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Cleary's Pharma Bites
FDI in Pharma, Biotech and Healthcare

Cleary Gottlieb Pharmaceutical, Biotech and Healthcare Group

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FDI Trends

1	Proliferation of FDI regimes in EU & globally – almost all EU member states have an active FDI regime in place.
2	Numerous areas covered and continually expanding, including in the pharma/biotech/healthcare sectors.
3	FDI reportability is primarily driven by the scope of the Target's activities and less so by financial thresholds.
4	Phase I review (>80% of notified deals) typically takes 2 - 3 months. Phase II review could last +4-10 months.
5	If a deal does not raise FDI concerns, Phase I filing and RFIs are light and comparable to a simplified merger process.

EU FDI

EU

— Several leading FDI jurisdictions (e.g., Germany, France, Italy) require FDI filing for an acquisition of a non-controlling interest >10/20/25% (the remainder require acquisition of "control").

— FDI review in EU is subject to a "screening cooperation" mechanism but no 'one-stop-shop':

- An EU member state undertaking national FDI screening will notify all other EU Member States and the European Commission of its ongoing review.
- The European Commission and other EU Member States may then intervene by submitting comments or opinion, though ultimate decision rests with the reviewing EU member state.

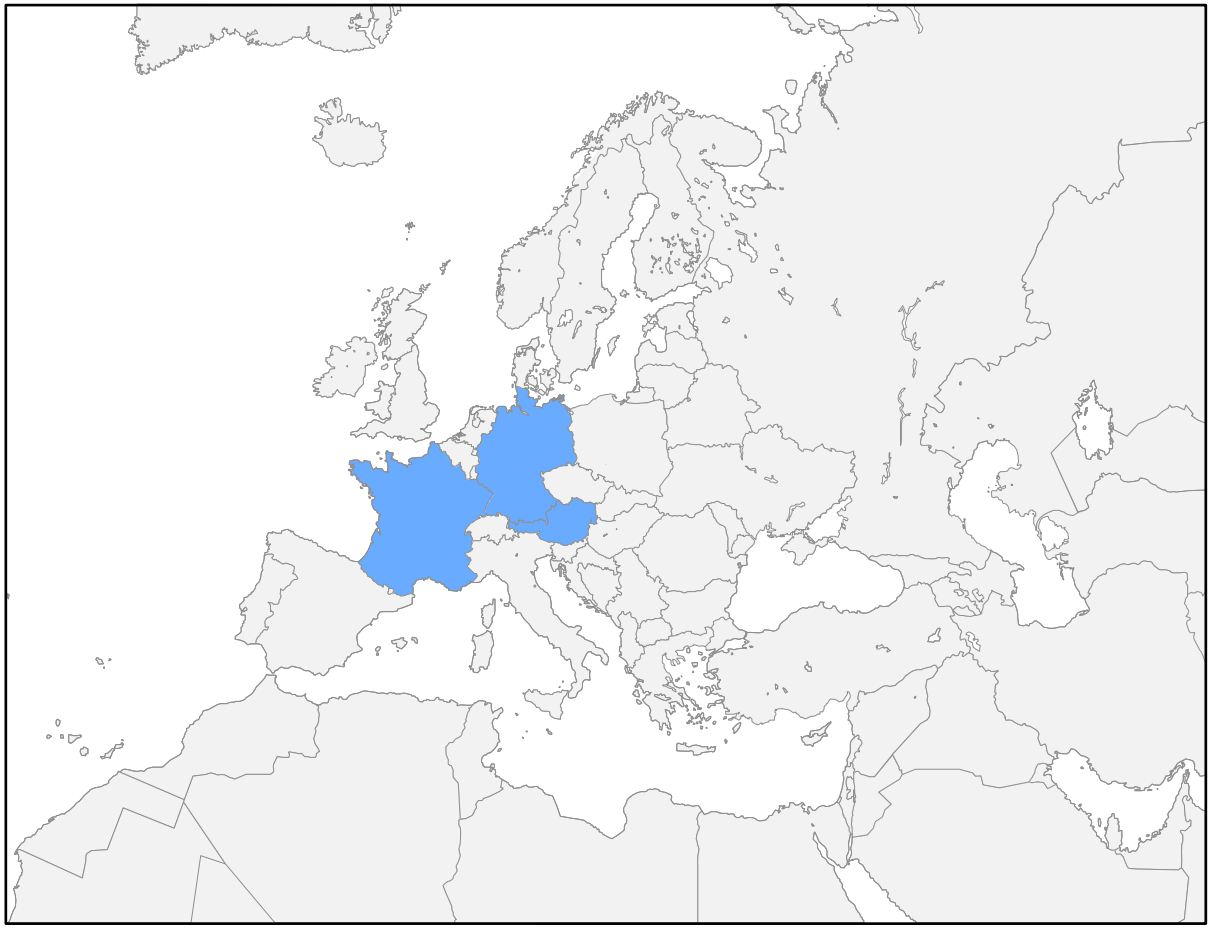
— FDI sector scope is typically defined broadly with little to no specific definition guidance.

