



PHARMACEUTICALS EXPORT PROMOTION COUNCIL

(Set up by Ministry of Commerce, Govt. of India)

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Of generics, politics and counterfeit medicines

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For many years, the quality of Indian generic drugs their effectiveness were suspect. On certain international platforms, attempts were made by vested interests to bar exports from India on these grounds. The allegations were crushed when the World Health Assembly at Geneva recently set aside prevailing definitions of “counterfeit drugs” and declared that a common ground should be allowed that involves developing nations to have a say.

It was a stupendous boost for the Indian government, which has been resolutely defending domestic pharma.

The government delegation questioned the basis of World Health Organisation’s (WHO) adoption of the International Medical Products Anti-counterfeiting Taskforce or IMPACT - a tool allegedly used by Big Pharma to counter generics exports than combating the real issues of fake and spurious drug trade. The Indian industry is clearly elated at the big triumph and so is the commerce ministry.

The world health body following fervent pleas from India realised that issues on counterfeiting are more the domain of world trade agreements and so the dispute should be resolved among countries by following the necessary local legislations than making it part of the WHO’s agenda.

According to industry experts, the situation could be taken to the desired gravity because certain Latin American, South East Asian and African countries could rally support behind India’s contentions. It may not be appropriate though to blame the international companies alone and accuse them of attempting to derail the export of generic drugs.

There is indeed a strong undercurrent of a global counterfeit drug business and all force should be applied to control its further spread before annihilating those elements completely.

It will be a great injustice if patients are put on questionable spurious products even as they battle for life. International Federation of Pharmaceutical Manufacturers has come out in the open to support IMPACT. IFPMA president Haruo Naito said, “Counterfeit medicines are a crime and our industry is serious about tackling this problem head on.”

He called perpetrators of counterfeit drugs criminals and added, “They pose a threat to global public health: deliberately and deceitfully they attempt to pass off their dangerous products as legitimate medicines, and risk patients’ lives in order to make illegal profits. This is not about commercial interest; this is about protecting patients, and we stand ready to be an active partner in WHO-led efforts, including IMPACT.” But IMPACT itself is seen by Indian companies as a lop-sided instrument which can run into controversies

and urgently requires a new interpretation.

A few Indian companies have been in controversy over manufacturing standards at their plants. The US Food and Drug Administration has been cracking down upon those who according to the regulatory agency pose a threat

to public health by deviating from the standard manufacturing practices. That principle is followed even for multinational companies.

But there is a marked difference in the way the issues are approached by the global buyers of Indian products.

International marketing experts suggest that the level of suspicion about Good Manufacturing Practice deviations - for raw materials and finished dosages — is much higher in the case of Indian companies compared with other drug firms.

That makes it extremely important for Indian drugmakers to strictly follow the QA/QC norms. While strong quality parameters can set new benchmarks for the rest of the Indian industry, it will be much easier for the government to protect its industry from unwelcome aspersions at international forums. It is very interesting to note that the divide between innovators and the generic companies have now almost faded.

With the exception of Roche AG, most other multinational companies have gladly embraced generic drugs business as their next business plan.

This shift will make it even more difficult for Indian companies to maintain their brand positions in the western markets. About a decade ago, much before generics comprised nearly three-fourths of the American prescriptions, Indian medicines were seen with doubtful eyes.

The brands were built over hard toil of a number of years. It will take a stronger conviction for Indian promoters to maintain their business interests as the biggest companies get gradually pitted against the giants of the drug industry. Indian companies cannot afford to get related in any ways with counterfeit drugs.