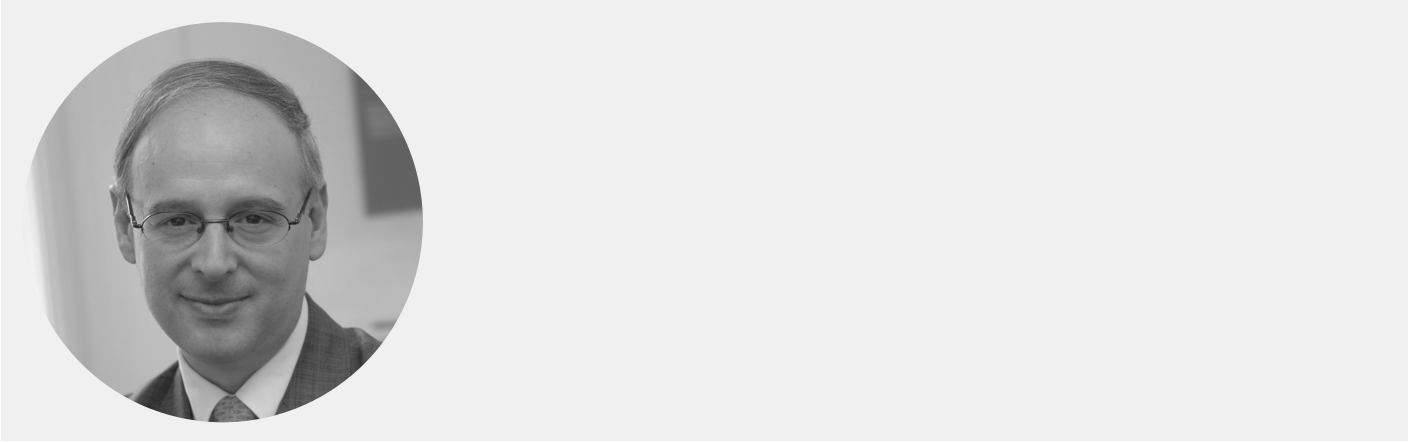
Interview: Dominique Giorgi – President, CEPS (Comité Economique des Produits de Santé), France



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The President of CEPS, the French pricing agency, reveals the issues around the launch of the hepatitis C drug Sovaldi in 2014 and of CEPS´ role to ensure that innovative products are available to all patients who are in need of them.

The Sovaldi case has focused public attention on the pricing of drugs in France. To what extent are such drugs a game-changer and what does it mean for pricing agencies around the world?

The price level at which the Hepatitis C product was set in 2014 led to a certain level of tension between CEPS and the pharmaceutical industry. Many people, including patients' associations and public institutions, had the feeling that the price demanded for such a drug was unacceptably high. At CEPS we have managed to ensure that such innovative products are available to all patients who are in need of them. Through negotiations, we obtained a considerable discount from Gilead Sciences for its hepatitis C virus product Sovaldi, obtaining a lower price for this product than the four other most established pharmaceutical markets in Europe (Germany, the UK, Spain and Italy). CEPS agreed a price of EUR 13,667 (USD 15,358.70) per 28-tablet pack, around EUR 5,000 (USD 5,620) lower than the initial list price, as well as rebates on the drug's cost in cases of treatment failure and performance. But this is not sufficient. For the first time, we had a product that per unit was very expensive, comparable to products treating cancer and rare diseases. Except that

hepatitis C is not a rare disease. There are almost 300,000 people in France in need of this treatment. Beyond these negotiations, we therefore had to put in place a system to lower the overall expenses for such medicines, to maintain our budget for 2015. We had to use a new framework and this has been very useful not just for limiting expenses, but also as a means of putting pressure on the industry, and allowing us to successfully negotiate with them.

Is the public ready to accept the cost of such products? What can be done to better explain the need for such drugs and how they ultimately benefit the community?

