Guidance for distributors of medical devices

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FIELD OF APPLICATION

This document is intended to provide guidelines for the distribution of medical devices.

The aim is to maintain a high level of quality throughout the medical device supply chain and to harmonize the procedures of distributors who distribute or supply medical devices. The set of measures taken by operators by applying the guidelines contained in this guidance is aimed at avoiding the presence of non-compliant and falsified medical devices in the distribution chain.

This guidance applies to all distributors of medical devices. The term medical devices as used in this guidance covers all medical devices including active implantable medical devices and in vitro diagnostic medical devices.

This guidance does not apply to medical devices that are further made available on the market after they have already been put into service, such as in the context of second-hand sale.

This guidance does not apply to clinical investigations.

As this guidance is supplementary to national and European obligations, adherence to it is not mandatory. However, following this guidance is a means of complying with legal obligations and is therefore strongly recommended.

CHAPTER 1 - QUALITY MANAGEMENT SYSTEM

1.1 Distributors of medical devices shall establish and maintain a quality management system that covers distribution activities with the aim of maintaining a high level of quality across the entire medical device distribution network.

1.2 The quality system implies the availability of sufficient and qualified staff to carry out the distributor's continuous activities as well as adequate and sufficient storage space, equipment and infrastructure to ensure that the delivered product maintains its quality and integrity.
The quality system should ensure that:

- only medical devices that comply with European regulations are distributed;
- the responsibilities for materiovigilance and the quality manager are clearly defined;
- adequate procedures are written and appropriate documentation is kept;
- Corrective and preventive actions (or CAPA) are taken to correct and avoid non-conformities.

1.3 The size, structure and complexity of the distributor's activities must be taken into account in the development or modification of the quality management system.

1.4 Where the distributor is a subsidiary of the manufacturer or supplier, roles and responsibilities may be defined in procedures established in a common quality system.

CHAPTER 2 - PERSONNEL

2.1 Wherever distribution activities take place, a person responsible for quality and a contact point for materiovigilance should be designated. Both responsibilities may be assigned to the same person. The management also foresees a backup if more than one person works in the company.

2.2 The Quality Manager is responsible for at least the following tasks:

- Ensure that the quality management system is implemented and maintained.
- Focus on the management of activities for which a registration has been made at the FAMHP and the accuracy and quality of the documentation.
- Ensure that initial and ongoing training programs are implemented and maintained.
- Coordinate and initiate immediate action in case of medical device recalls.
- Ensure that customer complaints related to the quality of medical devices are effectively treated.
- Select and purchase only from a legal manufacturer or importer or a distributor registered with the FAMHP.
- Approve any outsourced activities that may have an impact on the quality of medical devices.
- Ensure that internal audits/self-assessments are carried out with adequate and regular frequency, according to a pre-determined pattern, and that appropriate corrective actions are taken.
- Keep a careful record of delegated tasks.
- Decide on the final disposition of returned, rejected, recalled or falsified medical devices.
- Approve the return of saleable medical devices to stock.
- Ensure that any supplements to European and national legislation, applicable to certain products, are fulfilled.

2.3 The responsibilities of all employees involved in the distribution of medical devices must be documented.

2.4 The training and skills required to perform the various tasks related to the distribution activities of medical devices should be clearly defined within the company.

2.5 A training plan (initial training, task-specific training, follow-up training) relevant to the proper accomplishment of the assigned tasks should be established for each staff member involved in the medical device distribution activities.

2.6 All training activities must be recorded in detail, including: a description of the training, the duration and location of the training, the trainer, the persons trained, and whether the trainee has achieved the required level of competence in relation to the training objective.

CHAPTER 3 - DOCUMENTATION

3.1 Documentation includes all written procedures, instructions, agreements, data and records, whether in paper or electronic form. The documentation must be immediately available or searchable by the competent authorities.

3.2 It shall be sufficiently complete with regard to the distributor's field of activity and be written in a language that the staff can understand. The documentation must also be free of errors and written in clear and unambiguous language.

3.3 Any changes to the documentation must be signed and dated; the change must have been made in such a way that the original information remains legible. Where appropriate, the reason for the change should be stated.

3.4 Every employee shall have direct access to all necessary documentation relating to the tasks performed which fall within his or her competence.

Documents must be adjusted as they evolve. The documents must be archived for at least five years and be immediately available to the competent authorities.

Procedures

3.5 The distributor of medical devices shall have procedures and work instructions that include a detailed description of the distribution activities that have a direct or indirect impact on the quality of medical devices.

3.6 The procedures may be described in one single procedure (e.g. temperature control, cleaning and pest control in one procedure) or may be transversal (e.g. not having a specific procedure for traceability, which may be addressed in several procedures)

3.7 Procedures must be approved, signed and dated by the Quality Manager and may not be changed without the Quality Manager's permission.

