

GS1 UK consultation response

MHRA medical device regulation

November 2021

Please note GS1 UK have only responded to relevant sections of the public consultation. The final responses submitted have been highlighted below. Full details of the consultation can be found on the MHRA web page [here](#).

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Chapter 4: Registration and UDI – (Sections 17–21)

Section 17 – Identification within the supply chain

Section 17 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.

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.

Section 17 questions and responses

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

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

In terms of GS1 standards, product/device identification (UDI) is comprised of GS1's Identification Key for products and devices – the GS1 Global Trade Item Number (GTIN) plus additional attribute information (e.g., lot number, expiry date and sometimes serial number). The additional attribute information is necessary for traceability. GS1's Identification Key for locations is the GS1 Global Location Number (GLN). The use of GLNs are already being leveraged by economic operators, in particular as part of the "Scan4Safety" programme. Clear guidance on the assignment of the GLNs should be provided to ensure effective governance and integrity, also allowing for their efficient use and enabling traceability.

By adopting the Legal Entity GLN (which is used to identify organisations with authorisation to enter legal contracts and agreements) to identify economic operators, regulators will be able to have 100 per cent certainty as to which organisation is being referred to due to their global uniqueness. Although addresses may change, it would still be possible to have a clear understanding of the established Legal Entities associated with the organisation. This would enable a clear chain of custody to be established, ensuring accurate data for timely identification and response as and when required.

A central registry of allocated Legal Entity GLNs already exists in the form of GS1 UK's LocationManager – a national GLN registry. To date there are nearly 1,000 registered, active stakeholder organisations that are already using LocationManager as a GLN management tool. Regulators would also be able to access unique identifiers for the economic operators in one place.

Further to being used for organisation identification, GLNs can also be used to identify other locations at different levels such as a warehouse or a specific shelf in a warehouse, or a function such as an accounts department or billing contact. Using a standard form of identification then makes it easier to identify and trace organisations, specific locations, and relevant contacts, quickly and efficiently.

Both the GTIN and GLN can, and should, be used in tandem to achieve end-to-end traceability and reduce unwarranted variation. Using GLNs, locations of where the device (traced via the GTIN) is going, or has been, can be effectively tracked using these globally unique identifiers.

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?

The time period should be aligned with current business and regulatory practices.

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.

Unique identification allows devices to be accurately identified and traced through the supply chain, directly to the point of care/use. It is then possible to better monitor device performance and patient outcomes for post-market event reporting and recall management.

The Cumberlege Review and several HSIB reports reference the benefit of adopting GS1 standards and point-of-care scanning to do so. Refer to the HSIB report¹ sections 7.1 and 7.2. This is supported by the Scan4Safety evidence report which has also since been referenced in strategic NHS outputs such as The Digital Clinical Safety Strategy² and The What Good Looks Like Framework³.

As such, many medical device manufacturers are already using GS1 standards to identify their products so any transition timelines would likely be minimal with reduced impact to GS1 members. For those that supply global markets, many are already using GS1 standards for UDI to meet the legislative requirements of various global markets. E.g. the Global UDI Database (GUDID) for compliance in the USA, allows users to determine which standards they use for UDI. However, more than 90 per cent of medical devices in the GUDID are using GS1 barcodes on their primary packaging. Refer to Exhibit 9 in the 2012 McKinsey report for evidence⁴.

GS1 standards been mandated as part of NHS requirement for procurement in the UK and provider organisations have scope to use GS1 standards and services as part of existing national agreements. This would make it easier for both suppliers and trusts to meet the requirements. Adoption will also support compliance with legislation in Great Britain such as the MMDA⁵ and the development of MDIS⁶, which will require consistency across all the four nations.

1. https://hsib-kqcco125-media.s3.amazonaws.com/assets/documents/hsib_final_report_implantation_wrong_prostheses_during_surgery.pdf
2. <https://www.nhsx.nhs.uk/key-tools-and-info/digital-clinical-safety-strategy/#executive-summary>
3. <https://www.nhsx.nhs.uk/digitise-connect-transform/what-good-looks-like/what-good-looks-like-publication>
4. https://www.gs1.org/docs/healthcare/McKinsey_Healthcare_Report_Strength_in_Unity.pdf
5. <https://www.legislation.gov.uk/ukpga/2021/3/part/4>
6. <https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-sets/national-perioperative-data-standard-programme#medical-device-information-system>

Section 18 – medical device nomenclature

Section 18 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.

