Matheson

Competition and Regulation Briefing

Irish FDI Screening Regime – Application to the Life Sciences Sector

Executive Summary:

The key points in this briefing note may be summarised as follows:

- The new Irish FDI screening regime established under the Screening of Third Country Transactions Act 2023 (the "**Act**") came into force on 6 January 2025.
- Under the new regime, mandatory pre-clearance approval must be obtained from the Minister of Enterprise, Trade & Employment (the "**Minister**") for transactions by third country (ie, non-EU/EFTA) investors that involve an acquisition of 'control' or shares or voting rights above 25% or 50% and which relate to or impact upon one or more specified sensitive matters or areas potentially impacting security or public order in the State.
- The Minister also has a residual call-in power in respect of 'below-threshold' transactions. The current expectation is that the call-in power will be reserved for 'obvious' cases that raise potential national security issues which will be driven by both the target and third country investor profile.
- The filing analysis to determine mandatory notification obligations and the risk of a 'call-in' must be carried out based on the guidance document published by the Department of Enterprise, Trade and Employment in December 2024 ("**FDI Guidance**").
- Life sciences companies or investors in such companies from outside the EU/EFTA involved in M&A transactions may be 'in-scope' of the new Irish regime and so therefore need to be aware of potential mandatory pre-clearance approval requirements or potential 'call-in' risk that needs to be built into transaction timelines.

This briefing note sets out the key points that are relevant to Life Sciences companies or investors in such companies from outside the EU/EFTA. This note is based on the latest version of our general briefing note of January 2025 (see here).

Mandatory Notification Thresholds: Overview

Under the Act, a transaction is mandatorily notifiable if the following cumulative criteria are met:

1. A 'third country' (ie, non-EU/EFTA) undertaking or a connected person as a result of the transaction: (i) acquires control of an asset in the State; or (ii) changes the percentage of shares or voting rights that it holds in an undertaking in the State from below 25% to above 25% and from below 50% to above 50% ("**Limb 1**");
2. The value of the transaction is at least €2 million (taking into account all transactions between the parties in the last 12 months) ("**Limb 2**");
3. The same undertaking does not, directly or indirectly, control all the parties to the transaction ("**Limb 3**"); and
4. The transaction relates to, or impacts upon, one or more of the sensitive matters/sectors set out in Article 4(1)(a)-(e) of Regulation 2019/452, namely:
    i. Critical infrastructure (which includes the health sector);
    ii. Critical technologies and dual-use items as (now) defined in Regulation 2021/821 (which includes artificial intelligence, nanotechnologies and biotechnologies);
    iii. Supply of critical inputs (which includes critical health inputs);
    iv. Access to sensitive information, including personal data, or the ability to control such information; and/or
    v. The freedom and plurality of the media ("**Limb 4**").

Mandatory Notification Thresholds: Application to the Life Sciences Sector

General

Overall, any transaction in the life sciences sector that meets the mandatory notification thresholds set out above requires mandatory pre-completion approval from the Minister.

- First, in view of Limb 1, the transaction must involve a third country (ie, non-EU/EFTA) investor. This is the case where either the directly acquiring entity (ie, Bidco) or the ultimate parent entity is constituted or governed under a non-EU/EFTA country. Further, the transaction must also involve a change of control of an asset in the State (ie, a physical asset or potentially also a contract with an Irish customer) or an acquisition of shares or voting rights held in an Irish undertaking of 25% or above or 50%.
- Second, in view of Limb 2, the value of the transaction must be above the very low transaction value threshold of €2 million.
- Third, in view of Limb 3, the transaction must not qualify as an internal restructure (ie, all transaction parties must not be controlled by the same ultimate parent entity).
- Finally, in view of Limb 4, the transaction must "relate to, or impact upon" one or more of the sensitive matters or sectors cross-referred to in the Act (noting that the FDI Guidance states that the concept of "relate to, or impact upon" is considered broadly). These are considered further in the next section (except for the freedom and plurality of the media, which is unlikely to be relevant in the context of the life sciences sector).

Sensitive matters or sectors

The mandatory filing analysis will often turn on whether the Target's activities directly or indirectly relate to, or impact upon, one or more of the sensitive matters or sectors under the Act. This will be the case if the Target is directly active in one or more of the sensitive matters or sectors, or indirectly active in the sense of being a material supplier to providers in those sensitive matters or sectors.

