Developers guidance

Improving or updating medical devices after deployment

This is required guidance

It is legally required and it is an essential activity.

This Guide covers:

- Great Britain (England, Scotland, Wales)

From:

- Medicines and Healthcare products Regulatory Agency (MHRA)

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When updating digital technologies or medical devices that are already on the UK health and social care market, you will need to:

- assess how significant the changes are for each update, and
- consider whether you need to reapply for approval

Monitoring changes to the intended purpose of your technology

After placing your digital technology on the market, you may want to add new functionality or improve aspects of your technology. For example, you may need to update your technology to meet new security requirements. Or, if the performance of your technology drops, you may want to change or update your technology to improve or bring performance back in line with acceptable or prespecified levels. This is required for medical devices.

For medical devices it is important to understand whether this new functionality changes the intended purpose of the technology. If it does, extra reviews before the approved body or competent authority allows the update will be required and a complete re-assessment against the regulations may be needed.

For non-medical devices, you will need to consider whether previous evaluations (for example, health economic modelling) are impacted by the change.

If your medical device changes, you will need to justify such a change.

You may have to go back to the beginning of the technology lifecycle to:

- make sure you gain relevant approvals
- meet appropriate standards for the updated technology
- generate the relevant evidence to make sure the technology is still operating legally
- generate the relevant evidence to make sure the technology is safe and effective for its new purpose

Plans for change management should be in place during the technology development stage.

Determining significant changes to your digital technology

Updates to digital technologies are changes that happen after the technology has been placed on the market. These can be:

- minor (for example, removing bugs)
- significant, such as a software change that replaces previously required user input to a closed loop decision or change in use

For further detail on what constitutes a significant change see:

- Guidance for manufacturers and Notified Bodies on reporting of Design Changes and Changes of the Quality System
- Notified Body Operations Group

It is worth noting that technology changes may be done proactively or reactively. For example, a proactive change may involve updating a digital technology to improve user experience or resource usage based on customer feedback.

A reactive change may be based on a safety concern or change in cybersecurity requirements. Beyond determining whether a technology update is significant or substantial, you may need to consider how this relates to other aspects of post-market surveillance such as safety reporting.

Requesting to make a significant change

You must assess proposed updates to medical devices before they are deployed. This will form part of the internal release processes and benefit risk analysis under your quality management system.

When you have planned significant changes, you cannot deploy the technology without getting them ratified by the approved body overseeing the technology. This process will be assessed during QMS audits. Failure to comply with requirements can lead to additional costs and potentially the removal of your technology from the market.

Responses to safety concerns

In some cases, you will need to update a technology because of an identified or suspected safety concern. In this case, there are requirements under the UK Medical Devices Regulations (UK MDR 2002) under post-market surveillance to:

- assess incidents
- report them to the MHRA
- investigate the root cause, and
- address the issue

Within this process there are requirements to inform users of technology changes.

This information is not intended to replace formal statutory guidance regarding legal requirements. For an authoritative view of what regulations require beyond this digest, please see the relevant gov.uk web pages pertaining to the MHRA.