MDCG 2019-7
Guidance on Article 15 of the Medical Device Regulation (MDR) and *in vitro* Diagnostic Device Regulation (IVDR) regarding a 'person responsible for regulatory compliance' (PRRC)

Manufacturers[1] (paragraph 1)

"*Manufacturers shall have available* ***within their organisation*** *at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of medical devices. The requisite expertise shall be demonstrated by either of the following qualifications:*

(a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;

(b) four years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate the requisite expertise referred to in the first subparagraph by having at least two years of professional experience within a relevant field of manufacturing."

Clarification on qualifications

It shall be noted that:

- For the purpose of fulfilling the requirement laid down in point "a" of Article 15 (1), any qualification acquired outside the EU, including any university diplomas or certificates, should have been recognised by an EU Member State as equivalent to the EU corresponding qualification.

[1] Enterprises which employ at least 50 persons and whose annual turnover and/or annual balance sheet total exceeds EUR 10 million (Commission Recommendation 2003/361/EC of 6 May 2003).

- *Professional experience in regulatory affairs or in quality management systems relating to medical devices* should be related to the EU requirements in the field.

Meaning of "within their organisation"

The person responsible for regulatory compliance (PRRC) appointed would need to be an employee of the organisation.

Organisations with more than one legal manufacturer

Organisations with more than one legal manufacturer under the parent company would need to ensure that each legal manufacturer has its own PRRC.[2]

Can the PRRC be located outside the EU?

As to the location of the PRRC, it is important that a close linkage, of a permanent and continuous nature, is established between the PRRC and the manufacturing activities. For this reason, for manufacturers located outside the EU, it must be assumed that the PRRC should also be located outside the EU. On the other hand, for manufacturers located in the EU, it must be assumed that the PRRC should also be located in the EU.

Micro and small manufacturers[3] (paragraph 2)

"*Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC* ***shall not be required to have the person responsible for regulatory compliance within their organisation but shall have such person permanently and continuously at their disposal***."

Meaning of "permanently and continuously at their disposal"

The micro or small enterprise may subcontract the responsibilities of a person responsible for regulatory compliance to a third party, so long as the qualification criteria is met and the manufacturer can demonstrate and document how they can meet their legal obligations. For example, the PRRC may be part of an external organisation, with which the manufacturer has established a contract laying down provisions so as to ensure the permanent and continuous availability of that party. The contract should mention the relevant person's qualifications allowing compliance with points a and b of Article 15 (1).

Can the PRRC be located outside the EU?

For micro or small enterprises located in the EU, it must be assumed that any person to be permanently and continuously at their disposal should be also located in the EU.

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2 In the context of Article 15, the obligation for having available within the organisation at least one PRRC refers to the individual legal manufacturer.

3 Enterprises which employ fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million (Commission Recommendation 2003/361/EC of 6 May 2003).

Authorised representatives (paragraph 6)

"*Authorised representatives shall have* ***permanently and continuously at their disposal*** *at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for medical devices in the Union. The requisite expertise shall be demonstrated by either of the following qualifications:*

(a) a diploma, certificate or other evidence of formal qualification, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to medical devices;

(b) four years of professional experience in regulatory affairs or in quality management systems relating to medical devices."

Meaning of "permanently and continuously at their disposal"

The authorised representative may subcontract the responsibilities of a person responsible for regulatory compliance to a third party, so long as the qualification criteria is met and the authorised representative can demonstrate and document how they can meet their legal obligations. For example, the PRRC may be part of an external organisation with which the authorised representative has established e a contract laying down provisions so as to ensure the permanent and continuous availability of that party. The contract should mention the relevant person's qualifications allowing compliance with points a and b of Article 15 (1).

Can the PRRC be located outside the EU?

Taking into account that the Authorised Representative is located in the EU, it must be assumed that any person to be permanently and continuously at its disposal should be also located in the EU.

Roles and responsibilities of the person responsible for regulatory compliance within a manufacturer (paragraph 3)

For the purpose of this position paper, the roles and responsibilities of a PRRC have been cross-referred to the roles and responsibilities of a manufacturer, as stated in Article 10 of the MDR and IVDR. This paper does not interpret the roles and responsibilities of a PRRC. We recommend that any guidance on post-market surveillance, vigilance, clinical investigations and performance studies, created at a European level, should cross-refer to Article 15, paragraph 3 to provide guidance on what a PRRC of a manufacturer would be expected to do in these areas.

"*The person responsible for regulatory compliance shall at least be responsible for ensuring that:*

(a) the conformity of the devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released;"

Manufacturers "of devices, other than investigational [performance study] devices, shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this Regulation in the most effective manner and in a manner that is proportionate to the risk class and the type of device" (Article 10(9) of the MDR and Article 10(8) of the IVDR).

"*(b) the technical documentation and the EU declaration of conformity are drawn up and kept up-to-date;*"

Manufacturers "[of devices other than custom-made devices] shall draw up and keep up to date technical documentation for those devices" (Article 10(4) of the MDR and IVDR) and "shall draw up an EU declaration of conformity" (Article 10(6) of the MDR and Article 10(5) of the IVDR).

"*(c) the post-market surveillance obligations are complied with in accordance with Article 10(10) [Article 10(9) of the IVDR];*"

Manufacturers "of devices shall implement and keep up to date the post-market surveillance system" (Article 10(10) of the MDR and Article 10(9) of the IVDR).

"*(d) the reporting obligations referred to in Articles 87 to 91 [Article 82 and 86 of the IVDR] are fulfilled;*"

Manufacturers "shall have a system for recording and reporting of incidents and field safety corrective actions as described in Articles 87 and 88" (Article 10(13) of the MDR and Article 10(12) of the IVDR).

"*(e) in the case of investigational devices, the statement referred to in Section 4.1 of Chapter II of Annex XV [Section 4.1 of Annex XIV of the IVDR] is issued.*"

Manufacturers shall ensure that "a signed statement by the natural or legal person responsible for the manufacture of the investigational device [for performance study] that the device in question conforms to the general safety and performance requirements apart from the aspects covered by the clinical investigation [performance study] and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the subject."

Roles and responsibilities of the person responsible for regulatory compliance within an authorised representative (paragraph 3)

The PRRC of an AR should be responsible for ensuring that the tasks of an AR as specified in the given mandate, in accordance with Article 11(3), are fulfilled. .

Can one individual be the PRRC for a manufacturer and its authorised representative?

The person responsible for regulatory compliance for an authorised representative and for an 'outside EU' manufacturer cannot be the same person. There is a clear desire within the Regulations for the authorised representative to be adding an additional level of scrutiny and ensure that the supervision and control of the manufacture of devices, and the relevant post-market surveillance and vigilance activities are adequately effected. If the two roles were conducted by the same person, the additional level of scrutiny would be undermined.

For the same reason, the PRRC of a micro or small enterprise and the PRRC of the authorised representative of that same enterprise shall not belong to the same external organisation.