Generic Drugs: IMA Perspective

Dr KK Aggarwal, Dr R N Tandon, Dr A Marthanda Pillai, Dr Vinay Aggarwal & Dr R V Asokan

Preface

Hon'ble Prime Minister, Sh. Narendra Modi Ji has said that the Government is contemplating a legislation that will make it **mandatory** for the registered medical practitioners to prescribe **generic only drugs (generic- generic drugs or writing a generic drug without a brand name).**

IMA, **in principle, welcomes** usage of **generic-generic** drugs yet has **very serious concerns** regarding **quality assurance** and other complex issues involved.

To understand the whole issue, we first need to understand various terms used in the law In India, a generic drug can be marketed with following business model:-

1. Generic-Generic or **Generic only** drug (without brand name) and usually is supplied in institutional supplies.

"Generic name of the drug" is not same as generic drug and means the chemical name of the drug only.

Generic-Generic is made and marketed by local companies in the **unorganized sector** as the preparation with questionable quality.

2. **Trade Generic** (Generic marketed under a brand name) and usually is marketed and promoted through the trade chemists in the **unorganized sector** without any Medical Sales Representative and other Marketing Staff, no R&D set up, Lack of current Good Manufacturing Practices (cGMP) assurance in manufacturing plants with high margins to the chemists etc.

3. Branded Generic (Generic marketed under a brand name) and is usually marketed and promoted through the doctors using organized set up of well-trained medical sales representatives, marketing, medical staff, R&D set up, cGMP assurance in manufacturing set up called **organized sector** etc.

A single company may pursue one, two or all the three business models. If manufactured by the same company in the organized sector and/or if procured from other manufacturers in the unorganized sector, the quality may not be the same but the price may vary with very high trade margin in trade generic as compared to branded generic.

WHO and Generic drugs:

WHO and Schedule M of Drugs and Cosmetics Act, 1947 provides a comprehensive set of guidelines including recommendations on cGMP, inspection, product assessment, licensing, **quality assurance, manufacturing, good laboratory practices, quality control, testing and release etc.**

The most important characteristics of any drug is its Bioequivalence (BE) to the innovator product to prove its safety, clinical efficacy equivalence and cGMP compliance on continuous basis for sustainable supply. The BE of any drug depends on its formulation process, choice of excipients, dissolution profile, stability under different conditions to prove its claimed shelf life, in process manufacturing and quality controls, packaging, storage conditions, transportation, validation studies, annual stability data review, analytical testing validated procedures, continuous engineering maintenance of every equipment in the plant, continuous training and development of people, reviewing regularly manufacturing/plant/site data, taking action on deviations eg. Out Of Specifications, Out Of Limit, batch specific deviations, change control, presence of impurities and mode of release of the drug etc. to name a few.

While the manufacturing practices of a company in the organized sector making all three versions may be the same but those making the 'generic only' and Trade Generic version in the unorganized sector may not and usually does not comply with the cGMP of WHO and schedule M, especially if the company is a local company catering to the State/Region and not national market through the state licensing system.

A 2014 study has shown that 10.9% of the products tested were of poor-quality with presence of none or less than the required dosage of active pharmaceutical ingredients. Of this 10.9 percent, 7 percent contained less than the required dosage of active ingredients, while 3.9 percent were drugs without any of the necessary active ingredients.

It is worthwhile to mention here that testing some samples of a batch does not provide assurance of the product quality and safety. Batch to batch reproducibility, stability of the product is possible

only through a comprehensively designed Quality Management System in a company complying to cGMP standards.

India and Generic drugs:-

As discussed above ‘trade generics’ are sold at significantly higher prices in India with very high margin to chemist.

It is also true that given the widespread poverty, making available reasonably priced quality medicines in the market would benefit everyone. This led to the origin of "Pradhan Mantri Bhartiya Janaushadhi Pariyojana" in 2008 under the concept “Quality Medicines at affordable prices for all”. It was envisaged that the scheme would run on a self-sustaining business model. It was to be run on the principle of "No Profit, No Loss".