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.

Section 18 questions and responses

Q18.1 Please select which nomenclature, for purposes of medical device identification, should be required under the UK medical devices regulations:

GMDN because:

- It has global reach and is an international requirement in many continents
- It is based on original ISO/CEN standards
- It is currently under review (near finalisation) by the NHS Digital DAPB¹ process to become the NHS Standard for device classification

GMDN can also be cross-mapped to SNOMED CT – the NHS standard for clinical terminology (SCCI0034). A subset of GMDN terms are in the International Release of SNOMED CT, excluding IVD content, which are allocated an individual SNOMED CT Concept ID. The GMDN code and the SNOMED CT Concept ID can then be externally cross-matched using a 'mapping table' to allow for association between the two items. There is a collaboration agreement between GMDN Agency and SNOMED International and GMDN is the foundation of high-level medical devices in SNOMED CT.

This publication² explains: "In 2012, GMDN and the organization responsible for SNOMED [(IHTSDO)] entered into a cooperation agreement under which GMDN codes would be used to identify medical devices within the SNOMED system, which was developed to improve how clinically relevant information, including diseases, procedures, pharmaceuticals and devices (referred to as physical objects), is entered in EHRs. With this relationship, specific classes of medical devices can be associated with the procedures in which they are used."

Capturing device information in a standardised format significantly reduces the risk of reporting errors, preventing incorrect details being captured. Plus, associating the device with the procedure will provide an

accurate record for reporting, auditing, or outcomes monitoring. Lastly, associating this with the patient record allows for outcomes to be better monitored and product recalls to be processed quickly to prevent patient harm.

Recommendation seven of the Cumberlege Review³ support this: "A central patient-identifiable database should be created by collecting key details of the implantation of all devices at the time of the operation. This can then be linked to specifically created registers to research and audit the outcomes both in terms of the device safety and patient reported outcomes measures."

1. <https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/data-alliance-partnership-board>
2. <https://www.hpnonline.com/sourcing-logistics/article/13001529/got-classification>
3. https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf

Section 19 – Unique Device Identification

Section 19 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.

Section 19 questions and responses

Q19.1 Do you think that the UK medical devices regulations should include a definition of the term Unique Device Identifier?

Yes

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

It is important to align with the IMDRF definition¹ to ensure consistency with other global regulatory markets. The definition for UDI is as follows:

"Unique Device Identifier (UDI): The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific medical device on the market. The UDI is comprised of the UDI-DI and UDI-PI. Note: The word "Unique" does not imply serialization of individual production units."

The EU, as chair of the International Medical Device Regulators Forum (IMDRF) working group on UDI, strongly contributed to the preparation of this international guidance on a unique device identification system for medical devices, which was adopted in December 2013. The [European Commission](#)² provides the following definitions:

UDI-DI

The UDI-DI is a unique numeric or alphanumeric code specific to a model of device (and predefined counts of the device) and that is also used as the 'access key' to information stored in a UDI database.

UDI-PI

The UDI-PI is a numeric or alphanumeric code that identifies the unit of device production.

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

This should allow for serialised and non-serialised UDIs to enable traceability. In doing so, the MHRA will be able to have UDIs at a model level (UDI-DI) and also at a specific product level (UDI-PI). Even though not all devices will need the PI level of medical device information, some devices such as implants will. Again, this will ensure alignment with the global regulators body, IMDRF, to ensure uniformity of the overall approach and potential equivalence of regulatory approval from one country to another.

1. <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-udi-guidance-140901.pdf>
2. https://ec.europa.eu/health/sites/default/files/md_topics-interest/docs/md_faq_udi_en.pdf

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

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

According to the IMDRF¹, the requirements shall not apply to the device in case of the following circumstances:

- any type of direct marking would interfere with the safety or performance of the device;
- the device cannot be directly marked because it is not technologically feasible.

