Press release 5 March 2021

Economic regulation of medicines:

Leem and CEPS (the French Economic Committee for Health Products) sign a new three-year framework agreement (2021-2024)

This morning, CEPS Chairman Philippe Bouyoux and Leem Chairman Frédéric Collet signed a new three-year framework agreement at a ceremony attended by Olivier Véran, the Minister for Solidarity and Health, and Agnès Pannier-Runacher, Secretary of State for Industry to the Minister for the Economy and Finance.

Marking the conclusion of intense negotiations between Leem and CEPS, this framework agreement introduces profound revisions to some of the rules governing the setting and regulation of prices for medicines with the aim of achieving five key goals: shortening lead times, promoting patient access to innovation, boosting investment and exports, facilitating supplies of medicines addressing public health needs, and improving transparency, in accordance with the engagement letter sent to the Chairman of the Economic Committee on 19 February 2021 by the ministers supervising the CEPS.

The task of shortening lead times will be addressed specifically through the development of fast-track procedures in particular situations specified in the agreement, in parallel with the introduction of a new 'arbitration' procedure.

The issue of access to innovation is taken into account via several important measures, including net price stability during the first five years in which the most innovative medicines (ASMR 1 to 3 rating) are marketed, in light of uncertainties through the introduction of risk management contracts and/or the establishment of a new agreement-based policy on innovative technology treatments (gene and cell therapies).

For the first time, an entire chapter of the framework agreement is dedicated to measures designed to increase the appeal of France for inward investment in industrial production, digital solutions, research and development. More specifically, the new agreement also includes measures designed to encourage reshoring and promote exports, such as the possibility of early-stage dialogue with CEPS over inward investment projects and achieving enhanced price stability conditions for products exported in large quantities from Europe in general, and France in particular.

A number of provisions are designed to maintain supplies of medicines at a sufficient level to meet public health needs: access to a Europe-wide price for certain medicines that deliver incremental improvements (ASMR 4 rating) while meeting a public health need, the possibility of securing a higher price for all or part of a therapeutic class subject to supply issues as a result of its production cost, and price stability for medicines given an ASMR 5 rating during the first three years of marketing.

Lastly, the architecture of the agreement has been very significantly updated with the introduction of a simplified governance structure, the stated intention of strengthening the agreement-based policy and the implementation of legislative provisions on transparency, as provided for in the 2021 Social Security Finance Act.

"This agreement is the outcome of constructive and productive negotiations", ***says CEPS Chairman Philippe Bouyoux****. "It complies fully with government guidelines, at the same time as meeting the expectations of manufacturers. It forms part of a wider public health policy designed to ensure patient access to care under the best-possible conditions, at the same time as remaining within a sustainable financial framework. It also includes many advances, including opening up new options to accelerate our procedures. Above all, it seeks to introduce practical measures to promote innovation and encourage investment that contributes to improving the availability of pharmaceuticals. Together with recent ministerial guidelines, this framework agreement provides CEPS with a new roadmap to the future. It is ambitious, clear and shared with manufacturers".*

"This new framework agreement includes some very robust measures tailored to addressing the challenges faced by the pharmaceutical industry going forward", ***says Leem Chairman Frédéric Collet****. "It takes full account of the therapeutic innovations that are now emerging at pace, and does so in ways that will benefit patients and help deliver the government's goal of re-establishing France as a major force in pharmaceutical production. Thanks to the exceptional work carried out jointly with CEPS, companies now have a clear and understandable instrument for regulating and governing the agreement-based policy. In this agreement, the French State recognises the strategic importance of our industry".*

Flagship measures include:

A measure to reduce lead times	
Fast-track	Access within 15 days for medicines given an ASMR 1-3 rating dominant in terms of efficiency, medicines given an ASMR 4 rating dominant in terms of efficiency and saving, and medicines given an ASMR 5 rating priced below the comparator
Measures to facilitate access to innovation	
Advanced Therapy Medicinal Products	Guidance on the effective duration of comparators, taking uncertainties into account, calculating discounts and splitting payments
Orphan medicines	Confirmation of the possibility to renegotiate the conditions governing discounts where changes occur in the target population. Commitment to

	producing an amendment to the agreement within six months for the purpose of revising the budgetary package
Price stability and predictability	The 5-year stability period for the Europe-wide price of medicines given an ASMR 1-3 rating with a valid health economic assessment covers both the face value cost and the net price
Measures to encourage inward investment and exports	
Chapter dedicated to support for inward investment and exports	Introduction of a new chapter dedicated to support for inward investment and exports, with an introductory section that enables companies considering inward investment to meet proactively with the CEPS Chairman for a briefing on the agreement-based measures
High EU pricing for innovative products manufactured entirely in France	The opportunity to apply a high EU face value price to medicines given an ASMR 1 to 3 rating for which the key manufacturing stages (active ingredient, finished product and packaging) are all based in France
Support for exports	Two years of price stability - renewable on one occasion only - for products where at least one stage of manufacture is carried out in the EU - particularly in France - and more than 60% of the volumes produced are exported
Measures to facilitate supplies of medicines meeting a public health need	
Prices of medicines given an ASMR 1 to 4 rating	Where supplies of medicines given an ASMR 4 rating are insufficient to meet a medical need (that would not otherwise be fully or partially met) or public health need, European pricing may be accessed and applied
Price stability and predictability	Three years of price stability for medicines given an ASMR 4 and 5 rating Two years between price cuts
Measures to increase transparency and strengthen the agreement-based policy.	
Transparency of public investment in R&D	Companies must report to CEPS the amount of public R&D investment they have received and the amount of contributions they have made to public bodies. These amounts are published in aggregated form.
Outlook data	CEPS 5-year outlook for therapeutic innovations: provided by each company under the terms of an appendix to its agreement, and collectively through the annual Leem scanning horizon presentation

Visit the media space at www.leem.org for complete details on all the measures set out in the framework agreement

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