HERBERT SMITH
FREEHILLS
KRAMER

NAVIGATING FOREIGN DIRECT INVESTMENT REGULATION: PHARMACEUTICALS

Control of foreign investment in pharmaceuticals

Foreign Direct Investment (**FDI**) regulation is an area of increasing activity and enforcement worldwide. Against a backdrop of heightened geopolitical tensions and the residual pressure to keep strategic industries 'onshore', an increasing number of FDI regimes globally now apply not only to outright acquisitions but also to minority investments, even where the interests acquired do not confer control over the target business or its assets.

FDI controls typically require parties to notify a FDI agency of their intended transactions. Where a notification obligation applies, it will frequently be unlawful for parties to complete the transaction without first obtaining consent from the FDI agency. In some cases, however, countries do not maintain FDI screening regimes in this traditional sense but instead regulate FDI via "negative list" arrangements that limit or prohibit foreign ownership or impose other regulatory requirements on foreign ownership.

FDI regimes are typically applied as an additional layer of regulation on top of other rules such as merger control and industry regulations. Moreover, especially in significant cross-border investments, it is quite possible for multiple FDI regimes to apply to a single transaction. With this in mind, conducting a multi-jurisdictional FDI analysis is now an essential part of any M&A or investment due diligence exercise.

Common features of FDI regimes

- FDI regimes typically apply to specified classes of investments – increasingly these are not limited to controlling interests but can capture minority investments (eg as low as around 10%) even where they do not confer control over the target business or its assets.
- Often there are no turnover or other thresholds for the FDI rules to be engaged.
- Mandatory notification obligations may apply and clearance may be required before transactions can complete.
- Some regimes prohibit or restrict all foreign investment in specified industries.
- Decision-making can be far more politically-driven and secretive than in other regulatory processes such as merger control. Outcomes can therefore be harder to predict and more difficult to explain.

FDI and Pharmaceuticals

The importance of healthcare in general and pharmaceuticals in particular to national security interests was thrown into sharp relief by the Covid-19 pandemic. The risk of not being able to maintain a stable supply of pharmaceutical or diagnostic products or of not having access to infrastructure critical for public health meant that the scope of a number of FDI regimes has rapidly expanded in the last 5 years to include an increasingly wide range of activities within the pharmaceutical sector.

