A new paradigm for regulating drugs and pharmaceuticals

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Policy issues relating to drugs and pharmaceuticals have increasingly been in the spotlight in 2006; the impetus to this came from the saga of the sale of spurious drugs and the consequent *suo moto* action by the Supreme Court. Subsequently, a high level committee meeting on October the 2nd, 2006 decided to create a Drug Regulatory Authority (DRA); this positive regulatory change, which has the 'potential' to revolutionarize the regulation of pharmaceuticals in Pakistan was therefore very well timed. However this also generates the expectation that the regulatory authority will deliver on its ultimate outcome objective of making quality, efficacious and safe drugs affordable and accessible. Here it must be recognized that the creation of the DRA is an output of a process; in order for this output to impact outcomes a range of issues will have to be understood and addressed. What are these? How do they interplay? And where are their handles? is important to get a sense of, so that a number of caveats can be brought to attention, right at inception.

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The setting up of the Drug Regulatory Authority is just the first step in the long process of regulating the quality, the pricing and the accessibility of medicine in Pakistan

On good authority?

By Dr Sania Nishtar

drugs

The **first** consideration relates to the structure of the DRA, which has been created as a statutory and autonomous regulatory agency; it is here that the real issue lies. How 'autonomous' is 'autonomous'? How 'representative' is the 'governance of autonomous'? What are the 'prerogatives' of 'autonomous governance'? Where are the accountabilities? What kind of 'controls' would state institutions have on this regulatory agency? Who will ensure 'transparency' and according to what 'criteria'? These are important considerations which merit careful attention. Then again, even if the right ingredients at a governance and representation level are ensured, the DRA ultimately has to operate through the existing implementation arm, which is where the existing field force of inspectors, quality assurance teams and many inefficiencies and procedural malpractices factor-in. In order to mitigate these structural issues, a number of considerations will merit careful attention at the outset. On the one hand, the Drug Regulatory Authority will have to be appropriately mandated in a role beyond being a clearing house and its governance and management arrangements will have to be made meticulously transparent with broad-based representation so as to obviate commandeering by vested interest groups. On the other hand, the DRA will also have to be appropriately funded so that it can hire staff with appropriate capacity and/or incentivize existing staff structures and create an efficient incentives-performance-accountability nexus.

The **second** issue in relation to the DRA relates to the gaps in the norms and standards against which it would regulate. The DRA has been created on the premise that it would be made responsible for regulatory aspects of drugs and pharmaceuticals and monitoring of the implementation of the Drug Act of 1976 and the National Drug

Policy of 1997. And in this context, it makes sense to see if policy and legislation needs updating in the first place given that they are thirty and ten and years old, respectively.

The Drug Act of 1976 is, by and large, perceived to be a sound piece of legislation. Most of the weaknesses identified in the Act are contemporaneous such as those with reference to liberalization of trade under WTO and the recent information technology boom, which has created a new era for cross border marketing. However, there are other gaps in the Act as well particularly with reference to issues of quality assurance, phamacovigilance, data exclusivity and lack in clarity on the issue of drug pricing, which will need to be bridged in view of the potential impact of these on the scope of work of the DRA. The present Government has initiated steps to bridge another important gap in the law which relates to its lack of attention to traditional medicine; and it would be important to get that bill moved quickly so that traditional medicines can be brought under the scope of the new regulatory parameters. With reference to the National Drug Policy of 1997, there is a need to hone the 'operational' focus of the present policy with the understanding that the focus of a 'medicines policy' should be *to ensure the sustainable supply of quality, efficacious and safe drug, making certain that they are accessible and affordable for consumers and ensuring their rational use in health systems.* On this premise it is important to distinguish between a 'medicines policy' and 'pharmaceuticals policy'; the latter is linked to the medicines policy but focuses essentially on matters relating to trade, investment and Intellectual Property Rights. Cleary, state mandated agencies on health have to prioritize the medicines policy piece; in this context, it would be critical to outline the extent to which the DRA is mandated with a 'pharmaceuticals policy' implementation role vis-à-vis the Ministry of Health and the level of coordination it warrants with other sectors.

In the **third** place, in addition to the aforementioned important structural and normative aspects, a priority agenda for the initial scope of work for the DRA will have to be developed through consensus. The agenda should focus on *product and quality* regulation, *price* regulation and *IPR and patent* regulation.

With reference to *product and quality regulation,* the scope of work of the DRA can include approval and registration of drugs, granting of manufacturing and marketing licenses, regulation to deal with spurious drugs manufacture, ensuring mandatory GMP compliance, overseeing the conduct of clinical trials and ensuring the incorporation of Good Clinical Practices (GCP) protocols to stress on safety aspects of the patients and strict accordance to ethics. The mandate of the DRA vis-à-vis the role that the Ministry of Health will play in these areas will have to be delineated.

With reference to drug registration, there is a need to redefine the scope of registration in view of the understanding that many civil heath products, traditional medicines, medical devices and *in vitro* diagnostics are outside of its ambit. With reference to quality, the main focus of the DRA should be on strengthening and ensuring compliance with the stipulations of the quality assurance mechanism established under the Drug Act of 1976. A number of approaches can be pursued in line with this; these include making it statutorily binding for manufacturers to have independent quality control and pharmaco-vigilance units, mandating pre-marketing trials and post-marketing surveillance and introducing measures which can increase quality orientated competition among manufacturers.

