THE MMA | ISSUE 23 – Q3 2025

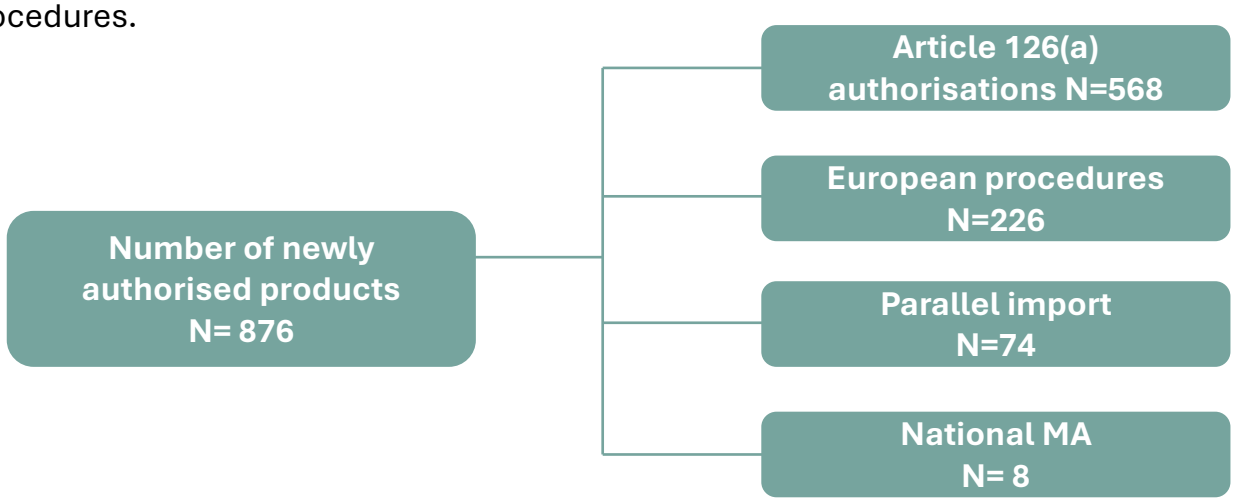
telegram

Welcome dear colleagues to our 3rd e-newsletter for the year 2025!

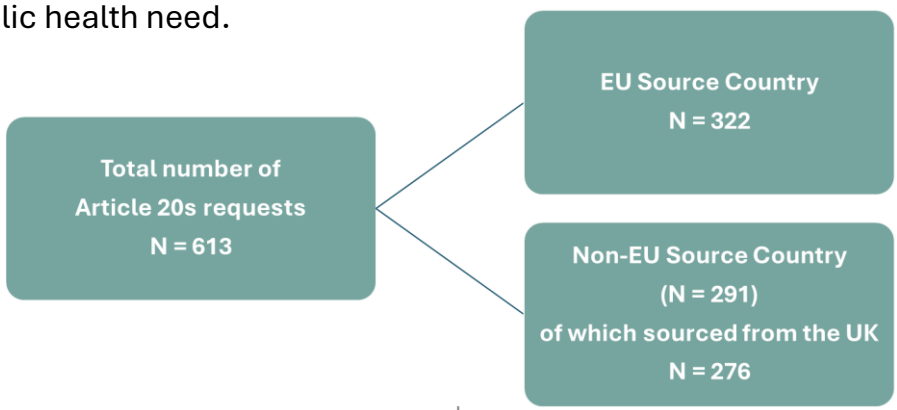
In this Issue

Ensuring Access to Medicines

Throughout 2025 the MMA remained committed to ensuring that patients in Malta have timely access to medicines that are safe, effective, and of high quality. Up to the third quarter, a total of 876 medicines were authorised through the different regulatory procedures.



The Article 20 exemption was used as an interim measure to counteract the risk of shortages and maintain accessibility to medicines on the local market when registration options through a MA, authorisation in line Article 126(a) of Directive 2001/83/EC and parallel importation have been exhausted as possible registration routes. By the third quarter of 2025, 613 exemption requests were granted by the Licensing Authority in view of a justified public health need.

