

Opinion of the French National Academy of Medicine on preparing for a major health or geopolitical crisis that could disrupt the national supply of healthcare products¹

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The subject concerns planning for the measures to be taken to ensure the supply of healthcare products in France in the event of a new health crisis or, given the current geopolitical tensions and instability, in the event of situation of international conflict that jeopardizes trade routes. Since the COVID crisis, a great deal of work has been carried out and various decisions have been taken, but the following points still need to be considered:

- The classification of medicines according to their 'criticality' based on a combination of their therapeutic essentiality and the risk of supply shortages or constraints
- Identifying in advance therapeutic alternatives for the most 'critical' medicines in the event of a shortage.
- Additional measures to be taken in the event of a shortage of 'critical' medicines or medical devices to encourage their use.
- Review of the coordination of the hospitals supply chain at national level.

1/ Drawing up the list of the most 'critical' medicines

An initial list of medicines (pharmaceutical products classified by Anatomical Therapeutic Chemical classification) designated as being of 'major therapeutic interest' has been drawn up by the "Agence Nationale de Sécurité du Médicament et des produits de santé" (ANSM), an agency for the safety of medication and Health products of the Health Ministry based on declarations from pharmaceutical companies, for which a two-month supply of stock is mandatory. However, these MITMs (more than 7,700, including generic medicines) are not classified based on recognized criteria of imperative therapeutic necessity.

Lists of medicines considered therapeutically 'essential' have been drawn up by the Direction Générale de la Santé (GDS, the public Health section of the ministry) and the European Medicines Agency. The DGS list was drawn up in collaboration with professional medical societies by assigning a score to each INN (International Nonproprietary Name) that reflects its therapeutic essentiality. However, its usefulness remains very limited, as this list covers only INNs and not the pharmaceutical products associated with a given INN (i.e. the various strengths, dosage forms and routes of administration).

Yet it is at the level of pharmaceutical products that shortages occur, particularly for injectable and pediatric forms. This DGS list of INNs must therefore be supplemented by a list of the pharmaceutical products (strengths, dosage forms) associated with each of these INNs.

The '**critical**' nature of a medicinal product or medical device stems from two factors: firstly, **its essential role in the treatment strategy** for a serious condition; and secondly, **a high risk of supply disruption or shortage**. It is the combination of these two factors that must be established for all medicinal products, by combining two scores for each medicine: one reflecting its therapeutic value (as proposed in the DGS list for INNs), the other reflecting the risk of a shortage (as proposed by the Giorgi report), which would make it possible to identify 'critical' medicines – that is, **those with the highest scores**, meaning those that are most

¹ Statement adopted by the Academy's Board of Directors

essential from a therapeutic perspective and most at risk of supply disruption. As recommended in the Giorgi IGAS report (1) on medicine shortages, this information should be collated in a database specifically designed for this purpose (rather than based on the unformatted PDF files submitted to the ANSM by manufacturers) and managed by ANSM and/or the Haute Autorité de Santé. The information provided by such a database, which could be queried in real time, would enable the “real time” identification of the actions required to ensure the supply of the most ‘critical’ medicines thus identified. Among these measures, consideration could be given to relocating industrial manufacturing (of either raw materials or finished products) at European level, or even at national level. The storage of the raw materials used in these products could also be considered alongside this relocation strategy, with the advance identification of facilities (in France or elsewhere in Europe) capable of processing them into medicines, such as contract manufacturers, hospital pharmacies and retail pharmacies.

It should be noted that no list of essential or ‘critical’ medical devices has been drawn up yet.

2 / Deciding on alternative treatments for these ‘most critical’ medicines

Therapeutic alternatives for the various indications covered by these ‘critical’ medicines – identified as **being of the greatest therapeutic importance and carrying a high industrial risk of supply disruption** – could be **established in advance** by the health agencies (ANSM, HAS) in close collaboration with the professional bodies for each medical specialty, under the auspices of the CNG (National Council for the Management of Hospital Practitioners and Senior Management Staff in the Public Hospital Service). This approach would enable doctors and pharmacists to be informed in advance of the available therapeutic alternatives for these critical medicines, the number of which is expected to be relatively limited.

The information currently provided by the ANSM on alternative treatments relates only to essential medicines facing supply constraints or shortages. Furthermore, it is incomplete and difficult to access.

Above all, the ANSM’s information does not cover the most critical medicines as defined above, in particular those at high risk of supply constraints or shortages. The ANSM’s information relates only to medicines currently experiencing shortages or supply constraints.

3/ Additional measures to be taken in anticipation of a crisis threatening the supply of the most ‘critical’ medicines and medical devices

- It seems appropriate to consider, in the event of a crisis, regulatory exemptions to allow the use of critical medicines beyond their recommended shelf life. Indeed, it appears that for most medicines, their quality is maintained well beyond their expiry dates. A European initiative could be launched to request that pharmaceutical companies carry out post-marketing authorization studies to refine the periods of use for their medicines.
- Similarly, in the event of a crisis, exemptions from the regulations could be considered to allow the reuse of certain single-use medical devices (which is currently prohibited in France).

4/ Medicines procurement and distribution channels

A review of the organization is currently underway within the Ministry of Health. The aim is to simplify the procedures followed by government departments and agencies (circular due by the end of 2025). In particular, the ordering and storage of 'critical' products are the primary focus. The Pharmaceutical Establishment for Health Reserves (formerly EPRUS, now part of Santé Publique France) will be transferred to a department with national remit within the Ministry of Health and attached to the DGS with the aim of shortening and streamlining the chain of command.

Recommendations

Given that, in the event of a major health crisis, epidemic, act of terrorism, war or border closure, France must be self-sufficient, the French National Academy of Medicine proposes that provision be made for:

- 1- The classification of medicines available on the French market by pharmaceutical specialty (and not solely by INN), in a dedicated database, using a dual scoring system based on therapeutic essentiality (referencing the score already established by learned societies and the DGS for INNs) and the risk of supply disruption (referencing the score proposed in the Giorgi report), enabling the most 'critical' medicines to be identified by combining these two scores.
- 2- The urgent identification of therapeutic alternatives for the most critical medicines (initially around a hundred at most), with information provided to prescribing physicians and pharmacists to enable a prompt adjustment of treatment in the event of a shortage.
- 3- The relocation, at European (or even national) level where necessary, of the manufacture of these critical medicines.
- 4- Where this proves feasible in practice and economically viable, consider stockpiling the raw materials used to produce these most critical medicines, while identifying in advance the establishments in Europe – and in particular in France – that are capable of manufacturing them into finished medicines (contract manufacturers, hospital pharmacies and retail pharmacies).
- 5- Putting in place regulatory exemptions required to extend the shelf life of the most critical medicines, as well as the reuse of certain single-use medical devices where possible.
- 6- A single, decision-making and executive command structure at the level of the DGS, exercising all or part of sovereign authority to oversee the procurement and supply of healthcare products for hospitals.

Reference

1; GIORGI D, de MAZANCOURT T, PICARD R (2021) Les vulnérabilités d'approvisionnement en produits de santé RAPPORT IGAS N°2021-058R / CGE N°2021/07/CGE/SG/MA