I think we are already at the limit of the public's comprehension regarding this issue. The public is very accepting and understanding of the high costs of medicines for conditions that are very rare, where only a handful of patients are affected, and the burden on public health is still comparatively light. The problem is when the cost of a drug is very expensive and the overall expenditure is also very high. This is much more difficult to understand.

The fundamental questions the public wants to ask are simple: how do pharmaceutical companies define their pricing policies? Is it through the costs of production, the costs of research, or supply chain and logistics? How are such costs calculated? For us to maintain this delicate balance between the public benefit and pharmaceutical profits, there cannot be a company that sets prices that are much higher than the norm.

You have been heading the institution for three years now. How has CEPS changed over this period of time?

CEPS has had to work within the overall environment in France of trying to balance the books and returning our finances to order. This is something which is now felt much stronger than it was three years ago. When I first arrived, CEPS was making EUR 450 million (USD 480 million) in price savings per year, now we are making EUR 1 billion (USD 1.12 billion) in terms of price saving. This shows the necessity of us having to continue to maintain our effectiveness in reducing our overall expenses.

We have also been focused on updating and adapting our price negotiation measures for new drugs, to renew our strategies and tactics. A clause regarding price and volume is common across many countries, but we have also implemented a new clause based on the performance of products where we can determine the efficiency of the drug. With the participation of industry, we can follow the performance of a drug. Such a measure can only be applied to certain molecules, and the process of conducting a performance review is very complicated. There are two types of contracts that we use. First, a contract that follows drug performance individually, for an illness

that affects less than 1000 patients. This allows us to put them in a comprehensive registry, allowing us to track their individual progress. The second type is based on sampling our target populations, which also works very well. In both cases, we must determine the criteria by which we will judge the efficiency of the molecule. Finally, we require studies of efficiency, which inform our price negotiations, and an important component is how innovative a product is compared to existing drugs.

What are the major strengths of French drugs pricing policy?

A major strength of our system is the use of ATUs (Temporary Authorisations for Use) allowing us to successfully provide patients with access to the latest innovative and experimental drugs that they require and which may not yet be commercially available. The criteria for receiving an ATU are very clear, especially to the industry. They know that the therapeutic value of the drug is a key criterion for application under this legislation, in addition to other issues like adhering to the conditions restricting the use of such experimental drugs. It places a very strong emphasis on therapeutic value.

In October 2014 LEEM (The French Pharmaceutical Companies Association) and CEPS signed a charter for the promotion of drugs (La nouvelle charte de la promotion du médicament.) Can you tell us about the idea behind this initiative?

CEPS is not solely a price negotiator, we are not just a means to achieve savings. We are also an instrument for the promotion of the good usage of drugs. We are involved in product negotiations with the pharma industry regarding sales volume. We are motivated by principles of public health economics but also the principles of public health itself.

We have updated the charter for the promotion of drugs to apply to all public health professionals, not just medical practitioners and doctors. The latter are a significant group but this initiative also includes other players such as nurses, midwives and pharmacists. Our aim is to update the areas to which this charter applies including both generalists and specialists, as well as hospitals. Increasingly the promotion of public health, especially prescriptions products, takes place within hospitals.

We have created a national watchdog organization to raise awareness of and promote public health and pharmaceutical initiatives. This is based on a survey we conduct with both hospitals and practitioners with regards to how pharmaceutical products are prescribed. We will have the right to ask companies to adjust their prescription levels if need be. For the moment, we have not yet utilized this function. We are still waiting for the final results of this enquiry, which we should have

by the end of this year.

For years people have been talking about individualized healthcare, with more expensive and more effective drugs. How is CEPS adapting to this changing environment?

There is a tendency to target, very narrow, specific genetic mutations using genetic therapy in order to tailor healthcare to the individual. This has been applied especially to rare drugs, which often results in very expensive therapies. For us, the goal is to avoid the inflation of prices in the face of this tendency; to focus on very specific, narrow therapies, and to urge companies to reflect on the cost-effectiveness of these therapeutic solutions.

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