



THE MMA

ISSUE 21 – Q1 2025

telegram

Welcome dear colleagues to our 1st e-newsletter for the year 2025!

In this Issue

A LOOK BACK | MoU WITH AIFA | TWINNING PROJECT | INDIA-MALTA COLLABORATION | MALTESE DELEGATION IN BALKAN COUNTRIES | AWARD IN CANNABIS | DOCTORATE IN PHARMACY ANNIVERSARY | EVENTS
EUROPEAN UPDATES | REGULATORY UPDATES

A LOOK BACK AT 2024...

The MMA upheld its mission to *safeguard public health through the regulation of medical products and pharmaceutical activities for human use*. Prominent events included:



MQF Level 6 AWARD in Pharmacovigilance
MQF Level 5 AWARD in Medical Devices



2 Staff Meetings



MoU with Ghana FDA



October



Med In Pharma

Mediterranean Conference Centre



EU-Funded
Twinning Light
Project



SEMINAR on
Antimicrobial Resistance
Uncovered



Science in
the City



MedSafetyWeek 2024



Participation in

JOINT ACTIONS

AGREEMENT WITH THE ITALIAN MEDICINES AGENCY | FEBRUARY

The renewed MoU between the MMA and AIFA enhanced the strategic partnership between both nations and their role in European pharmaceutical policies. This agreement aims to tackle shared challenges, including promoting access to innovation, ensuring system sustainability, and effectively managing medicine shortages.

This partnership highlights collaborative areas such as:

- Joint procurement and handling of shortage and access to medicines;
- Sharing of best practices in pharmaceutical regulatory science;
- Inspections and Training opportunities; and
- Exchange of expertise in technology systems and AI integration.



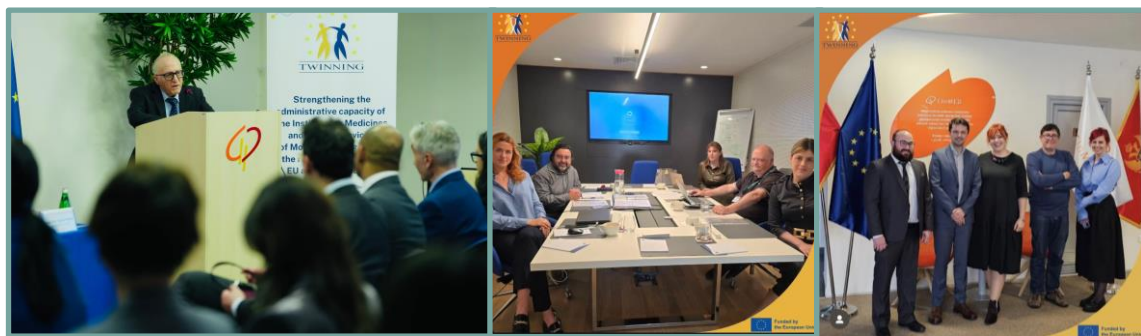
TWINNING LIGHT PROJECT | FEBRUARY

The Twinning Light Project with the Institute for Medicines and Medical Devices of Montenegro (CInMED) was launched in February 2025 in Podgorica, Montenegro.

This EU-funded project is composed of training activities and joint inspections, which aim to:

- Strengthen the administrative capacity and internal competencies of CInMED;
- Issue recommendations for further harmonisation of the legal framework in Montenegro to achieve alignment with the EU acquis.

The project marks Malta's central involvement as a role model NCA in the successful accession of Montenegro into the EU. Malta is contributing in aligning Montenegro's regulatory framework for medicines and medical devices with EU standards.



INDIA-MALTA COLLABORATION | MARCH

The meeting between the High Commissioner Mrs Gloria Gangte and Professor Anthony Serracino-Inglott, CEO of the Malta Medicines Authority, highlighted the positive recognition of Indian pharmaceuticals' advancements in innovative medicines.

Their discussion focused on enhancing healthcare collaborations between India and Malta, underscoring the potential for a stronger partnership in pharmaceuticals.



