

Chapter 1: Scope of the Regulations

Section 1 - Medical device and IVD scope

Background

- 1.1 The Medical Devices Regulations 2002 (SI 2002 No. 618, as amended) (UK medical devices regulations) currently set out definitions of a 'medical device' and an '*in vitro* diagnostic medical device' (IVD). Products that meet these definitions are regulated as medical devices or IVDs under the UK medical devices regulations. Where a product does not meet the definition of a medical device or an IVD, the manufacturer may still be required to comply with other regulations – for example, medicines or biocide regulations.
- 1.2 The scope of the UK medical devices regulations could be amended so that the Regulations encompass medical devices and IVDs captured within the Global Harmonization Task Force's (and/or its successor organisation, [International Medical Device Regulators Forum](#) (IMDRF) [internationally recognised definitions](#), and to account for advances in medicine, engineering or technology.
- 1.3 Altering the scope of the Regulations could result in some products that were previously either unregulated or regulated under different legislation, being brought into scope of the UK medical devices regulations. Conversely, it could also result in some products currently regulated as medical devices being removed from their scope.

Possible Changes and Questions

- 1.4 We now have an opportunity to bring certain products into the scope of the UK medical devices regulations where we consider there is a need to do so. For example, the Regulations could be broadened to cover products that possess similar risk profiles to medical devices and thus could be regulated as such. We also have an opportunity to remove from scope of the UK medical devices regulations, products that we consider could be more appropriately regulated under other frameworks.

Definition of a medical device

- 1.5 The UK medical devices regulations currently define a medical device as:

“any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which—

(a) is intended by the manufacturer to be used for human beings for the purpose of—

- (i) diagnosis, prevention, monitoring, treatment or alleviation of disease,*
- (ii) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*
- (iii) investigation, replacement or modification of the anatomy or of a physiological process, or*
- (iv) control of conception; and*

(b) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means, and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device;”

1.6 We could expand the scope of the UK medical devices regulations to include, for example:

- a. products without an intended medical purpose that have similar functioning and risk profiles to medical devices (please see section 2 below for more detail)
- b. products specifically intended for the cleaning, disinfection or sterilisation of devices
- c. products which support conception
- d. products for prediction or prognosis of disease
- e. products used for investigation, replacement or modification of a pathological process
- f. products which provide information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations

1.7 The definition of ‘medical devices’ in the Regulations could also be revised so that it refers to ‘disability’ rather than ‘handicap’.

Definition of *in vitro* diagnostic medical device

1.8 The UK medical devices regulations currently define an *in vitro* diagnostic medical device (IVD) as:

“a medical device which—

(a) is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination; and

(b) is intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information—

- (i) concerning a physiological or pathological state,*
- (ii) concerning a congenital abnormality,*
- (iii) to determine the safety and compatibility of donations, including blood and tissue donations, with potential recipients, or*
- (iv) to monitor therapeutic measures, and includes a specimen receptacle but not a product for general laboratory use, unless that product, in view of its characteristics, is specifically intended by its manufacturer to be used for in vitro diagnostic examination;”*

1.9 We could expand the scope of the UK medical devices regulations to include, for example:

- a. the term 'software' in the definition of IVD
- b. products providing information to predict treatment response or reaction (e.g. companion diagnostics)
- c. products which provide information concerning a physical or mental impairment
- d. products which provide information concerning the predisposition to a medical condition or a disease

Q1.1 Do you think the scope of the UK medical devices regulations should be expanded to include the additions suggested above? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q1.2 Please set out what (if any) further amendments you would like to make to the scope of the UK medical devices regulations.

Q1.3 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 1.1-1.2, including any impacts on you or other stakeholder groups.

Intended purpose

1.10 Currently, the UK medical devices regulations set out that 'intended purpose' means:

- a. *in relation to an active implantable medical device, the use for which it is intended and for which it is suited according to the data supplied by the manufacturer in the instructions relating to it;*
- b. *in relation to any other medical device, the use to which the device is intended according to the data supplied by the manufacturer on the labelling, the instructions for use and/or the promotional materials.*

1.11 'Intended purpose' in these provisions is best interpreted as an objective test, that is, the intended purpose of the manufacturer of a medical device or an IVD (and so its qualification as a medical device and subsequent classification) is assessed at the standpoint of an objective observer and is not a question of what the subjective intention of the manufacturer might be.

1.12 For the avoidance of doubt, the UK medical devices regulations could be amended to clarify that intended purpose is to be construed objectively with reference to the materials listed in the current definition above, but also other key materials such as a manufacturer's technical documentation (including clinical evaluation for a medical device). We also do not think there is any need to retain the distinction between active implantable medical devices and other general devices and would propose to remove that distinction.

- 1.13 This would clarify how the term 'intended purpose' is interpreted and bring it more into line with other jurisdictions such as the US. It would also make clear that the representations made in a manufacturer's promotional and marketing material must be consistent with the evidence underpinning their device.

Q1.4 Should we make clear that 'intended purpose' is to be construed objectively and that key materials such as a manufacturer's technical documentation may be used as evidence of intended purpose? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q1.5 Please set out the reasoning for your reply to question 1.4, including your views on the materials that should be taken to evidence intended purpose, and any implementation considerations and expected impacts of any proposed changes.

