THE MMA | ISSUE 18 – Q2 2024

telegram

Welcome dear colleagues to our 2nd e-newsletter for the year 2024!

IN THIS ISSUE

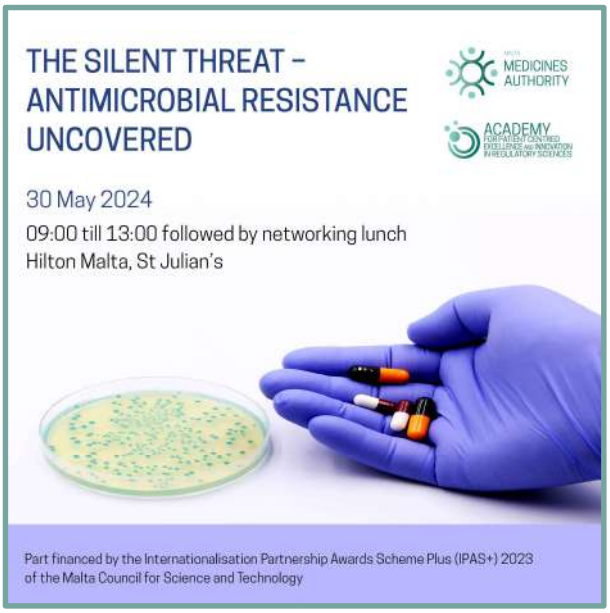
MMA Stakeholders Conference

Through stakeholder engagement, the Conference successfully delved deeper into aspects of a regulatory framework that unlocks excellence, extending beyond the concepts of compliance by surpassing the established standards and looking forward to innovation and progress.

THE SILENT THREAT – ANTIMICROBIAL RESISTANCE UNCOVERED SEMINAR | MAY

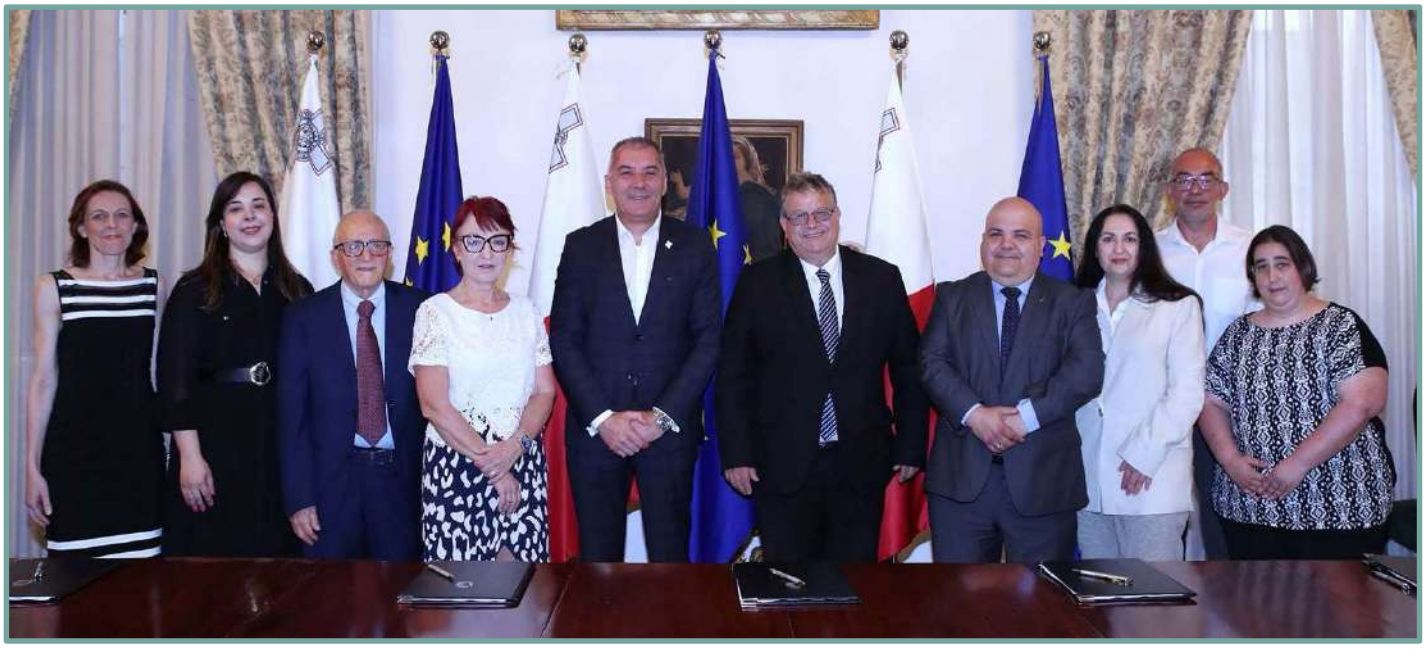
Local and international experts addressed the seminar delivering insights on national and international perspectives on new and old antimicrobial medicinal products for both human and veterinary use. Practices of local prescribing of antimicrobials and European measures addressing AMR surveillance were presented as well as aspects how to enhance access.