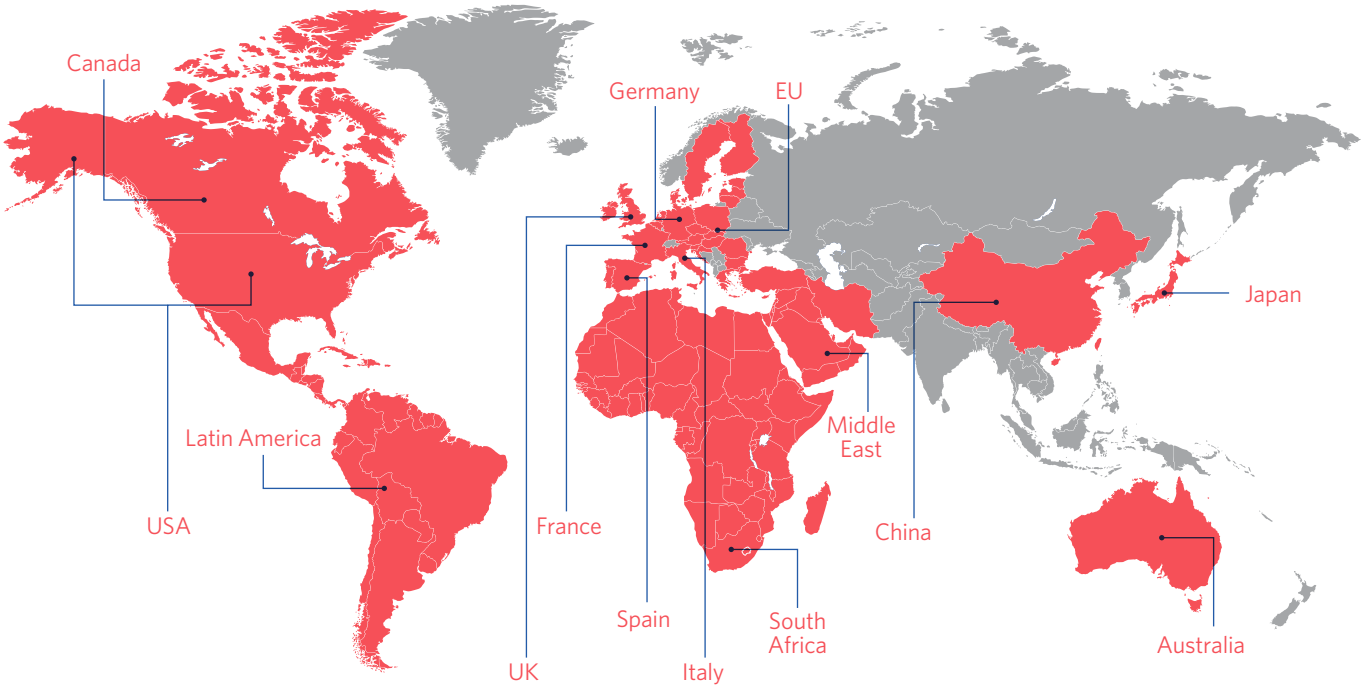
While the threat from Covid-19 has abated, concerns about the impact of future epidemics and the exposure of often-globalised supply chains in the pharmaceutical sector to disruptions in global trade have not. Consequently, what were sometimes meant to be temporary additions to the scope of certain FDI regimes to cover pharmaceuticals and the healthcare sector more generally in response to Covid-19 have become permanent.

The inclusion of pharmaceuticals within the scope of FDI regimes that have come into force more recently bears out the increased perceived criticality of the sector for national security. The sensitivities around FDI in this sector were well-illustrated by Servier's decision to abandon the sale of its generics subsidiary Biogaran in September 2024 following strong opposition from the French government, which publicly stated that "any non-European buyer should be ready for drastic conditions."

The scope of the pharmaceutical sector (and, indeed the healthcare sector more generally) is typically quite broadly defined and can include not only R&D and production infrastructure for medicinal products but their import and distribution and even pharmacovigilance activities. In some jurisdictions, notification may turn on who pharmaceutical products are supplied to (eg, public health authorities who provide critical healthcare services) or the technology used to develop or produce a pharmaceutical product.

In coming years, it is likely that innovative or critical medicines will be brought even more clearly into scope of FDI regimes and that factors such as therapeutic use, availability of substitutes and supply chain vulnerabilities will play an increasingly important role in determining the increased applicability of FDI regimes to pharmaceutical M&A.

Pharmaceuticals and FDI regimes around the world



EUROPE

UK

Under the National Security and Investment Act (**NSIA**) a mandatory and suspensory notification obligation applies to certain transactions involving a target entity that carries out certain activities in the UK in one or more of the 17 specified sectors (certain transactions that do not trigger mandatory notifications can still be reviewed at the authority's discretion). These include the "synthetic biology", "artificial intelligence" and "defence" sectors.

Pharmaceutical companies that use or research synthetic biology (ie, applying engineering principles to biology) to research, develop or produce medical products could be within scope of the NSIA where their activities involve the storage or ownership of sensitive human genetic information, certain forms of gene or cell therapy or where the medicines developed using synthetic biology could be used to deliver toxic or other illegal substances.

Additionally, where AI is used in areas such as medical diagnostics or where pharmaceutical companies supply products to the UK Ministry of Defence which are used for defence or national security purposes (which is very broadly defined), this could also bring a transaction within scope and trigger a mandatory filing and suspensory obligation under the NSIA.

