

## UK National Security and Investment Act 2021: What It means for Life Sciences Transactions

By [John Schmidt](#) and [Ludovica Pizzetti](#)

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### Snapshot

The UK National Security and Investment Act 2021 (NSIA) entered into force and became operational on 4 January 2022. As mentioned previously,<sup>1</sup> the NSIA represents a radical overhaul to the foreign investment screening in the UK: not only does it introduce for the first time a requirement (or, depending on the case, the possibility) to **proactively notify** deals with potential national security implications, but it also creates a **standalone regime**—which is **mandatory and suspensory in certain cases**—for transactions that may give rise to national security concerns.

The new regime (Regime) has significant implications for deals and investments in life sciences and will likely cause **increased burden, costs and uncertainty** for deals with some (even loose) UK nexus.

In terms of its impact, at the time the NSIA was enacted, the UK government estimated the Regime would result in 1,000—1,830 transactions being notified per year, with only around 70-95 cases called in for an in-depth national security assessment and only around 10 cases being subject to remedies. The government's first report published on 16 June 2022 and covering the Regime's first three months of operation up to 31 March 2022 (Report), suggests the number of notifications, as well as the number of cases called in for in-depth review, is in line with, and perhaps slightly below, these initial estimates. Specifically - and although, given the short period considered, the report cautions against drawing conclusions on long-term trends at this stage - the following points are worth noting: (i) **222 filings** were received in total in the first three-month period; of these, **196 were mandatory**, 25 voluntary and one was done retrospectively; (ii) of these 222 transactions subject to the government's review, **17 were called in for further assessment**; (iii) four of the 17 call-ins related to voluntary notifications; (iv) of the 17 cases subject to in-depth assessment, **only three have been ultimately cleared** so far, with the other 14 cases still being reviewed at the end of the reporting period.

A few important takeaways can be drawn from an analysis of the Regime and its first six months of operation:

- The scope is potentially **very broad**, particularly in the life sciences space. This is due to, among others, the broad definition of the sensitive sectors requiring mandatory notification, the inclusion of asset acquisitions (including licensing of IP) within the potential purview of the UK government, the low equity/voting rights thresholds to trigger a filing, as well as the broad extra-territorial reach.
- It is likely that businesses will **err on the side of caution** and elect to make filings in cases where the application is unclear—particularly given the draconian sanctions potentially applicable for failing to submit a mandatory filing, as well as the potential for the UK government to “call in” un-notified transactions for a period up to five years.
- BEIS has proven to be **open to discussion** and has issued several guidelines to help businesses navigating through the system. It has also generally been rather **swift** in responding to informal outreaches as well as providing clearance in no-issue cases.

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<sup>1</sup> See in particular our previous advisories “A New Mandatory UK Foreign Direct Investment Regime Gets Royal Assent: The Five Key Things You Need to Know” and “CFIUS—CFIUK: New Additional National Security Review of UK Acquisitions” available at <https://www.arnoldporter.com/en/perspectives/advisories/2021/05/a-new-mandatory-uk-fdi-regime-gets-royal-assent> and <https://www.arnoldporter.com/en/perspectives/advisories/2020/12/cfius-cfiuk-new-natl-security-review-of-uk-acqs>, respectively.

- The review/clearance process itself is significantly less iterative than for example the CMA’s merger control process or similar FDI reviews in other jurisdictions (e.g., Germany or Spain).
- The general **lack of communication** throughout the review process, the absence of any reasoning in the government’s decisions, as well as the general lack of public information and **transparency** concerning past deals, is likely to represent a challenge for businesses wishing to achieve legal certainty. One might expect further clarification on policy approaches once the Regime has been in operation for some time but at this stage it is too early to tell.

We have analysed below the most relevant features and practical considerations of this new regime, with a particular focus on the impact this is likely to have on transactions in the life sciences sector. There are still a number of question marks given its novelty, but we expect that the decisional practice in the coming months, as well as future reports, will shed some light.

## Q&A—All you need to know on the scope, operation and impact of the Regime

Key question	Answer
<b>Overview</b>	
Who is the <b>decision maker</b> under the Regime?	<p>The UK Government’s Secretary of State for the Department for Business, Energy &amp; Industrial Strategy (<b>BEIS</b>) is the final decision maker. A newly formed Investment Security Unit (ISU), which sits within BEIS, is the body in charge of administering the Regime and acts as the single point of contact for businesses: it is empowered to receive notifications, conduct the review and act as the central hub throughout the whole screening process.</p> <p>Depending on the case, other ministerial bodies (e.g., the Ministry of Defence or the Department for Digital, Culture, Media &amp; Sport), the CMA or other foreign authorities may be consulted as necessary.</p>
Does the Regime have any <b>retroactive</b> effect?	<p>For deals closed <b>after 4 January 2022</b>, BEIS has the power to “call-in” for review any transaction (regardless of the sector) for up to 5 years post-closing. This period is reduced to 6 months if BEIS becomes aware of the transaction—e.g., through the press or informal notification by the parties.</p> <p>Similarly, BEIS has the power to call in any deals (regardless of the sector) closed <b>between 12 November 2020<sup>2</sup> and 3 January 2022</b>, even though these were not subject to a potential filing requirement until 4 January 2022. This retroactive call-in power may be exercised up until five years from 4 January 2022; if the parties have informed or have made aware (e.g., through a press release) BEIS of the transaction, this period is reduced to 6 months from 4 January 2022 (i.e., until 4 July 2022) or from the day BEIS became aware of the transaction, if subsequent to 4 January 2022.<sup>3</sup></p>

<sup>2</sup> Date when the NSIA was passed by the UK Parliament.

