RELEASE NOTE

Present release of the application is the Beta Version and it is limited to the manufactures and their products who have participated with their data for the launching of the application. The verification of the authenticity of the drugs at Primary, Secondary and Tertiary level of packaging is restricted to the data provided by these manufacturers.

Frequently Asked Questions

Q1. Who is the Manufacturer?

Answer: Manufacturer means the manufacturer of drug formulations OR exporter having drug formulations manufactured on its behalf.

Q2. Who will be responsible for uploading the data on Central Portal?

Answer: The responsibility of the correctness, completeness and ensuring timely upload of data on the central portal shall be with the manufacturer

However, the manufacturer may extend the responsibility to anyone next to it in its supply chain i.e. Wholesalers/ Distributers/ Retailers etc. in its supply chain.

Q3. What are the pre-requisites for the manufacturer for uploading the data on the Central Portal?

Answer: Followings are the pre-requisites:

(i) The manufacturer must have manufacturer code and product code allotted by GS1 India.

(ii) The manufacturer must have Digital Signature Certificate of Class –II or Class-III issued by any Certifying Authority (CA) in India.

Q4. What is a Digital Signature Certificate?

Answer: Digital Signature Certificate (DSC) is the digital equivalent (i.e. electronic format) of physical or paper certificates. It contains the digital signature of the certificate issuing authority and the public key to identify and verify a particular person or entity. Digital Signatures are legally admissible in the Court of Law, as provided under the provisions of IT –Act 2000.

Q5. How and from where the DSC can be obtained?

Answer: A licensed Certifying Authority (CA) issues the digital signature. There are several Certifying Authority (CA) licensed by Controller of Certifying Authority (CCA) to issue a digital signature certificate under Section 24 of the Indian IT-Act 2000.

The list of the licensed Certifying Authorities in India is as follows:

(i) Safescrypt (www.safescrypt.com)
(ii) NIC (nicca.nic.in)

(iii) IDRBT (www.idrbtca.org.in)
(iv) TCS (www.tcs-ca.tcs.co.in)
(v) GNFC (www.ncodesolutions.com)
(vi) e-MudhraCA (www.e-Mudhra.com)

Q6. Why DSC is required?

Answer: The manufacturer is required to have DSC for confirming its identity and ensuring security of data being uploaded on the Central Portal.

Q7. What are the various levels of packaging for drugs in its supply chain?

Answer:***Primary packaging*** means the package which is in direct physical contact with the drug. ***Secondary packaging*** means the carton containing one or more primary packs or mono carton. A ***mono carton*** means a carton which contains only one primary pack. The ***tertiary packaging*** means a shipper containing one or more secondary packs.

Q8. How the data is required to be maintained by the manufacturer for various level of packaging?

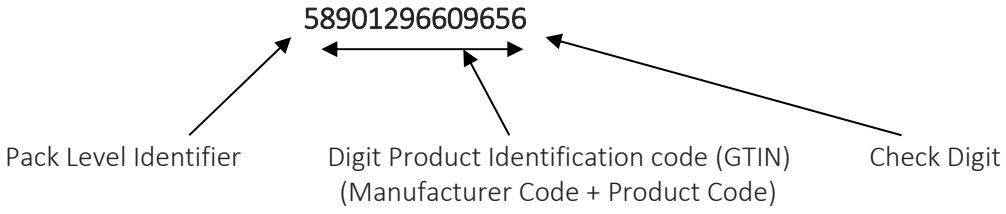
Answer:The manufacturer shall maintain the data in the parent-child relationship for three level of packaging i.e. Primary, Secondary and Tertiary packaging and their movement in its supply chain. However, maintenance of parent-child relationship between primary and secondary packaging is optional.

Q9. What is the 'Parent child relationship' for maintaining the data?

Answer:Parent Child relationship means the relationship of the data between all three levels of packaging with Tertiary as parent to Secondary(ies) and Secondary as parent to Primary(ies) packs. This would ensure to have the details of secondary(ies) within a Tertiary pack and details of Primary(ies) within a Secondary pack.

Q10. What is GTIN?

Answer:GTIN is the Global Trade Identification Number as per GS1 Global Standards. The 14 digit GTIN is being used in the DAVA system. The first digit of the GTIM indicated the level of packaging (0- for Primary, 1,2,&3 for Secondary and 5 for Tertiary), next 12 digits indicated the Manufacturer code and Product Code provided by GS1 India and the last digit is the check digit. E.g.



Q11. What is SSCC?

Answer:Serial Shipping Container Code (SSCC) is the unique 18digit code to identify any tertiary pack as a logistic unit i.e. a container for shipment.

Q12. Which guidelines need to be followed by the exporter in case the buyer from the importing country has specific requirements as per its country's regulation?

Answer: As per the DGFT notification no. 13/2015-2020 dated 22.05.2015, for the drug formulations manufactured for export purposes, the guidelines for barcoding would not be applicable if the government of the importing country has mandated or formally notified its intention to mandate a specific requirement and the exporter intends to avail the option of printing the barcodes in their format after duly obtaining the permission of DCGI or its nominee. However, the tertiary level of packaging will have additional printing of barcode as per DGFT guidelines in addition to importing country's requirement, if any.

Q13. Does the current system cover drug formulations for both export and domestic market?

Answer: Yes. Presently system covers the drugs formulation for exports. However, it is capable for the domestic market also once the requisite regulatory framework is notified by the regulatory agencies like DGCI, Ministry of Health and Family Welfare and the data is uploaded by the manufacturer on the Central Portal accordingly.

Q14. Can a customer verify his drug with mobile or laptop?

Answer: Yes, provided the data up to primary level is uploaded by the manufacturer on the Central portal.

Q15. Is it mandatory for manufacturer to upload the data on the Central portal?

Answer: Yes. As per the DGFT notification no. 13/2015-2020 dated 22.05.2015, the data shall be uploaded on the central portal of the Government of India by the manufacturer or exporter or its designated agency before release of the drug formulations for sale or distribution.

Q16. If the manufacturer wants to upload data of drugs for domestic supply?

Answer: Yes. The manufacturers willing to upload the data for domestic supply are welcomed to do so. Query facility for such data will be available through website/ mobile application.

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