SEP. 22

INFORMATIVE NOTE

HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

Medicines without a national Marketing Authorisation

Acquisition of intended exclusively for the production of parenteral bags

INFARMED - the Portuguese National Authority for Medicines and Healthcare Products ("**Infarmed**") has recently adopted Decision 089/CD/2022, concerning the regulatory framework for the acquisition of medicines without a national Marketing Authorisation ("**MA**"), intended exclusively for the production of parenteral bags.

This regulatory framework follows the need of holders of a manufacturing authorisation for medicinal products to acquire, within the European Economic Area ("EEA"), medicinal products without a national Marketing Authorisation ("MA"), solely and exclusively for the production of parenteral bags.

This regulatory framework follows the need of holders of a manufacturing authorisation for medicinal products to acquire, within the EEA, medicinal products without a national MA, solely and exclusively for the production of parenteral bags.

The possibility to buy medicinal products without a national MA is **subject to the following requirements**:

- The production of parenteral bags can only be carried out in the facilities already authorised for the manufacture of medicines, and **there can be no subcontracting** in this respect;
- Medicines without a national MA must be stored in the warehouses of raw materials for the production of parenteral bags of the MA holders in a **segregated, controlled, and restricted-access area**.
- A **record of the destruction of medicines** without a national MA purchased in the EEA and not used due to the expiry date or because they have been rejected must be sent to Infarmed on an annual basis.

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- In the production of these parenteral bags, it is not possible to use medicines without the qualification process for medicine suppliers having been concluded.

- The report on the qualification process of suppliers of medicines without a national MA acquired in the EEA used must be available at the production facilities of batches of parenteral bags in order to be made available to Infarmed for inspections.

- A detailed report must be sent to Infarmed every six months, containing the following information:

  i) Name of the medicinal products without a national MA acquired, batch, expiry date, quantity, and supplier;

  ii) Quantity of medicinal products used without a national MA, identifying the final product in which they were used, prescription number and respective requesting and receiving hospital;

  iii) Quantity used of medicinal products without national MA in the Quality Control Laboratory, in laboratory analysis, and the quantity stored for retention samples on its premises;

  iv) Quantity remaining of medicinal products without a national MA at the end of each production batch and stored in the raw materials' warehouse;

  v) The rejected quantity of the medicinal products without a national MA that have been acquired.

The obligations concerning communications to INFARMED must be performed by email to bolsas-parentericas@infarmed.pt.

This Decision came into effect on 24 August 2022. ■