<sup>3</sup> Very recent and notable examples include (i) French company Altice’s acquisition of a further 6% stake in British Telecom, which occurred in December 2021 (taking Altice to own 18%) and which was called in on 26 May 2022, and (ii) the acquisition of UK Newport Wafer Fab by Nexperia (Dutch subsidiary of Chinese company Wingtech) in August 2021 which was called in by BEIS on 25 May 2022.

Key question	Answer
	Deals closed <b>before 12 November 2020</b> are not subject to BEIS' jurisdiction.
Is a filing under the Regime <b>voluntary or mandatory</b> ?	<p>A mandatory filing is required, with a stand-still obligation until clearance is obtained, <b>if the Target is active in one of the 17 sectors</b> specified under the NSIA, which are considered as particularly sensitive and more likely to raise potential national security concerns.</p> <p>To obtain certainty that a transaction will not be subject, at a later stage, to the NSIA call-in powers, investors can also elect to notify transactions voluntarily if—<b>regardless of the sector concerned</b>—the transaction might have national security implications. Relevant to this assessment are:</p> <ul style="list-style-type: none"> <li>• the <b>nature/identity of the acquirer</b>—e.g., the acquirer has a bad track record for raising national security issues;</li> <li>• the <b>nature of the Target's activities</b> and whether the Target could be used to undermine national security (e.g., the Target's activities are closely related to one of the 17 sensitive sectors, can have a dual use, there is a shortage, etc.); and</li> <li>• the <b>nature and degree of the control</b> acquired—the stronger the rights/control/power acquired, the higher a potential risk.</li> </ul>
What is the relationship and the interaction with the <b>UK merger control regime</b> ?	<p>Although the review by BEIS under the Regime and that carried out by the CMA under the UK merger control regime are completely separate and independent, inevitably <b>a number of cases captured by the Regime will also be reviewed by the CMA</b>—either by its Merger Intelligence Unit as part of the CMA's market-monitoring activity or in the context of a formal merger control review.</p> <p>Active cooperation and information sharing between the CMA and BEIS is to be expected, as the CMA has made clear in its 2022 revised merger guidance, and as reflected in the Memorandum of Understanding (MoU) between BEIS and the CMA published on 16 June 2022.<sup>4</sup></p>
What are the <b>practical steps</b> that companies need to consider going forward?	<ul style="list-style-type: none"> <li>• Given the expected level of cooperation between BEIS and the CMA, if parties are only intending to notify their transaction to BEIS, it is advisable to consider <b>whether a proactive approach to the CMA should be made in parallel</b>.</li> <li>• <b>Deal documentation</b> may need to cater for both merger control and the NSIA processes, allowing appropriate <b>long-stop dates</b> for regulatory reviews, as well as including <b>risk mitigation</b> and appropriate <b>conditionality</b> clauses. Given the novelty of the Regime, this might represent a challenge until there is a relatively established practice on how the NSIA is implemented, including in relation to timing.</li> </ul>

<sup>4</sup> The MoU is aimed at enabling closer working between BEIS and the CMA by setting out the parameters for cooperation, coordination and information sharing between the two regulators in the context of transactions notified to both BEIS and the CMA.