Even if a transaction is not mandatorily notifiable under the NSIA, the government also has broad powers to "call-in" transactions in any sector. Moreover, mandatory notification obligations and/or call-in risk are not only relevant to investments in pharmaceutical companies directly but can be relevant where such companies are involved in sponsoring research by or developing research centres with UK higher-education institutions (especially in one of the 17 specified sectors). These are an area of particular focus under the NSIA resulting in a number of recent deals of this type either being cleared subject to the imposition of conditions or being abandoned after being called in for in-depth review.

EU

The Regulation for the screening of FDI into the EU on security and public order grounds became fully operational on 11 October 2020 (**EU FDI Regulation**). The EU FDI Regulation does not establish FDI screening at EU level but creates a framework for pan-EU cooperation on FDI screening:

Each Member State must notify the Commission and other Member States of any FDI in their territory undergoing screening.

The Commission may request information on FDI likely to affect security or public order of another Member State or a project or programme of EU interest.

Common criteria and standards are set for national FDI mechanisms (if maintained or adopted by Member States), but currently there is no obligation to adopt new FDI screening mechanisms. However, the European Commission has recently unveiled a proposal to update the EU FDI Regulation so as to require Member States to screen transactions relating to, among others, critical or innovative medicines.

France

France has an active FDI regime that imposes mandatory filing requirements. The regime is suspensory ie clearance must be obtained pre-closing.

Pre-completion approval is required from the Ministry of Economy (Ministère de l'Economie, des Finances et de l'Industrie) for foreign investments occurring in sensitive or strategic sectors if they result in the (i) acquisition of control of any French law entity or of branches/establishments (succursale) registered in France of a foreign company; (ii) acquisition of all or part of any business division (branche d'activité) operated by a French law entity; or (iii) for non-EU/EEA investors only, the acquisition, directly or indirectly, solely or in concert, of more than 25% of voting rights of a French law entity, or for listed French companies, 10% or more.

The sensitive/strategic sectors include:

a. activities prejudicial to national defence, public authority or to public order and public security;

b. infrastructure, goods or essential services that are vital to guaranteeing the protection of public health;

c. R&D activities prejudicial to the activities in (a) or (b).

Consequently, it is likely that transactions in the pharmaceutical sector with a French nexus would be within scope of the French FDI regime. This will particularly be the case where a party has a manufacturing or R&D presence in France (as shown by the Biogaran case) or is a significant supplier to the public health system.

In particular, it is likely that suppliers of medicines designated as essential would be regarded as particularly sensitive. Similarly, given the French government's long-standing promotion of the development and availability of generic medicines as a means of ensuring fair pricing, fostering competition, and containing healthcare costs (particularly those borne by the national social security system), transactions which could create concerns in relation to the supply of generic products are also likely to be of particular interest to the Ministry.

Germany

Germany has an active FDI regime that imposes mandatory filing requirements. The regime is suspensory ie clearance must be obtained pre-closing from the Federal Ministry for Economic Affairs and Climate Action.

The FDI regime is engaged by acquisitions of either: (i) 25% (direct or indirect control) of voting rights in a German company by a non-EU/EFTA company (in which case the Ministry is entitled to call-in the transaction for review); (ii) 10% if the target company operates in certain sectors (eg critical infrastructure in sectors such as pharmaceuticals), in which case a mandatory filing is triggered; or (iii) 20% in certain other sectors (in which case a mandatory filing is triggered).

Pharmaceuticals are one of the sectors that is within the scope of the regime and therefore there is considerable potential for investments in the pharma sector to require filings. This will particularly be the case where the transaction relates to the manufacture and/or distribution of APIs and/or finished form pharmaceuticals "essential for ensuring the health of the population" or medical devices used in the diagnosis or treatment of life threatening or contagious diseases (particularly when they are used for *in vitro* diagnosis). In 2024, investments in the health and biotech sector accounted for more than 10% of the total number of FDI filings that were made.

New investment screening legislation is expected to be adopted in Germany and is intended to clarify and potentially expand the scope of the sensitive sectors including in relation to essential medicines. Draft legislation has not yet been published: given the recent political developments in Germany (both the the early federal elections in February 2025 and the formation of the new coalition government in May 2025), new legislation is now expected in the second half of 2026.

