UK Digital Health – the future of software as a medical device

MHRA consultation on the regulation of software as medical devices – what you need to know

Any changes arising from the consultation on what software constitutes a medical and health device will impact how Digital Health companies operate in and from the UK.

The consultation proposes an update to the existing regulation of software as a medical device (SaMD), including AI as a medical device (AIaMD), particularly altering the risk classification and distance selling rules of these Digital Health software devices.

There will be a new regulatory framework for SaMD and AIaMD. The consultation provides an opportunity for you to shape what this new framework might look like.

We have set out below a summary of why Digital Health companies should be participating in the ongoing MHRA consultation and how to submit a response.

Key Dates

- The consultation opened on 16 September and closes at **11.45pm** on **25 November 2021**.
- The MHRA hosted a webinar on 5 October 2021 (10.30-11.30 BST) aimed at members of the health devices sector to provide further background on the consultation, its purposes and how to get involved. The webinar was recorded and will be made available on the MHRA website in due course.
- The MHRA is hosting a second webinar on 14 October (10.30-11.30 BST) aimed at members of the public.

Background

The Medicines and Medical Devices Act (2021) allows the MHRA to amend the Medical Devices Regulations 2002 to create a new regime for regulating medical devices in the UK. The new regime is scheduled to come into force on 1 July 2023. The consultation is canvassing views on what the new regime might look like and the form of any amendments to the existing Regulations.

The new regime will be designed to transform the Digital Health medical devices sector by:

- creating new access pathways to support innovations and make the UK an attractive destination for launching new medical devices;
- developing the regulatory framework for SaMD and AIaMD in order to attract a world class life sciences industry whilst keeping patient safety a top priority;
- reforming in vitro diagnostics (IVD) regulation; and
- becoming a sustainability pioneer through promoting the safe use of re-usable and re-manufactured medical devices and decreasing reliance on single use medical devices.

What is the purpose of this consultation?

The consultation is designed to develop a future regime for Digital Health medical devices with the aim of:

- improving patient and public safety;
- increasing transparency of regulatory decision making and medical device information;
- creating closer alignment with international best practice, and;
- developing flexible, responsive and proportionate regulation of medical devices.

The consultation is divided into 17 chapters relating to different aspects of the regulation of medical devices. Below, we set out a summary of the consultation chapters of most relevance to Digital Health companies and detail how responses to the consultation can be submitted.

Chapter 10: Software as a Medical Device

The existing Regulations contain few provisions aimed at regulating SaMD and AIaMD used by many Digital Health operators. The consultation is looking bring the existing Regulations up to date, seeking to develop a regime for regulation SaMD, including AIaMD, that is clear, effective and proportionate to the risks that such devices present.

In relation to SaMD, the consultation includes questions on the following areas:

- clarifying the meaning and scope of the term 'software';
- clarifying the meaning of distance sales and modifying the term 'placing on the market';
- changing the classification of risk categorisation of SaMD;
- introducing an 'airlock classification rule' to allow for temporary classification of some SaMD where the risk profile is unclear;
- pre-market scrutiny of SaMD;
- post-market requirements; and
- introducing minimum requires relating to cyber security and information security measures.

The questions specifically related to AIaMD concern potential amendments to the Regulations to require performance evaluation methods for diagnostic AI to take a comparable approach to the performance evaluation methods used for in vitro diagnostic medical devices.

For each of these areas, the questions focus on whether respondents think the suggested changes should be carried out and why. The consultation also seeks to find out what expected impacts the changes would have on stakeholder groups. Respondents are able to provide evidence to support their responses.

Section 58: Scope and definitions of 'software'

The MHRA is considering adding a new definition of 'software' to the Regulations. The definition proposed is extremely wide: "*a set of instructions that processes input data and creates output data*". This is consistent with the definition adopted by the European Commission.

The consultation asks respondents to provide their views on whether this definition is appropriate, if any other definitions should be added or amended to create greater clarity on what requirements apply to placing SaMD on the UK market, and provides the opportunity to share the impact the proposed definition will have on the respondent and other stakeholders.

Section 59: Distance sales

The MHRA recognises that SaMD can be deployed in the UK market via websites, app stores and other electronic means that may be hosted in other jurisdictions. As a result, the MHRA is considering whether regulatory change is required to clarify the existing Regulations or add further regulatory requirements for placing SaMD on the market where the websites are hosted outside of the UK.