Key question	Answer
	<ul style="list-style-type: none"> <li>Where a transaction is likely to raise national security concerns, parties should also carry out <b>remedy planning</b> at an early stage of the process; remedies could include governance requirements (e.g., board composition), security of supply commitments, R&amp;D spend commitments, data/information access, ring-fencing obligations, obligations to maintain strategic UK capabilities etc.</li> </ul>
<b>Jurisdiction</b>	
<p>Which <b>sectors</b> which may be relevant to life sciences transactions are caught by the <b>mandatory</b> regime?</p>	<p>Among the 17 specified sectors that warrant a mandatory notification are: <sup>5</sup></p> <ul style="list-style-type: none"> <li><b>Synthetic Biology</b>—i.e., the process of applying engineering principles to biology to develop biological components or systems that do not exist in nature, such as synthetic life, cells and genomes.</li> </ul> <p>Essentially, the UK government is seeking to capture biological activities that could present a risk if they were to fall into the wrong hands and could have a dual-use potential, such as technologies that could be used to produce or deliver toxic chemicals.</p> <p>Notably, relevant synthetic biology activities would include (i) the design and engineering of biological-based parts of enzymes, genetic circuits and cells, and novel devices and systems; (ii) redesigning existing natural biological systems; (iii) using microbes to template materials; (iv) cell-free systems; (v) gene editing and gene therapy; and (vi) the use of DNA for data storage, encryption, and bio-enabled computing.</p> <p>The sector definition captures various levels of the value chain, bringing into scope not only companies that carry out basic R&amp;D into synthetic biology or are active into development of synthetic biology, but also potentially their upstream suppliers (active in the provision of services that enable R&amp;D into synthetic biology) and downstream customers (active in the production of goods using synthetic biology).</p> <p>There are significant exemptions for certain activities falling within this sector, notably gene therapy, cell therapy, medical diagnostics, industrial biotechnology, as well as ownership, IP ownership or development of human/veterinarian medicines and immunomodulatory approaches that employ synthetic biology—as such, many transactions involving therapeutic companies may not be captured.</p> <p>Interestingly, according to the Report, in the first three months of operation of the Regime mandatory filings in the Synthetic</p>

<sup>5</sup> See Appendix III for a full list of the 17 sensitive sectors. Other sectors that could potentially be relevant for life sciences transactions could include “advanced robotics” and “advanced materials” - see <https://www.gov.uk/government/publications/national-security-and-investment-act-guidance-on-notifiable-acquisitions/national-security-and-investment-act-guidance-on-notifiable-acquisitions#biology> for more details. As such, certain targets active in the med-tech, medical devices and digital health sectors could also be captured.

Key question	Answer
	<p>Biology space represent <b>the minority</b> compared to all other 16 sectors—and precisely ~ 1% of all cases notified.</p> <ul style="list-style-type: none"> <li>• <b>Artificial Intelligence</b>— i.e., the process of researching AI or developing goods, software or technology that use AI for the purpose of, among others, the “identification or tracking” of objects, people, events etc. Besides clarifying that the NSIA captures entities that do necessarily qualify as “AI companies” (but simply incorporate or develop AI as part of their activity), BEIS’ guidance contains a wide definition of AI—this includes any technology which enables to “perceive environment through the use of data”, “interpret data using automated processing” or “make recommendations, predictions or decisions”. As such, the potential for application to life sciences companies is rather high. This could include, for example, the use of AI by health-tech companies to assess patients using real-time information, for example in the context of clinical trials conducted through wearable devices which collect real-time biometric or physiologically-relevant data related to the participants.</li> </ul> <p>Unlike Synthetic Biology, AI ranks at the top of the list of sectors where mandatory notifications have been made in the first three months—representing just short of 20% of all notifications.</p> <p>The assessment of whether the Target’s life sciences activities are within the scope of the mandatory regime is highly fact-specific and will require a careful consideration and specific due diligence at the outset of the deal—which will likely often require constructive engagement by the Target.</p>
<p>Which sectors are caught by the <b>voluntary</b> regime?</p>	<p>The voluntary regime applies to transactions in <b>all sectors</b> of the economy <b>outside of the mandatory notification</b> sectors noted above—parties should consider voluntarily notifying a transaction where this may be of interest from a national security perspective.</p> <p>As mentioned below, unlike the mandatory regime which only captures acquisition of entities, the acquisition of <b>assets</b> (regardless of the sector) is also captured by the voluntary notification regime. This includes the licensing of IP or other technology, especially if the IP or licensed assets are closed linked to one of the 17 sensitive sectors. Potentially a number of licensing, R&amp;D and collaboration agreements in the life sciences sector could therefore be subject to BEIS’ call-in powers.</p>
<p>What are the trigger events?</p>	<p>The NSIA applies to acquisitions of control of either:</p> <ul style="list-style-type: none"> <li>• a “qualifying entity”, i.e., any entity other than an individual, including a company, a limited liability partnership, an unincorporated association or a trust; or</li> <li>• a “qualifying asset” (only relevant under voluntary regime). “Qualifying assets” include a broad range of assets such as land, tangible moveable property, as well as intangible assets such as trade secrets, IP (including patent-protected compounds,</li> </ul>

