

Guide for **Distributors of Medical Devices**



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1 SCOPE

The purpose of this document is to provide guidance to industry on distribution of medical devices, *in vitro* diagnostic medical devices, and their accessories for human use in Ireland. For the purpose of this document, all such medical devices are referred to collectively as 'medical devices' unless otherwise specified. This document does not apply to clinical investigations. Additional obligations apply to distributors who also function as importers into the European Union. Further information regarding the obligations of importers of medical devices can be found on the Health Products Regulatory Authority (HPRA) website www.hpra.ie.

2 INTRODUCTION

The safety and performance of medical devices directly affects patient safety and health. The range of medical devices available is vast and they are used by a broad variety of users from the general public in their homes to the most critically ill patients in specialist clinical settings. Patients using devices include extremely vulnerable groups such as neonates and infants, the elderly, disabled and other patients who are particularly susceptible to diseases. Medical devices may also be used in high-risk surgical procedures and intensive care settings, where improper storage along the supply chain, amongst other aspects, may lead to undesirable, and in some cases extremely serious, consequences.

[Regulation 2017/745](#) on medical devices and [Regulation 2017/746](#) on *in vitro* diagnostic devices (together known as 'the Regulations') entered into force on 25 May 2017. The Regulations have a staggered transitional period. The obligations for distributors will apply with the full application of the Medical Device Regulation (MDR) after three years (May 2020) and full application of the Regulation on *in vitro* diagnostic medical devices (IVDR) after five years (May 2022).

These two Regulations replace the current European Directives for medical devices, including Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC. The requirements relating to distribution of devices are essentially the same in both Regulations.

This document aims to specify the obligations for distributors as outlined in the Regulations, along with supplementary guidance and frameworks that can be used by distributors to meet those obligations. In addition, it sets out the HPRA's recommendations for good distribution practices. **A distributor may have alternative methods for achieving compliance with the regulations and, if justified, these alternatives may be equally acceptable.**

3 LEGISLATIVE BASIS

At both national and European level, the legislative basis for distribution of medical devices will be based on the Regulations. The definitions relevant to medical device distributors are identified in table 1 below.

Table 1: Definitions as per the Regulations

| TERM | DEFINITION |
|--------------------------------|--|
| Distributor | any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the market up until the point of putting into service Note: Recitals 28 of the MDR and 26 of the IVDR also state that for the purpose of these Regulations, the activities of distributors should be deemed to include acquisition, holding and supplying of 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 |
| Importer | any natural or legal person established within the Union that places a device from a third country on the Union market |
| Authorised 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 |
| 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 |
| Placing on the market | the first making available of a device, other than an investigational device, on the Union market |
| Putting into service | the stage at which a device, other than an investigational device, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose |

Article 14 of the proposed Regulations describes the general obligations of medical device distributors. Article 25 of the MDR and Article 22 of the IVDR describes the obligations

relating to identification and traceability within the supply chain. The obligations relating to distributors are indicated in table 2 below.

Table 2: Distributors' obligations
(further details of the Articles referenced in this table can be found in Section 1 of Appendix 1)

| MDR AND IVDR ARTICLE 14 | OBLIGATION |
|----------------------------|---|
| Paragraph 1 | When making a device available on the market, distributors shall, in the context of their activities, act with due care in relation to the requirements applicable. |
| Paragraph 2 | <p>Before making a device available on the market, distributors shall verify that all of the following requirements are met:</p> <ul style="list-style-type: none"> a) the device has been CE marked and that the EU declaration of conformity of the device has been drawn up; b) the device is accompanied by the information to be supplied by the manufacturer in accordance with Article 10(11) [<i>Article 10(10) of the IVD Regulation</i>]; c) for imported devices, the importer has complied with the requirements set out in Article 13(3); d) that, where applicable, a UDI* has been assigned by the manufacturer. <p><i>*A UDI is a unique device identifier.</i></p> <p>In order to meet the requirements referred to in points (a), and (b) and (d) of the first subparagraph the distributor may apply a sampling method representative of devices supplied by that distributor.</p> <p>Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, it shall not make the device available on the market until it has been brought into conformity, and shall inform the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. Where the distributor considers or has reason to believe that the device presents a serious risk or is a falsified device, it shall also inform the competent authority of the Member State in which it is established.</p> |
| Paragraph 3 | Distributors shall ensure that, while the device is under their responsibility, storage or transport conditions comply with the conditions set by the manufacturer. |
| Paragraph 4 | Distributors that consider or have reason to believe that a device which they have made available on the market is not in conformity |

**MDR AND IVDR
ARTICLE 14**

OBLIGATION

with this Regulation shall immediately inform the manufacturer and, where applicable, the manufacturer's authorised representative and the importer. Distributors shall co-operate with the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer, and with competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or to recall it, as appropriate, is taken. Where the distributor considers or has reason to believe that the device presents a serious risk, it shall also immediately inform the competent authorities of the Member States in which it made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.

Paragraph 5 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 and, where applicable, the manufacturer's authorised representative, and the importer. They shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and keep the manufacturer and, where available, the authorised representative and the importer informed of such monitoring and provide them with any information upon their request.

Paragraph 6 Distributors shall, upon request by a competent authority, provide it with all the information and documentation that is at their disposal and is necessary to demonstrate the conformity of a device.

