



HAUT-COMMISSARIAT  
AU PLAN

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FORESIGHT

n° 11  
9 février 2022

# MEDICINES AND MEDICAL DEVICES: IDENTIFYING OUR VULNERABILITIES TO PROMOTE OUR INDEPENDENCE



## MEDICINES AND MEDICAL DEVICES: IDENTIFYING OUR VULNERABILITIES TO PROMOTE OUR INDEPENDENCE

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Foreword by François Bayrou  
High Commissioner for Planning

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The COVID-19 health crisis was a brutal revelator for our country, for its public opinion and its leaders. The French, who saw France as a country that was often at the cutting edge, or at least universally recognised in the field of medicine and pharmacy, had to face **the spectre of shortages in essential products**, for example in the field of anaesthetics, anti-inflammatory drugs, anti-cancer treatments, and even something as banal as paracetamol. The French people realised that these molecules were now produced far from its territory and that it no longer had **control over their supply**. At the same time, medical devices, masks, gloves, injection equipment and respirators were also very close to running out while world demand was exploding. The difficulties in making vaccines available have also made us aware of the issues involved in medical research and the industrialisation of the innovations that result from it.

The issue is undoubtedly old: many reports, studies and public action plans have been proposed on the subject over the last two decades. **Measures to secure supply already exist. Two categories of products are currently concerned: on the one hand, strategic stocks are set up for products deemed necessary to respond to health emergencies. On the other hand, a vast group of "Medicines of major therapeutic interest" (MMTI)<sup>1</sup>**, several thousand of them, have recently been the subject of **special measures** by manufacturers: security stocks and definition of shortage management plans.

It is all the more significant that, **despite these reflections and measures, the COVID-19 pandemic has brutally revealed the extent of our vulnerabilities.**

This is why, as soon as the Haut-commissariat au Plan was set up, we wanted to find a strategy for the nation on this issue. In December 2020, we aimed at to *"launching a reflection and an action plan to overcome our dependence*

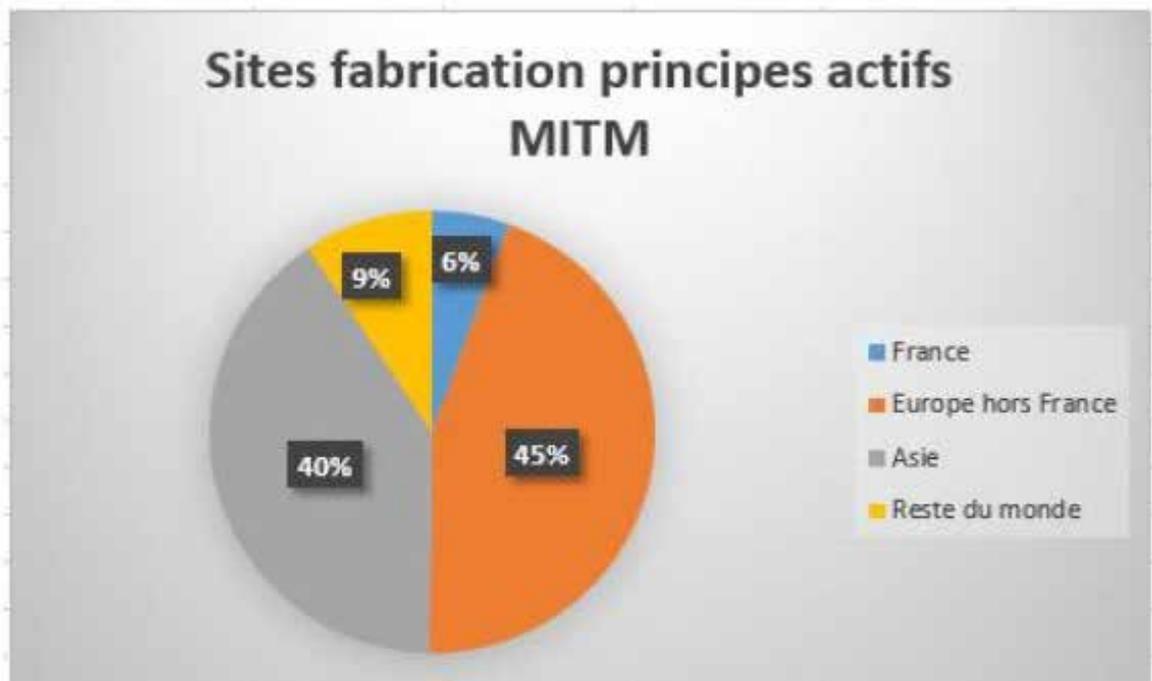
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<sup>1</sup> "Médicaments d'intérêt thérapeutique majeur" (MITM).

