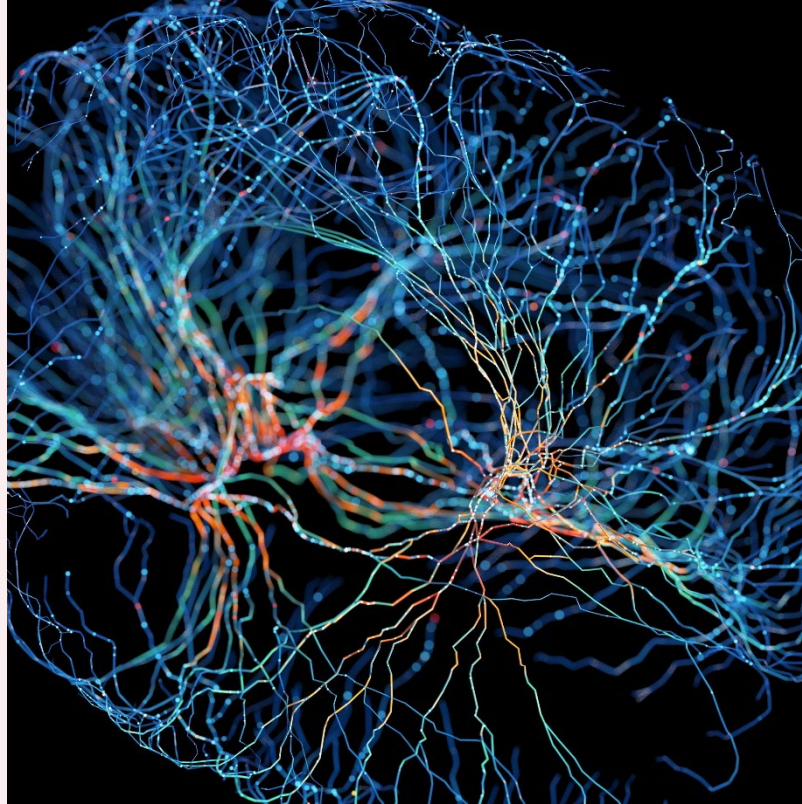


# Healthcare & Life Sciences Sector

## UK corporate criminal liability reforms: risks for the healthcare & life sciences sector

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Changes to the law on UK corporate criminal liability mean that the prospects that companies in the healthcare and life sciences may face criminal investigations and prosecutions are higher than ever. Reforms introduced under the Crime and Policing Act 2026 (CPA), which are now in force, will make it easier for prosecutors to hold companies criminally liable for the actions of individuals within them. These changes apply to all companies but some aspects of healthcare and life sciences companies' operations may expose them to heightened risk.

### Key takeaways

- 1 It has become easier for prosecutors to attribute the actions of individuals to corporate entities – if a "senior manager" (defined widely) commits any UK criminal offence, so may the company.
- 2 Where some issues may to date have attracted potential civil litigation or regulatory enforcement action, they could now also prompt lengthy and intrusive criminal investigations or prosecutions.
- 3 Businesses can mitigate risks by reviewing, refining and supplementing existing training and compliance arrangements. Identifying situations in which the conduct of individuals could expose the organisation to criminal liability and by implementing appropriate training, policies and other compliance measures.

### What is changing?

A company may now be held criminally liable where a "senior manager" commits a broad range of criminal offences while acting within the actual or apparent scope of their authority.

For many years, UK prosecutors have been significantly constrained when seeking to take action against corporates by rigid rules of attribution

(known as the "identification doctrine"). These have necessitated showing that the offence was committed by the company's "directing mind and will". In reality, decisions within large corporates are not usually demonstrably made by one individual. Rather, corporate groups usually function through responsibilities shared and delegated across borders and entities.

In recent years, changes to the law have already been introduced by the Economic Crime and Corporate Transparency Act 2023 (ECCTA) to address previous difficulties with pursuing companies for economic offences. Since December 2023, in order to establish corporate criminal liability for certain economic offences such as fraud, bribery and money laundering, prosecutors have not needed to identify a single individual embodying the company. A different approach has applied. They have been able to fix corporates with criminal liability by demonstrating that a "senior manager" has committed in-scope offences.