Distributors shall be considered to have fulfilled the obligation referred to in the first subparagraph when the manufacturer or, where applicable, the authorised representative for the device in question provides the required information. Distributors shall co-operate with competent authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market. Distributors, upon request by a competent authority, shall provide free samples of the device or, where that is impracticable, grant access to the device.

| MDR ARTICLE 25 AND IVDR ARTICLE 22 | OBLIGATION |
|--|---|
| Paragraph 1 | Distributors and importers shall co-operate with manufacturers or authorised representatives to achieve an appropriate level of traceability of devices. |
| Paragraph 2 | <p>Economic operators shall be able to identify the following to the competent authority, for the period referred to in Article 10(8) [<i>Article 10(7) of the IVD Regulation</i>]:</p> <ul style="list-style-type: none"> a) any economic operator to whom they have directly supplied a device; b) any economic operator who has directly supplied them with a device; c) any health institution or healthcare professional to which they have directly supplied a device. |

Article 16 of the Regulations details cases in which obligations of manufacturers apply to importers, distributors or other persons as outlined below.

Article 16 (1)

A distributor, importer or other natural or legal person shall assume the obligations incumbent on manufacturers if it does any of the following:

- a) makes available on the market a device under its name, registered trade name or registered trade mark, except in cases where a distributor or importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in this Regulation;
- b) changes the intended purpose of a device already placed on the market or put into service;
- c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.

Article 16 (2)

The following shall not be considered to be a modification of a device that could affect its compliance with the applicable requirements:

- a) provision, including translation, of the information supplied by the manufacturer relating to a device already placed on the market and of further information which is necessary in order to market the product in the relevant Member State;
- b) changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the product in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it. In the case of devices placed on the market in sterile condition, it shall be presumed that the original condition of the

device is adversely affected if the package that shall ensure the sterile condition is opened, damaged or otherwise negatively affected by the repackaging

Article 16 (3)

A distributor or importer who carries out any of the activities mentioned in points (a) and (b) shall indicate the activity carried out together with his name, registered trade name or registered trade mark and the address at which he can be contacted and his location can be established on the device or, where impracticable, on its packaging or in a document accompanying the device.

He shall ensure that he has in place a quality management system that includes procedures which ensure that the translation of information is accurate and up-to-date, and that the activities are performed by means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy. Part of the quality management system shall be procedures ensuring that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it in conformity with this Regulation.

Article 16 (4)

At least 28 calendar days prior to making the relabelled or repackaged device available, the distributor or importer referred to in paragraph 3 shall inform the manufacturer and the competent authority of the Member State where he plans to make the device available and, upon request, shall provide them with a sample of the relabelled or repackaged device, including any translated label and instructions for use. Within the same period of 28 calendar days, he shall submit to the competent authority a certificate, issued by a notified body referred to in Article 29, designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system complies with the requirements laid down in paragraph 3.

4 IMPLEMENTATION OF A QUALITY SYSTEM

In order to meet the legislative requirements and to ensure that only medical devices that comply with the legislation are made available for supply, it is recommended that distributors have a quality system in place. An effective quality system provides assurance that only medical devices which comply with legislative requirements are distributed, that non-compliant, defective or unsuitable medical devices can be detected, that traceability is maintained and that non-conformances and the introduction of changes are controlled. There are various established standards for quality systems, with ISO 13485 being the most commonly used quality framework in the medical device industry. While adherence to such a framework can be beneficial in providing structure to a quality system, it is not a requirement that a quality system is officially accredited to any specific standard.

The quality system is the responsibility of the organisation's management. It requires their leadership and active participation, and should be supported by staff commitment. A person should be appointed by the management who should have clearly specified authority and responsibility for ensuring that a quality system is implemented and maintained. A quality manual or equivalent should be established in which all distribution activities should be clearly defined and systematically reviewed.

Traceability of medical devices is fundamental to protecting public health in ensuring that full reconciliation is achievable in case of the need for prompt withdrawal of defective or unsuitable medical devices from stock that has been distributed or remains stored in the warehouse. The operation of an effective quality system for the distribution of medical devices can help maintain the integrity of the supply chain and ensure patient safety in the distribution of medical devices.

Some of the key components of a quality system are outlined below and further discussed throughout this document:

- Quality management
- Personnel and staff training
- Documentation and record keeping
- Medical device receipt, storage and supply
- Management of returned medical devices
- Falsified medical devices
- Medical device recalls
- Outsourced activities
- Transportation

Standard operating procedures (SOPs) should be established to clearly describe how key activities are carried out. In order to ensure that procedures are maintained and are reflective of current requirements, a periodic review should be performed. This review should be documented and any recommendations should be implemented.

Distribution of documents to staff should be controlled in a manner such that only up-to-date and approved documents are available in relevant areas and obsolete copies should not be accessible. This may be achieved by maintaining a distribution list with records of procedures issued and retrieved, including the dates on which these activities took place. Superseded master copies of procedures should be maintained for a period of at least six years.

It is particularly important that SOPs relating to activities in certain areas (e.g. receipt of material at the goods inwards area) are available to staff in the relevant area for reference as required.

SOPs should describe the different operations which may affect the performance of the medical devices. In addition, there should be procedures in place for:

- Training
- Documentation control
- Approval of suppliers and customers
- Order processing and deliveries
- Waste management
- Audits
- Change control
- Management review
- Quality risk management
- Management of Field Safety Corrective Actions/recalls
- Non-conformance management
- Corrective and preventive actions

A distributor should ensure that the quality system in place complies with the legislative parameters governing the distribution of medical devices. In such cases the distributor should perform a gap analysis of the specific requirements relating to the distribution of medical devices against its current operational standard. Differences in approach or gaps identified should be addressed through the introduction of additional procedures within the quality system as required.