on vital products and to ensure the future of our strategic sectors"<sup>2</sup>. Pharmaceuticals and medical devices were included in these "strategic sectors", defined as the sectors that are "fundamental", "essential", "vital", "for the security of the country and its population".

However, this project first required the identification of the pharmaceutical products and medical devices that should be considered as "critical" and the examination of our dependence on foreign suppliers for these products.

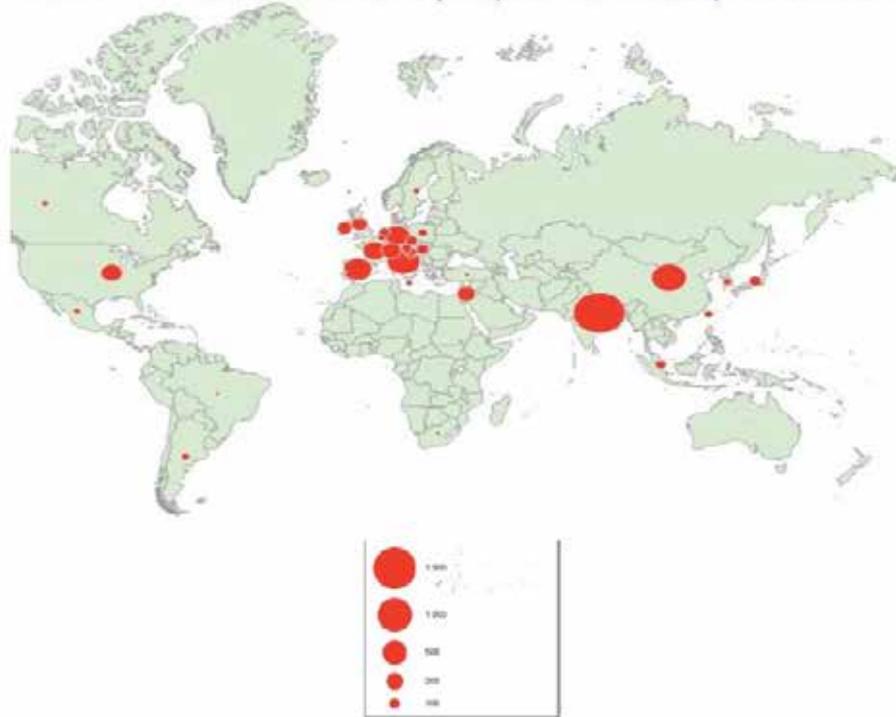
This was a major task. Of the 5,095 manufacturing sites for active medicinal ingredients listed by the French National Health Security Agency<sup>3</sup>, for 3,645 sites of MMTI production that were analysed, almost half are located outside the European Union: 6% are located in France, 45% in the "Europe outside France" zone, and 49% outside Europe (40% in Asia)



<sup>2</sup> Produits vitaux et secteurs stratégiques : comment garantir notre indépendance ?, Haut-Commissariat au Plan, Note d'ouverture n° 2, 18 décembre 2020 : <https://www.gouvernement.fr/produits-vitaux-et-secteurs-strategiques-comment-garantir-notre-independance>.

<sup>3</sup> Agence nationale de sécurité du médicament et des produits de santé (ANSM).

Carte 1 : Sites de fabrication de principe actif des MITM exploités en France



Source : "Health product supply vulnerabilities", Report, Support mission to the Haut-Commissariat au Plan, december 2021.

This awareness, from French and European public opinions, has already led to corrective actions that have been initiated. This must be emphasised.

