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Updates to the IMB Guide to Reporting of Quality Defects

GMP & Market Compliance Information Day, *27th September 2012*

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Market Compliance Technical Officer

Content

Recap on content of guidance note

Significant updates

Further guidance on initial investigation

Case studies – ask the audience!

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Reporting Guidance Note

- First published September 2010
  - Stakeholders (e.g. manufacturers, MAH, wholesalers)
  - Aim: Risk-based approach to Quality Defects

- Main content
  - legal requirements to report defects
  - classification of defects
  - criteria to determine if defect reportable
  - use of QRM
  - examples of defects and associated requirements to report

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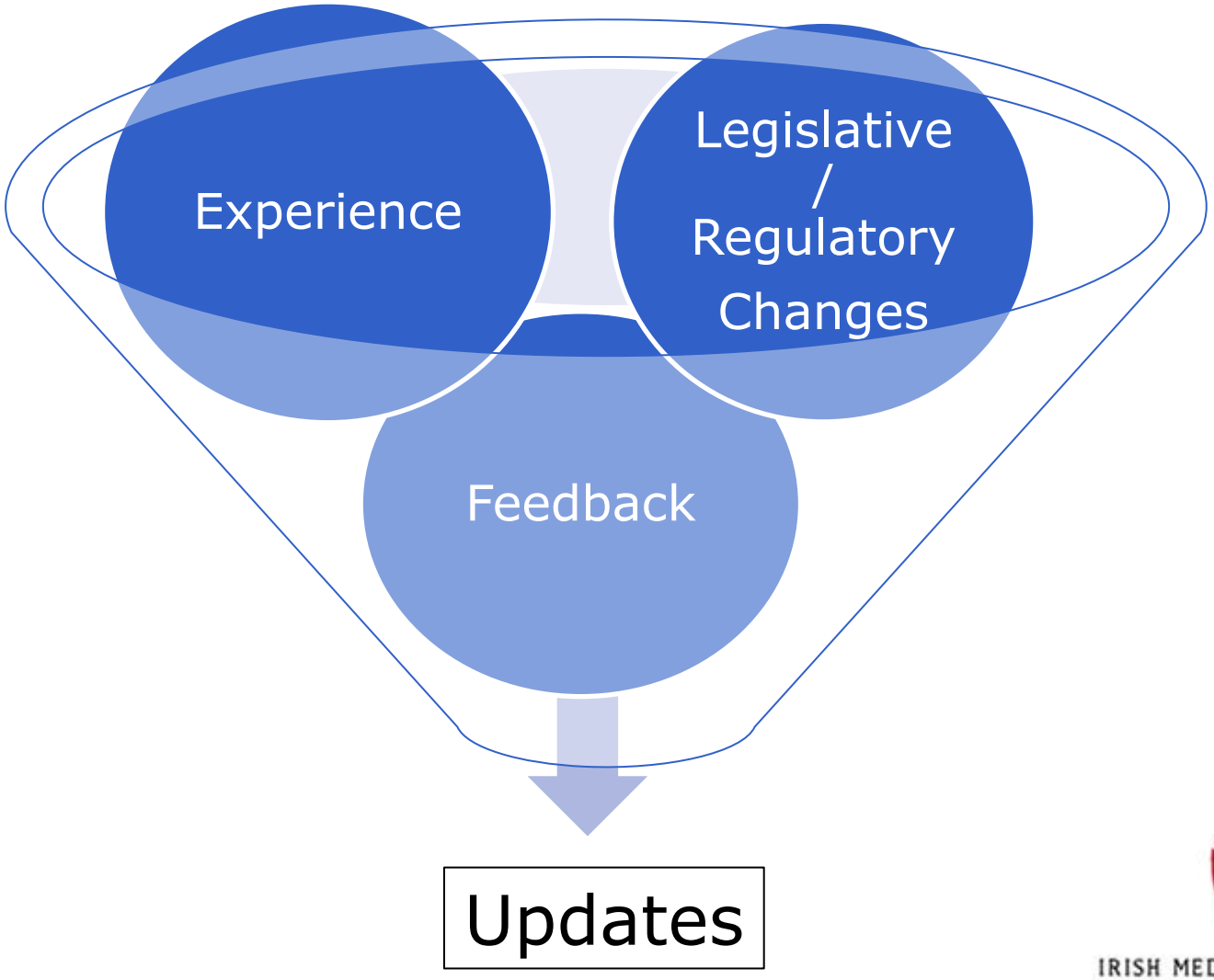
After Two Years.....



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Case Studies – Voting Pads

1. One report received from the Irish market
   - Tablets crumbling in all 3 blister strips in one pack
   - Sample available – sent to manufacturer (results available in 2 weeks)
   = Physical damage to oral solid dose

Question: 1 – Reportable 2 – Not reportable

2. One report received from the Irish market
   - One ampoule showing mild discolouration
   - Testing of complaint samples underway
   = Impurities / contamination of a sterile solution

Question: 1 – Reportable 2 – Not reportable

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(Significant) Updates to the Guidance Note

Scope

- Addition of **active substance manufacturers**

'In the event of a serious or potentially life-threatening situation, local, national and/or international authorities should be informed and their advice sought'

(as per Part II of the EU Guide to Good Manufacturing Practice).

