Sustainability Recommendations

Four Key Recommendations for the MHRA

1. Advocating the use of electronic Instructions For Use (e-IFUs) to reduce the excessive use of paper and the reduction of fuel in the transit of products.
2. Encouraging the use of QR codes on medical devices to improve information sharing.
3. Developing a regulatory process that takes account of equivalence and predication in alternative material approvals, to lessen the need for duplicative submissions.
4. Updating the guidance on remanufacturing and refurbishment to ensure clarity and accessibility when considering sustainability objectives.

Background

Medical device and in vitro diagnostic medical device regulation play an essential role in keeping patients safe, and patient safety must always remain the most important priority. However, the negative impact that the delivery of healthcare has on the planet cannot be underestimated. The NHS contributes 4% of the UK's total greenhouse gas emissions and has committed to reaching Net Zero by 2045. Regulation is a vital enabler to this transition, but currently it is acting as a barrier.

We do not wish for sustainability requirements to form part of any device regulation which should be focused on patient safety, but there is an opportunity, post-Brexit, to be leaders in this space. Any regulations should ensure that the UK is seen as an attractive place to conduct ethical and sustainable business practices, whilst continuing the leading drive that our NHS Net Zero commitments have started.

The task is to move away from business as usual, and towards ensuring regulations which allow for the sustainable changes that are needed from industry to tackle climate change. It is understood that this is a behavioural change, and that confidence will need to be instilled in these changes, which is why clear guidance is necessary.

The ABHI makes four recommendations to the MHRA.

1. Advocating the use of electronic Instructions For Use (e-IFUs) to reduce the excessive use of paper and the reduction of fuel in the transit of products

Physical IFUs require a large amount of resources and energy to produce, as well as being a considerable weight to transport. One ABHI member found that from just one of their many manufacturing plants, the paper consumption needed to produce IFUs could reach up to 125 tonnes per year, which equates to approximately 125 tonnes of CO2 per year. This does not account for the fuel used in transit and disposal of the IFUs after use.

Enabling e-IFUs into the regulation will reduce the environmental impact. Additionally, electronic versions will allow the manufacturers of devices to update the instructions when necessary, ensuring a higher level of safety, as well as reducing the need for different versions of IFUs to be printed for different languages and geographies. A further benefit could be that those with impaired vision could benefit from a read aloud option, improving access to information.

To ensure that healthcare facilities and patients without the relevant infrastructure are not disadvantaged, manufacturers should ensure that physical copies of IFUs are still available upon request, and are printable in situ by healthcare professionals and patients.

In the EU, paper based IFUs are required for self-test and near patient IVDs, and for any non-professional use of a medical device. This, therefore, represents an opportunity to improve on the EU requirements.

To enable e-IFUs, updates to MHRA systems may be needed to ensure access, such as for the forthcoming major update to the MHRA's public access registration database (PARD).

We recommend for this to be a legislative change and for it to be included in the upcoming consultation.

2. Encouraging the use of QR codes on medical devices to improve information sharing

QR codes have the capability to hold a vast amount of information. With this move, manufacturers could include important information, such as how to recycle their product and UKCA marking, without having to physically print it on the product. This could reduce the amount of packaging needed to fit this information on, as well as encouraging reuse and recycling capabilities.

The UK has an opportunity to drive this innovation to encourage global acceptance of QR codes. The ability to use them should be encouraged through guidance, whilst not making it mandatory, to ensure that regulatory requirements do not deviate from global standards. Leading the way in this area, and demonstrating best practice, could encourage other jurisdictions to follow suit.

As with e-IFUs, updates to MHRA systems may be needed, such as with PARD.

We recommend clear and updated guidance.

3. Developing a regulatory process that takes account of equivalence and predication in alternative material approvals, to lessen the need for duplicative submissions

To change a material used in a medical device, or its packaging, can be a costly and time intensive process. When a manufacturer is wanting to move to a more sustainable material, such as one that is more easily recycled or reused, the current process to do so may be a deterrent based on resources and time required, particularly if they will see no economic benefit in selling the product once it has been changed.

If we moved to a system that took account of equivalence in alternative material approvals, meaning that suppliers do not have to absorb the same cost or time burden in making the regulatory change, this would encourage suppliers to enter into this process, whilst ensuring that patient safety remains the highest priority.

We recommend for this to be a legislative change and for it to be included in the upcoming consultation.

4. Updating the guidance on remanufacturing and refurbishment to ensure clarity and accessibility when considering sustainability objectives

The MHRA has some guidance in this area, such as the guidance on 'Single-use medical devices: UK guidance on re-manufacturing' from 2016, but the linking guidance on reprocessing of single-use devices appears to be inaccessible on the document.

Other guidance to be updated should include 'Managing Medical Devices: Guidance for Health and Social Care Organisations' and 'Management of In Vitro Diagnostic Medical Devices' to include more information for end users around refurbishment and repair.

Despite some guidance being available, there needs to be clarity around the guidance and the difference between remanufacturing, reprocessing and repairing medical devices, as well as this guidance being easily accessible for manufacturers. Highlighting the guidance, particularly around remanufacturing medical devices and the parameters of interactions between hospitals, original equipment manufacturers (OEMs) and remanufacturers, is particularly critical; it needs to be clear what relevant parties can or cannot do in terms of remanufacturing. The guidance also needs to be clear around accountability and responsibility for regulatory compliance at each point in a device's lifecycle.

We recommend for there to be clear and updated guidance.

Patient safety should remain the highest priority, but we need these practical changes to be implemented to ensure support for the move towards a more sustainable ecosystem, whilst maintaining, if not improving, patient outcomes.

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