THE MMA | ISSUE 14 – Q2 2023

telegram

Welcome dear colleagues for our 2nd e-newsletter for year 2023!

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PEOPLE MANAGEMENT EVENTS

APRIL

Celebrating Easter 2023 at the MMA with traditional Maltese *figolli*.

The People Management team organised the first-ever MMA *Sports Day*! It was an opportunity for all employees to be active and work together in various fun physical activities and challenges.

MAY

During the *European Mental Health Week 2023* various activities were organised to raise awareness about mental health. Employees were encouraged to affix positive thoughts on a Mental Health Awareness Display, participate in a short walk and attend an interactive session delivered by a professional psychologist.

JUNE

The first MMA staff meeting of 2023 was organised on 23 June in *Gozo*! During the get together MMA employees had the opportunity to connect and foster stronger interpersonal relationships with each other.

GENERAL MMA UPDATES

VISIT TO THE MEDICINE EVALUATION BOARD | APRIL

The Minister responsible for the MMA, Mr Jo Etienne Abela together with the Chief Executive Officer of the Authority and other MMA representatives visited the Medicines Evaluation Board (MEB), the Dutch National Competent Authority, with the aim of strengthening cooperation between the two agencies and sharing of best practices.

THE PUBLIC SERVICE WEEK EXPO 2023 | MAY

During the Public Service Week Expo 2023, MMA employees educated the public about the MMA mission of safeguarding public health through the regulation of medical products and pharmaceutical activities for human use. The Expo provided an opportunity to share insights, best practices, and practical solutions to everyday challenges, network with peers and connect with industry leaders.

SEMINAR ON THE MANAGEMENT, COMMUNICATION AND PERCEPTION OF RISK | MAY

A seminar on concepts of risk related to quality risk management process, perception, and communication with specific consideration to medicines and vaccines was organised by the MMA Academy for Patient-Centred Excellence and Innovation in Regulatory Sciences. Keynote speakers included Professor Frederic Bouder from the University of Stavanger, Norway, and Dr Maresca Attard Pizzuto from the Department of Pharmacy at the University of Malta.

EUROPEAN IMMUNISATION WEEK 2023

In April, the MMA participated in the European Immunisation Week 2023. This annual campaign aims to raise awareness on the importance of immunisation in preventing diseases and protecting life. This year's campaign focused on improving vaccine uptake in the context of the European Immunisation Agenda 2030 and a global backslide in vaccination rates due to the COVID-19 pandemic.

DID YOU KNOW?

A person can expect to breathe in around **45 pounds** of dust over his/her lifetime!

GENERAL EUROPEAN UPDATES

Introduction of the new features to further strengthen Priority Medicines (PRIME) Scheme | **APRIL**

The European Medicines Agency (EMA) introduced new measures to the PRIority MEdicines (PRIME) scheme to improve support for the development of medicines for unmet medical needs. New features include a roadmap for each PRIME medicine, a product development tracker, expedited scientific advice and submission readiness meetings.

Measures to reduce the risk of severe, long-term side effects associated with Fluoroquinolone use | **MAY**

The Pharmacovigilance Risk Assessment Committee (PRAC) issued a reminder to healthcare professionals to restrict the use of Fluoroquinolone medicines due to the risk of severe and long-term side effects that may occur.

Fluoroquinolones should not be used to routinely treat non-severe infections, or non-bacterial infections as well as for the prevention of traveller's diarrhoea, or lower urinary tract infections.

EMA Recommendations for prevention and mitigation of medicine shortages | **MAY**

A guidance for the pharmaceutical industry for the prevention and mitigation of medicine shortages was published by EMA. Recommendations made include:

- Enhancing communication with National Competent Authorities and other stakeholders to identify potential or actual shortages as early as possible;
- Implementing shortage prevention and shortage management plans;
- Improving resilience of quality systems and of supply chains;
- Proposing initiatives for the equitable distribution of medicines meeting patients' needs.

