

# Chapter 4: Registration and UDI

## Section 16 - General background

### Background

16.1 The MHRA's ambition is to be world leading and patient-driven in the transparency of its regulation of medical devices in the UK – enhancing the transparency of information about medical devices from development through to use and disposal.

16.2 Historically, the MHRA has been limited in terms of the information about medical devices it can gather and disclose. It has not, for example, been able to publish specific information about adverse incidents relating to medical devices. However, the Medicines and Medical Devices (MMD) Act 2021 contains provisions (primarily in sections 16 and 39) that enable the Secretary of State to disclose information. Some of these powers relate specifically to the disclosure of information captured within a register of medical devices and information for the purpose of warning the public about concerns relating to the safety of medical devices.

## Section 17 - Identification within the supply chain

### Background

17.1 The MHRA is considering amending the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations) to require that economic operators (manufacturers, importers, distributors etc) share more information with the MHRA about the supply of medical devices, and to require economic operators to ensure the appropriate traceability of medical devices. The objective would be to improve the traceability of medical devices, which have been sold or are in the supply chain, in the event of an issue (i.e. a device recall) occurring with a particular model or device type.

### Possible Changes and Questions

17.2 The UK medical devices regulations could include a requirement for distributors and importers to cooperate with manufacturers, UK Responsible Persons (UKRPs), and public and private sector health institutions to achieve an appropriate level of traceability for medical devices.

17.3 For example, the UK medical devices regulations could be amended to require economic operators to be able to identify and record the following:

- a. any economic operator to whom they have directly supplied a medical device;
- b. any economic operator who has directly supplied them with a medical device;

- c. any public or private sector health institution or healthcare professional to which they have directly supplied a medical device;
- d. any lay person/user/patient directly supplied with the medical device.

17.4 The records described in paragraph 17.3 would need to be kept for a specific time period and provided to the MHRA upon request.

**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? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q17.2 Please outline any other traceability requirements which should be introduced for economic operators.**

**Q17.3 If we were to introduce a requirement for economic operators to be able to track the supply of medical devices, and to keep the records pertaining to that for a specific time period (as set out under paragraphs 17.3 and 17.4 above), what time period should be specified?**

**Q17.4 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 17.1-17.3, including any impacts on you or other stakeholder groups.**

## Section 18 - Nomenclature

### Background

18.1 Medical device nomenclature provides a coding system for medical devices. It is used to identify a medical device without the need for terms or descriptions which may not be understood across different languages. For example, by looking at the nomenclature code we can tell that the medical device is, for example, a bedrail, or a wheelchair.

18.2 Manufacturers of medical devices or their UK Responsible Persons (UKRPs) are currently required to register all medical devices being placed on the UK market with the MHRA in line with the grace periods provided for in the Regulations (with limited exceptions – see [MHRA guidance](#) for more details).

18.3 When registering medical devices with the MHRA and when reporting adverse incidents relating to medical devices to the MHRA, manufacturers (or their UKRP, if applicable) must submit a Global Medical Devices Nomenclature (GMDN) code to identify the medical device.

18.4 MHRA considers GMDN to be the best option for medical device nomenclature for the UK system. GMDN is the most widely used nomenclature system worldwide and

it is required by the US, Canada, Australia, Singapore, and other nations in regulatory submissions and UDI databases.

18.5 The EU Medical Devices Regulations (2017/745) and EU *in vitro* Diagnostic Medical Devices Regulations (2017/746), require manufacturers to assign European Medical Device Nomenclature (EMDN) rather than GMDN to medical devices, for regulatory purposes such as the submission of information to the EU database for medical devices – EUDAMED.

### **Possible Changes and Questions**

18.6 The MHRA considers that it has two options: it could continue to require the use of GMDN nomenclature for purposes of medical device identification, and the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations) could be amended to reflect this. Or alternatively, the UK medical devices regulations could require manufacturers to use EMDN nomenclature for purposes of medical device identification.

**Q18.1 Please select which nomenclature, for purposes of medical device identification, should be required under the UK medical devices regulations: (GMDN / EMDN / Other (please specify))**

**Q18.2 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 18.1-18.2, including any impacts on you or other stakeholder groups.**

## Section 19 - Unique Device Identification

### **Background**

19.1 Unique Device Identification is intended to provide a globally harmonised device identification and coding which allows unambiguous identification of a specific device on a market. The FDA, EU and other regulators have developed UDI systems in line with International Medical Device Regulators Forum (IMDRF) guidance.

