THE MMA telegram

ISSUE 12 – Q4 2022

Welcome dear colleagues for our last e-newsletter for year 2022!

In this Issue

EVENTS

Pink October and Movember at the MMA *(28-31 Oct; 15 Nov 2022)*

Pink October and Movember Campaigns were organised at the MMA to raise awareness on breast cancer and men's health issues. During Pink October, employees were encouraged to wear pink and give donations to support Community Chest Fund and Puttinu Cares. The Movember Campaign event aimed at increasing the understanding of prostate cancer, testicular cancer, mental health and suicide prevention.

MMA Staff Meeting *(6 Dec 2022)*

A team building staff meeting with a Christmas Murder Mystery theme was held to facilitate creative thinking, engage employees, build interpersonal relationships, boost motivation and collaboration among MMA staff. The meeting was addressed by MMA Management and a talk by a gestalt psychotherapist and mindfulness expert about self-care, well-being and teamwork at the workplace was delivered. The staff meeting served to end the year on a positive note and motivate MMA employees to face the upcoming year.

Med-In Pharma Conference 2022 *(17-18 Nov 2022)*

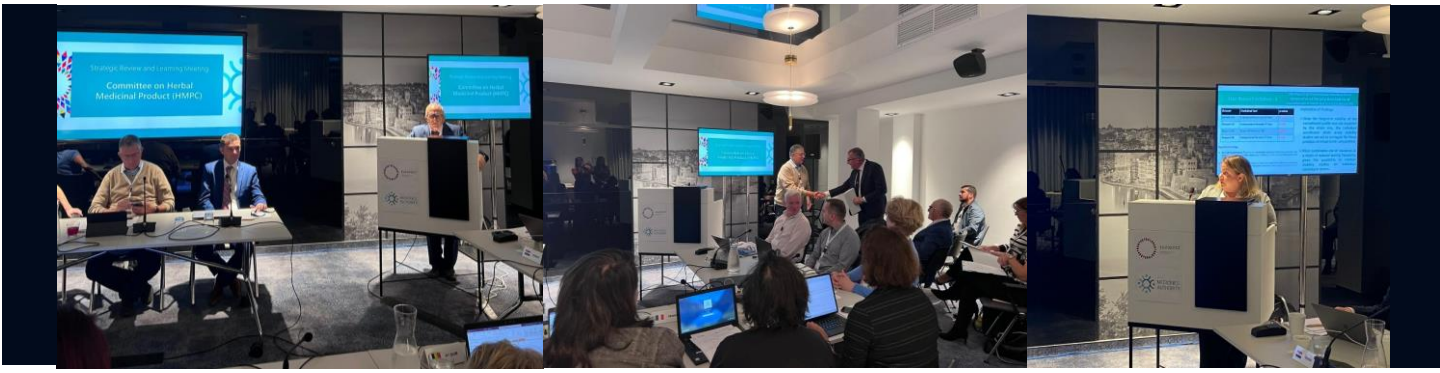
The Med-In Pharma Conference was organised by the MMA in collaboration with the Faculty of Medicine and Surgery, the University of Malta, and the Malta Chamber of Scientists. The conference promoted discussions on policy-making and regulation, health inquiry, medical innovation, and personalised, patient-focused technology. During the conference plenary sessions, short communication sessions, and poster presentations were conferred on development of innovative techniques, enabling technologies, smart factory and future trends in pharmacy and applied science.

GENERAL MMA UPDATES

Cannabinoid Conference (Oct 2022)
The International Annual Congress on Controversies of Cannabis-based Medicines (Nov 2022)

MMA representatives from the Cannabis for Medicinal and Research Purposes Unit presented studies on **interpretation of stability data** at two major conferences in Switzerland and Denmark. The conferences provided an opportunity for dissemination and networking on knowledge and experience related to evidence-based regulatory decision making in the field of cannabis for medicinal and research purposes.