Key question	Answer
	molecules, methods or technologies), software, databases, algorithms or formulae.
<p>What are the <b>thresholds</b> for acquisitions over qualifying entities and assets?</p>	<p>There is no monetary, transaction value or market share threshold,<sup>6</sup> but <b>only equity/voting rights thresholds</b> as set out below:<sup>7</sup></p> <p><b>Mandatory regime:</b> this applies to acquisitions of:</p> <ul style="list-style-type: none"> <li>• Shareholdings or voting rights in the Target which take the acquirer from 25% or less to more than 25%; from 50% or less to more than 50%; or from 75% or less to 75% or more;<sup>8</sup> or</li> <li>• voting rights that allow the blocking or passing of resolutions governing the affairs of the Target (regardless of the shareholding or the percentage of voting rights held in the entity). While minority shareholdings might be caught, pure minority protection rights—which do not provide the investor with any positive or veto rights over matters concerning the affairs of the Target—would not be captured.</li> </ul> <p>It is worth pointing out that also intra-group transactions, including internal re-organizations preliminary to third parties transactions, are caught by the Regime—however, it would seem reasonable to combine both the internal reorganization and the main transaction into one filing.<sup>9</sup></p> <p><b>Voluntary regime:</b> in addition to the thresholds under the mandatory regime, this applies also in case of acquisitions of:</p> <ul style="list-style-type: none"> <li>• “material influence”, i.e. the ability to materially influence the Target’s strategic decisions and commercial objectives. This can be achieved through the acquisition of board seats or veto rights over strategic decisions - shareholdings as low as 10-15% may be captured.</li> <li>• rights or interests in, or in relation to, a qualifying assets (even without the acquisition of the asset itself) resulting in the <i>ability to use the asset or direct or control its use</i>, or use, direct or control its use to a greater extent than prior to the acquisition.</li> </ul> <p>Applied to the life sciences sector, the following could be caught: (i) an exclusive license over IP (as it provides a right to control), (ii) a non-exclusive licence (as it provides the right to use), (iii) the subsequent assignment of an IP, (iv) a conversion of a non-exclusive</p>

<sup>6</sup> With the exception of some specific sectors where additional thresholds are set out, e.g., the communication sector, where a mandatory notification may only be triggered provided that the Target has, among others, a UK turnover of at least £50 million.

<sup>7</sup> In relation to “interests” and “rights”, the UK government has clarified that these count as acquired where, among others, the interests and/or rights are held jointly with someone else, are exercised under a joint arrangement or are exercisable only under certain circumstances and these circumstances have arisen.

<sup>8</sup> The UK government has clarified that if a target entity has a share capital, the thresholds relate to the percentage of shares held/acquired in the issued share capital of the entity; if the target entity does not have a share capital, the thresholds relate to the right to that percentage share of the capital or profits of the entity; if the target entity is a limited liability partnership, the thresholds relate to the right to that percentage share of any surplus assets of the partnership on its winding up.

<sup>9</sup> We are aware of both instances where parties have notified the two transactions in one filing and instances where the preliminary internal reorganisation has been notified separately. BEIS has informally indicated that it is open to take a pragmatic approach and look into ways of simplifying the burden for businesses; the Report confirms that BEIS has in some cases adopted a pragmatic approach and accepted a single filing covering multiple transactions, most notably in case of some internal re-organizations.

Key question	Answer
	<p>to an exclusive licence, or (v) the exercise of an option to increase or acquire IP rights. In such circumstances, parties will need to consider the potential for such IP licensing arrangement to give rise to national security concerns, particularly if the asset is closely linked to one of the 17 sensitive sectors.</p> <p>It is worth noting that all manner of IP licensing could potentially be captured, including licensing from university or research institutes.</p>
<p>Are there any <b>safe harbours</b>?</p>	<p><b>No.</b> There are no turnover, transaction value or market share safe harbours. There are also no exclusions for <i>de-minimis</i> revenues, nor a requirement for a UK entity (sales into the UK may be sufficient) or a carve-out for UK acquirers (a UK-to-UK acquisition could be captured)—see below.</p>
<p>What <b>nexus</b> to the UK does a transaction require?</p>	<p>The NSIA has a <b>broad extraterritorial reach</b>. Although BEIS has made clear that UK companies and UK-based assets are a priority, the Regime also captures international transactions where the Target, despite not being either based in the UK or having UK subsidiaries, has activities (e.g., from an R&amp;D facility) in the UK, and/or supplies goods or services in the UK (e.g., through distributors to UK customers), or is an asset used in connection with activities carried out in the UK and/or in connection with the supply of goods or services to people in the UK (e.g., machinery overseas that produces equipment used in the UK).</p>
<p>Does the NSI Act apply to <b>UK investors</b>?</p>	<p><b>Yes.</b> The NSIA does not distinguish between UK and overseas investors<sup>10</sup> and applies also to acquisitions by UK acquirers meeting the required thresholds. As such, and unlike the generality of Foreign Direct Investment regimes, the NSIA has the <b>potential to apply to UK-to-UK transactions</b>.</p>
<p><b>Process</b></p>	
<p>How is the <b>notification</b> done in practice?</p>	<p>A notification under the NSIA entails the submission by the acquirer of an online form available at <a href="https://nsi.beis.gov.uk/">https://nsi.beis.gov.uk/</a>.</p> <p>Although some detailed and potentially onerous information (e.g., on ownership structure, shareholders, directors etc.) is required, preparing a filing is generally less onerous and more straightforward than a merger filing (or a filing under other FDI regimes).</p>
<p>What are the timings for review?</p>	<p><b>Formal acceptance.</b> The review period only starts once BEIS has accepted the filing as complete. This in effect introduces a sort of pre-notification phase, where BEIS can request further information. There is no set statutory time for this, but in our experience so far BEIS has been rather swift in declaring completeness. According to the Report, the average time to accept filings has so far been 3 working days, which is rather promising—although we are aware of outliers where it</p>

<sup>10</sup> With specific regards to foreign investors, BEIS has indicated that the Regime is agnostic to the acquirer's jurisdiction, as is demonstrated by the number of proposed acquisitions by US investors which have been found to raise potential national security concerns (see e.g., the collapse of Nvidia's proposed acquisition of UK chip designer Arm, as well as BEIS' decision to call-in French telco Altice's proposed takeover of BT. That said, in the current geo-political landscape it would seem reasonable to expect Chinese and Russian investors to be subject to particularly close scrutiny.

