Using an authorised representative in the EU – duties and liabilities

Mathias Klümper and *Pascal Hofer* demystify the rules on authorised representatives.

EU legislation governing a manufacturer's use of an authorised representative and the obligations and liabilities of each party appears to be very misunderstood.

The Medical Devices Directive (93/42/EC), as amended by Directive 2007/47/EC, requires that non-EU manufacturers designate an authorised representative in the EU to represent them there. Competent authorities, however, vary in how they interpret the MDD rules on the matter. In addition, there is confusion regarding the responsibilities and accountabilities of both manufacturer and authorised representative.

This article clarifies the EU requirements and provides manufacturers with practical advice on how best to draft a contract with an authorised representative.

Different interpretations

The definition of authorised representative is contained in Article 1(2)(j) of the MDD:

> *Any natural or legal person established in the Community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the Community instead of the manufacturer with regard to the latter's obligations under this Directive.*

Article 14 of the MDD deals with the registration of persons responsible for placing devices on the market and it is important to note that Directive 2007/47/EC, which came into force in March 2010, amended this provision with regard to the number of authorised representatives a manufacturer can have. Prior to the amendment, Article 14 said that manufacturers placing devices on the market who did not have a registered place of business in a member state had to "designate the person(s) responsible for marketing them who is (are) established in the Community".

The amended Article 14, on the other hand, requires a manufacturer to designate a single authorised representative:

> *Where a manufacturer who places a device on the market under his own name does not have a registered place of business in a Member State, he shall designate a single authorised representative in the European Union. For devices referred to in the first subparagraph of paragraph 1, the authorised representative shall inform the competent authority of the Member State in which he has his registered place of business of the details referred to in paragraph 1.*

The pre-amended wording of the MDD made it possible for a medical device manufacturer to designate one or more representatives, whereas the amended wording should lead to the interpretation that a manufacturer may designate only one representative.

From a German legal perspective, it is also our understanding that the amended version of the MDD requires the designation of only a single representative, although to date, Germany's Federal Institute for Drugs and Medical Devices (BfArM) has not published a statement on the topic.

However, competent authorities from other member states have made statements that confirm they take a different view on the matter. The UK Medicines and Healthcare products Regulatory Agency, for example, has clarified that its understanding of a "single" authorised representative means one representative per family of products rather than one representative for all products a company markets in the EU. We understand that the Dutch regulatory authority also shares this view.

The authorised representative replaces the manufacturer that does not have a place of business in the EU and fulfils the manufacturer's duties and tasks under the MDD. The amendment of Article 14 and the (literal) requirement for a single representative make it easier for competent authorities in member states – and users of medical devices – to identify their contact person. The concept of a single authorised representative has also been adopted in Directive 90/385/EEC on active implantable medical devices in order to provide for a consistent concept for medical devices.

Duties and responsibilities

The responsibilities of an authorised representative are mainly the same as that which the medical device manufacturer would have had if its place of business had been within the EU. This results from the "agent concept", on which the concept of authorised representative is based. Authorised representative responsibilities under the MDD can be summarised as follows:

- collection and assessment of incidents reported after placing a device on the market (Article 10(2) and (3));
- conducting conformity assessment procedures according to Annexes III, IV, VII and VIII of the MDD as well as participation of a notified body (Article 11(8) and (9);
- conducting clinical trials (Article 15(1)and (7));
- taking action in case of unjustified CE-marking (Article 18(a));
- possibility of commenting on measures according to the MDD (Article19(2));
- stating its name and address on the labelling (Annex I, 13.3 (a)); and
- comprehensive retention obligations relating to certain conformity assessment procedures.

The above summary shows that the duties and tasks of the authorised representative have grown compared to those of the "responsible person" under the pre-amended MDD. It also highlights how the authorised representative now has mainly the same obligations as that of the manufacturer.

Manufacturer's notification obligation

According to Article 14(2) of the MDD, a medical device manufacturer that does not have a place of business in the EU must give notification of the authorised representative. Unfortunately, the MDD does not mention those authorities and other bodies that need to be notified. No direct reference can be made to Article 14(1) since the medical device manufacturer does not have its place of business in the EU.

