THE MMA | ISSUE 19 – Q3 2024

telegram

Welcome dear colleagues to our 3rd e-newsletter for the year 2024!

IN THIS ISSUE

SCIENCE IN THE CITY | SEPTEMBER

The MMA participated in Science in the City 2024 with the theme Justice, Equality, Diversity, Inclusion. The Authority engaged with the audience through educational discussions and entertaining activities, raising awareness on the MMA role and fostering a deeper understanding of the lifecycle of medicines and the patient journey.

BREXIT ADJUSTMENT RESERVE | SEPTEMBER

GOVERNMENT OF MALTA

FONDI.eu

The BAR is an initiative issued by the EC to assist European countries particularly affected by the exit of the UK from the EU. Through its constant work and efforts to mitigate the consequences faced with Brexit and adapt to regulatory changes, the MMA claimed expenditures incurred and paid within the reference period defined in the BAR Regulation, spanning from 1 January 2020 to 31 December 2023. The claimed expenditures equal to more than €800,000 and will replenish the public expenditure in support of other Government projects for the benefit of Malta.

The MMA wishes to thank the EC for this initiative and the MMA employees, who through their hard work and heartfelt commitment ensure the availability of safe, effective and good-quality medicines in Malta and the EU.

MMA AND GHANA FDA COLLABORATION | JULY

The Ghana FDA and the MMA renewed their commitment to enhance their collaboration by signing an MoU. This renewed commitment is set to transform and elevate collaborative efforts on:

- Advancing science and technology
- Enhancing capacity development in regulatory sciences
- Sharing of best practices on marketing authorisation and pharmacovigilance.

AWARD IN MEDICAL DEVICES | JULY

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

Attendees over the three-day course gained invaluable insights into the European Regulatory System for medical devices through real-world examples and case studies.

Appreciations to the expert speakers and participants for their contribution and support to the MMA Academy in fulfilling its commitment to address stakeholders' training needs.

EQUALITY MARK RECOGNITION | JULY

In 2024, the MMA was recertified by the NCPE with the Equality Mark. This recognition reflects the Authority's ongoing commitment to promoting diversity and inclusion in the workplace.

The MMA expresses its gratitude to everyone for their dedication in the pursuit of contributing to a more equal society.

TRAINING INITIATIVE ON MEDICINAL CANNABIS | AUGUST

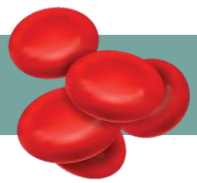
The MMA together with the Prevention Service Team at Sedqa Malta engaged through a specialised training initiative focused on the regulatory aspects of medicinal cannabis. This collaboration comprehensively covered multiple domains, contributing to enhanced collective knowledge for the benefit of the community.

WORLD PHARMACIST DAY | SEPTEMBER

The World Pharmacist Day provides an opportunity to celebrate the pharmacy profession and its contribution to primary health around the world. A networking session was addressed by the Superintendent of Public Health, the CEO of the MMA, the Head of the Department of Pharmacy at the University of Malta and the President of the Maltese Chamber of Pharmacists.

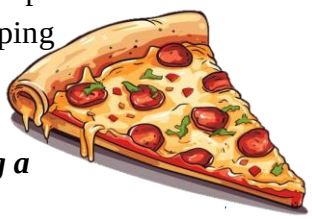
DID YOU KNOW?

The average red blood cell lives up to 120 days



FIRST STAFF MEETING | JULY

The 1st Staff meeting of 2024 involved strengthening interpersonal relationships between MMA employees whilst developing pizza-making skills.

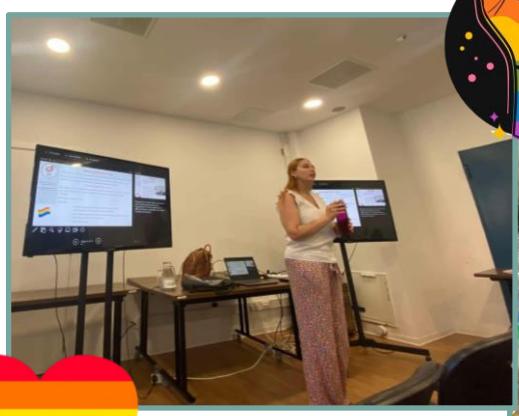


Teamwork is the key ingredient in making a successful pizza!

