

# Chapter 9: *In vitro* Diagnostic Medical Devices

## Section 52 - General background

### Background

52.1 The Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK medical devices regulations) defines an *in vitro* diagnostic (IVD) medical device as:

“any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, 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:

- a. *Concerning a physiological or pathological state, or*
- b. *Concerning a congenital abnormality, or*
- c. *To determine the safety and compatibility with potential recipients, or*
- d. *To monitor therapeutic measures”.*

52.2 The MHRA considers that there is a need to amend how we regulate IVDs, in particular to meet the fast-moving developments and innovation within the field of IVDs, and to bring our approach into line with current international standards.

52.3 This section considers possible amendments that could be made to the UK medical devices regulations to reflect the new developments within this field.

## Section 53 - IVD Classification Rules

### Background

53.1 The classification rules under the UK medical devices regulations enable a high proportion of IVDs (~80%) to be placed onto the market on the basis of self-declaration. Self-declaration is a process whereby a manufacturer can self-declare compliance to the relevant regulatory requirements without undergoing a third-party conformity assessment.

53.2 The UK medical devices regulations provide for four categories of IVDs, in order of increasing perceived risk to patient safety:

- **General IVDs**, i.e. all IVDs other than those covered below
- **IVDs for self-testing** (a medical device intended by the manufacturer to be able to be used by lay persons in a home environment) - excluding self-test medical devices covered below

- **IVDs in the classifications stated in Part IV of the UK medical devices regulations, Annex II List B<sup>1</sup>:** which, amongst others, includes reagents products for rubella, toxoplasmosis and phenylketonuria as well as medical devices for self-testing for blood sugar
- **IVDs in the classifications stated in Part IV of the UK medical devices regulations, Annex II List A<sup>2</sup>:** which includes reagents and products for HIV I and II, Hepatitis B, C and D, and reagent products for determining ABO systems and anti-kell including those used to test donated blood plus tests for screening.

## Possible Changes and Questions

53.3 We propose to amend the IVD classification rules to increase the level of scrutiny applied to IVD devices. These rules could, for example, be amended to take into account the intended purpose of the medical device and to reflect relevant international systems of regulation including the EU IVDR and the IMDRF approach. The aim of this approach would be to drive greater patient safety through increased medical device scrutiny of IVD products placed on the UK market.

**Q53.1 Should the classification rules for IVD products under the UK medical devices regulations be amended to align to the EU approach to IVD classification, as set out in the IVDR? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q53.2 Should the classification rules for IVD products under the UK medical devices regulations be amended to align to the International Medical Devices Regulatory Forum (IMDRF) approach to IVD classification? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q53.3 Are the current IVD regulatory requirements for each class of IVD proportionate to their risk? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q53.4 Does the current approach to classification sufficiently cover the digital/software aspect of IVDs? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q53.5 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 53.1-53.4, including any impacts on you or other stakeholder groups.**

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<sup>1</sup> As modified by Part III of Schedule 2A to the UK medical devices regulations.

<sup>2</sup> As modified by Part III of Schedule 2A to the UK medical devices regulations

## Background

54.1 Genetic tests can be used to provide information and data on a person's predisposition to developing a medical condition or disease. They can be used in healthcare under supervision of a medical professional or they can be purchased directly by individual members of the public who can perform the test at home and send their sample to a lab to obtain their results.

## Possible Changes and Questions

54.2 The UK medical devices regulations do not currently include specific requirements relating to genetic testing. Under the current regulations it is possible for a genetic test to receive a CE or UKCA marking on the basis of an analytical study which demonstrates the medical device's performance. This is due to these devices being classified as low-risk devices under the current UK medical device regulations. There has been a long-standing concern amongst stakeholders that the current regulatory requirements are not sufficiently robust within this area. This includes requirements around the information provided to users of genetic tests. The UK medical device regulations could be amended to reflect some of the concerns raised such as those relating to the risk classification of genetic tests and ensuring users of genetic tests are provided with the appropriate information on the nature, significance and implications of their test

**Q54.1 Should the UK introduce requirements around the information and data provided to individuals on the nature, significance, and implications of genetic tests? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q54.2 Should the UK medical device regulations be amended to align with the EU approach to the classification of genetic tests as set out in the IVDR? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q54.3 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 54.1-54.2, including any impacts on you or other stakeholder groups.**

## Background

55.1 Over the last few years there has been an increased interest in the use of personalised medicinal products, which require the accompanying use of a medical device or an IVD, to help quantitatively and qualitatively determine specific markers on patients. This is used to help assess patients' eligibility to receive certain therapeutic products. These medical devices are otherwise known as Companion Diagnostics (CDx).

## Possible Changes and Questions

55.2 The UK Medical Devices Regulations do not include specific provisions for a CDx device. These medical devices would typically fall under the lowest risk category. However, there have been concerns relating to how CDx devices are classified and the level of clinical evidence required to place these products onto the market.

55.3 Therefore, the UK medical devices regulations could be amended to:

- introduce classification rules specifically for CDx devices which are proportionate to their risk
- introduce specific clinical evidence requirements for CDx (please refer to Section 34 on requirements relating to performance studies for IVD devices, including CDx)

**Q55.1 Should Companion Diagnostics be treated differently to other IVDs? (i.e. with respect to classification). ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q55.2 How do we ensure the clinical evidence requirements for Companion Diagnostics are clear, appropriate, and proportionate to the risk? For example, should they differ for CDx that predict benefit / efficacy vs those that predict toxicity / harm?**

**Q55.3 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 55.1-55.2, including any impacts on you or other stakeholder groups.**

## Background

56.1 Please refer to Chapter 3, Section 9 on general requirements relating to Distance Sales.

## Possible Changes and Questions

56.2 The UK Medical Device Regulations do not include specific regulatory requirements around IVD products placed onto the UK market through distance sales. We propose that distance selling of IVD products should be required to comply with the UK Medical Device Regulations in order to be placed on the UK market.

**Q56.1 Should it be made clearer that providers of testing services who supply IVDs to the UK market (through electronic or other distance sale methods), are subject to the same requirements of the UK Medical Device Regulations as apply to economic operators in the traditional supply chain? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q56.2 Should it be made clearer that those selling testing services, which include the provision of IVDs into the UK, be required to register their medical devices with the MHRA? ('Yes' / 'No' / 'Don't Know/No Opinion')**

**Q56.3 Please provide your reasoning (including any available relevant evidence) to support your answers to questions 56.1-56.2, including any impacts on you or other stakeholder groups.**