TEXT to be included on sante.lu regarding quality defects

What is a quality defect of a medicinal product?

A quality defect of a medicinal product is defined as non-compliance with the specifications described in the Marketing Authorisation Dossier (MAD) or a deviation from Good Manufacturing Practices (GMP). This quality defect may affect the quality, safety and/or efficacy of the product.

Quality defects may be of different types and relate to:

- Contamination of chemical, particulate, or microbiological origin,
- Quantitative deviations (e.g., absence of a tablet in the blister),
- Qualitative deviations (e.g., unusual aspects of the product, smell, colour, transparency),
- Packaging anomalies (notice, packaging)

These quality defects can be detected at several levels:

- When analyses are carried out as part of quality controls by the marketing authorisation holders (MAH) and/or their representative,
- By wholesaler-distributors,
- When the product is delivered by a dispensing pharmacist or hospital pharmacist,
- When the product is used by the patient or a healthcare professional
- During analyses carried out in the context of market surveillance by the DPM or another competent authority
- When reporting a pharmacovigilance case.

The quality defect may or may not cause harm to the patient or healthcare professional. The quality defect may concern certain medicinal products of a batch, an entire batch or several batches.

The quality defects may be of three levels:

Critical / Class I	Defects having a significant, serious and severe impact on the quality, safety and/or efficacy of the product and posing a significant hazard to health
Major / Class II	Defects that may cause illness or inappropriate treatment, but are not Class I defects
Minor / Class III	Defects having no significant impact on the quality, safety and/or efficacy of the medicinal product and on human health

Why report a quality defect?

A quality defect of a medicinal product is likely to have an impact on the health or safety of patients.

Any declaration of quality defect shall lead to a thorough investigation by the MAH or their representative in order to identify the root causes and consequences. Quality defects may lead to a batch recall at national or even European level (depending on the defect), or changes to the precautions for use specified in the product information by the MAH. Any batch recall decision is validated by the DPM.

How to report?

Any quality defect must be reported to the DPM using the online forms and sent preferably by email or by post:

- Patient form
- Healthcare professional / wholesaler-distributor / marketing authorisation holder form

DPM contacts:

- E-mail: qualitydefects@ms.etat.lu for medicinal products for human use, or luxvet@ms.etat.lu for veterinary medicinal products
- Postal address: Division of Pharmacy and Medicines of the Health Directorate, Market Surveillance, 2, rue Thomas Edison, L-1445 Strassen, Luxembourg
- Telephone: (+352) 247-85592