Drug Regulatory Authority: A bad medicine for a terminal patient?

The Drug Regulatory Authority (DRA), being established by the government as what government spells a revolutionary step aimed at reforming messy yet crucial pharmaceutical sector, would serve only pharma industry at the cost of public interest. Even a cursory look on the draft law of the new authority can second this notion.

The government's decision to introduce this new autonomous body on the lines of other regulatory authorities like in telecom and power sectors, to regulate pharmaceutical sector is trumpeted as the solution to each and every problem in various pharma departments ranging from registration, pricing, monitoring to availability and rational use of medicines.

But apart from tall claims made in the media by the government functionaries, the DRA draft law is utterly disappointing as it provides neither anything new nor introduces any concrete and effective measure or reforming the flawed mechanisms and infrastructure for betterment in this sector.

It appears that government in the context of Supreme Court's suo moto on spurious drugs is trying to register some activism within through this cosmetic step. The Drug Control Organization, which is being replaced by the new authority, could have been used effectively if the rules and provisions provided in the Drug Act of 1976 were implemented in letter and spirit", he remarked.

It is very much obvious that DRA would provide ministry an opening to introduce some changes aimed at some convenient administrative reshuffling and will at best bring only superficial and cosmetic changes.

Health sector should not have been dealt with like telecom or power sector where the consumers' grievances are shown to be addressed through claims and farce hearings in Regulatory Authorities.

In health the consumer interest should be given top priority, given its importance, and no leeway should be provided to powerful industry players to enhance their influence in decision making.

The loopholes in the framework of the authority suggest that the new body would privatize the pharmaceutical regulation in the country, resulting in further price hike and access problems, as the framework invites more interventions from industry and less regulation from the state.

There is no doubt that DRA would bring Pakistan's pharmaceutical sector into a new pricing regime where drug prices would be controlled by the producers and not by the regulators as new authority gives maximum yet totally undue and unjustified room to the manufacturers in pricing mechanism.

The drugs are distributed in five categories and separate mechanisms for price control would be working. With the exception of WHO's Essential Drugs list, all other four categories are left almost unregulated and at the industry's behalf. The self-certification for pricing and third party certification for quality is what the authority's draft is offering, it simply means that quality drugs would be sold at higher prices and availability of essential drugs (direly needed in Pakistan) to all and sundry would become more difficult.

The draft law reveals that it is a political move as this new body is being established

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without establishing the need of such an authority.

Flaws in the framework and draft law are enough to see this new authority as eyewash and an attempt to divert the attention of people from real health issues. It is high time that government should refrain from farcical measures and be serious in addressing the real issues.

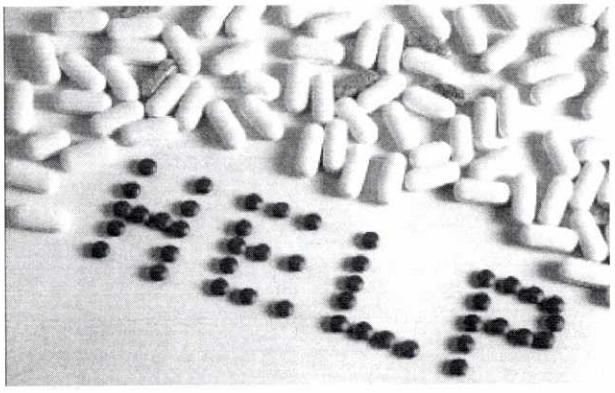
Corporatization of State's regulatory role

The Drug Act dealing with registration, manufacture, sale, import and export and all other relevant issues was enacted in 1976. The Drugs Control Organization (DCO) (www.dcomoh.gov.pk) working within the Federal Ministry of Health was empowered to implement the Act. Headed by grade 21 Civil Service officers and a work force of over 350 employees the organization has performed its functions over last 30 years though problems abound.

We have a very high number of drugs registered to be sold in our market. This is high compared to both our therapeutic needs and our regulatory capacity. Irrational use is abound on the one hand and on the other many Essential Drugs are chronically short or simply not available. Marketing ethics are in tatters and quality assurance has become a nightmare. The implementation of rules is sporadic and inconsistence. Above all pharmaceuticals remain out of reach of a massive number of people.

The lack of a clear pro-people vision; adhoc planning and strategies guided by political expediencies are at the core of our pharmaceutical mess. Lack of human resource both in terms of number and capacity is usually blamed for marked failures.