The applicability of those exemptions shall be based on evaluations of the size, design, materials, processing, or performance issues related to the device in question.

1. <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-190321-udi-sag.pdf>

Q19.7 Should the UK medical devices regulations include requirements for Basic UDI-DI to identify medical device models?

Yes

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

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

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

The UDI and/or the Basic UDI-DI should be provided for a medical device when it is useful for patient safety and the traceability of the device. For example reporting to The Medical Device Information System¹ (MDIS), vigilance reporting, yellow card incident reporting, etc.

Specifically, the Basic UDI-DI should be provided only if this information is used by authorities and supported by reporting data management systems.

1. <https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-sets/national-perioperative-data-standard-programme#medical-device-information-system>

Q19.11 Do you think that certain medical devices should be exempt from the UDI requirements?

Yes

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

The exemptions should be aligned with the IMDRF guidance¹ to ensure consistency and align with other global regulatory markets. "The regulators of the UDI System shall specify harmonized exemptions for certain devices such as investigational devices and custom made devices from UDI requirements."

In all UDI requirements currently adopted and/or implemented, there is an exemption for custom-made devices.

1. <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-udi-guidance-140901.pdf#page=10>

Q19.13 Should manufacturers of custom-made devices be required to assign a unique serial number to the device?

Yes

Q19.14 Please outline which issuing entities should be designated by the MHRA.

MHRA should align with the IMDRF UDI guidance¹ on issuing entities and designate GS1 AISBL (an international registered non-profit association) as an issuing entity.

GS1 has already been designated as a code-issuing entity for regulatory operations in EU, US, Saudi Arabia, Singapore, China and South-Korea. To standardise practices, it would be recommended that the MHRA should also designate GS1 AISBL as an issuing entity.

For the vast majority of medical devices, GS1 barcodes for UDI – GS1 Global Trade Item Numbers (GTINs) – are used on primary packaging in the Global UDI Database (GUDID), with more used for implantables. Please revert to Exhibit 9 in the McKinsey report² (2012, McKinsey&Company, Strength in unity: The promise of global standards in healthcare).

The use of a single global identification standard also facilitates accurate sourcing and mitigates the risk of procurement errors. This is particularly important when identifying and sourcing the right medical devices for procedures in light of patient safety considerations. Using alternative product identifiers, such as the manufacturer ID, or other standards, introduces inconsistency and can result in errors.

Adopting a single common global standard on a package will also serve to improve patient safety. This would make it easier to manage as GS1 standards are already mandated by the NHS and there would only be one standard to scan at the point of use/care.

1. <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-udi-guidance-140901.pdf>
2. https://www.gs1.org/docs/healthcare/McKinsey_Healthcare_Report_Strength_in_Unity.pdf

Q19.17 Do you think economic operators should be required to store the UDI numbers of certain medical devices?

Yes

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

All 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

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.

All active implantable medical devices data should be stored in Electronic Patient Records (EPRs).

This will enable greater efficiency for post-market surveillance and allow for the closer monitoring of patient outcomes in line with recommendation seven of The Independent Medicines and Medical Devices Safety Review¹ (2020, Baroness Julia Cumberlege CBE DL, First Do No Harm) for a central patient-identifiable database. Information should then be reported into the NHS Digital Medical Device Information System² to meet the data requirements.

1. https://www.immndsreview.org.uk/downloads/IMMDSReview_Web.pdf
2. <https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-sets/national-perioperative-data-standard-programme#medical-device-information-system>

Q19.21 Do you think that the UK medical devices regulations should introduce new rules for the UDI system, to provide clarity?

Yes

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.

Rules should be aligned with the IMDRF guidance to make sure there is a common set of requirements for patient safety globally. The rules should ensure that there is as little discrepancy as possible for identification and labelling of devices and refer to issuing agency rules to ensure consistency.

Using a common set of standards ensures medical device information is captured and shared in one format which will in turn make this information more accessible. It is important that this information is standardised to ensure there is interoperability between systems and organisations for the seamless functioning of the entire system. This would enable full end-to-end supply chain traceability as well as rapid notification for all stakeholders for Field Safety Alerts (FSAs) and Notifications (FSNs).

