# Joint Industry Position Paper on Economic Operators

## Introduction

The medical technology industry welcomes the introduction of provisions regarding economic operators within the European Commission proposed regulations on medical devices and *in vitro* diagnostics medical devices (together referred to as "proposals for medical device regulations"). A further clarification of the respective economic operators' tasks and responsibilities is needed and will benefit the functioning of the internal market while contributing to patient safety. However, further consideration needs to be given to the delineation of the tasks of the respective economic operators in order to take into account the specificities and the strengths of the current medical device regulatory framework.

## Considerations

The rules on economic operators in the proposed medical device regulations have been largely aligned with the New Legislative Framework for the Marketing of Products, which consists of Regulation (EC) No 765/2008 and Decision No 768/2008/EC of the European Parliament and of the Council[1]. While it is appropriate and important to set out clearly the obligations of the different economic operators, including importers and distributors, this should be done taking into account the specific obligations laid down in other parts of the proposed medical device regulations; Decision No 768/2008/EC confirms that for specific sector legislation, the legislator can depart from the common principles it includes to take into account the specificities of sectorial needs.[2,3]

Under the current Medical Devices Directive[4], when the manufacturer is located outside the European Union (EU), it is mandatory to designate an Authorized representative established within the EU who also acts as the sole representative in the EU towards market surveillance authorities. Furthermore, the

[1] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/9344 [OJ L 218, 13.8.2008, p. 30] and Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, and repealing Council Decision 93/465/EEC45, [45 OJ L 218, 13.8.2008, p. 82.]

[2] Recitals (5), (6) of Decision 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products

[3] Recital (24) of the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009

[4] Directive 93/42/EEC of 14 June 1993 concerning medical devices

Authorized representative must be identified on the label, ensuring a single contact point in the EU for authorities, healthcare professionals and citizens. This is critical in the context of the proper functioning of the vigilance system where a single contact point contributes to the optimal collection and communication of incidents.

This has even been reinforced in the proposed medical device regulations, where the Authorized representative has specific responsibilities regarding regulatory compliance, in particular with a requirement to have a qualified person responsible for ensuring regulatory compliance within their organization[5].

The proposed medical device regulations, in defining the responsibilities of the respective economic operators, and in particular the importer, did not take into account the fact that Authorised representatives play a pivotal role in representing the manufacturer in the EU towards, amongst others, the market surveillance authorities and ensuring the regulatory compliance of the medical devices produced by manufacturers based outside the EU. Therefore the tasks linked to the verification of the regulatory compliance should stay within the Authorized representative remit and the responsibilities of importers should be limited to physical checks in line with their role in the supply chain.

As highlighted in the impact assessment supporting the New Legislative Framework alignment package[6], the main reason for having introduced requirements on importers relates to (a) the verification of regulatory compliance, (b) the difficulty for market surveillance authorities to have a contact in EU (as authorized representatives are generally not mandatory in other sectors) and (c) the lack of traceability of the products throughout the supply chain. All those issues are answered by several provisions in the draft medical device regulation.

(a) The fact that a single Authorized representative has to be designated under the proposed medical device regulation who can be responsible to verify the regulatory compliance, as he would have the needed in house expertise to perform those duties, makes the obligations for importers regarding regulatory compliance redundant. Indeed, it would be less appropriate to make importers responsible for carrying out regulatory compliance activities besides physical checks on the products as they may not have the required regulatory expertise or a qualified person within their organization.

(b) The requirement to have a contact point in Europe is also met by the requirement to designate an Authorized representative. In addition to acting as the communication channel towards regulatory authorities, this (single) contact point is also used for the vigilance system. The vigilance system is

[5] Recital (28) of the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009

[6] SEC (2011) 1376 final. New Legislative Framework Alignment Package, Commission staff working paper Impact assessment, accompanying document to the 10 proposals to align product harmonization directives to Decision 768/2008/EC, Brussels 21.11.2011.

recognized as a specificity of the medical device regulation[7] deviating from the new approach framework and as the 'backbone' of a robust regulatory framework in this sector[8]. As the efficiency of the vigilance system directly depends on the exhaustive reporting of serious incidents by healthcare professionals, introducing a second contact point on the device labeling will be confusing and may lower the effectiveness of the system for collection of incidents. As the expertise on regulatory compliance would be within the Authorized representative organization with the qualified person, we believe that the Authorized representative should remain the only contact point in Europe indicated on the label.

(c) Regarding traceability, the proposed medical device regulations make clear that economic operators must be able to identify who supplied them and to whom they have supplied medical devices.[9] In addition, the draft medical device regulation also provides for a requirement for manufacturers to fit their devices with a Unique Device Identification (UDI) which allows traceability, and requires entering the information regarding economic operators in the European database, ensuring a full traceability and transparency within the supply chain.

**Conclusion**

Therefore, the medical technology industry is asking for a further consideration of the specificities of the medical device legislation when introducing the requirements of the new legal framework for goods in the new medical devices regulations. This includes a clear delineation between the responsibilities of importers and Authorized representatives in particular in the area of regulatory compliance. The medical technology industry is also calling for the deletion of the mandatory labeling of the importer on the device, as the single contact point in the EU should remain the authorized representative to guarantee the optimal functioning of the vigilance system.

**COCIR, EDMA, EUCOMED, EUROM VI and EUROMCONTACT represent the majority of medical device manufacturers in Europe.**

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[7] Recital (10) of the Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on market surveillance of products and amending Council Directives 89/686/EEC and 93/15/EEC, and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 1999/5/EC, 2000/9/EC, 2000/14/EC, 2001/95/EC, 2004/108/EC, 2006/42/EC, 2006/95/EC, 2007/23/EC, 2008/57/EC, 2009/48/EC, 2009/105/EC, 2009/142/EC, 2011/65/EU, Regulation (EU) No 305/2011, Regulation (EC) No 764/2008 and Regulation (EC) No 765/2008 of the European Parliament and of the Council

[8] Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, page 10.

[9] See, for example, Article 23 of Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, page 10.