— The following slides therefore provide illustrative examples of activities within the pharma/biotech/healthcare sectors that may potentially be captured by EU member state FDI rules.

— However, a case-by-case assessment is required based on specific activities (and importance) of the Target.

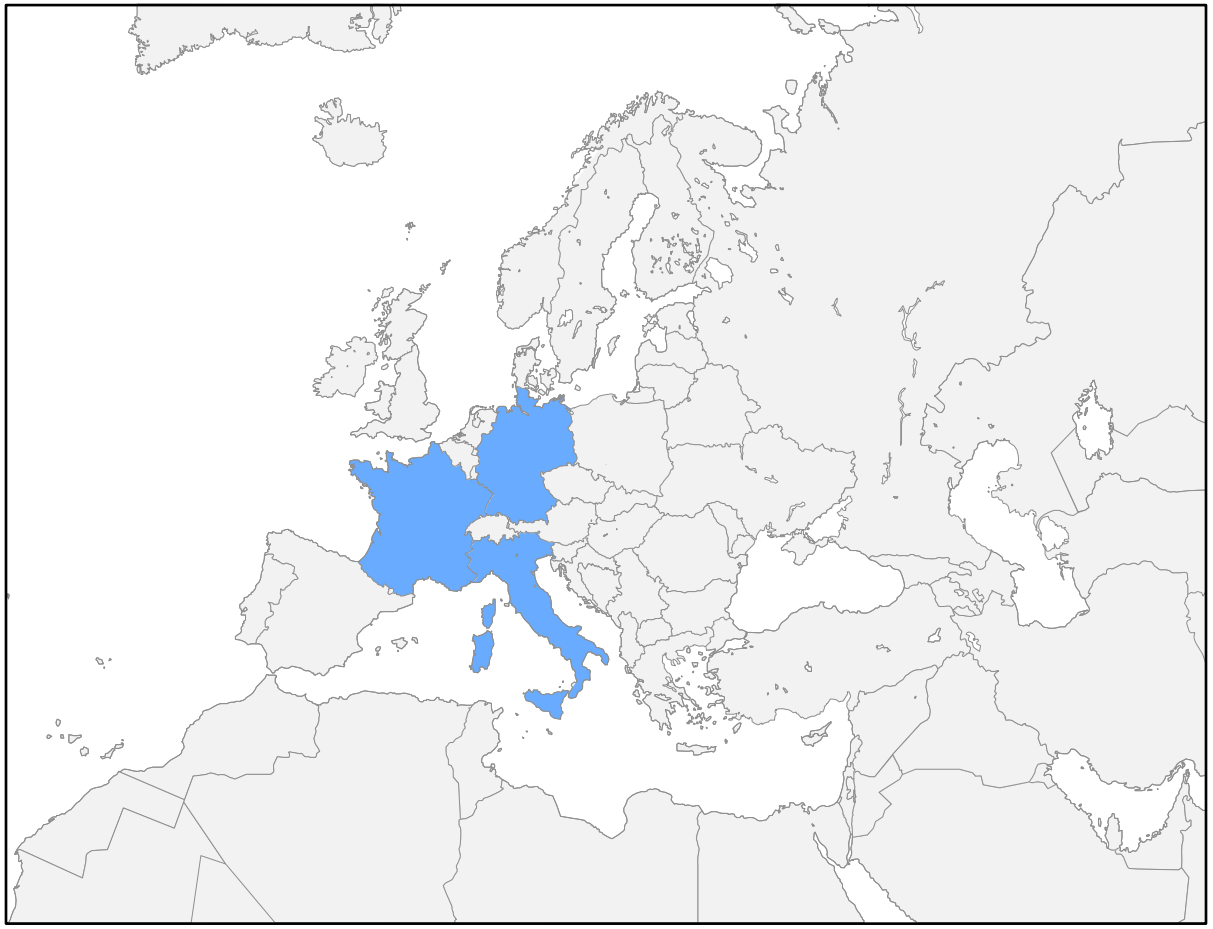
Healthcare R&D

— FDI filings may be required in France, Germany and Austria.



