



AVAILABILITY OF ALL MEDICINES

The National Academy of Pharmacy calls for a quick and strong response
In the interest of patients

Press release, October 26, 2022

The National Academy of Pharmacy is observing a constant increase in shortages of drugs and medical devices. In this context, it warns against the disastrous consequences that the French law known as LFSS 2023 could have on the increase in shortages of old and indispensable drugs.

Furthermore, it urges the public authorities to exempt, in the very short term, production sites, especially those producing injectable products, from possible coming electric power cuts. Such production stoppages (one-off or prolonged) would have immediate and long-term repercussions on the availability of all health products and on the quality of care.

The Academy once again¹ insists that, in addition to new drugs, some old drugs are still indispensable for patient care. These old drugs are often the only ones that can be used, especially as the first line of treatment, and sometimes have to be combined with new drugs within the same care pathway. However, the budget for reimbursable drugs is not increasing despite the aging of the population and the introduction of new, more expensive drugs, to the detriment of older drugs. In the event of a shortage, we know from experience that the substitution of one specialty by another in the same therapeutic class, particularly for generics, is not a sustainable solution (e.g., prednisolone, prednisone, major anti-emetics). Finally, in medico-economic terms, the disappearance of these old drugs would, in the best-case scenario, lead to their replacement by new ones that are much more expensive and increasingly difficult to finance from the social service budget.

The Academy regrets to note that, in the PLFSS 2023, the share of drugs in health expenditures would be 7% less than the expenditure recorded in 2022² (24.6 billion euros compared with 26.4 billion euros estimated in 2022) and that the level of price cuts announced remains very high (at least €800 million), which will continue to weigh on older drugs, not to mention the rebates to be paid by companies, including on these indispensable drugs, as well as the "safeguard clause". However, due to inflation, the drug and medical devices industry is experiencing a considerable increase in energy costs in addition to facing more specific difficulties in the supply of raw materials and components. The phenomenon concerns almost all the sector's supplies, with production costs having increased by 20% to 30% or even more in some cases.

The Academy is concerned about the inconsistency of these additional taxation projects, while in the preamble of the PLFSS 2023, it is emphasized that the health crisis has revealed the importance of preserving the supply capacity of the French market, especially for old drugs.

The Academy reminds that all drugs, regardless of their age, are subject to the same international standards of quality and conformity. These requirements are constantly becoming more stringent (especially for injectable products) and require permanent adaptation of the industrial tools and investments that is impossible for operators whose margins are being eroded, without counting the

costs resulting from the new regulations adopted in the interest of the patient (cost of inventories required by the state, serialization, additional studies regularly requested: ICHQ3D, nitrosamines, etc.).

After being forced for several years to reduce their margins due to regular price cuts and to rising costs, 71% of small and medium-sized pharmaceutical companies (SMEs) established in France are no longer marketing some of their medicines and are sometimes requesting the withdrawal of their marketing authorization (MA) of several of their products, to the detriment of national health security !³

The Academy anticipates an unprecedented increase in shortages in 2023, tensions and ruptures in stock, as well as discontinuations of marketing and withdrawal of authorizations, taking into account that the number of shortages went from 871 in 2018 to 3278 by September 30th 2022, an increase that was not solely due to the reinforced obligation to report shortages to the ANSM.

In this alarming context, it recommends:

- **Organizing a national conference on drug policy**, in association with the discussions underway on the same subject at the European level, to rethink the current system for setting the prices of old, indispensable drugs.
- **Urgently preventing reducing prices on the basis of therapeutic class**, as this method does not consider technical difficulties related to the galenic form (injectable drugs vs. tablets or oral solutions), nor the need to have forms/doses that are often produced in small quantities, at the limit of profitability, but essential for the treatment of specific populations of patients.
- **Revaluing the prices of indispensable old drugs**, especially injectables, which are not very expensive but costly in terms of production due to their constantly evolving technical nature.
- **Establishing, as a matter of urgency, a list of indispensable drugs** to give clear instructions to the French « Comité économique des produits de santé » (CEPS).
- **Similarly, exempting these medicines from the safeguard clause** and instead allowing them to benefit from a specific pricing regime.

The Academy is also very concerned about the absence of the pharmaceutical industry in the priorities of the government's energy sobriety plan⁴. It urges the public authorities to exempt the pharmaceutical industry in the very short term from possible future load shedding for drug production sites, especially those producing injectable medicines. Stopping the supply of electricity to these factories will inevitably stop the air treatment systems, the shutdown of the water loop... and will oblige them to discard batches, although these products are essential for public health needs.

1. https://www.acadpharm.org/dos_public/MEDICAMENTS_ANCIENS_INDISPENSABLES_2020.10.05_VF.PDF.
2. Health care spending is increasing annually by 2.5% (excluding the health crisis) while, at the same time, the share of drugs has fallen from 14% in 2010 to 11.1% in 2020.
3. Panorama conducted by D&C Consultants at the request of AMLIS (Association des Moyens Laboratoires et Industries de Santé, an Association representing small and medium-sized pharmaceutical companies)
4. The SME companies located in France employ 23,900 people on their production sites, which represents 50% of production jobs in the national pharmaceutical sector. Maintaining these plants is essential in terms of health sovereignty for our country, concerning these inexpensive drugs that are mainly targeted at everyday treatments, particularly for the most common chronic diseases.