NHS Scan4Safety healthcare supplier forum
Q&A responses

Question	Answer
How many trusts are already using Scan4Safety in theatres?	We are undertaking a baseline assessment of scanning uptake at the point of care across England. There were six demonstrator sites involved in the original Scan4Safety programme and a further four supported by NHSX in 2021/22. There are other organisations that have introduced scanning at the point of care, inventory management solutions and other systems.
Good morning, I have a question about the Medical Device Regulation 2002. In 2023 will the UDI (Unique Device Identifier) be mandatory for all risk classes? Thanks	The government intend to introduce UDI (unique device identification) requirements in the future regulations which are expected to come into force in July 2024.
Can you share the source where you got the news about UK MDR (medical device regulation) coming into force in July 2023?	The future Medical Device Regulations are expected to come into force in July 2024. Please see the MHRA webpage on the extension: https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices-and-extension-of-standstill-period
Morning, I understand GDSN (Global Data Synchronisation Network) isn't currently being proposed in Scotland, is it the source for Wales?	Not at present, but it is being kept under review.
Are you requesting GTINs (Global Trade Item Numbers) at all levels from suppliers? e.g. pallet, trading unit and unit of use	The requirement of the NHS is for all packaging levels to be issued a GTIN. There are no current requirements from the NHS healthcare providers or the EU MDR for logistics units such as pallets to be issued GTINs.
How are theatres catering for non-NHS staff like reps and how is it regulated?	Trusts visitor policies would apply to reps.
As you move towards Peppol transactions, will you be requiring suppliers to use Peppol providers that are on the latest version of Peppol which is BIS3?	Yes - Peppol providers and suppliers are expected to adhere to what Peppol mandates, which among other things includes BIS3 compliance. These mandates are not set by NHS Supply Chain however, we take these very seriously and continue to work with our providers and suppliers to make sure they meet these standards.
Morning, question around Peppol and GLNs. With regards to onboarding, how can suppliers make contact to manage the change and ensure there is limited impact to supply? Also will the GLNs be visible on the global location manager?	LocationManager is the NHS GLN registry and suppliers and NHS providers are adding GLNs to the registry. This is not currently a requirement in Scotland.
Our UKCA cert expires May 2024, therefore we will need to be transitioning to the new UK reg by the end of 2023 with our Approved Body. This transition period does not give much time to adopt the new	The future Medical Device Regulations are expected to come into force in July 2024. Please see the MHRA webpage on the extension: https://www.gov.uk/government/publications/implementation-

regs and then transition? Especially as there is no confirmed date yet.	of-the-future-regulation-of-medical-devices-and-extension-of-standstill-period We strongly encourage manufacturers to begin discussing recertification with their UK Approved Body as soon as possible.
UDI-DI, what if the item is very small, how can you put it on the item?	The government is considering whether there are valid exemptions to the UDI requirements.
When will the transition arrangements be officially published on the MHRA website? Here you mention it as something that will happen for sure, but many stakeholders have been careful to take this as certain, since they have not been published yet, besides being featured on the consultation.	The future Medical Device Regulations are expected to come into force in July 2024. Please see the MHRA webpage on the extension: https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices-and-extension-of-standstill-period We strongly encourage manufacturers to begin discussing recertification with their UK Approved Body as soon as possible.
Are there any provision/plans to address Approved Body capacity? We are already being told by the likes of SGS that our EU MDR certificate is unlikely to be issued before the implementation date. The UKCA scheme will push extra work onto certification bodies and could cause gaps in medical devices having valid certification.	There are currently four designated UK Approved Bodies within the UK, with six organisations currently in the application phase. The future Medical Device Regulations are expected to come into force in July 2024. Please see the MHRA webpage on the extension: https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices-and-extension-of-standstill-period
If the new regime comes into force after July 2023, can devices still be placed on the market with the CE mark only after the current July 23 deadline for devices to apply UKCA?	Yes, CE marked devices can be placed onto the GB market beyond July 2023. The future Medical Device Regulations are expected to come into force in July 2024. Please see the MHRA webpage on the extension: https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices-and-extension-of-standstill-period
What is defined as a medical device requiring UDI-DI?	This will be defined in future legislation. The government is also considering whether there are valid exemptions to the UDI requirements.
Why can we not be aiming for, not only to have patient cards, but personalised data for patients on their records? We can get a batch number for our covid vaccination, why not for our implants?	The requirement for health institutions/health care professionals to record the UDIs of all implantable devices preferably by electronic means will hopefully address this. As the ambition is for the UDI of the implanted device to be captured in the patient's Electronic Health Record.
What's the method of submission of Basic UDI and UDI-DI to MHRA?	UDI-DIs and Basic UDI-DIs can be manually entered, individually, via the registration system user interface. UDI-DIs can also be submitted via a bulk upload template which accepts up to 1000 UDI-DIs. Bulk upload functionality is not currently available at the Basic-UDI-DI level.
Is it possible that the deadline of June 2023 to transfer all the CE marks to UKCA marks could be postponed?	The future Medical Device Regulations are expected to come into force in July 2024. Please see the MHRA webpage on the extension: https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices-and-extension-of-standstill-period. CE marked devices under the EU MDR/IVDR can continue to be placed onto the Great Britain market for up to five years from when the new UK Medical Device Regulations come into force (i.e. July 2029).

