GROUPE
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Practical information

Distributors of medical devices

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Context

Since the regulations came into force, distributors, who were previously are given a large number of new obligations.

Regulations (EU) 2017/745 and (EU) 2017/746, applicable from 26 May 2021 and 26 May 2022 respectively, clarify the obligations of the various players in the lifecycle of a Medical Device (MD) or an *In Vitro* Diagnostic Medical Device (IVDMD).

Among the economic operators heavily impacted, we find the notion of distributor.

Article 2 defines a distributor as "any natural or legal person in the supply chain, other than the manufacturer or importer, who makes a device available on the market, up to the point where it is put into service".
By specifying that the distributor's activity stops at the stage of putting the devices into service, **the regulations cover** a **very wide** range of **operators**, including companies which sell devices at retail (pharmacies, supermarkets, online sales sites, medical equipment retailers, etc.) putting the devices into service, the regulations cover a very wide range of operators, including companies which sell devices at retail (pharmacies, supermarkets, online sales sites, medical equipment retailers, etc.).

The aim of this practical information sheet is to provide an overview of the **main obligations** incumbent on distributors before, during and **after devices are made available on the EU market.** It also outlines the prohibited and authorised activities for distributors. Finally, this practical sheet gives some recommendations on the quality management system to be put in place to meet regulatory requirements.

Key definitions

DISTRIBUTOR

Company established in the EU, forming part of the supply chain, other than the manufacturer or importer, who makes a device available on the EU market, up to the point where it is put into service.

MAKE IT AVAILABLE ON THE MARKET

To make available to the end user a device ready to be used for the first time on the EU market in accordance with its intended purpose.

SET IN SERVICE

To supply a device intended for distribution, consumption or use on the EU market in the course of a commercial activity, whether in return for payment or free of charge.

Distributor's obligations

Before making the DM/DMDIV available

DECLARE YOUR ACTIVITY

The company must register as a distributor with the national authority (in France, the ANSM) and keep the information relating to its activity up to date if necessary.

- It must identify the specific requirements of the Member States in which the products are distributed as regards the registration of operators.

CHECK COMPLIANCE OF THE SYSTEM

The distributor must check that :

- The device bears the CE mark *.
- The EU Declaration of Conformity is drawn up and translated *.
- The information (leaflets, labelling, etc.) provided by the
- manufacturer are present and compliant *
- The importer is identified (if applicable)
- The IUD has been assigned *

* The distributor has the option of carrying out sample checks.

DECLARE AND QUARANTINE NON-COMPLIANT DEVICES

- If the distributor detects/suspects a non-compliant device before making it available on the market, it must :
- Quarantine the product until it has been brought into compliance.
- Informs the manufacturer, the authorised representative and the importer. If the device presents a serious risk or is falsified, it also informs the competent authority in which the distributor is established.
- Keeps an up-to-date register of non-compliant devices.

Continuous

ENSURE TRACEABILITY

- Identify, trace and register DM/DMDIV suppliers, service providers and customers (upstream supply chain and downstream distribution chain).
- Record data enabling products to be identified unambiguously (including the IUD for class III implantable medical devices).
- Retain traceability data for the full regulatory period: 10 years for non-implantable medical devices and IVDDs, 15 years for implantable medical devices, from the time the last device concerned is made available.

CONTROL STORAGE AND TRANSPORTF

- The distributor ensures that storage and transport conditions comply with the conditions laid down by the manufacturer.

RESPOND TO REQUESTS FROM THE AUTHORITIES

- Responding to requests for information from the competent authorities on the compliance of medical devices/devices for human use.
- Cooperate in implementing corrective actions decided by a competent authority to eliminate a public health risk (recalls, withdrawals, etc.).
- Provide free samples or access to devices.
- Keep the registers required by the regulations available.
- To welcome and cooperate with the competent authorities during inspections, announced or unannounced, on its premises (including the premises of storage subcontractors).

