OPPI

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1. **Companies oppose extension of new drug validity period – The Economic Times**

Leading Indian drug makers have raised serious concerns over a commerce ministry proposal to extend the validity period of an approved 'new drug' from four years to 10 years. Backed by the department of industrial policy and promotion, an arm of the commerce ministry, the proposal is likely to be discussed at a meeting of the Drug Technical Advisory Board, a high-level consultative body in the health ministry, sources said.

In response to ET's queries, Kanchana T K, director general at Organization of Pharmaceutical Producers of India, said the group welcomed the proposal as this would be a step towards ensuring patient safety and that such a provision would streamline regulatory mechanism and would facilitate ease of doing business in India. She, however, did not see this to be linked to provisions for data exclusivity.

2. **Time to treat pharma sector's ailing gender quotient – The Hindu Business Line**

Compared to the rest of Corporate India, the pharma sector lags far behind in terms of the percentage of women it employs and the percentage of women in senior leadership positions. While the average percentage of women in the workforce in most sectors ranges from 15 per cent to 35 per cent, in the pharma sector, it is 10-15 per cent. A Mercer study puts it at 11 per cent. On the metric of women in senior leadership roles, the respective numbers are 10-25 per cent and 5-10 per cent.

The writer is Director General, Organisation of Pharmaceutical Producers of India (OPPI). Views expressed are personal.

3. **A due recognition – Deccan Chronicle**

Taking inspiration from Marie Curie's life, Hyderabad based Dr Prathama S. Mainkar has dedicated her life to research. She is the Senior Principal Scientist of CSIR-Indian Institute of Chemical Technology and was recently awarded the Woman Scientist Award by the Organisation of Pharmaceutical Producers of India (OPPI).

OPPI represents research-based pharmaceutical companies in India and has been appreciating work done in the pharma field since 1965. This recognition is bestowed on her for the remarkable contributions made to the pharmaceutical industry, both in early drug discovery and process development for generics.

4. **Critical illness drugs remain unaffordable – The Economic Times**
   Market dynamics and limited competition in biosimilars (approved versions of complex biologic drugs) and other life-saving drugs have resulted in little reduction in prices, making them unaffordable for many. Surprisingly, government measures to bring down their prices (through the Drug Price Control Orders, or DPCOs) too have been futile, making them out of reach for patients as treatments often run into lakhs of rupees. Biosimilars are used in cancer therapy, rheumatoid arthritis and other critical illnesses. Even in the case of medicines for hepatitis B and C like sofosbuvir, tenofovir and entecavir, which were brought under price control, there has been little change in the access scenario. Take the example of two biosimilars — rituximab and trastuzumab — where there is not much change in MRP, even after government brought these drugs under price control in April and May respectively. The National Pharmaceutical Pricing Authority (NPPA) ceiling price for breast cancer drug trastuzumab is Rs 55,812 (440 mg), marginally lower than that charged by companies at around Rs 58,000, while the ceiling price of another cancer drug rituximab (500 mg) is Rs 36,947, close to the MRP of Ristova (innovator Roche's brand) at Rs 37,500.

5. **Pharma cos alerted on cyber crime – The Times of India**
   Frauds have been using three or more different methods to siphon money after hacking into emails of businesses, especially the pharmaceutical sector, forcing Cyberabad police to caution companies to take required precaution. A certain email scam is targeting companies that send or receive foreign remittances. Three instances of the kind that occurred in the pharma industry have come to the notice of Cyberabad police.

   In a media release police said scamsters had hacked into the email server of one company to send emails to customers about a change in bank information. They also sent 'signed' confirmation letters to customers with this new bank information on the company's letterhead. The frauds may have got complete access to old emails sent by the company.

6. **Indian pharma sector going digital at a fast pace – The Economic Times**
   A digital wave is sweeping across the $17 billion Indian pharmaceutical industry and companies are dumping old ways of marketing for newer technology, a survey of 20 top drug makers in the country has found. This new technology ranges from scientific detailing to doctors to using newer algorithms for better insights into issues like patient compliance. The trend matches a similar switch in China over the last few years. The pharma industry’s marketing spends through digital platforms is estimated to shoot up nearly 50% in the next two years to touch Rs 220 crore, Bengaluru-based market research firm Indegene's study shows.

