- Set up through the Medicines Act in 2003 with functions delegated through the Licensing Authority
- Conducting EU Good Manufacturing Practice (GMP) inspections since 2004
- Full member of World Health Organisation (WHO) system for Pharmacovigilance and active in the European pharmacovigilance system since 2004
- Acting as Reference Member State (RMS) for marketing authorisation applications since 2007
- Part of the EU GMP Mutual Recognition Agreement (MRA) since 2007
- Members of the Joint Pharmaceutical Inspection Co-operation Scheme (PIC/s) since 2008
- Active participation in diverse activities and committees of the European Medicines Acency (EMA)
- Contributing to the drafting of EU legislation as European Member State
- Operating to a Quality Management System based on ISO standards
- Participating in the Benchmarking of the European Medicines Agencies exercise
- Participated in two EU funded twinning projects (training activities) with MHRA (UK)/ IMB (Ireland) and MEB (The Netherlands)
- Awarded six People Awards from the Foundation for Human Resources Development in the areas of Training and Development, Equal Opportunities, Employee Engagement award and the People Management Impact on Business Success

AWTORITÀ DWAR IL-MEDIĊINI

The Medicines Authority is delegated by the Licensing Authority to carry out functions for the regulation of medicinal products and pharmaceutical activities. The Medicines Authority is responsible for protecting and enhancing public health through activities which include evaluation of medicinal products and clinical trials and monitoring of medicinal products post authorisation. It is also responsible for the inspection and monitoring of pharmaceutical activities, monitoring of advertising of medicinal products on the market and enforcement of legislation. It supplies information about medicinal products, their rational use and availability on the market.

MALTAENTERPRISE

Malta Enterprise is the national economic development agency responsible for promoting and facilitating international investment in the Maltese Islands by offering investors excellent business opportunities and tailored services. The Malta Enterprise network operates in various countries around the globe, with offices or representations in embassies and consulates in Europe, North Africa, the Middle East, Asia, the United States and Australia. The Corporation also coordinates initiatives to promote the Islands' economic attractiveness.

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Published by the Medicines Authority with the support of Malta Enterprise

AWTORITÀ DWAR IL-MEDIĊINI

Regulation of

medicinal products and pharmaceutical activities in Malta

To protect and enhance public health through the regulation of medicinal products and pharmaceutical activities

Evaluation and authorisation of medicinal products

Every medicinal product is granted a marketing authorisation before being placed on the market based on a positive risk/benefit assessment of quality, safety and efficacy according to EU and national legislation

The Medicines Authority processes applications for the

- Granting, withdrawal, variations, renewals, revocation or suspension for all medicinal products related licences and authorisations
- Work-sharing of European procedures
- European clinical trials database

Malta as a Member State in the EU

- Encourages industry to include Malta as Concerned Member State (CMS) in Decentralised (DC) and Mutual Recognition (MR) procedures
- Participates actively in assessment of Centralised procedures (CP)

Malta as a European Union (EU) Member State accepts applications for acting as Reference Member State (RMS) for European Procedures to authorise medicinal products for the first time in the EU

Registration Procedures in EU

1. In the Mutual recognition procedure (MRP) a Member State may approve a previously EU-authorised product to be placed on the market in another Member State(s)
2. In the decentralised procedure (DCP) an applicant may apply for a marketing authorisation for a product not already authorised in the EU. This applies for both originator and generic medicinal products
3. An approval for a medicinal product intended for use in all EU Member States may be obtained by applying through the centralised procedure for special categories of products, for example, oncology and neurodegenerative disorders. These applications are coordinated by the European Medicines Agency

Scientific advice is offered for Applicants submitting applications where Malta is RMS.

Evaluation and authorisation of Clinical trials (CT)

The Medicines Authority evaluates clinical trial applications for clinical trials to be conducted in Malta. All clinical trials authorised in Malta are published in the European Clinical Trials Database. http://eudract.eudra.org/

Inspection and licensing of pharmaceutical activities

The main activities include the inspection and certification of pharmaceutical activities.

1. Inspection activities

- EU Good Manufacturing Practice (GMP) inspections of finished products' manufacturing sites both within the EU and in third countries; API manufacturers (EUand outside EU); partial manufacturers; importation activities and batch release sites
- EU Good Distribution Practice (GDP) inspections at wholesale dealers and brokers
- EU Good Clinical Practice (GCP) inspections of clinical trials
- EU Pharmacovigilance (PhV) inspections
- Pharmacy inspections

2. Certification

- Manufacturers and/or importation licences and handling of their variations;
- EU GMP compliance certificates
- Qualified Person (QP) authorisation for Malta
- Certificates of Pharmaceutical Product (CPP) to Industry for export to certain markets

3. Populating EudraGMP database

- EU Manufacturing and Importer`s licences
- EU GMP licences

http://eudragmp.eudra.org/inspections

The Medicines Authority is a participant of the Mutual Recognition Agreement (MRA). The European Community (EC) and MRA Partner Countries have established the MRAs to:

- Reduce technical barriers to trade
- Grant mutual acceptance of reports, certificates and authorisations
- Exchange information concerning procedures and
- Encourage greater international harmonisation

Inspectors work according to the "compilation of Community procedures on inspections and exchange of information"*

The Medicines Authority communicates with enterprises setting up an activity in Malta within the pharmaceutical industry and adopts a proactive approach.

*http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004706.pdf

Pharmacovigilance

The Medicines Authority

- Is responsible for the constant monitoring of the safety of medicines after authorisation
- Receives and transmits safety reports from within the EU and outside concerning authorised medicinal products
- Acts upon the information relating to the safety and quality of medicinal products;
- Publishes guidelines on the pharmacovigilance obligations for pharmaceutical companies which are available on the Medicines Authority's website
- Conducts pharmacovigilance inspections of Marketing Authorisation Holders (MAH) pharmacovigilance systems
- Processes routine and additional Risk Minimisation Strategies (Risk Minimisation Plans and Risk Minimisation Materials) and Direct Healthcare Professional Communications (DHPCs)
- Reviews and approves those activities that were designed to identify, characterise, prevent, or minimise risks related to the medicinal products