Needed: a new medicine

The monsoon session of Parliament holds the key to regulatory change for the pharma industry

By Ramesh Adige

English novelist and scientist C.P. Snow, once said: "Technology... is a queer thing. It brings you great gifts with one hand, and it stabs you in the back with the other."

It is unfortunate, but true, that crooks around the world use technology to produce fake goods. The production and sale of counterfeit or spurious goods is a menace to any country and needs to be dealt with sternly. Besides violating intellectual property laws, it causes revenue loss to the company as well as to the exchequer.

When it comes to drugs and medicines, spurious products can have lethal consequences on public health, comparable to weapons of mass destruction. For example, perpetrators of these crimes fill vials with water when the injectibles are meant to treat cancer! Stringent punishment seen) be the only way to deal with the problem. The Indian government is fully aware of the gravity of the situation and has even constituted several expert committees to find ways of combating the nuisance of spurious drugs in our country.

The death penalty handed out to China's former drug regulator for approving fake and substandard medicines points to Beijing's intent to send a stern message. A number of media reports termed the sentence to be unduly harsh. But whether it really was, is a matter of serious debate.

Currently, a producer of a fake drug in India, on conviction, can get away with imprisonment for five years. This is not a strong enough deterrent.

It is a welcome sign that the ministry of health and family welfare has initiated the overhauling of the Drugs & Cosmetics Act, 1940 (D&C Act), to provide stricter penalties. This follows the recommendations of various committees. In May 2005, a Bill to amend the D&C Act was introduced in the Rajya Sabha. Since then, the standing committee report has also been submitted, endorsing the proposed amendments. What is now required is a fast-track approach. The ministry should reintroduce the Bill in the monsoon session of Parliament, to approve the amendments in the Act.

Let's move on to another area which requires attention. In the current scheme of things, the pharmaceutical industry is regulated both at the Centre and state level. Multiple agencies, and a complex structure for governance and implementation, result in continuing disparities in the implementation of the D&C Act across the country. Against this backdrop, steps taken by the ministry of health and family welfare to establish the Central Drug Authority of India (CDAI)—to replace the Central Drugs Standard Control Organization (CDSCO)—are certainly laudable.

This autonomous body will help curb various evils with respect to manufacturing practices, laboratory practices, clinical practices, drug safety and efficacy as well as standardization and marketing. The CDAI will bring uniformity in licensing and enforce the various provisions of the D&C Act & Rules, 1945. For example, there will be standard procedures followed by all state licensing authorities for the grant of licence for new drugs, including fixed dose combinations. We hope that the CDAI will see the light of day in the coming monsoon session of Parliament.

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Yet another niggling anomaly remains in the way clinical trials are treated in our country. In new drug discovery and development, approvals are required at every stage of the trial process.

In India, unlike in the US or the European Union (EU), the law does not specify a 30-60 day definitive time limit for the regulatory body to accord approvals. The CDSCO has to seek the recommendations of the Indian Council of Medical Research. This means the involvement of multiple agencies and inevitable delays. On the other hand, pharma companies overseas benefit from automatic regulatory approvals within a predefined 30-60 day time frame.

The current legislation does not provide for early micro-dosing studies in humans, a norm in the US and the EU. The regulations in these countries provide that following basic toxicology studies in animals, early micro-dosing studies can be carried out in humans. This allows for early pharmacokinetic testing in humans, and helps to circumvent the potential 70% failure rate in the costly Phase 1 studies, which are typically carried out only after preclinical testing.

Experimental single dose Investigational New Drug (IND) applications are common in the US, and companies such as GlaxoSmithKline Plc have repeatedly used them to compare two compounds and arrive at the better one based on real human drug disposition data. Such early experimental single dose IND applications are not accepted in India and this becomes a competitive disadvantage.

Within the limited resources available, some excellent steps have already been taken by the CDSCO such as the creation of a separate panel for evaluation of biotech based drugs, a comprehensive adverse drug reaction monitoring programme, amendments to Schedule M (GMP), etc. But much more needs to be done.

Let us not forget that with the incentives extended for R&D, India can certainly aspire to be a research hub for the world.

Whether the government bites the bullet by making the necessary changes in the regulatory areas, remains to be seen. But if it does, it would have done the nation a great service.

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