The Global Language of Business

The MHRA public consultation on the future of medical device regulation in the UK – What you need to know

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MHRA consultation on the future regulation of medical devices in the United Kingdom

Background information

Now that The Medicines and Medical Devices Act has become legislation the Medicines and Healthcare products Regulatory Agency (MHRA) will issue new regulations as to the requirements of the future of unique device identification and identification of medical device economic operators in the UK. One of the regulations for the MHRA will be to register medical devices to create a database of devices on the UK market.

Timelines for the regulation to register medical devices are as follows:

- Class III **1 May 2021**
- Class IIa and IIb **1 Sept 2021**
- Class I **1 January 2022**

The future registration process is to include UDI and organisation identification to the regulations so if you have GTINs and GLNs already assigned now is a good time to include them.

About the consultation

The MHRA is inviting members of the public to provide their views on possible changes to the regulatory framework for medical devices in the United Kingdom (UK). The purpose is to develop a future regime for medical devices which enables:

- Improved patient and public safety;
- Greater transparency of regulatory decision making and medical device information;
- Close alignment with international best practice, and;
- More flexible, responsive and proportionate regulation of medical devices.

They are requesting the views of patients, medical device researchers, developers, manufacturers and suppliers, clinicians, other healthcare professionals and the wider public to help shape the future approach to regulating medical devices in the UK.

Deadline: The consultation closes at **11:45pm on 25 November 2021**.

Further information on the consultation can be found here.

The call to action

For the fundamentals of UDI to work efficiently, there needs to be no ambiguity as to what the product's primary identifier is. A sole, **globally unique identifier** should be used on the designated device – **one barcode standard only** – encompassing all the necessary production information i.e. batch/lot number and expiry date etc.

Organisations (such as medical device manufacturers, wholesalers, distributors, healthcare provider organisations, and solution providers) should also be **accurately identified by a single means that is universally recognised** – a standard, unique economic operator ID. This will improve the traceability of products to ensure compliance with regulation as a critical patient safety measure.

What you need to do

This is a unique opportunity for all healthcare stakeholders to help shape the future of UDI regulation in the UK.

Here are the two easy steps you need to follow to do so:

1. One nominated respondent needs to be allocated from your organisation to address the public consultation

2. Present your recommendations/suggestions regarding the use of a single, globally unique identifier for medical devices. **One barcode standard only**, used across all device packaging, to prevent confusion or identification errors.

Why this is relevant to GS1 UK members and partners

GS1 standards, namely Global Trade Item Numbers (GTINs) and Global Location Numbers (GLNs), are already being accepted by the MHRA and are more widely used both in the UK and internationally. Several stakeholder organisations are already using GS1 standards as part of their established processes to label products and pinpoint locations – both throughout the supply chain and in clinical settings.

The summary table below highlights why GS1 standards would be a fitting solution for UDI and economic operator ID.

A summary of the role of GS1 standards in medical device regulation

Global Trade Item Numbers (GTINs) *Globally unique identifiers for medical devices (the UDI)*	**Global Location Numbers (GLNs)** *Globally unique identifiers for medical device economic operators*	**GS1 UK LocationManager** *A central, national registry of GLNs for suppliers to the NHS*
The NHS eProcurement Strategy and subsequent Department of Health and Social Care (DHSC) Scan4Safety programme have driven the adoption of GTINs for products and GLNs for manufacturers and trusts.	GS1 standards are included in the NHS Digital contract for England and contracts for NHS Wales, Health and Social Care Northern Ireland, and NHS Scotland.	GLNs for manufacturers and trust legal entities are currently held in the national registry, LocationManager – the national database requested by the DHSC as part of the Scan4Safety programme.
GTINs are one of the identifiers that the MHRA will accept and meets the requirements of existing international UDI regulations. UDI-DI is currently requested from manufacturers during device registration with the MHRA.	GLNs are the identifier of choice for location for acute trusts in the NHS as defined in the NHS eProcurement Strategy. All medical device manufacturers supplying the NHS must use GS1 identifiers to meet the procurement mandate, even those currently using HIBBC.	LocationManager is provided as part of the NHS Digital contract for England and is included in the partnership agreements with NHS Wales, Health and Social Care Northern Ireland, and NHS Scotland.
The GTIN is key to Scan4Safety in improving patient safety by enabling products to be tracked and scanned at the point of care.	GLNs are being used for numerous use cases including inventory management, asset tracking and purchase to pay in the implementation of Scan4Safety programmes across England at present.	The registry is currently in use for manufacturers and trusts to share GLNs for ordering and invoicing purposes. More than 860 manufacturers are already registered with their information readily accessible for purposes such as these.
The MHRA has recommended that manufacturers incorporate a UDI device and header spreadsheet in their Field Safety Notices when informing customers of safety issues. Where GS1 standards are being utilised by the manufacturers, GTINs are requested as one of the unique device identifiers.	The uptake of electronic transacting (e-procurement)has increased. GS1 UK's recent work with NEP and PEPPOL Access Point providers continues to drive adoption of GLNs.	Medical device economic operators are already inputting information into this national registry.
	The MHRA has recommended that manufacturers incorporate a UDI device and header spreadsheet in their Field Safety Notices when informing customers of safety issues. Where GS1 standards are being utilised by the manufacturers, GLNs are requested as one of the unique identifiers.	
	GLN use facilitates the traceability	

