Philippe Lamoureux – Director, LEEM, France

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Philippe Lamoureux, director of LEEM, the pharmaceutical industry's association in France, reflects on the winds of change in the sector after the establishment of the Macron government, the 2018 Strategic Council of Health Industries (CSIS) and new pro-industry measures.

The July 2018 Strategic Council of Health Industries (CSIS) seems to have set a new tone, compared to the previous editions. Do you think CSIS 2018 will be a game changer?

Together with the 2005 and the 2009 editions, this was probably the most important CSIS. President Macron is very different from any other president we have had before. He is pro-business, an attitude that was no doubt shaped by his experience as a Minister of Industry and in investment banking. Hence, he considers pharma as an opportunity for the French economy, not only for attracting industry that may be scared off by Brexit but also due to the overall unstable political situation throughout Europe. This is what he affirmed at the CSIS and at the dinner, he hosted at the Elysée Palace on 9th July with the top 30 CEOs worldwide. He has a clear vision of our sector and of the weaknesses of the French system.

During the CSIS we tackled three keys issues. First, we decided to clarify and simplify the rules of economic regulation of the French system. Second, we focused on reducing time to market access. As you probably know, time to market in France is about 530 days, while the European directive prescribes a period of no more than 180 days for reimbursement and pricing decisions. Of course, in France, we have an Early Access Program – the ATU System (Autorisations temporaires

d’utilisation) – but this mechanism only covers around 10% of the patients clinically eligible for the drug, and is not designed to take into account the whole target population. President Macron’s aim is to decrease the time to market to the 180-day period before the end of his mandate. Third, the CSIS aimed, on one hand, to facilitate clinical trial approval by creating a more favourable environment, and on the other to reform the evaluation system by introducing more simplicity and predictability. The administration promises to completely reform the HTA (Health Technologies Assessment) system before the end of 2019.

The government has shown that it has a sharp sense of the challenges facing pharma, of the need to modernize production facilities, as well as the need to attract the production of new molecules to France.

Do you think this time the CSIS discussion will be followed by action?

We are walking a tightrope. The financial bill of October will be the true acid test: we expect this text to translate the commitments made during the CSIS. Furthermore, we also hope that the financial pressure applied by the government on pharma, mainly through price cuts, which was particularly excessive with the former government, to be lighter. In a nutshell, we call for coherence between the ambitions of the CSIS and the level of the economic regulation. A veritable “Révolution française”!

This ambitious strategy of the French government is built on clarity, room for innovation, easy market access, and predictability and visibility of the French evaluation system. However, President Macron will have to take into account that the fundamentals of the French economy remain the same, especially in terms of public debt and sluggish growth. Therefore, high ambitions of access to innovation are likely to put more pressure on the pricing of mature products. To sum up, CSIS 2018 was amazing, and we are now waiting for clear signals to be given in the financial bill. This remains to be seen in the coming weeks.

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How would you describe the perception of your member companies?

Most of our members show a keen interest in the commitments made by the government but are cautious at the same time. The plan is good. It all depends now on its execution. However, there is insufficient trust, stemming from experience with previous governments where we have seen that

France sometimes fails to keep all its promises. Rebuilding trust between the State and companies is a key issue. What really impressed the CEOs this year is that President Macron invited them back to the Elysée next year to measure progress and achievements. This is a real breakthrough compared to previous governments.

What is the position of the LEEM and its members towards Brexit, and how can this be an opportunity for the French pharmaceutical industry?

I would say that Brexit is more of a concern than an opportunity. One of the biggest issues in Europe today is drug shortages and Brexit could weaken the supply chain over the whole continent. Basically, drug production takes place at a European level with no barriers: for example, a product might be manufactured in one European country, released in another, packaged in yet another and commercialized throughout Europe. Thus, re-introducing barriers will threaten drug supply on both sides of the Channel. Unfortunately, health is not considered a top issue in the Brexit negotiations today, although it should be.

However, it could also be an opportunity for France to attract more production and investment in R&D. Luckily, we have assets and the government has recently started to make the right decisions: increasing the human resource capacity of the French drug agency to capture more European evaluation dossiers after Brexit. We have excellent public research, well-performing public hospitals, and we are currently simplifying the clinical trial process. Another asset is our political stability, now a rare trait in Europe. The only remaining weakness is access, which is why reducing time to market, as I mentioned earlier, is crucial. Market access visibility is a fundamental condition for clear decision making about investments. Once this aspect is improved, we will be in an excellent position to take leadership in the fields in which France excels, for example, cell & gene therapy, and oncology.

The pharma market in France has remained stable in recent years, with no significant growth or recession. What have been the key trends from 2015 to 2018?

The market is indeed stable, as you said. However, to date, innovation has been financed without increasing the drug expenditure budget. This means that the Health Authorities have put intense pressure on the price of mature products as well as on the development of generic medicines. Furthermore, the volume of drug consumption is decreasing slowly but steadily.

Up to this year, the hospital market has been dynamic as innovative products are first dispensed in a hospital setting. This year has seen a change in dynamics with a decrease in hospital drug expenditure due to the fact that some innovative products are now available in retail pharmacists. This is the case, for example, for the Hep C drugs. The change in the rules of economic regulation that we obtained with the CSIS 2018 is very important as, up to now, each of the envelopes (hospital and retail) were financially separate. This implied that even if you over-performed in savings with one envelope, you might still have been eligible for paybacks by poor performance with the other envelope. From now on, there will be one single envelope for the two markets.

Boehringer Ingelheim is going to open an R&D centre in Lyon, and Novartis will produce CAR-T therapies starting next year in Les Ulis (South of Paris). What major changes in the R&D environment have you witnessed in the past year?

The three main developments in pharma today are the shift from traditional chemistry to biotech, the use of a mixed therapeutic approach (where the drug is just part of a global health solution involving other technologies such as diagnostics or medtech), and the shift from product to service (for example, we are not only selling drugs but also associated services like compliance programs and health education). Collectively, with the switch from a traditional chemical industry to biotech, we are actively developing and promoting new skills and competencies. This was also one of the key issues discussed during the CSIS. The industry has been stable over the past years with a workforce of 100,000 people and a turnover of around 9,000 people per year. On one hand, we are expanding our recruitment policy to bring on board new competencies, and on the other, we are re-training certain populations in the current workforce to convert them to the new version of pharma. We are also developing more and more young people in co-op programs as well as developing some training programs in artificial intelligence. Furthermore, the government made clear during the CSIS its ambition to promote France as a leader in clinical trials. Consequently, an important reform is currently underway to deliver Clinical research approvals within 45 days.

There was discussion at the CSIS about creating a Health Data hub, which would be the first of its kind in the world. What is your view on this?

The public health system in France has developed the largest healthcare database in the world, covering the whole population. We are currently working with the authorities to allow the pharmaceutical industry to have access to the data within a clearly defined framework. On their

side, the pharma industry will be able to feed their own data into the database thus adding to its value. I believe that we can make France a worldwide leader in the field of pharmacoepidemiology and in real-life studies.

Would you like to offer some concluding statements to our international readers?

The present government has just announced a highly ambitious reform. This reform is crucial to modernize our health system and relies on the development of prevention as well as better articulation between hospital- and office-based healthcare. Consequently, the French system should become more efficient. This is a key challenge for our industry as only a profound transformation of our healthcare system will generate enough flexibility to embrace innovation and to stop using medicines as an adjustment variable to balance the healthcare budget. Last July, the government expressed willingness for renewed dialogue and implemented important and concrete reforms. Nevertheless, we still have key issues to tackle, particularly market access delays and sluggish growth. Everything now relies on the implementation.

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