L-Awtorità dwar il-Mediċini

Regulation of Medicines Supply Chain

Simon Serge

B Pharm (Hons)

Medicines Inspector

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Medicines Authority
203,Level 3,
Rue D'Argens,
Gzira,GZR 1368
Tel: (+356) 2343 9000
Fax: (+356) 2343 9161
Email: patricia.vella@gov.mt

Objectives

- To describe the three strata present in the supply chain of medicinal products, and how regulation is applied at each

- To identify risks present in supply chain and how these can be managed

Simon Serge *Medicines Inspector*
simon.serge@gov.mt

Manufacturer / Importer

- Converts starting materials into medicinal product
- Imports medicinal products from third countries
- Controls quality of medicinal product
- Has a Qualified Person available to release medicinal product to the market

Simon Serge *Medicines Inspector*
simon.serge@gov.mt

Qualified Person

- Secures that every product batch released is manufactured
  - according to Marketing Authorisation
  - in compliance with laws in force

Simon Serge *Medicines Inspector*
simon.serge@gov.mt

Qualified Person

- Ensures that every product batch imported undergoes
  - ➢ full qualitative analysis
  - ➢ quantitative analysis of at least its active constituents
  - ➢ all other tests and checks necessary to ensure the quality of the medicinal product is in accordance with its Marketing Authorisation

Simon Serge *Medicines Inspector*
simon.serge@gov.mt

Manufacturer / Importer

- Requires a licence from the Competent Authority
- Can only carry out activities included in scope of licence
- Must follow principles and guidelines of

  Good Manufacturing Practice
- Must follow conditions of licence
- Subject to regulatory inspection at least once every 3 years

  (as of 2013, frequency will be risk-based)
- Manufacturing sites in third countries audited by importer's QP

  and inspected by an EU/EEA competent authority

Simon Serge *Medicines Inspector*
simon.serge@gov.mt

Wholesale Distribution

- Refers to distribution within the EU/EEA
- Follows Good Distribution Practice guidelines
- Wholesale dealers have a Responsible Person available
- Subject to regulatory inspection (currently every two years, unless more frequent inspection necessary)

Simon Serge *Medicines Inspector*
simon.serge@gov.mt

Responsible Person

In Malta, eligibility limited to pharmacists recognized as suitable by the Medicines Authority

- Ensures that the license conditions are adhered to
- Ensures that the conditions for storage of medicinal products are in accordance with the requirements of the marketing authorisation and labelling
- Monitors all areas used for storage and distribution
- Maintains records as required
- Ensures that a quality system is developed and maintained in accordance with Good Distribution Practice

Simon Serge *Medicines Inspector*
simon.serge@gov.mt

Good Distribution Practice (GDP)

- that part of quality assurance which ensures that products are consistently stored, transported and handled under suitable conditions as required by the Marketing Authorisation or product specification.

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Community Pharmacies

- Every pharmacy and any store used by the pharmacy managed by a pharmacist
- Medicinal products prepared or dispensed only from a pharmacy and by a pharmacist
- All openings to the outside of the premises securely locked when the pharmacy is closed
- Safe disposal of pharmaceutical waste
- Generic substitution permitted (unless prohibited by prescriber)

Simon Serge *Medicines Inspector*
simon.serge@gov.mt

Community Pharmacies

- Minimum opening hours stipulated by legal notice
- Medicinal products protected from adverse effects of temperature, humidity, sunlight
- Medicinal products classified as POM or OTC
- Prescriptions for antibiotics valid for 10 days
- Other prescriptions valid for 6 months (unless repeat prescription)
- Exhausted prescriptions marked
- Inspected regularly, currently once every two years

Simon Serge *Medicines Inspector*
simon.serge@gov.mt

Community Pharmacies

- Pest control measures
- Surfaces and flooring easily wiped to facilitate cleaning
- Utensils for extemporaneous preparations

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Some Risks in Supply Chain of Medicinal Products

- Product quality inferior (non-compliance to GMP/MA)
- Incorrect storage conditions (loss of potency, excessive impurities)
- Counterfeiting
- Medicinal product not placed on local market
- Access to pharmacies
- Supply inadequate to meet demand
- Patient's right to be dispensed by a pharmacist usurped

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Thank You

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