The DRA should also enforce stricter regulatory measures to check the mushrooming of spurious drugs; these can include norms and standards for manufacturers and importers on sales through appropriate channels; regulation relating to the resale of local/imported and second hand machinery and regulatory stipulations relating to raw material sale and purchase in the market. The DRA will also have to develop its capacity to enforce stricter and transparent regulation to curb a number of illegal practices which contribute to the availability of spurious drugs in the market; these include possession of illegal and fake licenses to sell, duplicate documents, absence of warranty of purchase of all products, gaps in the sale purchase record of all products, inadequate storage practices at outlets and the absence of unqualified personnel at outlets. The DRA will have to develop its institutional capacity preferentially around this core agenda. The DRA should also create windows for the direct involvement of consumers in this arena on the premise that transparency and creation of avenues for consumer interventions can help regulate this sector in an efficient manner and allow broadening of regulation. This should enable the

common consumer to launch and follow up complaints against poor quality of medicines. The potential within civil society consumer protection agencies should be harnessed for this purpose.

On the issue of availability, on the one hand the DRA will have to work with the Ministry of Health on the National Essential Drug List (NEDL), which needs to be promoted given that it holds potential for ensuring the availability of high quality low-cost drugs in the public sector and in view of the understanding that it can be used as a tool for rationalizing pharmaceutical expenditure. However the priority agenda in this category would be to redefine the NEDL in order to scale down the number of drugs and eliminate outliers in terms of usage; another priority could be to study the price handles or factors that contribute or have the potential to increase or decrease cost along the supply chain and with a view to curtailing costs in procurement.

Also relevant to the issue of availability, is a set of complex factors, which leads to shortages of many drugs in the market; and it is here that DRA can play an effective role in mitigating/obviating shortages through a number of pragmatic measures. These can include adequate raw material quotas; support for legitimate manufacturing bottlenecks; adjustment of prices of drugs habitually short in the market so as to deter smuggling-out of those drugs; breaking manufacturing monopolies for drugs habitually short in the market; making it mandatory for medicines on the NEDL to be registered by more than one company and statutorily binding regulators to the terms and conditions of registration which also includes assurance of regular supply.

The DRA must also have a role as a priority in strengthening local regulations in line with the international code of marketing practises and ensuring compliance with these practises. Violation of this code such as those evidenced by hospitality-based incentive intense marketing practises, which adversely affect medical practise and treatment decisions of physicians; heavy and inappropriate discounts to retailers which are meant to push products and other unethical practises in order to enhance market share are well established. These will be a daunting challenge for the nascent DRA; notwithstanding, these are issues that must be the target of concerted long term focus.

The other important area for regulation is the area of pricing. The DRA needs to work closely with the Ministry of Health (which has the policy making prerogative) to develop a position on drug pricing; *this should essentially be with the understanding that the objective should be to focus on making low priced, quality, efficacious drugs available in the market.* However at the same time some incentives will have to be given to the commercial sector for quality improvements and for bringing the benefits of new and better treatment options. The feasibility of instituting policy measures to make low-price drugs available through other mechanisms such as differential pricing also need to be explored. The commercial sector advocates for the phased deregulation of a certain set of products and actives, price adjustments according to prices in countries with similar per capita incomes and voluntary price reductions while allowing subsequent increases up to the original price level. The feasibility of such policy interventions should be carefully explored through appropriate studies drawing lessons from the experience of deregulating price controls in 1993.

The third area of regulation relates to IPR and patent regulation. The scope of work of the DRA needs to play close attention to the implications of liberalization of international trade under World Trade Organization (WTO) agreements on access and affordability to drugs and should additionally, make proactive efforts to take advantage, as appropriate, of certain prerogatives that countries have, to override certain provisions of WTO in the interest of making drugs accessible. Pakistan is a signatory to the Agreement on TRIPS and has promulgated the Patents Ordinance 2000 to comply with its requirements. The DRA should begin by initiating research and studying and analyzing the potential impact objectively and develop a baseline position on the Pakistan-specific public health impacts of TRIPS. Under TRIPS the duration of patent protection has been increased from 16 to 21 years and it is perceived that strong patent protection could mean higher prices of drugs; however given that only 5% of the 1.2 billion pharma market is under patent and given that price determination is in the hands of regulatory agencies in Pakistan the 'actual potential impact' of this on drug prices needs to be determined. The extent to which this narrows the opportunity for local manufacturers who compete for market share of generics that are already in their maturity phase also needs to be assessed. In any case, the research and development base of the local pharmaceutical industry needs to be supported in the post WTO scenario given the commitments embodied in the law. This can be part of a much wider drive to increase investments in pharmaceutical R&D in order to make

the pharmaceutical sector more knowledge driven in a globally competitive environment; this approach is also in line with stated policy objective to increase pharmaceutical exports. The Ministry of Health has been collecting a Central Research Fund from licensed manufacturers at the rate of 1% of the gross profits over several years under Section 12 of the Drug Act 1976. Recently, there have been attempts to channel these funds for research activities. This is a sizeable fund, and the feasibility of using it for the stated purpose needs to be explored. Collaborative linkages should be established with agencies such as the Pakistan Pharmaceutical Manufacturers Association (PPMA), Pharma Bureau and the Pakistan Association of Pharmaceutical Physicians (PAPP) for this purpose. The potential within regional collaborative initiatives such as SAARC to enhance funding capacity in this area also needs to be explored.

The scope and scale of the afore-stated regulatory roles highlight the daunting uphill task that the DRA is up against. To deliver on an agenda as broad as this, the DRA will have to define a clear agenda, steadily develop its capacity and develop transparent implementing arrangements. However, there is much that is outside to the scope of this institutional arrangement which can influence its capacity to deliver in the stipulated role. Considerations relating to institutional structure and issues inherent to the norms and standards it is supposed to regulate against have already been alluded to. State agencies which will mandate the DRA in its role must focus their attention to these broader considerations and if they fail to do so, the DRA will just be another tier in the present arrangement of the administrative drug hierarchy.

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