Italy

Italy has an active FDI regime that imposes mandatory filing requirements. The regime is suspensory ie clearance must be obtained pre-closing from the Presidency of the Council of Ministers for qualifying investments.

Notifications are required for transactions relating to 'strategic assets' in four sectors. These sectors include certain activities in the health sector, including:

a. Technology (including digital technology) used in the delivery (including remotely) of health services;

b. biotechnologies used for the analysis of data and the application of biological knowledge for health and related diagnostics, prognostics and therapy; and

c. bioengineering technology and nanotechnologies used in the pharmaceutical and medical device sector or for diagnostic, prognostic and/or therapy purposes.

Additionally, where a company has annual turnover of >€300m, has >250 employees and is active in the health sector in Italy, it may be within scope of the Italian FDI regime even if it is not doing any of the above activities (there is some ambiguity as to whether the turnover/employees are in respect of Italy only or on a worldwide basis).

Spain

Spain has an active FDI regime. There is a suspensory FDI screening mechanism in place that applies in the following scenarios:

a. a foreign investor (broadly speaking non-EU and non-EFTA persons or, where the value of the investment is at least EUR 500 million or the Target is a listed company, non-Spanish EU and EFTA persons) comes to hold a stake equal to or greater than 10% of the share capital of a Spanish company in any Spanish company and/or Spanish asset; or

b. as a result of any transaction, the foreign investor acquires effective control of such Spanish company and/or asset; and either the investment is made in restricted sectors; or the foreign investor:

- **i.** is directly or indirectly controlled by the government (including state bodies or the armed forces) of a third country; or
- **ii.** has made investments or has taken part in sectors that affect public safety, public policy or public health in another EU Member State; or
- **iii.** there is a risk that the foreign investor conducts illegal activities affecting public safety, public policy or public health.

The restricted sectors include critical infrastructure in the health sector and the land and real estate crucial for that infrastructure as well as the supply of critical inputs in the health sector which includes (but is not limited to) software used in hospital information systems management, facilities management, prescription drug distribution systems.

New FDI regimes in Europe

A number of new FDI screening regimes have come into force in Europe in the previous two years. There are now FDI regimes or plans to implement FDI regimes in almost all of the EU Member States. Frequently the production and/or distribution of pharmaceuticals comes within scope of critical infrastructure and/or inputs for the purposes of these regimes. Other countries in which a mandatory FDI regulatory filing could be required in respect of an investment in the pharmaceutical sector (in that country) include: Belgium, Bulgaria, Czech Republic, Denmark, Estonia, Greece, Hungary, Ireland, Latvia, Luxembourg, Malta, the Netherlands, Poland, Romania, Slovakia, Slovenia and Sweden.

MIDDLE EAST

Middle East

FDI in the Middle East is relatively nascent, and the majority of jurisdictions do not have FDI regimes requiring pre-notification and clearance.

However some jurisdictions, such as Bahrain, have sector specific regimes in relation to healthcare where a change of control will result in a notification to the sectoral regulator.

In Saudi Arabia, an investment law applicable to all investors (local and foreign) came into effect in February 2025. The new law does not include a 'negative list' containing all activities in which foreign investment is prohibited but instead provides that ministerial approval will be needed to undertake 'excluded activities' as will be updated by relevant authorities.

AFRICA

Africa (excluding South Africa)

Most African countries do not have specific FDI regimes. Instead, they may regulate and monitor foreign investment through other means, such as through exchange control regulations and treasury approvals. In some cases, FDI regulation is more nebulous – regulation is carried out by way of broad policy considerations conveyed to investors through informal discussions with government or through licensing requirements imposed on an ad hoc basis at the time of the investment.

