Dear ECOO members,

Although the MDR came into force last year, the EU continues to work on guidance documents to facilitate the implementation of the requirements. ECOO continues to attend all MDCG meetings and provides input to consultations, wherever possible.

The European Commission has now published a **Q&A document on Articles 13 & 14 of the MDR**. This covers questions around the **role of distributors.**

As you may recall, we already included a section on the obligations of distributors in our **MDR Guidance Document for ECOO members** (page 6) – available in the Members Dropbox (MDR sub-folder). We added this Q&A document to the same folder.

Please **note** that the term "distributor" is MDR terminology to define responsibilities in the scope of the MDR. It does not mean that the professions of opticians and optometrists are reduced in their scope of practice. **Only national law can define the scope of practice, the MDR is a product legislation.**

According to the MDR (Article 2 (34)) '***distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service*.**

The Q&A on adaptable medical devices also stated that the person who adapts, adjusts, assembles or shapes an adaptable medical device for a particular patient is not regarded as a manufacturer but as a distributor.

The requirements of a distributor thus apply to opticians and optometrists but this definition is of course **only valid as long as the adaptation, adjustment, assembly and shaping does not modify the intended purpose of the device,** in which case the manufacturers obligations would come into effect.

The Q&A validates the information we already included in our guidance document. We recommend that you read the document but have summarised the **key points** for you here below:

- Individual shops, pharmacies or retailers are considered distributors under the MDR. They become an importer if they obtain the device directly from a non-EU based manufacturer or distributor and are then expected to comply with Article 13 of the Regulations.
- Distributors are not in charge of including information on the device, its packaging or in accompanying documentation but need to verify that it has been done by the manufacturer or importer. 'Accompanying documentation' has to reach the end user. This means that the distributor may not sell products where documentation or the importer's information is missing.
- On non-compliance matters, the distributors have the obligation to verify whether the requirements (Article 14(2)) are met before making the device available on the market.
- In case of non-conformity, distributors have the obligation to inform relevant parties (manufacturers and where applicable authorised representatives or importers) and to not make these devices available. The distributor is required to inform the competent authority (of the Member State in which it is established) if they believe the device presents a serious risk or is falsified.
- Distributors that have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall

immediately forward this information to the manufacturer. Distributors should keep a register of complaints of non-conforming devices, recalls and withdrawals and keep the manufacturer informed of such monitoring.

- Distributors are responsible for making sure that the devices they make available on the market, bear the CE marking, are accompanied by the required information and labelled in accordance with the Regulations, and have been assigned a UDI where applicable.

Should you have any questions on the Q&A, then please don't hesitate to let us know. We will then provide further information or if needed request it from the European Commission.

Best wishes,
Fabienne

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