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Leem 2017 New Year Message to the Media

Leem reveals the priorities for the next parliamentary mandate:

To guarantee patient access to the best-possible healthcare, to introduce a stimulating regulatory framework, and bring consistency back to the French model.

With three months to go before the presidential election, Leem Chairman Patrick Errard sets out the 2017 priorities for drug companies.

Leem passes a harsh verdict of the last parliamentary mandate, with its package of regulations whose burden is disproportionate to the level of expenditure on drugs in relation to the overall cost of healthcare provision. It also makes assessment mechanisms even more difficult to forecast, adds greater complexity to existing legislative and regulatory provisions, further extends market access lead times and increases the burden of industry-specific taxation. After five years of a policy that consciously penalises drug companies, their industry body is committed to ensuring that the next government recognises and embraces the strategic importance of this industry of the future and its potential contribution to the French economy in terms of growth, jobs, investment and manufacturing output. These priorities are fully consistent with the battles engaged by Leem in 2016 through its *Healthcare 2017 - time to choose* and 2017 Healthcare Collective, a historic gathering of healthcare providers.

A win-win contract with the State

Fully aware of the reduced room for economic manoeuvre available to France, and the difficulties faced by the healthcare system in delivering efficiency gains, Leem is calling for far-reaching change in the healthcare delivery model, and hopes to enter into a contract covering the parliamentary mandate with the next government in which both parties engage with equal enthusiasm. This contract covering the parliamentary mandate will replace the control of the drug policy at the highest level of government, and will address three key priorities:

1. **Guaranteed access for all patients to the best-possible healthcare**
2. **The introduction of a stimulating regulatory framework**
3. **Bringing efficiency and consistency back to the French model**

Guaranteed access for all patients to the best-possible healthcare

Leem demands that government agencies complete the plan to overhaul the drug assessment pathway begun via the Relative Therapeutic Index (ITR), accelerate and simplify clinical trial launch procedures, broaden access to health data for research and health economic evaluation purposes, and facilitate continuous assessment of drugs (real-life studies, etc.).

For their part, manufacturers give their commitment to boosting France's share in the total volume of clinical trials conducted in Europe, providing the data required to gain a clearer understanding of research pipelines, and strengthening public-private partnerships with hospitals and major French research institutions, such as AVIESAN, INSERM and CNRS.

The introduction of a stimulating regulatory framework

Leem demands that government agencies put in place regulatory mechanisms that allow the industry to return to growth and that put an end to regulations penalising the benefits of innovation. To initiate this transition from punitive regulation to incentive regulation, Leem proposes that the healthcare system efficiency gains made possible by technological progress are fed back into the system, and the introduction of a five-year framework law to develop a multi-year vision of expenditure control policy that is fully consistent with the priorities of public health and the essential organisational reforms. Leem also wishes to end the division of Rate L between retail and hospital pharmacies, and seeks a national healthcare expenditure target (ONDAM) for drugs that aligns consistently with the general ONDAM.

The next government must also reaffirm the priority given to the collective agreement policy, and resolve the apparent contradictions between the ministerial guidance letter sent to the CEPS Chairman and the framework agreement signed by CEPS and Leem.

Furthermore, Leem stresses the need for the rapid introduction of a policy that strengthens manufacturers' chemical-based drug production resources and facilitates the development of biotech drugs. Of the 48 marketing authorisations (MAs) issued by the EMA between 2014 and 2016, only 3 are produced by a manufacturing facility registered in France.

In return, manufacturers give their commitment to delivering a responsible transformation in professions and jobs, continuing the efforts they are already making in initial training, and intensifying the network of links between the pharmaceuticals majors and biotech startups.

Bringing efficiency and consistency back to the French model

Leem demands that the next government simplifies and stabilises the standards landscape by aligning French legislation with European legislation to avoid penalising French healthcare industries.

In return, manufacturers intend to make an active contribution to relaunching the Strategic Council for the Healthcare Industries to establish it as a coherent guidance body for drug policy.

Alongside conveying his best wishes for the New Year, Patrick Errard stresses the need for change in the ethical practices of the industry in accordance with the project promoted by CODEEM (the Conduct and Ethics Committee of the French Association of Pharmaceutical Companies). In 2017, Leem intends to focus more closely than ever on the issues surrounding industry correctness, ethics and reputation.

Patrick Errard sees these three issues as priorities at a time when: "*France is confronted by crucial challenges in terms of public health, the organisational structure of healthcare and the need to improve patient care. It is time for our political decision-makers to step up to their responsibilities and bring forward realistic and intelligible initiatives that pave the way for a bold healthcare policy with the ability to bring efficiency and consistency back to our healthcare system and facilitate patient access to innovative therapies".*

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