HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

1st December, 2014

Dear IEQAS members,

The Health Products Regulatory Authority (formerly known as the Irish Medicines Board) would like to highlight the **medical device vigilance system** which we maintain. The system was set up under the medical devices and *in-vitro* diagnostic (IVD) medical devices directives to minimise risks to the safety of patients, users and others.

The vigilance system achieves its objectives in several ways:

- through manufacturers and users submitting vigilance reports to the relevant competent authorities (the HPRA in Ireland);
- through the evaluation of reported incidents by the competent authorities;
- through the dissemination of information, which may be used to prevent recurrence of the incident, or to alleviate the consequences of such incidents, in cases when it is necessary to do so;
- by the medical device, including IVDs, being updated, modified or taken off the market in cases when it is necessary to do so.

There is a **mandatory requirement for manufacturers to report vigilance issues** in line with the European Guidelines on a medical devices vigilance system (MEDDEV 2.12-1).

In relation to **user reporting**, the HPRA currently operates a **voluntary system** whereby a user, healthcare professional or any other person who identifies a medical device safety issue can report it to the HPRA. The HPRA strongly encourages health care professionals and members of the public who have encountered a safety issue with a medical device that they have used to report the issue to us.

Increased levels of reporting from healthcare professionals and other device users may help in the early detection of adverse trends or safety issues. When the HPRA receives reports of safety issues from users or the public, we are obliged by the medical devices directives to ensure that the manufacturer of the device concerned, or his authorised representative, is also informed of the report. The source of the report will not be disclosed without prior permission.

Reports relating to safety issues or concerns about medical devices can be made by healthcare professionals or by members of the public by completing a 'Medical Device Incident User Report form' or by submitting a report through the HPRA's online reporting system, both of which are available on the HPRA website www.hpra.ie. Users may also report medical device safety issues to the HPRA by post (Medical Devices section, Human Products Monitoring Department, Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2), by email (devicesafety@hpra.ie) or by telephone (01 6764971).

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