IRISH MEDICINES BOARD

Evaluation of Counterfeit Cases

Impact of FMD & GDPs

Wholesale Distribution Information Day, 28th September 2012

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Healthcare Products
Distribution Manager

Contents

1. Review of UK counterfeit cases & contributory factors

2. Review of legislative & regulatory developments and their preventative effects
   - FMD
   - Revised EU GDPs

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UK: Case 1

Operation Singapore

Contributory Factors

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Complex Supply Chain

Non-legitimate participants

Legitimate participants

Wholesalers- Luxembourg
- Belgium
Trading entity-Ireland

Parallel Traders

Re-packagers

Wholesale

Pharmacy

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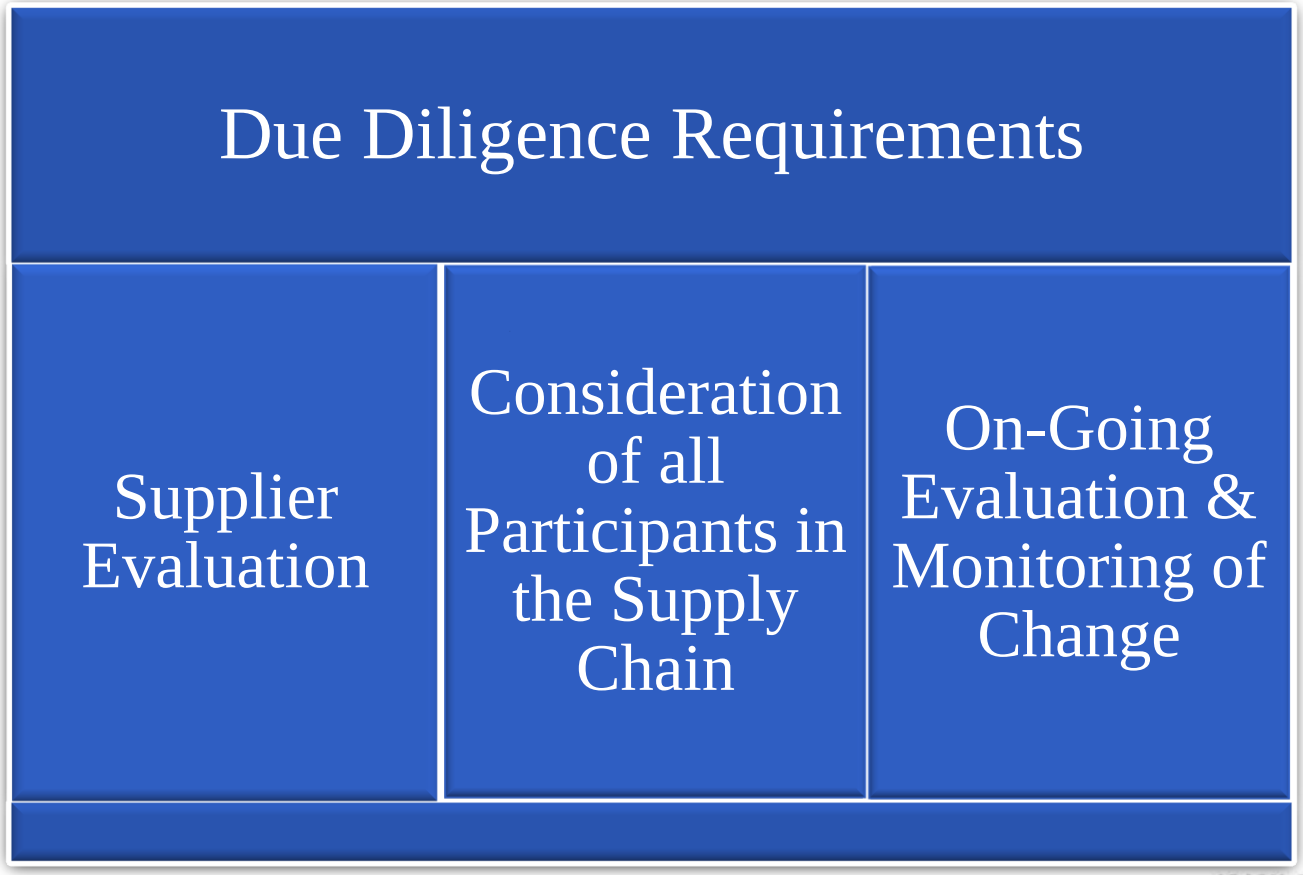
Factor 1: Due Diligence

