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The Security of Healthcare Product Supplies

Executive summary

2022 Annual Public Report

As a result of the pandemic, France, like its neighbours, experienced a sudden increase in demand for certain healthcare products, in particular, medicines used in intensive care units (curares, hypnotics), as well as protective masks (surgical and FFP2). Traditional supply chains struggled to respond, leading to some critical situations. Exceptional measures, the effectiveness of which remains to be seen, had to be implemented to deal with the difficulties arising from these shortages.

A problem brought to the fore by the health crisis

Tensions in supply chains brought on by the health crisis have only compounded existing, older ones, particularly those affecting medicines. However, their magnitude remains difficult to quantify. Indeed, even if the number of alerts of medicine stock shortages – or risks of shortages –, about which the pharmaceutical industry must inform the government, has increased sharply in recent years, the monitoring of this indicator is insufficient to grasp the actual evolution of supply chain tensions. Medical devices are not subject to any long-term monitoring.

In the event of a shortage, patients or prescribers sometimes have to resort to alternative products, where available. These substitutions expose people to potential for error, in particular when the packaging is different from that of the products usually administered. However, no national study has yet made it possible to assess the extent of these risks.

Shortages are largely rooted in the transformation of medicine production methods. Manufacturing supply chains have become globalised and have tended to fragment between multiple stages of production, which all rely on a number of different suppliers or subcontractors, which may be limited. As the Covid-19 pandemic reminded us, this results in significant vulnerabilities, which can affect supplies of healthcare products.

Distribution of production sites for active ingredients in the medicinal products sold in the European Economic Area

Asia: Europe's main supplier

Number of production sites for active ingredients in medicinal products sold in the European Economic Area (EEA)

Source: Le Figaro from EudraGDMP (European Union database on manufacturing authorisations and certificates of good manufacturing practice for medicinal products)

Public efforts and their as yet unproven effectiveness

Faced with these difficulties, two major series of measures have been put in place, the effectiveness of which cannot yet be assessed. On the one hand, the legislation has evolved towards strengthening the obligations of manufacturers, so as to better prevent shortages occurring in the first place. Since the law of 26 January 2016 on modernising our health system came into force, they have an obligation to outline shortage management plans, the purpose of which is to analyse the main risks likely to affect the production of medicinal products and to provide for specific measures to remedy them. However, these plans were not up to the task, which led to them being strengthened in 2020. Manufacturers are now required to plan for minimum stock buffers. The Ministry of Solidarity and Health and the National Agency for the Safety of Medicines and Health Products (ANSM) will, however, have to monitor compliance.

On the other hand, following the health crisis, efforts falling within the scope of industrial policies have been undertaken in order to reduce the vulnerabilities of the country's manufacturing base. Numerous and diverse calls for projects aimed at relocating healthcare product manufacturing plants have been launched, at the risk, however, of a scattering effect. A targeting effort is therefore necessary, as well as better expression of these efforts with those promoted by the European Union.

Recommendations

The Court recommends:

1. exploiting the various sources of information available (ANSM declarations, *Dossier Pharmaceutique* shortage reports, etc.) to better objectify the evolution of medicine supply shortages *(Ministry of Solidarity and Health, ANSM, Cnop)*;

2. setting up a system for reporting information on supply chain disruptions affecting medical devices for which such an event would have serious consequences for patients *(Ministry of Solidarity and Health, ANSM)*;

3. specifying the definition of medicinal products of major therapeutic interest by giving ANSM the power to include medicinal products that would justify this status, even when not suggested by manufacturers (and, conversely, to exclude them) *(Ministry of Solidarity and Health, ANSM)*;

4. for the most essential medicinal products of major therapeutic interest, carrying out an in-depth analysis of the risks of shortages and putting in place the types of measures (strengthening stock security, price increases, industrial policy actions) that seem most appropriate for preventing supply chain tensions as best as possible, working, where necessary, on a European level *(Ministry of Solidarity and Health, Ministry of the Economy, Finance and Recovery, ANSM)*.