

Welcome dear colleagues to our 4th e-newsletter for the year 2024!

IN THIS ISSUE

WORLD MENTAL HEALTH DAY | JAMS | PINK OCTOBER and MOVEMBER | MED-IN PHARMA | STAFF MEETING | MEDSAFETY | EVENTS | EUROPEAN SHORTAGES MONITORING PLATFORM

WORLD MENTAL HEALTH DAY | OCTOBER

This year's theme "*It's Time to Prioritise Mental Health in the Workplace*" was brought to life during a session hosted by Ms Michela Borg from the Health Promotion and Disease Prevention Directorate (HPDPD). MMA employees received valuable insights into promoting healthier lifestyles and preventing illness. The session particularly focused on the critical importance of mental well-being and provided participants with practical knowledge and strategies to enhance their health and well-being, underscoring the significance of a holistic approach to personal and workplace wellness.



JAMS | OCTOBER

The Medical Devices and Pharmaceutical Collaboration Directorate, lead of Working Package 5 within the EU4Health Programme JAMS 2.0, successfully hosted a working meeting between 30 and 31 October 2024. The meeting focused on vigilance and signal detection methodologies adopted by different competent authorities in the medical devices framework.



During the two-day meeting, different NCAs were involved in four (4) dynamic workshops on:

- i. Qualitative and quantitative evaluation of incident data and reports
- ii. Signal management, tracking and data sharing in the signal detection process
- iii. Use, challenges and solutions of International Medical Device Regulators Forum (IMDRF) codes
- iv. Management and analysis of signals, incident reporting and vigilance

PINK OCTOBER and MOVEMBER | OCTOBER/NOVEMBER



The MMA organised an enlightening talk in support of Pink October and Movember, emphasising the significance of men’s and women’s health.

The session featured a discussion on the five (5) most common cancers, fostering awareness and encouraging proactive health measures. A heartfelt thank you goes to Ms Mariella Galea from the HPDPD for sharing her valuable insights and expertise and contributing to the overall impact of the event.



MED-IN PHARMA SYMPOSIUM | NOVEMBER

The MED-IN Pharma Symposium organised during the Med-Tech World Summit provided a valuable opportunity for attendees to connect, share ideas, and engage in panels on innovation in healthcare and patient care. The contributions of MMA experts to the Summit aimed at providing regulatory insights on the latest advancements related to regulatory sciences in medicinal products and medical devices.

During a poster presentation session, the MMA showcased the results of research initiatives on:

- Medical device signal detection and surveillance
- Medical device clinical investigations
- Patient safety in medical devices
- Pharmacy practice



The Symposium reaffirmed the MMA’s dedication to acting as a global player by leading innovative research initiatives and optimising regulatory processes towards the benefit of the patient.

END OF YEAR STAFF MEETING | NOVEMBER

The End-of-Year Staff Meeting presented the accomplishments and the upcoming initiatives of the Directorates and Units for 2024 and 2025, respectively. During the event, the CEO took the opportunity to thank and recognise the efforts of all MMA employees for their contribution. Recognition was given to those who have devoted 10 and 15 years of service to the MMA. The event concluded on a light-hearted note with a team-building Bingo session, promoting camaraderie and strengthening connections among staff members.

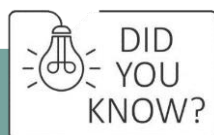


#MEDSAFETYWEEK 2024

The #MedSafetyWeek 2024 campaign promoted awareness on medicines safety by encouraging the monitoring and reporting of side effects. Tailored ‘To ask- questions’ were disseminated assisting patients and healthcare professionals to appropriately use, store and administer medicines. Emphasis was placed on the role of healthcare professionals in providing patient advice and reporting suspected side effects.



The tongue is covered in about 8,000 taste buds, each containing up to 100 cells helping you taste your food





MMA employees actively participated in the Christmas fundraising initiatives and contributed to the collection of:

- 50 gifts for the Toys for Tots wishlist
- €1,325 raised through a Cuti ruffle in aid of Dar tal-Providenza
- 12 filled boxes of essential items for Foodbank Malta
- Supplies to the Association for Abandoned Animals

A sincere THANK YOU to all whose kindness and generosity made this happen.

Your efforts truly make a difference!