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Updates (continued)

Introduction

- Slight update to reflect term from EU / Irish regulations:

  'recall or abnormal restriction on supply'.

  - general legal basis for reporting quality defects, as per Irish SIs, GMP Guide

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Updates (continued)

Guidance on initial defect investigation

- New section, incorporating Quality Risk Management, includes best practice guidance on information gathering, e.g:

  - obtaining further information on the defect, including samples, correspondence with defect reporter
  - batch distribution and complaint details
  - batch records and historical data

Combine above with QRM to assess **extent** and **risk**

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Updates (continued)

When might a quality defect be considered non reportable?

- Change made to Criterion (iii) - General rule not to report no longer applies to minor defects only

- Certain major defects may not be reportable

  - if a company has assurance that the defect is isolated and that other units on the market do not pose a similar risk.

  - if doubt exists, consult with IMB to determine

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Updates (continued)

Categories of Defects

- Some categories have moved from 'Should Always be Reported' to 'Should not Always be Reported'
  - Non-adherence to cold chain
    - When assurance obtained that product not affected
  - Unauthorised Product on Market
    - When identified prior to being made available for sale at primary wholesaler

- New category in 'Should Always be Reported'
  - Non-implementation of variation / transfer

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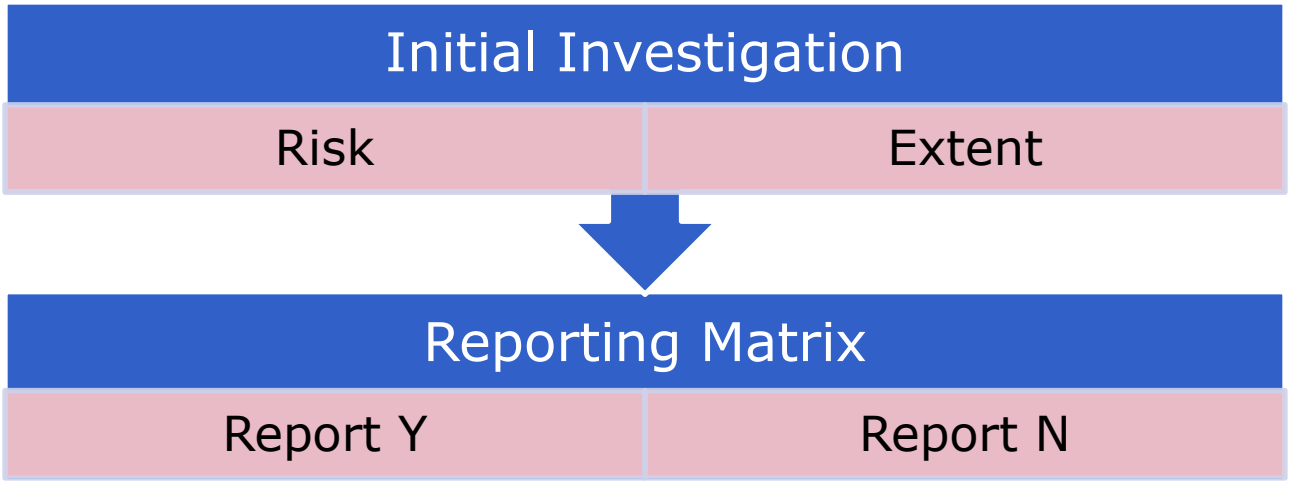
Updates (continued)

New Initial Investigation Reporting Chart



Appendix – Information to be provided to the IMB

- Product Details
- Distribution Details
- Details of defect and similar issues, investigations etc

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Case Studies – Voting Pads

1. One report received from the market
   - Tablets crumbling in all 3 blister strips in one pack
   - Sample available – sent to manufacturer (results available in 2 weeks)
   - Minor physical damage – reportable or not reportable?

2. Report received from the market
   - One ampoule showing mild discolouration
   - Testing of sample underway
   - Impurities / contamination of a sterile solution – reportable or not reportable?

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Case Study Answers

1. Batch on the market 3 weeks

   While sample being tested, 3 more complaints received of crumbling tablets

   Testing confirmed ingress of moisture into blister

   Retains tested – OOS for moisture content

   Recall to pharmacy level – defective blister foil

2. Testing of defect sample confirmed oxidation of active substance, but no OOS for assay or rel. subs

   Other retains unaffected, no complaints

   Batch Records did not indicate issue with batch

   Isolated to one unit, low to moderate risk

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Learnings from Case Studies

No right or wrong answer, based on initial information!

- Importance of **Information Gathering** (timely manner)!

Recommended

- Further correspondence with reporter
- Physical / photos of sample
- Total units of batch on market vs complaints
- Check retains / quarantined stock

- Can help decide if defect reportable / prevent further defective stock reaching the market

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Overall good practice for all scenarios!

How to Contact the IMB

- Relevant Contacts at the IMB for Quality Defects

- Online, at www.imb.ie
- By e-mail, to recallsandqualitydefects@imb.ie
- By telephone, using the following contacts:

Ms. Aoife Farrell, Quality Defects and Recall Manager
Ms. Breda Gleeson, Market Compliance Inspector
Ms. Deirdre O'Brien, Healthcare Products and Market Compliance Inspector
Mr. Rob Smyth, Market Compliance Technical Officer
Mr. Kevin O'Donnell, Market Compliance Manager

Office contact no.: +353-1-676-4971

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