

THE MMA

ISSUE 15 – Q3 2023

telegram

Welcome dear colleagues for our 3rd e-newsletter for year 2023!

IN THIS ISSUE

20 YEARS OF MMA | COLLABORATION AGREEMENT | MANAGEMENT REVIEW MEETING | AWARD IN BASIC REGULATORY SCIENCE | STAFF SATISFACTORY SURVEY | EVENTS | GENERAL EUROPEAN UPDATES | EMA PLAN FOR EMERGING PUBLIC HEALTH THREATS | ACADEMIA

20 YEARS OF MMA

Over the past 20 years, the MMA has grown, evolved, and achieved remarkable success by contributing to patient-centred care through the regulation of medical products and pharmaceutical activities for human use. A reception was organised at Villa Bighi in Kalkara to celebrate the 20-year anniversary. The Minister for Active Ageing, Dr Jo Etienne Abela, and the CEO of the MMA, Prof Anthony Serracino-Inglott, addressed the event.



COLLABORATION AGREEMENT WITH ST VINCENT DE PAUL RESIDENCE | JULY



The MMA and SVPR signed a collaboration agreement aimed at enhancing clinical pharmacy services. Both entities look forward to collaborate and conduct research about drug interactions and adverse drug reactions so as to further improve the quality of care for older citizens.



AWARD IN BASIC REGULATORY SCIENCE | SEPTEMBER

A three day-accredited course in basic regulatory science was organised by the MMA's Academy for Patient-Centred Excellence and Innovation. During the course, a networking forum was organised providing an opportunity for sharing of knowledge and best practices, supporting the delivery of pharmaceutical processes and services of excellence.

ANNUAL MANAGEMENT REVIEW MEETING | SEPTEMBER

The annual Management Review Meeting was held in line with the Authority's QMS as certified by ISO 9001:2015. The purpose of the meeting is to ensure the optimal functioning of the QMS, to assess the MMA's objectives, targets, and identify potential areas for improvement. Each Directorate/Unit presented initiatives carried out between June 2022 and July 2023 and proposed a way forward.

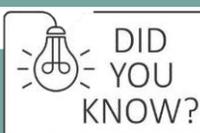


STAFF SATISFACTORY SURVEY 2023

A survey was disseminated amongst MMA staff so as to allow employees to express their opinions about their work life and experience. Employees indicated overall contentment, with 77% of the respondents (N=56) being honoured to work at the MMA and reported feeling part of a big family.

**YOUR OPINION
MATTERS**

If you live to age 70, your heart will have beaten around 2.5 billion times!



PEOPLE MANAGEMENT EVENTS

In celebration of *Cure Pride 2023* being held in Malta, an interactive networking session was delivered by the NCPE to MMA employees.

Through this session, MMA staff participated in a discussion about diversity, acceptance and inclusion in the workplace.



World Pharmacists Day 2023 was a chance to thank and recognise pharmacists and pharmacy professionals for their vital contributions by acknowledging and celebrating their role.

The MMA contributed to the celebration with a get-together and dissemination of lapel pins related to the pharmacy profession.



**End of Extraordinary
COVID-19 Regulatory
Flexibilities | JULY**

The EMA, the EC and the HMA agreed to discontinue the extraordinary regulatory flexibilities for medicines that were applied during the COVID-19 pandemic so as to mitigate the regulatory and supply challenges caused by the pandemic. These include resuming on-site GMP/GDP inspections and full labelling requirements.



**Measures for prevention of
antibiotic shortages over the
upcoming winter | JULY**

The EMA, EC and HMA issued recommendations for the prevention of shortages of key antibiotics. These include liaising with MAHs to increase the production of key antibiotics and close monitoring of supply and demand. The importance of prudent use of antibiotics to prevent antimicrobial resistance was addressed.



**Review of Data Regarding
Paternal Exposure to
Valproate | AUGUST**

The PRAC is currently reviewing data related to the risk of neurodevelopmental disorders in children whose biological father was exposed to Sodium Valproate up to 3 months before conception. It should be noted that male patients being treated with Sodium Valproate should not discontinue the medication without informing their doctor.



