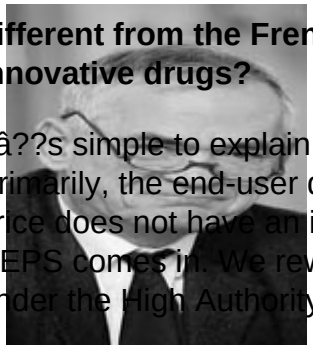
Interview with NoÃ«l Renaudin, President, ComitÃ© Economique des Produits de SantÃ© â?? CEPS

04.11.2009



e its innovative drugs based on a market approach which is very different from the French system. Could you explain how the French model rewards innovative drugs?

Itâ??s simple to explain as the market place doesnâ??t work for drugs for quite serious reasons. Primarily, the end-user does not have to pay in our market, so logically when you do not have to pay price does not have an influence. Somebody must interfere in a situation like this which is where CEPS comes in. We reward innovation by pricing through assessment that has been centralized under the High Authority for Health (HAS).

When a drug looks to come to market, the company who produces it asks for an evaluation from the commission. There are three criteria in this discovery process, the first of which is satisfaction of medical demand in the market and is established by SMR. Secondly, the improvement of medical benefit is examined by ASMR and clarifies the added benefit of the innovation against options already available. The grades for this level range from I-V where I means significant step forward for medicine and V indicates no improvement. Lastly, the distinguishing characteristics and size of the target population are examined.

Thus for innovations that are considered to be important enough we accept to pay what we refer to as the â??European priceâ?? so that the developer is appropriately rewarded. The discussion in this scenario is not necessarily about the price as it lies within the European standard but rather the volumes and conditions. If the new drug does not offer anything interesting in comparison to those already on the market, then we should have to pay less. Astonishingly, almost no country in the world follows this approach for pharmaceuticals despite the fact that when you typically bring something to market that is no better than the current offering you can demand a lower price. The US market is a great example for this phenomenon.

CEPS believes the best approach is to reward innovation through merit rather than allowing money to go indifferently to whatever drug comes to market.

When the ASMR model launched, health technology assessment models were highly innovative. Only recently has the US put money towards developing a similar system after years of depending on a market approach. How does this facilitate the pace of drugs from development to market?

We donâ??t want drugs to come to market quicker. In France, for the most innovative drugs there is a Temporary Authorised Use (ATU) system which allows for the use of these drugs in hospitals even before registration and is free to the developer of the drug. Thus, all the new drugs and technology

are available in hospitals. On the other hand, we are of the opinion that it is worth the assessment time before outpatient use. This allows for an examination into whether it deserves an innovative price or not.

As a result, the process takes six to seven months which can be perceived as a long time to market. As a result, the first patient may not have it as quickly as in the UK or the US, but the offering is more equitable with the French approach because from the moment one outpatient can receive it, everyone can.

The price registration model which allows innovations with high ASMR ratings to come to market was established in 2003 and liberalized in 2006. What effect has this had on the industry?

This procedure exists but is not frequently used in practice. Companies are allowed to give us their price and commit to conditions, like volumes according to target populations as well as commitment to paying back reimbursement in the event they overshoot these estimates. In a situation where the criteria are met, CEPS will accept the price quickly. However, this procedure is only available after the assessment period as the Transparency Commission needs to conclude the SMR, ASMR and population research which can take three to four months. Of course, our opinion is that this is time well used.

It is the intention that CEPS set prices based on the conclusions and findings of the Transparency Commission. Yet several research bodies such as IRDES have found discrepancies between the suggestions and actual pricing. What is your stance on this assessment?

I cannot think of a situation where we did not determine a price to be below the innovation level of ASMR. However, it is quite frequent that CEPS will consider a drug innovative when the Transparency Commission will have found it not to be. Regularly, there is a discrepancy in opinion on anti-epileptic and diabetes drugs because it is very difficult to show innovation in these fields. This is due to the fact that one drug is rarely better than another but altogether different so it is CEPS opinion that in order to stimulate the creation of alternative drugs in these fields we need to pay at an innovative level for drugs for drugs that do not meet higher ASMR requirements. In diabetes this is especially difficult because the gold standard treatment for type-II diabetes is Metformin which is now a generic. Therefore itâ??s impossible to price a new drug at a level cheaper than Metformin so we accept an innovative price level.

You are a very strong proponent of the generic market and recently noted the importance of setting up the French market carefully as the UK market-based approach has led to chaos in this field. What are you doing to establish a solid market and ensure generic companies are here in the long run?

If the world marketplace worked as the UK marketplace then there would be no more generic companies because they donâ??t earn money in that market. France wants a responsible market where we know the generic companies and where they make their drugs.

I often resist many comments from many people who say our generics are too expensive when compared to the global market. I prefer to let generic companies actually receive some money for their work because if they find business to be too difficult here they will all acquire their product from China or India which is exactly what I donâ??t want. I prefer to see European companiesâ?? products or the US for that matter but we typically donâ??t buy their products as it is too expensive.

Several groups, such as AGIPHARM, the association of American pharma companies in France, have noted the end of the blockbuster drug model as many patents come to expiry. The outlook is for a more individualized treatment market with more expensive yet more effective drugs. How is CEPS preparing for this changing landscape?

We donâ??t prepare. If I had prepared myself ten years ago when everyone was convinced it was the era of biotechnology and that chemicals were over then all of the personalized medicines would have been wrong. The transition has a long way to come and it will be gradual with one drug followed by another. So there will be time to measure the importance of the change in the marketplace.

What I am sure of is that there will be a diversification of the business model. Currently, big multinational companies understand they have to change but they donâ??t know exactly what they want. I cannot say any better than they can which way to orient development so we will have to wait and see what the players make of it. It is one thing to know the model is changing but entirely another to know what the future will bring.

See more interviews