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Compulsory barcoding decision halted

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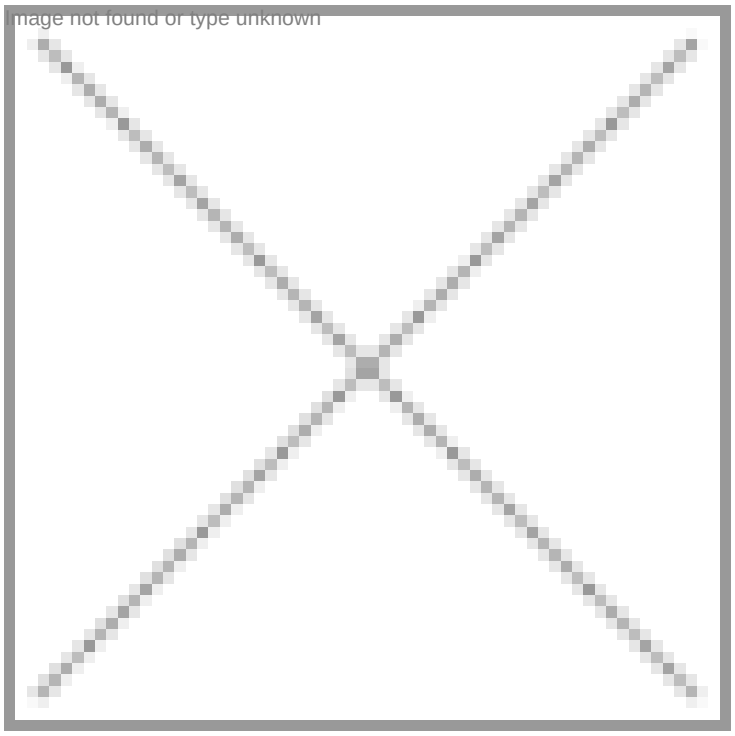
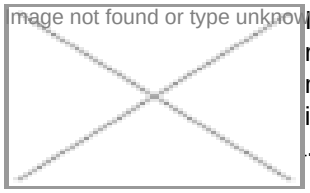


Recently, the Union Health Ministry decided not to take a hasty decision to enforce compulsory barcoding on all medicine strips, as the case is pending in the Allahabad High Court. BioSpectrum *explores what the furore is about?*



In May 2009, the Ministry of Commerce, Government of India was in for a rude shock, when they received a statement from Nigeria's NAFDAC, which stated that around $2.16 million worth of anti-malarial drugs bearing 'Made in India' labels were seized by the Nigerian authorities. The labels indicated that the drugs were manufactured in India, but the bill of loading revealed that they had .

In addition to this, there were reports doing the rounds in the African markets alleging all Indian generic drugs to be spurious or counterfeit drugs. The Indian Directorate General of Foreign Trade (DGFT) in its battle against counterfeit drugs, issued a notification on January 2011, making it mandatory for all pharmaceutical and even biological (like vaccines) companies to affix barcodes on their export products to track and trace their stock across the entire supply chain.

According to the mandate, the DGFT clearly states that products need to build track and trace capability for their exported medicines using barcode technology as per GS1 global standards. Such barcoding is required at primary, secondary and tertiary level packaging. This includes incorporating (at all the three levels) 2D and 1D (GS1 data Matrix) medicines at strip/vial/bottle level encoding unique product identification code (GTIN), batch number, expiry date and serial number. The deadline given to all pharma exporters to put barcoding systems in place is July 2011.

Figures and facts on the share of counterfeit products vary but the unanimous conclusion remains that India is moving towards being the hub for spurious medicines. A survey of 10,000 samples, funded by the World Health Organization (WHO)

and undertaken by the International Pharmaceutical Federation last year concluded that 3.1 percent of all drugs in India were counterfeit. Another survey stated that around 10-20 percent of drugs in India were counterfeit medicines. A follow-up survey, conducted by the Central Drugs Standard Control Organization (CDSCO), found the prevalence of spurious drugs at 0.046 percent of all medicines sold to customers.

Opposition to the mandate

Giving a bird's-eye view of the government's expectations from the industry, Dr Praful Naik, CSO, Bilcare Research, says, "The mandate is a wake up call for all Indian companies and ideally this should have been an industry initiative. Post the seizure in Nigeria, the Indian government does not want to take the blame for export of any spurious drugs to other countries. Before announcing the mandate, DGFT had taken consensus of industry bodies. I see this mandate from a positive angle."

The notification at large, has given rise to fierce opposition from the industry on the grounds that it could lead to delays and drastically hamper drug exports from the country. Baring the top Indian and MNC companies, who have already incorporated the practice into their systems, many medium and small-sized companies would view such an exercise as cumbersome and expensive. The cost of affixing barcodes (per pack) comes up to approximately one-and-a-half dollars, says an industry expert. The deadline of July 2011 is too short a notice. A section of the industry is also of the opinion that the mandate is a bit obscure and needs to be more clear in its specifications. For example, though the mandate is applicable to biotech products, many companies claim that it is still not clear to them as to which class of biotech products the mandate is applicable to.

The Indian Drug Manufacturers Association (IDMA) submitted a letter to the DGFT, stating that in a country like India where exports are equivalent to $10 billion and there are more than 3,500 exporters, implementing this system would not be practical. The association said that machinery for such type of barcoding is not available in India and exporters in the small scale sector cannot afford to implement it. The letter states that, "By introducing the above, we as a country are giving a wrong impression to the importing countries that we are producing counterfeit drugs and therefore the Government of India has put this type of restriction."

According to IDMA, the government should have a face-to-face 'open meeting' with industry players to understand feasibility of implementing such a system. Reports from the IDMA suggest that the DGFT is yet to respond to such a request.

Nayantara Som in Mumbai