Generic Drug Industry in India: The Counterfeit Spin

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Generic drugs are marketed after the expiry of patent or marketing rights of the patented drug and are available at an affordable price. The generic drugs are also approved by the respective controlling authority of a country as innovative drugs with regard to efficacy, bioavailability, etc. However, recently World Health Organization (WHO) provided a definition for ‘counterfeit drugs’ which covered generic drugs under its warp. Considering the representation from India and other South East Asian nations, WHO has put defining counterfeit drugs on hold, while agreeing to modify the same in their favour. This paper analyses various aspects of generic and counterfeit drugs and the likely impact of the WHO definition on the Indian pharmaceutical industry. It also critically evaluates recent seizures of shipments of generic drugs by EU under a WTO TRIPS regime based on the premise of free trade.

Keywords: Generic, counterfeit, WHO, pharma, seizure

The development of a new drug typically takes about 10 to 12 years and can cost as much as $1.5 billion. Each year, worldwide, only about 26 new chemical entities drugs enter the market (2005: 26, 2004: 24, 2003: 26, 2002: 28). These figures prove beyond doubt that pharma companies have a difficult road ahead for drug development. Hence, their investments in resources, time and research should be aptly rewarded by allowing them a monopoly in the form of patent protection for a stipulated period of time. This provides the R&D teams an ‘innovator’s prize’ for helping the patients to combat the diseases with latest drugs and also helps to maintain the vicious circle of finance to R&D and vice versa to further come up with new drugs. However, once the term of patent or associated marketing rights expires; other manufacturers are free to come up with generic versions of these drugs.

On the other hand, a generic drug is identical to and bioequivalent of a branded drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use which US Food and Drug Administration (FDA) also confirms. Respective countries have intensive procedures for drug approval wherein various generic versions also have to meet the stringent criteria in the same way as innovative drugs. The most important advantage with generic drugs is that they are cheaper as no R&D investments are involved as in the case of new drugs. The prevailing fierce competition also makes the manufacturers keep to low prices. Thus, generic versions help patients by making the drugs available at affordable prices while retaining the quality. In other words, generic drugs balance public interest especially in diseases like cancer and AIDS, the prevalence of which is very high, that too in developing countries and treatment with patented drugs is steeply priced.

With a five-year extension being granted to the President's Emergency Plan for AIDS Relief (PEPFAR) in August 2008, the Wall Street Journal has noted that much of the $131 million funding is spent on generic drugs. This is a marked departure from PEPFAR’s earlier and heavily criticized practice of purchasing only expensive, patent-protected and branded drugs. An estimated half of all prescriptions in the United States are now filled with approved generic drugs, which brings out their escalating importance.

The WHO Definition of Counterfeit Drugs

Recently, fate of generic industry was at stake when WHO defined counterfeit drugs as: ‘A medicine which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with correct ingredients or with wrong ingredients, without active ingredients, with insufficient active ingredients or with fake packaging’, thus, covering even generic drugs under the warp of counterfeit drugs. WHO estimates that while less than 1% of the drug supply in industrialized nations including the US is potentially

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counterfeit, it is to the tune of 10-30% for the countries having less legal or regulatory oversight? There is, however, no exact or speculated data to predict likely prevalence of counterfeit drugs in particular geographic areas of the world. WHO released a Report in 2006 describing counterfeit medicines as a global health crisis. Whatever be the magnitude of presence of counterfeit drugs worldwide, it can be unequivocally said that they have to be curbed in public interest. Numerous anti-counterfeiting initiatives have recently been launched for example, the Anti-Counterfeiting Trade Agreement (ACTA) (a plurilateral initiative of the European Union, Japan, United States and Switzerland), World Customs Organization on ‘Provisional Standards Employed by Customs for Uniform Rights Enforcement (SECURE)’, G-8 Countries’ Initiative on Counterfeits; WIPO’s Advisory Committee on Enforcement (ACE), Security and Prosperity Partnership (SPP) (between Canada, Mexico and US).

Besides these localized efforts, globally acceptable pharmaceutical norms and standards are also required as pharma products are being marketed internationally, with advent of globalization. Such international norms may serve as a gold standard to ensure safety and quality of medicines. To address the problem of counterfeiting on global front, an international consensus on quality, safety and efficacy standards for the distinction between generic and counterfeit drugs is of paramount importance. This would also help speed up access to medicines.

