Medicines & Healthcare products Regulatory Agency

MHRA

The table below explains the new Medicines Recall and Notification classifications and the associated defect risk classification.

Medicines Recall/Notification Classification	**Defect risk classification**
National Patient Safety Alert (NatPSA) equivalent to Class 1 Medicines Recall	The defect presents a risk of death or disability. These alerts will be issued via CAS as National Patient Safety Alerts and will be published on the MHRA website.
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.