

**LEEM'S REACTION TO ANSM'S STATEMENT ON FINANCIAL PENALTIES FOR FAILURE TO HOLD
SECURITY STOCKS OF MEDICINES**

We, the French pharmaceutical companies, are outraged by both the tone and the content of the ANSM's statement in the media this morning.

For many years, we have been working with ANSM on the subject of shortages. On a day-to-day basis, we work with the health authorities and respond transparently to their requests, through regular meetings of the interface committee, whether on shortages, the winter plan, TRACStocks, or the deployment of the 2024-2027 plan. We have mobilized our 270 members to sign the Charter of Commitment in record time, in November 2023. The entire sector is committed to finding concrete solutions.

With a constant concern for transparency and the collective interest, we have financed TRACStocks, a software program that enables us to better track stocks of MITMs (drugs of major therapeutic interest), and which has been extended to many molecules since its creation (1691 CIPs today).

In defiance of these cooperative efforts, the ANSM has today chosen to publish a particularly accusatory press release concerning sanctions against the laboratories, without having first informed the main parties concerned.

What's more, in its press release, the ANSM makes a misleading conflation between companies' obligations to declare tensions and actual shortages: declaration obligations have in fact recently been reinforced at the ANSM's request: the fact that they are increasing is therefore logical, but in no way means that the continuity of patient treatment has been compromised.

This is a shortcut for citizens, who risk rushing to their pharmacies out of a rekindled fear of drug shortages. Is this the role of a health authority?

This stance is all the more surprising given that the figures communicated last week by the ANSM show a significant drop in the number of stock-outs (-42% over the first 8 months of 2024 compared with the same period in 2023), as well as the risks of stock-outs (-21%).

This double discourse is a source of opposition between healthcare players, instead of bringing them together in the spirit of the 2023 Charter. It is tantamount to placing the responsibility for this complex situation on a single player - us, the companies - even though the Charter recognizes the shared responsibility of all players in medicines distribution.

Let's focus on cooperation and dialogue to bring patients the treatments they expect. As always, we are at ANSM's disposal to find the solutions the French need.

On the subject of sanctions

- We have repeatedly alerted public authorities to the fact that the creation of compulsory safety stocks for French territory alone is not an appropriate response:
 - It is unrealistic, as it does not take into account the conditions under which medicines are produced and used, combined with their financial constraints. It could even jeopardize the sales of certain products (particularly mature ones).
 - This obligation was conceived on a national scale, without taking into account the international dimension of the phenomenon. The issue should therefore be addressed at European level.
- We don't understand the authorities' campaign of automatic sanctions when, in most cases, the drug is available on the French market and enables patients to have access to the treatments they need.
- For several weeks now, we have also been alerting the authorities so that they can clarify for us on the criteria used to impose these sanctions.
- From the outset, we have been working closely and transparently to find solutions.

To provide effective and responsible responses to this complex issue, Leem calls for :

- **Move away from political posturing:**
 - We must stop treating the issue in a simplistic way, as if it depended entirely on the responsibility of a single player:
 - The subject of ruptures is complex and multifactorial.
 - Each player must assume his or her share of responsibility at the right level, not only the pharmaceutical firms but also wholesalers, pharmacists, health authorities and legislators
 - Avoid shortcuts, which are unnecessarily anxiety-provoking for French patients, and which antagonize the players rather than bringing them together:
 - Declarations of the risk of stock-outs do not necessarily reflect situations in which patients' health is affected.
 - Their increase simply reflects the fact that companies are being asked to declare earlier and more often, without the drug being unavailable.
 - In fact, ANSM figures show a downward trend in dry-run situations.
 - Avoid the temptation to tighten sanctions, which would be totally counterproductive and could accelerate marketing discontinuations.
- **Work together with Europe to develop solutions on the right scale.**
- **Take into account the realities on the ground** to build truly effective solutions:
 - It's not enough to press a button to increase production, guarantee raw material availability, manage storage space for thousands of references, etc...
 - Without this, security stockholding obligations will be ineffective or even counter-productive, let alone punishable.

"It is therefore urgent that all players mobilize constructively around solutions that are more efficient for patients, and sustainable for companies, so that they can continue to fulfill their mission: to provide the treatments every patient needs, when they need them", declares Thierry Hulot, President of Leem.

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