

LIFE SCIENCES IS A HOT TOPIC WHEN IT COMES TO FOREIGN DIRECT INVESTMENT CONTROL IN FRANCE



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Did the life sciences field become a strategic sector for the control of foreign direct investment following the COVID-19 pandemic?

Sophie Pelé : It is not new for public health to fall under the scope of foreign direct investment control.

In France, foreign direct investment started to be controlled in 1966. The scope of this control was significantly expanded in 2014 and public health became part of the expanded scope. In part, this was a consequence of the previous H1N1 flu pandemic which took place four years earlier.

France controls direct investments in "activities likely to affect public order and public security, relating to goods or services essential to guarantee the protection of public health"². This definition has remained unchanged since 2014.

This particularly cumbersome wording has however revealed two main advantages:

First, it would be simplistic to consider that any and all activities in the life sciences field are deemed strategic. The life sciences field is very broad and encompasses, for

instance, self-medication, dental practices, and food supplements. Therefore, only those goods and services that are deemed essential to ensure the protection of public health fall within the scope of control.

Second, the interpretation of what is deemed essential may vary across time and be adapted to fit different contexts. As such, it has undoubtedly been interpreted more and more broadly in recent years.

The main consequence is the difficulty to determine with certainty whether a given activity falls within the scope of control at any given moment or not. However, recent experience shows that the Ministry intends to give a reasoned interpretation for what is deemed strategic so as not to include all the activities related to the health sector within its scope of supervision. Even in this sector, which has proven to be particularly sensitive and under the spotlight recently, we have very recently seen certain areas of activity which have not been deemed strategic by the Ministry. For instance, in the field of medical insurance, which is compulsory for any healthcare professionals, intermediary services are not considered essential.

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² Article R. 151-3 II 8° of the French Monetary and Financial Code

Have there been significant changes recently?

Sophie Pelé : First of all, the pandemic revealed the conjunctural nature of French control of foreign direct investment.

It has been immediately adapted to the circumstances: as soon as the pandemic began, a Decree of 27 April 2020 added the biotechnologies to the list of critical technologies which fall within the scope.

Initially, the list almost mirrored the European regulation of 19 March 2019 which established a framework for the various national control tools, save for the field of biotechnologies. Despite this, I had never considered that biotechnologies were not strategic. In addition, medtechs (companies that produce medical devices, often in a particularly innovative way and using mechanical rather than biological processes) are not classed as biotechnologies. However, it would be premature to assume that they would be excluded from the scope of the control on foreign direct investment.

This highlights the limits of an overly political use of the tool: a more precise definition may remain incomplete and thus result in involuntary exclusions.

Other changes have occurred without being attributed to the pandemic: the life sciences field is, by its very nature, driven by innovation, and is therefore evolving very quickly. Interestingly, this results in a scrutiny exercised on it not only because the activities at stake are deemed likely to affect public order and public security, relating to goods or services essential to guarantee the protection of public health, but increasingly also because of its links to other strategic sectors, notably artificial intelligence, robotics (which is one way to categorise medtechs), and sensitive personal data.

What are the specificities of this sector in terms of FDI control?

Sophie Pelé : The life sciences field is unique in many aspects, all of which have consequences in terms of control of foreign direct investments.

First, the development of health products is particularly long and expensive. Development takes years and the outcome remains uncertain. To be authorised, a product must be proven to be safe and effective for humans through several clinical trials, which are extremely expensive.

From an investment point of view, this triggers a significant need for funding from a very early stage. Investors in the field should be ready to invest over the medium term and to take on the risk associated with drug development.

Moreover, the French healthcare ecosystem heavily relies on commercial research projects incorporating the results of academic research, which may trigger protection from an FDI perspective.

It is therefore necessary to strike a balance between attracting investors that are essential for the development of this sector and activating control mechanisms for the protection of strategic national interests when necessary.

In addition, the sector is under the supervision of a large number of departments of state, which would each have a say: the Ministry of Health, of course, but also, quite often, the Ministry of Defense, the Ministry of Education and Research, the Ministry of Industry, and sometimes even the Ministry of Justice. Those various interests may misalign and it only takes one to come forward, even belatedly, to trigger the eligibility of a business for FDI control. This also leads to expanding the list of commitments.

Finally, another specificity of the sector, which was widely evidenced during the pandemic, is the multiplication of strategic partnerships, such as between Pfizer and BioNTech. These partnerships, which take place through licensing deals, usually do not trigger any change of control and are therefore not subject to foreign investment control.

Do you see any differences with the approach to the sector in other control jurisdictions, elsewhere in Europe or in the United States?

Sophie Pelé : The pandemic has increased the overall focus of foreign investment control authorities on health-related transactions. Nevertheless, life sciences are not included in the list of sensitive sectors in all member states.

In Germany, for example, it has switched from an optional to a mandatory notification system, but the scope of strategic activities remains quite restricted.

For example, prior authorisation is only required for investments of more than 25 percent in the area of infrastructure for the production of treatments for life-threatening or infectious diseases or protective equipment such as masks.

In the United States, the approach is different. The control committee (CFIUS) examines investments in critical technologies, critical infrastructures and sensitive personal data. Health sector controls have recently been carried out mainly on the basis of this last aspect, since life sciences companies hold sensitive health information. On several occasions, investors have been requested to divest this sensitive activity to a third party: this was the case with the health application "Patients like me", which was sold to United Health after an acquisition by a Chinese investor.