At the national level, it has resulted in a series of measures taken in 2020 and 2021: **"calls for projects"**<sup>4</sup> and **"calls for expressions of interest"**<sup>5</sup> aiming at **increasing French industrial capabilities for health products** intended to combat COVID-19; **announcements made by the Strategic Council for the Health Industry**<sup>6</sup> regarding health independence.

Other initiatives have also been undertaken at the European level. In response to the crisis, the European Commission has recognised the need for European sovereignty in certain strategic areas, including health. In particular, at the end of 2020, the European Commission suggested to **strengthen policy coordination in the event of health crises within the European Union**, through a new regulation on serious cross-border health threats, as well as a revised mandate for the **European Centre for Disease Prevention and Control (ECDC)** and for the **European Medicines Agency (EMA)**. The Commission has also launched a **"structured dialogue"** (2021), with all stakeholders, to provide a **better understanding of supply chains**

<sup>4</sup> Appels à projet (AAP).

<sup>5</sup> Appels à manifestations d'intérêt (AMI).

<sup>6</sup> Conseil stratégique des Industrie de Santé (CSIS).

**and their vulnerabilities.** In parallel, on 16 September 2021, the Commission decided to create a **Health Emergency Preparedness and Response Authority** (HERA), based on the US model of the Biomedical Advanced Research and Development Authority (BARDA).

Nevertheless, the measures that were adopted, which tackle long-term challenges and deal with a general scope, because they concern several thousands of MMTI, might **need to be reinforced by targeted and rapid actions to define a plan to reduce the risk of shortages** and to deal with the most sensitive products as quickly as possible. Thus, **levels of vulnerability and priority should be more precisely defined.** If everything is considered a priority, nothing is really a priority.

Defining a simple and robust method for identifying the risks of shortages of the most crucial health products: this is the objective that the Haut-commissariat au Plan set in July 2021 to a *“Support mission”* composed of M<sup>r</sup> Dominique Giorgi, General Inspector of Social Affairs, M<sup>r</sup> Robert Picard and M<sup>r</sup> Thierry de Mazancourt, members of the General Council for Economy, Industry, Energy and Technology<sup>7</sup>. This Support mission was able to be set up with the support of the Ministry of Economic Affairs, Finance and Recovery and the Ministry for Solidarity and Health.

The issue is crucial: it is a question of **making a priority of a health independence policy without delay, by designating the medicines and medical devices which are in a particularly critical situation and for which the continuity of supply must be ensured.**

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<sup>7</sup> Conseil général de l'économie, de l'industrie, de l'énergie et des technologies.





## AN ORIGINAL METHOD FOR IDENTIFYING "CRITICAL" HEALTH PRODUCTS

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The Support mission's report offers an original and unprecedented method for identifying these particularly critical medicines and medical devices.

Thanks to the **data collection and data structuring** made by the French National Health Security Agency (ANSM) with the support of medicines manufacturers (these data were not previously used to identify our vulnerabilities but only to respond to the ANSM's missions), **the report suggests a method for identifying "critical" medicines, by cross-referencing two assessments in an unprecedented way: the "therapeutic criticality" of the products on the one hand and their "industrial criticality" on the other hand.**

- **"Therapeutic criticality"**: the major therapeutic interest and non-substitutable nature of certain drugs, as assessed directly by clinicians;

For the sake of speed and efficiency, the authors of the report called on a panel of recognised experts to assess a list of medicines of major therapeutic interest (a very broad category), specific to the sector under consideration. They were asked two questions:

- o Do you consider, regarding the nature of the disease or the damage, that the appropriate administering of this medicine is likely, in the short term, to guarantee the survival of the patient or that an absence of administering would represent a serious loss of chance for the patient?
- o In case of unavailability, in your experience, can this product be temporarily substituted by another one without possible consequences on the survival of the patient, or serious consequences on his prognosis?

**In other words, therapeutically critical drugs are those that are of major therapeutic interest and are not substitutable.**

> In order to demonstrate the operational nature of the proposed method, this analysis was effectively conducted for two classes of drugs, as will be explained below.

- **“Industrial criticality”**: the fragility of the production chains for these products. Evaluated with a “score” (ranging from 0 to 20), industrial criticality is determined by taking into account several criteria:
  - number of operators;
  - number of active ingredients production sites;
  - number of production sites for the finished product;
  - location of manufacturing and production.

