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The French Social Security Finance Bill for 2020

A legal text inconsistent with the goals set by the CSIS for patient access to treatment and the appeal of France for inward investment

Despite accounting for only 12% of overall health expenditure today, compared with 15% a decade ago, pharmaceuticals will once again be required to fund nearly 50% of the health service savings set out in the French Social Security Finance Bill (PLFSS) for 2020 (this percentage includes all regulatory measures, including price cuts, increased discounts, controlling medical expenditure, delisting, etc.).

With €920 million in pharmaceutical price reductions, the latest PLFSS follows the pattern of previous bills. Leem highlights the fact that the total amount of effective price cuts introduced in the past five years has reached the record level of €5 billion, at the same time as weakening our entire healthcare ecosystem and gradually moving our country into a position of dependency in terms of pharmaceutical supplies.

The regulatory policy implemented by France over the last decade and more has real and measurable consequences for the pharmaceutical industry; consequences that include the declining status of France as a manufacturing and research centre, the inability to attract the production of new drugs into our country, stagnation in terms of investment and employment, and sluggish export activity.

"At a time when the proactive policies of other major European countries are giving their healthcare companies the room for manoeuvre they need to facilitate access to innovative treatments, France is marginalising itself by pushing ahead with dissuasive regulation and depriving pharmaceutical companies of any real prospect of future growth", says Leem Chairman Frédéric Collet.

The disproportionate effort demanded from pharmaceutical companies to fund France's social security deficit contrasts starkly with the goals set out by the 8th Strategic Council for the Health Industries (CSIS) in 2018, which were reconfirmed by the President and Prime Minister in July this year, and which take up the challenge of boosting the appeal of France against a background of fierce international competition. The signals sent out by this PLFSS raise questions about the consistency of drug-related policy, and run the risk of further exacerbating the significant decline in national competitiveness that Leem has warned of for several years.

The accumulated volume of regulatory mechanisms no longer penalises only pharmaceutical companies, but now threatens access to treatment for French patients, as evidenced by:

1. **The non-availability to French patients of an increasingly large proportion of drugs available elsewhere in Europe**[1] (40% of drugs receiving EMA marketing authorisation in the last three years are not available to French patients - more than three times less than in Germany and the United Kingdom).
2. **Market access lead times** (four times longer than in Germany and United Kingdom), which puts France into 23rd place in Europe, between Slovenia and Bulgaria.
3. **The decline in the proportion of French patients involved in international clinical trials**, despite the fact that inclusion in research programmes is the earliest opportunity for patients waiting for therapeutic solutions to access innovative treatments.
4. **The significant increase in supply disruptions**. Although the French government recently announced increased penalties for manufacturers held responsible for disruptions in the supply of drugs, its proposal for further massive price cuts effectively creates the conditions for such disruptions by encouraging parallel exports and discouraging some manufacturers from supplying their products into the French market. Stresses and disruptions in the supply of drugs are a priority concern for pharmaceutical companies, as highlighted in the proposals they brought forward in February this year, and their commitment to work alongside central government and patients.
5. **The significant increase in unsuccessful hospital tendering rounds** as a result of so many pharmaceutical companies being no longer able to meet the tendering conditions applied, thereby reducing patient access to certain drugs.
6. **The reluctance of pharmaceutical companies to try and cope with the increasing opacity and unpredictability of Temporary Authorisation for Use**

[1] EFPIA study, 2018

(ATU) mechanisms. In PLFSS after PLFSS, the ATU has moved further and further away from its primary goal of providing early access to innovative treatments.

7. **The way in which the supplementary list is managed**, which generates innumerable inequalities of access to treatment that are widely recognised by healthcare professionals and patient associations.

"More than any other issue, innovation is both the central challenge and the most powerful opportunity for modernising our health system. We must therefore urgently abandon this regulation, which is inconsistent, opaque and totally unsuited to exploiting our ability to develop and offer breakthrough treatments to patients", stresses Leem Chairman Frédéric Collet.

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