Innovative medicines and medical devices: strategies to reduce liability and regulatory risks

New and innovative medicines and medical devices are in demand as healthcare systems all over the world buckle under financial pressures and aging populations require increasingly expensive treatment for chronic conditions. Rising demand means manufacturers must grapple with an increase in regulatory requirements and oversight. In recent years, manufacturers have had to respond to a steady stream of investigations and litigation alleging that innovative products have caused patients to suffer avoidable injuries or side-effects.

Manufacturers must use strategies to strike the right balance between innovation and risk mitigation, in order to bring their products and services to the market and keep them there.

We have set out six common issues that innovative manufacturers in the life sciences and healthcare sector may have to face, alongside strategies that can mitigate the associated risks.

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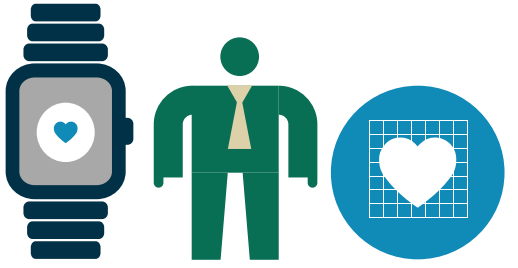

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Why is it important?

- Anecdotal evidence of serious side-effects, or early failure of your product leads to regulatory investigations and litigation.
- Data on how a product is performing will be generated once a product is placed on the market. This adds to the data collected during clinical trials or pre-market studies.
- Depending on the products, data can also be used as evidence to answer questions raised in court, demonstrate revision rates, patient demographics or the prevalence and nature of side-effects.

What's the risk?

Based on recent litigation:

- Some manufacturers have missed opportunities to act on performance data at an early stage.
- Some claimants have taken the initiative to collect and act on data to argue a product is defective.

Mitigation strategy

Use performance data to:

- **Track the ongoing performance of products** and, if needed, act swiftly to recall a product from the market or issue updated guidance to clinicians.
- **Engage with regulators** over the performance of a product to work with regulators at an early stage to cooperate over proportionate public statements or corrective actions needed to address safety concerns.
- **Generate well-sourced and peer-reviewed research** setting out the safe performance of your products, in order to be well prepared for any potential questions about the safety of products from regulators, patients or the media.

Example: A newspaper runs a campaign alleging that significant side-effects associated with your product make it dangerous. Performance data can prove/disprove this claim.

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Why is it important?

Investigations and litigation often concern products that have been historically launched in full compliance with regulations and standards at the time.

Any of the following can change how regulators and the courts view a product:

- developments in scientific understanding.
- new iterations of the product (particularly where software is updated).
- shifts in the public's tolerance of the risk of side-effects or injury.

What's the risk?

Once initial compliance with regulatory standards is obtained, it can drop down the agenda as time goes on.

When products are overseen by regulators, it can be tempting to think that their approval and compliance with existing regulations is enough to mitigate the risk of investigations or allegations that products are defective.

Mitigation strategy

If the public's or court's risk tolerance has shifted since your product was placed on the market:

- **Be alert to the prospect of changes in the accepted level of risk tolerated by the public or the courts**. If there is a chance your product would fall short of this standard, consider reviewing your compliance processes.
- **Consider working towards compliance with the next generation of regulatory requirements**, even before you are legally obliged to do so (e.g., when transition periods are in effect, but you can continue to supply products under old regulations).
- **Monitor criticism of any comparable competitors' products** and assess whether there are any learning points for your product, thereby reducing risk.

Example: A sudden shift in societal norms means that the risk of injury to a particular demographic of patient is no longer tolerable.

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Why is it important?

The information that accompanies your medicine or medical device may prove to be the key to persuading a court that your product meets the required standard and is not defective. You may be able to refer to the warnings in the product literature to show that risks were properly understood and explained. However, scientific knowledge of how a product performs, and understanding of the risk of side-effects or injury, develops over time. The literature that is given to users or clinicians may also become out of date if it is not kept under review.

What's the risk?

If literature that accompanies your product is not updated, it creates risk that relevant warnings aren't relayed to patients or that your product will be misused.

Mitigation strategy

Keep under review the literature that accompanies your product, in order to:

- **Determine whether** new understanding of side-effects, dosage, patient selection, surgical technique, monitoring or alternative clinical options means product literature needs to be updated.
- **Assess changes** to the manufacturing, distribution or packaging processes in case they could have a bearing on the risk of side-effects.
- Decide whether various sub-categories of product perform differently to each other and **consider issuing specific guidance for particular products**.