Many African countries also regulate foreign investment by ensuring that such investment is carried out in a responsible manner and for the benefit of the country (eg linking it to a social responsibility requirement to local communities or local industry). Some countries have sector-specific foreign ownership restrictions on activities within the pharmaceutical supply chain – for example, in Ghana, retailing finished pharmaceutical products is reserved for Ghanaian citizens or 100% Ghanaian owned enterprises.

Competition law regulations may include public interest considerations which may also bring transactions involving pharmaceuticals into the scope of review.

South Africa

While there is currently no separate FDI agency in South Africa, the South African Competition Commission (SACC) reviews mergers that meet prescribed financial thresholds.

Foreign investors will, through this process, often be required by the SACC and/or Department of Trade, Industry and Competition to provide commitments that are responsive to the SACC's public interest mandate, notably in respect of local ownership, employment and procurement.

Aside from a merger notification, there is no general obligation to notify acquisitions of South African companies by foreign investors, or the establishment of new South African companies by foreign investors.

Although there is no sector-specific code applicable to the pharmaceutical sector within the broader framework of the Broad-Based Black Economic Empowerment Act, the general compliance targets for local procurement of pharmaceutical materials and technologies and ownership by black South Africans (among other things) are relevant. While compliance with the code is not mandatory, the extent of compliance is taken into account (and is a requirement for state-owned enterprises to consider) when procuring goods or services or entering into other business relationships with private firms.

AMERICAS

Canada

- Canada has an active FDI regime. All acquisitions of control of Canadian businesses by non-Canadians are subject to review under the Investment Canada Act (**ICA**).
- Pharmaceuticals is not a specifically designated sensitive sector under the current regime, so whether a suspensory pre-closing filing is required will depend on a number of factors including: the value of the Canadian business, where the investor is from, whether the investor is state-owned, and whether it is a direct or indirect investment. Otherwise the filing can be made post-closing.
- Amendments to the ICA will introduce a mandatory and suspensory notification and review process for foreign investments in certain defined business sectors. As at the date of writing, the sectors to be covered have not been finalised. It is currently expected that these amendments will not enter into force until at least the second half of 2025.

USA

The USA has an active FDI regime (the Committee on Foreign Investment in the United States, **CFIUS**), which includes a mandatory filing component.

Notification under the CFIUS regime is largely voluntary and mandatory filings are generally only required (i) where the US target business produces or develops a product that is subject to US export control regulations or (ii) where a foreign government owns 49% or more of the investor and the investor will acquire 25% of more of a US business, where in both instances the US target business involves certain critical technology, sensitive personal data or critical infrastructure.

Transactions involving pharmaceutical companies may, in some instances, implicate critical technology or sensitive personal data (including but not limited to health information as well as genetic testing data), meaning that mandatory, suspensory CFIUS filings are sometimes required for investments in the sector. This is particularly the case in relation to pharmaceutical companies active in the biotech space which is an area of focus for the US government. CFIUS pressure points with respect to inbound pharmaceutical investments also arise where the transaction might raise US supply chain resiliency concerns, a national security focus for CFIUS in various sectors, not least the pharmaceutical industry in the wake of the Covid pandemic.

Even in the absence of mandatory CFIUS filing obligations, there is a very active CFIUS investigation and call-in regime that is not sector specific, and CFIUS has broad discretion to investigate and call-in for review covered transactions where CFIUS believes the transaction may present US national security concerns. Therefore, it is important to keep CFIUS in mind for any transactions in the US pharmaceutical space.

Latin America

Latin America

Regulation in the region is increasingly intense, including with respect to protection of the environment and communities.

There are few mandatory and suspensory FDI screening regimes that are active in the region.

ASIA-PACIFIC

Australia

Australia has an active FDI regime (**FIRB**). Mandatory filings are required for the acquisition of 10% or more of "national security businesses". While pharmaceutical companies are typically not held to be national security businesses and transactions in the sector do not result in mandatory notifications to FIRB, voluntary filings are strongly encouraged where the transaction relates to essential medicines (particularly those prescription medicines in the Australian government's Pharmaceutical Benefits Scheme).