Under Article 14(1), the manufacturer must provide the competent authority in the member state where it has its place of business with certain information. However, this provision may apply *mutatis mutandis*, meaning that the notification has to be made vis-à-vis the competent authorities where the authorised representative has its place of business. All competent authorities in the other member states will have access to this information via the European medical device database (Eudamed) according to Article 14a of the MDD. Under Article 14a(1)(a) of the directive, Eudamed also provides information on the authorised representative.

Manufacturers must provide the following information in relation to the notification of their authorised representative:

- name and address of the representative; and
- description of the relevant medical devices.

Further information can be required in relation to Class IIa, IIb and III medical devices if it is needed to identify a product, its labelling and instructions for use. Such additional information on devices in these risk classes must be provided by the authorised

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representative and not directly by the manufacturer (Article 14(2) of the MDD).

Liabilities

Authorised representatives are subject to liability under the Product Liability Directive (85/374/EEC); European medical device law does not provide its own liability provisions. However, the authorised representative is not automatically responsible for product defects.

According to Article 1 of the PLD, the manufacturer is liable for product defects. "Manufacturer" is defined as the person who presents himself as the producer of the product (Article 3(1) of the PLD). Where a manufacturer is based outside the EU, Article 3(2) and Article 3(3) are of great importance. A manufacturer that does not have a place of business in the EU is not affected by the provisions of the PLD. Consequently, a responsible person has to be found for damages caused by products that are manufactured by a non-EU manufacturer. Article 3(2) of the PLD reads as follows:

> *Without prejudice to the liability of the producer, any person who imports into the Community a product for sale, hire, leasing or any form of distribution in the course of his business shall be deemed to be a producer within the meaning of this Directive and shall be responsible as a producer.*

The PLD equates (for liability purposes) the person who is importing a product into the EU with its manufacturer. This raises a question of whether the authorised representative within the meaning of the MDD is automatically also responsible under product liability law.

A closer look at Article 14(2) of the MDD and Article 3(2) of the PLD shows that this is not necessarily the case. Under the MDD, it is only required to designate an authorised representative, whereas the PLD has further requirements. Only persons who handle the product and import it into the EU for certain purposes (sale, hire, leasing, etc) can be responsible under the PLD. Consequently, persons that do not technically have contact with the manufacturer can also be liable under the PLD in the event that they import products into the EU. By contrast, a certain level of "co-operation" between the non-EU manufacturer and the authorised representative is required for there to be regulatory responsibility under the MDD. However, it is not required that the authorised representative imports the products into the EU.

In practice, the person responsible under the MDD may diverge from the person having a product liability responsibility under the PLD.

Meeting the rules

In principle, there are two ways in which an international company can implement the requirements of the MDD on placing medical devices on the EU market.

On one hand, if a company has an affiliate located in the EU, that affiliate can undertake the tasks involved. On the other hand, it can appoint an external party (natural party or legal entity) to perform the role of the authorised representative. Appointing an external party is the only option available to manufacturers that do not have a base in the EU.

Whether an affiliate or an external party is used, both approaches require the creation of a contract that reflects a clear separation of duties. The appointee will, thereafter, act both on contractual grounds, according to the provisions of the agreed contract, and on public law grounds, according to the MDD. Considering that the MDD states only that the authorised representative has to be "explicitly designated" by the manufacturer, it would be sufficient to appoint the authorised representative orally. That said, it is advisable – particularly in view of the need for documentation vis-à-vis the competent authorities and for legal certainty reasons – to do so in writing and conclude a respective service contract.

Intragroup solution

If a manufacturer has an affiliate based in the EU, an intragroup solution can be a favourable option. The affiliate is likely to be more flexible concerning the routines and tasks of an authorised representative. Moreover, the affiliated group structure and the existing reporting lines can be used to ensure that contractual information duties are adhered to. Corporate or divisional quality guidelines ensure that all affiliates operate on equal or similar terms. Therefore, the contract must not provide explicitly for certain requirements. In fact, under the contract it is possible to refer to existing guidelines that cover, for example, complaint handling or vigilance.

