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The UFC – Que Choisir survey

This misinformation must stop: pharmaceutical companies are fully engaged and committed to making their treatments available to patients as quickly as possible

Leem has read this morning's article in *Le Parisien* regarding the survey conducted by the consumer group UFC - Que Choisir into shortages and disruptions in the supply of pharmaceuticals. Yet again, this article repeats inaccuracies and perpetuates a number of falsehoods around an issue of major concern and focus for pharmaceutical companies; concern that is highlighted by the proposals brought forward by Les Entreprises du Médicament (Leem) as early as February 2019, and the commitment of pharmaceutical companies to work alongside government in implementing the 2019-2022 roadmap published by the French Ministry of Health: *Combating shortages and improving the availability of pharmaceuticals in France.*

Leem fully understands and appreciates the concern of patients who fear that they may sometimes be unable to receive their treatments. All patients must be able to receive the medicines they need when they need them from the pharmacy of their choice. The non-negotiable priority of pharmaceutical companies is to make the treatments they produce safely available to patients as quickly as possible, which is why any supply disruption is always treated as a failure, regardless of cause.

Against the background of the current health crisis, the proliferation of disinformation campaigns seen in recent weeks regarding pharmaceutical supply chain pressures in France is particularly alarming for patients.

It is for these reasons that Leem today intends to untangle truth from falsehood by providing factual answers to the questions that the French are asking themselves about pressures and disruptions in the pharmaceutical supply chain.

1 - Is there really an 'explosion' of supply disruptions in France?

No. There is no explosion of supply disruptions. The French system improved its forecasting of supply chain pressures by introducing earlier reporting of disruption risks to the ANSM (French National Agency for Medicines Safety) in 2016, the result of which has been a statistical increase over the previous period.

So around one-third of the 1,504 alerts reported in 2019 led to the introduction of measures agreed between the ANSM and pharmaceutical companies to manage such pressures (quotas, imports, etc.), ultimately resulting in a small number of actual stock-outs.

2 - Are pharmaceutical companies responsible for supply chain pressures and disruptions?

Partially yes, but there are many factors influencing such pressures and disruption, and pharmaceutical companies share responsibility for those alongside every other stakeholder in the pharmaceutical supply chain. So because disruptions in supply are driven by multiple factors, it will not be possible to combat them effectively unless we engage in a collective response that addresses every aspect of the problem. The main cause of stock-outs relates directly to shortfalls in production capacity when confronted with unexpected increases and/or fluctuations in global demand for pharmaceutical products. And in today's extremely demanding pharmaceutical product safety environment, any issues around raw material availability or production process quality can lead directly to pressures in the supply chain.

It is regrettable that the issue of supply disruptions is being approached solely on the basis of an overstatement of pharmaceutical company responsibility, despite the fact that many reports agree on the multiplicity of actual causes (the Jacques Biot report of 2020[1], the French Senate information mission of 2018[2], the French National Academy of Pharmacy report of 2018[3], etc.).

3 - Are pharmaceutical companies scaling down production of their oldest products, supplies of which have been disrupted, in favour of newer, and therefore more expensive, pharmaceuticals?

No. This statement shows a clear lack of knowledge of what really happens in our industry. The companies that manufacture the oldest products are often not the same companies that discover and produce the most innovative pharmaceuticals. In many cases, it is SMEs and generic manufacturers that specialise in the production of older pharmaceuticals after their patents have expired. It is also important to understand that companies intending to stop marketing a particular pharmaceutical product must provide the health authorities with at least one year's notice.

4 - The obligation to maintain stocks of pharmaceuticals in France: what exactly does the law say?

Article 48 of the Social Security Finance Act (LFSS) for 2020 introduced three new obligations for pharmaceutical companies:

1) **The obligation to build up a safety stock:** The obligation on all Market Authorisation (MA) holders and *exploitants* to build up a safety stock for the national market *"which may not exceed four months' coverage of drug demand, calculated on the basis of the sales volume for the drug concerned over the last rolling 12-month period".*

2) **The obligation to prepare and implement a shortage management plan for all MITMs (medicinal products of major therapeutic significance)**, and not just those MITMs where stock-outs or the risk of a stock-out would pose a serious and immediate risk to patients, which is implemented since 2016.