BPPI (Bureau of Pharma PSUs of India), under the administrative control of the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India is the Implementing quality assurance agency of PMBJP.

In April 2010, BPPI got registered as an independent society under the Societies Registration Act, 1860 as a separate legal entity.

The vision of the project is to bring down the healthcare budget of every citizen of India through providing quality generic- generic medicines at affordable prices. Unfortunately, **this initiative failed to benefit the public**. **It has not addressed the purpose for which it was launched** since there were few takers due to lack of faith in quality.

IMA and Jan Aushadhi: India Medical Association (IMA) is for affordable, accessible and quality healthcare. IMA policy is to prescribe quality drugs at affordable cost. IMA promotes usage of drugs from NLEM **(National List of Essential Medicines).**

To promote Pradhan Mantri Bhartiya Jan Aushadhi Pariyojana, IMA has opened a Pradhan Mantri Bhartiya Jan Aushadhi Kendra (PMBJK) in its head quarter premises and recommends such Kendras should be opened in all the IMA buildings in India.

Medical Council and Generic drugs:

The clause 1.5 of the Indian Medical Council (Professional Conduct, Etiquette and Ethics) Regulations, 2002 has been amended in 2016 and notified in the Gazette of India on 21.09.2016, which reads as under:

"1.5 - Use of Generic names of drugs: Every physician **SHOULD** prescribe drugs with generic names legibly and preferably in capital letters and he/ she **SHALL** ensure that there is a rational prescription and use of drugs."

MCI by a circular dated 21.04.2017 has reinstated that all the Registered Medical Practitioners under the IMC Act to comply with the aforesaid provisions of the Regulations in its letter and spirit and has warned that any violation will attract disciplinary action by the concerned SMC/MCI.

In an RTI reply MCI has admitted that it does not have **even the definition of generic drug.**

MCI circular neither make it mandatory to write the generic name of the drug nor does it mentions not to write the name of the brand.

IMA does not feel that the current circular of MCI is for mandating not writing the brand name. If that was so, then the **'Jan Aushidhi'** drugs would not have been marketed in the country as it is also a brand for the purpose of marketing.

Even if we interpret MCI circular as mandating writing generic name of the drug without a brand name then the MCI circular is out of touch with realities on the ground and is bound to cause havoc in patient care and patient safety.

In India where substantial population of manufacturer operate in the unorganized sector, quality of the final product may not be assured and the law enforcement on quality of drugs needs substantial improvement, mere ordering the doctors to write generic drugs without a brand name is not in the interest of the society.

The objective of MCI is to regulate and prescribe minimum standards in medical education and the yardstick of ethics cannot be applied on this matter of usage of generic drugs with or without a brand name.

Doctors and Generic drugs:

If the Government's intention is to have doctors write only the generic name without the brand name for making drugs affordable, just shifting the onus on to the doctors alone will not help the purpose.

The root cause of the problem has to be analysed and solved by a multi-pronged approach.

It is well known that from the same company the generic-generic and trade- generic versions of a drug may be less expensive than the branded- generic ones but with very high distribution and retail margins sometimes more than 1,000% of the manufacturer's price. Distributors Retailers have a strong financial incentive to push generic- generic or trade – generic drugs, even if doctors prescribe branded drugs. **Such high discounts and price variations must be stopped.**

Therefore the rout cause of the challenge is when there is a differential pricing of generic-generic, trade- generic, and branded generic from the same company. If there is **one price** of the same drug from one company doctors can be sure about the affordability part and can then choose the brand offering consistent quality assurance.

The quality assurance mechanism in our country is very weak. India has more than 67,000 drug formulations, the quality assurance mechanism in our country can ascertain the quality control of only 15753 drugs annually (Combined testing capacity of all the Central Drugs Testing Laboratories).