On the reporting and data management, it is focused on the minimum viable requirements and includes data validation rules to ensure data quality and allow machine-machine submission.

Where there is not a specific regulation around when a new UDI-DI should be issued, the UDI-DI allocation rules of the code-issuing entity must be followed as long as there is no contradiction to the regulations.

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.

The overall aim is to establish a complete chain of custody from manufacturer to point of care and beyond. This enables the benefits of UDI to be attained across the entire lifecycle of the product. The recommendations are aligned with implementation in other countries and their lessons learned. An overview of recommendations can be found in the video published here¹.

1. <https://www.youtube.com/watch?v=kgG65RxxwM04&t=2134s>

Q19.7 – Yes, UK medical devices regulations should include requirements for Basic UDI-DI to identify medical device models if the MHRA wishes to harmonise with the requirements of the EU MDR/IVDR.

GS1 has developed the GS1 Identification Key – a Global Model Number (GMN) – to enable GS1 users to comply with the Basic UDI-DI requirements. It was specifically created to meet the EU requirement for the Basic UDI-DI and it is specific to a grouping of products from a single entity.

There are distinct advantages in being able to group products from within a ‘family’ where post-market surveillance or reimbursement coding at that level may be desirable, however it needs to be clearly defined in a way that is not overly complicated or prescriptive which would make it too hard to manage. It also needs to be clearly defined regarding its relationship to the product UDI.

A number of GS1 stakeholders have raised concerns at the complexity of the Basic UDI-DI concept as it is now within the EU. It is no longer focused on an aggregated identifier for a family of products and is much more complicated.

GS1 stakeholders have expressed concern that it would be difficult to reuse exactly the same ‘grouping’ as in the EU as it would require that all the different aspects of the MDR/IVDR are also included in the requirements.

The Basic UDI-DI is used for multiple purposes in the EU regulations. The key will be used in the different EUDAMED modules and is referenced in the relevant documentation, such as certificates (including certificate of free sale), EU declaration of conformity, technical documentation, and summary of safety and (clinical) performance. The EU Helpdesk question found here (<https://eu-udi.zendesk.com/hc/en-150/articles/360018649758-What-is-a-Basic-UDI-DI->) provides further information on this if necessary.

The Basic UDI-DI groups devices with the same intended purpose, same manufacturer, same attributes and the same essential characters. It could very well be that the same use for the Basic UDI-DI in the UK is not logical since products would be grouped differently (then a new definition is necessary), or these database modules and documentation do not exist or are very different.

It has been highlighted that though products may have the same conformity, because they are produced by different legal manufacturers, they are not able to have the same Basic UDI-DI under the EU MDR which may in fact lead to confusion versus improvements to processes.

GS1 stakeholders also expressed concern that the portfolio of products sold in the EU may not be the exact same as those sold in Australia or some other differences may exist in the regulations making it problematic to

implement in exactly the same way.

Q19.8 – Yes, manufacturers should be required to assign and apply UDIs to their medical devices before applying to Approved Bodies for conformity assessment. In addition, confirmation of the UDIs and Automatic Identification and Data Capture (AIDC) should form part of the conformity assessment.

Q19.13 – Yes, manufacturers of custom-made devices should be required to assign a unique serial number to the device because it gives traceability of the custom-made device back to the patient. Should the need arise, it is possible to identify the specific device that was used for/by the patient. With the accurate device identified, the manufacturer can then amend/adjust the bespoke device as a patient safety measure.

Q19.18 – Economic operators should be required to store the UDI numbers for all implantable medical devices to enable traceability from the point of manufacture to the point of care/use. This will allow for a complete chain of custody to be established, enable effective post-market surveillance and facilitate the ability to track and trace any medical device in the event of a product recall or Field Safety Alert (FSA) or Notification (FSN).

Section 20 – Great Britain database on medical devices

Section 20 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.

Section 20 questions and responses

Q20.1 Do you think that we should introduce the proposal outlined in paragraph 20.1?

