

OPPI in News

Pfizer GSK Rejig India Leadership Teams as Competition Hots Up, [The Economic Times - Mumbai](#)

Top multinational drugmakers Pfizer and GlaxoSmithKline have initiated major reshuffle of their senior leadership teams in India in the face of strong competition from nimble domestic rivals. US giant Pfizer on Monday informed its employees that its India managing director Aijaz Tobaccowalla will move back to the US just three years at the helm, while British major GSK Pharmaceuticals has announced that Annaswamy Vaidheesh will replace Hasit Joshipura as its head for India and South Asia regions with effect from August. Tobaccowalla will return to New York to the department of business technology, where he worked before, Pfizer told its employees in an internal note, according to two persons closely involved with the development.

Similar reports have appeared in:

[The Economic Times - Hyderabad](#)

IPR & Innovation

Date of receiving judgment copy matters more, says IPAB, [The Times of India](#)

Answering a crucial legal question about filing of patent and trademark appeals, the Intellectual Property Appellate Board (IPAB) has said the date of receipt of a certified verdict copy mattered over the date of passing of verdict. As it was not possible to file an appeal without receiving a copy, insistence to compute the time for filing appeal from the date of judgment would deprive a person of his/her right to file an appeal, the board said.

Access to Healthcare

Govt fails to re-launch 'Jan Aushadhi' stores, [Deccan Herald](#)

The government has missed the June 21 deadline of re-launching the "Jan Aushadhi" stores for selling cheap medicines in six states including Karnataka. "When we made the commitment, we did not fully understand the nuances of relaunching the 'Jan Aushadhi' stores because of which the slip-off happened. We need more time – may be another two-three months before we are ready," pharmaceutical secretary V K Subburaj told Deccan Herald here. The plan is to sell 549 inexpensive non-branded drugs from these outlets. The department of pharmaceuticals, under the Ministry of Chemicals and Fertilisers, outlined the roll out plan including a specific launch date to the Parliamentary Standing Committee on Chemicals and Fertilisers that submitted its report in April.

Ethics & Compliance

Health ministry needs to enforce prescription time frame validity to prevent medicine abuse & misuse, [Pharmabiz.com](#)

Health ministry should now look at enforcing time frame validity in doctor's prescription to ensure that there is no medicine abuse and misuse. This needs to be applied for all drugs coming under Schedule H and those out of its ambit. Such a move could bring in both patients and medical practitioners under scanner on the drug purchase and prescribing practices respectively, said Dr BR Jagashetty, former national advisor (drugs control) to ministry of health & family welfare and former Karnataka drugs controller. For this, the health ministry will now need to add a sub-clause in the Rule 65 of the Drugs and Cosmetics Rules, he added.

Medical & Regulatory

Ministry of Chemicals releases Task Force report on enabling growth of pharmaceutical sector, [Business Standard](#)

The Union Minister of Chemicals & Fertilizers, Ananth Kumar has released Task Force report on

enabling the Private Sector to lead the growth of pharmaceutical sector. Speaking at the release, the Minister said that the Government wants to encourage a robust Pharmaceutical Industry in the country that is upgraded, standardized, innovative, globally competitive and can produce formulations at affordable costs. To provide thrust to the sector, a Task Force on Enabling the Private Sector to lead the growth of Pharmaceutical Sector was set up by the Department of Pharmaceuticals. The Task Force was headed by Secretary, Department of Pharmaceuticals and consisted of representatives from Planning Commission, Department of Industrial Policy and Promotion, Department of Science and Technology, Department of Biotechnology and various Industry Associations including IPA, IDMA, BDMA, **OPPI**, AIMED, CII, FICCI, ASSOCHAM, FOPE etc. The Task Force has recommended measures to enhance regulatory support; suggested strengthening of infrastructural support; and recommended fiscal and financial support to the sector.

Single-window clearance for pharma sector on anvil: Ananth, [Business Standard](#)

To enable a single-window clearance system in pharmaceuticals sector, the government will set up a high-level committee next week to work out the modalities for the same. The committee will be headed by Pharmaceuticals Secretary V K Subburaj and the move follows a recommendation by the task force on enabling the private sector to lead the growth of the pharmaceuticals sector. "It (committee) will suggest a mechanism for single-window clearance for the pharmaceuticals industry," Chemicals and Fertiliser Minister Ananth Kumar told PTI. Stressing on the importance of having a single authority for clearance in the sector, he said key decision-making powers on various important aspects such "patents, licencing and pricing are with different departments".