PRIDE WEEK | SEPTEMBER

During PRIDE week, an interactive networking session was delivered by the NCPE. To MMA staff, who participated in a discussion about promoting equality by valuing diversity.

Rights can never be taken for granted



INTERDEPANTEMENTAL SESSIONS | SEPTEMBER

Employees attended the first two (2) interdepartmental sessions on functions and ongoing projects related to the ASID and the units within the Office of the CEO.

Participants gained valuable insights into:

- The Academy for Patients-Centred Excellence in Regulatory Sciences
- IncreaseNET EU4Health Action
- Regulation of Cannabis for Medicinal and Research Purposes
- Quality, Continuous Improvement, and Internal Audit Unit
- Information and Communication Technology

African Medicines Agency | AUGUST

NEW AGENCY

The EMA secured a €10 million grant from the EC to support and enhance African regulatory systems by establishing the AMA in collaboration with African, European, and international counterparts. The AMA will serve as a specialised agency of the AU focused on enhancing equitable access to quality, safe and effective medicinal products in the African continent.

The establishment of AMA is a unique initiative to enable the regulation and oversight of essential medicines on a continental scale, fostering greater collaboration among African countries.

Large Language Models | SEPTEMBER

AI

The HMA together with the EMA, outlined recommendations and principles targeted to all staff across EMRN using Large Language Models (LLMs).

Large Language Models pose challenges such as variability in results, the possibility of generating inaccurate responses and potential data security risks. These principles will enhance the understanding of the capabilities and limitations of LLMs by enabling effective leverage while avoiding potential pitfalls and risks.

Metamizole side effects | SEPTEMBER

MEASURES

The PRAC proposed measures to reduce the risks of agranulocytosis caused by metamizole. These recommendations aim to safeguard public health by preventing the occurrence of severe infections linked to a significant decrease in granulocytes.

Warnings were updated, and HCPs were advised informing patients to stop these medicines and seek medical attention at the first appearance of symptoms.

EU PILOT PROGRAMME FOR ORPHAN MEDICAL DEVICES

The EMA launched a pilot programme for experts to provide advice in the development and assessment of orphan medical devices in the EU. This programme will conclude in 2025, and a long-term support framework will be established.
Priority will be given to:

- Devices used in infants
- Treatment of life-threatening medical conditions
- Innovative devices with potential benefits

Further support is provided by a new set of guidelines issued by the MDCG, outlining criteria for the registration of orphan medical devices under the EU MDR providing essential guidance to manufacturers and notified bodies on the clinical evidence requirements.

March 2022

Support is provided by the EMA to the medical devices expert panel, offering expert opinions and insights to Notified Bodies.

June 2024

Guidelines issued by MDCG outlines specific criteria for the classification of a medical device as an orphan device.

2025

Target completion of the project. Establishment of a long-term support framework

The EU pilot programme will operate alongside the existing scientific advice pilot, which focuses on prioritising guidance for manufacturers regarding clinical development strategy and clinical investigations for devices intended to address unmet medical needs.

For more information visit
https://www.ema.europa.eu/en/news/new-pilot-programme-support-orphan-medical-devices

ACRONYMS

ASID – Advanced Scientific Initiatives Directorate
AMA – African Medicines Agency
BAR – Brexit Adjustment Reserve
CEO – Chief Executive Officer
EC – European Commission
EMA – European Medicines Agency
EU – European Union
FDA – Food and Drug Agency
HCPs – Healthcare Professionals
HMA – Heads of Medicines Agencies
LLMs – Large Language Models
MDCG – Medical Device Coordination Group
MMA – Malta Medicines Authority
MoU – Memorandum of Understanding
NCPE – National Commission for the Promotion of Equality
PRAC – Pharmacovigilance Risk Assessment Committee
UK – United Kingdom