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Pharma regulation

Getting the dose right

Ensuring effective implementation of the upgraded standards calls for voluntary compliance

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A manufacturer's critical role in ensuring supply of good quality pharmaceuticals requires both strong laws as well as their effective implementation via compliance. While addressing the former, the Drug Controller General of India recently announced that it shall put before the government a proposal to upgrade the current manufacturing laws so that they meet stricter international standards. Such an amendment, if eventually brought about, might present some challenges to begin with, but with uniform and effective implementation it promises to pave the way towards greater confidence-building, thereby making India a widely acknowledged source of safe and efficacious drugs.

At present, pharmaceutical manufacturers in India follow various good manufacturing practice (GMP) guidelines, depending upon the country where a manufacturer wishes to market the product. In order to market within India, the law requires compliance with GMP guidelines encoded in Schedule M of the Drugs and Cosmetics Rules, 1945. However, in order to export, the manufacturer may be required to follow the guidelines of and obtain certification from the USFDA, MHRA or other regulatory agencies. A number of other countries that have limited regulatory capacity of their own are participants of the WHO Certification Scheme and accept the Certificate of Pharmaceutical Product (COPP) which provides partial assurance of safety and efficacy of products being exported to their country. In such a scenario, for a manufacturer of a pharmaceutical product in India, the adoption of WHO-GMP guidelines is not aimed at enhancing quality domestically but instead to reach out to markets that require explicit adherence to these norms. But it is becoming progressively important that given the risks and complications involved in the manufacturing of complex new-age pharmaceuticals, efforts be made at increasing the quality standards to assure access to safe medicines.

Given that Schedule M has to be read in tandem with the Drugs and Cosmetics Act, 1940, and Drugs and Cosmetics Rules, 1945, the absence of a common reference document renders it difficult for non-legal experts to interpret the strict legal terminology

While being initially drafted, Schedule M guidelines were drawn upon from the WHO-GMP guidelines. A bird's eye view of Schedule M and WHO-GMP guidelines would reveal that all broad principles contained in the latter—including those for record keeping, validation, sampling, packaging, storage, etc—are to be found in Schedule M as well. Also, Schedule M, in its wording, provides comparative elbow room in terms of implementation. Thus, beyond the matter of upgrading these standards, an emerging concern pertains to interpretation and effective implementation of the existing guidelines. Given that Schedule M has to be read in tandem with the Drugs and Cosmetics Act, 1940, and Drugs and Cosmetics Rules, 1945, the absence of a common reference document renders it difficult for non-legal experts to interpret the strict legal terminology contained within these documents. As a result, regulators and manufacturers may not be on the same page with respect to understanding of guidelines.

Ensuring effective implementation calls for voluntary compliance to regulatory norms. This implies not only provision of strong incentives for manufacturers to maintain strict compliance but also warrants the necessity for having in place sanctions and deterrence mechanisms which deal with non-compliance. This might be a good time for the government to speed up the implementation of its much awaited Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS), which was devised to provide financial aid to medium enterprises to upgrade their plants. This scheme is envisioned to be a game-changer for medium players in both domestic as well as international markets as it would foster continuous technological upgradation and thereby enhance quality of medicines. At the same time, a more harmonised milieu for operation of these players should be strived for where Pharmaceutical Inspection Convention and Pharmaceutical Inspection Cooperation Scheme (PIC/S) can play a major role in building mutual confidence among drug regulatory authorities. The challenge is not upon the industry alone to meet the higher standards but also upon the regulator, since in order to regulate an increasingly sophisticated market environment it would have to equip itself with state-of-the-art testing facilities and train its inspectors and analysts in skills of the highest stature.

In this rapidly advancing technological era, the need for continuous improvement and upgradation cannot be underplayed in any sector. However, as mentioned earlier, it is important to note that norms however strict will be most effective if they are uniformly interpreted and implemented across all stakeholders. This is one of the most critical areas in drug regulation that calls for immediate attention. To survive in a globally-competitive scenario while continuing to deliver on the promise to provide safe and quality medicines to the Indian consumers, the policy landscape requires an approach that focuses on harnessing our strengths while at the same time addressing our operational limitations.

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