The seminar was organised by the Academy for Patients-Centred Excellence and Innovation in Regulatory Science in collaboration with the IPAS+.



SIGNING OF THE COLLECTIVE AGREEMENT | MAY

The new MMA - UHM Collective Agreement covering the period from 2022 to 2027 was signed after fruitful negotiations and collaborative efforts between the UHM Voice of the Workers, the People and Standards Division and the MMA. This comprehensive agreement brings forth numerous improvements including salary increments, performance bonus and the introduction of additional allowances. The new collective agreement paves the way for enhanced career progression for both scientific and administrative staff whilst ensuring the Authority's sustainability.



EU NTC 1O YEAR ANNIVERSARY | MAY

The MMA attended the events that mark the 10th anniversary of the EU NTC as a strategic collaboration between the EMA and the HMA. The EU NTC is an established platform that offers scientific and regulatory training opportunities to regulatory staff across the EU Network promoting continuous development to equip with the necessary expertise to navigate the complexities of the regulatory landscape of the life sciences and pharmaceutical sectors.

MMA QMS ON SHAREPOINT | MAY

The MMA QMS was recertified in January 2024 with ISO 9001:2015 and currently comprises of SOPs (n=134), policies (n=44), guidelines (n=40) and manuals (n=2). Since March 2024, the QMS documents have been transferred from Link Library to Microsoft © 2024 Sharepoint to align with technological advancements and enhance the accessibility of such documentation to all employees.

Management Quality System MCCAA
SM EN ISO 9001:2015
Reg. No. S082

MMA ANNUAL REPORT 2023

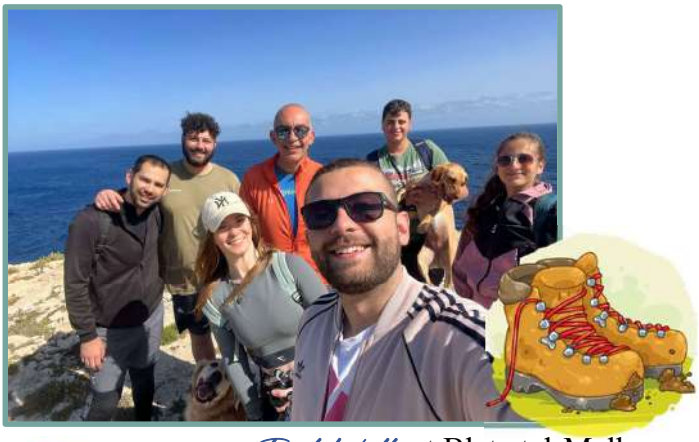
The Annual Report reflects the robustness, resilience and quality of our people and portfolio through the dissemination of the Authority's milestones, operations, statistical data and scientific initiatives achieved over the previous year. In 2023, the MMA successfully underwent two (2) comprehensive external audits, the BEMA and the JAP, which evaluated the organisational processes and adherence to pharmaceutical regulatory standards.

