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Client Alert

March 2022

United Kingdom: Foreign investment screening and healthcare

What are the implications of the new NSI Act regime and the Government's "public health emergencies" powers for healthcare and life sciences transactions?

In brief

On 4 January 2022, the new UK foreign investment review regime under the National Security and Investment Act 2021 ("**NSI Act**", available here) came into force.

The new rules require businesses and investors to submit mandatory notifications for certain acquisitions of, and investments in, companies active in 17 key sectors of the economy. They also grant the Government extensive powers to investigate and impose conditions on a wide range of transactions (including both corporate investments and asset transactions) on national security grounds.

The new NSI Act regime will operate alongside the Government's retained powers under the Enterprise Act 2002 ("**Enterprise Act**", available here) to intervene in transactions that raise certain public interest considerations. Of particular relevance to healthcare, these public interest considerations include "the need to maintain in the United Kingdom the capability to combat, and to mitigate the effects of, public health emergencies."

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This alert considers the implications for healthcare transactions of the new NSI Act regime, as well as the Government's retained "public health emergencies" powers under the Enterprise Act.

Key takeaways for healthcare and life sciences companies

- Since 4 January 2022, it has been a mandatory requirement to notify certain acquisitions and investments in companies that carry out activities in 17 key sectors of the UK economy. It has also been possible to submit voluntary notifications outside these sectors and for a broader range of transactions.
- The jurisdictional scope of the NSI Act is extremely wide. The new regime catches the acquisition of intangible assets (such as IP), certain minority investments, non-UK transactions and even internal corporate reorganizations.
- Non-compliance with the mandatory filing requirement risks significant criminal and civil sanctions.
- Mandatory sectors that are potentially relevant to healthcare transactions include "Synthetic Biology" and "Defence". Many healthcare transactions will fall outside these sectors but careful screening is required to ensure that this is the case.
- It is necessary to consider the risk of transactions being called-in for review under the NSI Act or under the "public health emergencies" provisions of the Enterprise Act, and therefore whether voluntary notification is appropriate. Voluntary notification should (in particular) be considered for the following types of transaction: (i) transactions that are relevant to the ability of the National Health Service (NHS) to address the COVID-19 pandemic (or future public health emergencies); (ii) transactions that result in any diminution of the UK's critical/strategic capabilities in the healthcare sector; or (iii) transactions that otherwise raise concerns about the security of supply of key medicines or medical equipment/devices.
- For cross-border healthcare transactions, we are increasingly seeing multiple foreign investment filings being required. It is crucial for parties and their advisers to coordinate foreign investment approval procedures globally so that substance is consistent and timetables are aligned.

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NSI Act (National Security)

The mandatory regime under the NSI Act requires acquirers to notify the Investment Security Unit (ISU) within the Department for Business, Energy & Industrial Strategy (BEIS) in advance of transactions where they will acquire a right or interest in relation to any entity that carries on activity in the UK in one of 17 specified sectors of the economy in one of the following ways:

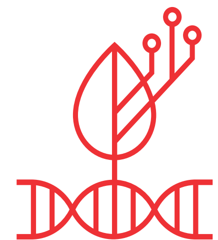
- Where this results in them holding **more than 25%, more than 50%, or 75% or more** of the total shares or voting rights in the entity, or
- Where this enables them to secure or prevent the passage of (any class of) resolutions governing the affairs of the entity.

The requirement applies to indirectly held interests and rights, to non-UK entities that carry out activities in a specified sector in the UK, and to intra-group transactions/reorganisations.

The 17 sectors of the economy where the mandatory notification requirement will apply are defined in the Notifiable Acquisition Regulations. The list includes traditionally sensitive areas (such as defence and critical suppliers to the government), critical infrastructure (such as energy and communications), and emerging technologies (such as artificial intelligence and synthetic biology). Potentially relevant sectors for healthcare transactions include synthetic biology and defence, as discussed below.

Synthetic biology

The NSI Act defines "synthetic biology" as "the process of applying engineering principles to biology to design, redesign or make biological components or systems that do not exist in the natural world". This includes gene editing and gene therapy.