Under the CPA, prosecutors may now use this approach in respect of all UK criminal offences. Prosecutors have a wide discretion when deciding whether to take action against companies (including those located or operating outside the UK where there is a sufficient jurisdictional nexus). In the healthcare and life sciences context, prosecutors will be most concerned with cases where decisions have been taken by individuals within entities located or operating in the UK or where decisions or actions have impacted directly on patients or other parties located in the UK.

UK criminal enforcement agencies are already actively seeking cases in which to test these changes to the law on attribution. Depending on the facts, in addition to the Serious Fraud Office and Crown Prosecution Service, specialist investigation and prosecution agencies including the Medicines and Healthcare Regulatory Authority and the Care Quality Commission may have an interest in examining possible misconduct by companies operating in the healthcare and life sciences sectors. Even if prosecutions do not follow, the effects of investigations, through, for example, extensive document production requirements, time consuming interactions with investigators, management distraction, reputational damage and follow on litigation can be significant and long lasting.

### **Why this matters for businesses in the healthcare and life sciences sectors**

Many aspects of healthcare and life sciences companies' operations already require sophisticated compliance and risk management arrangements, including in many areas where breaches of requirements may lead to potential criminal enforcement action. However, in most cases, these will not contemplate potential prosecution risk across all areas of companies' operations.

Multi-jurisdictional and bespoke supply chain arrangements and corporate structures may lead to pockets of concentrated risk. The definition of "senior manager" for these purposes is drawn widely. It includes not only the top levels of management within organisations, but anyone with "a significant role" in making decisions about how organisations' affairs should be managed or organised, or about how they are managed or organised in practice. For healthcare and life sciences companies, this could include, for example, individuals with responsibilities for managing

particular aspects of R&D, manufacturing, product approval or distribution. Conduct occurring outside the UK and scenarios in which work is carried out by other parties, for example under outsourcing or joint venture arrangements may fall within scope.

There have already been significant instances of NGOs pursuing complaints to criminal enforcement authorities to seek to spark investigations and prosecutions concerning healthcare and life sciences companies. The new rules on attribution, which now apply to many of the offences in which they may be interested (ranging from, for example, technical product safety offences, to offences based on animal cruelty, to more commercially focused competition law infringements) may catalyse greater numbers of such approaches. In some cases, activist groups may seek to bring private prosecutions themselves.

### Example scenarios

The table below sets out non-exhaustive examples of hypothetical scenarios in which healthcare and life sciences companies may face an elevated risk of corporate criminal liability.

Example scenarios	Underlying offences
<ul style="list-style-type: none"> <li>A senior manager omits key details when responding to questions asked by officers from investigating authorities.</li> </ul>	<ul style="list-style-type: none"> <li>Failure to respond to requirements to produce documents or provide information/providing misleading information to investigating authorities.</li> </ul>
<ul style="list-style-type: none"> <li>A senior manager responsible for sales within a private healthcare provider conspires with doctors to recommend unnecessary invasive medical procedures in order to secure fees from privately paying patients or from insurers.</li> </ul>	<ul style="list-style-type: none"> <li>Conspiracy to commit assault (possibly in addition to fraud offences).</li> </ul>
<ul style="list-style-type: none"> <li>A senior manager responsible for bringing a new product to market requires or approves unnecessary or inhumane laboratory testing.</li> </ul>	<ul style="list-style-type: none"> <li>Encouraging or assisting the commission of animal cruelty offences.</li> </ul>

### Steps to mitigate risks

Existing compliance arrangements will typically not contemplate the new corporate criminal liability landscape in the UK. Companies should take action now to identify and address gaps. Practical steps may include:

- delivering targeted training to senior personnel and teams involved in higher-risk functions;

- updating policies, approval processes, delegation arrangements and escalation routes so that concerns involving senior operational managers, executives, local business units or outsourced teams are identified and addressed promptly; and
- assessing the risk exposure created by affiliates, contractors, joint venture partners and other intermediaries, and testing how those third parties manage compliance risk before and during engagement.



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