Key question	Answer
	<p>has taken around 14 days. That suggests that this pre-acceptance stage can be much swifter than the UK CMA in the context of its merger control review. Once a filing is accepted as complete, BEIS generally tends not to engage in any further discussion with the parties, unless necessary—in this case, it will issue so-called information or attendance notices (see below). Hence the interaction with the review team either on timing or substance or other points is much more curtailed than in merger control procedures.</p> <p><b>Phase 1 review.</b> If a proactive notification is made (either mandatory or voluntary), BEIS has 30 working days<sup>11</sup> from acceptance of the filing as complete<sup>12</sup> to review the transaction and decide whether to approve it or issue a “call-in” notice for a Phase 2, in-depth, review. Based on the Report, on average BEIS has so far taken 24 working days to issue a Phase 1 clearance decision, with the shortest review period so far being 11 working days. All cases so far have been decided within the 30-day deadline.</p> <p><b>Phase 2 review.</b> For cases which require in-depth assessment from a national security perspective and for which a “call-in notice” is issued (either following a Phase 1 review or for non-notified transactions), BEIS has 30 working days (which can be extended by a further 45 working days) to reach a decision either approving, approving with remedies or prohibiting the transaction. Exceptionally, a further extension can be agreed between BEIS and the acquirer.</p> <p>The system further allows the use of “stop-the-clock” information request mechanisms during Phase 2, which could further extend overall timing. As such, review periods can extend to <b>five months or longer</b>, with a potential impact on deals timetable and delay to closing. That said, the UK government expects ~ 80-90% of cases to be cleared within the initial 30 working day review period in Phase 1, and this has been the case so far.</p>
<p>What information on notified transactions is made <b>public</b>?</p>	<p>The secrecy inherent in any national security regime means that there is very little information which is made public by BEIS. Details of notified transactions, cleared cases or cases having been called-in for review are generally not made public (although transactions subject to call-in review may be publicised by the press).</p> <p>Where a <b>final order</b> (placing conditions on the transaction, unwinding, or blocking a transaction) is issued at the end of a Phase 2, some information will become public—specifically parties, dates and summary of the order (but not the order itself).</p> <p>That said, parties to a transaction subject to BEIS’ scrutiny may issue public announcements about the review process and timing for clearance - particularly public companies subject to public disclosure obligations.</p>

<sup>11</sup> A working day is any day other than a Saturday, Sunday or a Bank Holiday anywhere in the UK.

<sup>12</sup> BEIS will communicate by email if it has accepted a notification as complete; the 30 working day review period begins on the day the email is sent.

Key question	Answer
<p>What <b>decisions</b> may BEIS adopt during/at the end of its review?</p>	<p>Phase 1—BEIS may:</p> <ul style="list-style-type: none"> <li>• require further information (so-called “information notice”) or require people involved in the transaction to attend meetings (so-called “attendance notice”) during the review process - these will <i>not</i> “stop the clock”;</li> <li>• <b>clear</b> the acquisition unconditionally at the end of its review - BEIS expects this to be the case for the great majority of notifications; and</li> <li>• <b>call-in</b> the acquisition for a Phase 2 review.</li> </ul> <p>Phase 2—if BEIS “calls in” a transaction<sup>13</sup> for a further assessment of national security risks, it may:</p> <ul style="list-style-type: none"> <li>• require further information (so-called “information notice”) or require people involved in the transaction to attend meetings (so-called “attendance notice”)—unlike in Phase 1, these <i>will stop the clock</i>;</li> <li>• <b>impose interim orders</b>—i.e., immediate and temporary controls (such as impeding the parties to exchange confidential information or preventing IP rights from transferring) to prevent actions that might undermine BEIS’ final decision—these will not necessarily be reflected in the final order;</li> <li>• <b>clear</b> the acquisition without conditions; and</li> <li>• <b>impose final orders</b> - i.e., clearing upon conditions<sup>14</sup> in order to mitigate risk, blocking anticipated deals or requiring a transaction to be unwound following its review. BEIS has the power to vary or revoke final orders.</li> </ul>
<p>How has the regime operated in practice so far?</p>	<p>Initial feedback on the operation of the Regime and the review carried out by the ISU, as well as the Report, suggest that:</p> <ul style="list-style-type: none"> <li>• the ISU has been generally swift in confirming completeness of applications, thereby promptly starting the formal clock;</li> <li>• the ISU has been quite open to discuss questions and quite responsive and quick in providing guidance following informal outreaches such as submissions of briefing papers;</li> <li>• the ISU has issued helpful and detailed guidelines to help businesses navigating through the new regime, including guidance on which transactions are in scope, as well as on how to complete a notification form; and</li> <li>• although there is little public information on pending and recent cases, the Report confirms, and it is also our experience, that BEIS has so far been swift in providing clearances—including in the context of a number of voluntary filings.</li> </ul>

<sup>13</sup> Either following a Phase 1 review, or a transaction subject to the voluntary regime and not having been notified.