The proposed DRA will replace the DCO without establishing that how would it be any better. It is supposed to be a 'smart, modern and paper-less' organization. It will hire (and fire)



professionals at competent salaries and benefit packages which invariably means hefty amounts. It will vie with the industry in attracting appropriate human resource. Regulatory officers of large corporations will love to make brief stop-overs at the authority in their pursuits of lucrative careers.

he plan has no answer to how would it guard against corporate influences with so many 'smart' corporate boys roaming in its corridors. Though the authority plans are ambitious about education and capacity building, it has no answer to how would it retain its staff along with their built up capacities once it enters the job market for its human resource requirement.

Being smart is one of the objectives of this new set-up. It will reduce the headcount further. But how would fewer people be able to regulate a sector with 400 manufacturers; 40 thousand registered products and many more thousands unregistered ones and over 60 thousand sales outlets is anybody's guess.

Between two of us

Bureaucracy and room for industry

While the executive cadre for the proposed Authority will be hired from the market, its policy board will be all comprised of health bureaucracy. It will be meekly linked to the democratic governance structure through the Federal Health Minister. The provinces will be

represented through Secretary Health and not by the provincial health ministers. The policy board also has no room for parliamentary committees. It proposes a 13 member team with 9 members of health bureaucracy; four experts and the federal minister.

This composition of the policy board is envisaged in one of the Act's drafts. There are many drafts of the proposed Act in circulation among various circles. The draft posted on the website of the Ministry of Health does not detail the composition or the number of members constituting this important body. It says that it is up to the Federal Government to appoint any and as many persons as the policy guides of this body.

The advocates of this authority are perhaps not clear about who should guide the new authority and are thus unable to make their number and composition part of the Act. But why are they in such a hurry to get this piece of legislation passed anyway? They better take their time and decide about this vital issue.

Regulation for sale

How would the authority be funded?

The Act establishing the Authority proposes the creation of a Drugs Regulatory Authority Fund that will receive grants and loans from the government and will also receive various kinds of service fees from the industry. For example, drug registration fee; manufacturing license fee etc. The frame work for the Drug regulatory Authority envisages a Rs 100 million annual budget for the organization.

Though the Authority will initially receive grants from the government; it has an objective of ultimately shifting its financial resource completely to service fees or in other words to industry. This is the government recipe of getting rid of the cost of regulating the pharmaceutical sector. This will also be the last nail in the public health interest coffin waiting for the burial since long.

Most of the world's pharmaceutical regulators receive service fees including the biggest among them, The Food and Drug Authority of the US. But the service fees are not more than half of the authority's budget. FDA can charge the industry its entire budget but this is done to keep the FDA in service of the people and ward off industry influence.

A body comprising private professionals, with industry persons on its policy board and dependent on pharmaceutical industry for its financial existence is equal to 'privatization of pharmaceutical sector regulation'.

In the neo-liberal economics the responsibility of producing and or delivering goods and services to the people are handed down by the state to the private parties but the state still jealously guards its right to regulate the market. In fact this is the only role left with the state in this economic system. Our economic philosophers, however, have gone one step ahead and are ready to put their right to regulate on sale as well.

The Rs 70 billion pharmaceutical market of Pakistan will be very happy to foot the Rs 100 million (one seventh of one percent of their turn over) bill for regulating them. They can dish out even more if the Authority, that will be autonomous in deciding salaries and perks of its members and staff, regulates them as per their wishes.

Do it yourself – the drugs regulation

The paradigm shift in quality assurance

The quality of pharmaceutical products is a big issue in our country. None of our industries qualifies on international quality standards. The issue of counterfeit drugs keeps taking its toll daily. It is a wide subject of debate, criticism and media attention. The recent initiative by the Supreme Court of Pakistan stands witness to this vast and grave problem.

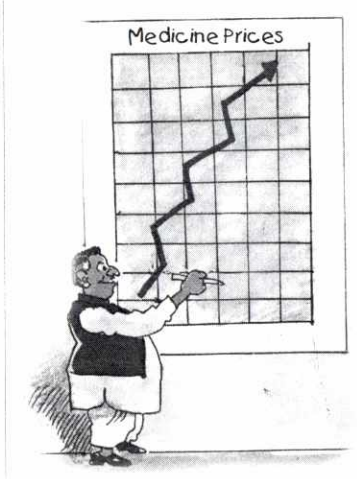
There is no question that the country needs to improve its quality standards and enforce them strictly. The DRA frame work however offers unique solutions. It does not want to wield a stick nor is it in favor of penalties, punishments and criminal proceedings against poor quality operators. It thinks that policing of the sector is not its job and it doesn't want to be seen by the industry as 'raiding party'. But how would it ensure quality then. It wants to *request* the industry to improve its quality.

