Guidance for Identification and Verification of Spurious Drugs

As per Drugs and Cosmetics Act, 1940 a drug shall be deemed to be spurious: if it is manufactured under a name which belongs to another drug; or

a) *if it is an imitation of, or is a substitute for, another drug or resembles another drug in a manner likely to deceive or bears upon it or upon its label or container the name of another drug unless it is plainly and conspicuously marked so as to reveal its true character and its lack of identity with such other drug; or*
b) *if the label or container bears the name of an individual or company purporting to be the manufacturer of the drug, which individual or company is fictitious or does not exist; or*
c) *if it has been substituted wholly or in part by another drug or substance; or*
d) *if it purports to be the product of a manufacturer of whom it is not truly a product.*

On 18.01.2022, the Drugs Rules, 1945 were amended vide G.S.R. 20 (E) providing that every Active Pharmaceutical Ingredient (bulk drug) manufactured or imported in India shall bear Quick Response Code on its label at each level of packaging that store data or information readable with software application to facilitate tracking and tracing. The stored data or information shall include the minimum particulars including Unique product identification code, Batch No, MFG date, Exp. Date etc. These rules have already been effective from 01.01.2023.

On 17-11-2022, the Drugs Rules, 1945 were amended vide G.S.R. 823(E) providing that the manufacturers of Top 300 brands of drug formulation products, as specified in Schedule H2, shall print or affix Bar Code or Quick Response Code on its primary packaging label or, in case of inadequate space in primary package label, on the secondary package label that store data or information legible with software application to facilitate authentication. These rules have already been effective from 01.08.2023. The list of Top 300 brands of drug formulation products, as specified in Schedule H2 is enclosed as G.S.R. 823(E)

The process flow for verifying the authenticity of the Drugs by reading the Bar Code or Quick Response Code is annexed below.

Process flow for verifying the authenticity of the Drugs by reading the Bar Code or Quick Response Code

Step 1

Check the primary/secondary label of the Drug for Bar Code/Quick Response Code

Step 2

Scan the Bar Code/Quick Response Code with the Mobile Phone

Step 3

Read the information received on mobile after scanning QR for product authenticity/genuineness.