The drug pricing policy

Published in The News International on January 06, 2015:

The drug pricing policy is on the prime minister's table for the final approval. Three dimensions of pricing need to be segregated: 1) Initial price setting, either of originator brands of new chemical entities (NCE) or their generic substitutes; 2) rationalisation of prices of medicines currently in the market; and 3) grant of annual price increase.

With regard to the first dimension, notwithstanding existing controversies, there is clarity in the policy direction since the prices of NCEs are to be fixed under the regional basket formula and that of generic substitutes, 30 percent less than the originator brand price. The third dimension can be debated, but from a policy stance its direction is clear as the annual price increase has been linked to the Consumer Price Index. The problem relates to the second point, where there are ambiguities and room for manoeuvrability.

First, the government's intention, evident in the title of the policy "to purge the [drug regulatory] system of discretion", would be seriously undermined and the policy would paradoxically end up increasing the discretionary powers of the regulator, the Drug Regulatory Authority. The reason for this is rooted in the simultaneous coexistence of price increase withdrawals and hardship policy covenants (grant of price moratorium waiver) in the same policy. The new pricing policy envisages withdrawing the 15 percent price increase, which has been in effect since 2013. This was granted initially by SRO 1002, subsequently struck down by the prime minister, and then upheld by the court when manufacturers challenged it. It is now the basis of the 15 percent price increase for the last twelve months.

For some categories of medicines (NCEs registered for longer than five years) the policy stipulates a further 30 percent price reduction. When price increase is struck down, most manufacturers will scramble to the regulator asking that they be accommodated under the hardship clause. Far from purging the system of discretion, the situation will make the regulator much stronger and fuel collusion even further.

Second, although there are price increase moratoriums and mandated price regulations for some categories, the overall impact on price of medicines is likely to be upwards, as one of the policy clauses enables generic products, which have a larger market share, to be priced the same as originator brands. Therefore, while the intent of the government may be to reduce medicine prices and purge discretion in regulation, the net effect may just be the opposite. That coupled with issues of shortages, which are highly likely as supply chain actors hold supplies, when initial price reductions take effect may create a negative fallout of the policy as soon as it is signed into effect.

Additionally, the mandated price reduction of NCEs, whilst they may still be under patent, means that there will be no incentive for the multinationals to introduce new innovative therapies; this may have implications for patient access, investment, and the overall government policy to facilitate the private sector.

It is therefore recommended that the summary sent to the prime minister by the Ministry of Health may be withdrawn for a review. The next iteration of the policy should address these distortions and make the pricing formula more transparent. In addition the policy must also mandate two other drug-pricing related measures in public interest, consumer education paralleled with price information systems.

There should also be a discussion on whose mandate it is to sign off on the drug pricing policy. Since the mandate of drug

regulation was given to the federal government by the provinces through resolution under article 147 of the constitution, it may well be that the Council of Common Interests and not the cabinet is the appropriate competent approval authority. Clarity needs to be sought in this connection.

In terms of a broader reflection on price regulation, I would also like to reiterate that regulation of prices of medicines is fraught with an ironic paradox. On the one hand, ensuring affordability should be a critical goal. On the other, medicines are also a 'product' in a market environment, where price increase has to be considered. The government must, therefore, recognise that price moratoriums are not the only policy lever to make cheaper and quality drugs available in the market and in the public system, and that a combination of approaches are needed at several levels to achieve the affordability objective.

For example, the government can select manufacturers on the basis of quality standards and negotiate advanced market commitments and bundle products for public procurements. The government can also incentivise manufacturers to produce medicines that are inherently cheaper by allowing for price adjustments and address other constraints, such as allocating adequate raw material quotas and help with solutions for genuine manufacturing bottlenecks. For example, hydrochlorothiazide is one of the cheapest and most effective medicines for treating high blood pressure. It costs Rs20 for 30 tablets but its production has never been incentivised. Such solutions require astute policy capacity and transparency in regulatory and procurement systems.

Finally it must be appreciated that the role of the government is not restricted to drug pricing in this area; safety and quality are equally, if not more, important objectives. In this respect, the National Drug Policy and the Drug Act need a holistic overhaul. Many gaps have emerged overtime since they

were introduced in 1997 and 1976 respectively – in particular, trends in technology, advertising and WTO agreements. Several of its clauses are exploitable. For example traditional medicine practised by 130,000 practitioners is outside the ambit of the law.

The DRA also needs a major governance overhaul. Decades-long lack of attention and under-resourcing of these institutions have resulted in clandestine manufacturing, a thriving black market, poor quality medicines and pervasive presence of spurious medicines. The pricing policy needs to be part of a mutually reinforcing policy agenda, which furthers public objectives in the health system, benefits consumers, creates an enabling environment for bona fide actors in the pharmaceutical industry and supply chain and creates barriers for black sheep. It is possible for all outcomes to be achieved through one policy instrument.

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