Similar reports have appeared in:

[The Economic Times](#)

Pharma task force pitches for review of drug price control order, [The Hindu Business Line](#)

The task force on pharmaceuticals has called for a review of the Drug (Prices Control) Order, 2013, and suggested rationalisation of the inverted duty structure on active pharmaceutical ingredients (API) on a par with pharma goods, whereby excise duty is reduced from the current 10 per cent. Releasing the report of the task force, which was headed by Pharmaceuticals Secretary VK Subburaj, to facilitate greater private participation in the pharmaceuticals industry, on Monday, Chemicals and Fertilisers Minister Ananth Kumar said the recommendations would be implemented over the next 100 days with reports of action taken to be provided on a regular basis over the same period.

New guidelines for e-pharma, [The Hindu](#)

The Central Drugs Standard Control Organisation has taken the first step towards formulating guidelines for e-commerce marketplace. Aimed primarily at ensuring the safety of consumers, Drug Controller General of India (DCGI) Dr. G.N. Singh explained this important move and noted: "The role, responsibilities and liabilities of e-commerce marketplace and the product sellers need to be clearly defined." He added that it was becoming even more critical to have a framework in place when the intermediary is selling drugs where the safety and health of the consumer is of paramount importance. The advent of technology has ensured the entry of e-commerce industry in the healthcare space in the form of e-pharmacy.

Protect Cancer Patients from Inhuman Trials, [The New Indian Express](#)

J S Mitchell CBE, FRS of Cambridge University UK, delivered a series of lectures on just one theme—"Cancer: If curable, why not cured?" This question still remains unanswered. The cancer patient is normally treated with surgery, radiation and chemotherapy or a combination thereof. The chemotherapy invariably becomes an integral part of cancer treatment despite high costs and serious side effects of anti-cancer drugs. Therefore, newer chemo-drugs with greater efficacy and less side effects are being constantly developed by several multinational pharmaceutical companies. India emerged as the most favoured place for such studies since costs involved in clinical trials are far less than in the Western countries. Now as it stands, all clinical trials are to be cleared and approved by the institutional review boards (IRBs) or institutional ethics committees (IECs), which look into the scientific merits of the project as well as the ethical aspects of patient care. The IRBs and IECs are constituted according to guidelines of the Indian Council of Medical Research and are required to be registered with the Drug Controller General of India (DCGI). All clinical trials using new drugs are also to be registered with the DCGI. To further facilitate clinical trials in India, a number of independent Clinical Research Organisations (CROs) have also emerged with their own IRBs.

CDSCO drug inspectors soon to get online training on cGMP, Pharmabiz.com

Aimed at empowering the central drug regulators with the similar regulatory knowledge as offered to the US FDA officials, the Central Drugs Standard Control Organization (CDSCO) will soon equip its drug inspectors with relevant areas of current Good Manufacturing Practices (cGMP) through an online training module. The US-based global leader in safety science Underwriters Laboratories (UL) will train around 15 officers from the CDSCO West Zone on critical areas including Good Manufacturing Practices (GMP), Good Clinical Practices (GCP), audit-readiness and remedial training. UL offers about 1,200 courses globally and has trained around 38,000 US FDA inspectors till date.

Other News on Pharma

Govt may cap orthopaedic implant prices, The Times of India

Soon, there may be ceiling prices, fixed by the government, on orthopaedic implants. Alarmed with the sharp spike in prices of orthopaedic implants, drug pricing regulator National Pharmaceutical Pricing Authority (NPPA) has directed manufacturers — such as Johnson & Johnson (J&J), Zimmer and Stryker — to submit details of production and pricing of their products, including those for knee and hip. At present there are no price caps on these medical devices. The companies will also need to submit the increase in prices effected by them over the last three years, the NPPA communication on June 17 said.

HLFPPT develops unique online device to monitor pregnancy test card and IUCD programmes, Business Standard

Tracking implementation of the Intra Uterine Contraceptive Device (IUCD) and Pregnancy Test Card for women in India's rural hinterland has become easier with HLPPT launching a unique software device that effectively monitors the functioning of these family planning devices and also tracks the performance of Health Service Providers (HSPs). The Computerised Monitoring Information System (CMIS), developed by Hindustan Latex Family Planning Promotion Trust (HLFPPT), assesses online the progress of its large-scale, multi-state programme on IUCD and Pregnancy Test Card (Nischay), being implemented in collaboration with the Ministry of Health & Family Welfare (MoHFW).

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Financial Express
