Serialization Requirements in Russia – Product Master Data

As per Annex No. 2 of Government Decree 1556 of December 14, 2018

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Master Data

- Art. 33 of Decree 1556* says
  - At description of drug products, information shall be entered in the information resource which ensures accounting and storage of reliable data on the goods according to the corresponding nomenclature of goods, and in the monitoring system by the following subjects of medicines circulation:

    (...)

    in the case of drug products **manufacture outside the Russian Federation** (foreign manufacture), by the **marketing authorization holders** or owners and (or) by their **Russian representative offices** or **authorized representatives**.

    The list of information to be supplied by the subjects of medicines circulation at description of drug products to the information resource which ensures accounting and storage of reliable data on the goods according to the corresponding nomenclature of goods, is specified in Annex No. 2.

- Annex II specifies the
  - "**List of Information** to be Supplied by the Subjects of Medicines Circulation at **Description of Drug Products for Human Use** to the Information Resource Which Ensures Accounting and Storage of Reliable Data on the Goods According to the Corresponding Nomenclature of Goods"

* DECREE No. 1556 of December 14, 2018

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Master Data as per Annex 2*

- Trade name of the drug product for human use (hereinafter the drug product).
- Brand (trademark).
- Number of the marketing authorization.
- Date of state registration of drug product.
- Name of the marketing authorization holder or owner.
- Address of the marketing authorization holder or owner.
- International non-proprietary name of drug product.
- Dosage form.
- Quantity of dosage measuring units of drug product
- Type of secondary (consumer) package of drug product (in the absence thereof, primary package of drug product).
- Material of secondary (consumer) package of drug product (in the absence thereof, primary package of drug product).
- Quantity (measure) of drug product in secondary (consumer) package of drug product (in the absence thereof, in primary package of drug product).
- Existence of an unlabeled primary package of drug product inside secondary (consumer) package of drug product (in case of secondary (consumer) package of drug product).
- Description of unlabeled primary package of drug product inside secondary (consumer) package of drug product.
- Name of filler (packer) (to be filled in if filling (packaging) takes place in the Russian Federation).
- Address of filler (packer) into secondary (consumer) package of drug product (in the absence thereof, into primary package of drug product) (to be filled in if filling (packaging) takes place in the Russian Federation).

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