

**FAQS ON IMPLEMENTATION OF GSR 823(E) DATED 17<sup>TH</sup> NOVEMBER, 2022 WITH RESPECT TO BAR CODE OR QR CODE ON TOP 300 BRANDS**

**Q. 1. What are the requirements for affixing the Barcode or QR code as GSR 823(E) dated 17th November, 2022?**

**Ans.** As per the notification vide GSR 823(E) dated 17th November, 2022, the manufacturers of drug formulation products as specified in Schedule H2 shall print or affix Bar Code or Quick Response Code (QR Code) which shall include the following particulars, namely:

- (i) unique product identification code;
- (ii) proper and generic name of the drug; brand name;
- (iv) name and address of the manufacturer;
- (v) batch number;
- (vi) date of manufacturing;
- (vii) date of expiry; and
- (viii) manufacturing licence number.

**Q. 2 When the said requirements of Barcode or QR code will become effective?**

**Ans.** As per the notification, it shall come into force on the 1<sup>st</sup> day of August, 2023.

**Q. 3. How the Unique Product Identification Code can be decided?**

**Ans.** The Unique Product Identification Code is to be decided by the manufacturer as per his own Standard Operating Procedure to ensure the identification of the product.

**Q. 4. Whether the notification is applicable to the 300 brands mentioned in the notification only?**

**Ans.** Yes, it is mandatory to print /affix QR Code on the 300 brands of the drug formulations as mentioned in the notification. However, if any manufacturer voluntarily wants to affix /print Bar code or QR Code for any other brand, he is free to do so.

**Q. 5. What is the applicability of this notification?**

**Ans.** This notification is applicable for all the indigenous as well as foreign manufacturers who are manufacturing these brands of drug formulations for marketing in the country.

**Q. 6. Whether all batches of brands of the drug formulations as specified in the notification is required to have Barcode or QR code?**

**Ans.** Any batch of brands of the drug formulations as specified in the notification which has been manufactured on or after 1<sup>st</sup> day of August, 2023, irrespective of the location of the manufacturing site, shall have the Barcode or QR code on its label as per the said notification.

**Q. 7. In case of inadequate space, how the Bar code or QR Code should be affixed on the label?**

**Ans.** As per the notification, in case of inadequate space in primary packaging label, the same may be affixed or printed on the secondary package label.

**Q. 8. Whether printing /affixing of the Bar Code or QR Code in case of imported product can be carried out in the country after custom clearance?**

**Ans.** Products should be preferably imported with affixed or printed Bar Code / QR Code on the label. However, Barcode or QR code may be affixed on the label in the country after obtaining the permission from the Licensing Authority as required under the Drugs Rules, 1945.

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