3.8 A procedure is needed to avoid uncontrolled copying.

3.9 It is important to ensure that valid and approved procedures are followed. Procedures should be regularly reviewed and updated. Procedures should be subject to a version control system. After a procedure has been revised, a system to prevent the accidental use of an obsolete version should be available. Obsolete procedures should be removed from workstations and archived.

Records and registers

3.10 Each time an activity (buying and selling, maintenance and control of storage facilities, complaints, returns and recalls) is carried out, clearly annotated records must be maintained so that all notable activities or incidents can be traced.

CHAPTER 4 - SUITABLE FACILITIES

4.1 Medical devices must be stored under the conditions prescribed by the manufacturer, if necessary, in an environment where humidity and temperature can be regulated. Where there are no specified storage conditions, there are no restrictions on the temperatures at which medical devices may be stored.

4.2 If specific storage conditions are required, continuous temperature monitoring should be performed and documented to ensure that appropriate storage conditions are maintained. This applies to all areas where medical devices are stored (e.g. bulk storage, quarantine, return areas, etc.).

Examples of symbols on the packaging relating to storage conditions:

-  temperature threshold
-  air humidity threshold
-  keep out of direct sunlight
-  keep dry

4.3 At least one calibrated thermometer should be used. Thermometers should be carefully positioned considering temperature variations in the storage area and the influence of external factors such as weather conditions. Maximum and minimum temperatures should be recorded daily, and the thermometer should be reset after the readings. The data should be evaluated regularly by the quality manager.

4.4 Facilities should be suitable for the appropriate storage and distribution of medical devices. Storage facilities should be clean and free of rubbish and dust. The storage facilities must be sufficiently lighted to allow safe working conditions. No unsuitable objects that could adversely affect the quality of medical devices may be present in the storage facilities. The goods must be stored in such a way (not in direct contact with the floor or wall) that moisture cannot penetrate, and also so that the facilities can be properly maintained. The facilities must be cleaned properly. It must also be ensured that medical devices are not influenced by direct sunlight or in the direct environment of a heating or cooling device.

4.5 Measures will be foreseen in case of deviations in storage conditions.

4.6 A preventive pest control system must be in place for both crawling and flying insects and rodents. A map must show the location of all pest control points and must be approved by the Quality Manager. All recommendations made by any external pest control service should be recorded. If recommendations are not followed, an explanation must be provided. All observations must be recorded.

4.7 A system should be in place to organize the turnover of stocks, whereby products that expire first are removed from stock first. The proper functioning of this system should be monitored at appropriate and regular intervals.

4.8 Expiry dates are checked regularly. Medical devices that have passed their expiry date must be separated from the saleable stock and may not be distributed.

4.9 Medical devices intended for purposes other than sale (quarantine, returns, recalls, for destruction, products awaiting VAT inspection, demonstration material, samples, rental, calibration of equipment, ...) must be separated from saleable stock and must be properly marked to avoid any transfer into the saleable stock. The distributor shall ensure that, where separation is done only by means of a computerized system, this system is at least as effective as if the products had been physically separated. These areas can be flexible in the sense that the size can vary.

CHAPTER 5 - ACTIVITIÉS

Introduction of a new medical device

5.1 Distributors should have a procedure for introducing new medical devices into their stock.

5.2 The approval of new suppliers of medical devices prevents falsified medical devices from entering the distribution chain. The distributor only buys from legal manufacturers and importers or from a distributor registered with the FAMHP. New suppliers should always be checked before any medical devices are purchased.

5.3 The specific documentation required to make a medical device available on the market must be requested and reviewed before placing the medical device in the commercial inventory.

Reception

5.4 Unloading areas for medical devices must protect the deliveries from bad weather during unloading.

5.5 The reception area should be separate from the storage area, in order to visually distinguish between, on the one hand, products that have just been delivered and still need to be checked and, on the other hand, products already approved and in stock.

5.6 A written procedure should be in place to identify and quarantine non-compliant or damaged products. Data on further actions should be documented on a case by case basis and be directly accessible for the FAMHP.

5.7 The distributor shall verify that all mandatory legal information is present on the packaging (outer and/or inner packaging). In order to comply with this requirement, a sampling method may be applied that is representative for the purchased products. Any sampling method applied must be justified on the basis of a risk analysis.

5.8 The distributor shall check that the information and indications provided by the manufacturer comply with the language requirements of the country of destination and the customer.

5.9 The distributor shall keep a copy (digital or physical) of all declarations of conformity and, where applicable, CE certificates of the medical devices he distributes/sells. He must also keep them available for his customers.

5.10 Medical devices requiring special storage measures, e.g. temperature and humidity conditions, must be immediately identified on receipt and stored in accordance with these requirements.

