

Wholesale Distribution/Importation Activities: Requirements

Information Session: Regulation of
Traditional Herbal Medicinal Products



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- Medicinal products placed on the local market must be in possession of a marketing authorisation/licence.
- Wholesale dealer's /Importer's licence is also required for the distribution/import of medicinal products and subsequent distribution in Malta or for export purposes.

Therefore both the product and the activity have to be licensed.

Wholesale dealing/Importation activities: requirements



What is wholesale distribution/importation?

Wholesale distribution of medicinal products refers to the procuring, holding, supplying or exporting medicinal products, apart from supplying medicinal products to the public. Products in this case are being brought into Malta from EU/EEA countries.

Importation of medicinal products refers to the procurement of medicinal products from a source outside the EU or EEA.

Wholesale distribution/Importation activities: requirements



Legislation

Wholesale dealing activity –

- EC Directive 2001/83 Articles 76 - 85
- Medicines Act III of 2003 Articles 54 – 65
- Legal Notice 386 of 2005

Importation activity –

- EC Directive 2001/83 Articles 40 - 53
- Medicines Act III of 2003 Articles 37 – 53
- Legal Notice 381 of 2005

<http://www.medicinesauthority.gov.mt/eulegislation.htm> EU
legislation

<http://www.medicinesauthority.gov.mt/legislation.htm>
Maltese legislation



Requirements

Wholesale dealer's licence (WDL) –

- Responsible Person (R.P.) –
 - A pharmacist (L.N. 386 of 2005)

Importer's licence (IL) –

- Qualified Person (Q.P.) –
 - Not necessarily a pharmacist but having a science background
 - Qualifications and experience are specified in Directive 2001/83 Article 49 as well as in L.N. 381 of 2005 Article 9
 - Requires a background in industry.
 - Eligibility is assessed by Medicines Authority

Wholesale distribution/Importation activities: requirements

Application for a WD's licence



- Application form can be downloaded from <http://www.medicinesauthority.gov.mt/applications.htm>

Consists of:

- Name/contact details of licence holder
- Site name, address, categories of products handled ex. OTC's, POMs, product classes
- RP details such as contact details, knowledge and experience
- C.V. of R.P., site plan, premises plan, MEPA permit, police conduct of applicant, Memorandum of Articles (if company)



- Application form can be downloaded from <http://www.medicinesauthority.gov.mt/application>
- Main differences from wholesale dealer's application include:
 1. Qualified Person
 2. List of products to be imported



1. Wholesale dealer's licence -
 - New application – €465.87
 - Renewal – €465.87

2. Importer's licence –
 - New application – €931.75
 - Renewal – €931.75
 - Those applicants who are already in possession of a GMP licence or of a WD licence – 50% of amount. Renewal remains the same.



- Site to have MEPA permit for the storage of medicinals in bulk
- Responsible Person/Qualified Person is to be present
- Quality system available i.e. procedures and any other pertinent documents describing the whole operation from procurement up to sale and delivery to customers
- Store is to be suitable for the storage of medicinal products



- Post-inspection letter is issued listing deficiencies, if any
- List of works, if any. Second inspection may be required depending on works that need to be affected
- If corrective actions are deemed to be acceptable, licence is recommended to the Licencing Authority and subsequently issued



1. Specific Information session on wholesale dealing and importation will be organised.
 - More detailed information
 - Held at Medicines Authority
 - For those who are being directly affected



2. One to one meetings with individual companies

All those interested to attend Info session are to send their name/company name and contact details on inspectorate.adm@gov.mt by end May 2010.

Thank You



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