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*The CESE Report on "Pricing and access to innovative medicinal treatments"*

**A study that makes a useful contribution to the debate but offers sometimes simplistic solutions**

Assessing and setting the price of innovative medicines, early access to treatment... In a report published this morning, the Economic, Social and Environmental Council (CESE) offers its considerations in an effort to regulate the rising prices of innovative medicines and facilitate access to treatment.

**Despite the at-times caricatured portrayal, Leem shares some of conclusions of the CESE, particularly those concerning the need to find new arrangements for financing innovative treatments, the much-needed reform of the health economic evaluation, the harmonisation of the therapeutic value assessment at European level (HTA), the importance of conducting real life studies, or indeed the better ability to anticipate and drive the medicines policy.**

**Leem however wishes to point out a number of issues on which it disagrees, particularly that of paying agencies being represented on medical technology and scientific committees.**

The debate on the cost of innovative healthcare products is legitimate. The advent of an unprecedented wave of innovative medicines is set to significantly improve living conditions for patients: recovery from hepatitis C, the transformation of some cancers into chronic conditions (lung, pancreas, etc.), the development of new and particularly effective modes of action to defeat certain diseases (immunotherapies, cell therapies, combination treatments, biomarkers, diagnostics, data exploitation, genomics, proteomics, and so forth). The cost of these innovations, along with the other factors responsible for the rise in healthcare costs, raises the legitimate question among the public of the sustainability of our healthcare system.

The CESE lays the groundwork for a meaningful debate. Leem regrets, however, that the report does not sufficiently place the issue of pricing and access to innovative medicinal treatments within a broader economic context of public spending control. Leem wishes to point out that:

1. Medicines are now the most tightly controlled single item of the National Healthcare Spending Target (ONDAM). Of the EUR 10 billion in cuts made by the government over the past three years (the ONDAM three-year plan for 2015- 2017), EUR 5 billion come from pharmaceutical company contributions.

2. The price of innovative medicines poses no threat to the health insurance budget because its share of healthcare spending remains relatively low, and the vast majority of medicines in France are lower in price than the European average. For example, the cost of cancer medicines accounts for only 2% of health insurance expenditure.

3. Medication is not only a source of expenses but also a generator of efficiency gains. Most importantly, the resurgence of therapeutic innovation is bringing about radical change to our healthcare system now that hitherto fatal diseases are being transformed into chronic conditions.

**Overhaul of the regulatory and pricing mechanisms: a necessity**

In its report, the CESE makes an observation long shared by Leem: that the regulatory and pricing mechanisms are no longer suited to the influx of innovations. Bringing change to the system for evaluating healthcare products is one of the commitments made by LEEM in its policy platform *"Health 2017 - Time to decide"* ahead of the coming Presidential elections. Through this flagship project, Leem is calling for medicines to be evaluated on a continuous basis, from early clinical trials to post-marketing monitoring, a proposal that aligns therefore with Recommendation 4 of the CESE which seeks to promote the evaluation in real life settings of the efficacy of costly medicines and to review prices, where applicable, according to product indications and the results of

such studies. Leem is also demanding wider use of healthcare data for research and health economic evaluation purposes in order to make a cost-effectiveness assessment of products under real-life conditions.

Leem welcomes the recommendation of the CESE to conduct prospective studies on the financial impact of innovative treatments. Finding smart financing mechanisms is what Leem is committed to achieving through:

- Performance contract mechanisms, sliding-scale discounts on some innovative products while prioritising the implementation of the framework agreement.

- Budget impact analyses to ascertain over several years the actual costs and savings generated within the health system through innovation.

**The representation of paying agencies on medical device and scientific committees: a misguided idea**

The CESE also recommends in its report that the Council of Health Insurance Funds be allowed representation on the ANSM, on the Transparency Commission of the HAS and on the National Committee for the Assessment of Medical Devices and Health Technologies (CNEDIMTS). This is a major point of contention for Leem, which has always advocated the separation of financial assessments from scientific assessments. The presence of paying agencies on medical technology and scientific committees set up within public authorities (ANSM and HAS) would be a hazardous combination by introducing a real risk of bias in the medical technology assessment.

**Complexity and opacity are not to be confused**

Similarly, Leem does not share the conclusions of the CESE on the lack of transparency in the pricing of medicines. The system is not opaque, as is demonstrated by the publication each year of a detailed report by the Economic Committee for Health Products (CEPS). The system is instead complex because medicines have widely varying profiles which require a differentiated approach to pricing depending, for example, on whether they cure, turn an incurable disease into a chronic condition, or improve patient quality of life.

Despite pursuing some relevant lines of enquiry, the report as a whole does not take sufficient account of the revolutions in healthcare that are disrupting our ecosystem: the resurgence of innovation but equally the transformation of deadly diseases into chronic ones, the wholesale reorganisation of the patient care pathway with an accelerated shift to outpatient care... Organisational, therapeutic and behavioural upheavals that require not an analysis focused solely on the price of innovative treatments but a comprehensive reflection shared by all stakeholders in the healthcare system.

*"The CESE report is one more proponent that calls for a radical reform of the medicines policy in France and its impact on the organisation of the care system, a reform advocated by Leem,* **according to Leem's Director General Philippe Lamoureux.** *Leem has always been open to this debate and is contributing to it through the 2017 Healthcare Collective".*

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