Regulating the drug regulator

State Drug Regulatory Authorities need to be empowered to become regulatory collaborators of CDSCO

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For a functional free market economy, the role of government is a much more important issue than the size of the government—'minimum government' is not necessarily the goal. Effective regulation is one of the key roles in a free market economy, especially in the domain of medicines as consumers lack technical expertise to ascertain the safety, quality or efficacy of medicines. Accordingly, the drug regulatory framework has to be technically and scientifically robust, and serve the public interest by harnessing the potential of the pharmaceutical industry. While policymakers have been quite successful in promoting India's health care industry, pharmaceutical sector in particular, there has been scant attention to a simultaneous strengthening of the drug regulatory framework and its processes. Recent interest by the Central Drug Standard Control Organization (CDSCO) to revisit India's Drugs and Cosmetics Act, 1940 and Drugs and Cosmetics Rules, 1945 is, therefore, welcome.

While there have been amendments in the Act and the Rules, their nature and impact have largely been piecemeal. Last year, ICRIER came out with two studies—'Administrative Structure and Functions of Drug Regulatory Authorities in India' and 'Drug Quality and Safety Issues in India'—based on interactions with major stakeholders at the national and international levels to analyse the nature and scale of regulatory challenges and develop a set of actionable policy recommendations. In the context of ongoing reforms, we would like to highlight some of the major ones.

From a structural viewpoint, one of the major challenges is the need to streamline the regulatory decision-making in the context of the federal division of competencies between the centre and the states. One way of achieving this is making CDSCO the coordinating authority for State Drug Regulatory Authorities (SDRAs), which can be operationalised by enacting a new legislation to replace the Act. Alternatively, the possibility of empowering SDRAs to become regulatory collaborators of CDSCO can be explored by extending the role of the Drugs and Consultative Committee (DCC) in key regulatory areas—for instance, in developing guidance documents to formalise standard operating protocols (SOPs) and interpretations of key legal provisions. Such a model exists in the EU in the form of Committee for Medicinal Products for Human Use (CHMP), that provides scientific opinions, with representation from all member states. The currently pending The Drugs and Cosmetics (Amendment) Bill, 2015 envisages representation from all SDRAs, but lacks sufficient details in terms of the functional scope, financial support, regularity of meetings, etc. Additionally, efforts for making the drug regulatory agency autonomous and appropriately empowered are needed for greater objective and operational effectiveness. In addition to these structural reforms, there is a need for greater clarity in the provisions of the Act. The Act and Rules appended are guiding documents for the regulatees, and in absence of proper reference documents and guidance, they often find it difficult to interpret and comply. Elaborate guidance documents will facilitate drug regulators' expectation from the industry in various aspects, including Schedule M compliance. Further, SOPs with respect to inspections and a digital database should be adopted. The DCC can develop such SOPs and ensure a regular space for dialogue on this issue.

Moreover, there have been several reports where doubts have been raised regarding quality of medicines available in and from India. The study on 'Drug Quality and Safety Issues in India' attempted to address these issues, firstly by bringing to fore differences in multiple definitions of poor quality medicines and their varied implications. Major policy recommendations were-uniformity in the interpretation of legal terminology contained in the relevant act and guidelines with WHO's SSFFC (substandard/spurious/falsely-labelled/falsified/counterfeit medical products) framework; rationalisation of work distribution across regulatory personnel; use of technological tools to bridge the gap in the data available to policymakers and need for driving pharma industry towards voluntary compliance and self-regulation. How the use of information technology and a barcode-based track and trace mechanism can play a pivotal role in effective regulation was also emphasised. Such a mechanism can be used to address a number of challenges that we are facing, including effective recall of poor quality medicines, tracking the true manufacturer in order to weed out spurious medicines and the consolidation of national database for the formulation of evidence-based policy action. Participation of all stakeholders towards making dedicated efforts in these critical reform areas could pave the way for India to become a widely acknowledged source of good quality and efficacious medicines.

With changes in public health needs and the global pharma industry, a strong and transparent framework for drug regulation is what is needed to protect and sustain the pharmacy of the world.

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Major recommendations from the studies

Structural changes

- Make CDSCO the controlling and reporting authority for SDRAs,

Or

Empower and strengthen SDRAs to become regulatory partners of CDSCO

- Make CDSCO independent and technically autonomous (politically accountable to the Parliament) statutory regulatory agency

Greater clarity in provisions of the Act

- Provisions for greater clarity on liability in case of manufacturing via third party agreements and loan licensing
- Product label needs mandatory inclusion of name and site of manufacture as well as marketing authorization holder in case of contract manufacturing
- There is a definite need for a guidance/reference document for schedule M (on the lines of those for WHO-GMP guidelines)
- SOPs to streamline the procedures

Provisions to facilitate compliance with the provisions of the Act

- Stringency with GMP non-compliance is needed. Fixed time frame for submission of response to 'Corrective and Prevention Action' (also known as CAPA) Report
- Encourage voluntary compliance - Revision of punishment from suspension of single production license to financial penalty.
- Rule 96 of the Rules should be amended for making a provision for bar coding on primary, secondary and tertiary packings of drugs.