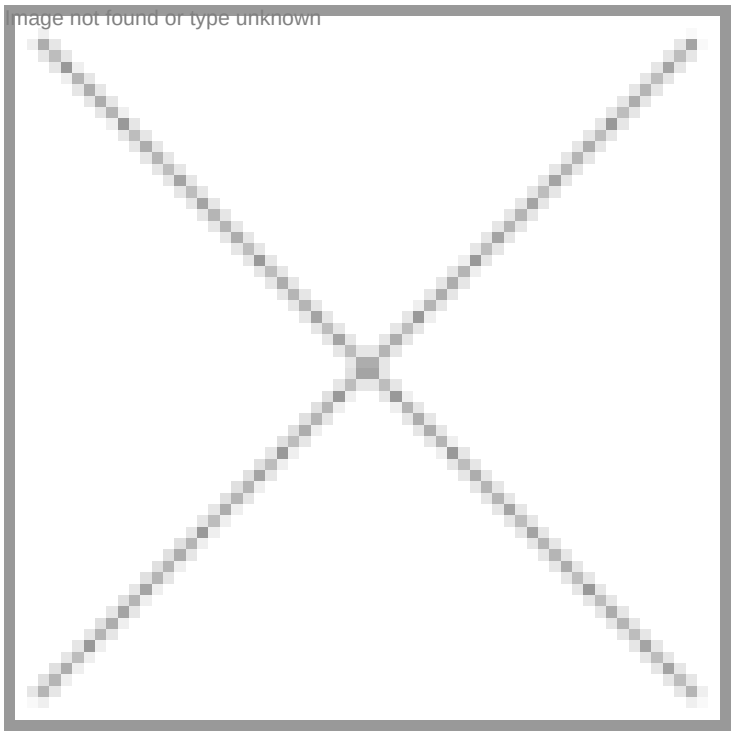
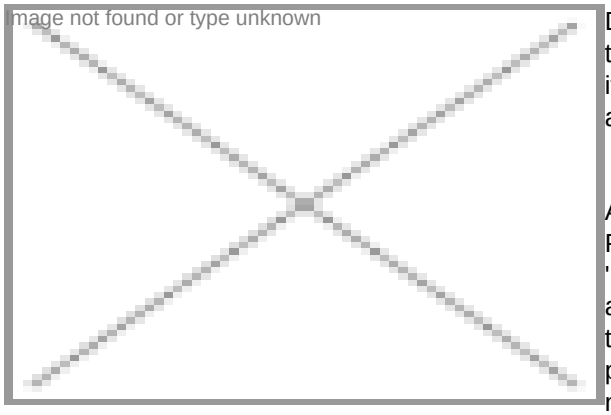
BioSpectrum the business of Bio & Health Sciences

BT firms meet their first deadline for mandatory barcoding

14 November 2011 | News



DGFT's second notification has been viewed by companies as detailed and the deadline as feasible since it mandates implementation of the track and trace system in a phased manner in the country



Despite fierce opposition from the industry, a couple of months earlier, the Director General of Foreign Trade (DGFT) was determined to stick to its initial notification on mandatory barcoding. In order to allay apprehensions of the industry, it decided to extend the deadline for

As per its notification, dated June 30, 2011, the DGFT amended its Public Notice No 21, issued on January 10, 2011, by mentioning, 'Exporters of pharmaceutical products will adopt a trace and track system and incorporate its features for exported medicines using barcode technology as per GS 1 global standards'. This includes packaging at the primary, secondary and tertiary levels. However, unlike its previous notification, the track and trace system, this time it will be introduced in a phased manner across the country. The deadline for incorporation of track and trace systems is October 1, 2011 for primary packaging, January 1, 2012 for secondary level packaging, and October 1, 2012 for tertiary level packaging.

The DGFT made this move after $2.16 million worth of counterfeit anti-malarial drugs bearing 'Made in India' labels were seized by the Nigerian authorities in 2009. Subsequent to this incident, drugs exported specifically out of India, were assumed to be counterfeit drugs and were put under the scanner by port authorities across Africa and Europe. In order to put in place a system of checks and balances for counterfeit drugs, the DGFT issued a notification in January 2011, making it

mandatory for all pharmaceutical and biotech companies to affix barcodes on their export products to track and trace their stock across the entire supply chain by July 2011.

The move was met with a barrage of criticism by the industry. It complained that compulsory barcoding would lead to high rise in costs, was unfeasible for implementation by medium and small size companies and above all, it will send wrong signals (on India being the hub for counterfeit drugs) to the global community. Accordingly, the Union Ministry of Commerce amended the notification by putting an extension to the said deadline.