DID YOU KNOW?

The stirrup bone is the smallest bone in the human body, located in the middle ear. It measures approximately 0.27cm in length.

To celebrate *World Book Day*, a book fair was organised. A total of €325 were collected and donated towards Thiago's Journey.

Books let you travel without moving your feet!



Trail Walk at Blata tal-Melh

A *Fire Warden Course* was held to equip participants with the necessary skills and knowledge to effectively manage fire-related emergencies and ensure the safety of everyone in our workplace. ***Safety first, Always!***

The second successful MMA *Sports Day* was organised on 17 May to promote a healthy lifestyle for all employees whilst encouraging teamwork through fun physical activities and challenges.

A leisure trip to Sicily

MEDICINES ACCESS

Strengthening of the supply chain | APRIL

The MSSG developed a set of recommendations to facilitate the availability and supply of critical human medicines in the Union. These include:

- Incentives for MAHs to enhance the manufacturing capacity and to monitor demand and availability of medicinal products

- Measures to coordinate stockpiling to mitigate fluctuations in demand and supply

- A MAH shortage prevention plan for medicines listed in the Union's critical medicines list

- Scientific and regulatory support for stakeholders to overcome challenges and risks associated with the supply chain.

SUSPENSION

Hydroxyprogesterone caproate medicines | MAY

The PRAC recommended the suspension of 17-OHPC within the EU due to the possible but unconfirmed risk of cancer in individuals exposed to this medicinal product while in the uterus.

Recent studies highlighted the ineffectiveness of 17-OHPC in preventing premature birth and lack of data available regarding its efficacy for other approved indications.

NEW TREATMENT

New gene therapy treatment for Haemophilia B | MAY

The EMA issued a positive recommendation for the granting of a conditional marketing authorisation for Durveqtix®. This treatment was supported by the PRIME scheme for severe and moderately severe haemophilia B in adults.

Durveqtix® (fidanacogene elaparvovec) is a gene therapy that replaces the coagulation factor IX and prevents the occurrence of bleeding events.

THE CRITICAL MEDICINES ALLIANCE

Established in January 2024, the CMA serves as a consultative mechanism that brings together pertinent stakeholders from EU MSs, industries, civil society, and the scientific community to address regulatory challenges and ensure timely and equal access to medicines for all patients in the EU. It aims to:

— Identify priority areas for intervention
— Offer solutions to strengthen the availability of critical medicinal products in the EU
— Prevent and address shortages of medicinal products

BACKGROUND

The CMA was established to integrate industrial and competitiveness dimensions in the regulatory aspect of the supply chain. Members of the Alliance are divided in two (2) working groups focusing on:

— Strengthening EU manufacturing capacities for critical medicines to better prevent and fight medicines shortages

— Diversifying supply chains, international partnership and cooperation.

For more information visit https://health.ec.europa.eu/health-emergency-preparedness-and-response-hera/overview/critical-medicines-alliance_en

TIMELINE

October 2023

Communication of the EU Commission addressing medicine shortages presenting the Alliance as a long-term action

December 2023

Publication of the first Union List of Critical Medicines

January 2024

Launch of the open call for expression of interest to join the Alliance

April 2024

First meeting

May 2024

MMA joined the CMA

ACRONYMS

MMA – Malta Medicines Authority
IPAS+ - Internalisation Partnership Award Scheme Plus
UHM – Unjoni Haddiema Maghqudin
EU NTC – European Union Network Training Centre
QMS – Quality Management System
ISO – International Organization for Standardization
SOP – Standard Operating Procedure
BEMA – Benchmarking of European Medicines Agencies
JAP – Joint Audit Programme
cm – centimeter
MSSG – Executive Steering Group on Shortages and Safety of Medicinal Products
MAH – Marketing Authorisation Holder
PRAC – Pharmacovigilance Risk Assessment Committee
OHPC – hydroxyprogesterone caproate
EU – European Union
EMA – European Medicines Agency
CMA – Critical Medicines Alliance
MS – Member State