4.1 The role of management

The role of management within the distribution operation should not be underestimated. The distribution of medical devices is the responsibility of the organisation's management and requires their leadership and active participation. It is imperative that management is involved, provides adequate resources and maintains oversight of compliance to the quality system. There should be a formal process for reviewing the quality system on a periodic basis. Senior management should be involved and the review should include a measurement of the achievement of the objectives of the quality system, and assessment of performance indicators that can be used to monitor the effectiveness of the quality system (e.g. complaints, non-conformances and corrective and preventative actions).

4.2 Change control

The purpose of a change control system is to enable distributors to identify, document and assess changes that they introduce and how this may affect compliance and performance of the device. Such changes may include, for example: a change in the settings of a heating system or the relocation of a medical device storage area within a warehouse. Such changes may have a significant impact and may have the potential to affect the performance of medical device distributed. Therefore it is vital that the change is conducted in a controlled manner.

A change control procedure and associated forms should be implemented and appropriately documented. The purpose of the procedure should be to ensure that all changes to the

operation are fully evaluated in terms of impact on the medical device's performance and traceability. The evaluation process should identify the areas impacted by the change, including processes, equipment, personnel, training, validation, quality system and regulatory implications. The required actions to give full effect to the change and ensure its implementation should be identified. In addition, changes should be formally approved prior to implementation. A system should be in place to ensure that all actions identified during the change control process have been completed within an appropriate timeline. The principles of quality risk management should be built into the change control process. Each change should be considered and a decision taken as to whether a risk assessment is required prior to approval of the change for implementation. The requirement for a risk assessment to be considered should be documented on the change control form.

4.3 Quality risk management

Quality risk management is a systematic process for the assessment, control, communication and review of risks to the safety and performance of the medical device. It is a valuable component of an effective quality system. Risk management may be used to assess the risk posed to the medical device as a result of a non-conformance from normal practices or to justify a proposed non-conformance from accepted practice. The use of risk management should be based on scientific knowledge, reason and practices. The level of detail contained within the risk management process should be reflective of the level of risk to the medical device. Implications for medical device safety and performance, security, traceability and follow up actions should be detailed. Risk assessments should be carried out by competent personnel and should be reviewed and approved by the relevant responsible personnel. It is recommended that companies have a procedure in place and that training is provided to staff. All documentation for risk assessments performed should be available to an inspector during the course of an inspection.

ISO14971 'Medical devices – application of risk management to medical devices' is the most frequently used risk management standard within the medical device industry. Whilst not all aspects will be relevant to distributors, there are concepts and methodologies that can be applied to medical device distributors. Other standards and risk management tools may be equally applicable.

4.4 Non-conformances, investigations and corrective and preventive actions (CAPA)

Non-conformances are deviations from the requirements of the Regulations and/or internal procedures. A procedure should be in place outlining the process for identifying, documenting, investigating and closing non-conformances that occur and the timelines involved. An assessment should be performed to determine medical device safety and performance implications and/or impact on the quality system.

It is important to note that distributors should commence the documentation of investigations immediately upon a potential non-conformance or incident being identified.

Should the outcome of an investigation conclude that no non-conformance has occurred, then the documentation of the investigation should still be maintained and available to an inspector. An example of this may be where an investigation is commenced into stock discrepancies identified during stock counts where the outcome of the investigation is the location of the missing stock.

Investigations should aim to identify the root cause of the non-conformance. Corrective and preventive actions (CAPAs) may arise as a result of non-conformances, internal audits, observations or from other incidents.

A log of non-conformances should be maintained and all investigations, root cause identifications and resulting CAPAs documented. CAPAs should be subjected to regular review to ensure their full implementation and they should be subject to formal checks of their effectiveness.

The principles of quality risk management should be built into the non-conformance process. Each non-conformance should be considered and a decision taken as to whether a risk assessment is required. The requirement for a risk assessment to be considered should be documented on the non-conformance form.

4.5 Complaints

In accordance with the Regulations, distributors who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, must immediately forward this information to the manufacturer and, where applicable, his authorised representative and the importer. Distributors must keep a register of complaints, non-conforming products, and product recalls and withdrawals. It is the responsibility of the distributor to keep the manufacturer (and, where applicable, the authorised representative and the importer) informed of any complaints or reports that may have an impact on product supplied to the market, and to provide them with any information upon their request. A contract or technical agreement may be in place between the distributor and the manufacturer specifying responsibilities relating to the handling of complaints, incidents and vigilance.

A procedure should be in place describing the process to be followed upon receipt of a complaint, an event or incident report. A complaint, event and incident report log should be established.

All complaints, events or incidents received should be evaluated and categorised into either a quality, technical/service, vigilance or distribution related complaint depending on the nature of the report. Complaints specific to activities performed by the distributor should be investigated by the distributor. The decisions and actions taken as a result of a complaint, event or incident should be justified and recorded. Where complaints are not reported to the

manufacturer or authorised representative/importer, this should be justified and documented. All communications regarding the complaint should be documented.

5 PERSONNEL AND STAFF TRAINING

Personnel involved in the distribution of medical devices should have the appropriate training and experience to adequately conduct their assigned duties. Training should be documented and recorded. Reporting structures and role profiles should be clearly established. There should be sufficient competent personnel to carry out all the tasks for which the distributor is responsible.