Industrial criticality score

| Indicateur                                    | Criticité faible                       | Criticité moyenne                        | Criticité forte                       |
|---|--|--|---------------------------------------|
| Nombre de laboratoires exploitant/4           | Plus de 5 exploitants<br>4             | De 2 à 5 exploitants<br>2,5              | 1 seul exploitant<br>1                |
| Nombre de fournisseurs de principes actifs/5  | 4 sites de fabrication PA ou plus<br>5 | 2 ou 3 sites de fabrication de PA<br>2,5 | 1 seul site de fabrication de PA<br>1 |
| Part des sites de fabrication de PA hors UE/3 | Moins de 30 % de sites hors UE<br>3    | De 30 à 70 % hors UE<br>2                | Plus de 70 % hors UE<br>1             |
| Nombre de sites de production /5              | 4 sites de production ou plus<br>5     | 2 ou 3 sites de production<br>2,5        | 1 seul site de production<br>1        |
| Part de sites de production hors UE/3         | Moins de 30 % de sites hors UE<br>3    | De 30 à 70 % hors UE<br>2                | Plus de 70 % hors UE<br>1             |

Source : "Health product supply vulnerabilities", Report, Support mission to the Haut-Commissariat au Plan, december 2021.

The minimum industrial criticality is scored 20/20, the maximum criticality 5/20. By convention, products that obtain a score of 10/20 or less are considered to be at **high risk (red)**. Products that score 14/20 or higher are considered to be in a **satisfactory situation (green)**. Products with an intermediate score should be given **special attention (orange)**.

- > This new and practical matrix is the first operational tool that can be used to determine whether a therapeutically critical drug represents a point of industrial vulnerability for our country.

In order to test the robustness of this method, the identification exercise was completed for two therapeutic areas:

- Cardiology;
- Anaesthesia and intensive care.

### > Cardiology

23 products were recognised as not only of major therapeutic interest but also non-substitutable:

#### Critical drugs from a therapeutic point of view in cardiology

| Classes de produits       | Dénomination commune (DC) | Commentaires  |
|---------------------------|---------------------------|---|
| Béta bloquants            | Propranolol               | Traitement hyperthyroïdie, tremblements essentiels, migraines                                   |
|                           | Nadolol                   | Troubles du rythme ventriculaires de l'insuffisance cardiaque mettant en jeu le pronostic vital |
| Sartans                   | Valsartan                 | Deux sartans seuls substituables entre eux pour l'insuffisance cardiaque                        |
|                           | Candésartan               |   |
| Antagonistes calciques    | Verapamil                 |   |
| Anti arythmiques          | Flecainide                |   |
|                           | Amiodarone                | sur indications précises  |
| Diurétiques               | Spironolactone            | Deux produits seuls substituables entre eux   |
|                           | Eplérénone                |   |
|                           | Furosémide                | Deux produits seuls substituables entre eux   |
|                           | Bumétanide                |   |
|                           | Hydrochlorothiazide       |   |
| Catécholamines            | Adrénaline                | forme injectable  |
|                           | Dopamine                  | forme injectable  |
|                           | Noradrénaline             | forme injectable  |
| Inotropes positifs        | Dobutamine                | forme injectable  |
|                           | Lévosimendan              | forme injectable  |
|                           | Isoprénaline              | forme injectable  |
| Digitaliques              | Digoxine                  | forme injectable IV et cpr  |
| Dérivés nitrés            | Dinitrate d'isosorbide    | injectable intracoronaire pour traitement du spasme en salle de coronarographie                 |
| Association               | Valsartan/sacubitril      | insuffisance cardiaque  |
| Antiagregant plaquettaire | Aspirine                  | substituts présentant effets indésirables   |
| Anticoagulant             | Warfarine                 | porteur de prothèse valvulaire cardiaque, insuffisance rénale                                   |

Source : "Health product supply vulnerabilities", Report, Support mission to the Haut-Commissariat au Plan, december 2021.

These critical products from a therapeutic point of view were then assessed for their industrial criticality.