FMD & Revised EU GDP Requirements



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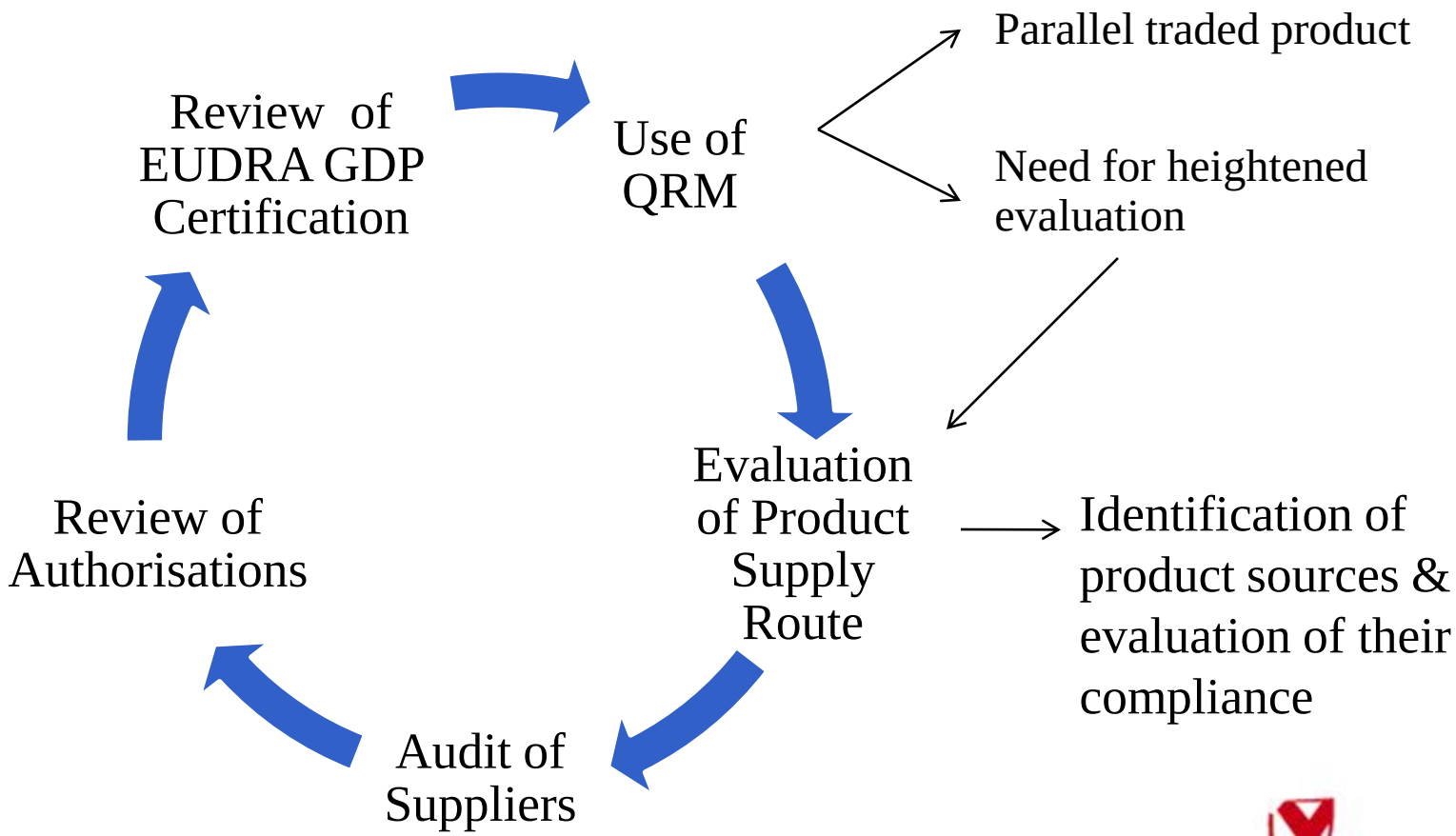
Due Diligence: Supplier Evaluation