7. **How Asia’s policy-makers are strategising to battle cancer – The Hindu Business Line**
   A year after Zhengchen Liu was diagnosed with cancer, he found the US drug regulatory had approved Gleevec for Chronic Myeloid Leukaemia (CML). Zhengchen Liu got onto a trial of this drug, in China. It’s been 15 years since, says Zhengchen Liu with New Sunshine Charity Foundation, recounting his experience where his wife was later diagnosed with CML. She got onto trials for the next generation of this drug and benefited, he says, adding much to his audience’s relief, that she too is cancer-free and the couple now are expecting their first baby. Touching on a challenge that is true of China and the region, he says that there is a timelag before a new drug gets to the country.

8. **A fair treatment needed in the national drug policy – The Economic Times**
   We recently saw the welcome declaration that the Indian government plans "a major overhaul of the country's drug policy that includes reducing the number of drugs under price control, doing away with the practice of periodic renewal of manufacturing licences, and making it easy to do medical and drug research in the country". Such an initiative, however, will need to navigate a complex system administered by a maze of entities: a health ministry that draws up the National List of Essential Medicines; a chemicals and fertilisers ministry that oversees the Department of Pharmaceuticals, which owns the National Pharmaceutical Pricing Authority; a commerce ministry that houses the Department of Indian Policy and Promotion responsible for protecting intellectual property rights (IPR).

9. **Health experts slam low GST on tobacco – The Times of India**
   Health experts and anti-tobacco crusaders on Tuesday expressed unhappiness over the Goods and Services Tax (GST) Council's proposal to place tobacco products in the 26% tax slab instead of the 40% they had expected. They said a 'sin rate' (tax on products like tobacco which are generally accepted as harmful) below 40% would not only result in adverse revenue generation but affect public health. Besides 40% tax, the experts had also lobbied for states' right to impose top-up taxes on all types of tobacco - cigarettes, bidis, smokeless tobacco and pan masala - to dissuade consumption.

10. **Most Indians are still unable to buy critical illness drugs, here's why – Businessinsider.in**
    Being able to bear the cost of critical illness drugs is still a big issue in India. Biosimilars (approved version of complex biological drugs) and other life saving drugs have had a little reduction in prices over the years. Even the government hasn't taken any big measures to bring the price down.

    Notably, ceiling prices are fixed by NPPA based on a simple average of price to retailer of products of companies with over 1% market share. Many countries like the US are now persuing legislation which will force companies to either disclose their R&D cost or explain pricing. This would be really helpful in making the pricing transparent. However, there is a section which feels that price control alone cannot improve access. "Competitive pricing, local production and compulsory licensing will drive down prices", says Indian Pharmaceutical Alliance secretary general D G Shah.

11. **Drug consultative committee to deliberate online pharmacy norms this week – Pharmabiz.com**
    Drug consultative committee under the Union health ministry is likely to meet on November 4 and November 6 to deliberate on aspects related to information technology which can be aligned with the drug regulations existing currently to suit patient needs among other major pain points. It is aimed at suggesting ways after the conclusion of the study by the sub-committee whether online pharmacy can be in the interest of the patient and patient safety, according to a senior official associated with the development.

    Guidelines on the same is currently being reviewed by a Sub-Committee set up by the 48th Drug Consultative Committee under the chairmanship of Maharashtra Food and Drug Administration Commissioner Dr Harshdeep Kamble.

12. **Health activists urge Indian govt to fix nine deadly gaps in its TB response – Pharmabiz.com**
    A group of health activists under the banner of Treatment Action Group has called upon the Indian government to fix nine deadly implementation gaps in India's TB response. The nine gaps identified by the activists include, the roll-out of daily fixed-dose combination (FDC) TB treatment for people with HIV (PLHIV); the provision of appropriately dosed pediatric FDC treatment for children; the scale-up of GeneXpert, a test that can diagnose TB and resistance to first-line TB drug rifampicin in less than two hours; the scale-up of drug susceptibility testing; the expanded rollout of TB drug

bedaquiline to treat drug-resistant TB, of which less than 100 courses have been accessed to date; isoniazid preventative therapy (IPT) for PLHIV to treat latent TB infection; IPT for children under five who are in close contact with people living with TB; the provision of rifabutin for treatment of TB co-infection with HIV; and the immediate end to use of the category II retreatment regimen.