

The French Social Security Finance Bill for 2021

**Leem acknowledges the significant reorientation
represented by the new Social Security Finance Bill**

Leem has carefully studied the text of the Social Security Finance Bill for 2021 submitted to the Council of Ministers this morning.

This text includes a number of significant reorientations in terms of government policy on pharmaceuticals. The measures set out in the Bill are consistent with those announced in recent weeks and contained in the *France Relance* national recovery plan put forward by the government.

Pharmaceutical companies welcome the strong signal sent by the significant reduction in the price cut envelope (€640m rather than the initial €920m), which again is consistent with the announcements made by President in his speech at Villeneuve-la-Garenne in August. This reduction shows a meaningful level of alignment with the government's stated desire to make the French pharmaceutical industry more competitive.

The total restructuring of the current system of access to, and management of, pharmaceuticals subject to ATU or RTU temporary authorisations and recommendations for use (Article 38), which has come about as a result of detailed consultation between the industry and public authorities, will improve the predictability of these early access mechanisms, which can only benefit patients. Nevertheless, Leem wish to make it clear that it will be paying very close attention to the proposed practical arrangements for implementing the intentions set out in this article.

Leem also notes the fact that the 2021 target for expenditure on regulated pharmaceuticals will be based on value (rather than on the M rate). The vote in favour of this amount being set in value terms was expected by the industry as part of achieving greater transparency around regulatory mechanisms. Furthermore, excluding 2020 from the calculation to set the base level for 2021 seems logical, given the atypical nature of this year as a result of the Covid-19 crisis.

Leem also notes the decision to withdraw the provisions for regulating innovative pharmaceuticals used in cancer care. It welcomes the decision by government to adopt an agreement-based relationship between the CEPS and the manufacturers concerned, and sees this move as reflecting a willingness to renew the process of agreement-based dialogue.

However, Leem regrets the introduction of a legislative measure designed to change the agreement-based allowance mechanisms. This provision, quite apart from the high degree of uncertainty surrounding its practical implementation, is clearly at odds with the existing rules governing such agreements.

Leem also recalls the request it made jointly with the professional bodies representing retail pharmacists and patient associations for the repeal of Article 66 of the 2020 Social Security Finance Act. In practical terms, this article - whose implementation measures have still yet to be announced - has a direct impact on pharmaceutical manufacturing in France and the wider Europe, and is therefore a major factor in weakening its overall offer.

“The signals sent out by this Social Security Finance Bill are encouraging and open up some meaningful opportunities for our companies”, says Leem Chairman Frédéric Collet. When put together with the the Relance France plan, these measures demonstrate the determination of our public authorities to learn from all the lessons of the Covid-19 crisis and boost the appeal and competitiveness of France in the strategically important healthcare industry sector. We must now ask ourselves about the level of industry growth essential in order to reconcile the ambitions of France for the real relocalization of manufacturing with providing access to the major advances in therapies that will become available to patients in the near future”.

Lastly, Leem intends to contribute to the work of the HCAAM (the body examining the future of health insurance), following its referral by the French Minister of Health Olivier Véran. Multi-year planning, decompartmentalisation of expenditure envelopes and improved information for members of parliament are all proposals that the organisation has been advocating for many years.

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