	of products throughout the supply chain and patient pathway to simplify the process for product recall for medical devices and improve post-market surveillance of devices.	

Key chapters for responses

There are two main chapters (chapter 4 and chapter 8) that will require feedback around the registration and use of unique device identifiers, the type of identifiers that should be used, and discusses the means to improve post-market surveillance of medical devices and in-vitro diagnostic medical devices (IVDs). However, you may also find some information in chapter 11 around implantable devices useful so reference to this has also been added.

Details regarding each of the chapters referenced above, have been outlined and highlighted accordingly for your convenience. Included below, in relation to the relevant sections, you will also find some supporting commentary to address the responses.

Chapter 4 – Registration and UDI

The MHRA's ambition is to be world leading and patient-driven in enhancing the transparency and safety of medical devices from development through to use and disposal.

The Medicines and Medical Devices (MMD) Act 2021 has expanded powers to disclose information about medical devices for the purpose of warning the public about safety concerns. Introducing new registration and identification requirements could enable the MHRA to make use of those powers effectively and in a targeted manner - and we are seeking your views on this matter.

Possible changes focus on **improving patient safety** and on **aligning with international best practice** and include:

- Improving the traceability of medical devices within the supply chain in the event of an issue occurring with a particular model or device type (**section 17**)

  Key questions will include:

  - Q17.1 Do you think the UK medical devices regulations should include the requirements set out in paragraph 17.1* for economic operators to ensure traceability of medical devices?
  - Q17.2 Please outline any other traceability requirements which should be introduced for economic operators.

  *17.1 notes can be found in the chapter four overview document referenced at the end of this section.

- Possible changes to medical device nomenclature use by manufacturers (**section 18**)
- Introducing a system of Unique Device Identifiers (UDI) which the MHRA could use to trace devices and patients and professionals could use to report incidents (**section 19**)

  Assignment of UDI

  Key questions will include:

  - Q19.3 Do you think the UK medical devices regulations should require manufacturers to assign UDIs to medical devices before they are placed on the market?
  - Q19.4 If you answered 'yes' to question 19.3, please outline any particular requirements which should be introduced in regards to how UDIs should be applied to medical devices and any aspects which require clarification.
  - Q19.5 Should devices that are reusable bear a UDI carrier (e.g. barcode) that is permanent and readable after each process on the device itself?
  - Q19.7 Should the UK medical devices regulations include requirements for Basic UDI-DI to identify medical device models?
  - Q19.8 Do you think manufacturers should be required to assign and apply UDIs to their medical devices before applying to Approved Bodies for conformity assessment?

Supporting information

GS1 is a designated UDI code-issuing entity and has authority to do so in accordance with existing international UDI regulations such as the EU Medical Device Regulation (EU MDR). Further to this, Basic UDI-DI is already a requirement for the EU MDR so it would be reasonable to reference this as a requirement in the UK also. It would also allow for greater traceability to the family product-type level. At the point of manufacture, devices should be marked with a unique device identifier before they are placed on the market. This will enable greater traceability from the outset allowing the device to be tracked and monitored for post-market surveillance. With medical device information linked back to the patient, via the proposed NHS Digital Medical Device Information System (MDIS), it would be possible to monitor patient outcomes as well as the safety of the devices. This is a crucial patient safety measure should any device-related product recall occur.

UDI Issuing Entities

Key questions will include:

- 19.15 UDI-issuing entities operate systems for assignment of UDIs. There are currently four designated issuing entities for the EU system - GS1, HIBCC, ICCBBA, IFA. For a future UK system, the MHRA could designate one or more issuing entity. Manufacturers could be required to obtain a UDI from an MHRA-designated issuing entity and apply this to the medical device before placing the device on the UK market.
- Q19.14 Please outline which issuing entities should be designated by the MHRA. In your response please provide the following information:

    a. should the MHRA designate one or multiple UDI issuing entities?

    b. if there should be one issuing agency, which one (and why)?

    c. if there should be multiple issuing agencies, which ones (and why)?

