THE MMA telegram

ISSUE 11 – Q3 2022

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

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EVENTS

MMA goes to Sicily

(29 June 2022)

A leisure trip to Sicily was organised with the aim to enhance relationships between employees outside the work environment, improve communication and inspire collaboration. Participating employees enjoyed a lunch in Ortygia, shopping and a wine tasting experience in a Sicilian Vineyard.

Management Review Meeting

(5 September 2022)

The MMA Management convened for the annual Management Review Meeting as required for operating an ISO-certified Quality Management System (QMS). Each directorate and unit presented actions that were taken during the previous year and laid out the proposed way forward, recommendations, and pending issues. This meeting aims to assess the effectiveness of the MMA's QMS and ensures its continued sustainability, adequacy, and effectiveness while addressing the possible need for improvement to quality policy, objectives, targets and other elements of the QMS.

Workshop on Cannabis for Medicinal and Research Purposes

(30 September 2022)

The MMA Academy for Patient Centred Excellence and Innovation in Regulatory Sciences organised a workshop to provide a forum for exchange of expertise and evidence on the current landscape of medicinal cannabis. Keynote speakers are Professor Robert Nistico and Professor Roger Pertwee, with insights being given by Professor Anthony Serracino-Inglott, Professor Charmaine Gauci, Dr Dylan Said, Dr Charlene Camilleri, and Dr Janis Vella Sziji

GENERAL MMA UPDATES

Resumption of Regular Work Schedule

In view of the lifting of COVID-19 restrictions, the regular work schedule resumed at the MMA on 1 August 2022. The MMA encourages employees to work from the office while offering the opportunity for remote/teleworking for up to 24 hours a week or pro-rata.

MMA/UHM Collective Agreement

Discussions between the UHM - Voice of the Workers and the Malta Medicines Authority regarding the new Collective Agreement, covering the period 2022-2026 are ongoing. The Collective Agreement aims to address concerns that affect employees and the workplace including working conditions and environment, benefits, as well as corporate policies and procedures.

Participation in the EU4Health Programme

The EU4Health Programme aims to provide instruments and solutions to support Member States in enhancing access to medicines, improving public health, and sustaining national health systems.

The MMA was nominated for participation in the Joint Actions on:

- Reinforced market surveillance of medical devices and in vitro medical devices
- Increasing capacity building of the EU medicines regulatory network
- Supporting the maintenance of the European Medical Device Nomenclature

DID YOU KNOW?

In one square inch of our hand we have nine feet of blood vessels, 600 pain sensors, 9000 nerve endings, 36 heat sensors, and 75 pressure sensors

MMA visits the Finnish Medicines Agency (FIMEA)

fimea
Finnish Medicines Agency

FIMEA welcomed the MMA for an onsite visit on 23 and 24 August 2022 in Finland. During this visit, meetings were held with the aim of engaging in a fruitful collaboration and exchanging best practices on Medical Devices regulation and Official Medicines Control Laboratory.

General Updates	Description
Medicines containing Nomegestrol or Chlormadinone: Risk of Meningioma	The Pharmacovigilance Risk Assessment Committee (PRAC) has recommended that medicines containing high doses of Nomegestrol or Chlormadinone should be used as a last-line treatment option, at the lowest effective dose and for the shortest duration possible. Patients should be monitored for Meningioma symptoms and should be contraindicated in patients with a history of Meningioma. These recommendations have been accepted by the Committee for Medicinal Products for Human Use (CHMP).
Interchangeability of Biosimilar Medication	The European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) confirmed that biosimilar medications authorised in EU member states are interchangeable with their originator medicine or other equivalent biosimilar medicines. This joint statement serves to harmonise the EU approach towards interchangeability of biosimilar medication, gives clarity for healthcare professionals, and increases access to biosimilar medicines for patients.
Recommendation of approval of Imvanex® for the prevention of Monkeypox disease	CHMP recommended to extend the indication of the Smallpox vaccine, Imvanex®, to include protection of adults from Monkeypox. This recommendation was based on data from several animal studies which showed protection against the Monkeypox virus in non-human primates vaccinated with Imvanex®. The effectiveness of Imvanex® against Monkeypox will be confirmed via data collection from an observational study that will be carried out during the ongoing Monkeypox outbreak in Europe.
Use of Topiramate in pregnancy and women of childbearing potential	PRAC is currently reviewing Topiramate for risk of neurodevelopmental disorders in children exposed to the drug during pregnancy. This review was triggered due to a study which showed a potential increased risk of neurodevelopmental disorders (especially Autism Spectrum Disorders and intellectual disability) in children born to mothers that were taking Topiramate during pregnancy.