External solution

Typically, the external party (or company) appointed as the authorised representative will be a legal entity. That said, Article 1(2)(j) of the MDD states that a natural person can also come into consideration. In addition, it is possible to be importer and distributor at the same time. In every case, it is of utmost importance that the authorised representative is literate across the products and respective regulatory requirements.

Contractual drafting

The service agreement should consist of the following standard provisions:

- preamble;
- parties' duties;
- remuneration;
- term and termination;
- confidentiality;
- liability;
- choice of law and venue; and, eventually
- the severability clause.

The following text covers only the specific characteristics.

The **preamble** gives the background to the agreement: "Manufacturer wishes to appoint Company as its authorised representative in accordance with the Medical Devices Directive for products that Manufacturer produces and which are sold in the European Union and Company wishes to accept such appointment on the terms and conditions of this agreement."

As **principle duty**, the assumption of the representation function should be named: "Manufacturer hereby appoints Company and Company hereby accepts appointment as Manufacturer's authorised representative for the products throughout the European Union."

The additional – non-exhaustive enumerated – contractual parties' duties are:

- allocation of necessary information: "Manufacturer shall provide Company with a list of products together with a copy of the Declaration of Conformity for all products or product families";
- assurance of compliance: "Manufacturer shall comply with the conformity assessment procedures";
- Labelling: "Manufacturer shall ensure that each product contains the name and address of Company including the label, the outer packaging or the instruction for use";
- authorities' contact person: "Company shall act on behalf of Manufacturer as necessary with competent authorities and notified bodies";
- company's obligation to provide manufacturer with information: "If Company receives correspondence from a competent authority or a notified body or is informed of serious incidents or potentially serious complaints which must be reported to a competent authority, Company shall immediately copy such correspondence and report such incident or complaint to Manufacturer so that Manufacturer may take appropriate action";
- documentation and record retention duties: "Manufacturer shall be responsible for maintaining the appropriate technical file and/or design dossier for each product and shall make each technical file and/or design dossier available on request to Company or to a competent authority"; and
- submissions to authorities: "Company shall submit the required notification to the competent authorities prior to the CE marked device going on sale in the European Union."

Within the affiliated group, it should be taken into consideration that the remuneration has to be adequate. Adhering to the arm's length principle[2], business relations among affiliated firms should be treated under the same usual market conditions. Particularly, usual market prices – which would have been negotiated with non-affiliated companies – should be agreed upon. Violations of this principle lead to a manipulated statement of profit and loss of the involved companies. Companies based in low-tax countries can tend to pay less to the affiliated company based in the high-tax country. The profit of the company in the high-tax country would be impaired. This results in the company paying fewer taxes.

Concerning external parties, monthly or yearly payments should be stipulated in order to remunerate the performance lump-sum.

Given the labelling requirements – the authorised representative is indicated on the outer package – long-**term** agreements are favourable in comparison to short-term agreements. Within the affiliated group, the agreement of an indefinite term with the possibility of termination by giving notice is advisable: "The Agreement shall come into effect with the signature of both parties and shall remain in full force and effect unless terminated by either party upon 30 days' prior written notice."

With external parties, a definite term – considering qualifying periods of one or two years – should be stipulated.

With regard to the question of **liability**, it should be assessed whether a limitation of liability or even an indemnity clause in favour of the authorised representative is requested.

Take-home message

The "take-home message" is that an authorised representative can be an EU-based affiliate of a medical device manufacturer or an external party. There are already a number of external service providers offering authorised representative services, in particular to smaller companies.

A written service agreement that governs the most important rights and duties should be concluded between the manufacturer and the authorised representative – be it an internal affiliate or an external service provider. Within the affiliated group, the remuneration must be effected according to the arm's length principle in order to avoid any tax issues.

The authorised representative is not automatically responsible for product defects. This is only the case if the authorised representative also imports the medical devices into the EU, as may be the case in an international company structure.

References

1. *Broad interpretation of "single" authorised representative requirement in EU confirmed, Regulatory Affairs Medtech, 24 April 2008 (from MHRA conference, Revision of the Medical Device Directives, London, 7 March 2008)*
2. *Cf Art 9 OECD Model Tax Convention*

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