Information Message

IM/2021/005 07 April 2021

Changes to IRIC safety alerts

This information message was originally issued as an email. Its content was subsequently converted to a document format for accessibility purposes and to enable better integration with intranets and local safety alert governance systems.

Information / background

MHRA publishes safety information which is distributed in Scotland by IRIC. Last year, MHRA made the medical device alert (MDA) format obsolete and replaced it with a new format called a National Patient Safety Alert (NatPSA).

This format is reserved for safety concerns involving risk of death or disability. Safety concerns which involve less serious risks will be published in other formats. The most recent format introduced by MHRA is the Device Safety Information (MDSI) web page.

Healthcare professionals are the target audience for MHRA's MDSI web pages. However, the subject matter may also be directly relevant to patients and for this reason MHRA may include actions which patients should take to protect themselves. Patients should access this information direct through the GOV.UK website. There is no expectation that equipment co-ordinators or clinicians will extend an MDSI cascade from IRIC to include patients. However, they may make separate arrangements to do so if deemed necessary following a local assessment.

IRIC, along with counterparts at the other devolved administrations, will normally be consulted on the content of MDSIs at the draft stage and will cascade a notification once published. The content of the webpage will be inserted in an attached PDF document and assigned a Scottish reference. This will enable it to be logged and tracked through local safety alert governance systems. It will also ensure it can be emailed or printed for anyone who cannot readily access the internet.

Three MDSIs will be issued today as follows:

MDSI (SC) 2101
Paclitaxel drug-coated balloons (DCBs) or drug-eluting stents (DESs): Reconfirmed position on use in patients with intermittent claudication and critical limb ischaemia. *Note that IRIC was not consulted on the content of this MDSI at the draft stage*

MDSI (SC) 2102
Medoject sterile hypodermic and blunt fill needles manufactured by Chirana T. Injecta – discontinue use. *Note that this was notified on 29 March 2021 under cover of IM/2021/003 and is reissued today using the new procedures*

MDSI (SC) 2103

Dexcom G6 Sensor: untested barrier methods to reduce skin reactions

More information on MHRA medical device safety information formats is available on the GOV.UK website.

Enquiries and further information

Enquiries (and adverse incident reports) in Scotland should be addressed to:

Incident Reporting & Investigation Centre (IRIC)
NHS National Services Scotland
Gyle Square, 1 South Gyle Crescent, Edinburgh EH12 9EB
Tel: 0131 275 7575 Email: nss.iric@nhs.scot

Reporting options are available on the HFS website: How to report an Adverse Incident

Further information about reporting incidents can be found in CEL 43 (2009) or by contacting IRIC at the above address.