrating the ‘50 Years theme: Healthy India, Innovative India’.

• OPPI hosted a dinner in Delhi to honour a visiting global pharmaceutical delegation of: Kenneth C. Frazier - Chairman & CEO, Merck & Co, Inc., Kenilworth, New Jersey, USA; and Hideshi Honda, President - Asia Region, Eisai Co Ltd. This event was in continuation of OPPI’s Golden Jubilee celebration and aligned with the theme ‘50 Years: Healthy India, Innovative India.’

NOTIFICATIONS

• The DoP constituted an Inter-Ministerial Coordination Committee as recommended by the Task Force on "Enabling the Private Sector to lead the growth of Pharmaceutical Industry" under the chairmanship of Secretary, Department of Pharmaceuticals.

• A Sub Committee was constituted by the Drugs Consultative Committee, under the chairmanship of Dr Harshadeep Kamble, Commissioner-FDA, Maharashtra, to examine the issue of sale of medicines over the internet, has extended the date for submission of views up to October 30, 2015.

• The CDSCO posted on its website, report of the 49th meeting of the Drugs Consultative Committee held in October.

APPOINTMENTS/PROMOTIONS

• Om Prakash Gupta, IAS 1992 batch (Maharashtra Cadre), has been appointed as Controller General of Patents, Designs & Trade Marks.

• Ravi Agarwal, IRS 1988 batch has been appointed as Joint Secretary (JS) Department of Disinvestments.

• Sanjiv Kumar, IAS 1992 batch (Union Territory cadre) has been appointed Joint Secretary, Department of Revenue.

• Vandana Gurnani, IAS 1991 batch (Karnataka cadre) has been appointed as Joint Secretary, Department of Health and Family Welfare in place of Nikunja Bihari Dahl who was in charge of RSBY.

• Kalpana Awasthi, IAS 1991 batch (Uttar Pradesh cadre) has been appointed Joint Secretary, DIPP in place of Shubhra Singh who was in charge of Land Acquisition, Industrial Licensing and National Manufacturing Policy (NMP).

• Pankaj Jain, IAS 1990 batch (Assam Meghalaya cadre) has been appointed as Joint Secretary, Department of Financial Services.

• Anita Chauhan from the Cabinet Secretariat Service (CSS) of 1998 batch has been appointed as Joint Secretary, Department of Science and Technology.