GENERAL MMA UPDATES

MALTESE DELEGATION IN BALKAN COUNTRIES | FEBRUARY

Members of the MMA management joined the Maltese delegation led by Minister Hon Jo Etienne Abela on a visit to Serbia and North Macedonia.

Meetings between representatives from the Governmental entities as well as the Competent Authorities of Serbia and North Macedonia, were held to identify opportunities for collaboration through the exchange of expertise on assessments of medicines and medical devices, and the sharing of best practices and training opportunities to foster the availability of medicines and medical devices in Malta, Serbia and North Macedonia.

These visits established strong foundations for future formal collaborations and agreements between the parties.



AWARD IN CANNABIS FOR MEDICINAL AND RESEARCH PURPOSES | MARCH

A three-day accredited course in Cannabis for Medicinal and Research Purposes provided participants with an in-depth overview of the regulatory, analytical, and clinical facets of medicinal cannabis, delving into legal frameworks, quality standards and security protocols for professionals in healthcare, pharmaceuticals, and research.

Heartfelt appreciation to all contributors for the great success of the course that had an international reach.

ACADEMY
FOR MEDICINAL AND RESEARCH PURPOSES

AWARD in Cannabis for medicinal and research purposes

Accredited at MQF Level 6 | Dates: 25-27 March 2025

Face-to-Face Sessions at the Malta Life Sciences Park, San Ġwann

A three-day programme covering regulatory, analytical, and clinical areas relevant to the field of medicinal cannabis, bridging legislation, science, and practical applications.

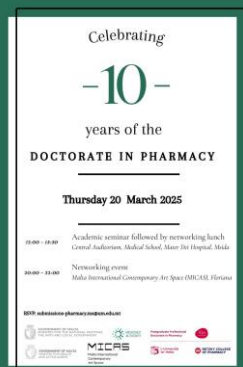
A networking platform for the dissemination of scientific acumen and the exchange of best practices and experiences, facilitating national and international collaboration, and promoting the development of individual skills in medicinal cannabis.

The MMA Academy is licensed as a Further and Higher Education Institution by MFHEA. License Number: 2021-004

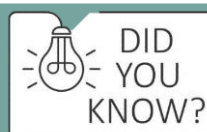
DOCTORATE IN PHARMACY 10 Year Anniversary

2025 marked the 10th anniversary of the Doctorate in Pharmacy course offered by the UoM in collaboration with the University of Illinois, Chicago.

61 PharmD students completed the course while being supported by the MMA through the International Fellowship Programme. Throughout this decade, the MMA invested over €1.5M to support Maltese and international students accomplish this milestone.



Have you ever smelled a scent, and a memory suddenly lit up in your mind? The olfactory nerve and hippocampus (memory area) are closely connected!



PEOPLE MANAGEMENT EVENTS

The IED, LD, and MDPCD carried out interdepartmental sessions, providing MMA employees with an overview of their structure and commitments.

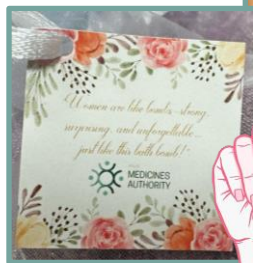


The traditional dessert Prinjolata is a must-have in Carnival!



Happy International Women's Day

to all our brilliant, dedicated, and hard-working women employees!



A get-together was organised to celebrate St. Patrick's Day. MMA employees gathered and played Gold Coin Toss game. No losers, everyone received a gift!



A memorial mass was held to honour **Michael Chetcuti** for his professional and personal contributions to the MMA.



February is known as the month of love. The Authority celebrated Valentine's day too!

NEW TREATMENT

**Treatment for
parasitic worm
infections | JANUARY**

The CHMP issued a favourable positive scientific opinion for Ivermectin/Albendazole, recognising its potential in treating endemic worm parasite infections including elephantiasis. These infections are transmitted through soil contamination by human faeces.

