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OPPI highlights need for robust OTC regulation

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A well-regulated OTC framework will empower patients towards responsible self-medication

The Organisation of Pharmaceutical Producers of India (OPPI), along with industry associations – FICCI and IPA-organised a webinar on the proposed Over-the-counter (OTC) regulations.

The webinar highlighted the need for a robust OTC Regulation in the country, in the interest of patients. Narender K Ahooja, State Drugs Controller (SDC), Food and Drugs Administration (FDA) Haryana who serves as the Chairman Subcommittee on OTC Regulations (also called Ahooja Committee) was invited as a key note speaker. Along withNarender Ahooja, Amit Duggal, Senior Drugs Control Officer, Chandigarh who is also a member of OTC subcommittee, also attended the webinar.

Over the years, OPPI has been leading the discussions on the need for a robust OTC guideline, in order to bring responsible health outcomes and improved standards in public health.

The discussions with Ahooja and Duggal covered the following key aspects of the proposed OTC policy:

- The OTC drugs will be classified as either OTC -I or OTC -II drugs. OTC-I will be sold through licensed retail pharmacy, but without the prescription of a medical practitioner and OTC – II, which commonly is referred to as GSL drugs, will be permitted to be sold through retailers, such as local grocers. So far as criteria to be OTC drugs are concerned, Shri Ahooja' s committee has informed that such drugs will have to meet strict safety criteria.
- Ahooja emphasized that all Manufacturing and Labelling norms under Drugs& Cosmetics Rules, 1945 will be strictly applicable to OTC drugs. On labelling, he mentioned that comprehensive labelling norms will be prescribed for OTC drugs and will have to be complied with, in addition to Rules 96 of Drugs and Cosmetics Rules.
- Further, advertisement requirements will be relaxed to allow dissemination of information related to the safe and proper use of OTC drugs. However, prohibitions and restrictions imposed under Drugs and Magic Remedies Act related to advertisement of health claims mentioned in the Schedule of the Act are likely to continue.

Commenting on the need for the Policy G Sathya Narayanan, Chairman-OPPI OTC Taskforce and Managing Director, South Asia, Galderma, said, " Our Study in 2018 has been much appreciated and welcomed by the regulatory authorities. Given the healthcare infrastructure in the country, a robust OTC Policy is the need of the hour. We are heartened to hear that the Drug Consultative Committee is looking to forward the recommendations of the OTC Sub-Committee to Drugs Technical Advisory Board (DTAB) , at the earliest, for a well-defined OTC Regulation in the country. The Regulation will empower patients to responsibly self-medicate and thereby ease the burden on the healthcare system. It will go a long way in delivering 'health for all', in the country and widen access to medicines in India."

Echoing the need for such a regulation, Milind Thatte, Co-Chairman - OPPI OTC Taskforce and Managing Director, Procter & Gamble Health said, " Keeping the patient at the centre, the proposed OTC Regulation will provide a framework for patients to be aware about the right product for the right ailment at the right time and the right way to use, thereby enhancing health outcomes and minimizing risk from misuse or abuse of medicines."