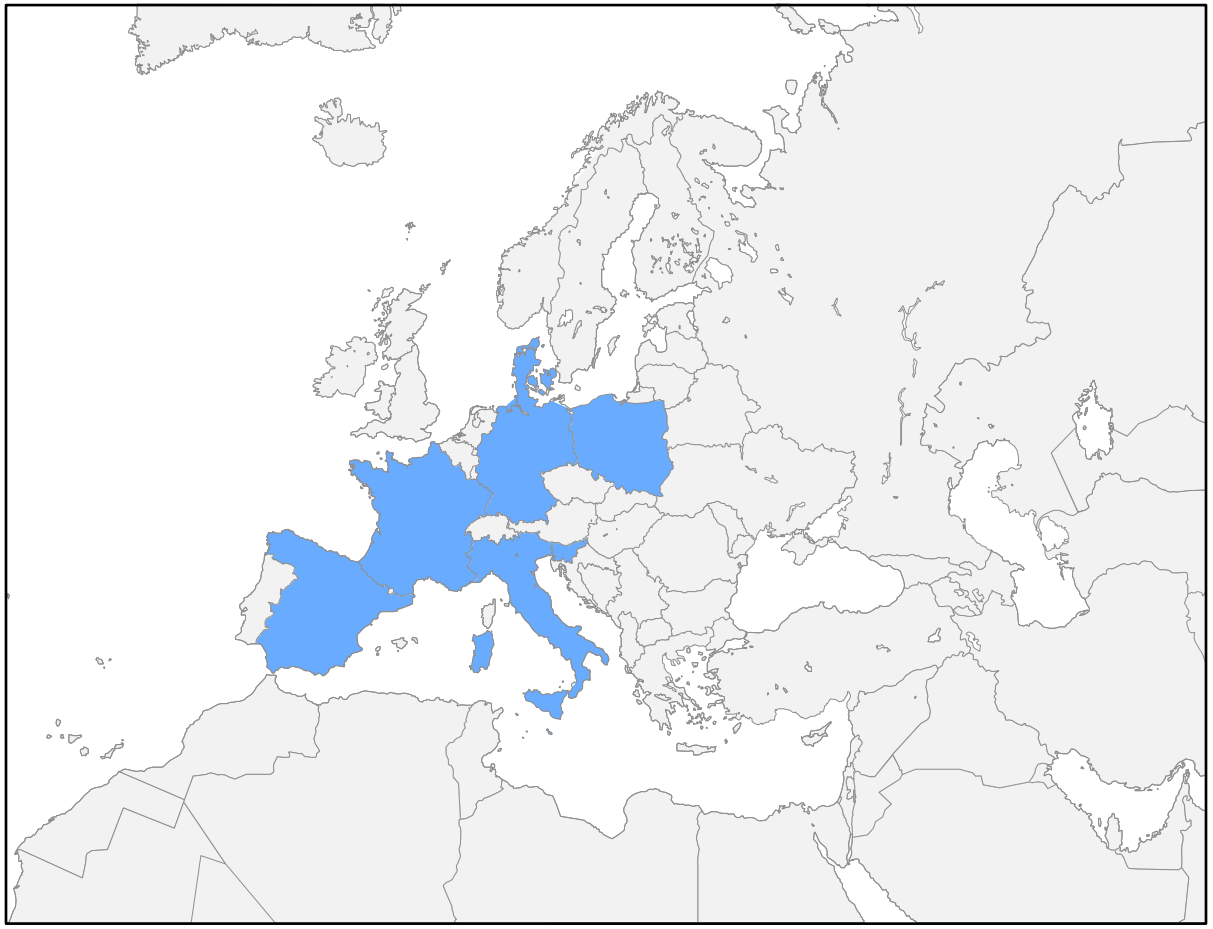
Medical Devices, Including Diagnostics

— FDI filings may be required in