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Commission's Pharma Package: Proposals - Counterfeits

Wholesale Distribution Information Day, 25/2/2010

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Introduction

- Purpose for GDP proposals
- Policy Options considered
- Definition
- Product Protection
- Wholesale Distribution



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Purpose- GDP

- Identify more easily falsified product
- Focus on packaging – physical
- Traceability – high risk products
- EU Frontier supervision - prevention



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Policy Options

- Tighten legal framework for
 - **Product Protection**
 - **Wholesale Distribution & Trading**
 - Import & Export
 - APIs
- Protecting the legal distribution chain



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Definitions

- Customs legislation-
 - **Regulation (EC) 1383/2003**
 - counterfeit = IPR breaches
- Counterfeit v falsified product (medicinal product legislation)
 - New definition?



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Consideration Product Protection

- Responsibilities
 - Notification of address in EEA
 - Goods in Transit/Import for export
- Safety
 - Responsibility for fixing safety features
 - Safety features & Risk Criteria
 - Verification of product



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Wholesale Distribution

- Subject all actors in distribution chain to conditions of wholesaling (except pharmacies, retailers)
- Strengthen GDP compliance inspections through
 - harmonised provisions:
 - GDP Community database
 - Compilation of Community Procedures for GDP
 - Proposed supplier auditing



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