However, it is worth noting that, there is no consensus among the member nations as to what actually are counterfeit drugs. In general, the member States of WIPO rely on WHO guidelines, standards and norms for regulation, safety and assurance of quality of medicines. WHO provides relevant expertise and technical assistance to members through activities such as guideline development, workshops and training courses, coordination and promotion of anti-counterfeiting measures, prequalification of medicines for priority diseases, pharmacovigilance for global medicine safety and regulatory and other information exchange? The trend of member nations relying on the definition provided by WHO in case of drug specifications might be applicable in the case of counterfeit drugs also. This entrusts the WHO report with greater responsibility, as not only does it affect the fate of diseased millions, but might also adversely affect the pharma industry across the globe.

The Fall out of the Exposition: The Indian Paradox

The genuine concern about the WHO definition is that it may end up negatively affecting the legitimate use of generic drugs and thus become an obstacle to access to medicines. At the same time, stakeholders concur on a clear and lawful distinction between generic drugs and the counterfeit drugs. The proliferation of counterfeit drugs in the country is a cause of concern and needs to be checked with stringent laws. Measures also need to be undertaken to arrest their spread across the borders and actually differentiating them from generic drugs, which are actually genuine.

The detrimental impact of this description of counterfeit drugs on Indian generic industry is very emphatic as situations here are also paradoxical. India on one hand has been identified as one among several developing countries that are regarded as the source of counterfeit medicines by the Organization for Economic Cooperation and Development (OECD). On the other hand, India's largest generic drug manufacturer, Ranbaxy, remains on FDA's list of companies producing generic antiretroviral drugs approved for PEPFAR. It is also worth noting that India is the fourth largest producer of pharmaceuticals in the world which accounts to 8% of world’s production by volume and 1.5% by value. Indian pharmaceutical industry ranks 17th in terms of export value of bulk actives and dosage forms. India exports its products to more than 200 countries around the globe including highly regulated markets of US, Europe, Japan and Australia. According to latest reports, nearly half of its revenue comes from exports, mainly from the EU and the US. Further, estimates show that revenues from Indian Pharma exports crossed over Rs 24,942 crores during 2006-07. The situation becomes even more decisive for India as according to Goldman Sachs study, it is estimated that India is estimated to be the fifth largest pharmaceutical market in the world by 2020, with sales of US$43 billion. Due to various reports as aforesaid regarding India as a source of counterfeit drugs, the WHO definition has been inviting opprobrium from the Indian pharmaceutical industry.

Controversial Elements in the Definition

The Indian pharmaceutical manufacturers and officials have assailed the word ‘history’, as it is considered to be ambiguous and capable of acting as a
market barrier for exports to countries. The exposition has also made industry experts and stakeholders to emphasize that it goes beyond the issues of ‘quality, safety and efficacy’ and could be used as a contrivance to project India as a centre of substandard and counterfeit drug production. The most controversial part of the definition is that any ‘false representation’ in relation to ‘identity, history or source’ would be considered a case of counterfeiting. False representation of identity and source applies not only to mere labeling of the products, but also to ‘its container or other packaging’. Thus, false representation with regard to any of those elements would make the product ‘counterfeit’ within the scope of the definition. This brings trademark issues also into play. The fake packaging and counterfeiting at local levels need to be checked through enforcement of IPR mechanisms. Trademark owners have strong incentives to ensure that the quality of their product is maintained. If trademarks are not enforced, substandard drugs or counterfeits would sideline the genuine ones. It must be noted, that though trademark enforcement in developing nations is lacking in vigour, it is not entirely impossible to cloak the rights holders as well as administrative authorities with powers to check the menace.

However, all differences in packaging may not be fraudulent. Sometimes, the difference in shape, colour schemes or packaging, may arise on account of batch to batch variation. Under the definition as currently worded, such drugs may be regarded as counterfeit despite having appropriate active pharmaceutical ingredients since it covers both branded and generic products under its ambit. Concerns have been raised that this could lead to India’s authorized exports of genuine drugs being termed spurious. Another factor deserving attention is that a medicine would be considered counterfeit according to the present explication, if, by no fault of the exporters, the medicine is smuggled into a different foreign destination. By necessary implication, if medicines originally intended for one country end up in another country where they are not registered, they would be declared fake.

