

Healthcare experts' question GOI's generic directive

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GOI's directive on prescribing generic drugs to medical practitioners will compromise the quality of care



The Bihar health department on June 1, 2019 issued a directive to doctors of the state government-run hospitals, to prescribe generic medicines and essential drugs list available at hospital outlets. The letter stated this directive is to be enforced from June 2 onwards.

However, who would be responsible if a patient did not respond to the prescribed generic medicines? Is there an assurance to the quality and efficacy of generic medicines circulating in the domestic market? These are the concerns looming amidst the medical fraternity.

This development is a reinforcement of the notification issued by the Medical Council of India in 2017 which mandates every physician should prescribe generic names and ensure rational prescription of drugs. If compliance of this provision fails, the letter stated, "strict disciplinary action" would be taken. Subsequently, on April 2017 Prime minister Narendra Modi announced plans of putting a legal framework to ensure doctors prescribe generic medicines. This move by the government is aimed at reducing healthcare expenses, but it should not be at the cost of quality. **Dr. Neelam Mohan, Director - Paediatric Gastroenterology & Hepatology, Institute of Digestive and Hepatobiliary Sciences, Medanta** said, "Personally, when I use a generic drug, I prefer the ones manufactured by a company which follows Good Laboratory Practice and Good Manufacturing Practice regulations. The government's decision to ask doctors to prescribe a generic name has made things complicated. I don't know where it was manufactured and whether good manufacturing regulations were strictly followed! We need a lot more clarity about manufacturing guidelines before it's tools out completely."

According to The Lancet study, more Indians die due to poor quality of healthcare (1.6 million people out of 2.4 million deaths in 2016) rather than having proper access to it. Also, India's score according to the report of the Office of Pharmaceutical Quality, which determines the quality of any manufactured product, is below the global average.

In this scenario, it is necessary for the newly formed government to place its higher focus on the quality of generic drugs available in the market since the poor quality will only deteriorate the growth of the pharmaceutical industry and hamper

India's position in the global market.

"Branded generics manufactured by research-based companies are backed by high-quality standards, reliable and sophisticated supply chain infrastructure, and clinical science and innovation. Everyone deserves to be benefited by the value branded generics bring in the form of assured quality standards, proven safety and efficacy, better absorption, and reduced side-effects. Generating awareness around the value of branded generics and differences between branded and unbranded versions is the key to aid patients in taking informed decisions and reinstall the trust in the overall Indian healthcare system," said **Amir Ullah Khan, Economist and Director of research at Aequitas**.

The absence of an international standard drug regulatory mechanism deters Indian doctors from trusting most generic drugs. The doctor prescribes a drug label keeping in mind the level of efficacy assured.

"When it comes to healthcare, it is not a battle between expensive brands and cheaper generics, but a movement for quality and safety of medication for consumers without compromising on the expected outcomes and the Standard Treatment Guidelines. Even as health policy circles frequently blame branded drugs for raising healthcare costs, the argument lacks substance. In fact, branded generics were introduced as a premise to make simple and complex drugs available at affordable prices," said **Bejon Kumar Misra, founder of Patient Safety and Access Initiative of India Foundation**.

While the government is advocating a generics-only model in a bid to make healthcare affordable and accessible. But, is India ready for the change?