5.1 Key personnel

It is suggested that each distribution centre appoint a person of appropriate training and experience who has primary responsibility for ensuring that regulatory responsibilities are met and that the quality system is effective. This person may also serve as the primary contact between the competent authority and the distributor.

Other duties that need to be carefully controlled and assigned to key personnel of appropriate training and experience include the segregation, storage and release of returned stock to saleable stock and the handling of product recalls and field safety notices.

5.2 Training

Training is a key component of any quality system.

The training and skills necessary to carry out the various operations should be clearly established. A training plan should be in place for each staff member to ensure that they receive induction training, task-specific training and ongoing training relevant to their role profile. This ongoing training should include training on updated SOPs.

The effectiveness of training should be determined and before taking on any role, staff should have shown the competency needed. Evidence to this effect must be recorded and maintained.

All training events should be documented in sufficient detail, including: a description of training, the duration and location of training, the training provider, who was trained and whether the trainee received the required level of competence with respect to the objective of the training event. For training on documents the revision number of the document should be included.

Both trainer and trainee should sign off on all training records.

Training could include but is not limited to:

- defined responsibilities for personnel
- access to and training on documentation relevant to their role
- storage requirements
- labelling checks
- reporting of non-compliances
- operation of segregated areas to minimise the risk of mix-ups
- recall/withdrawal procedures
- complaints procedures
- regulatory requirements and related guidance documents

6 DOCUMENTATION AND RECORD KEEPING

Article 25 of the MDR and Article 22 of the IVDR relate to the obligations of distributors to achieve an appropriate level of traceability of medical devices that they distribute.

Distributors should keep adequate records, including records of customers and suppliers to and from whom medical devices have been distributed. Records should include but are not limited to: medical device name and/or code, batch or lot number, quantities and delivery date. This information is especially important in the event of a recall or withdrawal from the market. In the event that a recall of a particular batch/lot is required, failure to record the batch/lot numbers involved in transactions may result in a full product recall being required.

Distributors must co-operate with manufacturers or authorised representatives to achieve an appropriate level of traceability of devices. They should be able to identify the following to the competent authority, for a period of ten years:

- to whom they have directly supplied a device, including healthcare professionals and institutions
- who has directly supplied them with a device

Records to be maintained by the distributor could include:

- copies of invoices relating to the receipt and supply of a medical device
- copies of orders relating to the receipt and supply of a medical device
- a list of approved medical device suppliers and details of the relevant medical devices
- a list of economic operators, health institutions and healthcare professionals, to include contact details of those to whom medical devices were supplied
- records of checks carried (for example labelling checks for CE marks) and the approval of medical devices into saleable stock

These records should be kept for ten years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, the period must be at least 15 years after the last device has been placed on the market. These records may be requested by the HPRA.

7 MEDICAL DEVICE RECEIPT, STORAGE AND SUPPLY

7.1 Introduction of a new medical device

A robust system for approval of new medical device suppliers is a key component in the prevention of falsified medical devices entering the supply chain. Distributors should have a procedure in place relating to the introduction of new medical devices to their inventory. For medical devices, the required storage and transport conditions and any additional requirements relating to their distribution should be documented. Where clarification is required, distributors should consult with their suppliers with respect to the classification of new medical devices. Documentation should be available for review relating to the introduction of each new medical device. Specific documentation required for placing a device into saleable stock is detailed in section 7.2 of this document.

It is recommended that a distributor of medical devices has a technical or contractual agreement in place with their supplier. The technical agreement serves as a basis for defining the division of responsibilities between the parties. However, it is important to highlight that each distributor retains ultimate responsibility for ensuring that the operations are compliant with legal requirements. A technical agreement between a distributor and their supplier should include, but is not limited to:

- relationship of parties and relevant contact details
- devices covered by the agreement and any specific requirements (e.g. storage conditions)
- transport specifications
- device traceability requirements
- responsibilities and procedural aspects in terms of recall/withdrawal procedures, handling returns, complaints (related to distribution and/or device safety and performance)
- review provision for ensuring the agreement maintains relevance to the ongoing operation

Where the distributor is a subsidiary of the manufacturer or supplying company, tasks and responsibilities may be defined within procedures in a common quality management system.

Distributors receiving medical devices directly from operators in a country outside of the European Economic Area may be considered to be importers. In accordance with legislation, importers have specific legal obligations in addition to a distributor's obligations.

The Regulations also state that where a distributor performs certain activities, they may assume the responsibility of a manufacturer. These activities include where a distributor:

- makes a device available on the market under their name, registered trade name or registered trade mark
- changes the intended purpose of the device already placed on the market or put into service
- modifies a device already placed on the market or put into service in such a way as to affect the compliance of the device

7.2 Placing devices into saleable stock

It is recommended that deliveries are examined at receipt to include checking for damage (including any breaches to sterile packaging) and appropriate remaining shelf life. A written SOP should be in place to enable detection and quarantine of any non-conforming or defective product.

There should be a system in place to enable the distributor to meet the requirements of Article 14 paragraph 2 of the Regulations. Before making the medical device available on the market, the distributor must verify that certain minimum requirements are met. This includes checking that a CE mark is present and that a declaration of conformity of the device has been drawn up. In performing this verification, the distributor may apply an appropriate sampling method that ensures that the samples selected are representative of the devices supplied by that distributor. Any sampling method applied should be risk-based and justified. Expiry dates should also be checked to ensure that expired medical devices are not supplied. For increased traceability it is recommended that batch or lot numbers are recorded. All the above mentioned checks should be recorded.