France, Germany and Italy.



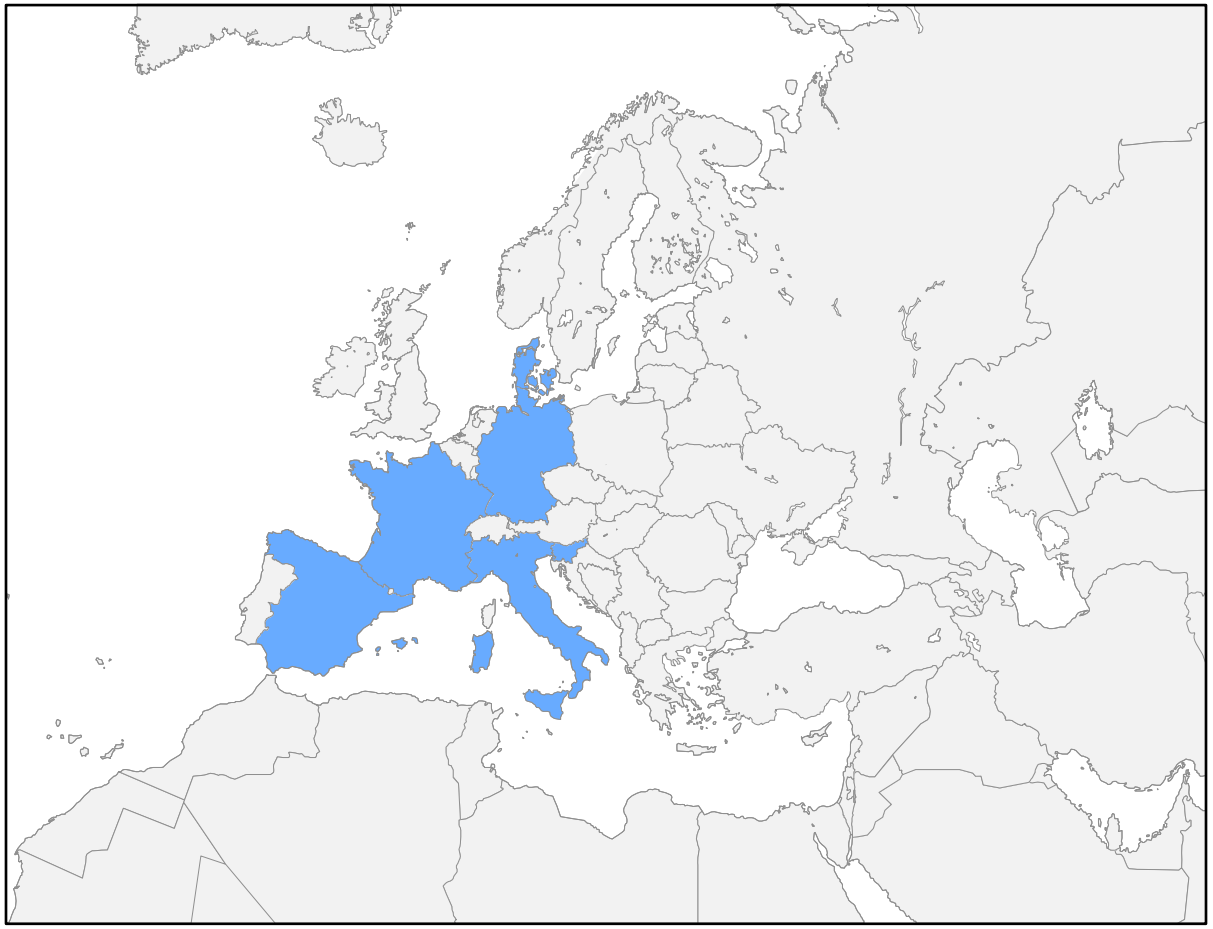
Medicinal/Pharmaceutical Products/Biotechnologies