<sup>14</sup> The NSIA does not contain a (non-exhaustive) list of remedies that could be acceptable where a national security risk is found.

However, BEIS has made clear that remedies may either be structural or behavioural (e.g., imposing limitations in terms of information sharing, board structure etc). BEIS has indicated that it will aim to only impose remedies that are **necessary** and **proportionate**, and has also encouraged businesses to come forward with remedy proposals for its own assessment, should they wish to do so.

Key question	Answer
<p>What are the <b>penalties</b> for non-compliance?</p>	<p>Non-compliance with interim and final orders, as well as with the mandatory notification and stand-still obligations may result in:<sup>15</sup></p> <ul style="list-style-type: none"> <li>• <b>fin</b>es of up to 5% of acquirer’s worldwide turnover or £10 million (whichever is higher);</li> <li>• personal criminal liability for directors of the acquiring company, including fines and possible <b>imprisonment</b> for up to five years (where the director knowingly or negligently missed a mandatory filing requirement).</li> <li>• <b>director disqualification orders</b> up to 15 years for directors of the acquiring company.</li> </ul> <p>Criminal sanctions (specifically, monetary penalties and/or imprisonment for up to two years) may also be imposed on individuals for failure to comply with information or attendance notices or for providing false or misleading information. Transactions falling under the mandatory regime which are not notified and/or complete prior to clearance are <b>null and void</b> (although they may be retrospectively validated).</p> <p>In case of a voluntary notification, although the acquisition may complete pending BEIS’ review (unless prevented by an interim order), this may be <b>unwound</b> if the government finds national security concerns.</p> <p>Given the novelty of the Regime, there have not been any enforcement cases so far and the Report indicates that, in the limited period covered, no civil or criminal penalties have been imposed so far. We will need to see how BEIS will use its powers going forward.</p>
<p>What are the main challenges expected to arise for life sciences transactions going forward?</p>	<p>As mentioned above, key considerations linked to the Regime include <b>deal certainty</b> and <b>timing implications</b>, as well as increased <b>costs</b> (including in terms of legal fees).</p> <p>The main challenges we see for life sciences deals include the following:</p> <ul style="list-style-type: none"> <li>• <i>The equity/control rights thresholds.</i> Companies in the life sciences sector are often small start-ups with potentially very valuable pipelines and need for quick access to cash to carry forward expensive R&amp;D projects - often raised on multiple rounds. The potential need for multiple filings at each stage, as well as in general the review and assessment process under the NSIA <b>might delay how quickly they can be funded, or discourage investors all together.</b></li> <li>• <i>The precise scope of the sensitive sectors.</i> Despite the government’s effort to provide more detailed guidance on the scope of the 17 sectors requiring a mandatory filing, it is likely that <b>a careful due diligence on the Target’s activities and close involvement and cooperation of scientists</b> and data</li> </ul>

<sup>15</sup> Before imposing penalties, BEIS may in some circumstances take action short of penalties, such as sending reminders or warning letters or requiring remedial action to secure compliance within a specified time period. BEIS has also indicated that it will aim to impose only penalties which are **necessary** and **proportionate**.