In addition, distributors must also verify that the following requirements are met:

- the medical device is accompanied by the information to be supplied by the manufacturer in accordance with Article 10(11) of the MDR and Article 10(10) of the IVDR (i.e. labelling and instructions for use). A risk-based sampling approach can be used for this check;
- for imported devices, the importer has complied with the requirements set out in Article 13(3) of the Regulations (i.e. importer's contact details);
- where applicable, a unique device identifier (UDI) has been assigned by the manufacturer.

Article 27(8) of the MDR and Article 24(8) of the IVDR require that distributors store and keep, preferably by electronic means, the UDI of the devices which they have supplied or with which they have been supplied, if those devices are class III implantable devices or belong to one of the categories of devices specified by the European Commission as requiring this traceability. Further information and guidance will become available on the [European Commission website](#) following the application of the UDI system during the implementation of the Regulations.

The verification checks should also be recorded.

The process for handling of non-conforming goods at goods-in should be described in a procedure, which should include where the medical device is stored, what documentation is completed and how the stock is controlled on the warehouse management system (if applicable).

It should be verified that all goods have been received from an approved supplier. To ensure this, goods-in personnel should have access to the list of suppliers approved under the company's quality system. Alternatively, an inventory management system may be used

which permits medical devices to be booked onto the inventory system only if the supplier is approved to supply that medical device.

Specific checks should be performed on medical devices requiring refrigerated storage. These checks should include, but are not limited to: checking that cold chain conditions were maintained during transportation, and checking that the consignment(s) were received within the validated transportation time if received in qualified cold-chain shippers.

If a medical device is received under quarantine status, there should be systems and procedures in place to ensure that it is not released into saleable stock until all necessary conditions have been met.

Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of the Regulations, they must ensure that the device is brought into conformity before it becomes available on the market. It is also a requirement that in this case, the distributor informs the manufacturer and, where applicable, the authorised representative and the importer.

Where the distributor considers or has reason to believe that the medical device presents a serious risk to patient health and safety or is falsified, they shall also inform the HPRA. If the distributor has made a medical device that poses a serious risk available in other markets within the EEA, the distributor is also required to inform the national competent authority in each of those markets. This requires that the distributor has a documented system in place relating to identification of serious risk and of falsified medical devices. Further information regarding the vigilance system for medical devices is available on the HPRA website www.hpra.ie.

Records should be available of all checks performed and these should be available to the HPRA during an inspection.

7.3 Traceability

Article 25 of the MDR and Article 22 of the IVDR describe the obligations relating to identification within the supply chain. Medical device traceability is achieved through maintaining adequately detailed records in relation to the sourcing and supply of medical devices. In the event of a product recall it may be necessary to determine the customers that received the medical device that was affected by the recall. In such cases, the maintenance of a system which includes tracking by batch/lot number is most valuable in terms of assisting and ensuring the swift conduct of the recall and limiting it to the affected batch/lot only. Other systems for traceability and recall are available and may be justified, e.g. where a specific lot number is not assigned to the device. The system used to maintain product traceability should be challenged periodically to ensure that it is capable of determining stock location. Distributors should be able to identify the following for the retention period applicable

- customers or entities to whom they have directly supplied a device;
- suppliers or entities who has directly supplied them with a device;
- any health institution or healthcare professional to which they have directly supplied a device.

A procedure should be in place describing the controls and traceability system in place for promotional samples and samples maintained by sales representatives. Details and quantities of medical devices supplied to sales representatives should be recorded and included in any recall action which may arise.

7.4 Storage

According to Article 14(3) of the Regulations, distributors must ensure that, while medical devices are under their responsibility, storage or transport conditions comply with the conditions set by the manufacturer. Storage conditions are normally specified on the containers, for example 'Store between 2 and 8°C', 'Store at -20°C' or 'Do not store above 25°C'. Medical devices must be stored in accordance with the labelled conditions, including potential relative humidity conditions. Where there are no specified storage conditions, there are no restrictions on the temperatures at which medical devices may be stored.

Continuous temperature monitoring must be performed and documented in order to ensure that the appropriate conditions are maintained, if applicable. This applies to all areas where medical devices are stored (e.g. bulk storage, pick-face, quarantine and returns areas). At a minimum, a calibrated max/min type thermometer should be used. The maximum and minimum temperatures reached should be recorded every day and the thermometer reset after the readings have been taken.

Temperature monitoring records should be reviewed and approved regularly to ensure compliance with the required conditions. Temperature excursions should be investigated immediately and documented. Consideration should be given to the potential impact that the excursion may have had on devices stored during that time period. In the event that there are multiple temperature excursions across a time period, the impact of the multiple excursions on the devices should be considered. The manufacturer of the medical device should be consulted to ascertain the effect of any excursions from the labelled storage conditions. The method for investigating excursions should be described in a procedure.

The distributor should review calibration certificates for temperature monitoring devices to ensure that the accuracy of the devices is acceptable. Documentation should be available for inspection demonstrating that this review has occurred.

Temperatures should also be monitored during periods when temperature measuring devices used routinely are being recalibrated. This may mean that auxiliary temperature measuring devices are required. These devices should also be calibrated.

Adequate rotation of stock (a 'first expired first out' (FEFO) or equivalent stock rotation system) should be applied to ensure that stock with adequate expiry is supplied.