Yes

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.

GS1 UK support, but realise, that the proposal should be a long term goal, and implementation should be done piece by piece to enable good implementation, learning, and scope for improvement. An electronic information system would enable one data registration and make information available to many stakeholders. It is important that the UDI-DI is the main key to ensure there is interoperability between systems for the seamless functioning of the entire system. This would enable full end-to-end supply chain traceability as well as rapid notification for all stakeholders.

Implementation of such a system would also support the delivery of recommendation seven of the Independent Medicines and Medical Device Safety Review¹ (2020, Baroness Julia Cumberlege CBE DL, First Do No Harm).

Capturing the UDI-DI would provide clear visibility of all implantable devices used at the time of operation and then allowing this detail to be attributed back to the patient. As a result, this would support post-market surveillance and vigilance reporting to improve patient safety and reduce unwarranted clinical variation.

1. https://www.immdsreview.org.uk/downloads/IMMDSReview_Web.pdf#page=23

Section 21 – Registration of medical devices

Section 21 background

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.

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.

Section 21 questions and responses

Q21.12 How should economic operators be identified within the MHRA registration system?

GLNs

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.

Q21.12 – Economic operators should be identified using GS1 Global Location Numbers (GLNs) in the MHRA registration system because these are already being used and are mandated for use across the NHS in England. Rules around GLN allocation exist to ensure their integrity can be maintained on a global scale. GLNs are extensively used by device manufacturers and allow for a complete chain of custody to be established.

By adopting the Legal Entity GLN (used to identify organisations with authorisation to enter legal contracts and agreements) to identify economic operators, regulators could have 100 per cent certainty as to which organisation is being referred to.

A central registry of allocated Legal Entity GLNs already exists (GS1 UK's LocationManager) – a national GLN registry. This is accessible to all healthcare provider organisations in the UK as part of existing agreements with GS1 UK. It is also accessible to all required stakeholders such as suppliers or manufacturers for a nominal charge. To date there are nearly 1,000 registered, active stakeholder organisations using LocationManager for GLN management.

Regulators would also be able to access these unique identifiers in one place. It would also be possible to perform accurate searches in contrast to searching for DUNs numbers which can increase the risks of data errors. GLNs can uniquely identify a specific organisation's Legal Entity, a DUNs number cannot. This is because each individual organisation has a DUNs number but for complex organisational structures such as large corporations, it is then difficult to determine which organisation is the correct legal entity to associate with the product.

With LocationManager, the organisation adds its single Legal Entity GLN to the database thus connecting the legal entity to the product so there is a reduced risk of error or confusion. Plus, information (such as address and contact information) associated with the Legal Entity GLN in LocationManager will be supplied and maintained directly by the economic operator. This makes it more flexible for updating details and maintaining accuracy.

GLNs can also be used to identify other locations at different levels such as a warehouse or a specific shelf in a warehouse, or a function such as an accounts department or billing contact. Using a standard form of identification then makes it easier to identify and trace organisations, specific locations, and relevant contacts, quickly and efficiently.

Chapter 8: Post-market Surveillance and Vigilance (Sections 48–51)

Section 48 – Post-market surveillance

Section 48 background

48.4. The MHRA considers that the UK medical devices regulations could be amended to clarify and strengthen the requirement for manufacturers to implement a post-market surveillance system, in respect of all medical devices they have placed on the UK market. This could be based on the manufacturer's post-market surveillance plan, which collates and utilises information from:

- a. serious incident data (see section 49)
- b. field safety corrective actions (FSCAs) (see section 49)
- c. non-serious incident data, trend reporting (see section 50)
- d. relevant literature e.g. scientific studies on the medical device or similar devices
- e. data from registries
- f. feedback and complaints from users and economic operators, and
- g. information regarding similar medical devices
- h. patient and public involvement.

We could require that the plan must outline how this information is to be collected and assessed.

Section 48 questions and responses

Q48.1 Do you think manufacturers should be required to implement a post-market surveillance system based on a post-market surveillance plan, which collates and utilises information from the range of sources listed in paragraph 48.4?