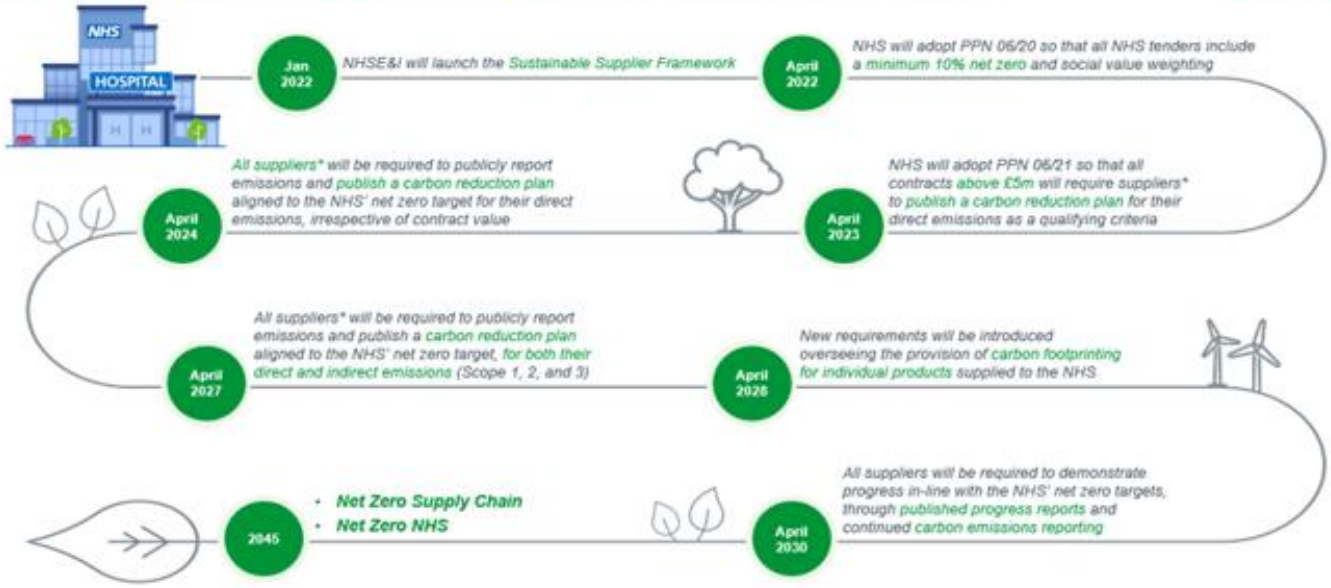
If a medical device manufacturer's MDD CE (Medical Device Directive/CE) certificate has already expired and they are currently going through the process to obtain EU MDR and UKCA marking, but the products have previously been distributed on the UK market (using the old MDD certification), can the distributor still obtain these items for sale in the UK?	Products that are placed onto the UK market are required to hold a valid certificate of conformity. Once the certificate has expired, these products can no longer be placed onto the UK market.
Has there been any news/update on an extension to the MDR transition deadline?	The future Medical Device Regulations are expected to come into force in July 2024. Please see the MHRA webpage on the extension: https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices-and-extension-of-standstill-period
Why have a separate MHRA reference for economic operators when you are insisting on UDIs, for which the recommended standard is GS1, so why not use theGS1 prefix or GLNs (Global Location Numbers)?	It was deemed necessary to introduce a unique actor identifier that is generated and issued by the MHRA. It is important that the identifier of choice indicates the role of the Actor (e.g. manufacturer/ supplier/distributor) and the country that the actor is located in. Location identifiers currently available do not exhibit these characteristics. Although it is not planned that the GLN will be a mandatory field in the future MHRA registration system, submitters will be able to provide another internationally recognised external reference such as GLN on a voluntary basis.
The response from MHRA regarding the public consultation considered, is it just a guide or does it supersede any previous formal publication from MHRA?	The government response to the public consultation outlines the policies which the government intends to introduce as part of the future Medical Device Regulations. The new regulatory requirements will take effect once the future legislation comes into force. The future Medical Device regulations are expected to come into force in July 2024. Please see the MHRA webpage on the extension: https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices-and-extension-of-standstill-period
In the event of a merge of license transfer, will the GTIN and GMN (Global Model Number) need to change, or only the new owner data on the GS1 website?	If the acquisition is of a company the GS1 Company Prefix can be transferred to the acquiring company. If not all products are acquired then new identifiers will need to be assigned to those products.
For IVD's that are sample collection kits, that don't require NB input that are CE marked and will need to be UKCA marked- is the deadline we are working to still June 2023? I presume the 5 year transition time does not apply to us. The intended market for our device is GB and EU.	The future Medical Device Regulations are expected to come into force in July 2024. Please see the MHRA webpage on the extension: https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices-and-extension-of-standstill-period. For IVDs that are certified under the EU IVDR and EU IVDD, these devices will be subject to a five year transition period (up to July 2029).
What is the NHS deadline for implementation of GS1 by suppliers?	The NHS in England set timelines in their original guidance and these have now all passed. For these programmes to achieve maximum benefit as soon as possible it is important that suppliers adopt GS1 standards as soon as they can and remember that the MHRA will set regulatory deadlines for UDI. Scotland is proposing to align implementation timelines to the EU UDI timeline and we would welcome feedback from