Quarantined stock should be kept separate from approved stock. There should be a system in place to ensure that quarantined stock is not available for picking or returned to saleable stock inadvertently. An inventory of quarantined stock may be maintained on a warehouse management system. The distributors should exercise care to ensure that, where segregation is achieved only by using a computerised system, this system is at least as effective as if devices were physically segregated. This is to ensure that devices that have been deemed as not suitable for saleable stock (e.g. falsified, recalled or defective medical devices) are not supplied to customers.

Any samples received by sales representatives should be stored and transported in accordance with the labelled conditions.

7.5 Pest control

The distributor is responsible for preserving the device through correct storage and transportation as applicable. Therefore it is recommended that a pest control programme is in place. At a minimum this should include rodent control. Further controls may be required for birds and flying and crawling insects and may include electrical fly killers, glue traps etc. Rodent control should cover both internal and external locations.

The programme should be described in a procedure. A bait map should show the locations of all pest control monitoring stations and should be approved by the distributor.

Any recommendations made by a pest control service provider should be completed and recorded. If recommendations are not completed, an explanation should be recorded. All pest control records should be approved by the distributor and maintained.

7.6 Medical device disposal

Disposal of medical devices should be controlled such that they cannot re-enter the supply chain. All medical devices that are rejected in-house, rejected when received as a return from a customer or recalled stock should, if instructed accordingly, be destroyed in an appropriate and timely manner and in accordance with waste legislation and any associated manufacturer instructions as provided in the product labelling and instructions for use. Consult with the manufacturer if required. The decision to dispose of medical devices should be documented and recorded.

There should be an inventory of medical devices placed into waste. Records and certificates of destruction should be maintained.

Service level agreements should be in place with third party contractors.

7.7 Validation and qualification

To ensure the robustness of processes and equipment used in the distribution of medical devices it is best practice to validate or qualify these systems. Processes should be validated where the resulting output cannot be or is not verified by subsequent monitoring or measurement. Validation must demonstrate the ability of these processes to achieve planned results consistently. All validation exercises should be documented and the scope of the validation justified. Validation should be completed prior to the use of the system or process in the routine distribution and sale of the medical device (prospective validation). In exceptional circumstances, where this is not possible, it may be necessary to validate processes during routine distribution (concurrent validation).

Validation of critical processes

In order to validate a process the distributor should first clearly describe/map the process (including the use of diagrams/flowcharts where relevant). The distributor should identify the critical steps within the process. Such steps may include goods-in, storage, order processing and dispatch. The distributor may further sub-divide these steps into the critical sub-steps involved in each individual process. For example, goods-in may be sub-divided into receipt on-site, delivery checking and acceptance, placing of goods into the goods-in area, detailed checking of medical devices, medical device acceptance or rejection and finally locating of goods to storage/picking/rejection area.

Once the distributor has identified the critical steps, a decision should be taken as to which steps require validation (or indeed whether all steps require validation). A risk management approach should be applied. Validation of processes should include an entire run through of a system from start to completion to ensure that each individual process does not have a negative impact on the following process. Records of the results and conclusion of validation and necessary actions arising from validation studies should be maintained.

The need for re-validation following a change to a system should be considered. Processes in use for some time should also be re-validated at a defined, justifiable period to demonstrate that they remain in a validated state.

Computer system validation

Before a computerised system (relating to distribution processes) is brought into use, it should be demonstrated, through appropriate validation or verification studies, that the system is capable of achieving the desired results accurately, consistently and reproducibly. The level of validation required will depend on the complexity of the system, whether it is a bespoke or 'off-the-shelf' system, and also the level of customisation performed on the system. The distributor should examine its systems and decide on the level of validation required using a risk management approach. There should be documentation available describing the computerised systems in use and the level of validation performed or planned to be performed. Software applications should be validated prior to initial use and, as appropriate, after changes.

Equipment qualification

In order to qualify a piece of equipment, a written protocol should be generated outlining how the qualification will be conducted. The protocol should describe the piece of equipment along with its critical functions and attributes. The protocol should describe how the correct operation of these critical functions and attributes will be verified along with acceptance criteria. The protocol should be reviewed and approved by the company.

Following completion of the qualification exercise a report which cross-references the qualification and/or validation protocol should be prepared, summarising the results obtained, commenting on any non-conformances observed, and drawing the necessary conclusions, including recommending changes necessary to correct deficiencies.

8 THE MANAGEMENT OF RETURNED MEDICAL DEVICES

A medical device should be considered to be a 'return' once it has left the premises of the supplying distributor and is subsequently returned to that premises. This may include the following examples:

- where a distributor supplies a customer with the incorrect medical device, which is subsequently returned
- where a customer returns a medical device to a distributor which they ordered in error
- where a medical device is received back to the premises of a distributor having never been received by the customer (e.g. because the customer's premises was closed)
- where a defective medical device is received back to the premises of a distributor for exchange or repair.

Distributors should be extremely vigilant in their assessment of the suitability of returned medical devices to be placed back into saleable stock. Once the returned medical device has been placed back into saleable stock it may not be possible to distinguish between the returned medical device and the remainder of the stock even if the batch/lot number of the returned medical device was recorded. The distributor must be fully confident that the safety and performance of the medical device has not been affected in any way whilst the medical device has been out of their care. Defective devices should be segregated from other stock and identified as defective.

When a return is received back it should be placed in a separate area so that there is no risk of it being returned to saleable stock prior to assessment in error. This separate area should be clearly segregated from saleable stock (either by physical means or by a validated computerised system).

All stages of the returns process should be documented. This documentation should allow all stages of the returns process to be traced, including the person conducting each stage/activity.