Time and again, major adverse events including death occur due to poor quality of drugs or contaminated drugs. e.g. one of the major reasons for number of deaths that had occurred in the sterilization camp held in Chhattisgarh was due to generic drugs used. The verdict of the Chhattisgarh High Court in this issue has gone in favor of the doctor. He has been exonerated and the deaths had been found due to sub-standard generic drugs used during the operative course.

It is not Government Laboratory testing the product that will assure quality of the product but strong overview, oversight by the regulator with strong teeth to act on the pharmaceutical manufacturers should they not comply to cGMP norms.

When generic name only prescriptions are insisted, anyone can buy any medicine from chemist stores even without prescription (Over The Counter sale of drugs).

Even if doctors prescribe in generic name, it will be the sales person (may not be qualified pharmacist) in the chemist shop who has no knowledge about drugs will decide which brand or form of drug is to be given. **By shifting the responsibility of choosing the brand to the salesperson in the chemist shop, the objective of reducing the cost of drug is not going to be achieved and other risks of safety and lack of efficacy due to poor quality will additionally emerge.**

Eventually what is appearing to be economical or affordable potentially may not a quality product and its pharmacoeconomic cost will be far higher.

The Government is serious about making drugs affordable, hence should insist with policy to ensure manufacturers market drugs under **one drug- one price- one company policy.** The Government should ban irrational combinations. Even our day to day commodities carry ISI mark before they come into the market. But no batch of drugs available in the market carries the seal of quality. Government should strengthen the licensing, inspection, cGMP compliance, quality assurance mechanism in drug manufacturing and ensure that each batch of drug available in the market is quality assured on sustainable basis.

IMA FOMA Delhi Resolutions (Federation of Medical Associations):

1. The **judgement to choose a rational drug and its format** vests only with the Registered Medical Practitioners. This right of the medical profession is sacrosanct.

2. IMA- FOMA also wants the Government to strengthen **Quality Assurance mechanisms** to ensure adherence to cGMP standards whether **generic - generic** or **branded generic** for patient safety.

3. For a rational prescription, doctors should choose drugs **generic - generic or branded generic** based on **quality, efficacy, safety and affordability** and write legibly and preferably in capital letters.

4. IMA-FOMA recommends that Government should **ban differential pricing of a drug** under different brand names (generic generic, trade generic or branded generic) by one company i.e. allow only one chemical drug, one company, one price)

5. IMA FOMA will be meeting the President of MCI, Union Health Minister and Prime Minister of India about the views of the medical fraternity on this issue. All the constituent members of IMA-FOMA shall communicate these IMA-FOMA Delhi Resolutions to its members.

IMA demands:

1**) Generic drugs (whether generic-generic or branded generic) should comply with:**

a. Efficient and effective quality assurance mechanism where every batch of the drug is of assured quality on sustainable basis.

b. Uniform process of manufacturing, quality control and release with strong regulatory oversight.

c. Ensured pharmaceutical equivalent and bioequivalence to innovator product.

d. Ensured adequate storage conditions and shelf life duly supported by adequate stability studies.

e. Uniform price of generic drugs irrespective of their formats

f. Has the same clinical indications

Seven steps for Government of India

1. Raise the Government expenditure on Health to 2.5 % of GDP from the current abysmal 1.1%.

2. Strong overview and oversight by DCGI and State Drug Controllers on compliance to cGMP practices in drug industry.

3. Strengthen the quality assurance infrastructure to the required level so that the quality of every batch of drugs is assured.

4. Deploy adequate regulatory manpower to enforce the laws regarding drugs.

5. Stop the Over the Counter (OTC) sale of prescription drugs without prescription and do not allow a company to market same drug in different prices under different brands.

6. Prevent quacks and alternative system from using modern medicine drugs.

7. Initiate awareness movement amongst doctors and patients to buy quality affordable drugs.

Conclusion:

Doctors are committed to the welfare and safety of patients. Economy of drugs is only one dimension of the issue. The multiple concerns as enlisted above have to be addressed first. IMA shall remain the voice of voiceless and continue its service in nation building diligently.