Ensuring availability

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Securing the supply of medicines of major therapeutic value

ANSM focuses on ensuring the availability of “essential” medicines, referred to as “medicines of major therapeutic value”, or those whose unavailability would pose a public health risk.

It assesses, approves, and, if necessary, coordinates the actions that pharmaceutical companies must take to secure patients’ access to these medicines. Pharmaceutical companies are responsible for ensuring the availability of the medicines they bring to market.

Find out more:

Securing the supply of medical devices and in vitro diagnostic medical devices (MDs and IVDMDs) deemed to be essential

ANSM ensures the availability of medical devices and in vitro diagnostic medical devices deemed to be essential, i.e. those for which a lack of supply could have an impact on patient care.

To date, there is no legislation framing the lack of available of these health products in France. Tensions and shortages may arise, for example, from manufacturing problems, a lack of starting material supplies, or issues in the distribution chain.

In order to pre-empt them and thus prevent an impact on patient care, ANSM has implemented a specific framework for France, stipulating that market operators must manage these shortage or potential shortage situations.

In this way, methods for managing these situations have been developed, so that awareness of a shortage or potential shortage liable to severely impact patient care, is handled pre-emptively and notified to ANSM.

Managing quality defects

ANSM processes and assesses all reports of medicine quality defects that it receives from pharmaceutical laboratories. These quality defects can occur during the manufacture of medicines and/or active substances.

Solutions are formulated in response to each report, according to different criteria and always taking account of the associated patient risk.

Several measures may be implemented:

- Batch Recall: in cases such as stability defects, cross-contamination or non-compliance with product specifications. Batch recalls are then carried out by the laboratory, in consultation with ANSM.
- Quarantine: when batches not yet distributed are affected by a quality defect, a quarantine procedure may be requested pending the results of the investigations.
- Alerts to potential users: if necessary, ANSM can issue an alert to patients and healthcare professionals.
- “Rapid Alerts”: the ANSM may issue Rapid Alerts about quality defects to inform the competent authorities in other countries.