Yes

Section 49 – Reporting of serious incidents and field safety corrective actions

Section 49 background

49.5 The MHRA considers that the UK medical devices regulations could be amended to clarify that manufacturers should report to the MHRA:

- a) any serious incident, including those which are expected side effects (e.g. those listed in the instructions for use)
- b) any field safety corrective action (FSCA) (see Section 47), including any FSCA undertaken in a non-UK country in relation to a medical device which has also been made available on the Great Britain market.

49.10. The MHRA considers that the UK medical devices regulations could be amended to specify further procedures for manufacturers regarding reporting of serious incidents and FSCAs, including:

- a) the manufacturer can submit an initial report that is incomplete followed up by a complete report
- b) manufacturers must report any field safety corrective actions in advance of the field safety corrective action being undertaken, except in cases of urgency
- c) manufacturers can provide periodic summary reports instead of individual serious incident reports for serious incidents that occur with the same device or device type and for which the root cause has been identified or a field safety corrective action that has been implemented, or where the incidents are common and well documented, where agreed by the MHRA.

Section 49 questions and answers

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?

Yes

Q49.6 Do you think the UK medical devices regulations should specify further procedures for manufacturers regarding the reporting of serious incidents and field safety corrective actions (FSCAs) including (but not limited to) the points made in paragraph 49.10 above?

Yes

Q49.7 Please outline any other requirements which should be introduced regarding reporting of serious incidents and field safety corrective actions should be.

Reporting should include complete UDI information (The unique device identifier – GS1 Global Trade Item Number (GTIN), and the additional attribute information/production information (e.g., lot number, expiry date and sometimes serial number)) together with all other appropriate standardised data that enables efficient traceability and patient safety.

By using NHS mandated GS1 standards (GTIN / Global Location Number (GLN) / Global Service Relation Number (GSRN) etc.), it will then also allow for products and devices to be followed throughout the supply chain. These details can then be matched to full procedural information (such as patient, device used, location of procedure, and clinician involved) to be captured for reporting. This will enable greater efficiency for post-market surveillance and allow for the closer monitoring of patient outcomes in line with The Independent Medicines and Medical Devices Safety Review¹ (2020, Baroness Julia Cumberlege CBE DL, First Do No Harm) recommendation seven for a central patient-identifiable database, and the requirements for the NHS Digital Medical Device Information System².

1. https://www.immidsreview.org.uk/downloads/IMMDSReview_Web.pdf
2. <https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-sets/national-perioperative-data-standard-programme#medical-device-information-system>

Q49.8 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 49.1-49.7, including any impacts on you or other stakeholder groups.

All NHS providers within the UK are members of GS1 UK so there will be no financial impact. Most medical devices manufacturers are also already members of GS1.

The Independent Medicines and Medical Device Safety Review¹ (2020, Baroness Julia Cumberlege CBE DL, First Do No Harm) provides reasoning why the measures described are necessary, and why UDI is required as a critical patient safety measure.

The measures suggested here will meet recommendation seven highlighted in the report: “Recommendation 7: A central patient-identifiable database should be created by collecting key details of the implantation of all devices at the time of the operation. This can then be linked to specifically created registers to research and audit the outcomes both in terms of the device safety and patient reported outcomes measures,” – facilitating post-market surveillance and the effective monitoring of any adverse events attributable to a particular medical device.

As evidenced in the Scan4Safety report², implementing GS1 standards and point of care scanning improves this efficiency and safety by enabling this information to be captured in real time, directly at the point of care.

- The release of 140,000 hours of clinical time back to patient care
- Non-recurrent inventory reductions of £9m
- Recurrent inventory savings worth nearly £5m across the six trusts

- At Leeds Teaching Hospitals NHS Trust, the average time taken for product recalls has fallen from 8.33 days to less than 35 minutes following the introduction of Scan4Safety. The organisation estimates it will save £84,411.07 each year on such recalls
- By introducing scanning in pharmacy, Royal Cornwall Hospitals NHS Trust reduced prevented-error rates by 76 per cent, including elimination of all errors caused by wrong patient, wrong drug, wrong dose and wrong form