Critical Infrastructure

The health and government contract sectors will generally be the most relevant in the context of the life sciences sector. The categories of entities caught within each are as follows:

- Health:
  - Healthcare providers, as defined in Article 3(g) of Directive 2011/24;
  - EU reference laboratories, as designated by the European Commission under Article 15 of Regulation 2022/237;
  - Entities carrying out research and development of medicinal products, as defined in Article 1, point (2), of Directive 2001/83;
  - Entities manufacturing basic pharmaceutical products and pharmaceutical preparations as referred to in Section C division 21 of NACE Rev. 2;
  - Entities manufacturing "medical devices" considered as critical during a public health emergency within the meaning of Article 22 of Regulation (EU) 2022/123; and
  - Entities holding a distribution authorisation as referred to in Article 79 of Directive 2001/83.
- Government contracts (ie, public administration):
  - Contracts with government bodies or public administration entities, such as the HSE and public hospitals in the State.

It is for parties and advisors to determine whether the Target's activities may be viewed as 'critical' in the State or whether the Target may be viewed as a material supplier to critical infrastructure providers, in accordance with various criteria set out in the underlying EU legislation.

Critical inputs

Under the Irish FDI Guidance, critical inputs are stated to include medicines for human use that are essential for the proper functioning of the EU healthcare system and whose shortage would lead to an interruption in treatment and thus serious harm to patients. The Union list for critical medicines is to be consulted, but this is stated to be non-exhaustive and that a case-by-case consideration is required.

Other potential types of potentially critical inputs in the health sector need to be assessed on a case-by-case basis.

Critical technologies/ dual-use items

Critical technologies and dual-use items within the specified categories (ie, including artificial intelligence, nanotechnologies and biotechnologies) are captured.

Dual-use items are those listed in Annexes I or IV of Regulation (EU) 2021/821, as well as EU military equipment under Council Common Position 2008/944/CFSP.

Critical technologies which are not defined as dual-use or military equipment may also be caught.

Access to Sensitive Information, including personal data, or the ability to control such information

Under the FDI Guidance, sensitive information is defined as data that must be protected from unauthorised access to safeguard the privacy or security of an individual, organisation or the State, and including personal data in accordance with the relevant GDPR categories, including 'special category' health data under Article 9 GDPR. Access to sensitive information includes the ability to process, license sell or store such information.

The relevant criteria under the FDI Guidance for determining a mandatory notification requirement include whether the transaction involves sensitive data that is held as an essential or critical part of the business or asset (ie, not in relation to data held on employees of the target undertaking or asset, or not essential or critical to the operation of the business); whether the volume of such data is 'substantial'; and/or the transaction relates to a business model that depends on generating turnover from such sensitive data.

Sensitive information may also relate to a government body, where access to such information has a national security dimension (ie, could be used to undermine security or public order in the State).

Call-in power in respect of 'below threshold' transactions

Under the Act, the Minister may 'call-in' a transaction for review where the following conditions are met:

1. Where the Minister has reasonable grounds for believing that the transaction affects, or is likely to affect, security or public order in the State; and
2. Where the transaction results in a third country undertaking acquiring control, legal rights or the ability to exercise effective participation in the management or control of an asset or undertaking in the State (ie, a lower threshold compared with the mandatory thresholds).

The Minister may exercise this power in the case of non-notifiable transactions for a period of 15 months post-completion, and in the case of non-notified transactions for a period of the later of 5 years post-completion or 6 months after the Minister becomes aware of the transaction.

The current expectation is that the call-in power will be reserved for 'obvious' cases that raise potential national security issues which will be driven by both the target and third country investor profile.

Review procedure

Where a mandatory filing is made or a transaction is called-in, the review procedure is as follows:

- Once a notification has been made, the Minister will issue a screening notice as soon as practicable to the parties which will have suspensory effect (ie, the parties should not take any action for the purposes of completing or furthering the transaction).
- The Minister concludes the review within 90 calendar days of the date of the screening notice. This may be extended to 135 calendar days by notice in writing.
- Where the Minister issues a notice of information (ie, equivalent to an RFI), the review period is suspended until the parties fully comply with the notice of information and the Minister certifies compliance.

At the end of the relevant period, the Minister must issue a screening decision providing reasons as to why the transaction was considered to affect or not to affect security or public order in the State. If the Minister fails to issue a screening notice by the end of the relevant period, the transaction shall be deemed to be subject to a screening decision that it does not affect security or public order in the State. The Minister may decline to give reasons where security or public order is affected.

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