THE MMA | ISSUE 17 – Q1 2024

telegram

Welcome dear colleagues to our 1st e-newsletter for the year 2024!

In this Issue

A LOOK BACK AT 2023…

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 4 **AWARD** in Basic Regulatory Sciences

2 Staff Meetings and **12** team-building activities

MED-IN PHARMA

MedInPharma

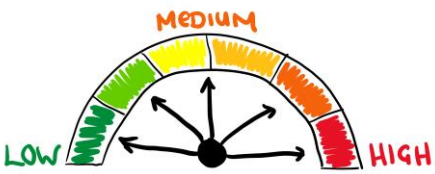
MED-TECH WORLD

2 New Memoranda of Understanding

Saint Vincent De Paul long term care facility

CInMED Institute for Medicines and Medical Devices of Montenegro

MMA 20th ANNIVERSARY



SEMINAR on Management, Communication and Perception of Risk

2 EU 4HEALTH JOINT ACTIONS

Market Surveillance of Medical Devices

Increased capacity and competence in the EU medicines regulatory network

BEMA V Audit and **JAP Audit**

AWARD IN PHARMACOVIGILANCE | JANUARY

The delivery of the first Level 6 Award in Pharmacovigilance was a milestone in providing a comprehensive understanding of the topic and knowledge on the EMA guidelines on GPV. It was truly inspiring to witness professionals from diverse backgrounds converging to discuss pharmacovigilance global trends.

Heartfelt appreciation to all contributors for their unwavering commitment and expertise, who played a pivotal role in the success of this course.

IncreaseNET- EU4HEALTH PROGRAMME KICK-OFF MEETING | JANUARY

This Joint Action within the EU4Health Programme was launched with the aim to:

- strengthening the capacity and competence building of European national medicines agencies in the field of medicines assessment,
- exchanging of knowledge, ideas, good practices and training programmes, and
- reinforcing the EU network by optimising existing capacities and supporting innovation.

Officers of the MMA are actively contributing to this Joint Action by leading Working Package 3 on the overall coordination, monitoring and reporting of the key tasks and activities.
MMA Representatives attended the kick-off meeting in Ljubljana.

MALTESE DELEGATION IN QATAR | FEBRUARY

Members of the MMA management joined the Maltese delegation led by Minister Hon Jo Etienne Abela in the visit to Qatar. The aim of the visit converged towards the strengthening of collaboration and sharing of best practices between the two governments on the coordination of aspects of health, pharmaceutical services and active aging.

CORPORATE SOCIAL RESPONSIBILITY WEEK | MARCH

The MMA is the first entity taking part in the 20th CSR week spearheaded by HSBC, Malta.

Ms Emma Saliba, Senior Head of the People Management Unit, proudly presented the initiatives carried out by MMA employees to help others in need and positively impact society, at the courtesy call by His Excellency the President of Malta, Dr George Vella.

VISIT BY ANTWERP UNIVERSITY

The MMA in collaboration with the Department of Pharmacy organised a networking session for a group of third-year pharmacy students visiting from Antwerp University.

The session aimed at exposing the students to pharmaceutical regulatory sciences through presentations from MMA employees and fellows.

DID YOU KNOW?

The nose can recognise a trillion of different scents!

All you need is love! Employees who submitted their baby photos entered the competition on Valentine's Day. The winner was announced during a networking lunch.

Happy *Employee Appreciation Day* to our incredible employees!

Cheers to all who make the Malta Medicines Authority an amazing workplace!

The world is a better place because of the strength and resilience of women.

Happy International Women's Day to all our amazing female employees!

When Women support each other, incredible things happen!

A bake sale in aid of *Smiling with Jerome* was organised as part of the MMA initiatives carried out within the Corporate Social Responsibility Week. With the help of MMA employees, €200 were collected and donated to provide support and assistance to individuals passing through difficult times.

GENERAL EUROPEAN UPDATES

ANTIMICROBIAL RESISTANCE

The importance of reducing antibiotic use | JANUARY

Trends of antimicrobial consumption and AMR were analysed in a report by ECDC, EFSA and EMA on E.coli for both human and food-producing animals.

This study showed an association between the decrease in the consumption of antibiotics and the reduction in antibiotic-resistant bacteria. These results highlight the success of the EU's actions to combat antimicrobial resistance in a One Health approach.