19.2 As set out in the glossary to this consultation, by Unique Device Identifier (UDI) we mean a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market.

19.3 Whereas medical device nomenclature helps us to identify the type of medical device, the UDI is unique to the medical device itself, enabling us to identify the medical device and who manufactured it or placed it on the market.

19.4 UDIs consist of:

- a. a UDI device identifier ('UDI-DI') specific to a manufacturer and a model of medical device
- b. a UDI production identifier ('UDI-PI') that identifies the unit of medical device production and, if applicable, the packaged medical devices. The different types of UDI-PIs include serial number, lot number, software identification and, manufacturing date or expiry date or both.

19.5 Manufacturers could be required to assign UDI to device labels or, for certain devices such as reusable devices, to the device itself.

19.6 Many manufacturers have already obtained UDIs for their medical devices and the MHRA currently requests UDI information at the point of medical device registration on a voluntary basis. The Medical Device Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations) do not provide a legal obligation for manufacturers to obtain or provide the MHRA with a medical device's UDI.

19.7 If all medical devices on the UK market were allocated and labelled with a UDI (UDI-DI and UDI-PI), this could significantly enhance the ability to trace and identify medical devices in the supply chain. For example, it could assist public and private sector healthcare professionals, economic operators and the wider public in reporting incidents related to medical devices to the MHRA and the manufacturer. Additionally, when a manufacturer needs to undertake a Field Safety Corrective Action and issue a Field Safety Notice requiring the return or modification of a range of their medical devices these could be unambiguously traced back through the supply chain.

19.8 Manufacturers could also be required to make use of Basic UDI-DI as the primary identifier of device models. Basic UDI-DI is used for administrative purposes to identify a group of products with the same intended purpose, risk class and essential design and manufacturing characteristics. Essentially, a manufacturer can group together similar types of medical devices under the same Basic UDI-DI so that these groupings can be recognised by others. Basic UDI-DI does not appear on the medical device label or packaging but it would be included in regulatory documentation, such as the Certificate of Conformity etc.

## **Possible Changes and Questions**

### ***Assignment of UDI***

19.9 The UK medical devices regulations could be amended to require that before placing a medical device (including an IVD) onto the UK market or putting a medical device into service, the manufacturer must assign, if applicable, to all outer packaging (not including shipping containers), a UDI which consists of a UDI device identifier ('UDI-DI') and a UDI- production identifier ('UDI-PI') The UDI-DI is specific to a manufacturer and a device and is also used as the "access key" to information stored in a UDI database. The UDI production identifier ('UDI-PI') identifies the unit of medical device production and if applicable the packaged medical devices. The

different types of UDI-PIs include serial number, lot number, software identification, and manufacturing date or expiry date or both.

19.10 The UK medical devices regulations could also require manufacturers to allocate Basic UDI-DI (defined in the glossary to this consultation) to their devices, and to provide this to the devices registration system and relevant regulatory documentation.

**Q19.1 Do you think that the UK medical devices regulations should include a definition of the term ‘Unique Device Identifier’? (‘Yes’ / ‘No’ / ‘Don’t Know/No Opinion’)**

**Q19.2 If you answered ‘yes’ to question 19.1, please outline what you think should be included in this definition.**

**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? (Yes/No/Don’t Know/No Opinion)**

**Q19.4 If you have 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? (‘Yes’ / ‘No’ / ‘Don’t Know/No Opinion’)**

**Q19.6 Please outline whether you think there should be any exceptions to this rule and please provide examples and reasoning.**

**Q19.7 Should the UK medical devices regulations include requirements for Basic UDI-DI to identify medical device models? (‘Yes’ / ‘No’ / ‘Don’t Know/No Opinion’)**

19.11 The UK medical devices regulations could be amended to require that manufacturers assign UDIs to their medical devices before applying to an Approved Body for conformity assessment (where they need to do so).

