THE MMA telegram

ISSUE 01 – Q1 2020

Welcome dear colleagues to our first e-newsletter!

It is with great pleasure to announce that the e-newsletter will be issued on a quarterly basis to communicate internal updates, upcoming projects, events and scientific facts with regard to the regulatory sciences.

EVENTS

A look back at 2019…

Throughout 2019, the Authority reinforced its mission to protect and enhance public health through the regulation of medicinal products and pharmaceutical activities.

Prominent events included:

- Hosting of the President of the Republic of Malta during a courtesy visit;
- Celebration of the pharmacy profession in ensuring safe and effective medicines for all during the World Pharmacists Day 2019;
- Two awareness campaigns on breast cancer during Pink October and polypharmacy during the #MedSafetyWeek;
- Organisation of two advanced training courses in European Medical Device Leadership and Regulatory Sciences as applicable to Cannabis for Medicinal and Research Purposes;
- Participation in Science in the City 2019 with the aim of inspiring young scientists on the development of medicines from research to patients;

- Inauguration of the Academy for Patient Centred Excellence and Innovation in Regulatory Sciences;

EVENTS

- Participation in several **scientific conferences**:
  i. 24th European Association of Hospital Pharmacists Congress, Barcelona, Spain, March 2019
  ii. European Association of Faculties of Pharmacy Annual Conference, Kraków, Poland, May 2019
  iii. Professional Society for Health Economics and Outcomes Research (ISPOR) 2019 conference, New Orleans, USA, May 2019
  iv. 19th Asian Conference on Clinical Pharmacy, Manila, Philippines, June 2019
  v. 79th International Pharmaceutical Federation World Congress of Pharmacy and Pharmaceutical Sciences, Abu Dhabi, UAE, September 2019
  vi. European Society for Medical Oncology congress, Barcelona, Spain, September 2019
  vii. 48th European Society of Clinical Pharmacy Symposium, Ljubjana, Slovenia, October 2019;
- Holding of a networking event on the **implications of cannabis for medicinal purposes**;
- Organisation of workshops for clinicians on **adverse drug reaction (ADR) reporting**;
- Hosting of **information seminars** for the public to raise awareness on the rational use of medicines, the influenza vaccine and the difference between over-the-counter and prescription-only medicines;
- Participation in the **Medical Cannabis World Forum**;
- Hosting of **high-level European meetings**:
  i. EMA Paediatric Committee Meeting
  ii. HMA WGQM (Working Group of Quality Managers) Meeting
  iii. Council of Europe EDQM Medicrime Inspector Workshop

Pink October

31 October 2019

Employees were encouraged to wear pink to support breast cancer patients and raise awareness on early breast screening

Malta Medicines Authority
Key Figures
2019

89 Employees at the Authority

19 Third country EU GMP inspections

48 Procedures with MT acting as RMS or rapporteur

107 Individual queries handled by the MIAU

189 Individual Case Safety Report (ICSRs) registered

46 Research publications and presentations

Acronyms: Malta (MT); Medicines Intelligence and Access Unit (MIAU); Reference Member State (RMS)

GENERAL UPDATES

The Malta Medicines Authority Annual Report 2019 is a compilation of milestones, statistical data and scientific regulatory initiatives achieved by the Authority during the preceding year of operation.

Upcoming Projects

- Electronic Visitors Log Book

Shifting from manual to electronic record keeping of visitors at the MMA premises. Visitors will log in and log out using the tablet on Level 3. The host of the meeting will be notified via email upon arrival of the visitors.

- Corporate Calendar

Keeping track of official events related to the Authority, including internal and external activities.

- Resource Card

Exploring the possibility of adopting a facilitated system for the Continuous Professional Development (CPD) allowance. Eligible employees will have a debit card making these funds easily accessible while decreasing administrative burden.

Healthy Lifestyle

In the current circumstances, it is important to keep active and eat healthy to maintain good physical and mental wellbeing. Employees are encouraged to follow the training programme which is being circulated virtually. Physical activity increases our productivity!

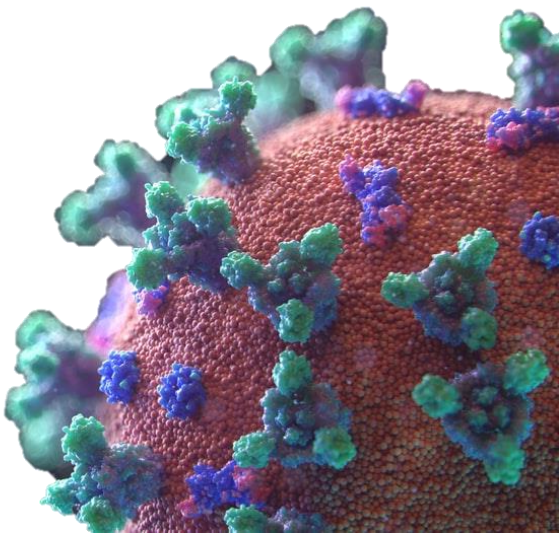
DID YOU KNOW?

Fun Fact!
Did you know that you have around 60 muscles in your face? Smiling is easier than frowning. It takes about 20 muscles to smile and over 40 to frown.
So, frown less, smile more!

COVID-19: Business Continuity and Employee Support Measures

To ensure continuity of business operations and to safeguard the health and safety of the workforce, the Management has communicated timely decisions in tandem with the direction by local authorities.

Through several support measures, including virtual counselling sessions and practical day-to-day tips, the Authority has been proactive in addressing the holistic wellbeing of its workforce amid this pandemic.



The Safety Features Regulation: Intercepting Falsified Medicines

The Delegated Act on safety features appearing on the packaging of medicinal products for human use (Regulation 2016/161/EU) emanates from the Falsified Medicines Directive (FMD) 2011/62/EU. This Regulation is an EU-wide legislation which came into force in February 2019 to ensure patient safety. It aims to prevent counterfeit medications and false information about the source of the medicines from entering the legal pharmaceutical supply chain. The FMD is only linked to prescription medications and does not cover over-the-counter medicines. It stipulates that the outer packaging of all medicines must have safety features which include an anti-tampering device (ATD) and a unique identifier (UI). The nature of the ATD will ultimately be decided by the manufacturer and if the ATD is broken, the medication cannot be dispensed. The UI is a unique 2D barcode which is made up of a serialisation number, product code, batch number and expiry date, enabling authenticity checks of the product before distributing or dispensing.

The product data of all medicinal products in the European Union is stored centrally in the European Medicines Verification System (EMVS) or 'hub'. This is a data repository which transfers data from manufacturers to all the National Medicines Verification Systems (NMVS) including the Maltese repository denoted as the Malta Medicines Verification System (MaMVS).

The Authority's Inspectorate and Enforcement Directorate, together with the pharmacy inspection team within the Scientific and Regulatory Operations Directorate have participated in relevant training and updated their inspection processes to enhance stakeholder conformity towards their FMD obligations.