Maurice-Pierre Planel – President, CEPS, France

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Maurice-Pierre Planel, president of the CEPS (Comité économique des produits de santé), details how the French government is unique in the way that they engage in drug pricing and comments on how the transformation of the French healthcare system will impact the CEPS's role in price negotiation.

You are often juxtaposing the utilitarian Anglo-Saxon model of drug pricing with the more universal French model. Can you tell us more about this comparison for our international audience?

This is quite a complicated matter. Many actors are under the "charm" of the Anglo-Saxon system. It has a certain mechanical rationality to it that renders it attractive. The system is primarily founded on the criteria of reimbursement.

France, on the other hand, focuses on price-setting, and it entails a completely different logic. It is hard for the French people to explain to the British people, the use of cost-effectiveness studies in France. I think the variation comes from a philosophical difference in our attitudes in our respective society.

In Britain, the utilitarian mindset catalyzes fewer revolts and less citizen outrage than in France. If a treatment or a drug is priced too high, and some can't get access to it, you don't really see the outrage that you would see in France. In France, if there was a treatment to which the population

cannot have access, you would see protests. Take, as an example, the rhetoric of the committee called Ethique et Cancer, who said that the access to medicine is a human right. So, you could say that there are both technical differences (i.e. the unique way that France uses “cost-effectiveness”) and philosophical differences that distinguish the Anglo-Saxon and French approaches to healthcare and drug pricing.

Additionally, one example of how we differ: the British use the QALY (quality-adjusted life year) metric to measure a drug’s value. It essentially allows regulators to measure the level of “quality life” given to a person by a treatment. Let us take Hepatitis C as an example: when discussing Hepatitis C treatment reimbursement, the British do not go about it as do the French. Naturally, when a treatment is publically reimbursed, it has a budgetary impact; yet, the British do not take that into account as the chief factor when reimbursing a treatment. Rather, they evaluate the QALY and decide to reimburse primarily according to that metric.

What do you consider as the strengths of the French pricing system?

I would say that the French system really helps society to avoid excessive prices for healthcare products. While there is some debate over the level of subsidization that should occur when purchasing certain treatments, nobody argues that there should not be fixed prices. Nobody wants to have the German system of purchasing, where companies fix their own prices for the first year of commercialisation. In France, the price is fixed beforehand.

Recently, it was announced that Alain-Michel Cerreti from France Assos Santé will join the board of the CEPS. How revolutionary will the patient participation in drug pricing negotiation be, and how difficult is it to incorporate the patient into the process?

I am in favour of the patient participation into the pricing process. Patients already have substantial roles at the HAS (Haute Autorité de Santé) and at the ANSM (Agence Nationale de Sécurité du Médicament et des Produits de Santé). At the ANSM, patient associations can provide their inputs to the agency through an interface committee and working group designed for. At the HAS, consumers participate in various commissions, such as the transparency commission (CT), the medical device and health technology evaluation committee (CNEDIMTS), etc. There is not at the moment a consumer representative in the CEPS.

Why aren’t they present in the CEPS? In 2016, it was decided that patients had the right to be admitted in the organization like they are in the HAS. They will be integrated, and they will have an impact on the CEPS decisions. I do not think, however, that this will solve all of the problems. Firstly, there are practical problems to solve, meaning for example that the consumer organizations have to find somebody to represent them. But, politically, I am not sure that it will solve all of the problems that the French society has with drug pricing and transparency.

Besides having patients represented, what are the other changes that you have overseen in your three years at the helm of the CEPS?

There are two that are noteworthy. The first has to do with the pharmaceutical innovations that came on the market. In the past couple of years, there have been innovative treatments that have become available to patients – yet they are very expensive. One great thing that the French healthcare system has done is to bring these treatments to the French people, and the CEPS has managed to greatly lower the prices.

Second, I would say that the role of the president of the CEPS has changed. It is no longer a position that simply outlines procedures to follow. Now, the CEPS takes into account the motivations of the companies and collects more supporting information for each product; we have revamped our methods for collecting information. We used to be only a procedural committee but now we changed into an entity that has deeper actions.

The rhythm of innovation in the healthcare industry is arguably at an all-time high. How is the CEPS planning to keep pace with all of the (often expensive) innovations that are emerging in the field?

While it is true that in the five or ten coming years there will be a number of innovative medicines that will change the drug market, it is important to remember that there is a separation between the thoughts of public and private entities. Today, we have two of such groundbreaking innovations: Novartis’s Kymriah and Gilead’s Yescarta, neither of which has been accessed by the HAS yet.

