Dear Reader,

The New Year has started with a buzz! The revised NLEM 2015 was announced towards the end of 2015. The UCPMP has got another three month extension till March 31, 2016. The debate on online pharmacies is now gathering momentum.

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**

- **Update on Roche Tarceva case:** Following the recent judgment in which the Delhi High Court upheld the patent of MSD’s patent for a drug for diabetes, the Delhi High Court, in yet another judgment, held that Cipla was infringing on Roche’s patent in lung cancer drug Erlotinib Hydrochloride, sold under the name of Tarceva. In this case Cipla avoided an injunction, which means it can continue selling its drug, as Roche’s patent expires in March 2016. The judgment is a positive sign for multinational pharma companies that spend extensively on research.
  - Glenmark and Roche reached an agreement regarding ongoing patent disputes relating to the anti-cancer medicine Erlotinib Hydrochloride. As part of the agreement, the companies have ceased all relevant patent litigation on this product and Glenmark has acknowledged the patent rights of Roche.

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**NLEM & PRICING**

- **Update on NLEM:** The revised NLEM ([bit.ly/1mBwpwD](https://bit.ly/1mBwpwD)) now covers 376 medicines and includes analgesics and antivirals to contraceptives, cardiovascular and anti-tuberculosis drugs. The drugs notified through Para 19 and included in NLEM 2015 are subjudice. OPPI has written to the Secretary, DoP on the issues relating to the implementation of price fixation in respect of the revised NLEM2015 and other matters.

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**HEALTHCARE ACCESS**

- **Update on the Jan Aushadhi Scheme:** The 31-member panel, tasked to review the JAS has in its report stated that the scheme has not been able to make much headway in opening Jan Aushadi Stores (JAS) in each district of the country. The report stated that only 170 stores have been opened so far and that only INR 16.86 crore out of the allocated INR 75 crore were utilised in the last three years. The major complaint remained the non-availability of all listed medicines, defeating the purpose of opening more stores.
**Separate Ministry for Pharma and Medical Devices:** The Union Minister for Chemicals and Fertilizers, Ananth Kumar said that the next year will see the emergence of a separate pharma and medical devices ministry.

**Hike in regulatory fees:** Government has proposed an over five-fold hike in regulatory fees for testing, manufacturing and selling medicines in the country. The health ministry has proposed to increase site registration fee for importing medicines to $10,000 from $1,500. The fee for registration of such imported pharmaceutical products is likely to go up to $5,000 from $1,000. The government has proposed a steep hike even in case of locally manufactured medicines. For any new product registration, companies may have to pay a fee as high as INR 2,50,000 as compared to INR 50,000 now.

**Revising Guidelines for Similar Biologics:** The Medical & Regulatory WG submitted comments on the revised Guidelines on Similar Biologics.

**E-pharmacies:** OPPI delegation met Dr. Harshdeep Kamble (Maharashtra FDA Commissioner), Odisha state drug controller and Dr Reddy & Dr Chandrashekhar (DY Drug controllers) on January 8. They were keen to hear the views of innovator companies on the emergence of online pharmacies. While the delegation expressed the improved pharmacovigilance as a healthy sign, challenges in the form of e-prescriptions, product substitution and cold-chain logistics were raised by the OPPI delegation.

**Update on the UCPMP:** The implementation of UCPMP has been further extended for a period of three months i.e. upto 31.03.2016.

**Stricter norms for pharma product ads soon:** It is understood that the health ministry and the Central drug regulator are now trying to tighten the norms and regulations to keep a check on such ads which may misguide consumers. Recently, a parliamentary committee on health and family welfare raised the concern of a ‘recurring delay’ in amending the Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and the Drugs and Cosmetics Rules, 1945. The committee had also suggested that the health ministry must initiate action for inserting a new provision of seeking prior approval for advertisement content.

**Union Minister for Chemicals & Fertilizers, Ananth Kumar inaugurated the India Pharma 2016 (January 7-9) in Bengaluru.** The event was aimed at increasing the overall growth of the pharma sector including exports, and focuses on increasing domestic production in the sector. The event also strived to encourage Make in India for manufacturing drugs and pharma machines, and also provides a platform to global investment community to connect with stakeholders. *(Business Standard)*.

