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Access To Innovation Looking Brighter In France

by Ian Schofield

French Biotech In Focus: The French biotech industry body France Biotech says that the authorities are making good progress in reducing the time taken to get new medicines on the market, but that low drug prices and high industry taxes remain key challenges for the industry.

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Two key initiatives taken by the French government over the past couple of years are helping to improve patients' access to innovative drugs, says the biotech industry's representative body, France Biotech.

These are a reform of the temporary use authorization (ATU) process, and the ability for new products to be launched as soon as the health technology appraisal (HTA) has been carried out and before the pricing and reimbursement processes are complete.

"Clearly, what the government is trying to do is to speed up the access to innovation for patients and for health care professionals and at the same time help biotech companies in general to make their products available earlier," according to Frédéric Girard, vice-president of France Biotech. This is "also helping the financing of the companies, that is for sure," he said, adding that it also allowed data to be collected for "accessing the normal reimbursement process later."

The drug access initiatives are the result of provisions in two consecutive social security financing laws passed in December 2020 (LFSS 2021) and December 2021 (LFSS 2022).

The LFSS 2021 introduced the reform of the ATU system, which is intended to allow early access to medicines for patients with a severe or rare disease where there is a high unmet medical need.

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Under the reform, the health authorities have simplified the ATU program, reducing the existing six systems to two, Girard told the *Pink Sheet* at France Biotech's 25th anniversary event in Paris on 7 July.

These are an early access authorization program, or AAP, which includes the cohort ATU; and a compassionate access program, or AAC, which includes individual ATUs. The reform took effect in mid-2021. (Also see "*France Implements New Early Access Pathway For Innovative Medicines*" - Pink Sheet, 5 Jul, 2021.)

Manufacturers are now required to make all requests for AAPs to the HTA body, the Haute Autorité de Santé (HAS), rather than to the regulatory agency ANSM.

"At the same time, they are asking companies to collect real-life data, and they agree that those real-life data could be part of the health economic dossier for the HTA later in the process," Girard said.

'Direct Access'

The LFSS for 2022 introduced the concept of "direct access" for medicines, whereby certain products in a specific indication can benefit from health service reimbursement for up to a year as soon as the opinion of the HAS has been published.

According to an article by consultancy KPMG published in January this year, the objective of this measure is to "provide patients and manufacturers with early market access compared to the normal 180 days, and to ensure a junction with the common law in the event of an exceptionally long negotiation period."

This system, which complements the early access set up by the LFSS 2021, has a wider scope than the early access scheme and mainly targets medicines that would not be eligible for this scheme.

To benefit from direct access, the company needs to file an application with the health and social security ministers no later than a month after the HAS has given its opinion on the inclusion of a product on one of the lists of reimbursed medicines.

According to this system, "under certain conditions, after the health economic assessment, you will be able commercialize your product with a free price and reimbursement, in parallel to the price negotiation," Girard said.

"And this is super important because the old process of market access after registration in France or drugs is around 520 days – one of the slowest in Europe. This is normally six months of HTA and the rest is price negotiation, so by allowing the company to commercialize right after the HTA, you save almost a year for the patient to access the innovation."

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Pricing And Reimbursement

Girard noted that the reimbursement level for a drug currently depends on the rating applied to it following the HTA, and that the French ratings are "on average lower, therefore this is leading to lower prices."

Over the last 20-30 years, French price levels have been sinking. Prices were not premium, Girard observed, but "it was quite a good price mark and it is becoming one of the lowest in Europe."

One pricing avenue that is being explored in France relates to costly gene therapies, which can cure serious and expensive-to-treat diseases with one administration. "You pay for one shot for a lifelong benefit. The question is, how do you book that in the government budget," he asked.

Under current regulations, the cost is booked as soon as the treatment is delivered, even though the benefits last well beyond that time. The French biotech industry is therefore discussing some sort of amortization of the cost of the gene therapy, for example splitting the expense over three or five years "which reflects in fact the reality of those treatments."

This would help matters because the health authorities have a strict spending envelope and if the budget is overspent, industry has to pay a special tax, Girard noted. "So this would certainly ease the access to innovation, gene therapy or cell therapy, if we had this system in place."

He also noted other novelties introduced by the LFSS 2022. One was the decision to allow the drug pricing committee to take domestic production into account when setting the prices of reimbursable medicines, which is intended to "support the independence of France in terms of strategic production."

Nonetheless, he said that there was still a long way to go in terms of drug price levels, "because we have lost that position we had in the past and we are now a market with quite low prices," which is "having an impact on the image of the country."

Tax And Operating Environment

Looking at the operating and tax environment for the French industry in general, Girard said it was "a bit of a mixed landscape."

France has one "unique benefit" in the form of the research credit, "whereby you can get some tax credit from every research investment you make in France. I think it doesn't exist anywhere, at least not a system of that magnitude," he said, noting that the system was not specific to the pharmaceutical industry and also applied to other industries. "You can just get a tax credit for research and development. So this is the positive side."

The negative side is that there are "something like 10 specific taxes on the pharma industry that

you'll find nowhere else in the world." He cited a report published at the end of May this year by consultancy PwC which "shows that the pharma industry in France is paying twice as much tax" as in other countries.

Updated with figures for 2021, the report, produced by PwC for the French pharma industry body Leem, said that France was again "in last place behind all other European countries in terms of its tax policy." France had the highest level of industry-specific taxation in Europe, "and this tax burden on pharmaceutical companies makes the country less appealing for inward manufacturing investment than its European neighbours," it declared.

Although the general taxation situation was improving in France, with reductions in corporation and manufacturing-related taxes, these changes still fell short of offsetting the heavy burden of specific taxation imposed on the pharmaceutical industry, "despite it having been identified as a strategically important crisis recovery sector," according to the report.

Still, Girard said that the authorities were "going in the right direction" with regard to improving the image of France in terms of market access. "Clearly, there have been very strong, very important changes in the French market over the last two years."

But he said the authorities needed to make sure they were keeping their promise and helping to improve access to innovative drugs. "Now we need to make sure this is working properly and, at the end of the day, make sure we have more innovation coming earlier to the market with a better price."