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The fight against spurious drugs

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Governance

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The issue of spurious drugs has been in the spotlight for some time now, beginning with the *suo moto* action by the Supreme Court in 2006 and the subsequent regulatory actions to the more recent creation of a sub-committee of the Senate's Standing Committee on Interior.

The problem has elicited strong reactions by several governments—severe but fleeting and short-lived. The idea here is neither to analyse individual decisions nor to delve into their motivation. It is to explain that the presence of spurious drugs in the market is a manifestation of erosion of capacity to regulate and govern, just as fever indicates systemic infection and changing temperatures herald climate change. The energy crisis and episodic shortages of essential commodities such as sugar and wheat are also likewise a reflection of deep-seated issues of governance. All of these are, therefore, neither amenable to quick fixes nor to fleeting coercive action, but need to be addressed by strengthening governance and oversight.

Analysis of the issue of spurious drugs highlights challenges at several levels, most of which have emerged over time due to under-resourcing of regulatory institutions and weak accountability mechanisms. The field force of federal and provincial inspectors who are meant to ensure that there is no mushrooming of clandestine manufacturing facilities and are mandated to exercise oversight to ensure quality at the retail level and in the distribution chain, have no incentives to perform. Systems of compensation are inadequate for sustaining livelihood as a result of which institutionalised collusion has become a way of working and is almost regarded as a norm. As a result, harmful spurious products get manufactured and find their way into markets.

These are detrimental in many ways. Patients suffer further because they don't get better despite out-of-pocket costs of treatment. The official economy gets hurt because spurious drugs contribute to the growth of the black economy and bona-fide businesses get affected because of infringements on their legitimate prerogatives. Lack of separation between policymaking and regulation also create an environment for collusion.

These systemic issues highlight the importance of mutually reinforcing interventions at several levels in order to overhaul regulation and strengthen governance. They call for a review of statutes to analyse where loopholes exist and underscore the need to take stock of problems in implementing standards. All this requires technical and administrative capacity and transparency in our systems of governance. A number of steps need to be taken in this connection.

First, there is the need to quantify the actual magnitude of spurious drugs. These are not just true spurious and adulterated medicines but also include counterfeit. The ministry of health's official reporting of the prevalence of spurious drugs is 0.4 percent; the Government of Punjab has recently reported a prevalence of 15 percent whereas earlier, a northern country's Trade Office alleged that 50 percent of medicines in Pakistani markets were fake. Although estimation of the magnitude of spurious drugs can be complicated because of reluctance of the retailer to divulge information and collusion between retailers, unlicensed manufacturers and inspectors, there are ways of getting a better sense of their magnitude through an independent cross-sectional survey, which the ministry of health should invest in. Secondly, there is the need to address weaknesses of the Drug Act, 1976. The Act has a strong quality of medicine-related covenants, its other weaknesses notwithstanding. However, some of its rules are exploitable, particularly provincial rules related to warranty of purchase; these have a direct relationship with inadvertently facilitating spurious drugs. Limiting the validity of the warranty is a logical regulatory option to address this issue.

The most critical weakness in the law with reference to spurious medicines relates to its scope, given that herbal, nutritional and traditional medicines are not within its ambit. The currently in-force Yunani, Ayurvedic and Homeopathic Practitioners Act, 1965, under which traditional and herbal medicine are dealt with in Pakistan, does not provide for regulating products. This means that "medicines" prescribed by 130,000 registered practitioners of traditional medicine are outside of any regulatory framework. This creates a major distortion as most of the spurious allopathic medicines are marketed under the herbal medicine cover. The Tibb-e-Yunani, Ayurvedic, Homeopathic, Herbal and other Non-Allopathic Drugs Act, 2002, has been in the pipeline for over seven years now and needs promulgation as a starting point to address this critical weakness.