5.11 Falsified medical devices may never be returned to the supplier without the knowledge of the FAMHP.

Delivery

5.12 Medical devices must be transported under the conditions prescribed by the manufacturer. The type of transportation should not affect the quality of the medical devices.

5.13 Each delivery (except for direct sales to private individuals) must be accompanied by a dated delivery note or invoice, the name of the medical device, if applicable the batch number/serial number/UDI, the quantity delivered, the name and address of the distributor and customer.

Traceability

5.14 A traceability system should enable the company to identify and contact all customers (except private individuals) immediately, for example in the event of a recall. A serial or batch number tracking system is the most effective, but other systems can also be applied when products do not have a specific batch number.

5.15 Distributors shall be able to identify, throughout the retention period, the following data for each activity related to each medical device: the date of the action, the name of the medical device, the name and address of the supplier, the name and address of the customer (except for direct sales to private individuals), the serial or batch number and the expiry date.

5.16 A traceability system must also be provided for display material, rental equipment, consignment and samples.

5.17 The same system must be available for deliveries abroad (outside Belgium).

5.18 The traceability system must be tested annually by means of a simulation.

CHAPTER 6 - RETURNS, COMPLAINTS AND RECALLS

Returns

6.1 Medical devices returned by customers should be marked as such and placed in quarantine pending further examination or sampling by the distributor/manufacturer.

6.2 Medical devices that have left the distributor's facilities or are removed from saleable stock can only be returned to the approved stock for supply if the following elements are confirmed:

- the safety and performance of the medical device have not been affected in any way;
- the medical device is in its original unopened, unused packaging and in good condition;
- the user can demonstrate that the medical device has been stored and handled continuously under the intended conditions;
- the medical device has an acceptable remaining expiry date;
- the returned medical device was originally sold, by checking the batch number/serial number/UDI and the expiry date.

6.3 Medical devices that do not meet the above conditions must be separated and identified as faulty.

6.4 Return to saleable stock can only take place under the responsibility of the Quality Manager. Medical devices must be returned to saleable stock in such a way as to maintain an efficient stock rotation system.

6.5 Records of returned medical devices must be documented. For each return, the documentation must contain the following information:

- Name and address of the customer returning the medical device;
- name or description of the medical device, batch number/serial number/UDI and quantity returned;
- reason for the return;
- use or disposal/destruction of the returned medical device and details of the assessment made.

Complaints

6.6 All oral or written complaints submitted should be recorded in order to assess complaint trends, the regularity of complaints related to product quality and the seriousness of complaints, with a view to taking further action and, if necessary, immediate corrective actions. These records should be available for inspection by the competent authorities.

6.7 Complaint registers should include at least the following information:

- nature of the complaint, including the name of the medical device with batch number/serial number/UDI (if applicable);
- date of receipt of the complaint;
- measures taken;
- the reply provided to the complainant, including the date the reply was sent;
- final decision taken for the medical device.

Recalls

6.8 The distributor should have a written procedure in place for recalls. This should allow for a rapid and efficient recall of defective and/or potentially dangerous medical devices from the market.

6.9 The recall procedure should indicate how a recall process is initiated, who should be informed and how the recalled products should be handled afterwards. A specified person (usually the Quality Manager) should be designated to implement and coordinate the recall action.

6.10 There shall be an effective and efficient method of identifying customers who have been supplied with a recalled medical device. The recall procedure should be regularly reviewed to ensure that the procedure is effective and capable of tracking all customers and medical devices in a timely manner.

6.11 In parallel, the procedure should also enable the company to draw up a product balance sheet ("reconciliation") quickly and accurately:

- number of products purchased and name of the supplier
- number of products in stock and location in the stock;
- number of products delivered;
- number of products recovered from customers after recall

to obtain a true and detailed picture of the location of each product.

6.12 A standard letter should be prepared for recalls and, if necessary, supplemented with the relevant information (product, manufacturer, batch number/serial number concerned, etc.). This document will immediately notify all customers (except private individuals) who are likely to have purchased the medical device. This document also communicates the instructions that the customer must follow.

6.13 Each recall must be recorded internally from the moment it takes place. This record must be made available to the FAMHP.

CHAPTER 7 - MATÉRIOVIGILANCE

7.1 The contact point for materiovigilance is responsible for ensuring that the manufacturer and, where appropriate, the authorized representative and importer are directly informed of complaints or reports from healthcare professionals, patients or users relating to suspected incidents involving a device which it has made available

7.2 The distributor should put in place a written procedure for materiovigilance. This should allow incidents to be reported quickly and effectively to the FAMHP.

7.3 The contact point for materiovigilance is obliged to ensure that the FAMHP is directly informed when it considers or has reason to believe that a device that was made available on the market presents a serious risk.

