

# Pharma & Healthcare Update

January 23, 2013

## BAR CODING REQUIREMENT FOR SECONDARY LEVEL PACKAGING OF EXPORTED MEDICINES ENFORCED ON JANUARY 1, 2013

### INTRODUCTION

The bar-coding requirements for secondary level packaging of pharmaceuticals exported out of India, as mandated under Director General of Foreign Trade's (DGFT) notification dated January 10, 2011<sup>1</sup> (the 'Notification'), have been enforced from January 1, 2013. Readers may recall that the Notification required all manufacturer and exporters, who are engaged in export of pharmaceutical products, to develop track and trace capability for their exports

### BACKGROUND

Around two years ago, African regulatory authorities seized some consignments of pharmaceuticals exported to Africa supposedly from India on the grounds of being sub-standard or spurious. These consignments had labels of 'Made in India' pasted on them, though it was later found that the same had originated in some other country. This had tarnished India's image globally. In view of this and other similar incidences, the DGFT in the Department of Commerce had issued a Public Notice on January 10, 2011 mandating track and trace surveillance system for all exports of pharmaceuticals and drugs from India on primary, secondary and tertiary levels of packaging labels following GS-1 global standards.

This track and trace system is being implemented in three phases-

- In the first phase, bar coding requirements for tertiary level packaging were enforced on October 1, 2012. Tertiary level packaging comprises of multiple secondary packs or pack levels. Tertiary packs are normally the ones which are dispatched as logistic units/shipments.<sup>2</sup>
- In the second and current phase, bar coding requirements for the secondary level packaging is now enforced. Secondary level packaging is a level of packaging that may contain one or more primary packages or a group of primary packages containing a single item.<sup>3</sup>
- In the third phase, bar coding requirements for the primary level packaging will be made enforceable on July 1, 2013. Primary level packaging is the first level of packaging which is in direct contact with the product. It may consist of a single item or group of items for a single therapy such as a Kit.<sup>4</sup>

### MADRAS HIGH COURT ORDER

The decision to enforce the Notification was supported by the Madras High Court. The Confederation of Indian Pharmaceutical Industry and Indian Drug Manufacturers Association had jointly moved Madras high court on December 19, 2011 challenging the Notification. However, on December 21, 2012, the Court ruled in favor of the Government and declined to offer any extension from the implementation of the barcoding on the secondary level packaging.

Some important aspects of the Notification

- Application: The export of Active Pharmaceutical Ingredients (API), Bulk Drugs and Intermediates have been exempted from the application of the Notification. The Notification is applicable to export of finished pharmaceuticals only.<sup>5</sup> Moreover, the requirements of bar coding on secondary level packaging will apply only to those exported pharmaceuticals, which have been manufactured on or after the date of enforcement of the requirement, that is, January 1, 2013.<sup>6</sup>
- Not an alternative to the standard labeling: The bar coding requirements will apply in addition to standard labeling requirement under Drugs and Cosmetics Act, 1940 and Rules, 1945.<sup>7</sup>
- Exemptions: If the country of import has any special bar coding requirements, then the Notification will cease to be applicable to export of pharmaceuticals to such countries.<sup>8</sup>

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IMPACT

The impact of the Notification has been discussed at length in the public domain by pharmaceutical associations and industry players. The requirements imposed by the Notification have led to increase in packaging cost. It may also lead to additional process burden, since the existing label approved from the country of import will have to be modified (that is, to add extra text / bar code).

However it is undeniable that the bar code system will reduce number of spurious drug which are exported out of India and assist in curbing the menace of spurious drugs.

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You can direct your queries or comments to the authors

<sup>1</sup> DGFT Public Notice No.21 (RE-2011)/2009-2014, available at <http://dgft.gov.in/exim/2000/pn/pn10/pn2110.htm> (last checked 09.01.13).

<sup>2</sup> GS1 India, "Implementation Manual for Barcoding using GS1 Global Standards for Tracing and Tracking of Pharmaceuticals and Drugs for Exports", available at <http://www.gs1india.org.in/gs1barcodes/07-Guidelines%20as%20per%20DGFT%20mandate.pdf> (last checked 09.01.13).

<sup>3</sup> Ibid.

<sup>4</sup> Supra Note 2.

<sup>5</sup> See DGFT Circular No.48 dt. 28.11.11, available at <http://164.100.9.245/Exim/2000/CIR/CIR11/cir4810.htm> and Pharmaceuticals Export Promotion Council of India's (Pharmexcil) circular on Status of Barcode dt. 31.12.12, available at <http://tracktrace.blogspot.in/2012/12/pharmexcils-circular-on-status-of.html> (last checked 09.01.13).

<sup>6</sup> See DGFT Circular No. 43 (RE-2010)/2009-14, available at <http://164.100.9.245/Exim/2000/CIR/CIR11/cir4310.htm> and Pharmexcil's circular on Status of Barcode dt. 31.12.12, available at <http://tracktrace.blogspot.in/2012/12/pharmexcils-circular-on-status-of.html> (last checked 09.01.13).

<sup>7</sup> Supra Note 2.

<sup>8</sup> See DGFT Public Notice No. 59(RE-2010)/2009-2014 available at <http://dgft.gov.in/exim/2000/pn/pn10/pn5910.htm> (last checked 09.01.13).

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