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Due Diligence: Supplier Evaluation

Supplier Evaluation → **Documented Outcome**

•QRM Approach

Technical & Quality Agreement

- •Roles & Responsibilities
- •Authorisation & GDP Compliance
- •Supply Chain
- •Review Provision*

*Critical component for monitoring of change

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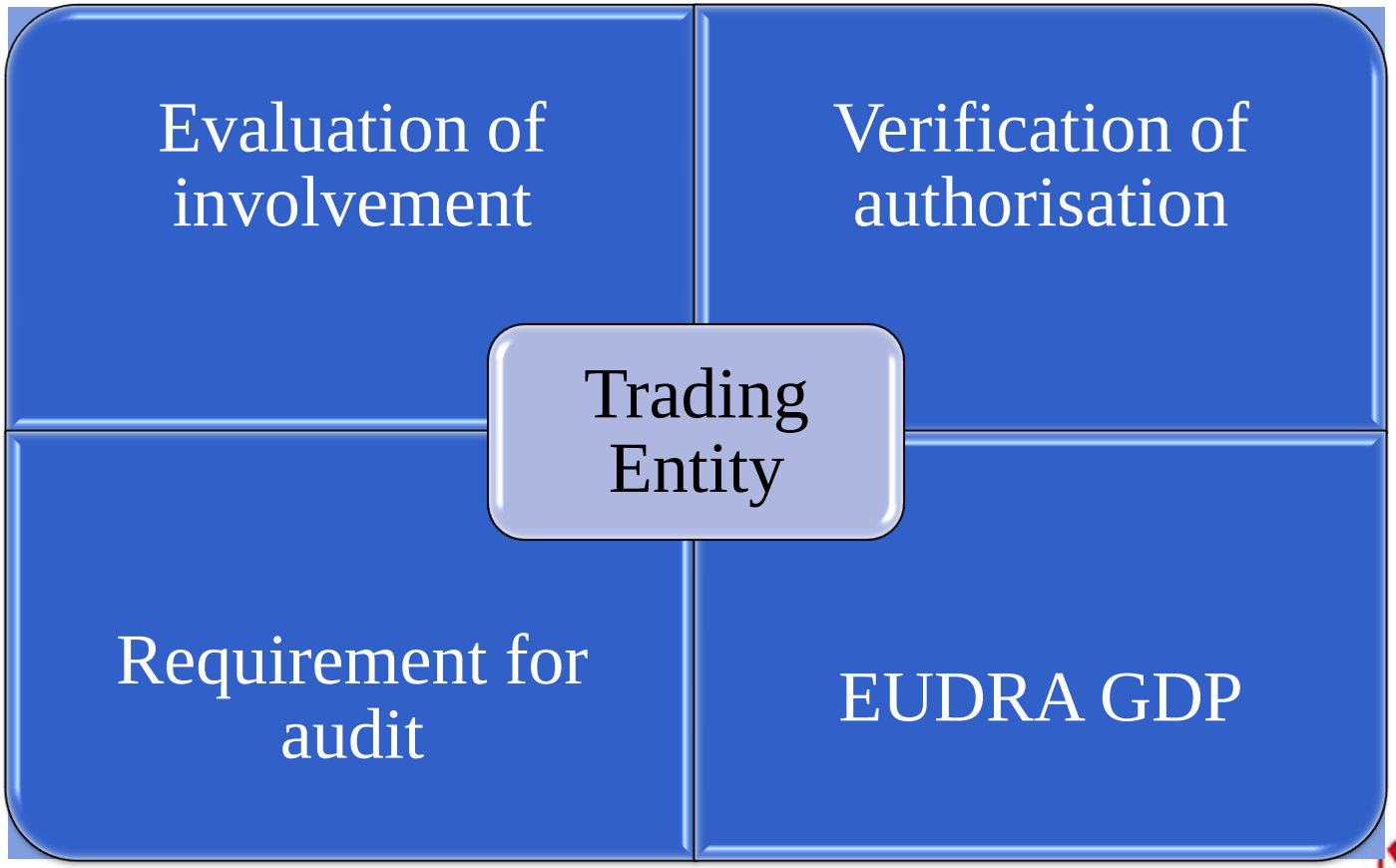
Due Diligence: Participants in the Supply Chain



