Implementation and Supply Assurance of Generic Drugs in Developing Countries

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INTRODUCTION

Generic drugs are popular with patients because of their low prices.

HOWEVER,

There are multiple obstacles to the implementation and supply assurance of generic drugs in developing countries.

PROBLEMS

1 *Patent protection*
2 *Differences in laws and regulations*
3 *Generics manufacturers' limitations*
4 *Public's prejudice*
5 *COVID-19*

EVIDENCE

1 *The **patent linking system** can automatically trigger the **suspension of approval** as long as there is **a blocking cause** (such as being sued for patent infringement). This skewed configuration is prone to **abuse of the approval suspension period system**.*

2 *In 2013, **Ranbaxy**, an Indian generics company, was found guilty of **falsifying safety data, fraud and selling fake drugs** in the US market. In December 2014, Italian drug safety for **India SRI KRISHNA Pharmaceuticals Ltd** in Indian **Hyderabad** production factory for testing, found ten major defects.*

3 *In China, the Ultra-low price of generic agents may **weaken patients' drug recognition and compliance**. In their opinions, price differences are usually used as a proxy for differences in quality. Generic drugs with too low a price seem to be impossible to be with good quality.*

SOLUTION

1 *Create **balancing clauses** outside the patent protection system. For patent linkage and similar systems, corresponding balancing measures can be designed to safeguard the interests of generic drug enterprises. For example, when an original drug manufacturer wishes to claim a patent and bring a lawsuit against a generic drug applicant, it must first demonstrate that the proceeding is valid; the compensation mechanism for damages due to the monopolistic behavior of original pharmaceutical enterprises should be introduced.*

2 *Improve **relevant laws and regulations**.*

Promote the conformity of relevant domestic laws with international standards; introduce and perfect the compulsory patent license system, enhance its feasibility; establish reliable generic drug development and manufacturing standards; monitor strict compliance with GMP and consistency evaluation of marketed generic drugs, and encourage cGMP certification.

3 *Protect and encourage **generic drug enterprises**.*

Adopt economic measures such as subsidies and price regulation to reduce the economic pressure of generic drug enterprises and ensure appropriate profits of generic drug enterprises, thus stimulating the production enthusiasm of generic drug enterprises and enhancing the trust of patients by the assured quality and quantity of generic drugs; strengthen investment in technology and human resources, guide generic drug enterprises to increase R&D efforts in frontier areas such as biosimilars, and encourage international cooperation while making full use of domestic pharmaceutical resources, to improve the innovation and R&D capabilities of generic drug enterprises.