**Industrial criticality of therapeutically critical cardiology drugs**

|  | Bêta-bloquants |         | Sartans   |             | Association            | Antagonistes calciques |           |
|--|----------------|---------|-----------|-------------|------------------------|------------------------|-----------|
|  | Propranolol    | Nadolol | Valsartan | Candesartan | Valsartan / sacubitril | Diltiazem              | Vérapamil |
| Nombre d'exploitants                     | 2,5            | 1       | 4         | 4           | 1                      | 4                      | 4         |
| Nombre de sites de fabrication PA        | 5              | 1       | 5         | 5           | 2,5                    | 5                      | 5         |
| Localisation des sites de fabrication PA | 1              | 3       | 1         | 1           | 2,1                    | 2                      | 2         |
| Nombre de sites de production            | 5              | 1       | 5         | 5           | 2,5                    | 5                      | 5         |
| Localisation des sites de production     | 3              | 3       | 3         | 3           | 2                      | 3                      | 3         |
| SCORE DE CRITICITÉ                       | 16,5           | 9       | 18        | 18          | 10                     | 19                     | 19        |

|  | Antiarythmiques |            | Diurétiques    |            |            |      |            |
|--|-----------------|------------|----------------|------------|------------|------|------------|
|  | Flécaïnide      | Amiodarone | Spironolactone | Eplerenone | Furosémide | HCT  | Bumétanide |
| Nombre d'exploitants                     | 4               | 4          | 4              | 4          | 4          | 2,5  | 1          |
| Nombre de sites de fabrication PA        | 5               | 5          | 5              | 5          | 5          | 5    | 1          |
| Localisation des sites de fabrication PA | 2               | 2          | 2              | 1          | 2          | 2    | 3          |
| Nombre de sites de production            | 5               | 5          | 2,5            | 5          | 5          | 5    | 2,5        |
| Localisation des sites de production     | 3               | 3          | 3              | 2          | 3          | 3    | 3          |
| SCORE DE CRITICITÉ                       | 19              | 19         | 16,5           | 17         | 19         | 17,5 | 10,5       |

|  | Catécholamines |               |          | Dérivés nitrés         | Antiagrégant | Inotropes positifs |              |
|--|----------------|---------------|----------|------------------------|--------------|--------------------|--------------|
|  | Adrénaline     | Noradrénaline | Dopamine | Dinitrate d'isosorbide | Aspirine     | Isoprénaline       | Levosimandan |
| Nombre d'exploitants                     | 1              | 2,5           | 1        | 1                      | 4            | 1                  | 1            |
| Nombre de sites de fabrication PA        | 2,5            | 2,5           | 1        | 2,5                    | 2,5          | 1                  | 1            |
| Localisation des sites de fabrication PA | 2              | 2             | 3        | 3                      | 2            | 1                  | 3            |
| Nombre de sites de production            | 1              | 1             | 1        | 2,5                    | 4            | 1                  | 1            |
| Localisation des sites de production     | 1              | 3             | 3        | 3                      | 3            | 3                  | 3            |
| SCORE DE CRITICITÉ                       | 7,5            | 11            | 9        | 12                     | 15,5         | 7                  | 9            |

Source : "Health product supply vulnerabilities", Report, Support mission to the Haut-Commissariat au Plan, december 2021.

By approaching the criticality of medicines (therapeutic and industrial approach) using this method, we can conclude that **in cardiology the production chains of six products considered to be of major therapeutic interest and non-substitutable appear fragile**. Measures should be taken on these products as a priority to secure supplies in anticipation of tensed situation.