COMPLY WITH REGULATIONS GOVERNING THE ADVERTISING OF DM/DMDIV

- Identify claims supported by CE marking by collaboration with the manufacturer
- Contribute to the promotion of products in compliance with European and national provisions in force.

RESPECT CONFIDENTIALITY

The distributor is bound by an obligation of confidentiality concerning :

- Personal data
- Confidential information of a commercial nature and business secrets, including intellectual property rights, unless disclosure is justified by the public interest.
- Application of the regulation, particularly with regard to inspections, investigations or audits.

After availability of the Dm/Dmiv

REPORT AND COOPERATE IN THE EVENT OF NON-COMPLIANT DEVICES BEING DISTRIBUTED ON THE MARKET

If the distributor detects/suspects a non-compliant device after it has been made available on the market, it must :

- Immediately informs the manufacturer, the authorised representative or the importer. If the device presents a serious risk, it shall also immediately inform the competent authorities of the Member States in which the product has been made available.
- Cooperates with the manufacturer, the authorised representative, the importer and the competent authorities.
- Implements the corrective measures required by the manufacturer or decided by the competent authorities.
- Keeps up to date registers of complaints, non
  recalls and withdrawals of products from the market

Prohibitions and authorised modifications

POINT OF ATTENTION

The distributor's activities present limits that must not be crossed and beyond which the distributor will have to fulfil the manufacturer's obligations (article 16).

- The manufacturer must be clearly indicated on the device made available on the market. If the distributor wishes to place a DM/DMDIV on the market in its own name, it is necessary to conclude an agreement with the manufacturer and to keep the name and role of the manufacturer clearly legible on the labelling.
- It is forbidden to change the purpose of a medical device already on the market.
- It is forbidden to make any modifications to a medical device which may affect compliance with the applicable requirements.
- Under certain conditions and to meet the needs of the market (specific local requirements for example), it is possible to carry out relabelling, introduce a leaflet (including translation), repackage or make changes to the outer packaging. To carry out any of these actions, the distributor must inform the manufacturer and the competent authority, and specify its name on the device,
  contact details and activities carried out.

The quality management system

SETTING UP A SMQ

The implementation of a quality management system (SMQ) is strongly recommended:

- The distributor must organise itself to meet regulatory requirements.
- It must be able to prove that its activities preserve the conformity of the DM/DMDIV and that it complies with its obligations.
- The distributor's activities are organised and framed by the implementation of a quality management system in accordance with the EN ISO 13485:2016 standard.

SMQ DOCUMENTS TO BE DRAWN UP AS A MINIMUM

Procedures :

- Checking devices before they are made available
- Sampling
- Controlling storage and transport conditions
- Traceability
- Treatment of non-compliant products
- Corrective action management
- Quarantining, making available and commissioning products
- Management of complaints, reports and vigilance
- Product withdrawals/recalls
- Communication with stakeholders (manufacturers, agents, etc.), importer, competent authorities)
- Sample management
- Management of inspections/visits by the competent authorities
- Control of service providers in the distribution chain
- Advertising control
- Data protection procedure (RGPD)

Records (documented evidence) :

- Claims registers
- Register of non-compliant devices
- Recall register
- Withdrawal register
- Declaration o f activity
- Database of products and players in the distribution chain
- Records of checks carried out before products are made available, together with proof of conformity: EU certificate, EU declaration of conformity, importer identification, instructions, labelling, IUD, etc.
- Product traceability system

Contracts, agreements and quality specifications:

- Confidentiality agreements
- Specifications between the manufacturer, agent, importer and distributor
- Specifications with critical service providers (examples): transport, storage, logistics, installation, maintenance, DM/ repair providers. DMDIV...)

To find out more...

Quglqugs ligns uťilgs :

Regulation (EU) 2017/745 on medical devices Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Blue Guide to the implementation of EU product regulation (2022) FAQ DM regulation - Obligations of economic operators - ANSM (sante.fr)

MDCG 2021-23

MDCG 2021-26

MDCG 2021-27

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