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# A new simpler and clearer system for early and compassionate access to medicinal products is now in place

Leem welcomes today's Official Journal publication of the decrees required to implement the far-reaching reforms to the exceptional access mechanisms for the funding of medicinal products announced in the Social Security Finance Act for 2021, which aim to make patient access to innovative products faster and easier.

These legal texts are the end result of the very significant body of complex work done by the health authorities (the French Ministry of Health, the Haute Autorité de Santé (the French National Authority for Health) and the Agence nationale de sécurité du médicament et des produits de santé (the French National Agency for Medicines and Health Products Safety)) since the beginning of 2020. They reflect the high expectations of pharmaceutical manufacturers, at the same time as implementing a government commitment made at the 2018 CSIS.

This reform of early access brings a new level of consistency and uniformity to the existing exceptional access mechanisms, which had accumulated many strata over the years, by creating two access and funding mechanisms clearly identified by their purpose:

- An 'early access' mechanism designed to provide pharmaceutical companies with the opportunity to request early-stage funding for innovative medicinal products designed to treat severe, rare or debilitating medical conditions, and which are likely to be covered by the French Assurance Maladie national health insurance system in the future

- A 'compassionate access' mechanism designed to provide funding for medicinal products that meet a therapeutic need in the treatment of severe, rare or debilitating medical conditions. This mechanism can be invoked by a prescriber or the health authorities, without the need to prove the innovative character of the products concerned.

The previous procedures had become increasingly complex over time in response to the emergence of new circumstances (extensions of indication, marketing authorisation being granted prior to early-stage funding, etc.), so Leem warmly welcomes the completion of this reform, which simplifies procedures in a way that enhances early access mechanisms unique in Europe and available to patients in France:

- By clarifying and simplifying the general framework around exemption arrangements for product funding;
- By setting a deadline for decisions to be made by the authorities;
- By making funding automatic as soon as access is approved;
- By making funding decisions and conditions more predictable;

- By introducing greater consistency to the medicinal product pathway, from early access to funding under the standard coverage procedure.

Over the coming days, these decrees will be supplemented by a series of measures setting out the financial terms and conditions of coverage, as well as details of the procedures essential to accelerating widespread implementation of the new scheme.

Looking beyond this challenging transition phase, Leem stresses that the work being done jointly with the health authorities should make it possible to achieve the simplification, legibility and attractiveness targets set by the reform.

"*The new system will shorten access times in France and be followed quickly by the far-reaching transformational changes to the mechanisms governing patient access to treatment targeted by the French President, and announced at the 2021 CSIS of 29 June"*, says Frédéric Collet, President of Leem.

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