**Ministry of Health’s final Notification GSR 918 (E) dated November 30, 2015 amending Drugs & Cosmetics Rules in respect of Phytopharmaceuticals**

**Action Taken by the Government on the Observations/Recommendations contained in the Sixth Report of the Standing Committee on Chemicals and Fertilizers (Sixteenth Lok Sabha) on Demands for Grants (2015-2016) of the Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals)**

**FIFTEENTH REPORT of Standing Committee on Chemicals & Fertilizers (2015-2016) (Sixteenth Lok Sabha) (Department of Pharmaceuticals) Jan Aushadhi Scheme**
CDSCO Circular dated December 01, 2015 to all Zonal / Sub Zonal and Port Offices, clarifying that permission under Rule 31 of Drugs & Cosmetics Rules, to import drugs having less than 60% shelf life is not required for the purpose of Tests and Analysis including Clinical Trials.

DCGI posted a Notice on its website informing that the Government of India has notified the National List of Essential Medicines (NLEM), 2015 on December 23, 2015.

Ministry of Health issued a Draft Notification GSR 1011 (E) dated December 29, 2015 recommending hefty increase in fees for Import / Test Licence / Registration etc.

Ministry of Health & Family Welfare issued a Circular dated December 29, 2015 informing that Government of India has, with a view to facilitate speedier trade across borders, decided to introduce risk based sampling of import consignments covered under Drugs & Cosmetics Act and Rules and FSSA 2006.

CDSCO issued a directive to all State Drugs Controllers to take strict action those indulging in online sale of medicines in the interest of public health, pending outcome/report of the DCC Sub Committee on the subject, as a spate of representations have been received from Individual, Public and Trade bodies raising the serious concerns on violation of D&C Rules, Safety, Efficacy, drug recall and storage conditions.


CDSCO through its Circular dated January 01, 2016 has written to all State Licensing Authorities informing that Vitamin K2-7 bulk drug (API) can be considered as deemed to be approved, as CDSCO has approved various formulations containing Vitamin K2-7.


The DGFT has issued Public Notice No. 52/2015-2020 dated January 05, 2016 which lays down the procedure for “Implementation of the Track and Trace system for export of Pharmaceuticals and drug consignments” as notified vide Public Notice No. 412015-20 dated 01.04.2015 (as amended).

The implementation date of IP Addendum-2016 is relaxed up to March 31, 2016.

CDSCO has issued a Notice today regarding implementation of e-Governance through online portal “SUGAM”. For smooth transition to the e-system, the CDSCO has decided that hard copies of the applications will be accepted from January 15, 2016 only from those applicants who have REGISTERED on the portal. Subsequently w.e.f. February 15, 2016 all the registered applicants should submit their application online along with submission of hard copies. Requirement of submitting hard copies will be reviewed once the system is fully functional and stabilized and will be notified accordingly.

Ministry of Health has issued G.S.R. 11 (E) dated January 06, 2016 containing draft rules to amend the Drugs and Cosmetics Rules, 1945.

The National Biotechnology Development Strategy (2015-2020) for the Department of Biotechnology (DBT), Ministry of Science and Technology, Government of India, was announced by the Government of India on December 30, 2015.

APPOINTMENTS/PROMOTIONS

- Bhupendra Singh, IAS (UP cadre 1985) has been appointed as Chairman, NPPA.
- Shailendra Kumar, Director-Health, has been promoted and transferred to Prasar Bharti. D K Sahu, Deputy Secretary, Health, has taken over the charge from him.
- The Cabinet has approved the appointment of Amitabh Kant, IAS (Kerala cadre 1980), Secretary, Department of Industrial Policy and Promotion as CEO, NITI Aayog, after his superannuation on February 29, 2016.
- Devendra Kumar Sikri, a former Gujarat cadre Indian Administrative Service officer from 1975 batch, has been appointed as the new chairman of the Competition Commission of India. He succeeds Ashok Chawla who completed his term on January 07, 2016.