

*Signing of the addendum to the Framework Agreement on the "CEPS new price negotiation procedure"*

**The Csis making good on its commitment**

On 24 April 2019, Leem and the Economic Committee for Health Products (CEPS) signed an addendum to the Framework Agreement with a view to improving the price negotiation procedure. This act of signing delivers on one of the important commitments made by the Strategic Council for the Health Industries (Csis) in July 2018, namely that of streamlining administrative procedures to accelerate market access for medicines.

Incidentally, the market access procedure in France takes 500 days on average, one of the lengthiest in Europe. The Csis aims to restore this period to 180 days as set by the European directive.

**A negotiation process that is more tightly regulated, transparent and efficient**

First and foremost, the addendum helps provide impetus to the negotiation process by setting a deadline of 15 days after the Transparency Committee delivers its opinion for the laboratory to submit its price dossier to CEPS, and by requiring CEPS to issue an initial counter-proposal within 4 weeks. The addendum also introduces an obligation to substantiate the price proposals. From now on, CEPS and the manufacturer will have to give reasons for their proposals and counter-proposals on existing legal, regulatory and contractual grounds.

A further commitment by the pharmaceutical companies and CEPS is better oversight of the price negotiations. The signed addendum provides for the introduction of a common system for assessing and monitoring lead times. The results of this monitoring process will be shared at each meeting of the Agreements Policy Steering Committee (CPPC) and set out in the annual activity report produced by CEPS.

Lastly, the pharmaceutical companies and CEPS have agreed to create a suspended status for dossiers under negotiation that can be triggered at the request of CEPS. If no new price proposal is forthcoming within 30 days, negotiations will be declared suspended. Either party may reopen negotiations at any time by forwarding a new proposal.

*"The government had pledged at the last meeting of the Csis to rapidly implement measures to speed up the administrative procedures involved in market access for medicines. The signing of the addendum to the agreement on the "CEPS new price negotiation procedure", which aims to regulate and hopefully speed up negotiations on drug pricing, sends out a strong signal, according to **Philippe Lamoureux, Director General of Leem**. We are hoping to engage in similar discussions very soon with the Transparency Committee of the National Authority for Health (HAS), which assesses actual medical benefit (SMR) and compares the medicines with already available treatments by assessing the improvement in actual benefit (ASMR) so that innovative therapies can be made more rapidly available to patients".*

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