

Pharmaceuticals: unpacking the news to set the record straight.

It is true that reports referring to ‘risks’ of disruptions in the supply of medicinal products have increased, but the same is not true of shortages themselves!

Earlier today, Leem became aware of a new campaign conducted by the French National League Against Cancer (La Ligue contre le Cancer) focusing on shortages of cancer treatment drugs. As a result, Leem would like to take this opportunity of correcting the facts and figures around this major public health issue.

Supply disruptions are a major concern for pharmaceutical companies. Where they do occur, the reasons are complex, and involve multiple links in the drug supply chain for which many different public-sector and private-sector stakeholders have responsibility. A process of dialogue between all these stakeholders - including pharmaceutical companies - has resulted in new rules, which are currently being introduced to reduce shortages and supply chain pressures. These changes will benefit everyone involved, but primarily patients. Pharmaceutical companies are committed to taking daily action as part of delivering continuous improvement in patient access to the therapeutic care they provide.

The increase in reports should not be confused with any increase in shortages

The fact that reports are becoming increasingly frequent reflects the reality that pharmaceutical companies are doing more to provide the ANSM (the French National Agency for Medicines and Health Products Safety) with advance notice of any risks or pressures in the supply chain.

The global Covid-19 pandemic has resulted in serious supply disruptions, so the number of reports in France has inevitably increased accordingly. In 2020, the ANSM received a total of 2,446 reports flagging up a risk of stock-outs, actual shortages or predicted difficulties in supplies of medicinal products of major therapeutic significance (MITMs), compared with 1,504 reports in 2019. But in reality, only **between 5% and 10% of these reports** required the ANSM to take **specific action to ensure the supplies to patients** (in the form of therapeutic alternatives, imports, restrictions on use, quotas, etc.), which equates to **between 120 and 240 of the medicinal products concerned out of a total of 15,000 distributed in France.**

These figures cover all therapeutic classes (anaesthetics, anticancer drugs, blood-derived products, etc.). In terms of anticancer drugs specifically, the ANSM has not seen any increase in the number of stock-outs, which have affected only 16 drugs to date.

It is important to underline the fact that all the reports issued by pharmaceutical companies result in immediate corrective action taken in conjunction with the ANSM to ensure that the products concerned become available as quickly as possible. For the benefit of both patients and pharmaceutical companies, this figure must be reduced, and each and every stock-out event focuses the energies of all those involved on finding solutions quickly.

A legal framework for anticipating shortages

The increase in the number of shortage-related reports seen in recent years has been driven by the 2016 introduction of an obligation on pharmaceutical companies to inform the ANSM immediately they forecast, become aware of, or are informed of, any potential stock-out event affecting MITMs, with the aim of introducing replacement measures at the earliest possible opportunity.

The 30 March 2021 French government decree on safety stocks stepped up the obligation to ensure up to 4 months' stock of certain MITMs. This increased obligation became effective on 1 September this year.

New information and forecasting tools

Pharmaceutical companies are fully committed to making their treatments available to patients as quickly as possible. Leem took the initiative on this issue by launching the TRACStocks platform in late 2020. Introduced in the midst of a health crisis in association with GEMME (the generic pharmaceutical companies association) and LEMI (the parallel pharmaceutical product importers professional body), this solution is designed to improve the process of providing the relevant authorities with full information on inventory availability. **This TRACStocks platform provides the ANSM with automatic monitoring of aggregate inter-company inventories.** TRACStocks has proved extremely valuable during the Covid crisis in terms of the most acute needs (i.e. resuscitation products), and could usefully be extended to cover other types of medicinal product.

Supply chain pressures are driven by multiple factors on an international scale, for which pharmaceutical companies take their fair share of responsibility. But eradicating these pressures will be possible only if we engage in a collective response that addresses every aspect of the problem: medical, manufacturing and economic. The slightest actual shortage is one too many for any patient who suffers as a result of it. In just the same way as healthcare professionals, patients must be able to access high-quality information whenever these situations arise.

[Press kit](#) the full Leem press kit on this issue is available at www.leem.org

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