A suitably competent person should perform the checks on returned medical devices. If the medical device is to be rejected then it should be placed into a reject area.

Personnel involved in the returns process should receive appropriate training and should have sufficient experience in relation to the handling of medical devices to increase their ability to identify falsified medical devices.

The distributor must ensure that the correct storage conditions have been maintained during the period the medical device was outside of the distributor's control. There must be no reasonable possibility that the storage conditions have been compromised during this period resulting in the risk to the performance and/or safety of the device.

There should be a register or log of returns in place which should include all medical device details and reasons for their return. The assessment performed on returned medical devices should be documented and should include the final disposition (i.e. approved for sale, quarantined, rejected or intended for destruction).

Special care must be exercised with the return of any medical devices requiring storage at low temperatures and sterile medical devices. Where a distributor decides to accept returns of medical devices requiring storage at low temperatures, the criteria for accepting these should be strictly adhered to and clearly described within a procedure. The distributor must have documented evidence available for review confirming that the medical device was maintained within the cold chain for the entire time period during which it was outside of its control.

It is considered best practice if sterile medical device stock is only returned to saleable stock where there is no reasonable possibility that sterility has been compromised. If there is any doubt about their storage then they must not be returned to saleable stock. Stocks of sterile products with broken seals, damaged packaging or suspected of possible contamination must not be returned to saleable stock.

Distributors should be aware of the potential for falsified medical devices to enter the supply chain through the returns process. All relevant staff members should be made aware of this.

9 FALSIFIED MEDICAL DEVICES

It is imperative that all distributors operate using good governance and display vigilance in their efforts to prevent falsified medical devices from being traded with other distributors or placed on the market. It is recommended that distributors put a process and related procedure in place and arrange training for staff to be followed in the event of identifying a suspected falsified medical device or of being notified that a (suspected) falsified medical device has been received.

Distributors should consider the following to help prevent the introduction of falsified medical devices into the supply chain:

- Be aware of the possibility of falsified medical devices being supplied inadvertently through legitimate sources.
- Have robust systems for ensuring the legitimacy of their suppliers and ensure that this is regularly reviewed.
- Maintain a list of approved suppliers and ensure that medical devices are only sourced directly from these approved suppliers. In this regard the approval process should include assessment of supply chain and where possible the authority of the supplier to supply the specific medical devices e.g. if devices are not received directly from the manufacturer, seek confirmation from the manufacturer or official distribution partners.
- Be familiar with the history of the supply chain for medical devices received and question previous stages in the supply chain, if deemed necessary.
- Train staff to be aware of falsified medical devices and what to look out for.
- Ensure that the goods-in procedure involves a detailed inspection of medical devices received, which is capable of identifying changes or unusual aspects to the appearance and packaging of medical devices.
- Be familiar with the market price of the medical devices they source and normal fluctuations in this price. Offers below expected fluctuation should be treated cautiously and investigated to ensure these are genuine.
- Be vigilant and do not allow themselves to be used by counterfeiters to 'launder' falsified medical devices.
- Be aware of the possibility of falsified medical device entering the supply chain through returns.
- Be knowledgeable of medical devices at risk of counterfeiting and ensure purchasers for the distributor are aware of such medical devices also.

A distributor in possession of a medical device that is found to be (or is suspected of being) falsified is responsible for the withdrawal and quarantine of the medical device from saleable stock. If a distributor located in Ireland is suspicious that a medical device that is being offered or that has been received is not genuine, then the distributor should inform the HPRA immediately. Medical devices which are suspected of being falsified should never be returned to the supplier without the consent of the HPRA.

Any suspicious approaches or activities noticed by a distributor should be reported to the HPRA without delay (enforcement@hpra.ie).

10 MEDICAL DEVICE RECALLS

The distributor should have a recall procedure in place. This is to enable the swift and effective recall from the marketplace of defective and/or potentially harmful medical devices. In the event of a recall the responsibility of the distributor will depend on where in the supply chain they act for the medical device in question.

The recall procedure should include, at a minimum, the following:

- the role of management
- nominated responsibilities for co-ordination of the recall action
- contact numbers for the company (at least three personnel) and the relevant HPRA staff contact points (vigilance@hpra.ie)
- requirement to discuss with the manufacturer and agree any action with the HPRA before recall action or communication to other customers is carried out
- description of the batch/lot traceability system and method of identification of medical device recipients within the distribution chain
- method of handling recalled medical devices currently in-house and those received back
- arrangements to ensure segregation of recalled medical devices from saleable medical devices
- arrangements for return of recalled medical devices to the manufacturer or for destruction
- investigation and reconciliation reports
- procedure to be followed in the event of a defect being discovered on-site

There should be an efficient and effective method for identifying customers supplied with a medical device subject to a recall. The recall procedure should be regularly challenged (recommendation of at least once per year) to ensure that the process is effective and capable of tracing all customers and medical devices in a timely manner. This challenge may involve identifying a particular batch of a medical device and reconciling quantities received with those in stock and distributed to customers. A mock recall need not be carried out where the company has participated in an actual recall during the previous year, which has utilised the same traceability system.

11 OUTSOURCED ACTIVITIES

Technical or contractual agreements should be in place for all outsourced activities relating to distribution of medical devices. The technical agreements should at least describe the roles and responsibilities of both parties including details as applicable on transportation arrangements, receipt of goods, documentation, recalls, returns, customer complaints, suspected falsified medical devices, and management of non-conformances and changes. The technical agreement serves as a basis for defining the division of activities and responsibilities between the parties. However, it is important to highlight that the distributor retains ultimate responsibility for ensuring that the operations conducted are compliant with legal

requirements. Technical agreements and procedures covering delegated activities may be reviewed during the course of a HPRA inspection.

