

# Safety-critical alerts are changing at the MHRA

News story

The MHRA will now issue all safety-critical alerts for medicines and medical devices that require action as National Patient Safety Alerts



The Medicines and Healthcare products Regulatory Agency (MHRA) is changing the way it issues safety-critical alerts to healthcare providers.

From now on, all safety-critical alerts for medicines and medical devices that require action to be taken by healthcare organisations will be issued as National Patient Safety Alerts. These alerts follow criteria and a template agreed by the National Patient Safety Alerting Committee (NaPSAC).

This is to ensure that National Patient Safety alerts:

- are only issued for safety-critical issues (those that have a risk of death or disability) that require organisations to act
- explain risk clearly and effectively
- have required actions that have been assessed for feasibility, safety, efficacy and cost-effectiveness
- can be quickly recognised and actioned by senior personnel
- have actions that are SMART (specific, measurable, achievable, realistic and timely).

Failure to take the actions required by any National Patient Safety Alert may lead to the Care Quality Commission (CQC) taking regulatory action in England.

All healthcare providers that currently receive medical device alerts and drug alerts should now ensure they subscribe to receive National Patient Safety Alerts [here](#).

In the short term, drug alerts and medicines safety communications that do not meet the NaPSAC criteria will continue to be issued as per the current format and process while the MHRA consults with the health system and

healthcare professionals to determine the best way for these to be issued going forward.

Safety communications for medical devices that do not meet the NaPSAC criteria will change and these changes will be communicated in due course.

NaPSAC consists of representation from all organisations that issue safety information to the NHS. It was established to improve the effectiveness of safety-critical communications and to support providers to better implement the required actions to ensure patients are protected.

The MHRA is the second organisation to be accredited to issue these alerts, after NHS England and Improvement's National Patient Safety team.

For more information on National Patient Safety Alerts, please visit:

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