[1] https://www.entreprises.gouv.fr/files/files/secteurs-d-activite/industrie/industries-de-sante/rapport-biot-et-al-ruptures-medicaments.pdf
[2] http://www.senat.fr/commission/missions/penurie_de_medicaments_et_de_vaccins/index.html
[3] https://www.acadpharm.org/dos_public/2018_06_20_AnP_RAPPORT_INDISPONIBILITE_MED_VF1.pdf

3) **The obligation to import an alternative at the expense of the company in breach**: In the event of disruption to the supply of a medicinal product of major therapeutic significance, and following commencement of the adversarial procedure, the ANSM will be able to demand that a company imports any appropriate alternative pharmaceutical product, where the supply disruption poses a serious and immediate risk to patients, and where those alternative pharmaceutical products that may be available and the measures indicated are not sufficient to cover national demand.

These new measures should make it possible to predict and prevent risks more effectively before they result in supply disruptions.

5 - Does the law allow the safety stock obligation to be extended to 4 months?

Yes. The decree implementing this law will, where necessary, enable the Director General of the ANSM to extend the safety stock obligation to 4 months where, for example, there are regular disruptions in supplies of a very important product for which no alternative treatment is available. But it would be clearly illogical to impose this obligation for pharmaceuticals that never experience supply issues, even where they are medicines of major therapeutic interest.

6 - Would introducing a blanket requirement to hold four months of safety stocks for all MITMs be likely to put an end to supply chain pressures?

No. Introducing a principle where safety stocks covering four months for all MITMs shall be built up is unrealistic in manufacturing terms given the number of medicinal products involved, and the quality standards governing the management of such stocks. It simply does not address the situation.

Lastly, extending the obligation to hold safety stocks of all MITMs (i.e. half the entire pharmacopoeia) to four months could be adopted by our national neighbours, thereby depriving French patients of the pharmaceutical products they need as other European countries reserve them for their own nationals (for the record, around 80% of MITMs in France are depending on foreign supplies).

7 - Is the relocalization of pharmaceutical manufacturing compatible with the obligation to hold four months of safety stocks for all MITMs?

No. This measure is incompatible with France's relocalization ambitions, and would have the opposite effect of accelerating the transfer of production capacity to other countries with lower production costs.

8 - Building up safety stocks is compatible with European regulations?

Probably not. In recommendations published this April[4], the European Commission highlighted the risk associated with any preventive stockpiling policy implemented by Member States. Any stockpiling measure taken unilaterally by a single country could lead to the harmful situation in which each country would try to outdo its neighbours to secure high stock levels, thereby dramatically worsening supply issues in France. The fact that every European country faces the same problems means that the solutions we develop must be concerted and measured.

[4] https://ec.europa.eu/info/sites/info/files/communication-commission-guidelines-optimal-rational-supply-medicines-avoid_fr.pdf

9 - Have pharmaceutical companies responded effectively to the increase in supply chain pressures and disruptions?

Yes. In many cases, the action taken by pharmaceutical companies, especially in terms of leveraging international stocks and restructuring production for the most essential medicines, has prevented supply chain pressures from resulting in supply disruptions that would otherwise compromise patient care. Pharmaceutical companies are also committed to informing healthcare professionals more effectively when supply issues arise, with the creation of a stock level database, involvement in the *DP Ruptures* online system, and the introduction of other measures. Lastly, pharmaceutical companies already hold safety stocks of most MITMs.

10 - What proposals does Leem have for preventing shortages of pharmaceuticals?

Leem initiated detailed work on supply disruption as early as 2018, and established it as a Strategic Council for the Healthcare Industries (CSIS) measure in the same year. It has also prepared an action plan shared with all pharmaceutical companies to reduce supply disruption of those pharmaceutical products most essential for patients. This plan was built around 6 operational priorities:

1. **Uprating** requirements for securing medicinal products of strategic importance to health (MISS)
2. **Reviewing** the mechanisms used by hospitals to invite tenders for medicinal products of strategic importance to health (MISS) and reviewing the economic operating conditions for retail pharmacies.
3. **Promoting** the location in Europe of production facilities for active raw materials and medicinal products of strategic importance to health (MISS);
4. **Optimising** information sharing between pharmaceutical supply chain stakeholders and patients
5. **Adapting** the distribution supervision in response to supply chain pressures and/or supply disruptions
6. **Improving** strategic guidance at national level and working to harmonise regulatory practices across Europe

As Leem Director General Philippe Lamoureux reminds us: *"The dissemination of incomplete information around such a sensitive issue naturally makes the population of France increasingly mistrustful not only of pharmaceutical companies, but also of our public authorities, health agencies and all the pharmaceutical product supply chain stakeholders who work on a daily basis to ensure the guaranteed continuity of supply for pharmaceutical products essential to French patients with Covid-19 and other serious chronic diseases".*

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