Northern Ireland NIAIC Alert

Department of Health
An Roinn Sláinte
Männystrie O Poustie
www.health-ni.gov.uk

Information

Reference:	Issued:	Valid to:
NIA-2020-03	**24th Sept 2020**	**Until withdrawn**

Changes to MHRA alerts

Summary

The Medicines and Healthcare products Regulatory Agency (MHRA) is now an accredited issuer of National Patient Safety Alerts. From now on, all safety-critical alerts for medicines and medical devices that require a response will be issued under the National Patient Safety Alert format. These alerts follow the criteria and template agreed by the National Patient Safety Alerting Committee (NaPSAC). This means there will be changes in what you receive from NICAS as set out below.

Medical Device Alerts

- Medical Device Alerts (MDAs) will no longer be issued.
- When safety issues with medical devices meet the criteria of a National Patient Safety Alert (likely to cause a death or serious harm) these will be issued nationally as MHRA - National Patient Safety Alerts. These will continue to be distributed and monitored under NICAS.
- MHRA medical device alerts will now use National Patient Safety Alerts reference numbers in the format - NatPSA-2020-007-MHRA. As such MHRA alerts will be interleaved with other Patient Safety Alerts therefore reference numbers for medical device alerts may not be consecutive.
- The MHRA have removed the ‘Action by recipients’ and ‘Information to recipients’ fields from their alerts and the website. These were originally introduced to give guidance and not to show that an alert was only needed in these areas. This has proven to be a source of confusion for users and has been replacing this with ‘This alert has been issued to’.
- For medical device safety issues which does not meet the above criteria, the MHRA are working with manufacturers to ensure they improve their processes for Field Safety Corrective Actions (FSCA) and Field Safety Notices (FSNs).
- The MHRA will also continue to take a targeted approach via email where a safety issues with medical devices can be identified as limited to specific number of sites.
- The other safety information from NICAS while continue to operate as normal.
- Liaison Officers should continue to action and provide assurance on alerts received until notified otherwise.

Longer Term

- The MHRA Devices Division is developing a pilot Safety Bulletin which will include information for health and care professionals on medical device safety. The bulletin will have the reference MDB/2020/XX and will be reissued in Northern Ireland via NICAS. It is anticipated that responses on action completed on these bulletins will not be collected via the NICAS website and the bulletin will not require the executive level oversight although this advice may be revised when further information becomes available.

Action

- Liaison Officers should review their escalation routes for MHRA Alerts to ensure senior oversight. This may mean co-ordination with other staff responsible for National Patient Safety Alerts distributed e.g. Medicines, Blood, HSC(SQSD), etc.

- Note the changes to the reference number for future MHRA medical device alerts and that they may not always be consecutive.

- Please contact the NIAIC directly if you have any questions or concerns related to MHRA – NatPSA's.