**> Anaesthesia and intensive care**

28 products in anaesthesia (use of products in the operating theatre) and 26 in intensive care, largely common to both fields, are considered to be of major therapeutic interest and non-substitutable:

Critical drugs from a therapeutical point of view in anaesthesia/  
intensive care

| Utilisation Bloc opératoire      |                                 |  |
|----------------------------------|---------------------------------|--|
| Classes de produits              | Dénomination commune (DCI)      | Commentaires                                 |
| <b>Hypnotique/sédation</b>       | Sévoflurane                     |  |
|                                  | Etomidate                       |  |
|                                  | Propofol                        | remplacement par Midazolam                   |
| <b>Morphiniques</b>              | Sufentanyl                      | remplacement par fentanyl                    |
| <b>Fluides et gaz médicaux</b>   | Oxygène                         |  |
| <b>Curares</b>                   | Atracurium                      | remplacement par cisatracurium               |
|                                  | Succinylcholine (Suxaméthonium) |  |
| <b>Antagonisation</b>            | Rocuronium                      | remplacement par atracurium                  |
|                                  | Protamine                       |  |
| <b>Catécholamines</b>            | Néostigmine                     |  |
|                                  | Noradrénaline                   | remplaçable par Adrénaline                   |
|                                  | Adrénaline                      | remplaçable par Noradrénaline+Dobutamine     |
|                                  | Dobutamine                      | remplaçable par Adrénaline                   |
|                                  | Atropine                        |  |
|                                  | Salbutamol                      |  |
| <b>Anticoagulation/antiagrég</b> | Isoprénaline                    | remplaçable par Adrénaline                   |
|                                  | Héparine non fractionnée        |  |
| <b>Antalgiques</b>               | Lidocaine                       |  |
|                                  | Ropivacaïne                     |  |
| <b>Autres</b>                    | Insuline                        |  |
|                                  | Méthylprednisolone              | remplaçable par Hemisuccinate hydrocortisone |
|                                  | Hemisuccinate hydrocortisone    | remplaçable par Méthylprednisolone           |
|                                  | Amiodarone                      |  |
|                                  | Oxytocine                       | indications en obstétrique                   |
|                                  | Sulprostone                     | indications en obstétrique                   |
| <b>Solutés de remplissage</b>    | Sérum salé isotonique           |  |
|                                  | Ringer Lactate                  |  |
|                                  | Bicarbonate de sodium           |  |

| Utilisation réanimation          |                              |  |
|----------------------------------|------------------------------|--|
| Classes de produits              | Dénomination commune (DCI)   | Commentaires                                 |
| <b>Hypnotique/sédation</b>       | Midazolam                    | remplacement par propofol                    |
|                                  | Propofol                     | remplacement par Midazolam                   |
| <b>Morphiniques</b>              | Sufentanyl                   | remplacement par fentanyl                    |
| <b>Fluides et gaz médicaux</b>   | Oxygène                      |  |
|                                  | Monoxyde d'azote             |  |
| <b>Curares</b>                   | Atracurium                   | remplacement par cisatracurium               |
| <b>Antagonisation</b>            | Protamine                    |  |
| <b>Catécholamines</b>            | Noradrénaline                | remplaçable par Adrénaline                   |
|                                  | Adrénaline                   | remplaçable par Noradrénaline+Dobutamine     |
|                                  | Dobutamine                   | remplaçable par Adrénaline                   |
|                                  | Atropine                     |  |
| <b>Anticoagulation/antiagrég</b> | Salbutamol                   |  |
|                                  | Isoprénaline                 | remplaçable par Adrénaline                   |
| <b>Autres</b>                    | Héparine non fractionnée     |  |
|                                  | Insuline                     |  |
| <b>Solutés de remplissage</b>    | Méthylprednisolone           | remplaçable par Hemisuccinate hydrocortisone |
|                                  | Hemisuccinate hydrocortisone | remplaçable par Méthylprednisolone           |
|                                  | Amiodarone                   |  |
|                                  | Furosemide                   |  |
|                                  | Lévétiracetam                |  |
|                                  | Phénytoïne                   |  |
|                                  | Sandostatine                 |  |
| <b>Solutés de remplissage</b>    | Acide zolédronique           |  |
|                                  | Sérum salé isotonique        |  |
|                                  | Ringer Lactate               |  |
|                                  | Bicarbonate de sodium        |  |

Source : "Health product supply vulnerabilities", Report, Support mission to the Haut-Commissariat au Plan, december 2021.

