Medicines & Healthcare products Regulatory Agency

MHRA

Update from the CAS Helpdesk: Changes to MHRA Drug alert titles and classifications

Ref: **CH/2021/002** Issued: 04 March 2021

In CHT/2020/002 we told you about the accreditation of MHRA as an issuer of National Patient Safety Alerts. As an update, we wanted to provide further information regarding MHRA Defective Medicines Report Centre safety messaging.

As previously indicated, the term 'alert' will no longer be used for any MHRA safety message which does not meet the criteria of a National Patient Safety Alert.

MHRA Drug Alerts are being renamed to Medicines Recalls (to replace what were previously Drug Alerts class 1-3) and Medicines Notifications (to replace what were previously Drug Alert: Caution in Use, Class 4). All Class 1 Medicines Recalls will meet the National Patient Safety Alert criteria and will be issued as National Patient Safety Alerts (NatPSA). Responses will be collected via the CAS website from NHS Trusts and Foundation Trusts. Any Recalls and Notifications that do not meet the National Patient Safety Alert criteria will not be published on the CAS website.

We ask that CAS Liaison Officers agree an escalation route to ensure Executive oversight for the implementation of actions required in these Alerts and Executive authorisation for recording 'action complete' on CAS, as we know that some Liaison Officers do not currently have a role in the response to MHRA Medicines Recalls/Notifications. This escalation route would need to encompass National Patient Safety Alerts related to defective medicines designated as 'straightforward' and National Patient Safety Alerts related to defective medicines designated as 'complex'. 'Complex' designation would typically apply if there is need to identify and intervene with patients who have already received the medication, rather than solely remove stock before it can be used.

Medicines Recall/Notification Classification	**Defect risk classification**
National Patient Safety Alert (NatPSA) equivalent to Class 1 Medicines Recalls	The defect presents a risk of death or disability. These alerts will be issued via CAS as National Patient Safety Alerts.
Class 2 Medicines Recall	The defect may cause mistreatment or harm to the patient, but it is not life-threatening or serious Note that a NatPSA may be issued for any type of defect that presents a risk of death or disability.
Class 3 Medicines Recall	The defect is unlikely to cause harm to the patient, and the recall is carried out for other reasons, such as non-compliance with the marketing authorisation or specification. Note that a NatPSA may be issued for any type of defect that presents a risk of death or disability.
Class 4 Medicines Notification	The MHRA also issues "Caution in Use" notices, where there is no threat to patients or no serious defect likely to impair product use or efficacy. These are generally used for minor defects in packaging or other printed materials. "Caution in Use" notices may also be issued where a defect has been identified but due to supply concerns product cannot be recalled, in these

	instances the alert will be used to provide advice to healthcare professionals. Note that a NatPSA may be issued for any type of defect that presents a risk of death or disability.
Company-led Medicines Recall/Notification	Issued where the licence holder is able to identify the affected customers, therefore it is not necessary to issue an alert to the entire NHS/healthcare system, as the issue is only relevant to a small number of recipients.

If you have been receiving Drug Alerts from us then you will receive email notifications when the MHRA issues these Recalls / Notifications, but the link will take you to where the recall or notification will be published on the MHRA website rather than linking to the CAS website.

The email you receive will come from safetyalerts@subscriptions.mhra.gov.uk to reflect this different delivery route and we ask that you add this address to your email safe senders list (or equivalent) to ensure these emails reach your inbox.

The MHRA Defective Medicines Reporting Centre operates an out of hours telephone cascade for any Medicines Recall issued out of hours. That cascade remains in place and is not impacted by the changes described in this update. The out of hours cascade will be supported by issue of the NatPSA via the CAS website.

These changes are part of the ongoing work underway by all alert issuers to become accredited to issue National Patient Safety Alerts.