

Medicinal product quality defects reporting

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Introduction

One of the ways in which the Medicines Authority protects public health is by minimising the risk to patients arising from the distribution of defective medicinal products. It achieves this by managing an assessment and communications system, between suppliers of medicinal products, the regulatory authorities and the users including patients, and when required oversees the removal of the defective medicinal products from the local market.

Holders of a manufacturer's, importer's and wholesale dealer's licence are obliged to report to the Medicines Authority any defect in a medicinal product handled under their authorisation that could result in a recall or abnormal restriction in supply. This includes possibly faulty manufacture, product deterioration, detection of falsified medicines

or any other serious quality problems with a product.

Reporting of suspected product quality defects

Reports of suspected defects may also be sent to the authorities by other competent authorities, healthcare professionals and members of the general public.

If a member of the general public has reason to believe that their medicine is not of an acceptable quality, they should, in the first instance, consult with their doctor or pharmacist who may then decide to refer the matter to the Medicines Authority, since the doctor or pharmacist may be in a better position to provide prompt advice and/or reassurance to the patient. However, if it is not possible to speak to a doctor or pharmacist and the patient feels that the

matter is urgent, they may contact the Medicines Authority directly.

The role of the Medicines Authority is to provide an assessment and communicate between suppliers of medicinal products, the regulatory authorities and the users. Where a defective medicine is considered to present a risk to public health, the marketing authorisation holder, the manufacturer or wholesale dealer as appropriate, is responsible for recalling the affected batch(es) or, in extreme cases, removing all batches of the product from the market. The Medicines Authority will normally support this action by the issue of a drug alert notification to healthcare professionals.

Product recalls

A product recall is defined as the retrieval from the marketplace of a batch or batches of any medicinal product which is/are the subject of a quality defect.

Product recalls are categorised according to the potential impact of the issue giving rise to the need for a recall, on patients and public health. There are three classes of recalls:

- **Class I recalls** – generally for critical quality defect issues. These are recalls which result from quality defects of medicinal products which are potentially life-threatening or could cause a serious risk to health;
- **Class II recalls** – generally for major quality defect issues. These are recalls due to quality defects which could cause illness or mistreatment but are not Class I;
- **Class III recalls** – generally for minor quality defect issues. These are recalls due to quality defects which are not likely to pose a significant hazard to health but where a recall has been initiated for other reasons.

In the case of Class I and Class II recalls, the Medicines Authority will notify regulators in other countries using the European Rapid Alert System.

Reporting of suspected quality defects

Suspected quality defects can be reported by using the Medicinal Product Defect Reporting Form.

Email: inspectorate.adm@gov.mt
Tel: 00356 2343 9000

medicinesauthority.gov.mt/recallsrapidalerts