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When we last met three years ago, one of your objectives was that ^{à??}one out of every two boxes^{à??} of medicines in France would be from a generic brand. That is unfortunately not the case ^{à??} yet. France still has a lower-than-average generic penetration rate (36%) and in 2017, the generic market even entered a recession. What has happened over the last few years, and why do we see a recession in the generics market?

Three years ago, we were seeing positive indicators that suggested the generics market was on the rise. Economic reports and industrial/political announcements were ambitious in promoting generics and biosimilars. The problem that we have had is an unprecedented drop in price over the past couple of years. This drop has weakened the economic standing of our member companies and other manufacturers. All the while, the costs that go into the manufacturing process, such as quality

controls and other regulatory procedures, have risen. This combination of rising costs and falling prices has been extremely hard for our industry and created this recession. Our members are struggling to revive their previous volumes of output.

What is your top priority in facing these challenges?

The top priority of generics, as a field, is to create further substitutions of innovators products with generics. The GEMME companies want to continue working with pharmacists and physicians in creating viable substitutes for society's most important drugs. But the pharmacists and us cannot revive the industry alone. We need to find a way to strengthen the trust of doctors and patients. We wish that doctors will play a more important role in the development of generic medicines and in the education of patients in the future.

What does the GEMME do to improve the communication between care providers and patients?

In France, as I am sure you have heard, the health care industry has an image problem. People are naturally distrustful of the pharmaceutical sector and the health care branches of the government. This is most likely due to a lack of patient education on healthcare matters. In France, we do not have an effective way of communicating to the public. They resort to researching medical issues themselves and conjuring up false notions. We must, as a country, improve education about health, the healthcare system and medicines.

This problem is being addressed, though. There has been a government-backed campaign to educate the society about generic drugs, and it has been a source of optimism for our industry. The campaign is supported by ANSM (Agence Nationale de Sécurité Medicament et des Produits de Santé), the Assurance Maladie (health insurance) and the Collège de la Médecine Générale. It is good that these organizations are supporting our message, as their involvement will signal quality. If we had to try and improve communications alone, the messages would be less impacting.

Alongside the CNAM (Caisse Nationale de l'Assurance Maladie), the Social Security, and media outlets like yours, it is important to spread messages about public health and drugs/medicines. It is also important to reiterate the message, over and over again. There was one public awareness campaign that had the slogan, "Les antibiotiques, c'est pas automatique" (Antibiotics are not an automatic fix). The campaign was founded to prevent the overconsumption of antibiotics, and it was very effective. People started to remember and think about the slogan, and it spread. We need more efforts like this, but for generics, and we need to constantly repeat the message that an increase in generics is in everybody's interest. While innovative researchers are turning more and more to biology for innovative drugs, let us not forget that, thankfully, *not everyone* needs CAR-T or Sovaldi; for now and for the foreseeable future, the majority of drugs consumed will be chemically made and for rather common ailments. Generic drugs are exceptionally valuable when this is taken into account - we can affordably produce quality drugs that provide treatment for many illnesses, freeing others up for intense R&D. The public needs to understand the value of the generics industry.

Stéphane Joly, the newly elected president of GEMME, wants to bring the market share of generics to over 50% by mobilizing the actors that you have mentioned, notably patients. Moreover, the CEPS (Comité Économique des produits de santé), HAS (Haute Autorité de santé), and ANSM are now including patients in their governing boards. Would you say that there has been an evolution in France around patient centricity?

I think that you need to make a distinction between the citizens and actual patients when having this conversation. Patient representation and citizen representation in these organizations and in healthcare, in general, will not produce the same outcome, as patients do not see the issues from the same angle as someone from the general public.

That noted, I think it is nice to give the patients a seat at the table. They bring a fresh and important viewpoint to the issues. Their participation will improve the healthcare providers' services and will also make the patient associations more comfortable, as they will be included and will have ample opportunity to convey any of their messages. This transparency and openness should quell the public's distrust of the healthcare sector.

What are the GEMME's top strategic priorities for the foreseeable future?

We have two. The first is to try and preserve the value of our product (by reversing the price drop and/or reducing regulatory costs). The average price of a box of generic medicine in France is EUR 3.50, which is particularly low! If we don't fix this price problem, we will risk the quality of production in our labs. The second priority that we have is to restore our output volume – it is as straightforward as that.

Everyone has been speaking about biosimilars for years and years, and only last year did they make it to the market in Europe. What has been the impact of the arrival of biosimilars in France?

It may be too early to tell. While the first biosimilars arrived on the market in 2006, several major products were commercialized only last year, so we do not quite know what we are dealing with yet. There are some innovative drugs that are advancing through the EMA approval processes, but they are not yet on the market.

Right now, we need to design and implement a framework for the installation of biosimilars that includes all actors in the healthcare ecosystem, and we need to start educating the public. If you explain the quality, value and benefits of biosimilars, you will not find too many people that oppose their arrival.

We also have to closely work with doctors, pharmacists and hospital staff. Everyone should come together and adopt a productive model to help introduce biosimilars to the market. Moreover, the CEPS (France's pricing agency) needs to ensure that we have an economically viable environment for biosimilar labs in France.

Drug shortages are a rising problem in France. Yves Lépine from G5 Santé and others have said that this poses a potential medical crisis in France, as the country is at risk of losing its health independence. What role do the generics producers have in

ameliorating this problem?

The French generics industry greatly helps abate this problem, as over fifty percent of the generics consumed in France were also produced in France. This is done through many sub-contractors and CDMOs that used to work with the innovators' laboratories. As research-driven companies have sold several of their plants in France to CDMOs, the latter were able to capture generics production, hence why now, in our membership base, we have several contract manufacturers.

So, French production is very important to the generic companies in GEMME. For us, health independence is very important as well. Health independence isn't only important insofar as innovation is concerned, but also for the sake of practicality in treating common illnesses. We are also very committed to guaranteeing a sustainable future for our manufacturers.

If the prices fall too far, it is going to become complicated to stay in business. It will become too expensive to meet the regulatory standards of the day (serialization, environmental protection standards, etc.) with the prices as low as they are. And this is a shame because France has an incredible workforce, a history of pharmaceutical excellence, and an ideal infrastructure for this type of business. Unfortunately, several companies have recently not chosen to set up shop in France, going instead to more competitive areas.

What are your thoughts on the July 2018 Strategic Council of Health Industries (CSIS)? Did it reflect the needs of the generics industry in France?

The CSIS was supposed to be focused on innovation and industry however, there was a much larger emphasis on innovation than on industry. There are not too many industrial reforms, particularly concerning manufacturing. Don't get me wrong there are some good measures in the CSIS that we supported as well, like reducing delays for regulatory approval. However, I did not see any special policies directed towards the generics industry. It would have been nice to hear about policy initiatives aimed at solving problems that hurt us the most, like the falling prices of generics.

Would you like to offer any concluding thoughts?

The French generics sector is halfway there, I would say. We have 36% of the market share in volume, but the last step ahead of us before we reach a more sustainable level of development comparable to other European countries such as Germany is attainable and would generate savings beneficial for the sustainability of the healthcare system. Overall, we need to increase the education of the public through advocacy and engage all actors in the medical ecosystem in order to gain a larger foothold in the market.

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