The third regulatory dimension relates to the several institutional regulatory arrangements, which are currently in place to ensure quality of medicines. At the governance, oversight and normative level, the Central Licensing Board, Drug Regulatory Board and the Drug Appellate Board exist at the federal level and Quality Control Boards have been established at the provincial level. Each of these has a dedicated mandate. The problem is at the level of implementation; part of this stems from mandating the same agencies in policymaking, regulatory and implementing roles, which creates space for manoeuvrability. At the federal level, creation of the Drug Regulatory Authority, which was approved in 2005, was envisaged as a mitigate against this by separating functions and entrusting regulation to an independent agency. However, work on that has not been forthcoming. It must be recognised that independent regulation has its own problems in an environment such as ours as it can fall prey to capture. Pakistan therefore needs to determine a locally-relevant solution in order to make drug regulation more effective and transparent.

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The other institutional regulatorys arrangement includes the field force of drug inspectors, which are meant to ensure compliance with rules at several levels. Federal inspectors of manufacturing facilities can invoke manufacturing licenses; both these as well as provincial drug inspectors are also mandated to exercise vigilance at the retail level in order to ensure quality in the distribution chain. These arrangements are fraught with many challenges, both quantitatively and qualitatively, as a result of which there is a unanimous consensus to have greater scrutiny and higher level of regulatory vigilance in these arrangements. Recently, the number of inspectors in the field has been increased from 144 to 250. However, this still remains inadequate to monitor about 300 licensed manufacturers and over 50,000 retailers and has very limited capacity to uncover clandestine manufacturers and their distribution chain. Additionally, as systems of compensation are not at all adequate to sustain livelihood, malpractices are rampant. Reform to improve the quality of medicines should address this issue as a priority by developing appropriate systems of remuneration, while at the same time enhancing accountability.

The third important institutional arrangement is the network of drug testing laboratories. Existing arrangements are inadequate and poorly resourced. The government needs to make appropriate investments as these form the backbone of quality regulation. The government should also subject sale/re-sale of local and imported second-hand machinery and raw material to greater vigilance in order to impose an implicit curb on unlicensed production facilities.

The ministry of health should take apex associations of pharmaceutical companies into confidence and explore how best to secure the distribution chain and incentivise the commercial sector to invest in track and traceability technologies and packaging protecting programmes; these can limit opportunities for spurious drugs to get into the market. The government should also develop independent evaluation arrangements for random batch reconciliation. Furthermore, drug regulatory arrangements at the federal and provincial level should work in close collaboration with custom and other border control authorities to curb smuggling of counterfeit medicines. Lastly, it is important to broaden the scope of public awareness to include measures that the general public can take in order to protect itself against purchase of spurious drugs. This is particularly important, given that regulation cannot be strengthened overnight, even if there is a political will to do so.

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The issue of spurious drugs has been in the spotlight for some time now beginning with the *suo moto* action by the Supreme Court in 2007 and the subsequent regulatory actions by the then government to the more recent creation of a sub-committee of the Senate's Standing Committee on Interior.

The problem has elicited strong reactions by several governments—severe but fleeting and short-lived. The idea here is neither to analyze individual decisions nor to delve into their motivation but to explain that the presence of spurious drugs in the market is a manifestation of erosion of capacity to regulate and govern. Just as fever indicates systemic infection and changing temperatures herald climate change, the presence of spurious drugs signal the presence of deep-seated issues relating to oversight. The energy crises, episodic shortages of essential commodities such as sugar and wheat are also likewise a reflection either of absence of accountability of decision making or exploitation of regulatory prerogatives and ensuing graft at several levels—each of these is a core issue of governance and is therefore neither amenable to quick fixes nor fleeting coercive action. These issues demand an astute analysis of statutes and institutional implementing arrangements.

Analysis of the issue of spurious drugs highlights challenges at several levels most of which have emerged over time due to under-resourcing of regulatory institutions and weaknesses in mechanisms of accountability. The field force of inspectors who are meant to ensure that there is no mushrooming of backstreet manufacturing facilities and are mandated to exercise oversight to ensure quality at the retail level and in the distribution chain have no incentives to perform.

