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1st Observatory to monitor access to medicines and attractiveness: France - far from optimum European standards

True to its word, Leem has set up the 1st Observatory to monitor access to medicines and attractiveness in France - an all-encompassing measurement tool entrusted to an external third party, leading management consultants, Roland Berger. France ranks as a mediocre European student based on the outcome of this initial exercise. Can France do better?

A mixed record. The observatory to monitor access to medicines and France attractiveness, set up by Leem following the 2023 Social Security Finance Act, has delivered its initial findings. The tool was designed with a dual objective in mind:

- To document potential lost opportunities of French patients in terms of availability and accessibility of medicines;
- To put into perspective the level of attractiveness of France compared to its European neighbours.

Three sources of information were compiled, namely public data, internal Leem studies and a survey involving pharmaceutical companies.

Accessibility and availability of medicines: France is lagging behind

On the one hand, significantly fewer new medicines are available in France compared to Germany, Italy or England. This is partly resulting from longer negotiating times and unfavourable economic conditions. At the end of 2022, 34% of medicines granted European marketing authorisation between 2018 and 2021 were not available in France. One-third of these were still at the assessment or negotiation stage.

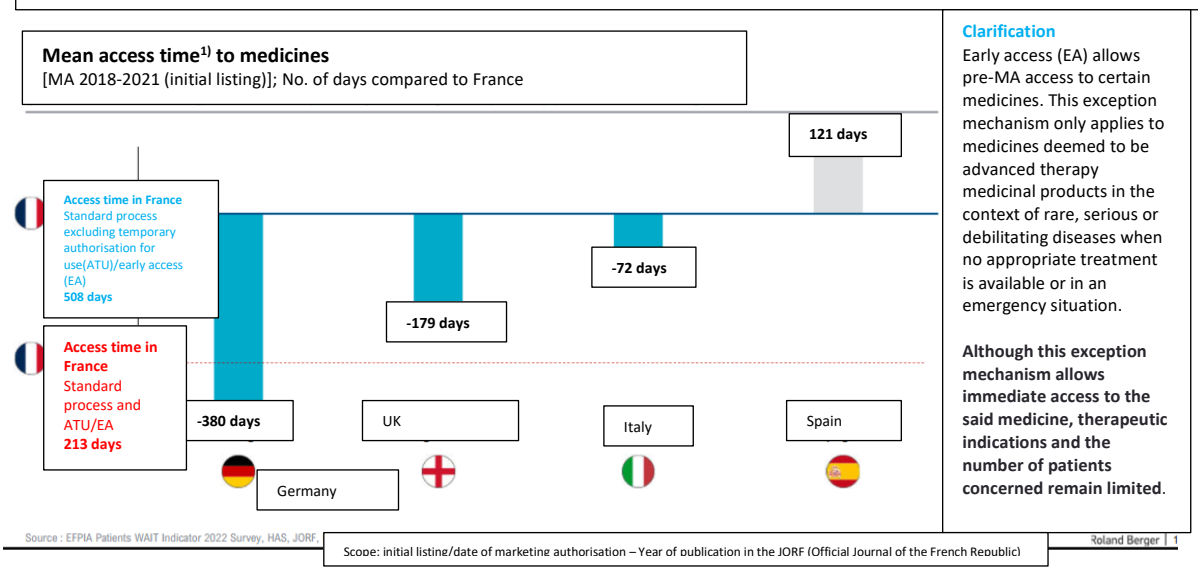
In addition, the time to market launch is still a very long way off the 180-day target set by the European Transparency Directive despite a notable improvement in assessment times by the French National Authority for Health (HAS). Except in emergency situations, German, English and Italian patients can access the medicines several months earlier than French patients.

Although the median time for file assessment by the HAS fell by 22 days between 2019 and 2022, the median time for negotiation with the CEPS (Economic Committee for Health Products) and publication in the Official Journal increased by 96 days over the same period. 13% of files that have received a marketing authorisation between 2017 and 2022 are still under negotiation or pending publication.

Under early access systems, initial patient access to medicines can be significantly fast-tracked prior to HAS assessment of the file and price negotiations. However, these mechanisms are intended for medicines that meet stringent criteria and for patients in the most critical situations.

On the other hand, common medicines have been in increasingly short supply in recent years, fuelling market competition in one-third of cases. The ANSM (French National Agency for Medicines and Health Products Safety) has recorded the withdrawal from sale of between 19 and 32 medicines every year in the last three years with a weakening financial balance being cited as the primary cause (60% in our survey).

The French early access procedure, which grants pre-MA access to certain medicines* for a limited number of patient populations, reduces the average access time in France by 295 days.



