



The ‘Counterfeit’ conundrum in pharma industry – Is it time for concerted action?

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The quality control measures at the customs with regard to the import and the export of medicines and APIs need to be strengthened to eliminate substandard, spurious, fraudulent and counterfeit medicines from international trade to or from India. An insight by Dr Gopakumar G Nair, Chief Executive Officer, Gopakumar Nair Associates

SSFFC — ‘the latest World Health Organisation (WHO) initiative on Substandard/Spurious/Falsely-labelled/ Falsified/ Counterfeit medical products’ has been making slow but steady progress through meetings in 2012, 2013 and the latest on October 29-31, 2014. A technically strong delegation comprising four seniormost drug regulators from (DCSO/DCGI) office represented India.

Countries like Brazil, Argentina, Ghana, Nigeria (NAFDAC-DG), the US, Europe and Korea were represented by strong delegations. However, not very surprisingly, China was represented only in token, by their officer in Geneva. India has been sending out ‘mixed signals’ to the global pharmaceutical community including WHO, primarily due to the genuine concerns expressed partially by the generic pharma industry and substantially by the civil society.

Consequent to the efforts of the MNCs and the western world countries to interpret ‘counterfeit’ as to include intellectual property violations and infringements also through International Medical Products Anti-Counterfeiting Taskforce (IMPACT) of WHO and Anti Counterfeiting Trade Agreement (ACTA) having met with strong resistance, WHO has come up with SSFFC which has excluded the originally inclusive IP Issues such as patent infringement from the ambit of SSFFC. It is time for India to look at the core issues seriously

and pursue permanent and futuristic solutions to the issues of quality, reliability, efficacy and good manufacturing practices.

A recent report by a US Organisation headed by Roger Bate had highlighted the lack of uniformity in quality of medicines supplied to Africa. The report had further emphasised on the substandard and spurious status purportedly of medicines from Indian origin. It is surprising that the American Enterprise Institute in Washington and their researchers could access unauthorised and unregistered medicines available in the African marketplace, while African and Indian healthcare regulatory authorities have failed to take a note. Stringent controls on pharma manufactures in India with regard to Good Manufacturing Practices (GMP) and quality excellence is called for. India needs to ensure that no unregistered medicines get exported to any country in the world. While, India is claiming to be 'Pharmacy of the World', any spurious or counterfeit medicines labelled as of Indian Origin, could substantially damage India's reputation for quality. In this context, upgradation and strengthening of infrastructure at Central Drugs Standard Control Organization (CDSCO) and Drug Controller General (India) (DCGI's) office is of utmost priority.

Of late, there have been many instances of spurious, substandard and counterfeit medicines originating in China, but labelled as of Indian origin have been reported to have surfaced in African markets. These are clear instances of counterfeit medicines, the source and origin being different from what is on the label. These type of counterfeits where the product label claims to be originating from a manufacturer, while the product has fraudulently been manufactured by a third party amounts to criminal practice and need to be detected and punished severely. The quality control measures at the customs with regard to the import and the export of medicines and APIs need to be strengthened to eliminate substandard, spurious, fraudulent and counterfeit medicines from international trade to or from India.

Tragedy struck a recent sterilisation camp in India where 15 women died after sterilisation, reportedly because of administration of contaminated and spurious antibiotic from a Raipur manufacturer. The said medicine has been found to be contaminated by zinc sulphide, a rat poison. The manufacturer appears to be a licensed manufacturer. Even though the drug manufacturing licence has been cancelled, the punitive action should include prevention by ensuring that the concerned persons are no more permitted to set up any other drug manufacturing facility anywhere in the world.

A blacklist need to be created to exclude persons with criminal record from getting back into the pharma manufacturing and trade. The Indian Drug Regulations under Drugs and Cosmetics Act and Rules thereunder need to be reviewed, strengthened and harmonized both in letter and spirit. India should join International Code of Harmonisation (ICH) as an observer with a view to become a regular member in five to ten years. This can only be done by strengthening the office of the DCGI.

In the emerging scenario, India needs to take confident strides towards quality assurance of global standards. The current apprehensions on interpretations of SSFFC medical products must be overcome by concrete propositions from India. The latest definition excludes patents and patent infringement disputes from the definition of counterfeit in countries and regions such as the US and the EU as well as ASEAN and RCEP. This negotiated compromise will lead to a better handling of quality issues across the board in pharma trade, globally.