	industry on this approach. We would however encourage suppliers to move as quickly as is feasible. No deadline is set by NHS Wales, but similar to NHS Scotland, the sooner the better so that we may scale up the use of the standards and enjoy the benefits.
What are the biggest challenges that the NHS is facing between the pharmaceuticals, PPE and medical device QR barcodes?	The challenges I've come across are actually caused by manufacturers not using the GS1 standards correctly. This includes the wrong barcode type, poor quality barcodes, and the data not being encoded correctly. With so many NHS trusts now using handheld smart devices, scanning of 2D barcodes is becoming more commonplace.
Could you tell us specifically what carbon footprint data is being captured and how widespread it is across SCCL portfolio (i.e. 1% of 75% of products)? How consistently are suppliers applying carbon measurement – is it apples for apples?	We have undertaken a scope 3 detailed assessment of the whole portfolio which we are currently reviewing. We undertook this so we had a consistent methodology.
And how is SCCL carbon data actively used - what decisions are made, are improvements tracked, is that information showcased to local buyers for nudge NHS behaviours?	The NHS Supplier Roadmap sets out our approach. Please see the image at the end of this document (on page 7) for further details.
I had also a question during the previous session about the timeline of the UDI requirements in the UK. Will this also be shared when the new legislation is released?	The UDI requirements will come into force as part of the future medical device regulations (i.e. in July 2024).
Can you share who are these six Approved Bodies are under review by MHRA?	Unfortunately, the MHRA are unable to share this information for confidentiality reasons.
Since Brexit, do all medical devices imported to UK need to be registered with MHRA? And who has to register it, the overseas manufacturer or the distributor/importer?	All medical devices placed onto the GB market must be registered with the MHRA. This can be by the legal manufacturer (if they are based within the UK) or by the UK Responsible Person (which the manufacturer must appoint if they are not based within the UK).
Caroline, was it difficult educating the third-party suppliers on the GS1 requirements and what they need to do their end?	As always, there is no clear yes or no to this question. Some third-party suppliers were easier to deal with than others, depending on: • English language skills • Size of the company (larger ones were more likely to have knowledge about GS1 barcoding and processes) Overall, my advice would be to engage as early as possible with your third-party suppliers to understand what their position is and whether they will likely face some difficulties or not.
For reusable devices, is it mandatory to have a unique serial number, specifically for hospital management of reprocessing cycles (if that is practiced in the NHS)?	UK legislation, through the new Medical Device Regulations, is due to come into effect from 1 July 2024 and will require manufacturers to: • assign Unique Device Identifiers (UDI) codes to medical devices before they are placed on the market • require reusable medical devices to bear a UDI carrier (for example, a barcode) that is permanent and readable after each process on the device itself • include requirements for Basic UDI device identifiers (Basic UDI-DIs) to identify medical device models

