THE MMA | ISSUE 13 – Q1 2023

telegram

Welcome dear colleagues for our 1st e-newsletter for year 2023!

In this Issue

A LOOK BACK AT 2022…

The Malta Medicines Authority (MMA) upheld its mission to *safeguard public health through the regulation of medical products and pharmaceutical activities for human use.*
Prominent events of year 2022 included:

AWARD in GDP at MQF level 5

PINK OCTOBER and **MOVEMBER**

Herbal Medicinal Products Committee

Workshop on **CANNABIS**

MED CANN world forum

CANNABINOID conference

MED-IN PHARMA

MedInPharma

MED-TECH WORLD

Seminars on **MEDICAL DEVICES**

2 staff meetings

Visit from the **MINISTER**

MMA goes to **SICILY**

FIMEA visit

COLLECTIVE AGREEMENT 2021-2025

uhm

BEMA V preparation

GENERAL MMA UPDATES

MMA STAKEHOLDER SURVEY | JANUARY

A survey measuring stakeholders perception on the quality of service provided by the MMA was conducted. An analysis of the results showed that stakeholders are overall satisfied with the performance and guidance on regulatory responsibilities. Stakeholders are encouraged to continuously provide their feedback through online platforms which will be promoted on a quarterly basis.

A ROLE MODEL AUTHORITY FOR CInMED | FEBRUARY

The MMA was selected by the Institute for Medicines and Medical Devices of Montenegro (CInMED) to act as a role model National Competent Authority to implement and achieve robust regulatory sciences functions and standards required to gain membership into the European Union. Representatives from CInMED were welcomed at the MMA and an MoU was signed focusing on areas of cooperation in the regulation of medicines and medical devices.

BENCHMARKING OF EUROPEAN MEDICINES AGENCIES V ASSESSMENT | MARCH

The MMA hosted a team of assessors as part of the BEMA programme, as established by the Heads of Medicines Agencies (HMA). The programme is based on the assessment of systems and processes in individual agencies against a set of indicators pertaining to the following areas:

- Management Systems
- Assessment of Marketing Authorisation Applications
- Pharmacovigilance Activities
- Inspection Services

This assessment provides an opportunity for the MMA to identify its strengths and best practices and to continuously work towards improving its regulatory and scientific functions.

ANNUAL REPORT 2022

The Annual Report 2022 reflects the robustness, resilience and quality of our people and portfolio. The yearly Annual Report is a corporate document which is disseminated amongst stakeholders to evaluate the Authority's performance by disclosing milestones, operations, statistical data, and scientific initiatives achieved and pursued by the MMA over the previous year

DID YOU KNOW?

It is believed that the main purpose of eyebrows is to keep sweat out of the eyes!

PEOPLE MANAGEMENT EVENTS

JANUARY

An online canteen was launched the very first week of January, with the opportunity to order your lunch and have it delivered to you *'al desko'*.

'Eat Right, Feel Right, Do more! Every time you eat you nourish your body'

The National Commission for the Promotion of Equality (NCPE) delivered training on *Equality and Anti-discrimination Law* to all MMA employees, fellows and students. Some topics covered were Sexual harassment, Equality between genders, and Law.

FEBRUARY

February is known as the month of *love*. The Authority celebrated this year with Valentine's day '*All about Love Trivia*'. A get-together was organised and the winner was announced.

Carnival '*Show off your creativity by wearing carnival accessories!*'

As part of the training and development, courses were delivered throughout the month of February. These courses targeted areas of *bullying at the workplace, English for business, mindfulness, and self-care and well-being*.

A memorial mass was held to commemorate Michael Chetcuti and his professional and personal contribute to the MMA.

MARCH

May every petal on the shamrock bring you *joy* and *good luck*!

A team-up day get-together was organised by playing non-alcoholic beer pong to celebrate St. Patrick's Day.

Employees were encouraged to embark on a journey of Lent Voluntary Work.