Entities will be within the synthetic biology mandatory sector if they carry out activities that consist of or include any of the following: (i) basic scientific research into synthetic biology; (ii) the development of synthetic biology; (iii) the production of goods using synthetic biology; (iv) the formulation of synthetic biology to enable the degradation of materials; or (v) the provision of services that enable the activities in (i) to (iv).

However, this is subject to certain exceptions, of which the following are particularly relevant to healthcare transactions: (i) any approach used to gather clinical information to make a clinical decision or to make a diagnosis; (ii) gene therapy where it is used solely for the purpose of replacing missing or defective genes to restore phenotypes to achieve a therapeutic effect; (iii) cell therapy where cells are modified by genetic engineering and then introduced into a patient to treat disease; and (iv) the ownership, ownership of IP or development of human/veterinary medicines or immunomodulatory approaches. Therefore, in most cases, healthcare transactions will be outside the scope of the mandatory regime even where the target's activities involve synthetic biology (although merger parties may nevertheless decide to submit a voluntary notification given sensitivities around this emerging technology).

Defence

Entities will be within the mandatory "defence" sector for the following reasons (i) if they carry out activities that comprise or include the research, development, production, creation or application of goods or services that are used or provided for defence or national security purposes and (ii) if they are a government contractor (or sub-contractor) and/or hold classified information. In the healthcare context, this will clearly be relevant to certain products designed specifically for defence applications (e.g. nerve agent antidotes), but also for those adapted to the unique demands of military applications (e.g. portable, gas-powered ventilators).

Call-in powers

The NSI Act grants the Government the ability to review transactions (including acquisitions outside the mandatory notification sectors and share or asset transactions that are not subject to the notification requirement) where a trigger event occurs and the Secretary of State reasonably suspects that this may give rise to a risk to UK national security. This can apply to the following:

- Acquisitions of rights or interests relating to entities (including those outside the 17 mandatory notification sectors) that result in holdings of share or voting rights meeting the thresholds for the mandatory notification trigger events;
- Acquisitions of rights or interests that, alone or together with other interests or rights held, enable the acquirer to exert material influence over an entity;

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- Acquisitions of rights or interests in relation to an asset that allow the acquirer to use the asset or to direct or control how the asset is used (or to do this to a greater extent than prior to the acquisition).

The Government has published a statutory statement on how the call-in power will be used. This explains the risk factors the Secretary of State will take into account and the areas of the economy where a call-in is most likely to take place. The statement notes that a call-in is more likely to happen where entities undertake activities in or "closely linked" to the mandatory notification sectors or where assets are or could be used in connection with such activities.

Broad jurisdictional scope

Unlike many foreign investment regimes globally, the NSI Act does not apply monetary or share of supply jurisdictional thresholds to identify qualifying transactions. Instead, the Government has jurisdiction to call-in any transaction that constitutes a "trigger event" (as described in the sections on mandatory screening and call-in powers above) for an in-depth national security assessment under the new regime, regardless of its size or value.

Acquisitions of assets comprising land, tangible moveable property or any ideas, information or techniques that have industrial, commercial or economic value are also in scope. This includes purchases of bare assets, such as IP, trade secrets, databases, source codes, algorithms, formulae, designs/plans and software.

The new regime has an expansive geographic nexus, capturing acquisitions of non-UK entities and assets (e.g., foreign IP or infrastructure) as long as they carry out activities in or supply goods or services into the UK (or are used for this purpose).

Although the political focus is likely to be on foreign inward investment, the rules apply to transactions by both UK and non-UK acquirers alike. The regime does not provide for any exemptions based on the country in which the investor is based (and it does not provide an exemption for or pre-approval of investors or certain categories of investors).

The Government has issued guidance about the extraterritorial reach of the NSI Act to explain how the NSI Act could affect people or acquisitions outside the UK. This guidance explains that an overseas or IP/intangible asset is likely to be in scope of the regime if it is used in one of the following ways: (i) by someone in the UK; (ii) by someone outside the UK to supply goods or services to the UK; or (iii) to generate energy or materials that are used in the UK. The guidance restates that there would always need to be either an activity carried out in the UK (in the case of an asset, it needs to be used in connection with such an activity) or a supply of goods or services to people in the UK (in the case of an asset, it must be used in connection with such supply).