**Recommendation for
Approval of New Adapted
COVID-19 Vaccine |
SEPTEMBER**

The CHMP recommended the authorisation of the new adapted COVID-19 vaccine - *Spikevax XBB.1.5*. This vaccine can be used for the prevention of the Omicron XBB.1.5 sub variant of COVID-19 in both adults and children over 6 months of age. Spikevax safety profile has been studied extensively and common side effects include mild pain, redness, and injection-site reactions.

EMA plan for emerging public health threats

The EMA developed a number of strategies to counteract as well as aid global response to existing and emerging public health threats such as pandemics, antimicrobial resistance and biological/chemical threats. As part of these strategies, the EMA developed a health threats plan aimed at ensuring a fast and efficient response.

OBJECTIVES OF THE EMA HEALTH THREATS PLAN

Initiation and coordination of scientific and regulatory activities

Assembly of EMA's Emergency Task Force

Support for international colleagues, stakeholders, and public health authorities in third countries

Provision of information on the outcome of medicines review to EU stakeholders

In accordance with the plan, EMA designated teams and expert groups from the Committees and relevant Working Parties to deal with any threats or crises. These include the:

Executive Steering Group on Shortages and Safety of Medicinal Products

The MSSG monitors supply chains and prevents shortages of medicinal products.

Crisis Response Steering Group (Gold level)

This group provides guidance on the major scientific, regulatory and communication aspects.

Health threats Responsive team (Silver level)

This team ensures the continuity of EMA operations during health crises by following the health threats plan and decisions.

Preparing for, responding to and communicating on serious and emerging health threats is of primary concern in the EMRN strategy. The initiatives outlined in this plan also serve to complement ongoing EC measures in this area.

ACADEMIA – ONGOING DOCTORATE-LEVEL RESEARCH PROJECTS

“Piloting extended community pharmacy services”

AIMS AND OBJECTIVES

This research addresses the piloting of extended services in community pharmacy practice. The objectives are:

To identify the infrastructure required to offer extended services in community pharmacy

To develop practical standards for their provision

To test the feasibility of implementing extended community pharmacy services

METHODOLOGY

Identification of SOPs and infrastructure required by community pharmacies to offer extended services

Updating of SOPs based on patient impact, practicality, and relevance to practice, and development of checklists for community pharmacists

Validation of SOPs and checklists by an expert panel

Feasibility testing of extended community pharmacy services was carried out over a three-month period with ten participants for each extended service selected through convenience sampling

PRELIMINARY RESULTS

Eleven SOPs covering medicine use review, patient review, and advice and treatment services were selected. A new SOP covering urinalysis was developed. The infrastructure required for service provision includes a private consultation area, 8 to 20 minutes per patient encounter, at least one pharmacy support staff, medical devices and consumables, documentation forms, result sheets, and referral letters. The main updates made to the SOPs concerned the provision of outcome of review and/or results to patients, auscultator replaced with automated blood pressure measurement, waist circumference replaced by waist-to-height-ratio measurement, improved documentation processes and reference to evidence-based guidelines during service provision. Each checklist is divided into before, during and after the consultation.

DISCUSSION

The outcomes of the research are practical SOPs and checklists to be used by community pharmacists to facilitate the provision of high-quality and safe extended pharmacy services in the context of collaborative care.

VALERIE ARIANE RIVERA

ACRONYMS

CEO – Chief Executive Officer

CHMP – Committee for Human Medicinal Products for Human Use

EC – European Commission

EMA – European Medicines Agency

EMRN – European Medicines Agencies Network

ETF – Emergency Task Force

EU – European Union

GDP – Good Distribution Practice

GMP – Good Manufacturing Practice

HMA – Heads of Medicines Agencies

MAH – Marketing Authorisation Holder

MMA – Malta Medicines Authority

MSSG – Steering Group on Shortages and Safety of Medicinal Products

NCPE – National Commission for the Promotion of Equality

PRAC – Pharmacovigilance Risk Assessment Committee

QMS – Quality Management System

SOP – Standard Operating Procedure

SVDP – St Vincent De Paul Residence