GENERAL EUROPEAN UPDATES

General updates	Description
Mandatory use of CTIS for new clinical trials applications | **JANUARY**	All new clinical trials applications are to be submitted via the Clinical Trials Information Systems (CTIS). This system will serve as the single-entry point for submission by sponsors and regulatory assessment, and provide easy access to structured data and documents on clinical trials for patients, healthcare professionals, scientists and the general public.
Support for development of new paediatric medicines | **FEBRUARY**	The European Medicines Agency (EMA) and the European Commission (EC) published a report capturing initiatives taken as part of the 2018 EMA-EC action plan for the development of new medications for paediatric patients. This report included key measures, such as: • Increased focus on unmet medical needs; • Adaptation of regulatory processes to improve support for innovation; • Increased alignment of data requirements between decision makers.
Safety review of medications containing pseudoephedrine | **FEBRUARY**	Following reports of posterior reversible encephalopathy syndrome (PRES) and reversible cerebral vasoconstriction syndrome (RCVS), the Pharmacovigilance Risk Assessment Committee (PRAC) started to review medicines containing pseudoephedrine. The outcome of this assessment will determine whether marketing authorisations for pseudoephedrine-containing medications will be retained unchanged or whether these should be varied, suspended or withdrawn throughout the EU.
Provision of scientific advice for high risk medical devices | **FEBRUARY**	EMA initiated a pilot project aimed at developing an efficient scientific advice procedure for high risk medical devices (class III devices and class IIb active devices intended to administer and/or remove medicinal product(s)), prioritising orphan devices, medical devices used in paediatric patients, devices used in life-threatening medical conditions, and novel devices.

EMA-EC Paediatric action plan

To address challenges hindering the optimal implementation of the Paediatric Regulation (EC) No. 1901/2006 and sustain the development of therapies for diseases that only impact paediatric patients, The EMA-EC Paediatric Action Plan was published in 2018. This lays out a series of short-term objectives aimed at addressing the identified challenges to the implementation of the Paediatric Regulation. Four years after the publication of this action plan, a number of positive results were noted.

TIMELY COMPLETION OF PIPS

Initiatives aimed at ensuring timely completion of PIPs included a framework issued by the European Network of Paediatric Research at EMA (Enpr-EMA) on clinical trial preparedness. Steps were taken to identify best practices and develop structured guidelines on the extrapolation of data for applicants and Marketing Authorisation Holders (MAHs). Training was also provided to empower youths and their parents, enabling them to play an active role in the planning of clinical trials.

IDENTIFICATION OF PAEDIATRIC MEDICAL NEEDS

A number of steps were taken to identify paediatric patient's needs, including participation in multi-stakeholder fora. These resulted in the prioritisation of medical product development in accordance with current unmet needs and guided product-specific discussions on Paediatric Investigation Plans (PIPs) and waivers.

IMPROVING THE HANDLING OF PIP APPLICATIONS

A 'stepwise PIP' is being implemented to improve management of PIP applications. This concept was developed by a focus group comprised of participants from the pharmaceutical industry, EMA and PDCO. This stepwise approach would allow for changes to be made to the PIP over time should new evidence become available. Updates were also made to the PIP summary report template to reflect this new approach.

STRENGTHENING THE COOPERATION OF DECISION MAKERS

Strategies aimed at improving coordination between decision makers were developed by ensuring regular communication between the Paediatric Committee (PDCO) and the Clinical Trials Coordination Group (CTCG). Measures were also taken to strengthen the relationship between the EMA and the US Food and Drug Administration (FDA). An international working group was also set up with the aim of facilitating the performance of multi-regional paediatric clinical trials.

INCREASING TRANSPARENCY AROUND PAEDIATRIC MEDICINES

Work is currently being carried out to update the community register of medicinal products to include links to PIP data. A public register containing information on paediatric clinical trials which are currently recruiting will be made available. This register is also envisaged to report the results of paediatric clinical trials in simple terms understood by lay persons and patients.