



INDIAN DRUG MANUFACTURERS' ASSOCIATION

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PARTNERS IN GLOBAL HEALTHCARE

Shri Rajeev Kher,
Commerce Secretary,
Department of Commerce,
Ministry of Commerce & Industry,
Government of India,
Udyog Bhavan, New Delhi

Sub: Implementation of Barcoding on Primary Packs

**Ref: DGFT Public Notice No. 54 (RE-2012)/2009-2014
dated 5th April, 2013**

Dear Sir,

Greetings from Indian Drugs Manufacturers' Association.

We request your indulgence in the crucial issue of barcoding on primary pharma packs for export consignments for Tracing and Tracking purpose. We have, vide our various representations and in meetings with you informed about the impracticalities, both economically and logistically, of implementing barcodes at all levels of Pharma packaging, especially on Primary packs.

You will also be aware that barcoding on all stages of formulation packs is not implemented in any country, as many formulation packs such as strips, vials, etc are so small that even legally mandatory information such as ingredients, warnings, batch number, price, name and address of manufacturer is very difficult to accommodate.

However, we have in good faith, agreed to implement barcodes on tertiary and secondary packs. We reiterate that it is physically not possible to put barcodes on primary packs. This was confirmed when a similar drug tracking system was dropped from the Generic Drugs User Fee Act in USA earlier, as even the largest Pharma market considered tracking

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every individual unit as “too expensive and burdensome for manufacturers, suppliers and health care professionals”. Although USA has reconsidered the matter, US FDA has been directed to issue Guidelines by 1st Jan 2015 so that trace and track on individual packs could be considered two years later.

You will appreciate that every manufacturer and exporter will have to buy/upgrade machines, digitalise huge data and set up a whole new team which would require large investments and would be difficult to execute. Our SMEs would not be able to afford setting up machinery that costs upwards of Rs 1 crore and also requires additional skilled manpower.

Our exporters are required to register their products with the importing country, and take necessary approvals of their regulators and comply with the regulatory requirements and languages that vary from country to country.

Efforts will need to be made to evolve a “Global Track and Traceability” programme using a harmonized barcoding system which will be acceptable to all countries across the globe rather than impose a Unilateral Standard which may not be acceptable to the importing countries. Also, many of our companies manufacture products for foreign companies on contract manufacturing (neutral labeling) and such requirements of barcode are not stipulated by these Companies. In countries which do not have any Trace and Track requirement, Indian Trace and Track guidelines can be implemented only after their acceptance of these guidelines.

Therefore, you will agree that barcoding on primary packs is neither practical nor possible. The Indian Parliamentary Standing Committee on Health and Family Welfare in its 59th Report, presented to Parliament on 8th May 2012, has clearly stated in para 15.2 that “Taking advantage of the confusion created by MNCs over fake and counterfeits, the so-called anti-counterfeit solution providers that sell barcode and other technologies are propagating and lobbying for the use of such expensive, impractical methods by making them legally compulsory. Use of barcodes will increase the cost of drugs without any benefit to consumers.” Hence a thorough examination of regulatory, technical and cost implications is very much required.

As reasoned above, exporters will not be able to implement the barcoding system on primary packs and implementing the same at present will bring all our pharma export activities worth over Rs. 80,000 crore to a standstill and deny people and Governments all over the world access to our safe and affordable quality generic drugs, not to mention heavy loss to the national exchequer.

We again request your urgent indulgence and, on behalf of the entire Pharma exporting community, appeal to you to withdraw or at least keep in abeyance the Public Notice as above seeking to implement barcodes on Primary pharma export packs.

Considering the importance of the matter and the general impact it would have on Pharma Companies in India, we thought it appropriate to address the present appeal to your good self and seek your intervention in the matter for a favourable solution.

Yours sincerely,



S V Veerramani
President