The MHRA proposes modifying the definition of 'placing on the market' to clarify when SaMD deployed on websites, app stores and via other electronic means that can be accessed in the UK amounts to 'placing on the market'. The consultation asks respondents to provide their views on whether there is a need for such clarification. The MHRA also requests details of any potential impacts such a change would have on the respondent and other stakeholders.

Section 60: Classification: Risk categorisation

The MHRA is proposing to alter the classification of SaMD in order to make the level of scrutiny applied to such devices commensurate with level of risk those devices pose. It also seeks to harmonise the classification with international practice.

The risk categorisation that is being proposed is the same as that adopted by the International Medical Device Regulators Forum.

The consultation asks respondents to detail whether they think the UK classification rules should be amended in this way and to set out any impacts such change might have.

Section 61: Classification: Airlock classification rule

The MHRA is considering introducing an 'airlock classification rule', which would allow some SaMDs to receive a temporary high risk classification where the risk profile is unclear. This could enable early market access for novel and innovative SaMD whilst ensuring the safety of users until the risks are fully understood.

The consultation asks respondents whether they think an 'airlock classification rule' should be introduced and why. The consultation also requests details of any anticipated impacts an 'airlock classification rule' would have on the respondent and other stakeholders.

Section 62: Pre-market requirements

SaMD is already subject to the essential regulatory requirements that broadly apply to all medical devices. However, the MHRA is considering whether any additional essential requirements should be put in place specifically for SaMD to ensure appropriate levels of pre-market scrutiny.

The consultation asks respondents whether they think additional requirements for SaMD should be introduced, the reasons for this, and any anticipated impacts. The consultation also asks for respondents' views on whether the essential requirements for SaMD should be separate from other general medical device types.

Section 63: Post-market requirements

The MHRA is proposing two key changes:

- in order to allow for accurate and swift reporting via the Digital Yellow Card Scheme, SaMD would have a hyperlink to MHRA endorsed websites where a person can 'report an adverse incident with a medical device' where appropriate; and
- certain SaMD change management processes such as 'predetermined change control plans' should be provided for.

In relation to the first change, the consultation asks respondents whether the Regulations should mandate a 'report advertise incident' link be included and to provide their reasoning for this view.

In relation to the second change, the consultation asks respondents if regulations should enable pre-determined change control plans and what these should entail.

Section 64: SaMD Cyber Security

In order to ensure SaMD has sufficient cyber and information security in place, both in relation to the direct safety of the device and security of personal data, the MHRA is proposing minimum safety requirements for manufacturers.

The consultation asks respondents whether they think existing regulations should include cyber and/or information security requirements, what these should be, and the potential impacts of such a change for the respondent and other stakeholders.

Section 65: Artificial intelligence as a/in a medical device (AIaMD)

This is a subset of SaMD and the MHRA sees the above changes as beneficial for AIaMD as well. However, the MHRA is also proposing specific changes to the regulations with regards to AIaMD. Specifically, the consultation proposes amending the Regulations to require performance evaluation methods for diagnostic AI to take a comparable approach to those used for in vitro diagnostic medical devices (IVDR), particularly in relation to scientific validity and analytical and clinical performance.

With regards to AIaMD, the consultation takes a broad approach and asks respondents if there are any other statutory changes needed to effectively regulate AIaMD that were mentioned with respect to SaMD. Respondents are given the opportunity to share their suggestions.

The consultation also asks respondents for their views on whether the use of IVDR-type performance evaluation methods for AIaMD would be appropriate and whether the Regulations should mandate the logging of outputs of further auditability requirements for all SaMD or just AIaMD for traceability purposes.

The MHRA asks respondents to share their reasoning and any impacts these changes would be likely to have, including how burdensome these requirements would be for different stakeholders.

How to respond to the consultation?

Respondents are able to provide responses on the particular chapters that are of interest or relevance. It is not necessary to comment on the entire consultation document, although this can be done if desired.

The MHRA is proposing bold, widescale change to the regulation of medical devices in the UK, particularly with respect to SaMD and AIaMD. These proposals will undoubtedly impact how Digital Health companies are run and operate in the UK. This consultation provides an opportunity to give feedback, to articulate any concerns with the proposals, and, ultimately, to help shape the future regulation of medical devices in the UK. Responses can be completed and submitted online via the MHRA's website.

Please let us know if you would like to discuss how the proposed changes to the regulation of Software as a Medical Device may impact your Digital Health business and if you would like any assistance in making your submission to influence the shape of future regulations.

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