China

China has an FDI screening regime as well as a screening list (Negative List). The Negative List regime applies to acquisitions by foreign investors in Chinese companies (and other forms of foreign investment in China) and does not apply monetary jurisdictional thresholds.

The mandatory notification regime extends to industries relevant to important infrastructure or other important fields relating to national security. In the pharmaceutical space, areas such as advanced medicines, critical devices or biotech will likely be held to be within scope of the mandatory notification regime.

Japan

Japan has a reasonably active but limited FDI regime. The regime is generally only mandatory and suspensory in respect of certain listed Japanese companies that are active in defined sectors. These sectors include pharmaceutical and medical products and biopharmaceuticals (which forms part of the wider 'public safety' sector'). Acquisitions of 1% or more of the shares or voting rights in these listed companies engage the regime.

Outlook for the future

In recent years, FDI regulation has featured increasingly on the radar for cross-border M&A, against a backdrop of amplified protectionist rhetoric.

Since Covid-19, pharmaceuticals have been a key sector for FDI agencies and it is likely that the FDI scrutiny to which pharmaceutical transactions and investments are subject is only likely to increase. For example, the proposed amendments to the EU's FDI Regulation currently under discussion would establish a minimum range of critical sectors which Member States' FDI regimes need to catch; one of the proposed critical sectors is critical medicines. Some EU Member States are already broadening the scope of their existing FDI regimes such that they would potentially cover pharmaceutical transactions; the Dutch government has published an amendment to its FDI regime that would bring biotechnology (including in a pharmaceutical context) within scope.

Globally, we would expect that, as existing FDI regimes develop and new regimes come into force, pharmaceuticals will increasingly be in scope for FDI regimes and that FDI agencies will take a significantly more interventionist approach (particularly where transactions could result in a risk to pharmaceutical production and R&D, IP being transferred to undesirable jurisdictions or to the security of supply of key pharmaceuticals).

Contacts

UK, US, EMEA

Veronica Roberts
Partner, Head of Competition/Antitrust, Regulation and Trade, UK
T +44 20 7466 2009
veronica.roberts@hsfkramer.com

Andre Pretorius
Partner, London
T +44 20 7466 2738
andre.pretorius@hsfkramer.com

Joseph Falcone
Partner, New York
T +1 917 542 7805
joseph.falcone@hsfkramer.com

Kyriakos Fountoukakos
Managing Partner, Competition/ Antitrust, Regulation and Trade
T +44 7920 455 155
kyriakos.fountoukakos@hsfkramer.com

Dr Marius Boewe
Partner, Germany
T +49 211 975 59066
marius.boewe@hsfkramer.com

Iria Calvino
Partner, Co-Head ESG EMEA, Madrid
T +34 91 423 4091
iria.calvino@hsfkramer.com

Christopher Theris
Partner, Corporate, Paris
T +33 1 53 57 65 54
christopher.theris@hsfkramer.com

Francesca Morra
Partner, Italy
T +39 02 3602 1371
francesca.morra@hsfkramer.com

Jean Meijer
Managing Partner, Johannesburg Office
T +27 10 500 2642
jean.meijer@hsfkramer.com

Chris Walters
Partner, Head of Middle East Corporate, Dubai
T +971 4 428 6338
chris.walters@hsfkramer.com

APAC team

Stephen Dobbs
Partner, Sydney
T +61 2 9225 5511
Stephen.Dobbs@hsfkramer.com

Nanda Lau
Managing Partner, Shanghai Office
T +86 21 23222117
nanda.lau@hsfkramer.com

Adelaide Luke
Partner, Head of Competition, Asia
T +852 21014135
adelaide.luke@hsfkramer.com

Graeme Preston
Managing Partner, Asia, Tokyo
T +81 3 5412 5485
graeme.preston@hsfkramer.com

For a full list of our global offices visit **HSFKRAMER.COM**

© Herbert Smith Freehills Kramer LLP 2025 DES0004446/110825