A clear and detailed notification

DGFT's amended mandate to implement track and trace systems in a phased manner rather than in one go, has been viewed by a majority of industry observers as a prudent move. It drastically eases down the pressure to set up capital-intensive infrastructure systems in a limited time span. Says Dr Praful Naik, CSO, Bilcare Research, â€œThe practice of implementing it in a phased manner will ease the pressure for many companies. In the previous notification, barcoding of export drug consignments had to be done all at once for all levels of packaging, which made it a complex process.â€?

While multinational companies had already been following serialization processes prior to the first notification, a couple of Indian companies have also put in their infrastructure in place in order to meet the deadline, including firms like Glenmark, Cipla and vaccine companies like Serum Institute of India and Haffkine Biopharmaceuticals. Says Ashok Saxena, head, technical operations, Glenmark Pharma, â€œWe have adhered to the deadlines given by the Government (in this case October 1, 2011). I feel that it would be difficult for small companies, but they would gradually adapt this practice.â€?

Another change in the second notification is the mention of the fact that the Government would establish a central portal for tracking and tracing exported products. The portal would be a central server, which would contain all the data and details of manufacturers in the country. This data can be accessed by any importing country. An exporter can upload information onto this central portal rather than investing a huge amount of funds in setting up a separate server. â€œThe central portal which is to be set up by the Ministry of Commerce, is a huge leap and would save costs for a number of small and mid-size companies, for whom setting up separate servers for data management would be a problem,â€? adds Dr Naik.

The second notification, according to many experts, is more detailed and systematic. While it calls for setting up of a track and trace system, at the same time it also calls for authentication systems which would also check the authenticity of a product. A barcoding system might identify the product but it might not be successful in checking its authenticity. The notification mentions that, 'authentication features will be added in due course and integrated with the trace and track system.'

Biotech companies gear up

Like its pharmaceutical counterpart, the biotechnology industry in India to a large extent derives its business revenues from exports. According to the 2010-11 BioSpectrum-ABLE annual survey for the biotechnology industry in India, the sector clocked revenue worth `17,249.34 crore in FY 2010-11, out of which exports made up 51 percent of the overall revenue contributing a total of `8,852.34 crore. Biopharmaceutical exports contributed `5535.4 crore over last year's exports of `4767.66 crore.

Post DGFT's mandate, biotechnology companies, while maintaining that they did not have a choice but to implement the practice (without which their consignments could not move forward), have at the same time opined that the timeline given to them, this time, has been feasible.

A majority of Indian vaccine companies, in particular, have already met their deadlines. An official from the vaccine major, Serum Institute of India (SII), Pune, says, â€œWe have already implemented the system. Being a major vaccine producer, we use sophisticated methods and systems and lot of our products are exported which does require barcoding. Investment has never been an issue for us. I feel the deadline is good enough for us and the government has given us a lot of time to put the systems in place.â€?

SII's products are supplied to international health agencies like the World Health Organization (WHO), United Nations Children's Fund (UNICEF), Pan American Health Organization (PAHO) and also to more than 140 countries across the globe. Its vaccines are being used in the national immunization programs of several countries. SII supplied its HIB vaccine to the Global Alliance for Vaccines and Immunization (GAVI), PAHO and UNICEF.

Mumbai-based Haffkine Bio-Pharmaceutical, a public enterprise engaged in the manufacture and supply of a wide range of biological and non-biological products comprising bacterial and viral vaccines, supplies its vaccines to bodies like the UNICEF. Officials from the company told BioSpectrum, that while they have met the requisite deadline, the company is taking additional steps to ensure that the practice is fully followed.

Says an official from the company, â€œWe even send our officials for training on barcoding implementation since we are particular on quality in manufacturing.â€? The hitch however is that it is unclear where to position the barcoding label on the vaccine vial. â€œThe polio vial for our vaccines is heat sensitive and very small. We are still unclear on the place where the label is to be positioned,â€? adds the same official.

For a section of biotech companies, it is still not clear whether the notification is applicable even to biotech APIs alike. Says an official from Concord Biotech, â€œWe are still not sure whether this mandate is applicable just to formulations or to API companies like us.â€?

The cost of implementing such a system has been the bone of contention between the Government and the industry since the mandate was first passed in January 2011. The cost for one 2D label is around a dollar. High-end printers and scanners lead to additional costs. Industry experts opine that smart and intelligent costing models will come to the biotech sector's rescue. An outsourcing model would hence fit the Bill.

Moreover, biotech companies also opined that the government's central portal system would save them the cost of setting up separate servers. â€œI feel if and when this system comes into place, business in the country would grow multifold. An importing country would rather look at India than a developed nation. However, the challenge remains that many Indian companies still do not understand the benefits of such a system,â€? adds Dr Naik.

There are speculations amongst experts that this could lead to an increase in the cost of drugs. The percentage of the hikeis, however, at present, unclear.

Nayantara Som