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Factor 2: Strong Commercial Incentive

100 Packs —X 10→ 1,000 Packs

- Increased Availability of Product
- Strongly linked with due diligence for supplier evaluation

- Trigger for QRM Approach
  Review of the T&Q Agreement
  Review of supply chain
  Justification for the increase

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Factor 3: Information Exchange

•Suspicions relating to possible falsified medicine, not divulged to CA

Mandatory requirements for information exchange relating to falsified medicines

FMD

•Manufacturers : Article 46(g)
•Wholesalers: Article 80(i)

} Directive 2001/83, as amended

Revised EU GDPs

•Paragraphs 5.11, 6.3- obligations
•Paragraphs 6.13-6.16 - defined procedures

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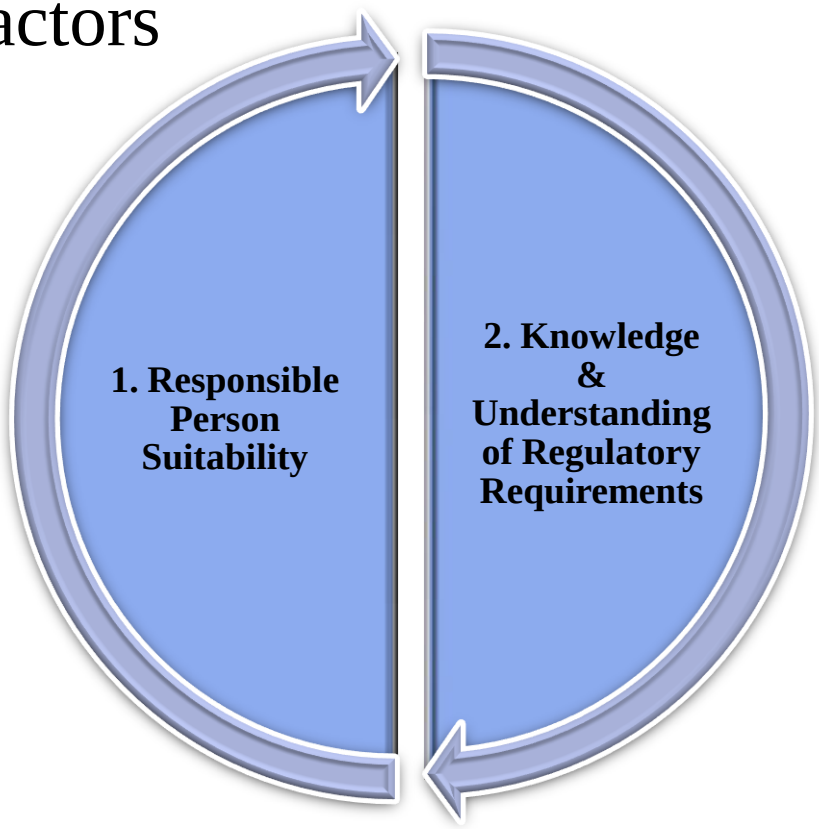
UK: Case 2

Falsified Truvada & Viread

Contributory Factors



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RP Suitability

Revision of EU GDPs/ Chapter 2 Personnel- General Issues

- More detailed requirements for RPs & other personnel;
- Specific emphasis on personnel being “competent” to perform their roles;
- More detailed requirements for definition of roles and responsibilities;
- Need for ensuring adequate availability of resource;
- More detailed training requirements;
- Includes scope for assessment by authorities of the adequacy of personnel based on risk.

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RP Suitability

Revision of EU GDPs/ Chapter 2 Personnel – the RP

Key Factors

- Qualifications have to be appropriate to the level of responsibility
- Scope to consider the level of qualification of the RP in the context of risk & complexity of the operation
- Highlights the primary function of the RP is to ensure compliance with legislation

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RP Suitability

Revision of EU GDPs/ Chapter 2 Personnel – the RP

Detailed Responsibilities

- 12 listed areas of responsibility
- Responsibility for performing the qualification & approval of suppliers
- Responsibility for contract approval

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Third Country Importation

Third Country Importation from Bulgaria factor in Truvada & Viread case

Revised EU GDPs/ Chapter 5- Operations

- Includes the need for distributors receiving medicinal products from third countries to hold a manufacturing/ import authorisation.

