



PRESS RELEASE

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Medicine shortages: Leem's 6-point action plan to prevent and better manage high-risk situations

On Tuesday, February 19, Leem put forward an action plan to reduce disruptions in the supply of the most essential medicines to patients. This action plan is consistent with the recommendations of the French Senate's Fact-Finding Mission on Medicine and Vaccine Shortages, the outcome of which was delivered on 2 October 2018. The plan was developed in conjunction with the pharmaceutical companies and covers all stakeholders in the supply chain. It is broken down into 6 operational priorities.

In common with all stakeholders (patient associations, healthcare professionals and health authorities), LEEM - the French Pharmaceutical Companies Association - is acutely concerned about pressures placed on the supply chain that may lead to supply shortages. It has become an increasingly widespread issue in recent years due to the growing complexity of the production chain, technology, oversight and regulatory requirements. External factors such as manufacturing capacity unable to meet increasing global demand and problems with the supply of active ingredients also play a role. Thus, the number of notifications to ANSM of actual or potential stock-outs of high therapeutic value medicines (MITM) rose from 400 per year between 2014 and 2016 to 538 in 2017. Supply shortages are a multi-causal worldwide phenomenon and as such are a public health issue that concerns all stakeholders in the medicine supply chain, from manufacturers (pharmaceutical companies) to dispensers (dispensing chemists), and including distributors. It is the patient however who is always first to be impacted.

A mobilisation plan long in the making

The pharmaceutical companies have been mobilising resources for years in an effort to reduce supply disruptions. They have introduced tighter stock monitoring measures to anticipate the risks of supply shortages. They are working actively with ANSM (French National Agency for Medicines and Health Products Safety) to provide healthcare professionals with information on low stock levels and offer patients alternative solutions. They have produced shortage management plans for high therapeutic value medicines (MITM) and have set up emergency call centres where professionals can be reached.

In the specific case of vaccine shortages, manufacturers have pledged to provide monthly real-time status updates on available vaccine stocks containing the required valency in real-time in the event of supply difficulties and to provide health authorities with details of shortage management plans for all vaccines in the vaccination schedule, as provided for by the Law of 26 January 2016 on the modernisation of the French healthcare system. Vaccine manufacturers are committed to investing in Europe to reduce production times and increase vaccine production capacity.

A shared action plan

Leem is now seeking to engage with the public authorities to put forward an action plan shared with all stakeholders that aims to reduce disruptions in the supply of the most essential medicines to patients. These proposals were made in conjunction with the work undertaken in preparation of the measures introduced by the Strategic Council for the Healthcare Industries (CSIS) on supply shortages of cancer drug therapies.

This work has additionally helped the companies put their position across clearly to the French Senate Committee on the prevention of supply shortages, which delivered its findings on 2 October 2018.

This action plan is focused on the following main areas:

- 1. Defining which medicines are of strategic importance to health (MISS) and require heightened security measures;**
- 2. Reviewing hospital tendering systems for medicines of strategic importance to health (MISS) and the economic conditions for their use in non-hospital settings;**
- 3. Encouraging the location in Europe of facilities for the manufacture of active raw materials and of medicines of strategic importance to health;**
- 4. Optimising information sharing among stakeholders in the medicine supply chain and with patients;**
- 5. Adapting the regulatory framework governing distribution in the event of supply pressures or shortages;**
- 6. Strengthening strategic management nationally and promoting the harmonisation of regulatory practices at European level.**

*"Preventing supply shortages is a matter of top priority, responsibility for which lies with our companies but equally with all stakeholders in the supply chain. The aim of this Action Plan is to involve all stakeholders in the medicine supply chain, according to **Philippe Lamoureux, Director General of Leem**. We have a duty to reassure patients and to make every effort to ensure that medicines are made available as quickly as possible. "*

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