THE MMA telegram

ISSUE 08 – Q4 2021

Welcome dear colleagues to our fourth e-newsletter for year 2021!

EVENTS

Stakeholders conference for the launch of the Malta Medicines Authority Strategy to 2025

The Malta Medicines Authority (MMA) Strategy to 2025 was launched on 1 December in the stakeholders conference with the theme *Science Meets Practice*. The event was addressed by keynote speakers including the Minister for Tourism and Consumer Protection, the Parliamentary Secretary for Public Cleansing and Consumer Protection, the Superintendent of Public Health and the Head of Pharmacy Department at the University of Malta

The objectives of the MMA Strategy to 2025 were discussed throughout the conference, where the Authority aims to reinforce its power to navigate through market challenges and continue contributing towards a level of excellence in medicines, medical devices and pharmaceutical regulation ultimately enhancing the protection of public health. The MMA aims to sustain its contribution towards the implementation of the European Commission (EC) Pharmaceutical Strategy and the European Medicines Agency (EMA) and Heads of Medicines Agencies (HMA) work programmes, arising from the Joint HMA-EMA network strategy to 2025.

During the stakeholders conference, the MMA Top Management communicated their main roles, responsibilities, achievements, and outlook of the Authority in relation to their respective area of the regulatory sciences. The weighting given to stakeholder outreach and perspective was reflected in a stakeholders interactive panel discussion session whereby two relevant themes were presented for debate. The panellists represented healthcare professionals, patient groups and pharmaceutical operators.

The conference was followed by a networking session which presented an opportunity for the sharing of knowledge and best practices, steering the translation of pertinent provisions into day-to-day excellence and high-quality healthcare solutions.

The Malta Medicines Authority would like to thank all the participants who actively contributed to the success of the conference and looks forward to organise more networking sessions with our stakeholders.

MMA Academy Accredited Course - *Award in Medical Devices*

The MMA Academy for Patient Centred Excellence and Innovation in Regulatory Sciences organised an accredited course leading to an *Award in Medical Devices* between 30 November and 2 December which is recognised as Level 5 on the Malta Qualifications Framework (MQF). Mr Piero Costa, a tutor from the British Standards Institution and adjunct Professor at "Politecnico di Torino" was the keynote speaker addressing the course which covered key areas including risk class of devices, safety and performance requirements, technical documentation, risk management, conformity assessments, post-marketing surveillance and good distribution practice.

Interactive workshop sessions were organised on the Medical Device Management System (MDMS) and the organisation, registration and notifications of medical devices. A summative assessment was performed at the end of the course to evaluate participant learning.

Through this educational initiative, the MMA Academy intended to convey solid theoretical grounding in conjunction with practice-oriented implementation of key principles and requirements emanating from the recently established European Medical Device and In-Vitro Diagnostic Regulations along with recognised standards and guidelines.

Inauguration of the Medical Devices, Pharmaceutical Collaboration and Entrepreneurship Directorate

On 19 November, Hon. Clayton Bartolo and Hon. Dr Deo Debattista inaugurated the newly established Medical Devices, Pharmaceutical Collaboration and Entrepreneurship Directorate which manages the regulatory framework for medical devices including the development of National centralised management systems which carry out the registration of local economic operators, register medical devices placed on the local market and incorporate a reporting system for medical device incident reports.

The Directorate has effectively attracted two (2) Notified Bodies in Malta to assess the conformity of medical devices and aims to continuously monitor the performance of Notified Bodies registered in Malta.

Staff Meeting 2021

The annual team-building staff meeting took place on 21 December. The Chairperson provided insights on key achievements and challenges faced by the Authority during the COVID-19 pandemic. The main themes discussed include crisis management, organisational growth and sustainability, expansion of the MMA regulatory portfolio and core service deliverables.

DID YOU KNOW?

Fun Facts!

Did you know that an aligned team delivers better results? An effective teamwork in the workplace exists when employees have their visions and goals in alignment.

So remember, teamwork divides the task and multiplies the success of a task or a project!

Approval of the content of a draft Commission Notice on the application of the Union's pharmaceutical acquis in markets historically dependent on medicines supply from or through parts of the UK other than Northern Ireland

EUROPEAN COMMISSION

Brussels, 17.12.2021
C(2021) 9668 final

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Communication to the Commission

Approval of the content of a draft Commission Notice on the application of the Union's pharmaceutical *acquis* in markets historically dependent on medicines supply from or through parts of the United Kingdom other than Northern Ireland

The Malta Medicines Authority has been engaging with the pharmaceutical industry and other stakeholders to address issues of accessibility to medicines brought about by Brexit. After months of negotiations and bilateral meetings between Malta and the European Commission, on 17 December proposals were published to ensure the continued long-term supply of medicines and to address outstanding supply concerns.