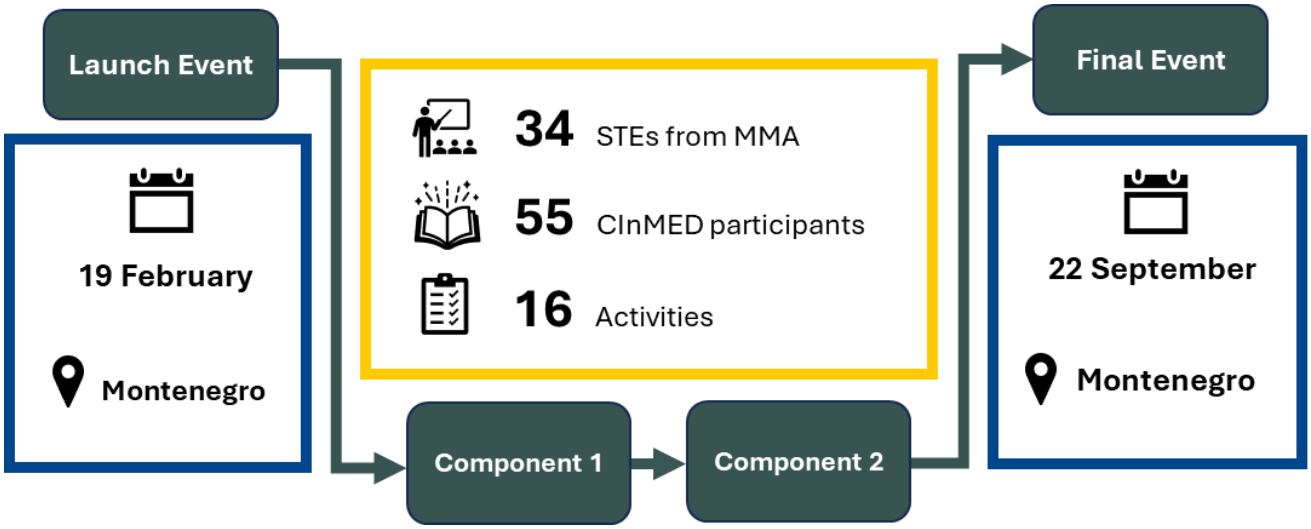


TWINNING LIGHT PROJECT

The MMA and CInMED successfully concluded their eight- month EU-funded collaboration.
The project was divided in 2 Components:

1. Strengthening administrative capacity and internal competences of the CInMED

2. Recommendation for further harmonisation of legal framework in Montenegro to achieve alignment with EU acquis



Sixteen key activities were carried out through training initiatives to strengthen administrative capacity in line with the EU accession requirements.
Activities included joint assessments and inspections, training on medicine shortages and communication strategies, strengthening vigilance systems for medical devices, and workshops to analyse gaps between the Montenegro framework and the EU pharmaceutical acquis.

GENERAL MMA UPDATES

MEDICINES REGULATORY SYSTEMS STRENGHTENING IN SUB-SAHARAN AFRICA | AUGUST

The Advanced Scientific Initiatives Directorate and the Post-Licensing Directorate, participated in an EMA-funded grant aimed at strengthening medicines regulatory systems in Africa.

Training on pharmacovigilance was delivered to the Medicines Control Authority of Zimbabwe (MCAZ) to expand expertise in post-marketing surveillance and contribute to capacity building for enhanced medicine safety.

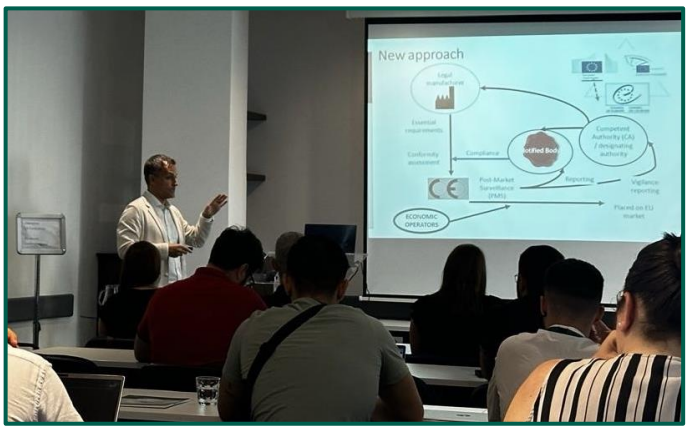
Interactive sessions covered the areas on:

- Periodic Safety Update Reports and risk management plans
- Quality management system and audits
- Adverse Drug Reactions
- Educational initiatives and stakeholder outreach

AWARD IN MEDICAL DEVICES | SEPTEMBER

The course organised by the Academy for Patient-Centred Excellence & Innovation in Regulatory Sciences brought together local and international professionals for a comprehensive overview of the latest regulatory frameworks and best practices in the field of medical devices.

The three-day programme provided skills and competencies relevant to GDP, presented from perspective of both manufacturer and national competent authority.



Thanks to the expert speakers and participants for their valuable contributions and support to the MMA Academy.

GENERAL MMA UPDATES

THE INCREASENET 2025 COLLABORATION SUMMIT | SEPTEMBER

IncreaseNET is an EU-funded project under the EU4health programme, involving 29 partners, mainly NCAs, with the aim of building capacity through targeted training, on-the-job learning and enhanced collaboration.

On 25 September 2025, the MMA proudly hosted the hybrid IncreaseNET 2025 Collaboration Summit at the historic Manoel Theatre in Valletta. The event brought together over 100 experts across the EMRN to drive efficiency and strengthen partnerships in regulatory sciences. Focus was given to *Work Package 7- Efficient Use of Resources*, showcasing tangible progress and sharing strategies to optimise regulatory operations. The Summit fostered meaningful connections and exchange of ideas, continuing the momentum of initiatives supported through the EU4Health programme 2021-2027, proving that collaboration is the key to a stronger Health Union.

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Call for Abstracts

Members of the scientific community are invited to submit abstracts focusing on innovative techniques, recent advancements in medical devices and technologies, and emerging trends in the fields of medicine and surgery, pharmacy, dentistry. Submissions will be reviewed by the Med-In Pharma Scientific Committee.

Sun exposure for 15 minutes/day is the primary method of boosting serum vitamin D levels. This accounts for numerous health benefits

MEDICINES ARE NOT SWEETS | SEPTEMBER

The MMA actively participated in the European social media campaign titled 'Medicines are not sweets', launched by the HMA. The coordinated message from European NCAs aimed to raise awareness among citizens on the importance of the responsible use of OTC medicines. An official video featuring the MMA CEO amongst representatives from other competent authorities was disseminated to convey the message of the campaign. This was supported by daily posts on the MMA social media channels.

For more information scan the QR code!

SCIENCE IN THE CITY | SEPTEMBER

The MMA participated in Science in the City 2025 under the theme '*Past Forward*'. The Authority engaged the audience through educational discussions and entertaining activities, raising awareness about its role and focusing on the evolution of scientific knowledge and methodologies from the past to the present day.

Five (5) interactive and educational activities were conducted, each aligned with key public health themes. These included methods for measuring glucose and blood pressure, the evolution of vaccines, the properties of natural products and the responsible use of medicines.

Interdepartmental session

Employees participated in the recent interdepartmental session organised by the Office of the CEO, which focused on outlining the roles, responsibilities and objectives of the Legal Unit and the FCS Unit.

The session aimed to enhance cross-functional understanding, promote collaboration, and ensure alignment with the broader organisational goals. Attendees had the opportunity to engage with representatives from each unit, gaining insights into their core functions and how these contribute to the overall mission of the Authority.

MMA celebrated Pride Week once again

On 5 September, an informative session led by Ms Joana Micallef explored the history and significance of Pride in Malta. Through interactive case scenarios, participants were encouraged to reflect and discuss the importance of raising awareness about sexual harassment.

Promoting equality by valuing diversity

Closing Event – Twinning Light Project

The successful conclusion of the Twinning Light Project was marked by a final event in Montenegro that celebrated the collaborative efforts and achievements of all involved partners. This milestone marked a significant step in strengthening CInMED regulatory capacity in line with EU accession requirements. The MMA expressed its sincere appreciation to all contributors and looks forward to continuous collaboration with CInMED.