**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? (‘Yes’ / ‘No’ / ‘Don’t Know/No Opinion’)**

19.12 The UK medical devices regulations could be amended to include requirements for the use of the UDI and/or Basic UDI-DI in certain circumstances, including the following:

- a. on the Certificate of Conformity (see Chapter 6, Section 26) for the medical device (Basic UDI-DI) – responsibility of the Approved Body
- b. on the Declaration of Conformity (see Chapter 6, Section 28) for the medical device (Basic UDI-DI) – responsibility of the manufacturer
- c. in the patient implant information provided for an implantable medical device (UDI-DI) (see Chapter 11) – responsibility of the manufacturer
- d. when registering medical devices (see Chapter 4, Section 20) with the MHRA (Basic UDI-DI and UDI-DI) – responsibility of the manufacturer or UK Responsible Person
- e. when reporting serious incidents e.g. death of a patient which could have been caused by the medical device (see Chapter 8, Section 47) to the MHRA (UDI-DI) – responsibility of the economic operator making the report
- f. when issuing field safety corrective actions (FSCA's) e.g. advising the recall of a device due to a safety issue (see Chapter 8, Section 49) to the MHRA (UDI-DI) – responsibility of the manufacturer

**Q19.9 Do you think the UK medical devices regulations should stipulate that the UDI or Basic UDI-DI of a medical device should be provided in the circumstances set out in paragraph 19.12? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q19.10 Please outline any other circumstances in which the UDI or Basic UDI-DI should be provided for a medical device.**

19.13 The UK medical devices regulations could be amended to exempt certain medical devices from the requirement to assign a UDI. Such medical devices could include custom-made medical devices (see Chapter 12, Section 53) and investigational medical devices/medical devices for performance study (see Chapter 7, Section 44).

19.14 Manufacturers could alternatively be required to assign a unique serial number to custom-made medical devices before they are placed on the UK market or put into service. This number should be retained by the manufacturer.

**Q19.11 Do you think that certain medical devices should be exempt from the UDI requirements? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q19.12 If you have answered 'yes' to question 19.11, please outline what medical devices should be exempt.**

**Q19.13 Should manufacturers of custom-made devices be required to assign a unique serial number to the device? ('Yes' / 'No' / 'Don't Know/No Opinion')**

## ***UDI Issuing Entities***

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)?**

## ***UDI retention and storage***

19.16 The UK medical devices regulations could include a requirement for secure data storage of the UDI of medical devices by economic operators, health institutions and healthcare professionals by electronic means for a specified time period.

19.17 The UK medical devices regulations could be amended to include a requirement for manufacturers to keep an up-to-date list of all UDIs they have assigned to medical devices as part of the technical documentation for the medical device.

**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? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q19.16 If you answered 'yes' to question 19.15, how long should manufacturers be required to hold this information? When responding to this question, please indicate whether you think there should be different minimum periods of retention depending upon type of device / risk classification.**

19.18 The UK medical devices regulations could be amended to require economic operators (e.g. manufacturers, importers, distributors) to store and keep, by electronic means, the UDI of certain medical devices which they have supplied or with which they have been supplied. This requirement could apply to all implantable medical devices, or to certain types of implantable medical devices.

**Q19.17 Do you think economic operators should be required to store the UDI numbers of certain medical devices? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q19.18 If you have answered 'yes' to question 19.17, please select which groups of medical devices should fall under this requirement:**

- a. all implantable medical devices
- b. Class III implantable medical devices
- c. Class IIb implantable medical devices
- d. Other – please specify
- e. don't know/no opinion

19.19 The UK medical devices regulations could be amended to require healthcare professionals and/or health institutions to store and keep by electronic means, the UDI of the medical devices which they have supplied and to which patient they have been supplied or with which they have been supplied. This requirement could apply to all implantable medical devices, or certain types of implantable medical devices.

**Q19.19 Do you think healthcare professionals and/or health institutions should be required to store the UDIs of certain medical devices? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q19.20 If you have answered 'yes' to question 19.19, please outline what types / risk classification of medical devices should fall under this requirement.**

- a. all implantable medical devices
- b. Class III implantable medical devices
- c. Class IIb implantable medical devices
- d. Other – please specify
- e. don't know/no opinion

19.20 The UK medical devices regulations could be amended to introduce rules for the UDI system to help clarify the requirements of the Regulations. Rules could, for example, set out circumstances in which a new UDI-DI would need to be assigned to a given device, e.g. a change in trade name of the manufacturer or change in sterility of the device.