Example: Instructions for Use accompanying an implant are not updated when new contraindications become apparent.

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Why is it important?

Your product may not start its life subject to healthcare regulations, but this can change.

Your product may become subject to the healthcare regulatory system once new regulations are introduced or regulators issue new guidance.

If this happens, you will need to adapt to a new regulatory system that involves working with regulators and complying with sector specific standards.

In some cases, you will need to engage a Notified Body (in the UK: an Approved Body) in order to achieve compliance with healthcare regulations.

What's the risk?

Healthcare regulations can expand and capture a wider range of products.

This is a particular risk in the case of "borderline" products (products whose status is unclear until it has been determined by the regulator).

Mitigation strategy

Be alert to regulators' industry-wide investigations in order to be prepared to:

- Assess whether you have the option to **demonstrate that your product does not meet the relevant statutory definition** of a "medical device" or a "medicine".
- **Analyse the impact** of your product being regulated under healthcare regulations if it is now considered a "medical device" or "medicine".
- **Put in place systems needed to ensure** compliance with new ongoing obligations, including reporting on adverse events to the regulator and updating the literature that accompanies the product.

Example: You have been producing a consumer product for some years but a regulator carries out an investigation and decides your class of products should be classified as "medical devices".

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Why is it important?

Supply chains are ever more complex.

If you are the ultimate manufacturer, you may become the obvious target of litigation or investigations where compliance failures, committed by other parties, lead to patients and users suffering avoidable injuries.

What's the risk?

- There are non-compliant businesses in your supply chain.
- Issues caused by a defective model or batch can be exacerbated where parties in the supply chain do not comply with their obligations to track and recall products.

Mitigation strategy

Cooperate and negotiate with your supply chain to:

- **Assess where liability or regulatory risks lie** in the manufacturing and distribution process, and areas where you can take steps to reduce risks, then negotiate with the supply chain to allocate liability via contractual agreements.
- Ensure that other parties in the **supply chain are performing their functions over post-market surveillance**, especially with identifying any issues early on, making it easier for you to investigate and take any corrective actions as needed.
- Consider the **insurance provisions** in place within the supply chain, to guard against insolvency risks.

Example: A supplier provides non-compliant materials, which cause injury. The supplier then goes into administration, leaving you as a sole defendant.

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Why is it important?

Manufacturers of products that are used to treat people in the hundreds, thousands or even millions, run the risk that litigation will involve multiple claimants and jurisdictions.

It is often the case that litigation begins in one country and then spread to others because the claimants' cause of action is transferable.

Litigation can also spread from one product to another, even if the second product was produced by a different manufacturer.

What's the risk?

- Failing to take decisive steps if faced with multi-claimant litigation can prove costly in the long term.
- Litigation can take years to resolve but the decisions made at the outset can have a significant bearing on the success of your defence from allegations that your product is defective.

Mitigation strategy

Seek to contain litigation and assess the prospects of a successful defence by taking steps to:

- **Analyse the number of products** placed on the market and calculate what proportion of them will provide claimants with the basis for a claim by assessing a) if a manufacturing defect is limited to specific batches and/or b) whether a particular demographic of the patient population is most at risk.
- **Assess where in the world there is a risk of claims**. Assemble a team to coordinate all work carried ou defending claims to avoid the risk that the procedural timetable in one country could run ahead and affect the prospects of defence in other countries.
- **Invest and discuss with your legal team** (who can help you assess your prospects of resolving the litigation successfully at an early stage) **and leading individuals** who are amongst the most qualified in their field and equipped to act as expert witnesses (and instruct them before the competition does).

Example: Claimants in the US allege that a pharmaceutical company failed to adequately warn patients of a cancer risk; claimant law firms in other jurisdictions take note and advertise for clients.

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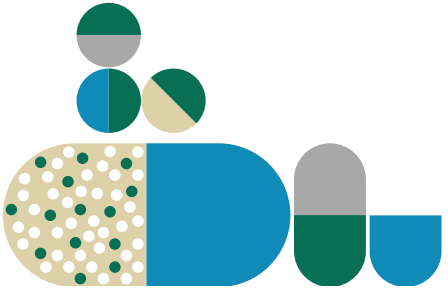

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