Medicines & Healthcare products Regulatory Agency

Update from the CAS Helpdesk:

Alert ref: **CHT/2022/001** Issued: 17/02/2022 safetyalerts@mhra.gov.uk

Summary

The Medicines Supply Team at the Department of Health and Social Care (DHSC) and the Commercial Medicines Unit at NHS England and Improvement (NHSEI) are now accredited issuers of National Patient Safety Alerts for medicine supply issues.

From week commencing 14th February 2022, all communications of medicines supply issues by DHSC or NHSEI that carry a significant patient safety risk (Tier 3 or Tier 4, see Appendix) and meet the National Patient Safety Alert Criteria will be issued as National Patient Safety Alerts. These alerts follow the criteria and template agreed by the National Patient Safety Alerting Committee (NaPSAC). From this date, Supply Disruption Alerts will cease to exist.

Changes to Supply Disruption Alerts

All medicine supply issues that meet the National Patient Safety Alert criteria will now be issued as National Patient Safety Alerts (NatPSA) which replace the old Supply Disruption Alerts (SDA). Responses will continue to be collected via the Central Alerting System (CAS) website.

Medicine supply issues that do not meet the NatPSA criteria will continue to be issued via other communication pathways, as outlined in the appendix below.

Reference numbers for National Patient Safety Alerts will always be noted in the following format: NatPSA/Year/Number/Issuing organisation

For example: NatPSA/2022/006/DHSC or NatPSA/2022/006/CMU.

The numbers will run sequentially, so the next NatPSA issued will take the next number in the sequence (007, 008, 009 etc) regardless of which organisation is issuing the NatPSA.

Actions

- Identify appropriate escalation routes within your organisation for NatPSAs to ensure executive oversight.
- Review systems for implementing the actions required by NatPSAs including reviewing policies, processes, and governance systems. NatPSAs typically require action to be centrally coordinated on behalf of the entire organisation.
- Note the dual running period, as all issuers of alerts via CAS transition to the NatPSA format, and action all alerts in the appropriate manner.
- Contact us via email if you have any questions or concerns: DHSCmedicinesupplyteam@dhsc.gov.uk

National Patient Safety Alerting Committee and NatPSAs

As previously advised, NatPSAs will have clear, effective actions that you must take to manage safety-critical issues.

All NatPSAs need executive level oversight (or the equivalent in organisations without executive boards) of governance systems that provide evidence that the required actions have been fully completed before any NatPSA is recorded as 'action completed' on CAS.

There will be a period of dual running whilst all organisations go through the accreditation process. This means you will see a mixture of NatPSAs and existing alerts over the next 12 months. Over time, the volume of alerts that are not NatPSAs will diminish as more organisations receive accredited status.

During the period of dual running continue to action all alerts issued through CAS.

Complex and Straightforward Alerts

Each NatPSA is designated as either 'complex' or 'straightforward', and providers are required to take a different approach to each:

- 'Complex' alerts require actions that cannot be delivered by any single division or professional group within an organisation and will require the organisation's executive leader to nominate a senior clinical leader relevant to the alert to coordinate delivery.

- 'Straightforward' alerts may be actioned on behalf of the whole organisation by agreed senior leaders (for example, an agreement that the chief pharmacist will ensure all stocks throughout the organisation are checked for a NatPSA requiring removal of a specific drug batch).

It is anticipated that most medicine supply issue related NatPSAs will be complex in nature.

Changes for CAS officers

A CAS officer at a provider is typically the person who will receive a patient safety alert when issued and has responsibility for updating the CAS system around their organisation's progress in implementing an alert's required actions.

As previously advised, the introduction of NatPSAs represents a significant change for CAS officers. Rather than disseminating alerts to multiple teams and divisions as they have previously, CAS officers are required to ensure NatPSAs rapidly reach the designated executive and relevant senior leader who will be coordinating delivery of an alert's required actions.

They should only be recording NatPSAs as 'action completed' on CAS once all actions have been completed and they have the authorisation of the designated member of the executive team.

