Protecting patients from harm with drug alerts and recalls for defective products

Medicines Management provides essential evidence-based information for nurse prescribers and those involved in administering medicines

**WHY ARE RECALLS AND DRUG ALERTS NECESSARY?**

Drug alerts and recalls are carried out to protect patients from the harm that may be caused to them by defective medicines.

A defective medicine is one that is likely to be harmful under normal conditions of use, one that does not comply with its marketing authorisation (its registered specification), one that is lacking in therapeutic efficacy or one that has not been manufactured in accordance with standards of good manufacturing practice.

Recalls are usually carried out by the marketing authorisation holder, the manufacturer or the importer, and are normally intended to inform distributors, healthcare professionals and others that particular batches should be withdrawn from the distribution chain and, where necessary, from patients and carers.

Manufacturers, importers and distributors are obliged to inform the UK medicines and medical devices regulator, the Medicines and Healthcare products Regulatory Agency (MHRA), of any suspected quality defect in a medicinal product that could or would result in a recall or a restriction on supply.

Healthcare professionals also have a responsibility to inform the MHRA of any matter that the agency might reasonably conclude relates to a quality defect.

Patients or members of the public who have reason to believe that their medicine is not of an acceptable quality should first consult their doctor or a pharmacist who may then decide to refer the matter to the MHRA.

**REPORTS TO THE MHRA**

All reports of defective or suspected defective medicines made to the MHRA are referred to its defective medicines report centre (DMRC).

The DMRC provides an emergency assessment and communications system between suppliers, regulatory authorities and users. It does this by receiving and assessing reports of suspected defective medicines, monitoring and advising, and directing actions. It communicates the details of actions with the appropriate urgency to recipients of the products and other interested parties in the UK and elsewhere by means of drug alerts.

In many cases, the DMRC will issue a drug alert to recipients (healthcare professionals) in and outside the NHS to support a recall.

Not every substantiated defect results in a drug alert. Some organisations are able to identify every customer (patient) who received the defective product – for example with some hospital-only products – and, where the MHRA is assured that all customers can be reached, the DMRC may decide not to issue a drug alert.

The MHRA must be advised of any defect that could result in a recall. Organisations must not undertake any recall without first discussing this with the DMRC.

Drug alerts are classified into four categories, depending on the potential for harm and the speed with which action should be taken.

A class I alert is issued when a defect is potentially life-threatening or presents a serious risk to health. Class I alerts are also issued for counterfeit products because their composition is unknown so they can potentially cause harm. The response to a class I drug alert should be immediate on receipt.

A class II alert (action within 48 hours) is issued when a defect could cause illness or mistreatment. A class III alert (action within five days) is one that, although not posing a significant hazard, nevertheless requires action.

Where a defect poses no threat to patients, or is unlikely to impair product use or efficacy, the DMRC may issue a class IV ‘caution in use’ alert.

Class I and class II alerts are also sent by way of an established rapid alert system to medicine regulators in other countries.

The MHRA knows that a recall may significantly affect product availability. In such cases, the DMRC consults with the Department of Health and the NHS Purchasing and Supply Agency before a course of action is decided.

Drug alerts and recall notices usually include instructions on what to do to ensure that the defective batch is removed and how to return it to the recalling organisation.

It is important that the product is removed from all locations. Nurses can assist by checking ward stocks when they receive notification.

It can be difficult to reach all patients who may have received a defective product as a recall or drug alert will normally go only as far as the healthcare professional or pharmacy. If a patient-level recall is required, a notice will be reported in newspapers and, in extreme cases, it will be on radio and television.

**A BUSY SECTION OF THE MHRA**

- The DMRC receives about 600 reports of suspected defective medicines each year, of which fewer than 10% are normally substantiated.
- Reports in 2008 resulted in 35 drug alerts, of which one was at class I. Packaging, labelling and patient information leaflet errors comprise the highest incidence of defects resulting in recall.
- All drug alerts are followed up by the DMRC to ensure that defective products have been withdrawn and the manufacturer or importer has acted to prevent a recurrence of the defect.
- The MHRA encourages everyone to be vigilant, in particular pharmacists, nurses, doctors and patients. It treats all reports as potentially serious in its primary role of protecting public health.

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