Committee on Herbal Medicinal Products (HMPC) Meeting (Nov 2022)



The MMA hosted a strategic review and learning meeting of the **Committee on Herbal Medicinal Products (HMPC)** on behalf of the Czech Republic's Presidency of the Council of the European Union. Representatives from EU member states engaged in discussions on herbal and drug interactions, risks associated with exposure to multiple chemicals and a presentation on the regulation of Cannabis for Medicinal and Research Purposes was delivered by MMA colleagues.

#MedSafetyWeek and World Antimicrobial Awareness Week (Nov 2022)

The MMA participated and promoted two social media campaigns: the **#MedSafetyWeek** aimed at increasing awareness on the importance of monitoring of side effects and encouraging reporting of side effects by both healthcare professionals and patients. The **World Antimicrobial Awareness Week** aimed at improving understanding of Antimicrobial Resistance (AMR) and push for the adoption of best practices by policymakers, healthcare professionals and institutions, as well as by the public.

DID YOU KNOW?

Every one of your muscle fibres is thinner than a human hair strand, yet can hold up to 1,000 times its own weight

GENERAL EUROPEAN UPDATES

General Updates	Description
New Vaccine for protection against Dengue	The Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion regarding Takeda®, a tetravalent vaccine used for protection against Dengue virus serotypes 1, 2, 3, and 4 in people aged over four years. This is the first case in which CHMP simultaneously assessed a product meant for the EU market via the centralised procedure as well as for the non-EU market via the 'EU-Medicines for All' programme. This programme aims at addressing global unmet needs in a faster and more efficient manner.
Recommendations for minimisation of ADR risks associated with Janus Kinase (JAK) Inhibitors	The Pharmacovigilance Risk Assessment Committee (PRAC) issued recommendations for minimisation of risks of serious Adverse Drug Reactions (ADRs) caused by JAK inhibitors for chronic inflammatory conditions. Recommendations include use of these medications as a last line in patients over 65 years of age, those at risk of serious cardiovascular events and/or cancer, as well as smokers. The PRAC also recommended caution in patients with risk factors for Venous Thromboembolism (VT). These recommendations have been endorsed by CHMP.
Best Practices for combating Antimicrobial Resistance	The International Coalition of Medicines Regulatory Authorities (ICMRA) published a report regarding successful initiatives adopted by countries in an effort to overcome the threat of Antimicrobial Resistance (AMR). The report highlights best practices developed in accordance with the EU Commission's 'One Health' approach.
Withdrawal of pholcodine medicines from EU Market	As a result of a safety assessment of medicines containing pholcodine, the PRAC found that the use of these medicines within 12 months of general anaesthesia using Neuromuscular Blocking Agents (NMBAs) increases the risk of anaphylactic shock. In view that no measures were identified to reduce this risk, the PRAC recommended the withdrawal of the marketing authorisation for medicines containing pholcodine.

Updates Related to Treatments and Vaccines for COVID-19

Updates	Description
Recommendation for approval of Comirnaty® and Spikevax® for children over six months of age	The CHMP recommended an extension of the use of the COVID-19 vaccines Comirnaty® and Spikevax® for children aged six (6) months to four (4) years and six (6) months to five (5) years respectively. Vaccine doses for this age group will be lower than those authorised for older age groups. Both vaccines were the subject of studies evaluating immune response in the concerned age groups by measuring the antibody level against the SARS-CoV-2 Virus.
Authorisation of VidPrevtyn® Beta as a COVID-19 booster vaccine	The CHMP made a positive recommendation regarding the authorisation of the COVID-19 vaccine, VidPrevtyn® Beta, as a booster in adults who already received at least one dose of an mRNA or adenoviral vector COVID-19 vaccine. VidPrevtyn® Beta was the subject of two immunobridging trials which compared the immune response elicited by this vaccine with the immune response elicited by other already authorised vaccines. The CHMP's recommendation was accepted by the European Commission and VidPrevtyn® Beta was granted a Marketing Authorisation.
Bivalent original/Omicron BA.4-5 mRNA vaccines may be used for primary vaccination	The EMA Emergency Task Force (ETF) recommended that adapted mRNA bivalent vaccines targeting the original strain and Omicron BA.4-5 subvariants of SARS-CoV-2, as of now only authorised as boosters, may be used for primary vaccination against the COVID-19 virus. The ETF reached this conclusion after a review of non-clinical data and studies of the immune response of unvaccinated persons naturally infected for the first time with Omicron BA.4-5.