Seizure of Indian Generic Drug Shipments

On the export front, Indian generics have already started courting trouble with recent seizures of generic consignments by EU from India which were en route to destinations like Brazil, Columbia and Peru where they could be legally sold, while they infringed patents in EU member states. EU enforced EC Council Regulation No. 1383/2003 to seize drugs in transit via its territory. On 4 December 2008, the Dutch authorities seized a cargo of generic medicines en route from India to Brazil. The cargo consisted of 570 kilograms of losartan potassium, an active pharmaceutical ingredient used in the production of medicines for arterial hypertension. It was sent by Indian company, Dr Reddy’s Labs to the Brazilian importer EMS. The cargo was held back by Dutch authorities for 36 days, after which, it was released and directed back to India. Losartan potassium does not enjoy IP rights in India, the country of origin, nor in Brazil, the country of destination. The confiscation generated considerable controversy regarding the status of generics vis-a-vis counterfeit drugs. Other companies that faced confiscations at EU have been Chandigarh-based Ind-Swift Laboratories Ltd, whose shipment was headed to Venezuela and Cipla Ltd, whose consignment to Peru was seized at Amsterdam. Cipla reportedly abandoned the consignment as the cost of litigation was disproportionate to the value of the consignment.

The latest confiscation has been a UNITAID funded shipment consisting of 49 kilograms of abacavir sulfate tablets at Schiphol Airport by Dutch customs authorities under the misleading claim that it contained counterfeit goods. UNITAID issued a statement on its website that the drugs were not counterfeit nor did the shipment infringe any intellectual property rights. UNITAID clarified that these were medicines used in the second-line treatment of HIV/AIDS manufactured by Indian company Aurobindo and were approved by WHO as well as temporarily qualified by USFDA.

Seizures such as these adversely affect the patients who eagerly await these life saving drugs and for whom interruption in the therapy might be dangerous. While raising concern about the increasing confiscation of generic medicines, UNITAID also urged the Dutch government to hasten the release of medicines. Brazil has also expressed its anguish over the seizure of goods in transit on grounds that they might be violating IP rights conferred by a patent registered at the country of transit, which is nowhere provided for in TRIPS. In fact, Article 52 of TRIPS speaks of seizure only if the final importation violates IP in Member State. Such excessive and inappropriate interpretation of IP rights, granting extraterritorial effects, runs counter the objectives and purposes of the TRIPS Agreement.
The Indian representatives have remarked: ‘Measures of this nature have an adverse systemic impact on legitimate trade of generic medicines, South-South commerce, national public health policies and principle of universal access to medicines.’ The industry lobby group, Indian Pharmaceutical Alliance (IPA) also urged serious action against seizures which surface a sensitive issue affront the developing nations vis-a-vis the developed nations: that of access to affordable medicines.\(^{12}\)

These detentions act like non-tariff barriers against the spirit of free trade as envisaged by the WTO and Articles 41.1 and 41.2 of TRIPS.\(^{13}\) The above provisions of TRIPS clarify that enforcement procedures ‘shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse’ and the procedures for the same shall be ‘fair and equitable.’ The seizures are clearly TRIPS plus, and even abrogate the public health postulates of Doha Declaration of 2001. India had earlier sought clarifications from EC on its definition of counterfeit drugs.\(^{14}\) In the aftermath of this development, India and Brazil joined hands to avert adoption of the annotation of counterfeit drugs in the WHO General Assembly meet.

It seems that intellectual property protection has attained primacy over public health concerns in attempting to place counterfeit medicines. It may be emphasized that strengthening IP protection has to be in accordance with the interest of the developing nations as also the public health prescriptions in both domestic as well as international laws.

The WHO Executive Board Meet

The members of the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), which is a WHO initiative during the inter-country consultations on combating counterfeit medicines, stressed the need for a consensus in finalizing the matter. Consequently, in order to deal with the apprehensions of the Indian Pharmaceutical industry about bringing non-health issues that have no direct implications on the safety of a drug, within the ambit of the definition of counterfeit medicine, WHO invited India on board while proposing a change in the definition of counterfeiting at the World Health Assembly. In this meeting, India’s suggestions were accepted and the word ‘history’ was also deleted. The WHO Executive Board meeting in Geneva in January 2009 approved India’s stand to modify the present definition. Currently, WHO has decided to keep the definition in abeyance before the final report can be revealed at the May 2009 World Health Assembly meeting.\(^{15}\)

The May meeting would set the standards on counterfeit medicines as well as clarify the steps that need to be taken by the Indian generic industry to forge a survival strategy. Looking at the volume and breadth of this industry and parallel import provisions; a middle path will have to be carved out to give effect to the TRIPS mandate of public health and access to medicines.

Conclusion

The harmonization of the definition of counterfeit medicines is essential to avoid genuine generic medicines being considered counterfeit - a term normally associated with illegally produced or supplied medicines that may or may not conform to quality specifications. India has stressed that a generic or branded medicine not registered in a particular country, but available in that country is not counterfeit, but simply an unregistered product. False representation would also allow quality defects and system errors in manufacturing process to be tagged as counterfeiting. All these factors demand a due consideration of the definition, before it is universally applied.

References