Enterprise Act (Public Interest)

Under the Enterprise Act, the UK Competition and Markets Authority (CMA) can review "relevant merger situations" on competition (merger control) grounds. However, the Enterprise Act also allows the BEIS Secretary of State (SoS) to assume responsibility for determining whether such transactions may be expected to operate against certain public interests specified in the Act. The relevant public interest for healthcare transactions is "the need to maintain the capability to combat, and to mitigate the effects of, public health emergencies". This was added to the Enterprise Act in 2020 following the start of the COVID-19 pandemic.

As is the case with the UK's merger control regime, notification of a transaction that falls under the "public health emergencies" ground is voluntary (provided the transaction is not also subject to the NSI Act regime described above). However, the CMA has an obligation under the Enterprise Act to inform the SoS when it is investigating a transaction on competition grounds that it believes may also raise material public interest considerations. Moreover, the SoS may issue a public interest intervention notice (PIIN) proactively, thereby prompting a public interest review, whether or not the CMA has already commenced an investigation.

While the public interest regime does not feature a mandatory filing requirement, it may be advisable to notify the following types of transaction: (i) transactions that are relevant to the NHS' ability to address the COVID-19 pandemic or any future public health emergency (e.g. suppliers of vaccines, antivirals, antibody tests, ventilator equipment or, personal protective equipment); (ii) transactions that result in any diminution of the UK's critical/strategic capabilities in the healthcare sector, or (iii) transactions that otherwise raise concerns about the security of supply of key medicines or medical equipment/devices.

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What are the key features of the notification process?

The process for notifying transactions on a mandatory or voluntary basis under the NSI Act is set out below. For transactions that raise "public health emergencies" considerations, engagement with the Government can also be undertaken with BEIS via the special email address (PHEconsideration@beis.gov.uk) that has been created for this purpose.

- **Notification**: The format and details required for mandatory and voluntary notifications are set out in the Prescribed Form and Content of Notices Regulations. Broadly, the notification forms require details of the following:
  - The acquirer, the target and trigger event, including the following:
    - Any relevant mandatory notification sectors;
    - Government security classifications and national security vetting clearances, UK regulatory licences, government supply relationships and R&D funding;
    - Pre-acquisition and post-acquisition ownership structure charts for the qualifying entity;
    - Non-UK government roles in operations or decision making;
  - Arrangements between the acquirer and other parties (e.g., other investors);
  - Any related approvals, notifications or submissions being made (including to overseas authorities);
  - The anticipated timeline for the transaction.
- **Pre-notification**: The ISU will ask questions about the transaction during a period of pre-notification (which could last several weeks), after which it will accept a filing as complete and commence the initial screening period.
- **Initial screening period**: If a transaction is notified (voluntarily or because of a mandatory requirement) the Government will have a maximum of 30 working days from the moment the notification is declared complete to perform an initial screening. The aim of the screening stage is for the Government to decide whether to call-in the deal for a more in-depth assessment.
- **Assessment period**: If required, a detailed national security assessment will start once the Government issues a call-in notice. This can occur following the screening period (for notified transactions) or when the Government decides to call-in a transaction that has not been notified to it. The detailed national security assessment comprises an initial review period of 30 working days, followed by a possible extension of an additional 45 working days. Thereafter, an additional extension must be mutually agreed. The Government has powers to require that businesses and investors provide any information that may be relevant to the assessment.

