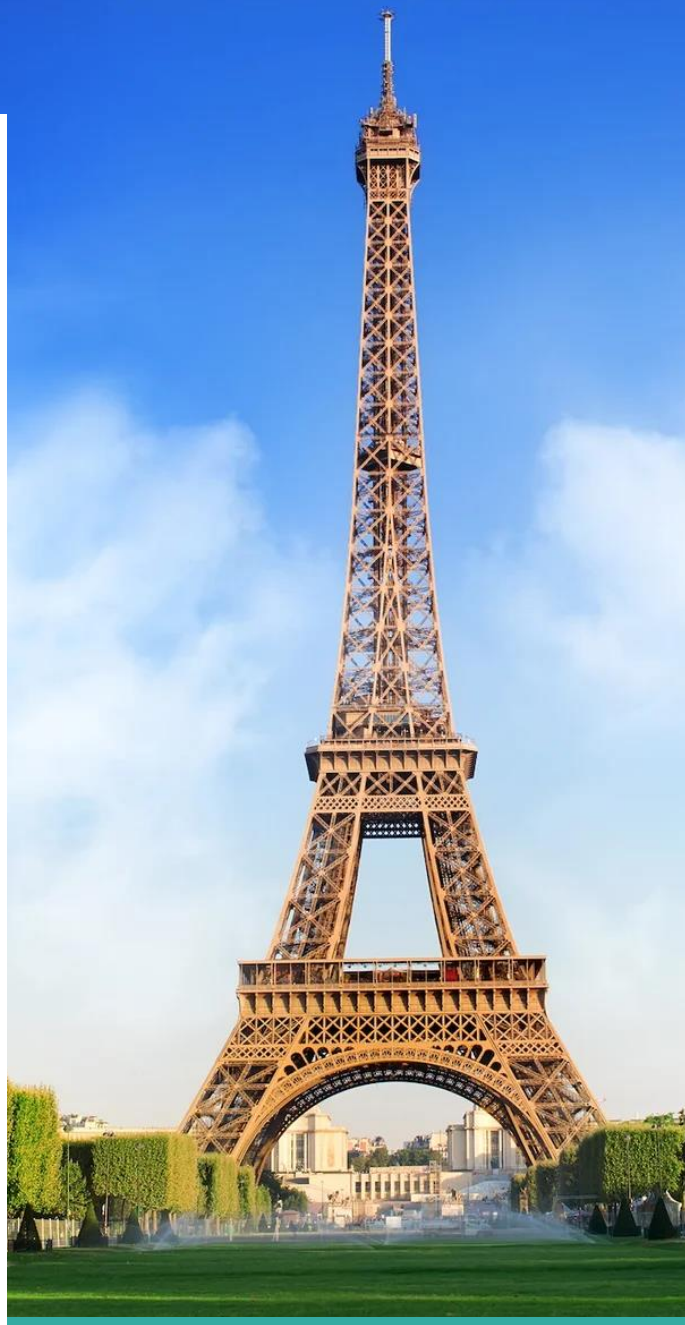
The new Leem-CEPS framework agreement: an asset for orphan drug access in France?

France 2021



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LEEM-CEPS : Framework agreement

National payers in Europe are facing increased pressures on their healthcare budgets. On the one hand, the recent pandemic has temporarily shifted the attention on COVID-19-related resources such as research, treatments, and vaccines which has led to significant unexpected expenditures. Regarding the Europe's big 5, they each invested an average of 5,88% of their 2019 GDP[1] in immediate fiscal impulse to respond to the crisis. On the other hand, payers want to improve patient care by providing access and funding innovative treatments, by the increasing the number of high-cost treatments being developed and commercialized. 20-30 new advanced therapy medicinal product (ATMP) filings are expected in Europe annually over the next 5 years[2].

While companies are willing to put products on the world's second biggest pharma market[3], Europe, they are facing the complexity of dealing with 28 different European Union member states market access policies. Market Access Guidelines and Frameworks between pharmaceutical industry and health care payers have been accelerating in Europe in response to the need of controlling health expenditures such as guidelines on pricing & reimbursement (P&R) of medicines in Italy[4],the new 2021 action plan of the Spanish Ministry of health[5], the HTA processes review by the National Institute for health and Care Excellence (NICE) in the UK, and the new framework agreement in France[6] .

The French framework agreement between CEPS (The Economic Committee for Health Products - the public payer negotiator) and LEEM (the industry association for drug companies operating in France) defines the rules for setting drug prices according to the legislative framework. It is one of the essential tools of the Government's drug policy and demonstrates the priority given to contractual relations with manufacturers[7].

After an unprecedented collective effort, the new framework agreement was signed on March 5th, 2021. It changes the rules considering the experience gained from the last few years of negotiations, the current health crisis and the commitments made by the President of the French Republic to take better account of industrial investment in setting drug prices. This new framework agreement profoundly revises certain rules around five main objectives and reflects the desire to: reduce time to access, facilitate access to innovation, encourage exporting and investment, facilitate supplies of medicines meeting a specific need, increase transparency and strengthen the contractual relationship.

What about orphan drugs and this new framework agreement?

Regarding the EU5 countries, Austria, Belgium, and Ireland, for the eight countries in total, orphan drug expenditure experienced a compound annual growth rate (CAGR) of 16% and 14,1% in France; whereas total pharmaceutical expenditure experienced only 3% over the same period[8](2010-2017). To enable general patient access to orphan drugs under conditions that are acceptable to the companies and the national health insurance scheme, article 15 of the new framework

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agreement introduces two new ideas concerning orphan drug P&R: budgetary package and performance contract.

The budgetary package is the first element brought to the table. Indeed, the Committee may request that in return for accepting a price consistent with those applied internationally, companies marketing orphan drugs whose annual cost per patient exceeds €50,000 undertake to supply the medicine concerned to all patients eligible for treatment, and without restriction for a capped total revenue amount in the form of a fixed price[9]. The parties agreed to conduct a review to potentially change this provision, leading to the creation of an amendment within 6 months.

Second, a performance contract can be negotiated between the two parties. This contract defines the pricing of products where therapeutic benefit has been seen to vary within treated populations and if there exists the possibility of a quasi-exhaustive real-world measurement of performance given the limited number of patients[9]. This contract offers the option to renegotiate the conditions governing clawback payments when changes occur within the target population.

These new tools reflect a will to ensure faster reimbursement and access while considering the importance of health economics and the impact of orphan drugs on the budget. However, as innovation brings more and more high value products in the orphan drug area, health systems are more and more concerned about their ability to sustain the growing economic burden of orphan drugs.

Therefore, we believe that more and more sophisticated payment schemes will be tested and implemented by payers and pharma companies in the future, making the quality of framework agreements fundamental to the attractiveness of countries, and to the delays of patient access to innovation.

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