— FDI filings may be required in Germany, Poland, Denmark, France, Italy, Malta, Slovenia, and Spain.



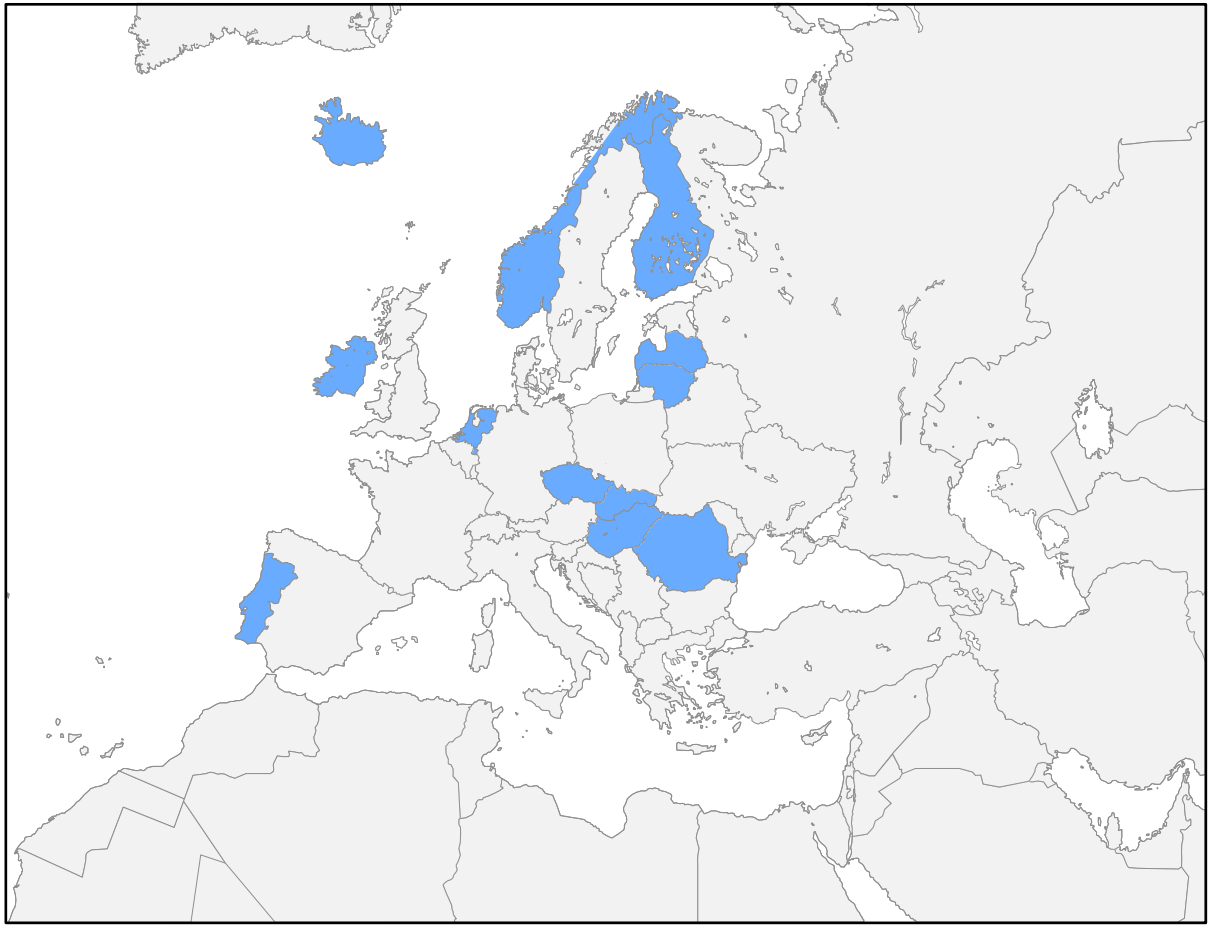
Health-Related Critical Infrastructure

— FDI filings may be required in Denmark, Germany, France, Italy, Slovenia, and Spain.



‘Catch-All’ Activities Related To “Vital” Public Interests

— FDI filings may be required in Finland, Hungary, Czech Republic, Iceland, Latvia, Norway, Romania, Lithuania, the Netherlands, Portugal, Ireland, and Slovakia.



Ex-EU FDI

UK

— New mandatory national security regime applies to 17 sectors. Likely to catch pharma deals primarily under the definition of the **synthetic biology** sector, but potentially also under others (e.g., AI).

Mandatory filing in the synthetic biology sector

— Mandatory filing where:

- The investor acquires (i) shares or voting rights crossing the 25%, 50% or 75% thresholds, or (ii) the ability to pass or block resolutions; and
- The target is active in the UK in the synthetic biology sector.
  - Relevant activities include R&D, production, and enabling services.
  - Several exceptions from filing requirement (e.g., if used in human/veterinary medicines or immunomodulatory approaches, unless the technology uses or could be used to produce or deliver toxic/harmful chemicals).

— Other transactions, including asset deals, can be called in for review under the national security regime (up to 5 years post-closing or up to 6 months after Government is aware of deal) but no filing required.

— Pharma transactions could in principle be reviewed under the separate *public interest* regime. During pandemic UK Government added power to review mergers to preserve "capability to combat… public health emergencies." Power has not been used to date.

U.S. CFIUS

Mandatory filing unlikely in most pharma deals

— Mandatory CFIUS filing possible where:

- A foreign investor acquires control or certain non-controlling rights over a target U.S. business that produces, designs, tests, manufactures, fabricates, or develops "critical" (i.e., export controlled) technologies; or
- A foreign investor acquires a >25% interest in a target U.S. business that conducts activities related to critical technologies, critical infrastructure, or sensitive personal data and the foreign investor is >49% owned by a foreign government.

Voluntary filing may be advisable in certain biopharma deals

— Caution is warranted in biopharmaceutical transactions involving targets that:

1. Collect and maintain sensitive personal data (even in small amounts).
2. Engage in activities involving so-called "emerging" technologies.
3. Are critical to biopharmaceutical supply chain security.

Australia & New Zealand

— FDI filings in Australia and New Zealand may, in certain circumstances, be triggered regardless of the activities of the Target:

Australia	— Mandatory filing may, among other, be triggered where: • The buyer is a "foreign governmental investor" – interpreted widely to include an investor in which *e.g.*, US pension funds hold >20%; and • The buyer acquires >20% in an offshore parent entity with an Australian subsidiary regardless of its activities (*de minimis* exception available).
New Zealand	— Mandatory FDI filing where: • The buyer acquires >25% in New Zealand assets valued >NZ$ 100 million.

Take Aways

FDI – Practical Take Aways

1	It is prudent to conduct a FDI analysis in M&A pharma deals to identify any potential filing requirements; counsel can do so in 1-2 weeks.
2	Unlike merger control jurisdictional analysis primarily driven by financial thresholds, FDI analysis requires more data, time, and judgment calls.
3	However, upfront information collection may help establish a reasonable basis to try to avoid FDI filings in majority of transactions.