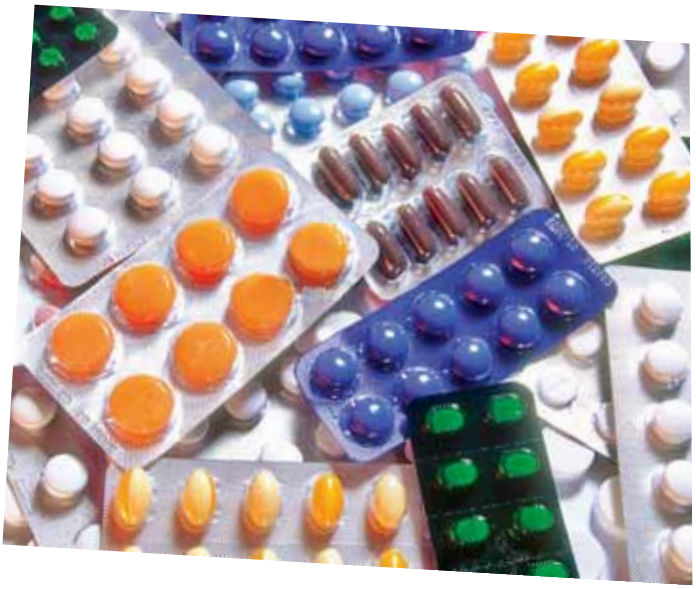
Indian generics industry

'WHO'm to blame?

Multinational companies have been approaching the World Health Organization (WHO) to formulate guidelines that would put generic versions of patented drugs in the same bracket as 'unsafe and ineffective', thus posing a threat to the huge generics market in India. Indira Rao catches up with a few key industry players to gauge their reactions.



Dr J M Khanna
executive director – Science and Technology, Jubilant Organosys Ltd

The World Health Organization (WHO) defines counterfeit drugs as, 'A medicine, which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded as well as generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging.' This definition is not adequate since generic medicines are in effect, high-quality drugs manufactured by producers other than the patent holder, having similar composition as the original, and are found to be safe and efficacious.

Generic formulations are the bioequivalent versions of innovator drugs that are clinically safe and effective. These are launched after the patent of the innovator product expires. Counterfeit and spurious drugs cannot be compared to generic drugs since generics contain the same active or inactive ingredient as the innovator product and are certified quality products that go through stringent regulatory approvals before hitting the market. Branded generic versions of drugs are well-accepted products that are sold globally with approvals from the respective local regulatory authority. Therefore, it is critical to make a distinction between counterfeit, spurious and generic drugs. It is essential for the Indian government and Indian pharma companies to join hands and take up the cause of the generic pharma industry.

The generic pharma industry is governed by stringent quality regulations that are implemented by respective regulatory authorities of each country. India is a preferred destination today for generic pharma companies like Teva, Sandoz, Mylan, etc, who have set up base in India – a country that has strengthened its patent regulations in line with global standards. In fact, India has the maximum GMP-compliant and USFDA-approved manufacturing plants outside the US.

The need of the hour is to foster international cooperation. Efforts like the patent cooperation treaty to which 116 countries including India are signatory, ought to be strengthened. All countries need to strengthen their regulatory authorities and be more vigilant to ensure that fake and spurious drugs do not enter the market. On the other hand, the industry needs to adopt innovative packaging techniques that create barriers for duplicators and help in distinguishing original drugs from fake ones.

WHO needs to differentiate between authentic generic medicines and fake & spurious drugs in its definition of counterfeit drugs. Over the years, the generic pharma industry has significantly helped the government bring down its healthcare expenditure. Hence, this industry now needs encouragement to ensure quality and affordable healthcare for all.

Prasad Joshi
manager – Corporate Affairs (Technical), Plethico Pharmaceuticals Ltd

India has acquired a strong position as a producer and exporter of inexpensive generic medicines. These medicines can treat with efficacy & safety and are at par with their patented counterparts. The exports of Indian generic medicines have addressed healthcare needs of developing countries since a long time now. Generic medicines serve the purpose of treating poor people who cannot afford the extremely expensive patented and branded drugs coming from MNCs who largely operate from developed countries. With so many benefits being offered by the generic versions of patented drugs, terming them as unsafe and ineffective is baseless. In fact, they are as equipotent, effective and safe as their original maker's product. They are steadily gaining acceptance in global markets and are also being encouraged by federal governments in most of the advanced pharma markets of the EU/US. No health ministry would permit the use of unsafe, ineffective or inferior quality medicines. And this is not only with respect to active ingredients added but also with the excipients & suitability of the packaging used.

According to me, for a responsible organisation like WHO to even consider putting generic versions of patented drugs in the same bracket as unsafe and ineffective is not correct. WHO has been renowned for its pioneering work and also for its ongoing efforts to support & develop quality healthcare infrastructure in different parts of the world, especially in least developed countries (LDCs) and developing countries like India, Brazil, etc. The role of WHO is to promote public health and affordable medicines to needy people; those who are deprived of quality medications & augmented healthcare services. It is not to enforce IP rights with commercial implications in areas like counterfeiting.

In order to thwart the attempt of the MNCs, Indian pharma majors need to unite and fight out the battle. They need to voice their opinions and objections about International Medical Products Anti-Counterfeiting Taskforce (IMPACT) move through the Drug Controller of India at WHO forums. The basic reason for this is that patients in dire need of medicines globally should be able to afford treatment, which is possible by generics only. In India, all major industry associations like the IDMA, IPA, SPIC, CIPI and FOPE have been opposing the WHO move as yet another attempt by big MNCs to kill Indian generic drug makers. In order to make our generics business grow we need to have strong representations at international forums linked to the global generic drugs business. This should be done by our industry and government officials. We also need to willingly support government & WHO procurement and healthcare programmes with generic versions.