A regulatory and budgetary framework to be overhauled

The French pharmaceuticals market is a major economic sector. It is currently losing momentum on the international stage despite significant investments in production as well as research and development. France is being left behind by its European peers when it comes to the production of new medicines, especially originator biologics, generics and biosimilars. Only 48 of the new medicines granted authorisation between 2017 and 2022 are currently produced in France compared to 122 in Germany. Overall, France is exporting less and less of the mature medicines it produces and is importing more and more advanced therapy medicinal products that are under-produced on the home market.

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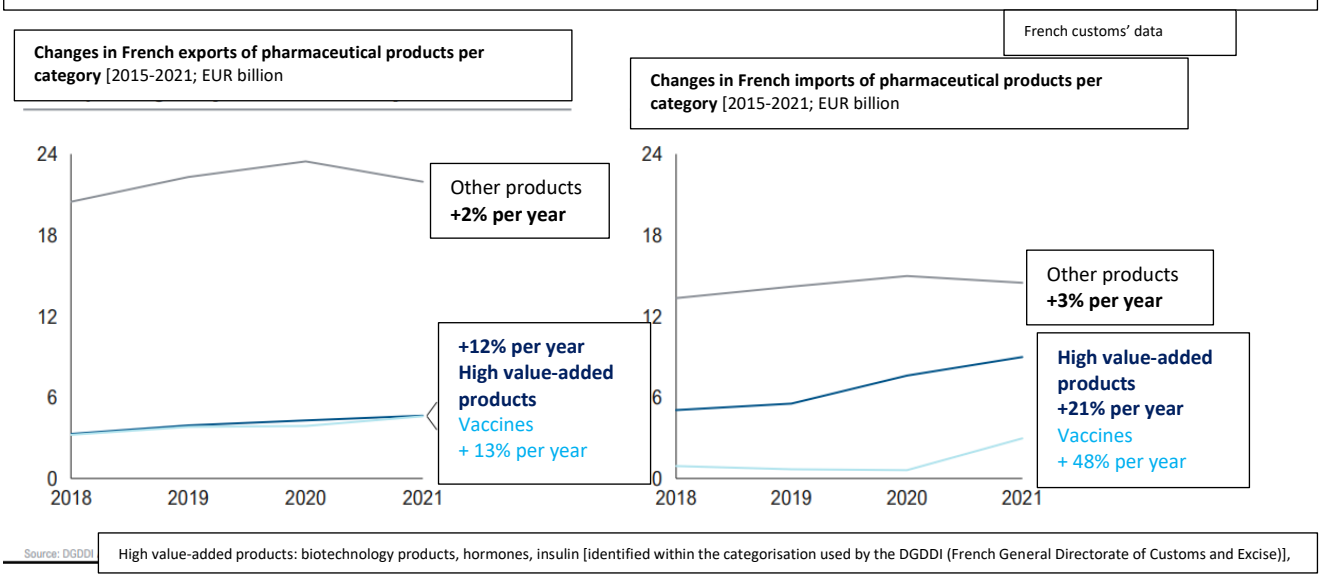

French manufacturers are voicing their fears, in particular because of the complexity and unpredictability of regulations and growing budgetary pressure. 64% of respondents to the Leem survey believe that R&D expenditure should remain stable in the future and 55% cite complex regulations as the main obstacle to their development.

In light of these results, France's assessment is clear-cut: “Average. Can do better". Admittedly, the country is not in a dire situation *per se*, but it all comes down to our ambitions. In 2021, when introducing the Healthcare 2030 Innovation Plan, the French President announced that his overriding ambition was to make France the leading European nation in terms of health innovation and sovereignty by 2030. But there is still a long way to go.

“This initial snapshot confirms that there is a ‘medicine emergency’ that we have to address if we want to make France the leading European nation in terms of health innovation and sovereignty, to echo the sentiments of the French President within the strategic framework, namely the ‘Health 2030 Innovation Plan,’” explains Leem President, Thierry Hulot*. “This is why we eagerly await the conclusions of the expert panel, commissioned by Prime Minister Elisabeth Borne, on the system for financing and regulating health products. And the budgetary decisions to be taken in the autumn as part of the PLFSS 2024 (Social Security Finance Bill) will have to be consistent with the ambitions outlined. The pharmaceutical companies will be extremely vigilant in this respect*”.

At this stage, the Observatory remains a snapshot at a given point in time. Future monitoring periods will highlight changes over time in terms of access to medicines and France's attractiveness. Going forward, the observatory will continuously evolve in a bid to incorporate new analytical methods as the data become available and the need for an objective overview arises.

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