It plans to introduce a system whereby industry will be encouraged to go for third party quality certifications. The DRA in return will offer incentives mostly in terms of prices of their products. If at all this naïve scheme works, it will divide the market into good quality but expensive and low or poor quality but cheaper products. This is already an established rule of the market that it serves, and serves quality to, those who pay. What addition will the DRA 'intervention' will make to this rule? Will this 'intervention' make available good quality products to those who need this but can't pay for it? If it doesn't then the DRA's act is not serving its purpose.

The paradigm shift in Pakistan's quality control outlook is actually an admission of its failure. The state is acknowledging that its earlier conceived strategy to ensure that the people of this country are offered quality products has not worked. It is good to admit to ones short comings. But only when the admission is backed by a resolve to rethink strategy and renew its efforts and not when one is trying to absolve itself of its ultimate responsibility and shifting the onus to another party.

Fueling the fire

Pricing policy for Essential and non-Essential drugs



The proposed DRA framework divides the drugs into five categories and sets up different rules for each category. The first category includes drugs that are listed in the WHO list of Essential Drugs. The prices of these drugs will be controlled by the DRA.

There are two questions here. Why are we using the WHO list when the WHO itself advises the member countries to take the list as a guideline and prepare their own National Essential Drugs Lists. Pakistan has been preparing its own NEDL and keeps reviewing it as well. Why would the DRA not be controlling the drugs included in the national list? More importantly, what does 'control' mean here?

The number two category is of non-Essential Drugs and the companies will be free to fix and raise their prices here. Presently too Pakistan divides its registered products into controlled and de-controlled lists. This was a rather adhoc arrangement to deal with the side effects of the newly introduced deregulation therapy of the 1990s adopted when it had threatened to kill the patient.

The Ministry of Health abandoned its earlier role of fixing and allowing raises in the prices of

drugs in 1993 and the prices doubled and tripled over night. The media hue and cry and the consequent political fall out made the ministry to announce a freeze. To respond to the industry pressures however it divided the drugs into two categories. The system is in place since then and is awaiting a considered and visionary policy to replace those fire-fighting measures. So much for the long wait! We are at square one.

The division of the drugs into Essential and non-Essential and controlled and de-controlled sections has changed the shape of the market. The industry has moved its focus to non-Essential and de-controlled drugs. If an industry is allowed to make a 100 rupee profit on the sale of one pack of a non-Essential Drug, would it ever bother to earn the same profit by selling 100 packs of a cheaper Essential Drugs.

The high margin non-Essential Drugs offer the companies huge sums to be invested in marketing and promotion. This has orphaned all the Essential Drugs with no one ready to adopt them. On the other hand it has helped the companies touch new lows in marketing ethics. The present prescription as part of the DRA builds further on this failed experience instead of learning a lesson.

Setting a thief to catch himself

Prices of new patented drugs

The third category of the drugs under the new system would be of the new chemical entities under patent of certain corporation. The DRA will require the CEO to hand it a certificate under the penalty for perjury stating that it is being sold in the country at a price equal to lower than 'comparable marketing areas' around the world. The CEO will issue such a certificates on 10th of July of every year and legalize any raise in price of its products.

The certification under penalty of perjury means that if proven false the person issuing the certificate will have to face criminal proceedings. The authority is requiring this certification by the industry obviously because it is not willing to or not capable of judging that what type of deal the company is offering to the people of this country. It is shifting the onus of proof on to the industry.

But if the main regulator admits to its incapability to assess the industry's claim then who else on earth will be able to do that. Will there ever be any criminal proceedings against any of the CEOs falsely certifying that they are offering the best possible deal to our people. This is a cruel joke.

To add insult to injury, the words 'comparable marketing areas' have been added. Markets are dynamic places and there are innumerable variables working in a complex relation. Companies can always choose from and play with one of those variables justifying whatever price they have fixed for their products. If they fix a higher price of a product in Pakistan compared with a country with same size of population and incomes, they can still say Pakistan is a high security risk country and they need to cover their investment through this rate of return.

The self certification is a hoax. It will be a worthless piece of paper serving no purpose but one tell companies to sell their products at whatever price pleases them.

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