Date	8/5/17
Publication	Times of India
Edition	Bangalore
Media Type	Newspaper

'We need a system which provides quality drugs at low cost'

TIMES NEWS NETWORK

Bengaluru: If the government wants doctors to prescribe only generic drugs, the question arises: "Do we get the best medicine at the least price?" In an email interaction, chief managing director of Biocon Kiran Mazumdar-Shaw says, "Though cheaper, these drugs may not be as safe and effective." Excerpts:

Your views on Prime Minister Modi's proposal to make doctors prescribe generic drugs mandatory. Would you agree with the move?

The intent behind the move is laudable. However, implementation is going to be a challenge because India's drug regulation system, in its current form, makes it difficult to determine whether each generic drug sold in the country has been made at cGMP (current Good Manufacturing Practices) compliant facilities, passed uniform quality checks and offers safety and efficacy to the patient. Most doctors in India currently opt for branded generics as they are assured of quality.

The Interview

For the new policy to work, the government will need to align the central and state regulatory frameworks to ensure a uniform quality monitoring system. Every generic drug approved for sale must meet similar standards of safety, efficacy and reliability. This will need an empowered regulatory body with competent and adequate staff to enforce consistent compliance. The government's mission of providing affordable access can only be met through a regulatory ecosystem that enables provision of medicines of highest quality at lowest cost.

Generics which have proven bioequivalence could be certified and carry a logo

In terms of quality, do you see a difference between generic and branded generic drugs? Please explain the price matrix.

Most drugs sold in India are, by default, generic. Branded generic drugs are marketed under a brand name given by the manufacturer, and typically carry a small premium since they are manufactured at world-class facilities which conform to stringent cGMP guidelines and require large investments.

Branded generics are bioequivalent to innovator products and comply with international regulatory standards. In the absence of bioequivalence studies and cGMP compliant processes, the efficacy and safety of generic drugs get compromised. These 'generic generics', though cheaper, may not be safe and effective for the patient. As suggested by pharma specialist Dinesh Thakur, all generics which have proven bioequivalence could be certified by the regulator and carry a distinct logo or hologram on the packaging.

How would it impact companies like Biocon?

Biocon is largely an export-oriented company, with 70% of revenues coming from global markets. Our domestic formulations business is relatively small and that too, is largely biologics, hence we are not a very significant player in the Indian generics market in terms of size.

Your suggestions to the government on ensuring affordable pricing of medicines?

Most developed nations offer universal insurance coverage, which offers cost protection and a large safety net for people seeking medical care. Low health insurance penetration in India, unfortunately, means the common man has to meet the bulk of healthcare spend from his own pocket which often pushes him into poverty. To ensure access to affordable healthcare, India needs to create a highly effective, sustainable, technology-based universal healthcare coverage (UHC) model – it should include a robust drug e-procurement and distribution system, which allows an efficient and transparent tendering process. The Tamil Nadu healthcare model provides a good template for this as it ensures that people have access to a reliable supply of essential drugs at affordable rates at the point of care.