Will Peppol become mandatory for suppliers to the NHS?	Peppol is already a requirement of the NHS eProcurement Strategy in England.
Does Scan4Safety rely fully on barcodes/QR codes, or does it already include other non-visible UDI scannable items to add further security?	There are no regulatory requirements in GB for security features and not something required of the NHS eProcurement Strategy.
When can we expect the new UK regulations to be released following the response to the consultation paper?	The future Medical Device Regulations are expected to come into force in July 2024. Please see the MHRA webpage on the extension: https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices-and-extension-of-standstill-period. Under the World Trade Organisation (WTO) Technical Barriers to Trade agreement, the Secretary of State will be required to share the draft regulations on the future medical device regime for comment. The period for comments must last for at least 60 days prior to the regulations being laid in Parliament. The draft regulations will be published by the WTO and will provide an opportunity to all our key stakeholders to review and comment on the draft legislation before it comes into force.
If a medical device manufacturer's MDD CE certificate has already expired and they are currently going through the process to obtain EU MDR and UKCA marking but the products have previously been distributed on the UK market (under the old MDD certification) can a distributor still obtain those products for sale in the UK?	Products that are placed onto the UK market are required to hold a valid certificate of conformity. Once the certificate has expired these products can no longer be placed onto the UK market.
Are there plans to align UK MDR 2002 with EU MDR 2017/754? Manufacturers?	The public consultation on the future Medical Device Regulations received strong support for alignment with the EU MDR/IVDR in several areas of policies, this has been reflected in the Government response.
NHS has been instructing suppliers to register GTIN in GDSN, MHRA does the same in DORS (Device Online Registration System). Can NHS agree suppliers not to continue registering data in GDSN?	The GDSN and DORS are used for completely different purposes and have different functionality. Suppliers should work with their NHS customers on whether the GDSN is the most effective way of sharing data with them at this time as this will vary across the customer base.
Could you please share the link for the proposed new legislation?	The Government response to the consultation can be accessed at: https://www.gov.uk/government/consultations/consultation-on-the-future-regulation-of-medical-devices-in-the-united-kingdom. The future Medical Device Regulations are expected to come into force in July 2024. Please see the MHRA webpage on the extension: https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices-and-extension-of-standstill-period. Under the World Trade Organisation (WTO) Technical Barriers to Trade agreement, the Secretary of State will be required to share the draft regulations on the future medical device regime for comment. The period for comments must last for at least 60 days prior to the regulations being laid in Parliament. The draft regulations will be published by the WTO and will provide an opportunity to all our key stakeholders to review

	and comment on the draft legislation before it comes into force.
Can you comment on transitional arrangements for UDI?	The timelines relating to UDI requirements will be detailed in the future legislation. The future Medical Device Regulations are expected to come into force in July 2024. Please see the MHRA webpage on the extension: https://www.gov.uk/government/publications/implementation-of-the-future-regulation-of-medical-devices-and-extension-of-standstill-period.

Building net zero into NHS procurement



To account for the specific barriers that Small & Medium Enterprises and Voluntary, Community & Social Enterprises encounter, a two-year grace period on the requirements leading up to the 2030 deadline, by which point we expect all suppliers to have matched or exceeded our ambition for net zero.