Strengthening supply chain of anti-D immunoglobulins | JULY

Anti-D immunoglobulins are currently the only available treatment for preventing RhD immunisation during pregnancy, that can cause serious harm to the foetus, including potentially fatal outcomes.

Plasma containing anti-D immunoglobulin is collected from donors and remains the sole source for manufacturing these medicines. As the number of donors is declining, EU Member States are urged to secure supply by reducing unnecessary use and establishing joint procurement.

New injection for easier prevention of HIV infection in the EU and worldwide | JULY

EMA recommended the granting of marketing authorisation for Yeytuo® (lenacapavir) for PrEP. This treatment in combination with safer sex practices aims at reducing the risk of sexually acquired HIV-1 infection in adults and adolescents at high risk.

Lenacapavir, a first-in-class substance, binds to the proteins forming the HIV-1 capsid, disrupting their assembling and stability, thereby inhibiting viral replication and preventing infection.

This new therapy represents a significant achievement. Clinical trials are demonstrating high efficacy and improved adherence due to its twice-yearly subcutaneous injection, offering a discreet and long-acting alternative to daily oral dosing.

Warning about sharp rise in illegal medicines sold in the EU | SEPTEMBER

The EMA and HMA issued a warning about a sharp rise of illegal GLP-1 receptor agonists (e.g. semaglutide, liraglutide, tirzepatide) being sold online for weight loss and diabetes. These unauthorised products, often promoted on social media and fraudulent websites, may lack the claimed active ingredients or contain harmful substances, posing serious health risks to patients.

Prescription medicines cannot be legally sold online in all MS. To help consumers identify legitimate online pharmacies, the EU introduced a common logo that links to national registers of authorised retailers.

The logo includes the national flag and a verified link (as shown in the image on the side). Only flags from EU countries, as well as Norway, Iceland, and Liechtenstein are permitted.

MDR AND IVDR: PUBLICATION OF A CONSENSUS STATEMENT FROM THE EU COMPETENT AUTHORITIES TO THE EU COMMISSION

In June 2025 24 NCAs gathered in a workshop in Utrecht and signed a consensus statement to the EU Commission. The aim of the statement is to strengthen the coordination and governance of the regulatory system for medical devices at EU level to help address fragmentation and enhance harmonisation and effective application in practice. As result of the workshop 5 key improvements were outlined.

Five (5) key improvements

Improved EU Governance

Strengthen coordination to reduce fragmentation and support harmonisation within the EU

Centralised Key Functions

Create a cohesive structure for clarity and consistency in regulations

Enabled Patient-Centred Access

Use adaptive approaches for timely access while ensuring safety

Simplified Regulations

Cut unnecessary burdens and support fair access for all stakeholders

Investment in Resources

Ensure sustainable funding and fair compliance costs for long-term efficiency

For the official statement issued by CAMD click here:
https://www.camd-europe.eu/regulatory/publication-of-a-consensus-statement/

ACRONYMS

CAMD – Competent Authorities for Medical Devices
CInMED – Institute for Medicines and Medical Devices of Montenegro
CEO – Chief Executive Officer
EMA – European Medicines Agency
EU – European Union
EMRN - European Medicines Regulatory Network
FCS – Finance and Corporate Services
GDP - Good Distribution Practice
GLP-1 – Glucagon-Like Peptide-1
HIV - Human Immunodeficiency Virus
HMA – Head of Medicines Agencies
IVDR - In Vitro Diagnostic Medical Devices Regulation
MDR – Medical Device Regulation
MCAZ - Medicines Control Authority of Zimbabwe
MA – Marketing Authorisation
MMA – Malta Medicines Authority
MS – Member States
NCAs – National Competent Authorities
OTC – Over-The-Counter
PrEP – Pre-Exposure Prophylaxis
RhD – Rhesus D antigen
STEs – Short Term Experts
SITC – Science in the City
UK - United Kingdom