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10th edition of iPHEX kicks off in grand way

LAXMI Yadav

THE 10th edition of the International Exhibition for Pharma and Healthcare (iPHEX)-2024 kicked off in a big way on August 28 at the India Exposition Mart Limited (IEML) in Knowledge Park II, Greater Noida, Delhi-NCR.

The inauguration of the three-day India's largest pharma exhibition and business-to-business event was graced by Nitin Kumar Yadav, IAS, Joint Secretary (Export Products-Pharma), Department of Commerce, Ministry of Commerce and Industry, and Dr. Rajeev Singh Raghuvanshi, Drugs Controller General of India (DCGI), Ministry of Health and Family Welfare who were Guests of Honour. Lena Nanun-

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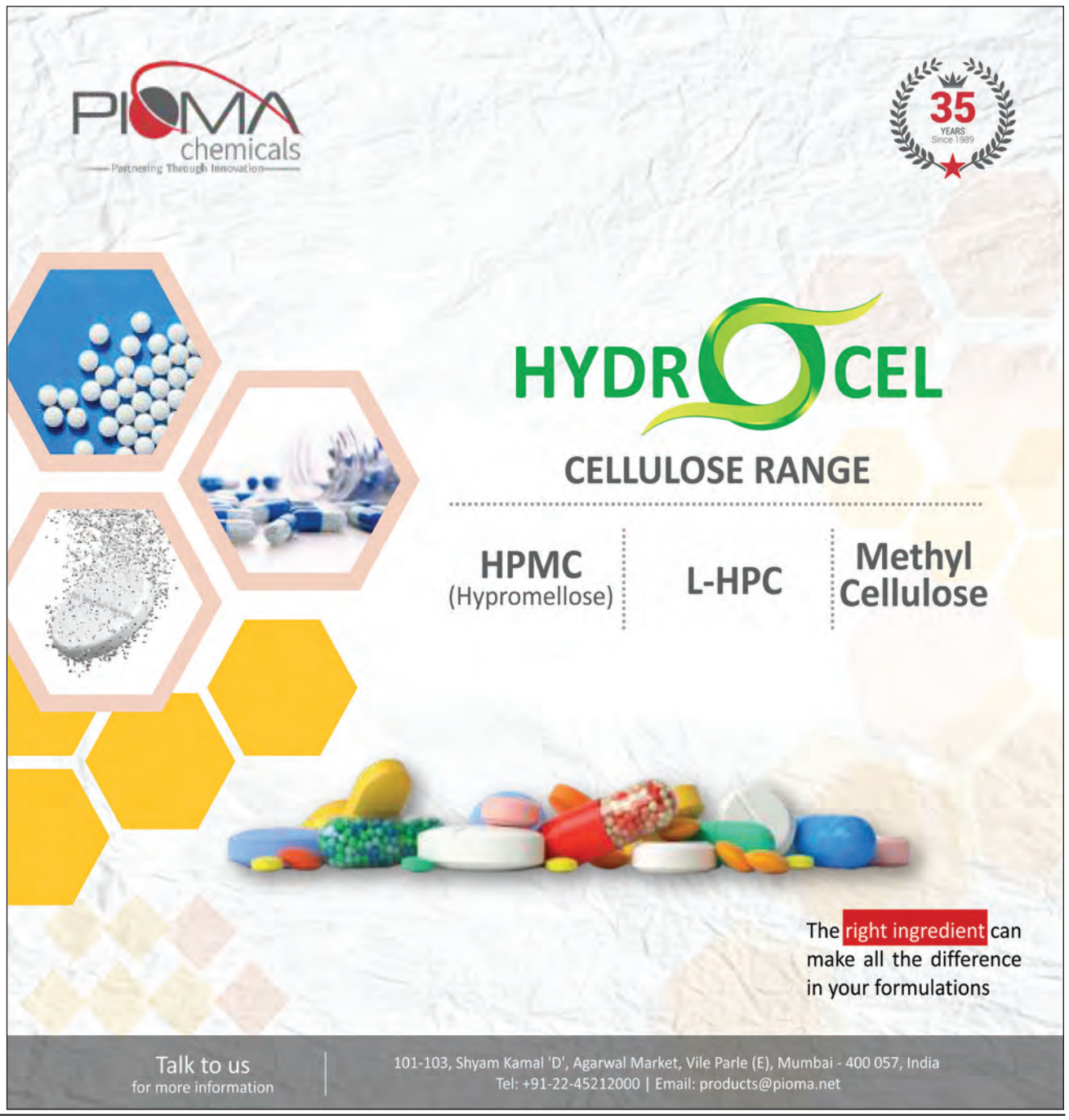

Industry backs ban on 156 FDCs, looking for grace period to liquidate existing stock

Laxmi Yadav

Even as the drugmakers have backed the ban on 156 fixed-dose combinations (FDC), they are looking for a grace period to liquidate the existing stock.