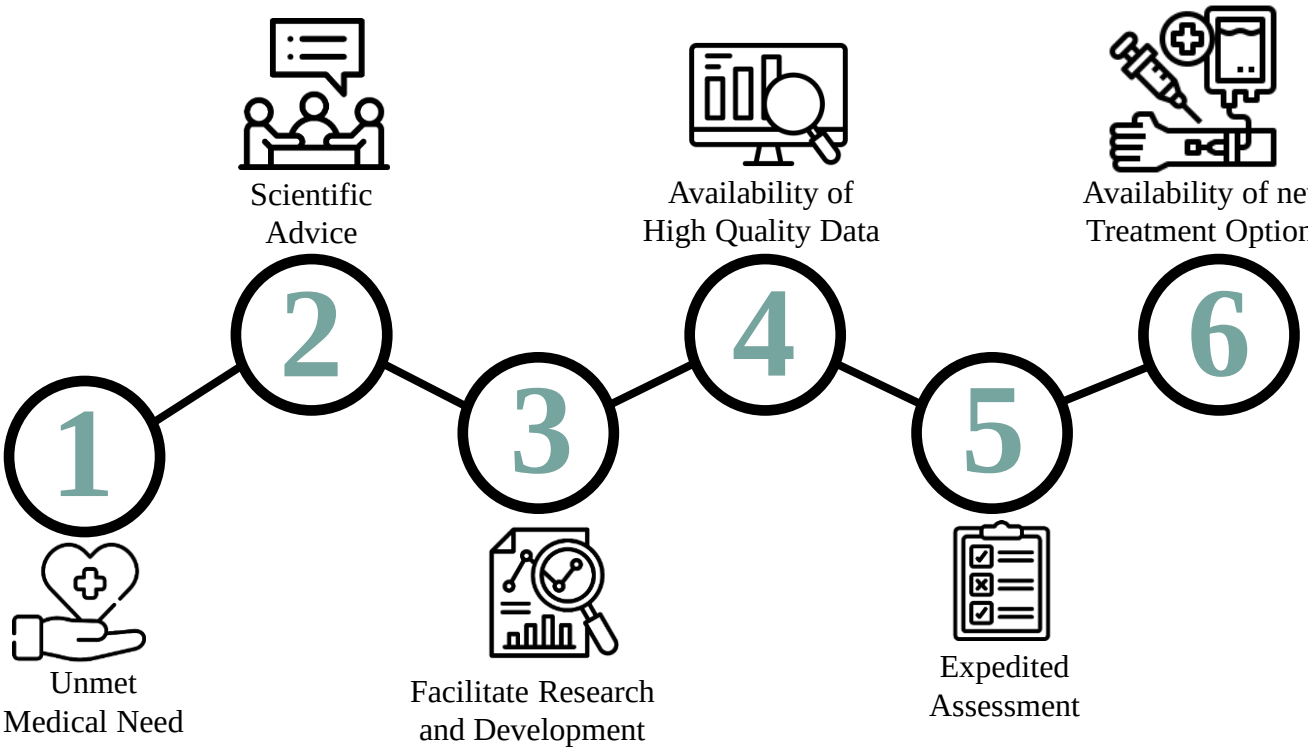
Using Real World Evidence (RWE) in Regulatory Decision Making | **JUNE**

The European Medicines Agency (EMA) has published a report on the use of studies conducted using Real World Data (RWD). Such studies are important in that they complement data obtained using clinical trials and may be used to support regulatory decision making for both pre- and post-authorisation assessments of medicines.

EMA Priority Medicines Scheme - PRIME

The EMA Priority Medicines Scheme, PRIME, is a programme launched to provide support for Research and Development of innovative medicines targeting unmet patients' medical needs. This scheme involves improved and continuous dialogue with the pharmaceutical industry to optimise the process of medicine development and ensure more efficient and earlier access to these medicines for patients.

PRIORITY MEDICINES SCHEME



The PRIME Scheme is based on already implemented regulatory procedures, namely scientific advice availability as well as the expedited assessment procedure for innovative medicinal products.

Scientific advice is provided by a selected rapporteur from Committee for Medicinal Products for Human Use (CHMP) or from the Committee for Advanced Therapies (CAT) and it is coordinated with an expert group comprised of members from various EMA scientific committees and working parties.

POSITIVE IMPACT FOR PATIENTS

- Fulfill patient needs
- Advantageous alternative treatments
- Earlier access to therapies

POSITIVE IMPACT FOR MEDICINE DEVELOPERS

- Optimised medicine development plans
- Quicker assessment
- Incentives towards unmet needs