Quality defects, falsified products and rapid alerts

Jacques Morénas
Deputy Director
Inspectorate and Companies Department
The French Health Products Safety Agency (AFSSAPS)
telephone : 33 1 55 87 39 17
fax : 33 1 55 87 39 12
e-mail : jacques.morenas@afssaps.sante.fr

afssaps
Agence française de sécurité sanitaire des produits de santé

Agenda

- Handling of suspected quality defects
- Rapid Alert System (RAS)
- Falsified Products

Handling of suspected quality defects

Goal: to record and handle notifications of suspected defective products during and outside working hours

Handling of suspected quality defects

Definitions

- *Suspected defective product.* A medicinal product about which a report has been received suggesting that it is not of the correct quality, as defined by its Marketing Authorisation.

- *Batch recall*. The action of withdrawing a batch from the distribution chain and users. A batch recall may be partial, in that the batch is only withdrawn from selected distributors or users.

Handling of suspected quality defects

Responsibility

Holders of an authorisation under Article 40 of Directive 2001/83/EC (i.e. manufacturers and importers of medicinal products) are obliged under Article 13 of Directive 91/356/EEC and GMP Guide 8.8 to report to their Competent Authority any defect in a medicinal product handled under their authorisation that could result in a recall or abnormal restriction in supply. It is normally the Qualified Person who has this responsibility.

For competent authorities : It is crucial to design a person/ or a structure responsible to record, handle notifications, propose and apply actions

Handling of suspected quality defects

Different phases

Always using Quality Risk Management (QRM) principles and as defined in the related SOP of the Compilation of EU procedures

- Recording information

- Collecting and assessing information
  - if the quality defect is real (take care on pharmacovigilance / adverse drug reaction due to a quality defect)
  - if there is more than one complaint [on the concerned or other batches]
  - if the quality defect is related to manufacture, storage, transport or use
  - risks for public health
  - risks for stock outage
  - existence of alternative products

Handling of suspected quality defects

- Sampling (collecting the involved suspected defective products + the concerned batch at the manufacturing site + other batches to check if the problem is dedicated to one or more batches)
- On site inspection (if necessary)
- Testing samples (OMCL)
- Preparing the decision (HMA or other designated person) using Quality Risk Management principles
- Validating the proposal (internal Quality Management System)
- Implementing the decision (by the NCA and the manufacturer/ marketing authorisation holder) which affect a batch; different batches of the same products, different batches of products manufactured in the same workshops, withdrawal of the marketing authorisation and/ or the manufacturing authorisation

Handling of suspected quality defects

- Sharing the information (internet, professionals, Rapid Alert System, …)
- Filing and archiving the dossier

Rapid Alert System (RAS)

Using principles as defined in the relevant SOP of the Compilation of the EU procedures (handling RAS and recalls arising from quality defects)

Each NCA should develop a system for the transmission of information by means of a rapid alert between the Competent Authorities of EU and EEA countries (the “Member States”), CADREAC, PIC/S, EDQM and MRA partners relating to the recall of medicinal products which have quality defects, including counterfeit or tampered products, when urgent action is required to protect public health.

The aim of the Rapid Alert System is to transmit only those alerts whose urgency and seriousness cannot permit any delay in transmission.

Rapid Alert System (RAS)

Class I : defects are potentially life threatening

Class II : defects could cause illness or mistreatment, but are not Class I

Class III : defects may not pose a significant hazard to health, but withdrawal may initiated for other reasons.

Rapid Alert System (RAS)

Responsibility differs following the nature of the marketing authorisation:

- Centralised
- Mutual recognition/ Decentralised procedure
- National

Falsified products

Emergence with globalisation of the market of medicinal products, internet access, lifestyle products, costs of medicinal products, lack of harmonised regulations and cooperation between NCA.

At the EU level, different activities ongoing

- The Commission initiatives (pharma-package)

- The EU network of enforcement officers (HMA initiative)

- The EDQM initiatives

- The EMA and MS initiatives

Falsified products

The Commission initiatives (pharma-package)

- Obligation of safety measures (prerscribed medicines and risk-based

- Improvement of the legislation and related guidances on wholesaling activities (including the development of the EudraGDP database

- Improvement of the legislation and related guidances on API (qualification of API suppliers, audit of the suppliers by the manufacturer of the medicinal product)

- Waiting for the final co-decision between the EU Parliament, the EU Commission and the EU Council.

Falsified products

The EU network of enforcement officers (HMA initiative). Five workstreams ongoing:

- Wholesale and distribution
- Internet threats
- Counterfeits medicines
- API and counterfeits threats
- Training and education

Falsified products

The EDQM initiatives:

- Project for a track and trace service for medicines

- Council of Europe Anti-Counterfeiting Convention: convention against counterfeiting of medical products and similar crimes involving threats to public health (Medicrime)

Falsified products

The EMA and MS initiatives:

- New GDP guidelines (aligned with those from WHO)

- A new set of EU SOP dedicated to training of inspectors, format of wholesaling authorisation, inspection …..

Хвала вам на аттентон

Thank you for your attention