Substandard (Defective) Medicines

Purpose of this procedure:

A substandard medicine is one which does not meet the quality specification set by national standards or specification of the medicine's licence. This may be in relation to the poor manufacturing practice, inadequate quality control, incorrect storage, or inappropriate packaging/labelling. This procedure guides staff on the process to follow when notified regarding a substandard medicine or when staff believe that a medicine may be substandard. Substandard medicines are also referred to as defective medicines.

The Procedure:

1.0 Substandard medicine

1.1 Notification of a substandard medicine may occur via various routes:

- Official notifications of substandard medicines are issued from the Scottish Government as a Medicines Recall. These include the required timescale for action.
- From the manufacturers or suppliers
- Identified by Pharmacy staff or end users

1.2 The Director of Pharmacy and Medicines must ensure that there are systems in place to address notifications by any route. They must ensure that there are systems in place to investigate local reports of substandard medicines, to withdraw from use other affected stock if appropriate, and to inform the Scottish Government, Pharmacy and Medicines Division, if there are implications for the rest of the health service.

1.3 Systems must also be in place to check if an identified substandard medicine has been issued or used within NHS Lothian, to alert clinical staff and to withdraw from use any substandard medicine that has been issued, if necessary, within the required timescale for action.

1.4 Substandard medicines or potentially substandard medicines must be withdrawn from use in an appropriate timescale to minimise risk to patients.

1.5 If any member of staff or independent contractor has reason to believe that a medicine is substandard, they must inform a pharmacist immediately. The pharmacist is responsible for taking appropriate action such as supporting the completion of an incident or DATIX report.

1.6 Any person who discovers a defective medicine must ensure that the product, container, and other packaging are retained. If the defect has been discovered following reconstitution or mixing with another preparation, then the mixture, remaining unmixed constituents, and all containers and other packaging must also be retained. All retained materials must be placed in a sealed container, clearly marked 'Do not use', and returned to the pharmacy as soon as possible. A member of the pharmacy team should be informed in advance of this item being returned to pharmacy.

Associated materials/references:

The Safe Use of Medicines Policy