Amit Chawla, Director, McW Healthcare; National Secretary/ Vice Chairman, Federation of Pharma Entrepreneurs (FOPE) - Madhya Pradesh Chapter said, "The recent drug ban has severe implications for the industry. The medications are in the distribution channel. Batches and packing materials are in production. While we agree with the government's decision to ban irrational medications, they ought to have given the industry more time to clear out its stock."

Hailing the FDC ban, Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance, "The discussion on FDC is going on over a period of time with recommendation from Kokate committee and Nilima Kshirsagar committee. This is a right step in the interest of patients and all aspects have been taken into consideration."

Several manufacturers are seeking legal recourse following the ban to sell off existing stock.

A writ petition has been filed by Emcure Pharmaceuticals seeking quashing of the notification dated August 12, 2024, whereby the manufacture for sale and distribution for human use of the fixed dose combination of S(+) Etodolac + Paracetamol (subject matter FDC) was prohibited with immediate effect.

S(+) Etodolac + Paracetamol is among 156 FDCs banned by the government through a notification on August 22.

The drug firm stated that the report of the sub-committee, on the basis of which the ban has been notified by the government, has not been made public till date. It stated that it remains unclear why complete prohibition of the subject matter FDC has been recommended.

The petitioner contended that the impugned notification is non-speaking and not in compliance with the judgment of the Supreme Court in Union of India and Anr. v. Pfizer Limited and Ors. (Civil Appeal No. 23472 of 2017).

It drew the attention of the court towards an order passed by the Coordinate Bench in Lupin Limited & Anr. Vs. Union of India and Anr in June 2023.

In the light of the aforesaid order passed by the Coordinate Bench and in order to maintain parity, the court on August 22 granted interim protection for S(+) Etodolac + Paracetamol already in the distribution network. It directed that the drugs which are already in the distribution channel shall not be withdrawn. However, no fresh manufacture of the drugs will take place till the next date of hearing i.e. January 15, 2025, the court stated.

In addition, no coercive steps will be taken against the petitioner for the drugs which are already in the distribution channel, the court observed.

The petitioner has been directed by the court to file details of the stock of their drug as on today within a week and also give an affidavit of stock in circulation, within one week. Four weeks were given to the government to submit the counter-affidavit.

Said Harish K Jain, President, Federation of Pharma Entrepreneurs, "Patient safety is our top priority, hence we support the government's decision to ban irrational medications which have gone through proper scrutiny. We are providing members with requisite legal and technical assistance in cases where someone is specifically aggrieved."

"We urge manufacturers to refrain from producing FDCs without a proper product manufacturing license and approval from the designated authority," he said.

He urged the government to keep the industry in confidence in case of an impending ban and grant a grace period to industry in case of a drug ban in the future in order to liquidate the stocks. Many of the currently banned FDCs are manufactured by big houses and are very popular with physicians. Huge inventory is present in the supply chain, and an immediate ban is not only problematic to the industry but also to physicians and patients who have to identify a proper alternative, he stated.

Dr. Sanjay Agrawal, Ahmedabad based leading pharmaceutical consultant and editor- in chief of IJM-Today said "The decision to halt the manufacture, sale, and distribution of these medicines with immediate effect has left many drug companies in a difficult position, especially regarding how to handle products already in the market."

"The inclusion of pre-1988 drugs in this ban is particularly surprising, as these medications have been in use for decades without any substantial evidence of harm. It raises questions about the rationale behind this sudden decision, especially when many of these combinations, like Ginkgo Biloba and Methylcobalamin, have been considered useful and are naturally derived," he added.

"It's also worth noting that companies typically seek legal recourse following such bans, and courts often allow them to sell off existing stock. However, the sudden nature of this ban could have significant adverse effects on pharmaceutical companies, healthcare providers, and patients alike. There seems to be a disconnect between the initial approval process for these drugs and the decision to ban them. Ideally, the approval for manufacturing and marketing should involve a thorough review by technical experts to prevent situations where a sudden ban disrupts the industry and impacts patient care, he said.

The potential advantages of FDCs over separate component prescriptions or monotherapy include: (i) improved response rates by utilizing different mechanisms of action, (ii) faster achievement of the desired effect, (iii) reduced toxicity by counteracting adverse reactions between medicines, and (iv) combining sub-therapeutic doses for enhanced safety, particularly in cases like HIV treatment. These benefits often result in lower healthcare costs, stated Dr Agrawal.

34 more multivitamin FDCs are being examined by the government following the recent FDC ban. These FDCs were found to be irrational and perhaps harmful by an expert group.

FDCs contribute more than 50 percent of the domestic pharmaceutical market. Even though the Indian government started taking action in late 2007 to limit the supply of FDCs that the states had approved in defiance of the Drug and Cosmetic Act, the move actually sparked a 10-year process that included court cases and ended with the Supreme Court ordering the government to ban 328 irrational FDCs in 2020 - the largest FDC ban so far.