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Case study on the implication of Bar code in Indian Pharmaceutical industry.

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ABSTRACT

Barcode on package of medicines is very vital to ensure the quality of domestic and export markets. To facilitate the customers in India to ensure the safety and legitimacy of a drug with the help of internet, the health ministry has come out with a device called 'Track and Trace'. This method is useful to guarantee the drugs marketed in India are authentic products. As per the Government notification, barcode for pharmaceutical products will be made mandatory. According to commerce ministry this barcode is helpful to find out the origins of shipment. Commerce ministry in India expressed that this barcode would curb the sales and export of spurious drugs which carry the tag of made in India. This case study covers the perception of drug manufactures, drug exporters about the compulsory compliance of barcode on pharmaceutical packaging.

Keywords: Pharmaceuticals in India, Package, Barcode, Drug manufactures, Exporters

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INTRODUCTION

Indian pharma can enhance their global presence only with the help of quality which can be ensured through bar-coding, live mint (2015)¹. Pharma firms in India have three levels of packaging, namely, primary, secondary and tertiary. According to Directorate General of Foreign Trade (DGFT), having barcodes on primary level packaging had to be followed from 1 July 2014, and later it was postponed up to a new date was informed². In general to design and produce the container or wrapper for product is packaging. Packaging can be used as an important marketing tool because of the influence of many factors, which in general includes the primary package, the secondary package and the shipping package, Philip Kotler, 2003. As per the Gazette of India, public notice no.4/2015-2020, dated 1 April 2015, package which is in direct physical contact is called primary packaging, carton enclosing many primary packs together with a mono carton is called secondary package and shipper enclosing several secondary packs is called tertiary packaging. Any item like retail goods, medical records, machinery, medicines ... can be automatically identified using automatic data-capture technologies with the barcode symbols³. Pharmaceutical Industry revenues are anticipated to US\$ 45 billion during 2012-20 at a CAGR of 12.5% and by 2016 pharmaceuticals sales are expected to increase to 27%⁴.

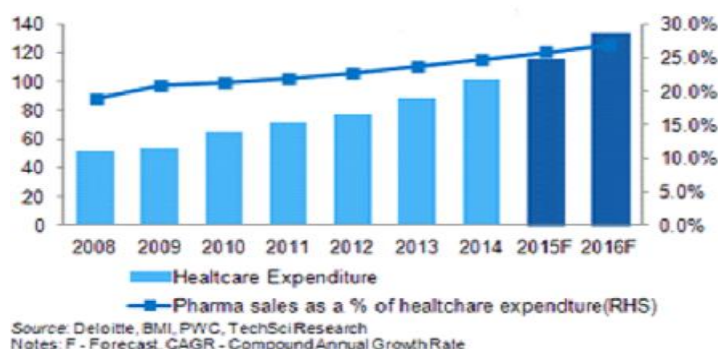


Exhibit-1- Pharma sales as a percent of total health care spending**

**Source: <http://www.ibef.org/industry/pharmaceutical-india.aspx>

Pharma sales as a percent of total health care spending is given in exhibit 1. In exhibit 2, revenue of Indian pharmaceutical sector (US\$ billion) is given.

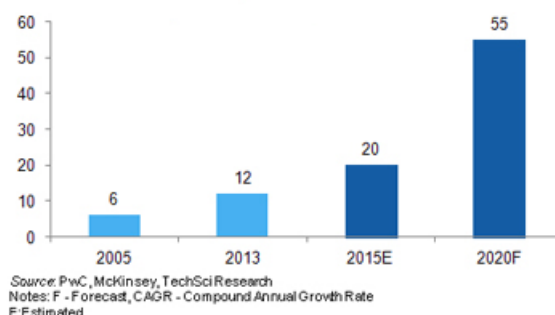


Exhibit-2-Revenue of Indian pharmaceutical sector (US\$ billion)

**Source: <http://www.ibef.org/industry/pharmaceutical-india.aspx>

With regard to revenue of pharma sector, by 2020 pharmaceuticals market is anticipated to reach US\$ 55 billion at a CAGR of 12.79 per cent in 2015 and cost of production of in India is considerably lesser than that of US and is almost half of that of Europe⁵. Due to growing consumer expenditure, fast urbanisation, and

raising healthcare insurance, by 2025 market size of Indian pharmaceutical is anticipated to increase to US\$ 100 billion⁶. According to Organization of Pharmaceuticals producers of India, to come out with a new medicine to treat patients will take about 10-15 years, which is a long process of drug discovery and for each successful drug the average R&D cost is estimated to be \$800 million to \$1 billion⁷. According to a report by equity master with regard to volume, Indian pharmaceuticals market is the third largest and with regard to value Indian pharmaceuticals is the thirteen largest⁸. With regard to volume, Indian generic drugs exports is accounting for 20% of global exports and branded generics lead the pharmaceuticals market which comprises almost 70 to 80% in India⁹.