The broad challenge, though, for the CEPS will be the prices of such innovative medicines. But in the case of Kymriah or Yescarta, there are concerning a target population of 100 patients, which is quite a few compared to other therapeutic areas. Even if the CEPS agrees to the current prices

announced by Novartis and Gilead, it will represent ‘only’ a part of our overall health budget. I suppose the challenges will manifest according to how the market evolves: if Novartis or Gilead are able to remain the only actors in the market with such treatments, then the cost will be high. We saw this with Hepatitis C treatments a few years ago. But, if others companies are able to create competiting treatments, then the prices will lower, and the job of the CEPS will be easier. But until that happens, the challenge is in how to evaluate new drugs like CAR-T cells; the treatment seems to be incredibly effective for children, but not for adults. The HAS will have to establish their value. From there, the challenge will be pricing the drug until competitors enter the market – how can we find a sustainable price when there is a temporary monopoly over a certain treatment? It is very difficult.

Another challenge is the epidemiological shift that occurs with medical improvements. For example, in oncology, we used to spend a consequent amount of money on treatments that extend a patient’s lifetime for several months. But now, treatments have improved and cancer became a chronic (not fatal) disease. While this is excellent for patients, obviously, it creates economic challenges – the expensive treatments are now delivered for a longer period, creating a hefty expense. The prices of these treatments will need to be lowered in such cases. It is a tough challenge to tackle.

How is the CEPS preparing itself to adopt big data and artificial intelligence?

We are in a particular position because our sources of information are gathered from the outsides systems. We obtain information from, for example, the HAS and the medico-administrative databases. I think that new big data technologies would help to find a better way to monitor medical advancements/progress in a more systematic way.

As far as big data and AI are concerned, I think that implementing a system that sifts through decades-worth of data and can prepare reports is the absolute dream for our department. Unfortunately, I fear that such an innovation will not come around until I will be retired.

While multinationals, and even some startups, can use AI technologies already, it is much more difficult to apply such technologies to the healthcare sector and even more in the pricing process for healthcare products. There is no reason that AI technologies will not be able to help us more efficiently to analyze a dossier in the future, but for now, we operate with more modest systems.

How will the 8th edition of the Strategic Council of Health Industries (CSIS) and President Macron's recently unveiled healthcare plan impact the CEPS and your goals as its President?

First, I think it is important to distinguish between two things: what the President said recently to the public, and the corresponding announcements that are integrated within the government organizations.

The President wants a change in the healthcare system and in access to healthcare more generally. He wants better coordination between the hospitals and facilities and better care for patients. That, in and of itself, will not have a direct impact on the CEPS and the prices of medicines. But, what these announcements will do is cause changes in the innovation of science and therapy. After all, a changed healthcare ecosystem will require a change in healthcare products system, which is where the CEPS will be impacted.

So, President Macron's plans will have an indirect impact on the CEPS, as they will undoubtedly cause a shift in the way that medical products, therapies and treatments are designed. For example, in the field of chemical medical production, there are increasing oncological treatments that are designed for homecare and not for hospital care. Now, while this may be favourable in many aspects, it will also come with other problems; people may try to stop their own treatment or may misuse these drugs, as there is no nurse at their bedside like there would be at hospital. Thus, it will become necessary to have somebody at the household present that can help patients receive treatment. There will eventually be a moment where the subject of organizational shifts in the healthcare sector and that of surrounding medical products will cross each other.

The CSIS is a different conversation. This meeting was held to increase the attractiveness for France in healthcare industry. Here, stakeholders met to strengthen the industry of health sector, often digging into the purely technocratic matters with which these actors grapple. For example, they discuss taxes and they discuss IT systems and data, etc. The overall goal of the CSIS is to discuss the economics and business side of healthcare.

In conclusion, would you like to share with our audience your vision for the CEPS?

That is a complicated question because the CEPS is bound to undergo unpredictable changes as we enter in the era of patient participation in healthcare regulation. Moreover, as the healthcare system changes in favour of ambulatory treatments rather than hospital treatments, the role of the CEPS will change too. The former model of purchasing treatments and medicines for hospital use

will become less pertinent, whether this change will happen within 18 months or ten years. What will be the role of the pricing committee then, when the majority of medicines will be delivered through outpatient procedures? Only time will tell.

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