THE MMA | ISSUE 22 – Q2 2025

telegram

Welcome dear colleagues to our 2nd e-newsletter for the year 2025!

In this Issue

Twinning Light Project

The EU-funded project continues to thrive throughout the second quarter of 2025, offering an excellent opportunity to reinforce the collaboration between Malta and Montenegro while driving meaningful and impactful results for the accession of Montenegro to the EU.

10 - 11 April
Montenegro

Quality defects

Interactive training sessions focused on monitoring rapid alerts and assessing quality defects in medicines, featuring practical case studies from Malta.

8 April
Online

First Steering Committee Meeting

A comprehensive overview of completed and upcoming activities, budget expenditures, and outstanding queries for Q1 was shared and discussed with CInMED and the EUD to Montenegro.

27 May
Malta

Diplomatic meeting

An official visit by the Minister of Health of Montenegro was held in Malta.

13 - 14 May
Malta

Operational systems

Workshops on medicine registries, FCS and PMU management systems, and risk management were held to foster the exchange of best practices and strengthen operational effectiveness.

2 - 5 June
Malta

2– 4 June
Malta

Assessment of medicinal products

Joint review sessions explored the assessment of generic medicine quality documentation, featuring real-world case studies from applications submitted in Malta.

Variations of quality assessments

Joint review sessions focused on assessing variation documentation using real-world examples from submissions across Member States to promote practical learning and alignment to EU standards.

KEY MEDICAL DEVICES DISCUSSIONS AT CAMD MEETING | APRIL

The MMA actively participated in the CAMD meeting, held in Warsaw, Poland from 8 - 9 April. CAMD continues to be a vital platform for EU NCAs to collaborate on shared challenges, propose innovative tools and align regulatory practices across Europe.

During the working party, participants addressed several high-priority topics shaping the future of medical devices in the EU such as:

- Clinical Trials applications to support evidence based decisions
- SSIN Form Harmonisation to align the Suspected Serious Incident Notification form and streamline reporting
- Cybersecurity Guidelines introducing updated, harmonised recommendations to strengthen digital safety
- Artificial Intelligence as applicable to medical devices
- Advertising Regulations to harmonise legislation on medical devices promotion.

HMA LAUNCHES 1ST OFFICIAL NEWSLETTER | APRIL

HMA
Heads of Medicines Agencies

The HMA officially launched its first newsletter to inform stakeholders about key regulatory developments, collaborations and strategic updates across the European medicines network.

This monthly publication reflects HMA's commitment to transparency, collaboration and forward-looking regulation. Its purpose is to enhance communication efforts by showcasing the achievements and challenges shared within the EMRN.

The first issue, published in April, covered topics such as the HMA-EMA joint statement on unregulated ATMPs, the EMANS strategy to 2028, CMDv document updates, new nominations within regulatory institutions and highlights of past and upcoming events and opportunities.