**Q19.21 Do you think that the UK medical devices regulations should introduce new rules for the UDI system, to provide clarity? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q19.22 If you have answered 'yes' to question 19.21 please outline what rules the UK medical devices regulations should include in regard to the UDI system.**

**Q19.23 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 19.1-19.22, including any impacts on you or other stakeholder groups.**



## Section 20 - Great Britain database on medical devices

### Background

20.1 We are considering capturing and processing information submitted to MHRA about medical devices (such as registration data, vigilance, post-market surveillance, and market surveillance regarding medical devices) in a series of integrated databases (electronic information systems). This would enable the MHRA to bring together all the information about medical devices on the market to ensure enhanced transparency and effective market surveillance activities.

### Possible Changes and Questions

**Q20.1 Do you think that we should introduce the proposal outlined in paragraph 20.1? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q20.2 Please provide your reasoning (including any available relevant evidence) to support your answer to question 20.1, including any impacts on or implementation considerations for you or other stakeholder groups.**

## Section 21 - Registration of medical devices

### Background

21.1 Under the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations), all medical devices (including IVDs) need to be registered with the MHRA before being placed on the UK market in line with grace periods in the Regulations.

21.2 When registering a medical device with the MHRA, manufacturers or their UK Responsible Person currently need to provide the address of their registered place of business and a description of each category of medical device concerned. However, MHRA also asks for further information about the medical device on a voluntary basis as detailed in our guidance.

21.3 The registration database could be expanded to collect more detailed information about medical devices on the UK market. The MHRA, Approved Bodies, economic operators, healthcare professionals and the public would then have access to detailed medical device information which in turn would enhance their ability to make informed decisions about the use of or supply of a device.

## Possible Changes and Questions

### ***Expansion of data required at point of medical device registration***

21.4 The UK medical devices regulations could be revised to expand the required information that manufacturers or their UK Responsible Person (UKRP) (if any) must provide to MHRA before a medical device is placed on the UK market. They could be required to provide the information set out in List One (at the end of this section) to the MHRA.

**Q21.1 Do you think manufacturers should be required to provide the information in List One (at end of this Section) to the MHRA upon medical device registration? ('Yes' / 'No' / 'Don't Know/No Opinion' / 'Some – please specify which aspects')**

**Q21.2 Please specify any changes proposed and your rationale in relation to question 21.1.**

21.5 Currently, only UK-based manufacturers or UK Responsible Persons are permitted to submit information to the MHRA registration database. Given the extra information that may need to be submitted to the registration database (see section 21.4 above), the MHRA is considering permitting other parties to submit information such as non-UK based manufacturers.

**Q21.3 Which of the following entities should be permitted to submit device registration information to MHRA (select all that apply):**

- a. UKRPs and UK-based manufacturers (current requirement)
- b. non-UK based manufacturers
- c. authorised third party submitters
- d. other – please specify

**Q21.4 What mechanisms should be in place to submit data?**

- a. web form
- b. machine-to-machine (e.g. HL7 etc)
- c. other – please specify

### ***Transitional arrangements***

21.6 The UK medical devices regulations could set out timeframes for when medical device registration details need to be updated to include the additional required information. This could be phased in with different timeframes for completion depending on medical device class, in a similar manner to the registration requirements introduced earlier this year (detailed in MHRA guidance [here](#)).

**Q21.5 Please outline the timeframes that you think should apply to this additional registration information.**

### ***Disclosure of medical device registration information***

21.7 The UK medical devices regulations could set out that MHRA may ensure that information submitted to it by medical device manufacturers and their UK Responsible Persons (UKRP) and/or other economic operators set out in List One below in this section is published and accessible to the public free of charge subject to relevant data protection requirements. This would mean that a member of the public could search the MHRA's register for detailed information on a medical device.

**Q21.6 Should the information that the MHRA gathers at the point of medical device registration be made publicly available via a website or similar platform? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q21.7 If you have answered 'yes' to question 21.6, please outline what information should be shared and provide your rationale and key considerations or limitations (please note sharing of information would be subject to UK GDPR requirements).**

### ***Registration of medical devices pre-market approval***

21.8 The UK medical devices regulations could include a requirement for manufacturers to register with the MHRA and submit the information in List One below, before applying to an Approved Body for conformity assessment (where required). During the application process manufacturers could be required to provide their MHRA registration account number to the Approved Body, so that the Approved Body can verify medical device registration.

Chapter 6, Section 26 sets out proposals for Approved Bodies to input information about the status of conformity assessment certificates they have issued into the device registration system. Please see Chapter 6, Section 26 to provide comments on this.

