HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

14th August 2017

Re: Step-by-Step Guide – When to Report a Medical Device Adverse Incident

Dear Sir/Madam,

The Health Products Regulatory Authority (HPRA) has been working closely with hospitals and health professionals to drive quality improvement in medical device safety. The approach has focused on three inter-related areas:

- Disseminating safety information
- Promoting the role of 'designated person / vigilance officer'
- Encouraging user reporting

We would welcome the involvement of your association/ organisation in these initiatives.

As the national competent authority for medical devices, the HPRA, periodically publishes and circulates medical device safety notices which highlight potential safety and/or quality issues associated with medical devices that are placed on the Irish market. The majority of these notices are for the attention of health professionals including those working in hospitals, community healthcare organisations and other health facilities. It is important that these publications reach the relevant professionals and we understand that a number of your members may receive our safety notices through our direct email system.

A pivotal part of the success of the system is that the recipient of these communications ensures the further internal distribution to the relevant personnel for implementation of the recommended actions where applicable. To facilitate this process the HSE, in collaboration with the HPRA, has identified, in some health institutions, a designated person / vigilance officer who has the responsibility for the management of such communications within their organisations. For more information on the role of the 'designated person / vigilance officer' please visit our website www.hpra.ie.

To assist in the encouragement of user reporting of medical device adverse incidents, the HPRA has also developed a Step-by-Step Guide, detailing when and how to report a medical device adverse incident. The HPRA circulated copies of this guide to all hospitals in Ireland and we have attached a copy for your reference. We would appreciate if you could support this communication by disseminating the guide to your members and consider providing a link to it on your website. If you would like additional hard copies of this guide, please do not hesitate to contact us at devicesafety@hpra.ie.

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The HPRA would welcome an opportunity to support these initiatives by presenting to your members on our role and the dissemination of safety information at one of your meetings or your annual conference. Please do not hesitate to contact us should you wish to arrange this.

Your assistance in these matters is greatly appreciated.

Yours faithfully,

Patrick Murphy
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