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The OP-ED: Some Indian Drug Makers Need a Fix

Several weeks ago, India issued directions that drugs will be sold under their generic name rather than their brand names. This caused an uproar among drugmakers, some of which made noise about taking legal action (back story). But there is more to this story than marketing considerations or mere inconvenience.

Brand and generics drugs sold in India can have different levels of purity. This means that the customer is not getting the correct dosage with every tablet. And there are signs that many companies are not using the best manufacturing technology and appropriate analytical equipment to produce consistent and high-quality products.

Since low-potency drugs sell, companies will use the threat of a lawsuit to avoid any changes in their practices. Batch-to-batch variability is acceptable to these companies. Yet it is clear that these companies are putting the general population, including their own families, at risk. In addition, brand-name companies do not want to lower their prices to generic levels, thus reduce their (profit) margins.

Most of the time, we get to read about the glorious status of India's pharma business. This is basically due to exceptional growth in exports. However, not many outside of India are terribly familiar with its domestic market. About 7,000 drugmakers are registered with Central Drugs Standard Control Organization. This number is different from the number cited in a report issued by the upper house of India's Parliament. About 550, 814 and 150 are registered with the US FDA, World Health Organization and European Directorate of Quality Medicine, respectively.

Yet it is not known how many have been inspected by their respective regulatory bodies, because the information is not in the public domain. The companies operating in those markets overseen by these agencies have high profit margins and will do whatever is necessary to meet standards, but active pharmaceutical ingredients produced for India and other markets can be of different quality. And different pharmacopeia standards add to the complexity.

Companies serving the Indian market are supposed to meet what is called the schedule M (Indian cGPM standard). Compared to WHO or FDA cGMP standards, however, the Indian standard is very lax. And how many of the facilities meet the Indian regulatory standard is not known. But companies meeting 'schedule M' will not be able to meet brand drug standards unless investment is made in technology and equipment.

A report from the upper house of the Parliament of India states that there are not enough personnel to carry out inspections and approval of the drugs produced by Indian companies. Besides inspection of drug formulation units, API producers have to be inspected also. This is an added regulatory burden. Based on general business practices, it would be a challenge to access and authenticate quality of drugs from such plants. This is a sad state of affairs.

29150 Bryce Road
Pepper Pike, OH 44124
USA

girish@epcotint.com
(216)-223-8763;(216)-292-0626(W)
(216)-292-0626(F)

By having a single generic form of a drug, the Indian government wants to eliminate differences in price and quality that exist between the same molecule, whether brand or generic. However, the media reports tell us that several steps need to be taken before price and quality equalization can happen.

1. Brand drugs are priced higher than the generic drugs, therefore, the sales commission is much higher for everyone in the supply chain. Since the generics are priced considerably lower, the revenue earned by everyone in the supply chain is lower. Thus to generate the same commission revenue, the overall sales of brand sellers will have to be considerably higher. This would be perturbation in the existing supply chain, and not an acceptable scenario. Thus the brand sellers will resist the sale of generics.

Brand sellers in India are a very powerful lobby and have significant influence, and have the potential to prevent the government's move to generics. The supply chain lobby could also raise the selling price of generics, knowing well of their inferior quality, to account for loss of their profit margins. This could negate the government's intention to lower drug prices unless price controls are enforced.

2. For the existing generic producers to meet the quality standard of brand drugs and have their products approved, they will have to invest in equipment and necessary approval process, a challenge that could be met by few. Generic companies that invest in upgrades will have to raise their selling prices to recoup their investment. Prices could inch to brand levels. This will be quite contrary to the government's intention to achieve price and quality equality. Companies that do not invest will either go out of business raising unemployment in this sector or will go underground - i.e. producing counterfeits.

3. If government forces price equalization through price controls, drug shortages could result, as the brand producers are not going to lower prices to generic levels. Generic producers will take short cuts to fill the supply gap and, at times, quality could be questionable unless government can police such situations with appropriate penalties. India's policing ethics may be a hindrance.

4. Even if the companies are able to invest and do what would be necessary to meet the drug quality standards, government regulatory infrastructure is not set up to implement its own guidelines. This is due to not having properly trained staff and not having the necessary standards. If the brand producers are able to meet the shortage created by lack of availability of generics, question could be: Would the average consumer be able to afford the brand drugs?

The Indian government has good intentions in making quality drugs affordable to all at reasonable prices, but its policies and methods are not in place to achieve the goal. Without having the necessary inspection and approval systems in place it seems that the cart has been put in front of the horse. Political patronage and unethical practices will have to be replaced by transparency and honesty to produce quality drugs, as companies are dealing with human life. Once all the methods to produce quality drugs are in place only competition will determine the lowest price.

The drive to lower the cost of quality drugs can be an opportunity for entrepreneurs who can produce drugs using the best technologies and methods that are cost effective and sustainable. This is very feasible and if implemented it could change the landscape in and outside India.

Girish Malhotra, PE
EPCOT International

29150 Bryce Road
Pepper Pike, OH 44124
USA
girish@epcotint.com
(216)-223-8763;(216)-292-0626(W)
(216)-292-0626(F)