Section 2 - Products without a medical purpose

Background

- 2.1 There are a number of products on the market for which a manufacturer claims only an aesthetic or another non-medical purpose, but which are similar to medical devices in terms of their functioning and risk profile. For example, non-prescription coloured contact lenses carry similar risks to prescription contact lenses.
- 2.2 These products, for which the manufacturer does not claim an intended medical purpose, are not currently regulated under the Medical Devices Regulations 2002 (SI 2002 No. 618, as amended) (UK medical devices regulations), despite having the potential to cause risks similar to medical devices, such as risks of infection or injury.
- 2.3 The MHRA considers that these products could be regulated under the UK medical devices regulations to ensure that they meet higher requirements for safety. Please see below for a non-exhaustive list of groups of such products. In addition to the products listed below, the MHRA will consider the scope for regulating as medical devices, other products without a medical purpose that are put forward in response to this consultation.

Groups of products with an aesthetic or other non-medical purpose not currently regulated under the UK medical devices regulations

- a. Non-prescription contact lenses or other items intended to be introduced into or onto the eye for cosmetic rather than medical purposes, including those which contain software e.g. coloured lenses, cosmetic iris implants
- b. Products intended to be totally introduced into the human body through surgically invasive means e.g. buttock implants, Radio Frequency Identification (RFID) chips
- c. Products intended to be partially introduced into the human body through surgically invasive means e.g. microneedling products, horn implants

- d. Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by injection, excluding those for tattooing e.g. dermal fillers
- e. Equipment (including software) intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty - e.g. cryolipolysis
- f. High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment e.g. hair removal lasers
- g. Equipment intended for brain stimulation that applies electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain e.g. transcranial direct current stimulation
- h. Diagnostic tests for health and wellbeing e.g. genomic testing for diet/nutrient optimisation, genomic testing for skin care, lactate testing for fitness training.

Possible Changes and Questions

2.4 The MHRA considers that the scope of the UK medical devices regulations could broaden to cover products with similar functioning and risk profiles to medical devices and their accessories, such as those listed above. This would ensure more stringent regulation of these devices - for example, in the manufacturing or post-market surveillance stages. Please see Chapter 7, section 33.12 for a question about the pre-market studies that products without an intended medical purpose could be subject to.

Q2.1 Do you think the scope of the UK medical devices regulations should be broadened to include devices without a medical purpose with similar risk profiles to medical devices? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q2.2 Please provide your reasoning for your response to question 2.1.

Q2.3 If you have answered 'yes' to question 2.1:

- a. please outline which products from the list at paragraph 2.3, and any others, you consider should be brought into scope of the UK medical devices regulations.
- b. please describe how these products should be assessed to ensure that they are safe and perform as intended.
- c. please outline how you think these products should be classified (for example, whether they should be classified in line with medical devices that have similar functions and risks).

Q2.4 Do you think that manufacturers of the products listed at paragraph 2.3 should be required to register them with the MHRA? (see Chapter 4, Section 21 for further information on registration requirements) ('Yes' / 'No' / 'Don't Know/No Opinion')

Q2.5 Please provide any other comments you wish to make about the possible regulation of products without a medical purpose as medical devices and your reasoning (including any available relevant evidence) to support your answers to questions 2.1-2.4. Please include any impacts on, and implementation considerations for, you or other stakeholder groups.

Section 3 - Exclusion of products that contain viable biological substances

Background

- 3.1 The Medical Devices Regulations 2002 (SI 2002 No. 618, as amended) (UK medical devices regulations) do not explicitly include or exclude products that contain viable biological substances (e.g. bacteria) from the scope of the Regulations.
- 3.2 The UK medical devices regulations could clarify that products that contain or consist of viable biological substances are excluded from the scope of the Regulations. The objective would be to avoid confusion and inappropriate regulation in cases where other regulatory frameworks may be more suitable for these products.

Possible Changes and Questions

- 3.3 The MHRA considers that products which contain or consist of viable biological substances (e.g. micro-organisms) could be explicitly excluded from the scope of the UK medical devices regulations. Again, the objective would be to provide further clarity and prevent inappropriate regulation of these products.

Q3.1 Do you think that products which contain viable biological substances should be excluded from the scope of the UK medical devices regulations? (('Yes' / 'No' / 'Don't Know/No Opinion')

Q3.2 Please provide your reasoning (including any available relevant evidence) to support your answer to question 3.1, including any impacts on you or other stakeholder groups.

Section 4 - Exclusion of food

Background

4.1 The Medical Devices Regulations 2002 (SI 2002 No. 618, as amended) (UK medical devices regulations) do not explicitly include or exclude food or food-based extracts from the scope of the Regulations.

Possible Changes and Questions

4.2 The UK medical devices regulations could explicitly state that food is excluded from the scope of the Regulations. This would prevent persons from claiming that a food-based product can act as a medical device due to a perceived medical claim - for example, a cranberry-based product preventing cystitis.

4.3 It is MHRA's view that a food-based product should not fall under the UK medical device regulations. We therefore consider that food could be excluded from the scope of the UK medical devices regulations to in order to provide further clarity and prevent inappropriate regulation.

Q4.1 Do you think that food should be excluded from the scope of the UK medical devices regulations? ('Yes' / 'No' / 'Don't Know/No Opinion')

Q4.2 Please provide your reasoning (including any available relevant evidence) to support your answer to question 4.1, including any impacts on you or other stakeholder groups.