Key features of the NSI Act process are as follows:

- **Timing**: The majority of healthcare transactions are unlikely to raise concerns requiring the deal to be called in for a longer in-depth review. As such, they will be cleared following the pre-notification and initial screening periods described above.
- **Remedies**: Following the assessment period, the Government may impose any remedies it considers necessary and proportionate to prevent the identified national security risks. Remedies may include restricting the permitted share ownership levels, outlining provisions around guaranteeing supply or maintaining capabilities in the UK, or (as a last resort) prohibiting or unwinding transactions.
- **Transparency**: The call-in and assessment process will be largely opaque - the Government has referred to sensitivity around making decisions public where it believes national security risks could arise. The Government intends to publish call-in decisions and decisions in cases cleared without remedies where this is necessary and appropriate (e.g., where one of the parties is a listed company with disclosure obligations) and to provide aggregated information in annual reports of activity to the UK Parliament regarding timelines, efficiency and outcomes. However, information about decisions on cases resulting in remedies will be published.
- **Appeals**: There is no opportunity to appeal the Government's substantive decision on the merits (although full appeals of any civil penalty decisions will be allowed). This means that it will only be possible to seek judicial review of decisions on grounds such as irrationality, illegality or procedural impropriety. The Government considers that it is best-placed to assess the

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national security risk that decisions in the NSI Act regime are intended to address and that it would not be appropriate for courts to remake these decisions.

- **Interactions with other processes**: The timeline will run in parallel with any merger control/public interest process under the Enterprise Act.

What are the consequences of failing to notify a transaction?

Penalties for failure to notify:

- The mandatory regime under the NSI Act is suspensory, meaning that transactions cannot be completed until clearance has been received. If a transaction that is subject to mandatory notification completes prior to obtaining clearance, it will be legally void. Furthermore, if an acquirer fails to submit a mandatory filing, it risks significant financial penalties (up to 5% of total worldwide turnover or GBP 10 million, whichever is higher) and criminal liability for directors.
- There are no penalties for failing to submit a filing where a transaction raises public health emergencies issues but does not fall within the mandatory NSI Act regime.

Retrospective call-in risk:

- If it is not notified of a transaction that has national security risks, the Government has the ability to step in retrospectively (including after completion) to address those risks. The Government has six months from "becoming aware" of a non-notified transaction in which to call-in the transaction for review, subject to an overall deadline of five years from the "trigger event" of the transaction. However, the five year limit will not apply to deals requiring mandatory notification - this means that there is no definitive end date by which the Government must act. The Government, in theory, could become aware of the transaction many years after closing, call it in within six months of gaining that knowledge, and impose remedies (including, as a last resort, prohibiting the deal) if it raises national security concerns.
- If a transaction does not raise national security risks (but is nevertheless deemed to raise "public health emergencies" issues), it may be referred for an in-depth "phase 2" review under the Enterprise Act only where it has not yet taken place or it took place no more than four months previously, unless the transaction took place without having been made public and without the CMA being informed of it (in which case, the four-month period starts from the earlier of the time the transaction was made public or the CMA was told about it).

Practical insights and experience

- The Government was keen to stress throughout the legislative process for the NSI Act that the UK remains open for foreign investment. However, the risk remains of an expanding category of national security issues being conflated with industry policy factors in assessments carried out under the NSI Act. This is particularly the case as the Government is heavily focused upon developing the UK's life sciences capabilities.
- Merger parties in the healthcare sector have generally taken a cautious approach around the need to notify transactions given the NSI Act's broad jurisdictional criteria, draconian penalties, and call-in risks, as well as the ambiguous scope of the "public health emergencies" ground under the Enterprise Act. We expect this approach to continue, leading to a material volume of voluntary notifications being submitted.
- The UK is not alone in changing its foreign investment screening rules. Indeed, for cross-border healthcare transactions, we are increasingly seeing multiple filings being required. In some jurisdictions (e.g. Germany), this reflects specific concerns in the healthcare space (particularly around security of supply), while in other jurisdictions there has been a push to expand foreign investment scrutiny more generally across sectors. As a result, it will be crucial for parties and their advisers to coordinate foreign investment approval procedures globally so that the substance is consistent and timetables are aligned.
- In addition to concerns regarding the ownership of companies producing products related to the fight against COVID-19, we are starting to see foreign investment authorities express broader concerns around the security of supply of key medicines and medical devices. In some cases, this is resulting in acquirers needing to commit to continue supply post-transaction in order to gain clearance.
- Patient data has started to feature prominently in foreign investment reviews in other jurisdictions. We expect this trend to continue and to be part of the UK analysis where relevant.

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