Foodbank
Lifeline Foundation

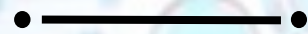
**Improved access to
Mpox medicines |
OCTOBER
ACCESS**

A workshop organised by the EMA with international regulators within ICMRA highlighted the development, research and availability of vaccines and therapeutics for Mpox.

Key discussions included:

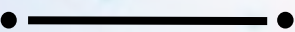
- Reviewing the epidemiological status of Mpox and the accessibility of vaccines in African countries;
- Addressing evidence gaps in vaccinations for children and pregnant women; and
- Establishing robust surveillance systems and regulatory pathways for new vaccines and treatments.

International regulators emphasised the importance of large clinical trials to generate crucial evidence for expedited development and approval of Mpox medicines and supported a coordinated approach to address current and future public health emergencies.



**Minimised risks
between Mysimba©
and opioids |
NOVEMBER
ADVICE**

An updated safety guidance on the risks of the interaction of Mysimba© (naltrexone/bupropion), a weight loss medication, with opioid-containing medications was published by EMA. The documents highlighted the reduced effectiveness of opioids and the onset of potentially severe adverse reactions, such as seizures and serotonin syndrome when used alongside other antidepressants and opioids. Recommendations were made against the prescribing of Mysimba© to opioid-dependent patients, patients receiving treatment with opioid agonists, and individuals experiencing acute opioid withdrawal.



**Alzheimer's disease:
A new early
treatment |
NOVEMBER
TREATMENT**

Despite the negative opinion issued in July 2024, the CHMP recommended the granting of a marketing authorisation for Leqembi© (lecanemab), a treatment for mild cognitive impairment or mild dementia due to Alzheimer's disease.

The re-evaluation highlighted the reduced incidence of induced amyloid-related imaging abnormalities (ARIA), a serious side effect that causes swelling and potential brain bleeding, and the positive benefits of Leqembi© in slowing disease progression in patients with only one or no copy of the ApoE4 gene variant.

THE EUROPEAN SHORTAGES MONITORING PLATFORM: MONITORING OF SHORTAGES IN THE EU

The European Shortages Monitoring Platform (ESMP) was officially launched in November 2024 to enable MAHs to report routine shortages of centrally authorised medicines. The Platform was designed to enhance information exchange:

**Prevent
Identify
Manage**
shortages



**Ensure
Availability**

**November 2024
Launch**

Transition period

**February 2025
Mandatory**

This platform represents a significant milestone in addressing medicine shortages, centralising and automating data collection by

***PROVIDING REGULATORY AUTHORITIES WITH REAL-TIME ACCESS TO
VITAL INFORMATION.***

Future updates will expand the functionalities of the ESMP for MAHs and NCAs, enabling the reporting of supply and availability of medicines during crises and preparedness efforts, and promoting a more resilient healthcare system across the EU and EEA. These actions are coordinated by the EMA's MSSG, which aims to proactively monitor and address medicine shortages as exemplified by the management of antibiotic shortages experienced in 2023-2024.

In support of ESMP users, the EMA published a user guide and a set of frequently asked questions and delivered trainings and webinars assisting MAH and other stakeholders in the transition.

For more information visit

<https://www.ema.europa.eu/en/news/european-shortages-monitoring-platform-enables-better-monitoring-shortages-eu>

CHEERS TO ANOTHER YEAR
OF

HARD WORK
AND
DEDICATION!

MAY THE YEAR 2025 BE MOST
PROSPEROUS, FILLED WITH
SUCCESS, HAPPINESS AND
LAUGHTER



ACRONYMS

ARIA – Amyloid-related imaging abnormalities
CEO – Chief Executive Officer
CHMP – Committee for Medicinal Products for Human Use
EEA – European Economic Area
EMA – European Medicines Agency
ESMP – European Shortages Monitoring Platform
EU – European Union
HPDPD – Health Promotion and Disease Prevention Directorate
ICMRA – International Coalition of Medicines Regulatory Authorities
IMDRF – International Medical Device Regulators Forum
JAMS – Joint Action on Market Surveillance of Medical Devices
MAH – Marketing Authorisation Holder
MMA – Malta Medicines Authority
MSSG – Medicines Shortages Steering Group
NCA – National Competent Authority