1. https://www.immndsreview.org.uk/downloads/IMMDSReview_Web.pdf

2. <https://healthcare.gs1uk.org/scan4safety/>

Section 50 – Trend reporting

Section 50 background

50.3 The MHRA considers that the UK medical devices regulations could be amended to require manufacturers to report:

- a) for general medical devices and IVDs - any statistically significant increase in the frequency or severity of incidents that could have a significant impact on the benefit-risk analysis*
- b) for IVDs - any significant increase in expected erroneous results established in comparison to the stated performance of the IVD or respective assays.*

Section 50 questions and responses

Q50.2 Please provide your reasoning (including any available relevant evidence) to support your answers to question 50.1, including any impacts on you or other stakeholder groups.

Speedy reporting can help to identify wider product issues in the market and give accurate information to clinicians. Furthermore, if aligned to NHS Digital’s Medical Devices Information System (MDIS), this data can help prevent further patient safety issues and allow clinicians and patients to have a more informed decision on the medical device used.

Section 51 – Analysis of serious incidents and field safety corrective actions

Section 51 background

51.3 The MHRA considers that the UK medical devices regulations could be amended to include minimum requirements for the content of the field safety notice (FSN) to ensure all FSNs are drawn up to the same standard and that they contain all the information that the MHRA considers important. The UK medical devices regulations could set out the requirement for manufacturers to issue FSNs as part of their Field Safety Corrective Actions and to submit the draft content of the FSN to the MHRA for review where necessary, except in cases of urgency. The Regulations could require that the field safety notice includes the medical device nomenclature (see Chapter 4, Section 18) and relevant UDIs (see Chapter 4, Section 19).

Section 51 questions and responses

Q51.1 Do you think manufacturers should be required to issue field safety notices (FSNs) as part of their field safety corrective actions and to submit the content of the FSN to the MHRA for comment, except in cases of emergency?

Yes

Q51.2 Do you think the UK medical devices regulations should set out the minimum requirements for the content of field safety notices issued by manufacturers?

Yes

Chapter 11: Implantable Devices – (Section 66)

Section 66 – Implantable devices

Section 66 background

66.6 The UK medical devices regulations could be amended to require manufacturers of implantable devices to provide patient implant information with the medical device when placing it on the market, in both digital and physical card or leaflet format. Health institutions could be required to make this information available to patients having implantable devices both during the process of seeking informed consent to a procedure for an implant, and at the point where a procedure introducing an implant has been completed. The UK medical devices regulations could require health institutions to hold this information securely and to log this information onto patient records. It could require that the implant information include the following:

a. information allowing the identification of the medical device, including the medical device name, serial number, lot number, UDI, and medical device model, as well as the name, address and website of the manufacturer

b. any warnings, precautions or measures to be taken by the patient or a healthcare professional with regard to reciprocal interference (interaction between a medical device and an instrument e.g. an MRI scanner, which negatively affects the medical device or the instrument) with reasonably foreseeable external influences, medical examinations or environmental conditions, including a caution that risk may emerge during use of an implantable device; any information about the expected lifetime of the medical device and any necessary follow-up e.g. where the patient might require repeat scans to ensure the medical device is still in place

c. any other information to ensure safe use of the medical device by the patient, including the overall qualitative and quantitative information on the materials and substances to which patients can be exposed.

There could be a requirement to update the digital implant information where appropriate.

Section 66 questions and responses

66.10 Do you think that post-market requirements for implantable devices could be strengthened by:

a. Clarifying or strengthening the requirements around use of obsolete models of implantable medical devices?

Yes

b. Introducing a requirement for implant information to be provided to recipients of implantable devices?

Yes

Q66.11 Do you think that the UK medical devices regulations should require manufacturers of implantable devices to provide implant information for recipient patients with the device when placing it on the market as set out in paragraph 66.6?

Yes

Q66.12 If you have answered yes to question 66.11:

a. should manufacturers be required to provide implant cards/leaflets to healthcare settings/professionals?

Yes

b. what should be included on the implant card and patient information leaflet?

Implant card should contain the GTIN (including serial number and relevant production information) and GLN – as this will aid alignment with MDIS and other required registries.