Updates Related to Treatments and Vaccines for COVID-19

Updates	Description
EMA reviewing data on Sabizabulin for COVID-19	EMA is looking at available data regarding use of Sabizabulin for treating COVID-19, including a study carried out involving hospitalised patients suffering from moderate to severe COVID-19 treated with this drug. Sabizabulin works by binding to parts of microtubules, which play a role in helping SARS-CoV-2 enter and leave cells. This may interfere with the virus lifecycle and limit its replication and spread.
Review of conditional marketing authorisation application for Skycovion® COVID-19 vaccine	EMA started a review of a conditional marketing authorisation application for Skycovion®, a vaccine for protecting against COVID-19. The applicant, SK Chemicals GmbH, has submitted data on how well the vaccine triggers the production of antibodies against the original strain of SARS-CoV-2, as well as data on the safety and quality of the vaccine.
First adapted COVID-19 booster vaccines authorised across the EU	CHMP recommended that the adapted COVID-19 vaccines, Comirnaty® Original/Omicron BA.1 and Spikevax® bivalent Original/Omicron BA.1, are authorised in the EU for use in patients above the age of 12 and who have received primary vaccination against COVID-19. These vaccines are now authorised across the EU following a European Commission decision issued on 1 September 2022.

The Pharmaceutical Strategy for Europe

Malta is being consulted in the implementation of the Pharmaceutical Strategy for Europe, a patient-centred strategy adopted on the 25 of November 2020 by the European Commission. The strategy aims to ensure the quality and safety of medicines across Europe while boosting global competitiveness in the pharmaceutical sector.

The major goals of this strategy are:

Fulfilling unmet medical needs and ensuring accessibility and affordability of medicines

Unmet medical needs will be prioritised via Research and Development for new treatments for rare diseases and microbial infections to combat antimicrobial resistance (AMR). Legislation on paediatric and orphan medicines will also be revised and collaboration amongst committees and Health Technology Assessment (HTA) bodies will be improved to address unmet needs. Incentives for the pharmaceutical industry will be revised and may include the introduction of more conditions in exchange for an increase in patient access to medicines. Action will also be taken to support increased generic/biosimilar competition, to enforce EU competition rules, to carry out an assessment of public procurement procedures, and to improve cooperation between member states on HTA. Affordability of medicines will be improved by revising legislation to decrease stumbling blocks for market competition, developing cooperation amongst National Competent Authorities (NCAs), improving transparency, and continuing with assessment of the adequacy of national health systems.

Enhancing Resilience

Supply chain security and medicine shortage prevention are top priorities laid out in the strategy. Other main considerations of the strategy are ensuring the production of high quality, safe, and environmentally sustainable medicines, and strengthening Europe's heath crises response mechanisms through the introduction of an EU Health Emergency Response Authority (HERA).

Supporting a competitive and innovative European pharmaceutical industry

Competition within the EU pharmaceutical industry will be encouraged by improving the supplementary protection certificates system, the introduction of a European Health Data Space, and support for public-private and public-public partnerships. Digital transformation and innovation initiatives will include improving communication and cooperation on evidence generation between regulatory authorities in the areas of medicines and medical devices, supporting the use of high-performance computing and artificial intelligence, and ensuring access to 10 million genomes for research purposes. Regulatory efficiency will also be promoted via initiatives including, simplification of pharmaceutical legislation, and revision of the variation framework for medicines.

Ensuring a strong EU voice globally

Initiatives for increased EU presence in global affairs include support for the work carried out by the WHO and pushing for the adoption of common national standards regarding the quality, safety, and efficacy of medicines.

The objectives laid out in this strategy will be carried out over several years, in partnership with EU Member States, and will ensure that medicines reaching patients in the EU are innovative, safe and of high quality.

Academia – Ongoing Doctorate Level Research Projects

Concepts in Pharma Entrepreneurship

Innovation and entrepreneurship are critical aspects which support economic growth and development. Healthcare systems are constantly faced with challenges which require the undertaking of innovative practices for their transformation. Improvements in healthcare may be achieved when applying entrepreneurship to pharmaceutical processes.

The aim of the study is to answer research questions regarding entrepreneurship in the pharmaceutical field related to the contribution entrepreneurship has to innovation, the concept and role of education and training in the evolvement of entrepreneurship, developing a framework for entrepreneurship in regulatory sciences and measuring accountability in entrepreneurship.

The study of concepts in entrepreneurship in pharmaceutical processes will enable the identification of knowledge and competences needed to successfully identify, create and pursue new endeavours. In the context of this research, entrepreneurship is considered beyond the traditional sense of business and financial planning. In this study, entrepreneurship is considered as a product of creative thinking, the taking of calculated risk when embarking on new ventures, and evidence-based decision making as related to a progressive pharmaceutical scenario.

Lara Giudice

Constituents of cannabidiol products

The study is basically related to the analysis of cannabidiol products. The aim is to develop, validate and accredit an analytical method to determine tetrahydrocannabinol in cannabidiol oil. The study is divided into four phases:

1) systematic literature review
2) selecting the best method of sample preparation
3) method validation and
4) accreditation of developed and validated method. At present, the study focuses on improving the precision of the analytical method.

Lovely Lynne Gallo