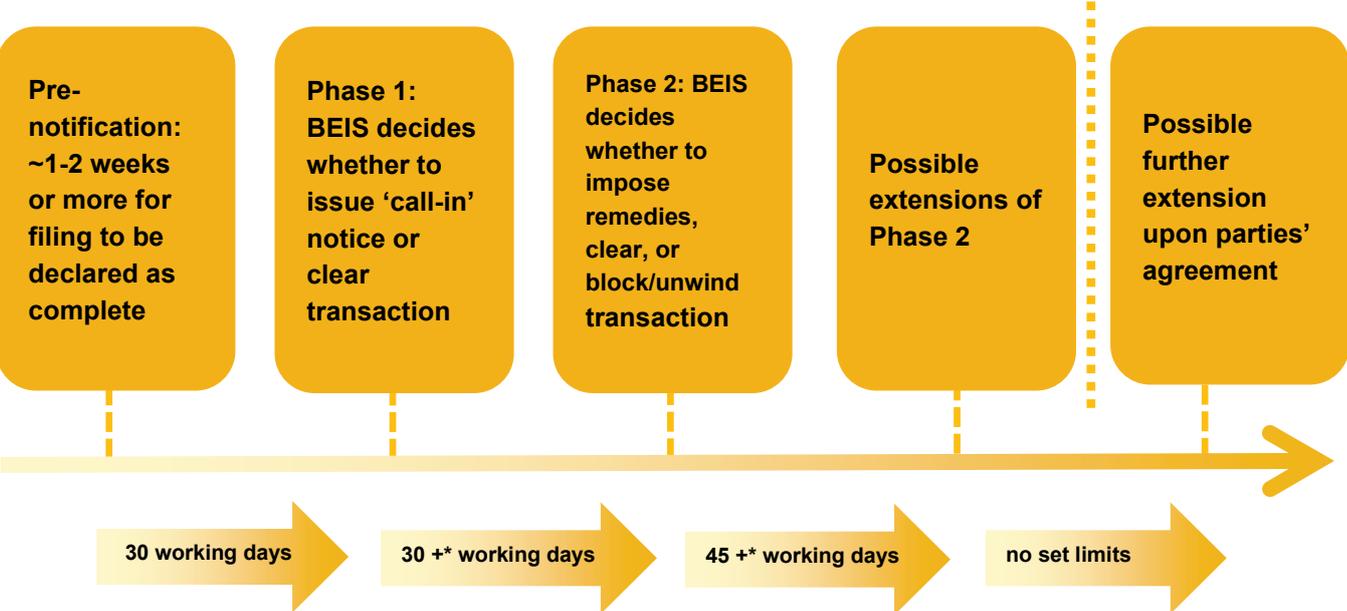
Key question	Answer
	<p>science operators to this end might be necessary—with an inevitable drain on resources, as well as the timing implications that carrying out such an assessment might entail.</p> <ul style="list-style-type: none"> <li>• <i>The concept of “investor risk”</i>. <b>Co-investment strategies</b> - which are particularly important in R&amp;D projects concerning innovative medicines—could be affected if partners are seen as a potential political concern.</li> <li>• <i>The inclusion of asset deals</i> within the potential scope of the NSIA. Since <b>licensing deals</b> (which are particularly relevant in the life sciences sector) could be caught under the voluntary regime, this might add another potential hurdle for life sciences companies seeking to monetise their efforts.</li> <li>• <i>The very low UK nexus required</i> for a transaction to fall within the NSIA—a Target with <b>no UK sales or subsidiaries</b> carrying out R&amp;D activities in the UK might potentially be caught.</li> </ul> <p>From a more general perspective, the following are also worth noting:</p> <ul style="list-style-type: none"> <li>• The severe potential consequences for non-compliance with a mandatory notification requirement, as well as the potential for transactions falling within the voluntary regime to be called-in for up to five years post-closing—as such, it is likely that investors and acquirers will take a cautious and extensive approach towards filing.</li> <li>• The possibility that internal restructurings may also trigger a filing—meaning that a very wide array of transactions might require a notification.</li> <li>• The low threshold for a filing obligation—material influence is sufficient.</li> <li>• The lack of transparency of BEIS’ decision-making activity - even a clearance or a call-in decision will not state the reasoning for clearing or calling in a given transaction, making it harder for the parties to understand BEIS’ reasoning and make representations as to why national security concerns would not arise in the specific case.</li> <li>• BEIS’ active monitoring of the UK market (albeit with no institutionalised mechanisms such as the Merger Intelligence Unit at the CMA) in order to detect potentially relevant transactions—which makes it unlikely that relevant transactions could remain under the radar.</li> </ul>
<p>What happens to the existing <b>Public Interest Intervention Notice (PIIN)</b> regime?</p>	<p>The national security ground for a PIIN (which, prior to the Regime coming into force, enabled BEIS to review transactions for national security concerns) has been repealed, following entry into force of the much more far-reaching NSIA. However, the other grounds for BEIS intervention under the PIIN regime (media plurality, <b>public health emergencies</b> and financial stability) continue to apply and be available to BEIS in parallel to the standalone new foreign investment regime.</p>

Key question	Answer
	<p>We previously flagged<sup>16</sup> that—with the introduction in June 2020 of “public health emergencies” as an additional grounds for BEIS intervention with a PIIN—acquisitions over Targets manufacturing vaccines, personal protective equipment, or essential medical supplies could potentially be caught under the PIIN regime. As such, it seems that acquisitions in the healthcare sectors might be subject to the potential application of two separate intervention mechanisms, in parallel or in alternative: a mandatory (or, depending on the case, voluntary) notification regime under the NSIA, as well as the potential for the UK government to intervene <i>ex-officio</i> on “public interest” grounds in relation to transactions meeting the UK merger control thresholds.</p>