Regulatory Aspects of Antimicrobial Resistance

Antimicrobial Resistance (AMR) is a foremost emerging health threat that requires urgent action on a global scale and was designated by the World Health Organisation (WHO) as one of the top ten (10) global public health threats being faced by humanity. In response to this, the European Commission (EC) initiated the European 'One Health' Action Plan against AMR and the European Medicines Agencies Network (EMRN) listed AMR as a focus area in its 2020-2025 strategy.

The three main objectives of the EU One Health Action Plan Against AMR

Making the EU a best practice region	*Boosting research, development, and innovation on AMR*	*Shaping the global agenda*
• Promotion of the correct use of antimicrobials; • Improve collaboration between different health sectors; • Work towards infection prevention measures; and • Monitoring of resistance patterns and antimicrobial use.	• Working with partners in EU member states and in the industry to study AMR in bacteria; viruses, fungi, and parasites; • Mainly focused on pathogens such as Tuberculosis, HIV/AIDS, Malaria, and other pathogens on the WHOs priority list.	• Focusing on fostering a stronger EU global presence; • Cooperation with other countries, including developing countries; • Development of a global research agenda.

AMR in Human Medicines: European Medicines Agency (EMA) Role

EMA took a number of initiatives with the purpose of combating the threat of AMR mainly focusing on education on proper antimicrobial use and supporting the development of new antimicrobial medicines.

Supporting the Development of new Antibiotics for Human Use

The Innovation Task Force (ITF) was established in 2019 to provide regulatory advice to companies developing medicines for treatment and/or prevention of bacterial and fungal infections.
Guidelines were provided regarding the use of pharmacokinetic and pharmacodynamic analysis for antibiotic development and the designing of clinical trials. This was jointly developed with the US Food and Drug Administration (FDA), and the Japanese Pharmaceutical and Medical Devices Agency (PMDA) to assist developers in designing clinical trials that fulfil the conditions of different regulatory authorities.

Analysis of Consumption and Resistance

In collaboration with the European Food Safety Authority (EFSA) and the European Centre for Disease Prevention and Control (ECDC), the EMA studied the possible correlation between human/animal antibiotic consumption and the emergence of AMR.
The results of these investigations are produced in joint inter-agency antimicrobial consumption and resistance analysis (JIACRA) reports. These reports serve to better understand AMR patterns across Europe and to give policymakers a deeper understanding of the problem.

Academia – Ongoing Doctorate Level Research Projects

A Framework to Support Educational Courses for Pharmaceutical Workforce Development

The aim of the study is to develop a framework to support courses for the pharmaceutical workforce in order to update the workforce with latest advancements in the pharmacy field. The study will be carried out at the Malta Laboratories Network – Institute for Scientific Development (MLN-ISD). The study has 2 phases, phase I focuses on the identification of quality management system processes, procedures and courses which require validation. Phase II focuses on the development and validation of a gap analysis tool, tailored to assist in the accreditation process of the courses. The development of this tool within a framework scenario assists the accreditation process which drives institutions to achieve and sustain high standards to increase trust and confidence of the public whilst boosting the institution's accountability.

Jimenrose Borra

Thank you for your great contributions made this year

Wishing your hard work, dedication and team spirit to pay off well!

May the year 2023 be the most prosperous, filled with success, happiness and laughter

MALTA MEDICINES AUTHORITY