



PRESS RELEASE

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***Leem's New Year press conference***  
**2018: And if we were to focus on health?**

**In his New Year press conference on 18 January 2018, Leem's Chairman Patrick Errard gave an initial appraisal, eight months after the presidential election, of the action taken by the government. As the economic policy of the new government begins to unfold across several sectors of the French economy, the pharmaceutical industry has so far been largely overlooked in the "*spirit of reconquest*" extolled by the President of the Republic in his addresses.**

2017 was a watershed year for the pharmaceutical industry. " *Our companies ticked all the boxes in the economic programme set by the President of the Republic, according to Patrick Errard, Chairman of Leem. "France's industrial influence on the international stage", "countrywide reindustrialisation", "innovation and the knowledge economy" and "employment, learning and training". Expectations were high indeed.* "

**Patient access to innovative treatments is now under threat**

The PLFSS (French Social Security Finance Bill) for 2018, however, has thwarted industry hopes in terms of fostering innovation and an attractive industrial environment. While the major global economies are turning to their healthcare industries as strategic tools for industrial recovery, the pharmaceutical industry in France continues its slow but inexorable decline in contrast to the current economic dynamism observed among our European neighbours. Several indicators point to this worrying deterioration in the country's attractiveness:

- **France was included in 2016 in 26% of European clinical studies compared to 31% in 2015.** This figure is unequivocal: France is becoming increasingly less attractive as a destination for conducting clinical trials of new medicines.
  
- **21 of the 282 medicines approved by the European Medicines Agency were produced in France between 2012 and 2016.** In this same time, Germany produced 86, the United Kingdom 68 and Ireland 39. In the space of 10 years France has gone from being Europe's leading manufacturer of medicines to ranking fourth place.

- **No level I (major) ASMR<sup>1</sup> was awarded by the Transparency Commission of the HAS in 2016 and 2017.** This score of zero - when the reality of innovation is plain for everyone to see - brings our medical-scientific evaluation system into disrepute and prompts an urgent overhaul of the drug assessment procedures in France.

**Leem's biggest warning however is about the deteriorating conditions of access to medicines by French patients:** longer market access lead times; France's weakening status in clinical research which delivers the most innovative treatments for patients; tighter controls of temporary authorisations for use (ATU) schemes; an escalation of supply shortfalls; the development of preliminary agreement mechanisms; the unwillingness on the part of government to develop innovative mechanisms ... all of which reflect this worrying deterioration.

Leem is particularly concerned about the issue of **early access to advanced therapies**

- Between 2014 and 2016, access lead times in France between the marketing authorisation date and the publication of prices in the *Journal Officiel* averaged **530 days** for products not eligible for ATU status (35% of which held ASMR status with clinical added value).
- Over the same period, products eligible for ATU status were available on average 210 days before their MA date (i.e. 318 days before Germany and the UK), but **only to 10% of the target population!**

### 2018: a decisive year

The year ahead is set to be decisive for France in terms of attractiveness. A year with some all-important dates. Weak but very real signals have been sent by the government to the pharmaceutical companies: an end to the excessive transposition of European directives and the incipient reform of the health economic assessment of medicines through the relative therapeutic value (VTR) mechanism. These complement the government's revival of the **Strategic Council for Healthcare Industries (CSIS).**

**Leem welcomes the reinstatement of the CSIS** so that collectively, under the auspices of the highest levels of government, the tools can be found to restore France's appeal and competitiveness in the health sector. Whether it be administrative performance and simplified procedures, patient access to innovation, clinical research, or job transformation ... Leem endorses the areas of work announced by the Prime Minister which reflect the measures set out by the pharmaceutical companies in their policy platform "Health 2017 - Time to Decide" during the 2017 presidential campaign.

**The second date is the PLFSS for 2019.** " *This PLFSS has to be a major turning point that brings about sustainable reform and facilitates early access by patients to the most innovative and*

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<sup>1</sup> Improvement in medical benefit (ASMR)

*effective treatments," continues Leem's Chairman. The failure to structurally transform our health system as a path to modernising the distribution of care in our country would be a resounding failure not only for the government but also for French society as a whole. "*

**The third date is the renewal of the Framework Agreement with the Economic Committee for Health Products (CEPS).** The renegotiation of the Framework Agreement is closely linked to the reform of the health economic assessment. Leem also wishes to point out that the removal of the ambiguities and contradictions set out in the ministerial guidance letter is a prerequisite for the reopening of negotiations. Sent to the Chairman of the CEPS in August 2016, this letter raises deep concerns about the future of the agreements policy, a core element of transparent medicines policy in France.

For Patrick Errard, *"The timely convergence of the CSIS, the national health strategy, the reform of the assessment process by the HAS, and the renegotiation of the Framework Agreement opens up tremendous opportunities for our industry to re-establish itself as a contender on the international stage. This planetary alignment will not happen a second time in the five-year presidential term. Together, the government and Leem must seize this opportunity. "*

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