UPDATE

PRECAUTIONARY MEASURES

Potential risk of neurodevelopmental disorders | JANUARY

CMDh and PRAC endorsed precautionary measures to reduce the risk of neurodevelopmental disorders in children born to males who were administered valproate-containing medicines 3 months before conception. These measures recommend:

- Consider contraception for both partners during and 3 months after stopping the treatment
- Inform the HCP if there is an intention to conceive a child
- Avoid semen donations during and 3 months post-treatment

NEW TREATMENT

Amyotrophic Lateral Sclerosis | FEBRUARY

EMA reported that a new ALS treatment will be granted a marketing authorisation. Qalsody®, an antisense oligonucleotide, binds to the mRNA of SOD1 gene and reduces the amount of defective protein. It is foreseen that this new treatment will reduce the symptoms of ALS in adult patients.

NEW TREATMENT

First oral monotherapy for Paroxysmal Nocturnal Hemoglobinuria | MARCH

The 1st oral treatment for adults with haemolytic anemia suffering from PNH was recommended by EMA for the granting of a MA. Fabhalta® (iptacopan) targets Factor B and prevents intravascular and extravascular haemolysis, resulting a reduce need of blood transfusion.

This decision showcase the EMA's PRIME scheme, which provided scientific and regulatory support for this new treatment and assists in the development of therapies potentially addressing patients' unmet medical needs.

DARWIN EU® COORDINATION CENTRE

The DARWIN EU is a coordination centre established by the EMA and EMRN, to work towards the collection of timely and reliable real-world data evidence on the use, safety and effectiveness of medicines.

Data is collected and made available to EMA and NCAs by pooling a portfolio of observational data and addressing knowledge gaps through non-interventional studies.

RECENTLY COMPLETED STUDIES

Studies carried out within the Centre include:

- A study carried out between 2013 and 2022 on patterns in medicines administered to adults and children with SLE during treatment.
- Acknowledgment of patient characteristics, patterns and chances of survival in over 30,000 European patients diagnosed with multiple myeloma between 2012 and 2022.

This was 1 of the 2 first pilot cases used for the RWD by HTA for decision-making.

TARGETS AND DATA

- Seeks to extend the Centre to 10 new data partners
- Operates with 20 public/private institutions from 13 different countries and pools data from 130M patients across Europe
- Gathers data from hospitals, primary care, health insurance, registries and biobanks

TIMELINE

- Project initiation **2021**
- DARWIN EU establishment **2022**
- Developing and using DARWIN EU **2023**
- Full operation mode **2024**
- Leverage the EU Health Data Space **2025**

For more information visit https://www.darwin-eu.org/

Cannabis-based products: analytical implications and impact on regulation

Gilbert Mercieca

Background

The project investigates the quality parameters applicable to Cannabis from an analytical perspective and their impact on the regulation of Cannabis.

The objectives of this study involve the development, validation, and implementation of analytical techniques relevant to Cannabis-based products.

The research is intended for Cannabis testing and comparing properties of Cannabis in different dosage forms and from different sources, alongside the assessment of how the outcomes of this research impact the establishment of official standards and their adoption in regulatory frameworks.

Procurement of Safe Medical Devices

Geofrey Neyra

Background

This study examines the medical device procurement practices of Switzerland, Singapore, and South Korea, which are recognised for their regulatory excellence and procurement efficiency by the WHO.

It is aimed at enhancing patient safety in Malta, it employs document analysis and thematic synthesis to identify effective procurement strategies, regulatory compliance, and stakeholder engagement practices.

The findings suggest that successful procurement relies on strong regulatory standards, clear practices, and collaboration, proposing a strategic framework to improve Malta's medical device procurement and healthcare quality.

ACRONYMS

ALS – Amyotrophic Lateral Sclerosis
AMR – Antimicrobials
BEMA – Benchmarking of the European Medicines Agency
CMDh – Coordination Group for Mutual Recognition and Decentralised Procedures - Human
CSR – Corporate Social Responsibility
Dr – Doctor
ECDC – European Centre for Disease Prevention and Control
EFSA – European Food Safety Authority
EMA – European Medicines Agency
EU – European Union
GVP – Good Pharmacovigilance Practice
HCP – Healthcare Professional
HSBC – Hongkong and Shanghai Banking Company
HTA – Health Technology Assessment
JAP – Joint Audit Programme
MA – Marketing Authorisation
MMA – Malta Medicines Authority
mRNA – messenger Ribonucleic acid
MQF – Malta Qualification Framework
NCA - National Competent Authority
PhV – Pharmacovigilance
PNH – Paroxysmal Nocturnal Hemoglobinuria
PRAC – Pharmacovigilance Risk Assessment Committee
PRIME – Priority Medicines
RWD – Real World Data
SOD1 – superoxide dismutase type 1