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Drug exporters need more time to implement barcode: Pharmexcil

Peethaambaran Kunnathoor, Chennai

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Although the Union commerce ministry's decision to implement the barcode system (1D /2D barcode) for pharmaceutical exports from July 1 is appreciable in terms of brand India promotion, industry sources feel that the time given for the exporting units to implement it is too short and it needs to be reviewed.

Pharmaceutical Export Promotion Council (Pharmexcil) has already made a representation to the ministry of commerce highlighting various issues that have emerged following the government order. Pharmexcil is now waiting for the ministry's reply, said Bhavin Mehta, COA Member, Pharmexcil.

If the exporters, including those from the SME sector, are forced to implement it in the present form before the deadline ends, the total pharma exports from India will come to a standstill as SME sector as well as big companies are not geared up to face the challenge. The short span of time fixed for implementing the rules has become a concern for Indian pharmaceutical exports which is growing at a rate of 14 per cent YOY, he said.

While addressing the pharma exporters of Chennai, he said brand promotion is an indispensable factor if India is to be projected in other countries, and it has to be done. But to achieve the goal, a great amount of efforts and preparation is required, hence sufficient time has to be provided to the exporters. The time factor should not be a bottleneck to flow of products from India to other countries. The health ministries of other countries take a period of 9 months to 12 months for giving the registration, and in case of amendments, they take around 6 months, if they do not have any query in the amendment after paying the amendment fees.

While speaking to Pharmabiz on the sidelines of the meeting, the Pharmexcil COA member said "the Ministry of Commerce has issued a circular to implement 1D or 2D barcode on all exports originated from India. The step taken by the ministry is praiseworthy keeping in view brand India promotion when India is being targeted as the originator of counterfeit medicines as claimed by some foreign companies. Here the only problem our exporters face is the short duration which needs to be reviewed. Pharmexcil has given representations to the MOC and to the DGFT".

While delivering a talk on the barcode system, he said all the goods to be exported to various countries are done based on registrations received from health ministries of other countries. During registrations, the exporters submit their sample which is identical to the commercial shipments. Once the samples are approved, the exporters get registrations, and they are supposed to dispatch goods as per the sample pack submitted during the pre registration time. So, if the 1D or 2D barcode needs to be implemented, the exporters

shall have to approach the MOH of each country and file application for an amendment in the art work incorporating the same. Moreover, for the amendment in registrations, some countries demand amendment fees which ranges from USD 100 to USD 1000 per product. This will become an additional burden to the exporters, especially the exporters of the SME sector.

Bhavin explained that as per the new rules, every exporter of pharmaceutical product has to build track and trace capability for their export products using barcode technology as per GS1 technology global standards. The same will need to be done at primary level, secondary level and tertiary level packaging labels.

The primary level packaging contains incorporation of 2D (GS 1 Data matrix) barcodes on medicines at their strips or vials or bottles, encoding unique product identification code (GTIN), batch Number, Expiry date and serial number of the primary pack.

In secondary level, incorporation of barcodes (1D or 2D) encoding unique product identification code (GTIN), batch number, expiry date and serial number of the secondary pack.

In the tertiary stage, incorporation of barcodes (1D), encoding unique product identification. He said the GS1 system of standards is the most widely used supply chain standard system in the world.

As regards infringement of patent, Bhavin said whoever without authority makes, or uses or offers to sell or sells or imports any patented invention during the term of the patent, it is infringement.

He said now the pharma exports from India are worth 10.3 billion USD and it is growing at a rate of 15.3 per cent YOY. In 2014, the country expects a target of 22 billion USD. The meeting of exporters was organised by Pharmexcil in association with IDMA Tamil Nadu branch.