7.4 The decision tree on the FAMHP website is used to determine whether an incident should be notified to the FAMHP.

7.5 Any communication regarding incidents should be made to the FAMHP via the following address vigilance.meddev@fagg-afmps.be.

CHAPTER 8 - DELEGATED ACTIVITIES

8.1 If a specific activity related to the distribution of medical devices (reception, storage, transport, returns, recalls, complaints, materiovigilance, etc.) is outsourced, the distributor must ensure that the contractor is aware of and complies with the procedures applicable to this activity.

8.2 The client and the contractor shall establish a written quality agreement clearly setting out the tasks of each party with regard to the delegated activity. However, it is important to remember that the distributor retains the final responsibility for ensuring that the delegated activity meets the legal requirements.

8.3 The quality agreement, as well as the procedures for outsourced activities, must be made available during an inspection by the FAMHP.

CHAPTER 9 - INTERNAL AUDITS

9.1 In order to verify the efficacy of the company and its compliance with the quality system and legislation, an internal audit plan must be established. This plan should be based on a risk analysis of all medical device activities within the company. Internal audits may cover one or more activities simultaneously.

9.2 After an internal audit, a report must be prepared containing the results of the audit. Corrective and preventive actions arising from the internal audit should also be recorded in this report.

9.3 All identified non-conformities must be closed in a timely manner.

APPENDIX – DEFINITIONS

Active implantable medical device: any active medical device that is designed to be partially or wholly introduced into the human body or into a natural orifice by means of surgery or clinical intervention and which is intended to remain in place for at least 30 days after the procedure.

Authorized representative: any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation.

Batch: a defined quantity of medical products processed in a single process or a series of processes, such that it is expected to be homogeneous.

CAPA: corrective and preventive actions

CE marking of conformity or CE marking: a marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in the Regulation and other applicable Union harmonization legislation providing for its affixing.

Corrective action: an action taken to remove the cause of a potential or existing non-conformity or other undesirable situation.

Customer: any individual, end user and distributor to whom medical devices are sold or supplied.

Distribution (= making available on the market): any supply of a device, other than an investigational device, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge.

Distributor: 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.

Falsified device: any device with a false presentation of its identity and/or of its source and/or its CE marking certificates or documents relating to CE marking procedures. This definition does not include unintentional non-compliance and is without prejudice to infringements of intellectual property rights.

Good Distribution Practice (GDP): a quality management system that ensures that the quality of medical devices is maintained through all stages of the distribution chain, from manufacturing to delivery.

Importer: any natural or legal person established within the Union that places a device from a third country on the Union market.

Incident: any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect.

In vitro diagnostic medical device: any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:

- concerning a physiological or pathological process or state;

- concerning the predisposition to a medical condition or a disease;
- concerning the predisposition to a medical condition or a disease;
- to predict treatment response or reactions;
- to predict treatment response or reactions;
- to define or monitoring therapeutic measures.

Specimen receptacles shall also be deemed to be *in vitro* diagnostic medical devices.

Manufacturer: a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.

Materiovigilance: the study and follow-up of incidents that may result from the use of medical devices. This will allow dangerous devices to be taken off the market and defects in medical devices to be identified and resolved, in order to improve the level of quality of the devices and the safety of patients and users.

Medical device: any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations.

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilization of devices.

Non-compliant: A non-compliant medical device is a medical device that does not meet the legal requirements for medical devices as set out in European and national legislation.

Preventive measure: a measure taken to eliminate the causes of a deviation or other undesirable situation and to prevent its occurrence.

Private individual: any natural person who acquires or uses medical devices solely for non-professional purposes.

Procedure: description, according to a logical, coherent and detailed plan, of the actions to be taken, the measures to be taken, the technical means and the documentation to be used in order to carry out, in a reproducible manner, an action or series of actions. These procedures shall be documented as far as possible.

Quality: the degree to which a set of properties and characteristics meets the relevant requirements (standards).

Quality management: the set of measures that should ensure the preservation of the quality of the medical devices during storage and distribution. Quality management includes good distribution practices.

Quarantine: the status of medical devices physically or by other effective means isolated, while awaiting a decision on their release, rejection or re-commissioning (reprocessing).

Recall: any measure aimed at achieving the return of a device that has already been made available to the end user.

Serious incident: any incident that directly or indirectly led, might have led or might lead to any of the following: a) the death of a patient, user or other person, b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, c) a serious public health threat.

Traceability: process of collecting and recording data that allows for quick identification of the history, the application or location of what is sought.

"Unique Device Identifier" — „UDI": a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market.

Work instruction: document describing the way in which an action is to be performed and the resources to be used. Instructions are distinguished from procedures by the fact that they generally relate only to a specific action, service, machine or person.

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