

***Crisis Management regarding Defects of Centrally Authorised Products***  
**Classification of Batch Recalls for Quality Defects**

**Class 1:** Defects, which are potentially life-threatening or could cause serious risk to health.

Examples:

- 1.1: Wrong product (label and contents are different products).
- 1.2: Correct product but wrong strength, with serious medical consequences.
- 1.3: Microbial contamination of sterile injectable or ophthalmic product.
- 1.4: Chemical contamination with serious medical consequences.
- 1.5: Mix up of some products (“rogues”) with more than one container involved.
- 1.6: Wrong active ingredient in a multi-component product with serious medical consequences.

**Class 2:** Defects, which could cause illness or mistreatment but are not Class 1.

Examples:

- 2.1: Mislabelling: e.g. wrong or missing text or figures.
- 2.2: Missing or incorrect information - leaflets or inserts.
- 2.3: Microbial contamination of non-injectable, non-ophthalmic sterile product with medical consequences.
- 2.4: Chemical/physical contamination (significant impurities, cross-contamination, particulates).
- 2.5: Mix up of products in containers (“rogues”).
- 2.6: Non-compliance with specification (e.g. assay, stability, fill/weight).
- 2.7: Insecure closure with serious medical consequences (e.g. cytotoxics, child-resistant containers, potent products).

**Class 3:** Defects which may not pose a significant hazard to health but where a recall has been initiated (perhaps not required by the competent authority) for other reasons, but are not Class 1 or 2.

Examples:

- 3.1: Faulty packaging: e.g. wrong or missing batch number or expiry date.
- 3.2: Faulty closure
- 3.3: Contamination
  - microbial spoilage
  - dirt or detritus
  - particulate matter