TECHNOPATH

1st May 2017

Reference: HPRA Draft Guide to Distribution of Medical Devices, including in vitro diagnostic Medical Devices

Dear Justin,

We are grateful for the opportunity to utilize IMSTA in order to respond to the recently published HPRA Draft Guide to Distribution of Medical Devices.

As you are aware TECHNOPATH distribute products across a variety of markets including Healthcare, Biotechnology and Clinical diagnostics and, as such, the guidelines directly affect our business and the ways in which we conduct that business.

TECHNOPATH are currently accredited to ISO 9001 and 13485, as well as being a certified holder of a Good Distribution Practice license issued by the HPRA in 2014. We note from the HPRA email introducing the draft guidelines that the guidelines would "essentially constitute good distribution practice (GDP) for medical devices". As a current holder therefore of a GDP license from the HPRA and having completed the requisite audit in order to achieve same, we would like to raise concerns with several of the recommendations included in the draft.

We would be keen to reinforce that we fully support any attempts to ensure our industry in Ireland operates to the highest possible standard and TECHNOPATH commit fully to any reasonable measures that promote this agenda. The draft document as published however presents some difficulties, which, if enacted will potentially have a detrimental effect on distributors in Ireland being able to deliver a safe, cost efficient service to the variety of customers, served throughout the Island.

We outline in the attached document the areas that cause us concern and we would welcome any opportunity to address these directly with the HPRA prior to any guidance being issued or formalized. We are, as ever, grateful to IMSTA for providing a forum which enables us and similar companies to voice our concerns and, again, we reiterate our support to engaging with any engagements that may occur following the submission of the IMSTA feedback.

Yours sincerely

Seamus McAuley

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1. The draft document states the following:

"Two EU Regulations (together known as 'the Regulations') are in draft at the time of writing, one for medical devices and one specifically for in-vitro diagnostic medical devices. They are:

- *- 'Proposal for a Regulation of the European Parliament and of the Council on medical devices and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation 1223/2009'. Ref -COM (2012) 542 ['the medical device Regulation']*
- *- 'Proposal for a Regulation of the European Parliament and of the Council on in vitro diagnostic medical devices' Ref - COM (2012) 541 ['the IVD Regulation']*

When legally applicable, these two Regulations will replace the current European Directives for medical devices; including Council Directives 90/385/EEC and 93/42/EEC and 98/79/EC. It is anticipated that requirements relating to distribution of devices will be essentially the same in both Regulations.

This is a best practice guidance document published in advance of the final adoption of the new Regulations placing legal obligations on the distributors of medical devices. It is anticipated that the requirements for distributors will essentially constitute good distribution practice (GDP) for medical devices. This document aims to provide supplementary guidance to distributors in that regard taking into account the proposed obligations for medical device distributors in the two Regulations. It sets out the Health Products Regulatory Authority's (HPRA) recommendations for best practice and other considerations for distributors of medical devices."

As outlined in this statement the HPRA appear to be pre-empting the new EU guidelines by proposing these recommendations ahead of the final EU regulations being published. It would seem premature to ssue draft guidelines which would attempt to support the introduction of new EU legislation before said EU legislation is finalised and converted to law. This also ignores the need for the new directives, when published as European Law, to be transposed into Irish Law from the overarching EU regulations.

TECHNOPATH would suggest a sensible alternative is to await the final publication of the new EU legislation in order to ensure effective translation in the final format.

2. There are several references throughout the document which relate to the Traceability od any medical device supplied. The recommendations appear to impose some unreasonable expectations upon distributors which are outlined below:

Article 14, proposed of the proposed regulations

"Before making a device available on the market, distributors shall verify that all of the following requirements are met:
(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);
(d) that, where applicable, a UDI has been assigned by the manufacturer.

In order to meet the requirements referred to in points (a), (b) and (d) of the first subparagraph the distributor may apply a sampling method that is representative of the devices supplied by that distributor"

The HPRA Guide, section 7.2 Receiving has further specified
"Before making the medical device available on the market, the distributor must verify that certain minimum requirements are met. This includes checking for the presence of a CE mark and that a declaration of conformity of the device has been drawn up. This check should be performed on a sample from each batch of each medical device received"
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 medical device Regulation (corresponding to Article 10(10) of the IVD Regulation) (i.e. labelling and instructions for use). A risk-basedsampling approach can be used for this check;
- where applicable, a Unique Device Identifier (UDI) has been assigned by the manufacturer.
The verification checks should also be recorded.

The recommendations here would appear to suggest that a distributor, upon receipt of a delivery from a manufacturer/supplier their warehouse will have to check and document for the presence of a CE mark, for a declaration of conformity and the presence of a IFU/DFU for each batch in each shipment. This is a very time consuming task that will require excessive extra paperwork but more importantly appears futile as:

- CE certs / Declarations of conformity do not specify batch number but instead only include product family name and product codes.
- Checking for IFU / DFU will require the warehouse to open a sample number of kits and/or product packs thus breaking seals leaving these products as not saleable.

Article 14 of regulations only requires confirmation both have been drawn up & distributor may apply a sampling method which again appears ambiguous and potentially conflicting as the guidelines further request in sections (a) & (b) that these procedures should be incorporated into procedure for the introduction of a new medical device to our inventory.

Further to these requirements recommendation 7.3 "Traceability" states the following:

"Article 25 of the medical device Regulation (corresponding to Article 22 of the IVD Regulation) describes 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 a specific batch/lot of a medical device which 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. The system used to maintain product traceability should be challenged periodically to ensure that it is capable of determining stock location".

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As you will be aware the HSE has recently introduced the National Distribution Centre (NDC) in Tullamore which has been another cause of concern for Distributors of medical devices in Ireland specifically in relation to Traceability.

The guidelines further refer to the new EU articles which state that

"Economic operators shall be able to identify the following to the competent authority, for the period referred to in Article 10(8) [Article 10(7) of the IVD Regulation]:

1. *(a) any economic operator to whom they have directly supplied a device;*
2. *(b) any economic operator who has directly supplied them with a device;*
3. *(c) any health institution or healthcare professional to which they have directly supplied a device."*

To date the NDC has not received a designation as being an economic operator and so any product delivered to the NDC will mean that the supplier (or distributor) will potentially not be able to meet the third criteria of being able to identify any health institution or healthcare professional who has received one of its devices.

It would seem that the draft guidelines are placing requirements upon distributors that they are unable to meet through no fault of their own and as a consequence of wider HSE and HPRA requirements. This lack of traceability needs to be addressed by either removing the NDC as a supply point if they cannot provide Traceability to the Healthcare professional beyond or can provide this information to the supplier at source.

This issue further affects recommendation 10 in the draft guidelines which states:

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……"

Clearly if the distributor no longer has visibility of where the device supplied currently sits within the supply chain due to lack of ability by the NDC to provide it, then the distributor will again face the potential of being in breach of the guidelines through no fault of their own action.

3. Computer validation

As a part of recommendation 7 the document states the following in relation to copmuter systems used by distributors"

"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

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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".

Whilst TECHNOPATH do not have any concern with the spirit of this recommendation we recognise that Computer systems can represent a large capital investment and would therefore suggest that the HPRA must provide a more thorough recommendation in relation to this area to primarliy instruct Distributors on what is applicable when considering computer validation and what software options are applicable to this area of the medical device supply.

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