Linking this information to the GSRN will then allow these details to be accurately attributed to a patient which will also align with MDIS and other required registries.

Patients would have more information to report on the Yellow card scheme – enabling faster product recalls for other patients if this information was shared. Enable alignment to yellow card standard for medicines (DCB1582) by provision of coded information to allow electronic communication.

This detail would also support recommendation six highlighted in The Independent Medicines and Medical Devices Safety Review (IMMDSR) pertaining to adverse event reporting: "Recommendation 6: The Medicines and Healthcare products Regulatory Agency (MHRA) needs substantial revision particularly in relation to adverse event reporting and medical device regulation. It needs to ensure that it engages more with patients and their outcomes. It needs to raise awareness of its public protection roles and to ensure that patients have an integral role in its work."

MRI compatibility information would be ideal as there are delays in scanning when implant information is not available.

c. should manufacturers be required to make available implant information in both physical and digital formats, (for example, in the form of a card, leaflet or other appropriate format)?

Yes

d. Should the manufacturer be required to update the digital implant information where appropriate?

Yes

e. should health institutions be required to make this information available to patients who have been implanted with the device?

Yes

f. should health institutions be required to log the implant information onto the records of the patient implanted with the device?

Yes

Chapter 12: Other Product-Specific Changes (Section 67)

Section 67 – Re-manufacturing single-use devices

Section 67 background

67.5 The MHRA considers that the UK medical devices regulations could be amended to introduce specific requirements for re-manufacturers of single-use devices, requirements could include:

- a. that the re-manufacturer should meet all relevant criteria of the UK medical devices regulations and apply a UKCA marking to the product to attest conformity
- b. that the re-manufacturer applies an appropriate Quality Management System
- c. that an Approved Body must:
 - assess whether the re-manufactured single-use device meets all the relevant provisions of the UK medical devices regulations
 - confirm the validity and surety of all re-manufacturing processes and that they meet the relevant provisions of the UK medical devices regulations
 - ensure re-manufacturer compliance with the appropriate Quality Management System
- d. that the re-manufacturer accepts all liabilities and obligations for the re-manufacturing of the single-use device
- e. that the intended use of the re-manufactured medical device should not differ from the intended use of the original product (not including claims for single-use)
- f. that the packaging and instructions for use clearly state that the single-use device is a re-manufactured version of the original and that the re-manufacturer can be clearly identified on the packaging and labelling
- g. that the re-manufacturer has appropriate post-market surveillance and adverse event reporting procedures in place.

67.6 The MHRA considers that the UK medical devices regulations could be amended to introduce requirements that would apply in cases where a person re-manufactures a single-use device on behalf of a healthcare institution. Requirements could include:

- a. that the supply of the re-manufactured single-use devices should be through a closed loop contract between the re-manufacturer and the healthcare institution (e.g. hospital or clinic). At no time should a re-manufacturer or healthcare institution sell or provide a re-manufactured single-use device to any other third party
- b. that a re-manufactured single-use device should only be used on an individual patient during a single procedure and, after that use, the single-use device should be returned to the contracted re-manufacturer.

Section 67 questions and responses

Q67.1 Do you think that the UK medical devices regulations should include the requirements for re-manufacturers of single-use medical devices set out in paragraph 67.5?

Yes

Q67.2 Please outline any other requirements which should be introduced for the re-manufacturing of single-use devices.

These requirements should be aligned with the IMDRF guidance¹ and what is required in other countries.

The GTIN allocation rules² should be followed in alignment with UDI regulation for UDI assignment after re-manufacturing for serialisation purposes.

1. <http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-190321-udi-sag.pdf>
2. https://www.gs1.org/docs/gsm/healthcare/GS1_Healthcare_GTIN_Allocation_Rules.pdf

Q67.3 Do you think the UK medical devices regulations should introduce the requirements set out in paragraph 67.6 for re-manufacturers of single-use devices on behalf of healthcare institutions?

Yes

Q67.4 Please outline any other requirements which should be introduced for the re-manufacturing of single-use devices within healthcare institutions.

The rules should not be different.