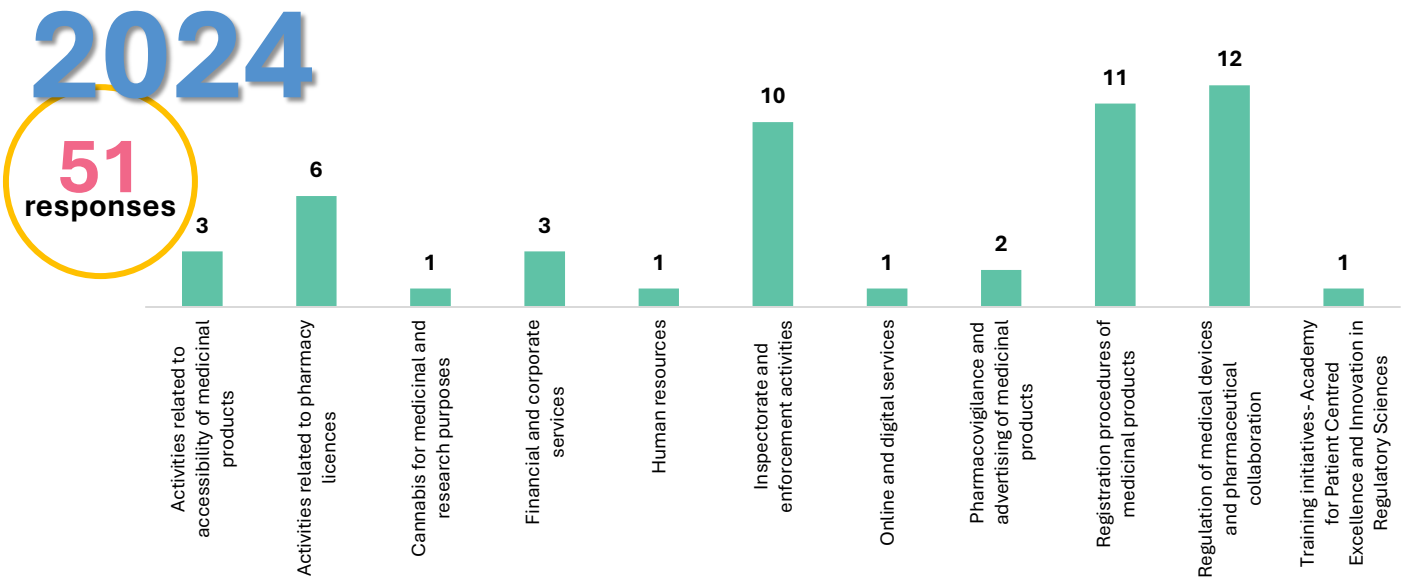
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Subscribe and receive the HMA newsletter through the following link.

STAKEHOLDER SURVEY

The MMA disseminates this survey to proactively assess stakeholders' perspectives on the services provided by the Authority. All input is crucial in helping us enhance the quality of our services while maintaining a patient-centred approach in regulatory sciences, which is recognised as an essential milestone of the MMA strategy.

From 1 January to 31 December each year, the online form remains available to continuously collect feedback. The responses are shared with the relevant Directorate/s and Unit/s and addressed accordingly. A report is compiled, which is collectively discussed during internal management meetings to review key findings and identify opportunities for actionable improvements, ensuring continuous enhancement of processes and performance across the organisation. The below graph illustrates the feedback received in 2024:



ANNUAL REPORT 2024

The Annual Report underscores the robustness, resilience, and high calibre of both our personnel and portfolio by highlighting the Authority's key milestones, operational achievements, statistical performance and scientific initiatives over the past year. The MMA has further strengthened its position as a centre of excellence in regulatory science, a leading authority in medicinal product safety and a committed advocate for patient-centred healthcare.

Roughly 10% of the population perceives cilantro as having a soapy taste. This is due to genetic variation in taste receptors.

DID YOU KNOW?

MMA EVENTS

During the Easter holidays, a group of employees and their children participated in a beach clean-up organised in collaboration with the Cleansing and Maintenance Division, combining environmental responsibility with a meaningful family activity and a cleaner environment.

The annual **Sports Day**, aimed at fostering physical health, encouraging teamwork, and strengthening professional networking among participants. This event provided an excellent opportunity for individuals to engage in a variety of athletic activities, promote wellness, and build stronger collaborative relationships within the organisation.

The **Mid-Year Staff Meeting** was held with a focus on promoting a healthy work-life balance. As part of the initiative, staff participated in a rich cultural experience that explored the historical heritage of Gozo. The itinerary included insightful visits to key landmarks in Gozo offering a deeper appreciation of Gozo's cultural roots while fostering team engagement in a relaxed and educational setting.

The much-anticipated **trip to Sicily** was successfully organised once again! This cherished tradition brought together participants for an unforgettable journey filled with stunning landscapes, rich history, delicious cuisine and vibrant culture. It was a wonderful opportunity to reconnect, explore, and create lasting memories under the Sicilian sun.

GENERAL EUROPEAN UPDATES

NEW TREATMENT

First treatment against severe thyroid eye disease | APRIL

The EMA recommended the marketing authorisation for Tepezza®, a monoclonal antibody for adults with moderate to severe TED, also known as Graves' eye disease. Teprotumumab targets orbital fibroblasts to reduce inflammation and potentially slow TED progression.