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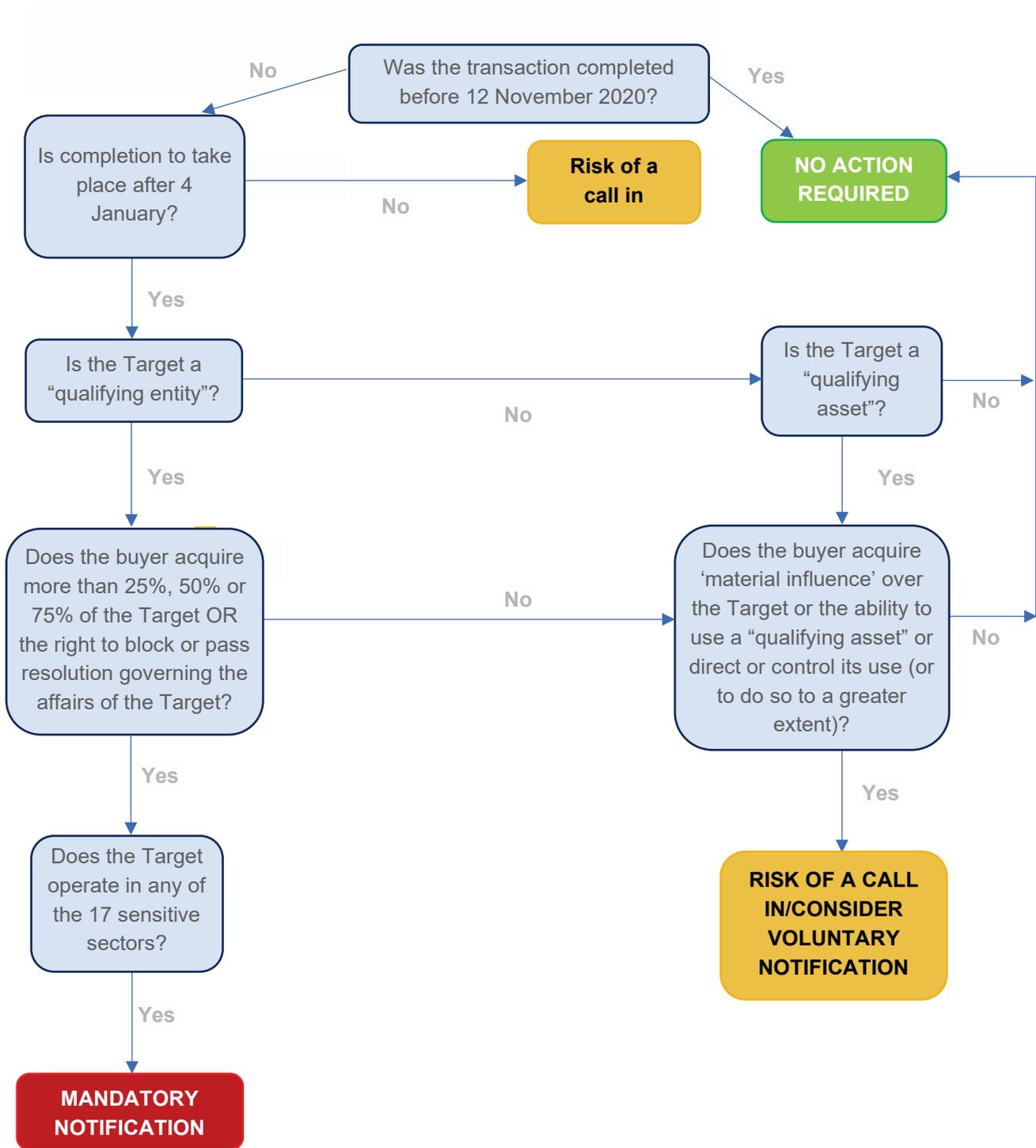
<sup>16</sup> See our previous advisory “Merger Control in the UK—Three and a Half Things You Need to Know” (available at <https://www.arnoldporter.com/en/perspectives/advisories/2020/09/merger-control-in-the-uk>).

## Appendix I—Timeline



\* The symbol “+” indicates the possibility for BEIS to issue information or attendance notices “stopping the clock”.

## Appendix II—NISA process—Flowchart



## Appendix III—the 17 sectors triggering a mandatory notification

The 17 areas of the economy which are considered more likely to give rise to national security risks and which trigger a mandatory filing requirement are:

- Advanced Materials
- Advanced Robotics
- Artificial Intelligence
- Civil Nuclear
- Communications
- Computing Hardware
- Critical Suppliers to Government
- Cryptographic Authentication
- Data Infrastructure
- Defence
- Energy
- Military and Dual-Use
- Quantum Technologies
- Satellite and Space Technologies
- Suppliers to the Emergency Services
- Synthetic Biology
- Transport

## Authors

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**John Schmidt**  
Partner  
London

[john.schmidt@arnoldporter.com](mailto:john.schmidt@arnoldporter.com)

+44 (0)20 7786 6255



**Ludovica Pizzetti**  
Counsel  
London

[ludovica.pizzetti@arnoldporter.com](mailto:ludovica.pizzetti@arnoldporter.com)

+44 (0)20 7786 2961