Summary information

GS1 is the longest established, and most widely used, of the UDI code-issuing entities and the use of GS1 standards is mandated by the NHS. Furthermore, because GS1 standards are globally unique and both system and device agnostic, they are already being used internationally to comply with existing global UDI regulations. In order to ensure that the UDI used is truly unique, it would be advisable to have a single UDI issuing entity and one standardised means of identifying the required devices using a single barcode standard.

UDI retention and storage

Key questions will include:

- Q19.15 Do you think manufacturers should be required to keep an up-to-date list of all UDIs they have assigned to medical devices as part of the technical documentation?
- Q19.17 Do you think economic operators should be required to store the UDI numbers of certain medical devices?
- Q19.19 Do you think healthcare professionals and/or health institutions should be required to store the UDIs of certain medical devices?

Summary information

In order to be able to effectively track and trace devices throughout the supply chain and the patient pathway, directly to the point of patient care, both manufacturers and healthcare provider organisations should be required to store and access the necessary UDI. This is a key patient safety requirement which will enable effective product recall in the event of any field safety notification.

- Bringing together all the information about medical devices on the market in a single database to enhance transparency and market surveillance (**section 20**)
    - Q20.1 Do you think that we should introduce the proposal outlined in paragraph 20.1*?

* 20.1 notes can be found in the chapter four overview document referenced at the end of this section. This proposal pertains to the introduction of medical device register.

Summary information

In order to improve post-market surveillance of products it would be necessary to hold required device information at national level. This will enable greater transparency for all manufacturer and provider organisations across the UK to improve patient safety, care and outcomes. The Cumberlege Review provides the evidence behind the requirement for such a database to be put in place.

- Expanding and publishing medical device registration information (**section 21**).

Information updates

Key questions will include:

- Q21.12 How should economic operators be identified within the MHRA registration system?:
    a. MHRA generated reference number (not internationally recognised)
    b. DUNs (internationally recognised external reference)
    c. GLN (internationally recognised external reference)
    d. other (please specify)

Summary information

Nearly a thousand supplier organisations have already registered their GLN information in LocationManager, the national GLN registry – a registry that was established at the request of the Department of Health and Social Care (DHSC), to support the requirement that all parties and their significant locations be identified by a GLN. Access to this registry is available to all healthcare provider organisations as part of the respective contracts between GS1 UK and the corresponding healthcare arm's length bodies across all four UK devolved nations.

A summary of chapter four can be found here.

Chapter 8 – Post-market surveillance, vigilance, market surveillance

After a medical device is placed on the market, manufacturers must continually monitor the performance of the medical device. This is called post-market surveillance. We are seeking views on expanding and clarifying requirements to improve patient safety by enhancing the ability of both the manufacturer and the MHRA to identify issues.

Possible changes focus on **improving patient safety** and include:

- Introducing post-market surveillance plans, which outline how information is to be collected and assessed (**section 48**)

- Clarifying requirements for reporting of serious incidents and field safety corrective actions (**section 49**)
    - Q49.1 Do you think the UK medical devices regulations should include requirements for manufacturers to report incidents and FSCAs to the MHRA including points (a) and (b) as above*?

  * Reference to points a and b can be found in the chapter eight overview document referenced at the end of this section.
- Ensuring that manufacturers report trends of all types of incident, whether serious or otherwise, to the MHRA (**section 50**)
- Defining minimum requirements for the content of field safety notices (FSNs) to ensure that all FSNs are drawn up to the same, high standard (**section 51**).

A summary of chapter eight can be found here.

Chapter 11 – Implantable devices

Implantable medical devices bring with them some unique challenges – procedures to introduce them and to stop using them can be highly invasive; they are used for a longer duration than many other types of medical devices and their removal brings additional risks or may not be possible.

Possible changes focus on improving patient safety and promoting innovation and include:

- Expanding the scope of regulation to include temporarily implanted devices
- Up-classifying certain implantable devices
- Introducing more stringent pre- and post-market requirements, including reducing the reliance on equivalence in the assessment of implantable medical devices and introducing a requirement for implant information to be provided to patients
- Introducing more controlled access to implantable medical devices
- Increasing the level of information the MHRA captures and shares about implantable medical devices.

A summary of chapter 11 can be found here.

Details of the other sections of the consultation can be found in the overview here.

Submitting your feedback

The consultation will be open for ten weeks and will close at **11:45pm on 25 November 2021**.

You will need to complete the relevant sections of the form to share your feedback.

Complete the submission

Support and further information

For any further information about GS1 standards and UDI requirements, feel free to get in touch with us at GS1 UK and a member of the healthcare team will get back to you. You can email us at healthcare@gs1uk.org.

For additional information about the consultation can be found on The Government website here.