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Comments on Proposals Relating to

Public Consultation on Medical Devices Distributor Guidance

[HPRA] Draft Guide to Distribution of Medical Devices, including *in-vitro* diagnostic Medical Devices

Comments or Questions Submitted

1. The guidance seems to follow the general requirements for economic operators (especially for distributors and importers) detailed in the forthcoming Regulations for medical devices and in-vitro diagnostic medical devices. As such, the guidance seems well aligned with these new Regulations. It is recommended the guidance be reviewed again once the Regulations are published.
2. In connection with the forthcoming regulations on medical devices it would be useful to understand the HPRA plans regarding this guidance. When does the HPPRA intend to publish this guidance? Once published, will there be a transition date by which distributors and other economic operators will need to comply? Will any transition timescale be linked with the transition timescales foreseen in the new Regulations?
3. Article 14 on page 7 states, "Distributors, upon request by a competent authority, shall provide free samples of the device or, where that is impracticable, grant access to the device". No mention is made of the need to coordinate and communicate with the legal manufacturer and/or EC Authorised Representative on such matters and it is recommended that further detail is provided in the guidance so that there is transparency and cooperation regarding such requests.
4. In Section 4 of the Guidance, It is recommended that distributors have a quality system in place. This is something we support. However, being only a recommendation, it is likely some distributors may choose to ignore this, and therefore not have the same rigorous controls in place as other distributors. Also having a quality system in place is not the same as requiring a certified Quality Management System. It would be useful to understand what HPRA's thinking on this is, and whether or not they will be likely to legislate for this is in the future, and if so when is this likely?
5. In Section 4, 7th Paragraph on page 8, the guidance states, "In order to ensure that procedures are maintained and are reflective of current requirements, a periodic review

should be performed". It is not clear who should perform this periodic review. Should it be performed by the distributor, legal manufacturer or EC Authorised Representative and/or the HPRA?

6. In Section 4, 10th Paragraph on page 9, the guidance states, "Any distributor operating to accredited quality standards should ensure that its operation also complies with the legislative parameters governing the distribution of medical devices". What current legislative parameters governing the distribution of medical devices currently exist in Ireland? If none currently exist, are there any plans for the development of such legislation? Some commentary on this may be useful.
7. Section 4.2 details the requirements for a distributor to implement a change control and change review process. As the distributor may be seen as a custodian of a manufacturer's medical device up until it is placement with a healthcare provider, it would be useful to consider expanding the guidance to ensure that the manufacturer is made aware of and agrees with changes proposed by a distributor that may impact the safe storage, handling and distribution of a manufacturer's medical device.
8. Section 4.3 introduces requirements for a distributor to undertake risk management activities. This would be a significant change for distributors and may be completely new to many of them. It is recommended that concrete examples of risk management requirements in the context of a distributor are carefully spelled out and made more explicit in the guidance to assist distributors, and guide them as to elements of risk management to be considered.
9. In Section 4.5 3rd Paragraph on Page 11, the guidance states, "All complaints, events or incidents received should be investigated and categorised into a quality, technical/service, vigilance or distribution related complaint depending on the nature of the report". Will a distributor be in a position to make a determination of whether or not a complaint is vigilance reportable, or is this more the responsibility of the legal manufacturer?