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Medicinal products shortages

This issue has been in the spotlight for many years and is making a major comeback in national and European legal and regulatory news.

France

The draft decree implementing the Law on the Financing of Social Security (LFSS) for 2024 will enable the implementation of measures to combat medicinal products shortages. It addesses the security of supply of medicines of major therapeutic interest (MMTIs) and covers three aspects.

Officinal special formulae

The first aspect relates to the conditions under which the Minister of Health may authorise, by order, on an exceptional and temporary basis, the production of the special officinal formulae now provided for in 3° of article L. 5121-1 of the Public Health Code.

The purpose of this authorisation is to deal with stock shortages or the discontinuation of marketing of an MMTI by the MA holder, or to deal with a serious public health threat or crisis.

For the record, Article L. 5121-1 3° provides that these special officinal formulae may be made by pharmacies holding the authorisation referred to in the second paragraph of Article L. 5125-1-1, on their own behalf or on behalf of another pharmacy.

These formulae comply with the following requirements:

a) they must be subject to medical prescription;

b) they must be prepared in accordance with a monograph published by the ANSM;

c) they must be prepared from a raw material for pharmaceutical use supplied by the pharmacy pharmaceutical facility of a public healthcare establishment authorised by the ANSM. To date, only the AP-HP (Assistance Publique–Hôpitaux de Paris, i.e. the regroupment of all public hospitals of Paris and suburbs) hold such authorisation.

Thus, the production of these special pharmaceutical formulae is strictly regulated. This should ensure the provision of high-quality treatments to patients and limit opportunities for pharmacies to compete with the MA holders of the affected medicines, unlike the situation that developed in the United States with certain GLP-1 agonists.

In August 2022, the FDA declared a supply shortage of semaglutide, thereby allowing "*compounders*" (pharmacy chains and "*telehealth*" services) to compete with the MA holder by offering patients low-cost versions of this molecule. The revenues generated, and in some cases their market capitalisations, were such that they challenged the FDA's decision to declare the end of the shortage in February 2025.

Types of Public Health Surveillance Measures

The second part of the draft decree defines the types of public health surveillance measures that may be taken by the ANSM to ensure appropriate and continuous supply by MA holders and operators to meet patient needs.

These measures relate to adapting distribution, importing alternative medicinal products, or any other equivalent action, along with their implementation timelines and the procedures for lifting the measures.

Obligation to find a buyer or grant a licence

Finally, the draft decree sets out the terms and conditions for implementing the obligation to find a buyer or grant a licence.

With regard to the declaration of suspension or cessation of marketing of a MMTI provided for by law (article L. 5124-6-II), the draft refers to guidelines defined by decision of the Director General of the ANSM. It specifies that these guidelines must address the foreseeable impact on patients of the suspension or cessation of marketing, as well as the therapeutic alternatives available on the market.

Although the legislator intended this measure to apply to mature medicinal products, the draft decree does not specify how the condition relating to protection under intellectual or industrial property rights is to be applied. It is up to the Director General of the ANSM to assess the conditions of application of the obligation to find a buyer and, consequently, to inform the marketing authorisation holder. This lack of precision is likely to give rise to difficulties in the application of the obligation incumbent on marketing authorisation holders, given the situation of the medicinal product concerned with regard to protection under intellectual or industrial property rights.

They will have the option of submitting their observations to the ANSM once the latter has set the date for implementation of the obligation, but the relevance and effectiveness of this mechanism is questionable.

When it comes to finding a buyer, the law leaves it up to the MA holder to grant a licence to operate the product or to transfer it. It must make its intention public on a dedicated web page on its website.

It must then examine each application individually and submit a report to the ANSM. If, within a period of one month from receipt of the report, the Agency considers that the need cannot be met on a permanent basis, it may ask the MA holder to grant a licence for the manufacture and use of the medicinal product to a pharmaceutical establishment owned by a legal entity governed by public law, which it designates.

In this situation, the MA holder is obliged to grant the right to operate and manufacture the product, without being able to grant the MA itself. This solution presents significant regulatory and legal risks for the MA holder. The draft decree also specifies that this concession '*has no impact on the obligations incumbent on the marketing authorisation holder* '.

In principle, the licence is limited to two years, but it may be '*tacitly renewed at the end of each two-year period in the absence of a decision to the contrary by the Director General of the Agency* '. It can only be terminated ' *if a company markets a medicinal product on the French market, the active ingredient of which is identical to that of the medicinal product that was the subject of the concession, under conditions that enable the need to be covered on a permanent basis'*.

On can measure how this situation could prove to be, at the very least, " *uncomfortable.*"

The issue of shortages is also at the forefront of the European stage.

European Union

The EMA has recently clarified its data access policy for the European Shortages Monitoring Platform (ESMP), established under Regulation 2022/123 concerning the enhanced role of the EMA in crisis preparedness and management related to medicines and medical devices. The ESMP became fully operational on 29 January 2025.

Data Access for the ESMP

The EMA has outlined the different levels of data access available to various stakeholders via the ESMP.

According to this categorization scheme:

- Stakeholders, including the general public, patients, consumers, and academia, will have Level 1 access.
- MA holders, their contractors, and suppliers will have Level 2 access.
- National competent authorities will have Level 3 access.
- The EMA and the European Commissioner will have the highest level of access to potentially sensitive information.

Meanwhile, the European Commission has recently released a regulatory proposal following extensive consultations with stakeholders. This proposal aims to complement the measures suggested in the revision of the pharmaceutical package to address vulnerabilities in the critical medicines supply chain and ensure the security of supply and availability of these medicines—the Critical Medicines Act (CMA).

Draft CMA

The scope of the proposed regulation primarily focuses on medicinal products listed as "*critical medicines*" within the Union, as established following the 2023 communication and updated a year later. It also introduces a new category, "*medicines of common interest,*" defined as "*a medicinal product, other than a critical medicine, for which, in three or more Member States, market functioning does not sufficiently guarantee availability and accessibility for patients in the quantities and presentations required to meet patient needs in those Member States.*"

Whilst the first category is already well-defined, the second may prove more challenging to delineate and is likely to evolve over time, potentially creating uncertainty for the companies involved. This categorisation will have implications, particularly for selection procedures in public procurement processes.

The proposal establishes a framework to encourage and facilitate investments in production capacities for critical medicines, their active substances, and other key inputs within the Union. Strategic projects may benefit from administrative support and priority treatment for obtaining regulatory approvals.

Member States will be authorised to provide financial support for these projects. In return, beneficiaries will be required to prioritise supplying the European market and make their best efforts to ensure that critical medicines remain available in the Member States where their products are authorised. Moreover, the Member State providing financial support for the project may request the beneficiary to supply the quantities of medicine, active substance, or other inputs necessary to prevent shortages in one or more Member States.

The draft regulation aims to mitigate the risk of supply disruptions and strengthen availability by leveraging national or European public procurement procedures. For critical medicines, Member States will need to adopt additional criteria beyond price, such as stockpiling obligations or diversification of supply chains. Furthermore, for critical medicines where supply chain vulnerabilities have been identified due to a high dependency on a single third country or a limited number of third countries, contracting authorities may apply criteria favouring suppliers who manufacture a significant portion of these critical medicines within the Union.

For other medicines of common interest, contracting authorities could favour candidates manufacturing a significant proportion within the Union.
The regulation also provides for leveraging aggregated demand from participating Member States through collaborative procurement procedures.

Finally, the objective is to support the diversification of supply chains, notably by facilitating the conclusion of strategic partnerships by the Commission.