DRA: a case for hope

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The bill creating a much-needed federal drug regulatory authority – Drug Regulatory Authority of Pakistan – was enacted into law recently. The World Trade Organisation (WTO) agreements have made it binding on all countries to have independent drug regulatory authorities, without which key flexibilities permissible under the Doha Declaration on Public Health cannot be availed.

On the domestic front, the 18 Amendment to the constitution omitted the entry "Drugs and medicines" along with the Concurrent Legislative List, which had earlier given provinces the mistaken notion that drug regulation could be a subnational prerogative, leading to an unnecessary year-long federal-provincial turf battle over drug regulation. It was only after 125 lives were lost in the Isotab-related drug deaths in Lahore that the matter of drug regulation veered in the right direction.

Now that the authority has been created, it is time to take stock of the safeguards that need to be built to make it effective. First, independent regulation needs robust and transparent governance or it will fall prey to vested interest groups. It is also crucial that appointments are made on merit, and to ensure technical competency. The fact that there is a fine line between the policymaking mandate and regulatory prerogatives in this law creates all the more reason for transparency in governance.

Second, with respect to potential weaknesses of the new regulatory authority, the broader policy and institutional context has to be brought to bear. The authority, no matter how well resourced, technically astute and independent can not operate in a vacuum. Its primary purpose is to provide for

“effective control and enforcement of the Drug Act, 1976”, which is where there is a problem. The Drug Act has many exploitable covenants and other gaps that have emerged as a result of recent trends in technology, advertising, and WTO agreements.

Moreover, traditional medicines prescribed by over 130,000 practitioners are outside its ambit. The Yunani, Ayurvedic and Homeopathic Practitioners Act 1965, under which traditional and herbal medicine is dealt with in Pakistan, does not provide for regulating products. The Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal and other Non-Allopathic Drugs Act, 2002 has been in the pipeline for over seven years now. The new act has also brought devices and biological substances in the regulatory net, an important step since that is an area where collusion and price gouging is pervasive.

Third, the institutional infrastructure upon which the Drug Regulatory Authority will be dependent for the execution of its mandate needs critical inputs to overcome existing constraints. Drug testing laboratories, which are now rightly under the regulatory authority’s wing, need a major fiscal and technical impetus. In human resource terms, the field force of drug inspectors is not only quantitatively paltry (250 inspectors to monitor over 600 manufacturing facilities and over 50,000 retail outlets), but also qualitatively weak. Graft is the norm in regulation, both at the manufacturing and retail levels.

To a certain extent, it is the grossly inadequate systems of compensation that fuel what can be labelled as ‘subsistence graft’. These systemic distortions will have to be addressed by the authority as a priority. Also, innovative means will have to be adopted for implementing and incentivising pharmacists’ training. There are around 200 pharmacists in the 50,000 retail facilities as of now; the national capacity to train pharmacists will not be able to cover the gap in the next 20 years. A cross sectional survey conducted in the third

largest city showed that only 19 percent of pharmacies met licensing requirements. Only 22 percent had qualified pharmacists, 10 percent had temperature monitoring and only four percent had alternative supply of electricity for refrigerators.

A final word of caution. As the government brings the implementation arrangements of this act to fruition, they should try and separate two kinds of malfunctions which result in the creation of spurious and falsified medicines. Within this context, I would like to draw attention to a major consensus article in the British Medical Journal. The paper focuses on the question of achieving international action on falsified and substandard medicines and proposes a global treaty to address this international menace.

It also looks at a new taxonomy of medicines, one that classifies medicines into legitimate and illegitimate. The paper divides illegitimate into two further categories. One: falsified medicines – those where there has been a criminal and fraudulent intent. The second category indicates regulatory or quality failure and manifests either in unregulated or substandard medicines. To illustrate a case in point, the case of the Isotab drug disaster in Lahore was a regulatory failure of the quality assurance systems of both the manufacturer and regulator and, while not done with a criminal intent, was serious nonetheless. Overlaps notwithstanding, the paper recommends that the former category, “falsified”, should be prosecuted by the justice system not just as civil negligence or regulatory violation but as a crime.

The new Drug Regulatory Authority presents a case for hope, but if the systemic impediments and potential distortions and loopholes in the law are not addressed, it may lead to an even worse failure than what the earlier red-tape variant of drug regulation resulted in. When harmful products get access to the market not only do they hurt the economy because of the

black market, and hurt bona fide businesses because of infringements on their legitimate prerogatives, they also harm and kill humans. Those that stand in the way of creating transparent regulation could well be the victims one day.

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