These therapeutically critical products were assessed for their industrial criticality:

**Industrial criticality of anaesthesia/intensive care therapeutically critical drugs**

|  | Curares    |            |               |            |               | Anesthésie générale          |          |              |            |           |          | Hypnotiques |           |         |                  | Gaz médicaux |            |             | Catécholamines |  | Antagonisation |
|--|------------|------------|---------------|------------|---------------|------------------------------|----------|--------------|------------|-----------|----------|-------------|-----------|---------|------------------|--------------|------------|-------------|----------------|--|----------------|
|  | Atracurium | Rocuronium | Cisatracurium | Mivacurium | Suxamethonium | Hydroxy-4 butyrate de sodium | Fentanyl | Rémifentanyl | Sufentanyl | Midazolam | Propofol | Fluranes    | Etomidate | Oxygène | Monoxyde d'azote | Atropine     | Salbutamol | Néostigmine |                |  |                |
| Nombre d'exploitants                     | 2,5        | 2,5        | 2,5           | 1          | 2,5           | 1                            | 1        | 2,5          | 1          | 2,5       | 2,5      | 1           | 2,5       | 1       | 2,5              | 1            | 4          | 1           |                |  |                |
| Nombre de sites de fabrication PA        | 1          | 5          | 2,5           | 1          | 2,5           | 1                            | 1        | 2,5          | 1          | 2,5       | 2,5      | 2,5         | 5         | 2,5     | 2,5              | 5            | 5          | 2,5         |                |  |                |
| Localisation des sites de fabrication PA | 3          | 2          | 2             | 3          | 1             | 3                            | 1        | 3            | 3          | 2         | 3        | 3           | 3         | 3       | 3                | 3            | 3          | 3           |                |  |                |
| Nombre de sites de production            | 2,5        | 5          | 2,5           | 1          | 2,5           | 1                            | 1        | 2,5          | 1          | 2,5       | 2,5      | 2,5         | 5         | 2,5     | 2,5              | 5            | 5          | 2,5         |                |  |                |
| Localisation des sites de production     | 3          | 3          | 3             | 3          | 3             | 3                            | 3        | 3            | 3          | 2         | 3        | 3           | 3         | 3       | 3                | 3            | 3          | 3           |                |  |                |
| SCORE DE CRITICITÉ                       | 12         | 17,5       | 12,5          | 9          | 11,5          | 9                            | 7        | 13,5         | 9          | 11,5      | 13,5     | 6,5         | 13,5      | 17      | 13,5             | 12           | 20         | 12          |                |  |                |

|  | Solutés               |                |      | Antalgiques |           | Anticoagulation |
|--|-----------------------|----------------|------|-------------|-----------|-----------------|
|  | Bicarbonate de sodium | Ringer lactate | NaCl | Ropivacaïne | Lidocaïne | HNF             |
| Nombre d'exploitants                     | 4                     | 4              | 4    | 1           | 2,5       | 2,5             |
| Nombre de sites de fabrication PA        | 5                     | 5              | 5    | 1           | 5         | 5               |
| Localisation des sites de fabrication PA | 3                     | 3              | 3    | 3           | 3         | 2               |
| Nombre de sites de production            | 5                     | 5              | 5    | 2,5         | 5         | 5               |
| Localisation des sites de production     | 3                     | 3              | 3    | 2           | 3         | 3               |
| SCORE DE CRITICITÉ                       | 20                    | 20             | 20   | 9,5         | 18,5      | 17,5            |

|  | Autres            |                                |           |               |           |                    |
|--|-------------------|--------------------------------|-----------|---------------|-----------|--------------------|
|  | Méthylpredisolone | Hémisuccinate d'hydrocortisone | Oxytocine | Lévétiracétam | Insulines | Acide zolétronique |
| Nombre d'exploitants                     | 2,5               | 1                              | 1         | 4             | 2,5       | 2,5                |
| Nombre de sites de fabrication PA        | 4                 | 1                              | 2,5       | 5             | 5         | 5                  |
| Localisation des sites de fabrication PA | 2                 | 3                              | 2,5       | 1             | 2         | 2                  |
| Nombre de sites de production            | 2,5               | 2,5                            | 1         | 5             | 5         | 5                  |
| Localisation des sites de production     | 3                 | 3                              | 3         | 2             | 2         | 3                  |
| SCORE DE CRITICITÉ                       | 14                | 10,5                           | 10        | 17            | 16,5      | 17,5               |

Source : "Health product supply vulnerabilities", Report, Support mission to the Haut-Commissariat au Plan, december 2021.