Systems of compensation are inadequate for sustaining appropriate livelihood as a result of which institutionalized collusion has become a way of working and is almost regarded as a norm. As a result, harmful spurious products get manufactured and find their way into markets; these are detrimental in many ways. Sick and poor patients suffer further because they don't get better despite out-of-pocket costs of treatment. The official economy gets hurt because spurious drugs contribute to the growth of the black economy and bonafide businesses get affected because of infringements on their legitimate profit-making prerogatives. Lack of separation between policy-making and regulation also create an environment for collusion.

These systemic issues highlight the importance of mutually reinforcing interventions at several levels in order to overhaul regulation and strengthen governance. They call for a review of statutes to analyze where loopholes exist and underscore the need to take stock of problems in implementing standards and ensuring distribution chain security. All this requires technical and administrative capacity and transparency in our systems of governance. A number of steps need to be taken in this connection.

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First, there is the need to quantify the actual magnitude of spurious drugs. These do not just include true spurious and adulterated medicines but also include counterfeit. The Ministry of Health's official reporting of the prevalence of spurious drugs is 0.4% based on the results of a nationally representative survey. The Government of Punjab has recently reported a prevalence of 15% based on a smaller sample size, whereas earlier, a northern countries' Trade Office alleged significantly higher levels. In view of this conflicting evidence, the first priority should be to document the exact magnitude through an independent third party evaluation. Secondly, there is the need to addressed weaknesses of the Drug Act of 1976. The Act has strong quality of medicine related covenants, it's other weaknesses notwithstanding. However, some of its rules are exploitable particularly provincial rules related to warranty of purchase; these have a direct relationship with inadvertently facilitating spurious drugs.

The most critical weakness in the law with reference to spurious medicines relates to its limited scope, given that herbal, nutritional and traditional medicines are not within its ambit. The currently in force *Yunani, Ayurvedic and Homeopathic Practitioners* Act 1965, under which traditional and herbal medicine is dealt with in Pakistan, does not provide for regulating products. This means that *'medicines'* prescribed by 130,000 registered practitioners of traditional medicine are outside of any regulatory framework. This creates a major distortion as most of the spurious allopathic medicines are marketed under the herbal medicine cover. The *Tibb-e-Unani, Ayurvedic, Homeopathic, Herbal and other Non-Allopathic Drugs Act*, 2002 has been in the pipeline for over 5 years now and needs promulgation as a starting point to address this critical weakness.

The third regulatory dimension relates to the several institutional regulatory arrangements, which are currently in place to ensure quality of medicines. *At the governance, oversight and normative level*, the Central Licensing Board, Drug Regulatory Board and the Drug Appellate Board exist at the federal level and Quality Control Boards have been established at the provincial level. Each of these has a dedicated mandate. The problem is at the

level of implementation; part of this stems from mandating the same agencies in policy making, regulatory and implementing roles, which creates space for maneuverability. At the federal level, creation of the Drug Regulatory Authority, which was approved in 2005, was envisaged as a mitigate against this by separating functions and entrusting regulation to an independent agency. However, work on that has not been forthcoming. It must be recognized that independent regulation has its own problems in an environment such as ours as it can fall prey to capture. Pakistan therefore needs to determine locally-relevant solutions in order to make drug regulation more effective and transparent.

The other institutional regulatory arrangement includes the field force of *drug inspectors*, which are meant to ensure compliance with rules at several levels. Federal inspectors of manufacturing facilities can invoke manufacturing licenses and provincial drug inspectors are mandated to exercise vigilance at the retail level in order to ensure quality at retail outlets and in the distribution chain. These arrangements are fraught with many challenges, both quantitatively and qualitatively, as a result of which there is a unanimous consensus to have greater scrutiny and higher level of regulatory vigilance in these arrangements. Recently, the number of inspectors in the field has been increased from 144 to 250, but still remains inadequate. Additionally, as the systems of compensation are not at all adequate to sustain appropriate livelihood, malpractices are rampant. Reform to improve quality of medicines should address this issue as a priority by developing appropriate systems of remuneration, while at the same time enhancing accountability.

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