**Q21.8 Do you think the UK medical devices regulations should include a requirement for manufacturers to register with the MHRA before applying to an Approved Body for conformity assessment and for the Approved Body to verify this registration? ('Yes' / 'No' / 'Don't Know/No Opinion')**

### **Information updates**

21.9 The UK medical devices regulations could be amended to require that, within a specified time period (for example, 30 days) of any change occurring to the information submitted by the economic operator, that economic operator should update that information in MHRA's registration system.

**Q21.9 Should economic operators be given up to 30 days to update an MHRA registration record after a change has been made to a device's registration details? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q21.10 Please provide reasoning to support your answer to question 21.9.**

21.10 The UK medical devices regulations could require the economic operator to confirm the accuracy of any data they have submitted to the MHRA registration system no later than one year after submission of the information, and then every second year thereafter.

**Q21.11 Do you think the UK medical devices regulations should include a requirement for economic operators to confirm all data submitted in their registration one year after submission and then every second year thereafter? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**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)

For questions on registration requirements for health institutions please see Chapter 3, Section 8.

**Q21.13 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 21.1-21.12, including any impacts on you or other stakeholder groups.**

**List One – Information that could be submitted to the MHRA registration / UDI system (not an exhaustive list)**

1. Type of economic operator, for example manufacturer, UK responsible person, importer
2. Name, address and contact details of the economic operator (include the trade name if applicable)
3. Name address and contact details of the person or persons responsible for regulatory compliance
4. Type, number and expiry date of the certificate issued by the approved body and the name or identification number of that approved body
5. Other countries in which the medical device is or has been placed on the market or made available
6. Risk class of the medical device
7. Remanufactured single-use medical device (y/n)
8. Reprocessed single-use medical device (y/n)
9. Presence of a substance which, if used separately, may be considered to be a medicinal product and name of that substance
10. Presence of a substance which, if used separately, may be considered to be a medicinal product derived from human blood or human plasma and name of this substance
11. (For IVDs) Presence of tissues or cells of human origin, or their derivatives (y/n)
12. Where applicable, the reference number of the clinical investigation / performance study or investigations / studies conducted in relation to the medical device

13. Where applicable, a summary of the clinical investigation / clinical performance study (see chapter 7)
14. The periodic safety update report or post-market surveillance report (upload with each registration renewal – see Chapter 8, Section 48)
15. Specification as to whether the intended purpose of the medical device is other than a medical purpose
16. Where applicable, the summary of safety and clinical performance (see Chapter 7, Section 47)
17. Status of the medical device (pre-market, on the market, no longer placed on the market, recalled, field safety corrective action initiated)
18. (For IVDs) indication as to whether the medical device is a 'new' medical device
19. (For IVDs) indication as to whether the medical device is intended for self-testing or near-patient testing
20. MRI safety status information
21. Quantity per package configuration
22. The Basic UDI-DI (see Section 19)
23. UDI-DI (see Section 19)
24. Secondary / additional UDI-DI (where applicable)
25. If applicable, the unit of use UDI-DI (where a UDI is not labelled on the medical device at the level of its unit of use, a 'unit of use' DI shall be assigned so as to associate the use of a medical device with a patient)
26. The manner in which production of the medical device is controlled (expiry date or manufacturing date, lot number, serial number)
27. The medical device nomenclature code (see Section 18)
28. if applicable, medical device model, reference, or catalogue number
29. If applicable, clinical size (including volume, length, gauge, diameter)
30. additional product description (optional),
31. if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use)
32. If applicable, additional trade names of the medical device
33. Labelled as a single-use medical device (y/n)
34. If applicable, the maximum number of reuses
35. Medical device labelled sterile (y/n)
36. If applicable, sterilisation provider
37. Need for sterilisation before use (y/n)
38. Containing natural rubber latex or dry natural rubber latex (y/n)
39. Where applicable, information which has been provided on the medical device label for medical devices containing substances which are carcinogenic, mutagenic or toxic to reproduction and substances having endocrine-disrupting properties for which there is scientific evidence of probable serious effects to human health in a concentration above 0,1 % weight by weight
40. URL for additional information, such as electronic instructions for use
41. If applicable, critical warnings or contra-indications
42. An undertaking that manufacturers have met the requirement to have measures in place for recompense for negative impacts of a medical device

Please see the chapter on environmental sustainability and public health impacts for an opportunity to comment on requiring a summary of environmental impact at the point of device registration, among other possible changes (Chapter 13).