Saharsh Rao
president – Contract Research, Neuland Laboratories

Generic drugs have been proven to be scientifically safe and effective as their branded equivalence. Therefore, I see no reason for reversing this observation of putting generic versions of patented drugs in the same bracket as unsafe and ineffective. There is a clear guidance by the USFDA and other regulatory authorities of the world as to what constitutes a generic equivalence of the innovator drug. As per the current FDA regulations, the bioequivalence of the generic version of the brand product must be between 80 to 125 per cent and this equivalence is to be determined using a bioequivalence study on human subjects. The result of this study constitutes evidence that would be filed as part of generic company's abbreviated new drug application (ANDA). In the current scenario, any company that plans to introduce generic drugs into the market has to prove to the healthcare authority that this drug is equivalent to the innovated drug. As long as the study shows bioequivalence, there is no statistical evidence which states that the generic drug is less unsafe or efficacious than the innovated drug.

So, in order to thwart the attempt of the MNCs, the action plan of Indian pharma majors should be to present scientific evidence on safety and effectiveness to the WHO. Indian companies must continuously innovate to reduce the cost of manufacturing the generics drug, and thus grow the business. The basic role of the generic industry is to deliver healthcare benefits to patients at a lower cost. As long as pharma companies look for ways to provide a low-cost alternative to expensive blockbuster drugs there will be an opportunity of growth for generic drug players.

However, one has to keep in mind that besides cost-effectiveness, companies will also have to adhere to the regulatory & manufacturing approval of the market they plan to export to. As the market for generic drugs is primarily export-driven and caters to the demand from developed markets of the world, Indian companies will have to keep both the above-mentioned points balanced. Also, since globally most governments are reducing the expenditure on healthcare, the market for generic drugs is huge.

S Ramesh
president – Finance and Planning, Lupin Ltd

India is the global leader in the manufacture and sale of generic versions of drugs. It exports about Rs 30,000 crore of generics every year, of which about 15 per cent goes to African countries alone. Since healthcare is one of the most regulated industries globally, it is therefore implied here that in order to supply drugs to any market, a company is expected to adhere to the strictest quality & manufacturing standards, ones that are at par with the best in global practices.

Today, an attempt is being made to qualify Indian generic drugs as being unsafe, ineffective and spurious. This will not only mean monetary losses for manufacturing companies but also affect millions of patients in the developing world who may not be able to access affordable life-saving drugs. The pharma industry (Indian generic medicine manufacturers) needs to work fast in order to thwart attempts by these global bodies, innovator companies and the international communities at large.

The first step in this direction should be to increase awareness about generics and their role in lowering the average cost of healthcare, as a result of which neglected and lower sections of society can also gain access to healthcare options. The second step would be to highlight the safety and efficacy of generics. These steps, along with collaboration between industry players, and a united front, would help in countering these attacks and making generics more widely accepted across the world.

India is already the top player in the generics business. In order to sustain this position and be ahead of the race, there is a need to constantly invest in R&D. Also, intellectual property will become more & more expensive and companies that are able to identify this and plan for it will be the ones that will emerge as new winners. Current macroeconomic trends point to shrinking margins and drying pipelines for global innovator companies, and we are witnessing a worldwide movement of big pharma companies towards generics. In order for growth to be sustained, clear and committed efforts need to be made in R&D. Collaboration between the government and private companies on a common platform would help ensure that risks can be mitigated and this will to a large extent, help secure the future.

Tapan Ray
director general, Organisation of Pharmaceutical Producers of India (OPPI)

While tackling the menace of counterfeit medicines, vested interests or petty sentiments should not come in the way and make the pressing public healthcare issue irrelevant. There are three clearly emerging views on the global issue of counterfeit drugs.

First, innovator companies feel that the generic pharma industry and drug regulators are not really keen on effectively addressing and resolving this global public health issue. Second, generic companies and drug regulators feel that the problem is not as acute as it is projected to be, and that innovator global pharm companies are trying to exploit the situation to fight against generic medicines and parallel imports through their intense advocacy campaign. Third, some other group, including a section of NGOs claim that an important public health sentiment is being used by R&D-based global pharma companies to extend intellectual property rights (IPR) to patients' safety issue, allegedly for vested interest. These organisations have taken their arguments to various international platforms like the Anti-Counterfeiting Trade Agreement (ACTA) and IMPACT of WHO, for effective resolution of their grievances.

According to me, the magnitude of the problem with counterfeit medicines has been inflated. Apprehensions from some section of the generic pharma industry that attempts are being made by the interested groups within the industry to bring generic drugs under the purview of counterfeit medicines, is indeed unfounded.

And, there have been no threats to non-patent infringing legal generic medicines from any developed country around the world. Why there should be any such threat at all, when the world is witnessing global pharma companies scaling up their generic business operations? On the contrary, generic pharma business – in almost all developed markets across the world – is growing at a much faster pace than patented products of innovator companies and this trend is expected to continue at least in the short to medium term.

There is enough data to establish that counterfeit drugs are posing a growing menace to the humanity. All stakeholders should join hands to address this public health issue, (leaving aside petty commercial interests) be it generic pharma companies or research-based pharma companies across the world – India being no exception.