- Includes products imported for the purpose of exportation

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Safety Features

Safety Feature Requirements: Falsified Medicines Directive

- ✓ Longer term solution to be implemented from 2017
- ✓ Provide verification of product authenticity through unique identification feature
- ✓ Provide full track, trace history

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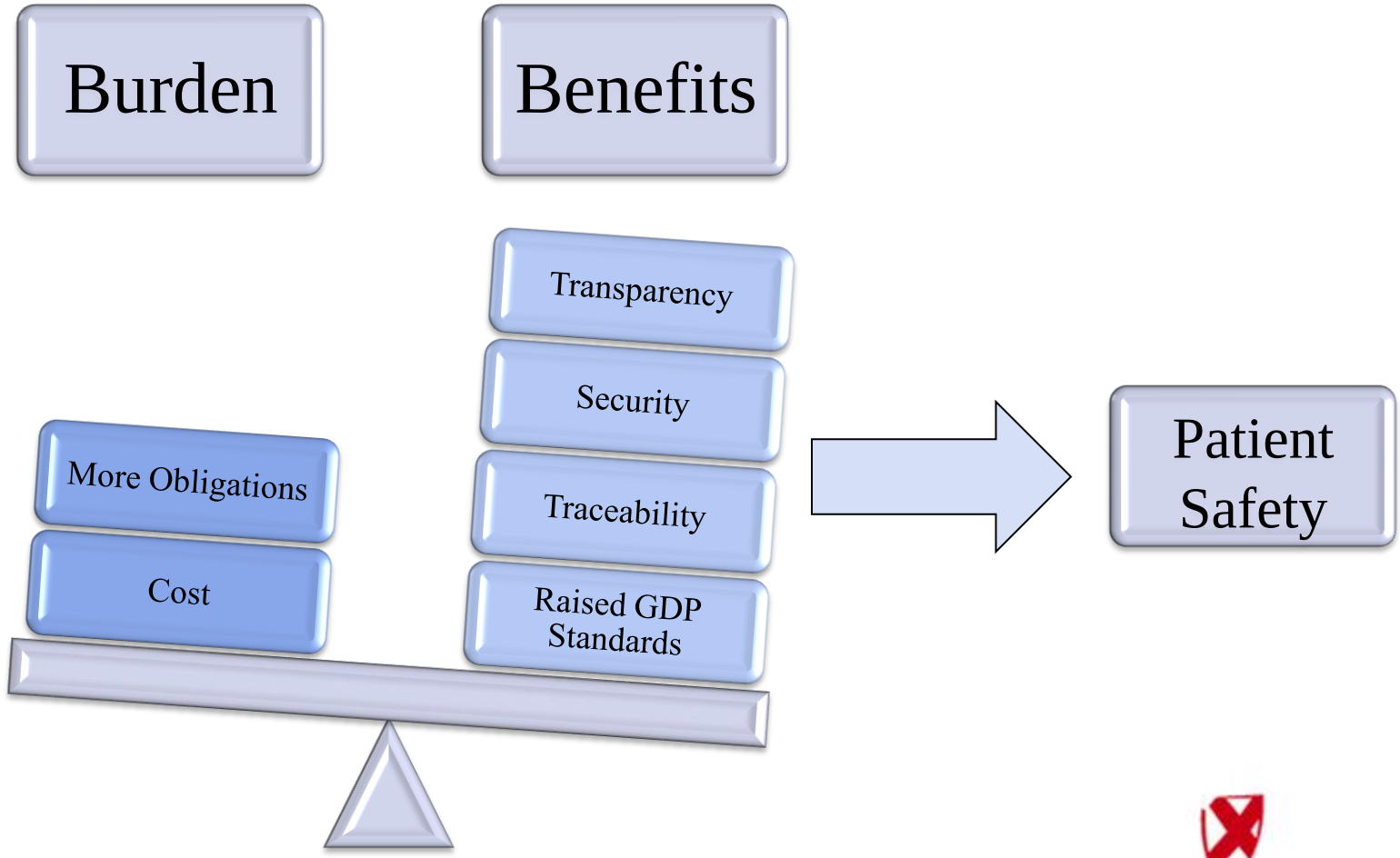
FMD & Revised EU GDPs



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Follow Up

Questions

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