Appendix

Table 1: Clinical Escalation Categories and potential communication pathways

Tier	Definition	Characteristics (not all characteristics needs to apply when assigning a tier)	Potential communication pathways (to be used as appropriate and may only be issued to relevant parties)
Tier 1	Likely to carry low patient safety risk. Management options should result in patients being maintained on the same licensed medicine.	• Alternate manufacturers of the same medicine (form, strength) are able cover demand and meet the full supply gap • No differences in licensed indications between the out of stock product and alternative suggested • No monitoring requirements related to switching • Clinical review not required • No requirement to amend prescriptions • Alternative strength /formulation of the same medicine is sufficient to meet the supply gap **AND** no further clinical /management advice is required. A simple change of formulation or strength to meet the required dose may require more management advice in primary care (prescription amendments) whereas this may not require additional support in secondary settings.	Not routinely communicated however, options could be: • Online Medicines Supply Tool hosted on Specialist Pharmacy Service (SPS) website. • NHSE/I CMU fortnightly generics supply issues report is distributed to all Regional Pharmacy Procurement Specialists (RPPSs) and local procurement leads in secondary care in England. • Email to RPPSs.

Tier 2	Likely to carry moderate to high patient safety risk. Require more intense management options, than tier 1 issues.	• An alternative strength/formulation of the same medicine is sufficient to meet the supply gaps, but further clinical/management advice is required to help manage the switch
		• Therapeutic alternatives are available, and there are moderate clinical and patient safety risks associated with switching. The following should be considered when assessing risk:
		  ○ If the level of monitoring is more or less than standard of care.
		  ○ Level of potential operational input from healthcare professionals
		  ○ The level of clinical risk as advised by expert clinicians.
		• Unlicensed imports of the same medicine can be sourced in sufficient amount to meet expected demand
		• Issue can be rapidly addressed at source e.g., likely to impact very few patients/organisations
		• Managing available supply via allocations/mutual aid
		• Use of a SSP might be appropriate.
			• Communications issued via a Medicines Supply Notification (MSN) which can be disseminated to primary and/or secondary care, via various routes including the NHSE/I commissioning system and NHS mail.
			• Tier 2 issues will also be reported on the Online Medicines Supply Tool and CMU fortnightly generics supply issue report as for Tier 1 issues (England).

Tier 3	Likely to carry high patient safety risk and or high operational burden that requires	• Therapeutic alternatives are available but there are clinical risks associated with switching and monitoring is required. • High operational burden. • No or limited clinical alternatives available.	Escalated to MSRG • Issuing a National Patient Safety Alert (NatPSA), where the criteria are met: “More likely than not of one or more potentially avoidable death or disability in healthcare in England in a year as defined by National

	systemwide action	• Clinical expert team may be set up to provide specialised clinical advice to manage supply issue. • The product is one designated by the MHRA where a patient should be maintained on the same brand or where switching between preparations is particularly difficult. • It may be appropriate to request the consideration of exceptional regulatory measures by the MHRA (for example, the extension of product expiry dates). • The patient safety risk is increased because the group affected is likely to be considered a vulnerable population such as neonates, paediatrics or people with learning disabilities, or because of issues such as disease, age, social circumstance or access to services.	Patient Safety Alerting Committee (NaPSAC)." to the NHS via the MHRA Central Alerting System (CAS). • Otherwise issue a tier 3 Medicines Supply Notification (MSN) which can be disseminated to primary and/or secondary care, via various routes including the NHSE/I commissioning system and NHS mail to include, where MSRG agrees, *the use of the CAS mailing list with an email and a link to Online Medicines Supply Tool.*
Tier 4	Carries very high patient safety risk and requires system wide action at a national level, this may include additional support from outside the health system.	• Likely to have a life-threatening impact on patients • A supply gap remains (and no viable therapeutic alternatives exist) following the exhaustion of supply and clinical management plans at previous tiers of escalation • May require the support of agencies outside the health system (e.g. Department for Transport, police services) to support its management • Clinical expert team may be set up to provide specialised clinical advice to manage supply issue	• Issuing a National Patient Safety Alert (NatPSA), where the criteria are met to the NHS via the MHRA Central Alerting System (CAS) • Additional supportive and targeted comms may be required as signed off by SRO