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ANSM requests medical device manufacturers who send out a field safety notice to place upon it the barcode of the involved devices

BON USAGE - RECOMMANDATIONS

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Consultations carried out by the ANSM with pharmacists who distribute or use medical devices or in vitro diagnostic medical devices show that most of the field safety notices they receive (FSN) do not enable to easily identify the involved devices, leading to a risk of reducing the effectiveness of the corrective measures.

In order to facilitate the identification of the devices involved by a field safety corrective action, we recommend that manufacturers specify the following data, directly in the field safety notice (FSN or appendix or web link that can be consulted directly):

- **Carriers used for the automatic identification and data capture** (barcodes or matrix bare codes) of the targeted medical devices, in particular those already possessing a UDI (unique device identification), in the computerized stock management.
- The **types of final recipients** in the supply chain, to the knowledge of the manufacturer: community pharmacies, hospital pharmacies, medical biology analysis laboratories, city care structures, large and medium-sized supermarkets, home healthcare providers...
- The **exhaustive list of references and batches or serial numbers targeted** by the field safety corrective measure (unless all are targeted).

Reminders on European regulations

According to Articles 87 and 89 of Regulation (EU) 2017/745 on medical devices and Articles 82 and 84 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices, in case of field safety corrective action with respect to a device, the manufacturer shall ensure that the information is brought to the attention of users of the device without delay by means of a field safety notice. This notice shall allow the correct identification of the device(s) involved, in particular by including, on the one hand, the relevant UDIs and, on the other hand, all the actions to be taken by users.

Moreover, pursuant to Article 27 and Part C of Annex VI to the Regulation (EU) 2017/745, and Article 24 and Part C of Annex VI to Regulation (EU) 2017/746, cited above, the UDI, which shall allow the identification and facilitates the traceability of the devices, shall be placed on the label of the device and on all the higher packaging levels.

In addition to the UDI, clearly placed on the label, there are for example one-dimensional or linear barcodes, two-dimensional or matrix barcodes, RFID identifiers. These technologies, which enable the automatic capture of data, are called “AIDC” (automatic identification and data capture), and are used notably for the computerized stock management of devices.