The active ingredient is teprotumumab and it is designed to block the autoimmune activation of orbital fibroblasts (specialised cells in the eye sockets), potentially inhibiting the development and progression of TED.

ADVICE

Measures to minimise risk of suicidal thoughts with finasteride and dutasteride medicines | MAY

A recent EU-wide medicines review of finasteride and dutasteride identified suicidal ideation as a potential side effect. The strength of evidence varies by indication, active substance and formulation.

Suicidal thoughts: now listed as a side effect of finasteride, especially 1mg
Warnings updated: Include risks of mood changes and sexual dysfunction
Patient card added to 1mg finasteride packs to guide action if symptoms occur
Doctors advised to stop treatment if patients report mood or sexual issues
Dutasteride warnings updated as a precaution (same drug class)

ANTIMICROBIAL RESISTANCE

Changes to the use of the antibiotic azithromycin | MAY

The resistance of pathogens against azithromycin increased in recent years. In view that it is crucial to maintain the effectiveness of this antibiotic, EMA revised the benefit-risk balance for oral formulations and vein infusion of azithromycin. This resulted in a change in therapeutic indications for moderate acne vulgaris, eradication of Helicobacter pylori and prevention of exacerbations of eosinophilic and non-eosinophilic asthma.

This review led to amended and harmonised therapeutic indications, dosing recommendations and target age groups.

GUIDELINE ON INCLUSION OF PREGNANT AND BREASTFEEDING INDIVIDUALS IN CLINICAL TRIALS

The guideline developed by the ICH provides a comprehensive framework for the ethical and scientific inclusion of pregnant and breastfeeding individuals in clinical trials. It aims to address the historical exclusion of these populations which has led to significant data gaps and suboptimal treatment decisions. EMA accepts suitable feedback on the guideline till 15 September 2025.

Key objective and general principles

Consideration of the use of medicinal products in pregnancy and breastfeeding from early development through post-approval.
Plan proactively to collect relevant data or provide rationale if not collected.
Engage early with regulatory authorities throughout development.

Pregnancy-Specific Guidance

- Integrate pregnancy considerations early in drug development
- Assess maternal–foetal risks and benefits using all available data
- Engage regulatory authorities early to ensure ethical trial design
- Minimise the burden on pregnant participants
- Plan for robust real-world data collection, addressing challenges like mother–fetus linkage and background risks

Breastfeeding-Specific Guidance

- Carefully assess potential effects on both the breastfed child and the mother
- Prioritise ethical considerations and minimise participant burden
- Collect real-world data post-approval on medicinal product transfer into breastmilk
- Monitor the impact on infants using appropriate data platforms
- Track outcomes in breastfeeding dyads to ensure ongoing safety evaluation

Ethical Considerations

Including pregnant and breastfeeding individuals in clinical trials is ethically supported by the Declaration of Helsinki and ICH guidelines. Ethics Committees or IRBs preferably with relevant experience must assess whether trial risks are justified by potential benefits. Additional safeguards and specific informed consent measures should be in place to protect the individual, foetus and breastfed infant.

Benefits of the Guidelines

Fills critical evidence gaps
Improves better clinical decision-making
Enhances maternal and infant health outcomes
Promotes ethical, globally harmonised research
Supports regulatory efficiency and product access

For further details on the guideline, click on the following link:
https://www.ema.europa.eu/en/documents/other/ich-e21-guideline-inclusion-pregnant-breastfeeding-individuals-clinical-trials_en.pdf

ACRONYMS

CAMD – Competent Authorities for Medical Devices
CInMED – Institute for Medicines and Medical Devices of Montenegro
CMDv – Coordination group for mutual recognition and decentralised procedures for veterinary medicinal products
ICH – International Council for Harmonisation
IRBs - Institutional Review Boards
EMA – European Medicines Agency
EMRN – European Medicines Regulatory Network
EU – European Union
EUD – European Union Delegation
FCS – Finance and Corporate Services Unit
HMA – Head of Medicines Agencies
MMA – Malta Medicines Authority
NCA – National Competent Authority
PMU – People Management Unit
TED – Thyroid Eye Disease
SSIN – Suspected Serious Incident Notification