N.b. : The industrial criticality score for hydrocortisone hemisuccinate and oxytocin is red (not orange) because there is only one operator and either only one active ingredient manufacturing site or only one production plant.

Using the dual approach of the criticality of drugs (therapeutic and industrial approach), we can conclude that, **in anaesthesia/intensive care, the production chains of 8 products considered of major therapeutic interest and non-substitutable appear vulnerable.** Measures should be taken on these products as a priority to secure supplies in anticipation of a tensed situation.

**This unprecedented method and its application to two series of products show that it is possible to establish a map of our vulnerabilities as far as medicines are concerned.**

**The Haut-commissariat au Plan therefore invites the public authorities to take up this approach and to generalise it.**

The first lists of medicines considered as critical from a therapeutic point of view are based on consultations with experts; if they are to be completed, they will have to give rise to additional consultations, particularly with learned societies and patients associations. With regard to production chains, it will also be necessary to carry out a complete analysis of the vulnerabilities and responses for each critical product, for which only the manufacturers can provide an account.

In general terms, this approach should be extended to all therapeutic areas, in order to provide the public authorities with an exhaustive and precise vision of the therapeutic and industrial criticality of pharmaceutical products in all fields of medicines.

**The transposition to medical devices of the measures adopted for the medicinal product sector is more delicate. The possibility of drawing up a list of critical medical devices is not excluded, but no Member State in Europe has produced one.** However, the Support mission makes a practical suggestion, based on the identification of medical devices deemed essential in situations of health crisis and vulnerabilities in the value chains, but without being able to claim exhaustive analyses due to the lack of available data.

Finally, the authors of the report put forward **22 recommendations to reduce the risk of shortages of identified medicines.**



## THE REPORT'S 22 RECOMMENDATIONS

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The Support mission suggests a framework for action – adapted to the characteristics of the identified vulnerabilities - through 22 courses of action.

In addition to **consolidating measures for monitoring, strategic storage and production under public supervision of the critical products identified**, and **strengthening dialogue and cooperation with the sector's industries**, the Support mission stresses the **European dimension** and in particular the fact that some measures should be considered at a Union level as far as **regulations and industrial coordination are concerned**.

In general terms, the Support mission stresses the need for a **programme to rationalise the system for collecting and monitoring information on the supply of health products**, through, for instance, the **establishment of a global map of tools for managing stocks of medicines**.

Finally, the Support mission highlights the **need to ensure strong and sustainable interministerial governance to manage the problem of preventing and managing shortages of health products**. Public action to avoid shortages and to restore and maintain our health sovereignty at the highest level must mobilise many ministerial departments. No ministerial department or agency has so far appeared to the Mission to be able to ensure this action with the appropriate authority and resources.

The Mission therefore advocates **coordination of all ministerial stakeholders in health products policy**; three alternative organisational scenarios are envisaged to guarantee the sustainability of the objectives and resources allocated to the independent health policy.

The creation of an interministerial delegation for health independence, with simple means of impetus and coordination, does not seem capable of meeting the challenges highlighted in this report.

On the other hand, the creation of an *"Agency for Health Sovereignty"*<sup>8</sup>, the counterpart of the Agency for Innovation in Health (AIH)<sup>9</sup> the creation of

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<sup>8</sup> Agence de la souveraineté sanitaire.

<sup>9</sup> Agence de l'Innovation en Santé (AIS).

which was decided after the last Strategic Council for Health Industries<sup>10</sup>, or better still (to avoid adding a new administrative unit) the enlargement of the competences of the AIH, which would be renamed the Agency for Innovation and Health Sovereignty, with the task of identifying and dealing with supply vulnerabilities, appear to be appropriate solutions. They would also ensure coordination and synergies with the European agency HERA.

- > **Through this new approach and methodology, the Haut-commissariat au Plan intends to make a concrete contribution to the ambition that has been set: within the framework of the European strategy, the aim is to regain health independence, to commit France resolutely to a national policy adapted to the vulnerabilities identified.**

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<sup>10</sup> CSIS.