12 TRANSPORTATION

Medical devices must be transported appropriately and in accordance with labelled storage conditions (including sterile conditions if applicable) and written procedures. Where contract service providers are used, the distributor must make itself aware of the operating procedures of that party (e.g. by audit). This assessment should include examination of the transportation methods and routes. The distributor should be fully aware of, and agree to, any operations sub-contracted to another party by the contract service provider. The contracted arrangements for transportation should be documented in a service level agreement, and should include details of any sub-contracting.

The distributor must ensure that medical devices are not subjected to prolonged periods of storage during transportation.

13 INTERNAL AUDITS

In order to ensure and determine the effectiveness and compliance of the business with its quality system and legislation, an internal audit or self-inspection programme should be established. To this end, a risk based internal audit plan should be prepared that covers all the unit operations carried out in the course of business over a defined period of time. Any plan should be realistic and capable of achieving its objectives. Internal audits may cover individual unit operations (and be conducted more frequently) or numerous operations within their scope.

An internal audit or self-inspection log should also be established to record the scope of any internal audits carried out, the outcomes of any internal audit carried out and the actions (corrective and preventative) arising from any internal audit carried out. An audit log capturing such detail should prove useful with respect to trending the effectiveness of the quality system and determining the content of future self-inspection plans.

For all internal audits or self-inspections carried out, a detailed report should be prepared and any non-conformances identified should be closed out in a timely manner.

14 FURTHER INFORMATION

For queries on the distribution of medical devices in Ireland, contact the Health Products Regulatory Authority at the following address:

Compliance Department
Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
D02 XP77

Telephone: +353-1-6764971

Fax: +353-1-6764061

E-mail: compliance@hpra.ie

Information is also available on the HPRA website at www.hpra.ie

APPENDIX 1 FURTHER GUIDANCE

1 Selection of Articles from the Regulations

Medical Device Regulation

Article 10(8)

Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56, available for the competent authorities for a period of at least ten years after the last device covered by the EU declaration of conformity has been placed on the market. In the case of implantable devices, the period shall be at least 15 years after the last device has been placed on the market.

Upon request by a competent authority, the manufacturer shall, as indicated therein, provide that technical documentation in its entirety or a summary thereof.

A manufacturer with a registered place of business outside the Union shall, in order to allow its authorised representative to fulfil the tasks mentioned in Article 11(3), ensure that the authorised representative has the necessary documentation permanently available.

Article 10(11)

Manufacturers shall ensure that the device is accompanied by the information set out in Section 23 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible, clearly comprehensible to the intended user or patient.

Article 13(3)

Importers shall indicate on the device or on its packaging or in a document accompanying the device their name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted, so that their location can be established. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.

IVD Regulation

Article 10(7)

Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 51, available for the competent authorities for a period of at least ten years after the last device covered by the EU declaration of conformity has been placed on the market.

Upon request by a competent authority, the manufacturer shall, as indicated therein, provide that technical documentation in its entirety or a summary thereof.

A manufacturer with a registered place of business outside the Union shall, in order to allow its authorised representative to fulfil the tasks mentioned in Article 11(3), ensure that the authorised representative has the necessary documentation permanently available.

Article 10(10)

Manufacturers shall ensure that the device is accompanied by the information set out in Section 20 of Annex I in an official Union language(s) determined by the Member State in which the device is made available to the user or patient. The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient.

The information supplied in accordance with Section 20 of Annex I with devices for self-testing or near-patient-testing shall be easily understandable and provided in the official Union language(s) determined by the Member State in which the device is made available to the user or patient.

Article 13(3)

Importers shall indicate on the device or on its packaging or in a document accompanying the device their name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted, so that their location can be established. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.

2 Field safety corrective actions

An incident report can lead to the need for a Field Safety Corrective Action (FSCA) to be taken. An FSCA is an action taken by a manufacturer to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. An FSCA can result in:

- the return or recall of a medical device to the supplier or manufacturer
- modification of the medical device
- modification to the clinical management of patients
- exchange of the medical device
- destruction of the medical device
- retrofit by the purchaser of the manufacturer's modification or design change
- advice or a Field Safety Notice (FSN) given by the manufacturer regarding the use of the device (e.g. where the device is no longer on the market or has been withdrawn but could still possibly be in use as in the case of implants, or where there is a change in analytical sensitivity or specificity for diagnostic devices)

Distributors should note that a device modification can include permanent or temporary changes to the labelling or instructions for use, software upgrades including those carried out

by remote access and advice relating to a change in the way the device is used (e.g. when an IVD manufacturer advises of a revised quality control procedure such as the use of third party controls or more frequent calibration or modification of control values for IVDs).

It is the manufacturer's responsibility under the legislation to inform Member States of an FSCA. An FSN is a communication sent by a manufacturer to users or customers (including distributors) in relation to an FSCA. Nonetheless, a documented procedure for handling FSCAs notified by the manufacturer should be in place. In addition, the system established should be capable of handling the reporting of FSCAs where the distributor is responsible for initiating or reporting an FSCA. The document should clearly outline the various responsibilities with respect to the planning, conducting and reporting of the corrective action taken. The procedure should also clearly stipulate that the HPRA should be notified before any FSCA is undertaken and/or communicated onward.