BARCODING

Bar coding can be read by bar code scanners and bar coding is a sequence of parallel vertical lines with bars and space¹⁰. With product packages, bar coding can be used globally as price tags, carton labels, identification of products and enormous data is made accessible for the users along with GS1 when it is read by scanners¹¹. According to Ministry of Micro, Small and Medium Enterprises (MSME), to promote exports as per the market development assistance scheme for MSME Unit, 75% will be reimbursed if they use bar code¹². In order to ensure the safety of medicines ideal packaging could facilitate the traceability of the product from the manufacturer to the customer. Ideal packaging is useful to avoid fraudulent medicines and expired medicines. In pharmaceutical packaging, dates of expiry for perishable products, barcodes, sales information, codes about lot and dates to facilitate tracing and recalls are given by coding and marketing. Currently bar coding uses new characters like uppercase alphabets. Traditionally pharmaceuticals packaging is expected to protect the drug, improve the shelf lives and now it is extended to avoid drug tamper, spurious drug, child protection, right dosage for the patient¹³. If Radio Frequency Identification (RFID) is fixed during the pharmaceutical packaging, traceability of the medicine from the manufacturer to the patient, authenticity of medicines, and competence of pharmaceutical supply chain can very well be facilitated¹⁴. In order to develop the export market, according to Pharmaceutical industry, Indian Pharmaceutical firms have to guarantee the quality and bar coding could facilitate in this regard¹⁵. Indian government told pharmaceuticals firms to use bar coding at three levels of packaging namely primary, secondary and tertiary to understand the track and trace of their exported drugs. The Ministry of Commerce and Industry, Government of India, established the Pharmaceutical Export Promotion Council (PHARMEXCIL) in 2004, for the promotion pharmaceuticals exports in India¹⁶. Indian Pharmaceutical export is accounting to US\$ 15.5 billion during 2014–15 and India exports to over 200 countries¹⁷.

IMPLICATIONS OF BARCODING

Generic drug makers perceive the bar coding may be a threat to their business. 40% of the Indian pharmaceuticals exports are from small and medium sized pharmaceuticals firms and bar coding standard may affect their business. Bharat R. Desai, Chairman of the Indian Drug Manufacturers' Association (IDMA) in Gujarat, opined that financial situation of the Small and Medium-sized Enterprises (SMEs) was not good to set up parent-child relationships between strips of drugs and their packets and they already had bar-codes on secondary and tertiary packages¹⁸. New bar coding rules will affect the 10,000 to 15,000 people who work in the 1,000 SMEs and according to PHARMEXCIL in India total exports of the SMEs is accounting to around 20,000 crore, Vidya Krishnan (2015). According to another IDMA member, implementation of parent child bar coding will affect the exports of the SMEs' which mainly comprises of Latin American and African countries, Vidya Krishnan (2015). The main aim of bar coding pharmaceutical packaging is to restrain the distribution of fake drugs, but SMEs feel that this new bar coding will ultimately spoil their business. SMEs in India perceive that PHARMEXCIL in India helping global pharmaceutical firms, Vidya Krishnan (2015). In order to control the spurious medicines made by other nations which carries our made in India tag for exports, government of India has made bar-coding of mono cartons of drugs shipped out of the country from July 2015 as compulsory, to safe guard the name of our country, Soma Das & Dilasha Seth, 2015. This bar coding will enhance the image of pharmaceuticals firms in global market. Bar coding on mono cartons is on par with the global standards and is useful to find the source of a specific medicine. A prerequisite to bar-code primary packaging has been deferred because of the complex technological aspect quoted by the industry, Soma Das & Dilasha Seth (2015). Bar coding on mono cartons is on par with the global standards, which is useful to find the source of a specific medicine.

According to Directorate General of Foreign Trade (DGFT), mono cartons were considered to be part of primary level packaging, would now be considered as secondary level packaging¹⁹. The obligation to use barcodes on tertiary level was put into practice since October 2011 and for secondary level packaging since January 2013²⁰.

CONCLUSION

Packaging is very important for any product and pharmaceutical packaging can ensure the authenticity of the drug, shelf life of the drug, child protection and right dosage for the patient. In order to promote the pharmaceuticals export, quality of the drugs can be ensured by proper packaging and bar coding on the various levels like primary, secondary and tertiary. Indian pharmaceuticals companies, Small and Medium Enterprises (SMEs), think that this bar coding standard may spoil their domestic business and export. Hence, it is up to the Indian government to take appropriate measure with regard to new bar coding norms and promote the interest of the stakeholders of Indian pharmaceutical companies.

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