Ivermectin is an antiparasitic agent effective against a range of infections in both humans and animals, while Albendazole is a broad-spectrum antiparasitic that targets various intestinal parasites. Together, these medications provide a potent treatment option for managing parasitic infections.

NEW TREATMENT

**New Chikungunya
vaccine | FEBRUARY**

The EMA recommended the grant of a marketing authorisation for Vimkunya®, the first vaccine in the EU aimed at protecting people aged 12 and above against Chikungunya. Chikungunya is a viral disease caused by CHIKV, transmitted primarily by infected mosquitoes and prevalent in southern EU countries including Malta.

Vimkunya® was supported by the EMA's PRIME scheme, which facilitates early and enhanced scientific and regulatory support for medications that have a significant potential to meet patients' unmet medical needs.

NEW TREATMENT

**First topical gene therapy
treatment for dystrophic
epidermolysis
bullosa | FEBRUARY**

Vyjuvek® is an EMA-authorised gene therapy treatment that offers and enhances the quality of life for patients suffering from DEB, an ultra-rare genetic skin disorder. The treatment involves a genetically modified herpes simplex virus that delivers the normal COL7A1 gene directly to the wounds, and it is applied topically in small droplets once a week.

Vyjuvek® was supported by the EMA's PRIME scheme, which aims to address unmet medical needs in patients.

NEW TREATMENT

**Combination of cystic
fibrosis medicines to treat
patients with rare
mutations | FEBRUARY**

CHMP recommended extending the therapeutic indication of Kaftrio® and Kalydeco® for cystic fibrosis patients aged 2 and older with at least one non-class I mutation in the CFTR gene.

The combination of the two medicines improves the function of the abnormal CFTR proteins, leading to less viscous mucus and digestive juices less thick, thereby relieving symptoms associated with the disease.

EMANS 2028 - A strategy for changing times

The EMA and HMA published the strategy titled ‘Seizing opportunities in a changing medicines landscape’, which is divided into six focus areas and built upon the strategy of EMANS to 2025.

This strategy will guide the European Medicines Regulatory Network until 2028 to ensure a transparent and forward-looking approach to managing the network's public health priorities.

The key aspect of the strategy is the ‘One Health Approach’ which recognises the close connection between the health of humans, animals and the wider environment.

Today – EMANS Strategy 2028

2021 – EMANS Strategy 2025

Renew EMANS Strategy – 2028

The six themes



1. Accessibility

Facilitating pathways for access to medicines through healthcare systems in the EU.



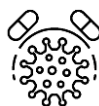
2. Leveraging data, digitalisation and Artificial Intelligence

Improving decision-making, optimising processes and increasing efficiency.



3. Regulatory science, innovation and competitiveness

Creating a regulatory and research environment that accelerates the translation of innovation and improves the competitiveness of the EU's healthcare sector.



4. Antimicrobial resistance and other health threats

Preparing the EU for potential threats including antimicrobial resistance.



5. Availability and supply of medicines

Strengthening the availability of medicines to protect public and animal health.



6. Sustainability of the network

Ensuring that the network has available resources to support its scientific and regulatory decision-making, taking full advantage of technological advances.

ACRONYMS

AI – Artificial Intelligence
AIFA – Agenzia Italiana del Farmaco
CEO – Chief Executive Officer
CFTR – Cystic fibrosis transmembrane conductance regulator
CHIKV – Chikungunya Virus
CHMP – Committee for Medicinal Products for Human Use
CInMED – Institute for Medicines and Medical Devices of Montenegro
DEB – Dystrophic epidermolysis
EMA – European Medicines Agency
EMANS – European Medicines Agencies Network Strategy
EU – European Union
FDA – Food and Drugs Authority
HMA – Head of Medicines Agencies
IED – Inspectorate and Enforcement Directorate
LD – Licensing Directorate
MDPCD – Medical Devices and Pharmaceutical Collaboration Directorate
MMA – Malta Medicines Authority
MoU – Memorandum of Understanding
NCA – National Competent Authority
Pharm D – Doctorate in Pharmacy
PRIME – PRiority MEDicines
UoM – University of Malta