

# Chapter 13: Environmental sustainability and public health impacts

## Section 71 - Environmental sustainability and public health impacts

### Background

71.1 The manufacture, use and disposal of medical devices can impact the environment in a range of ways, including impacts that arise from the:

- sourcing of raw materials
- manufacture and transport of medical devices
- decontamination, repair and sterilisation of medical devices, and,
- disposal of medical devices and packaging, especially from incineration of single use plastics.

71.2 Activity is underway across Government that has the potential to preserve and protect our environment and deliver positive impacts for public health. This spans activity focussed on reducing greenhouse gas (GHG) emissions, improving air quality, tackling waste and plastic pollution, and protecting the natural environment. For example, recognising the need to tackle climate change, in June 2019 the UK Government set a target for reducing UK GHG emissions to 'net zero' by 2050. In addition, the [Environment Bill 2020](#) will bring into UK law environmental protections and recovery, making sure that we have a cleaner, greener and more resilient country for the next generation.

71.3 We are interested in how our future regime for medical devices could help drive more environmentally sustainable manufacture, use and disposal to ultimately improve and safeguard public health. We recognise that, in addition to regulatory changes, other measures, including the use of international standards and guidance, can also have a role to play.

### Possible Changes and Questions

71.4 Developing our future regulatory framework for medical devices provides an opportunity to consider how this can better support the reduction of the environmental impact of medical devices to safeguard and improve public health. This could include enabling, encouraging and/or requiring manufacturers, other economic operators and users of medical devices to consider and reduce this environmental impact.

71.5 As we look at possible amendments to the UK medical device regulations, we are considering a number of options, including:

- a. **Environmental and public health impact assessments:** introducing a requirement for manufacturers to complete, as part of their conformity assessment for a medical device, an assessment of the device's impact on both the environment and public health. Examples of information this might capture include waste and emissions associated with the device and whether it can be reused, re-processed or recycled. A summary of the assessment could be made publicly available to support more informed medical device use choices.
- b. **Introduce waste management responsibilities into the medical device supply chain** which could concern: reducing the environmental impact associated with a device (including its manufacture, use, packaging, disposal, recyclability, and any sterilisation and re-manufacture), and to consider using less hazardous materials that are easier to dispose of safely.
- c. **Introduce a requirement that devices must be designed and manufactured in a way that reduces, as far as possible, the risks posed to public health by substances or particles that may be released from the device** including wear debris, degradation of products and processing residues.
- d. **Broaden the circumstances in which electronic (rather than paper) labels and instructions for use can be used for medical devices** taking account of the need for patient safety and access. The UK medical devices regulations currently allow that, for certain medical devices and in certain circumstances, electronic instructions for use (e-IFUs) can be used rather than printed versions. The relevant device must be intended to be used by healthcare professionals, have an adequate risk assessment conducted for electronic format, be available in paper copy if requested, and have the same content as the paper version would. See [MHRA guidance on e-IFUs](#) for more detail.

71.6 Please see Chapter 2 on classification for an opportunity to share views about how sustainability considerations could be better taken into account in classification of medical devices.

**Q71.1 To what extent are you or your organisation already implementing, or planning, activities to reduce the impact of medical devices on the environment? Please outline any key activities you have underway or planned.**

**Q71.2 Do you see a need for additional requirements to be placed on economic operators in order to encourage them to consider and/or mitigate the environmental impact of medical devices they place on the UK market? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q71.3 Please explain the rationale for your response to question 71.2 and any expected impacts.**

**Q71.4 What are your views on the options for change outlined in paragraph 71.5? Please state your rationale, key implementation considerations and the expected impact of these options.**

**Q71.5 What other changes or key considerations do you think are needed to ensure more sustainable medical devices?**

**Q71.6 What are the key implementation considerations for the options outlined in paragraph 71.5 and any further potential changes you consider are required?**

**Q71.7 Please set out which options could be introduced quickly (within 1-2 years) and which could be introduced within a longer timeframe?**