Medicines & Healthcare products Regulatory Agency

MHRA

Update from the CAS Helpdesk: Changes to MHRA alerts and amendments to the website

Alert ref: **CHT/2020/002** Issued: 17/09/2020 safetyalerts@mhra.gov.uk

MHRA Alerts

- 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 system-wide response will be issued as National Patient Safety Alerts. These alerts follow the criteria and template agreed by the National Patient Safety Alerting Committee (NaPSAC).
- This means there will be some changes to what you receive from CAS 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 (more likely than not to cause a death or disability in a year) these will be issued as National Patient Safety Alerts and we will collect responses from NHS Trusts and Foundation Trusts via the CAS website.
- For other safety issues work is underway with manufacturers to ensure they improve their processes for Field Safety Corrective Actions (FSCA) and Field Safety Notices (FSNs)
- Targeted approaches via email will also be made where safety issues with medical devices can be locally identified.
- 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 issued via CAS. Responses will not be collected via the CAS website and the bulletin will not require the executive level oversight required for National Patient Safety Alerts. Feedback will be sought on the pilot Safety Bulletin and this information will help inform how MHRA disseminates safety information in future.

MHRA Dear Doctor Letters

- The MHRA Dear Doctor Letters, which until now have been issued via CAS, will now be issued as National Patient Safety Alerts. Responses will be collected via the CAS website from NHS Trusts and Foundation Trusts.
- We ask that CAS Liaison Officers identify an escalation route to ensure senior oversight for these alerts, as we know that some Liaison Officers do not currently receive MHRA Dear Doctor Letters.

MHRA Drug Alerts

- All Class 1 Drug Alerts and some Class 2 Drug Alerts will meet the National Patient Safety Alert criteria and will be issued as National Patient Safety Alerts. Responses will be collected via the CAS website from NHS Trusts and Foundation Trusts.
- We ask that CAS Liaison Officers identify an escalation route to ensure senior oversight for these alerts, as we know that some Liaison Officers do not currently receive MHRA Drug Alerts.
- Please note that the MHRA Defective Medicines Reporting Centre does operate an out of hours telephone cascade for any Class 1 alerts issued out of hours. That cascade remains in place and is not impacted by the changes described in this update.
- Other Class 2 Drug Alerts and those which are Class 3 and Class 4 will continue to be issued via CAS as they are at present; responses will not be collected via the CAS website.

Reference numbers for National Patient Safety Alerts

- Reference numbers for National Patient Safety Alerts will always be in the format beginning NatPSA/Year/Number/Issuing organisation e.g. NatPSA/2020/006/NHSPS
- The numbers will run sequentially, so the next National Patient Safety Alert issued will take the next number in the sequence (007, 008, 009 etc) regardless of which organisation issues it.

The Devolved Nations

- There will be no change to how safety messages are currently shared with Northern Ireland, Scotland and Wales.

Longer term

- The MHRA will be embarking on a programme of stakeholder engagement with health and care professionals about all aspects of its work. This will include the format and content of safety messaging. We will tell you more about this work and how you can get involved shortly.
- The MHRA has been identified as leading work with all safety alert issuers to explore how safety messages that do not meet NaPSAC criteria can be effectively disseminated to the health and care system. We plan to initiate this work in the autumn of 2020.
- The other issuers of alerts from CAS are working through the National Patient Safety Alert accreditation process and we will update you once this completes; please continue to action any alerts you receive in the interim.

Alerts issued out of hours

- Wherever possible we will always try to avoid issuing any safety messaging outside of Monday to Friday 08:00 – 17:00. However, at times this is unavoidable, and we have issued several messages out of hours in recent months.
- We do hold a separate list of email addresses for issuing any alerts out of hours. If your organisation wishes to add email addresses to this list, then please contact us.
- If we do issue an alert out of hours, then we will also issue it to those recipients that would usually receive it in hours.

Changes to the CAS website

- National Patient Safety Alerts are now highlighted on the website on the 'Search alerts' pages via a blue background and white text. Each unique alert page also includes the logo.
- We will shortly be making some minor changes to the action categories which are selected on the website when recording a response – we will update you on this in the coming weeks ahead of the changes going live.
- We are removing the 'Action by recipients' and 'Information to recipients' fields from alert emails and the website. These were originally introduced to indicate whether a response via the CAS website was needed, not to show that an alert was for information and did not need action. This has proven to be a source of confusion for users and we are replacing this with 'This alert has been issued to'.
- Alert Compliance data for National Patient Safety Alerts is now being published via the website. Note that we currently collect responses from NHS Trusts, and it is these which are published.

Action

- In light of these changes review your escalation routes for National Patient Safety Alerts to ensure senior oversight
- Note the changes to the CAS website
- Please contact us at the helpdesk if you have any questions or concerns