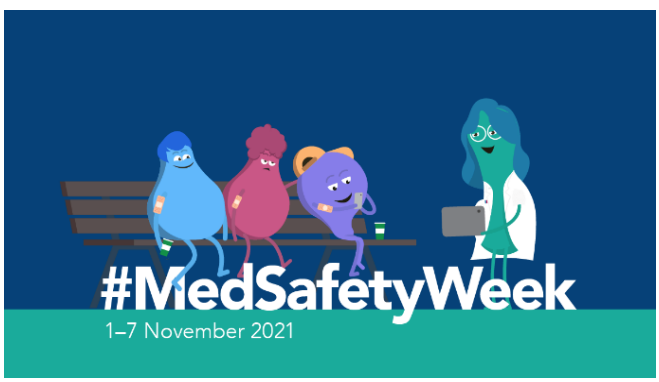
The notice is intended to bridge the gap from 1 Jan 2022 until the agreement and adoption of the legislative derogation. As a result, Malta, Cyprus and Ireland will benefit from certain derogations for a three-year period. For example, during this period in these three countries, importers of medicines will be able to import medicines from the UK without the need of manufacturing authorisations. Medicines intended for the Maltese market will not need to be batch tested again in Malta or the EU if they have already been tested in the UK. This will give stakeholders more time to adapt to the regulatory requirements brought about by Brexit.

Breast Cancer Awareness Campaign

Breast cancer is the most common form of cancer in women, accounting for 28% of the total in the WHO European Region[1]. During the month of October, the MMA supported Breast Cancer Awareness initiatives through the development of a campaign video which aimed to raise awareness with the public that screening can result in early detection and more favourable prognosis. Campaign promotional material were disseminated with employees, who were urged to give donations to breast cancer foundations.

[1]World Health Organisation. Breast Cancer. [cited 26 December 2021]. Available from: https://www.euro.who.int/en/health-topics/noncommunicable-diseases/cancer/news/news/2012/2/early-detection-of-common-cancers/breast-cancer.

#MedSafetyWeek 2021 Campaign



The MMA participated in the 6th annual and global #MedSafetyWeek social media campaign, coordinated by the WHO Uppsala Monitoring Centre (UMC) by sharing social media material to raise awareness on the importance of getting vaccinated and reporting all suspected adverse drug reactions with vaccines.

Pharmacovigilance of COVID-19 vaccines

Vaccination is one of the most successful public health interventions which is highly effective at reducing disease spread, avoiding hospitalisation, preventing complications and deaths. Vaccines in the European Union (EU) are authorised on the basis that the benefits outweigh the potential risks for the target population. Potential adverse effects, or any other vaccine-related problems are not all detected at the time of the initial marketing authorisation, hence the need for the pharmacovigilance of the vaccine.

Pharmacovigilance is the science and activities relating to detection, assessment, understanding and prevention of adverse effects or any other medicine/vaccine related problem. A pharmacovigilance plan ensures that the safety of all vaccines is monitored throughout their use in healthcare practice. Figure 1 outlines the studies involved in the development, evaluation, approval and monitoring of the vaccine.

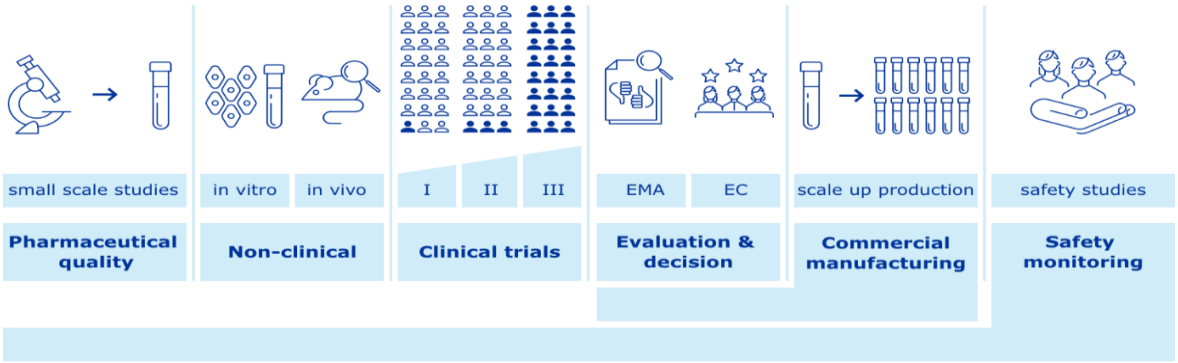


Figure 1: The studies involved in the development, evaluation, approval and monitoring of the vaccine.

Source: https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/vaccines-covid-19/covid-19-vaccines-development-evaluation-approval-monitoring.

Acronyms: European Medicines Agency (EMA), European Commission (EC)

In the EU there is a robust regulatory system for the safety monitoring of vaccines whereby vaccines can only be approved and used if they comply with all the requirements of quality, safety and efficacy EU pharmaceutical legislation. Figure 2 delineates the system involved for the monitoring of adverse drug reactions in the EU.

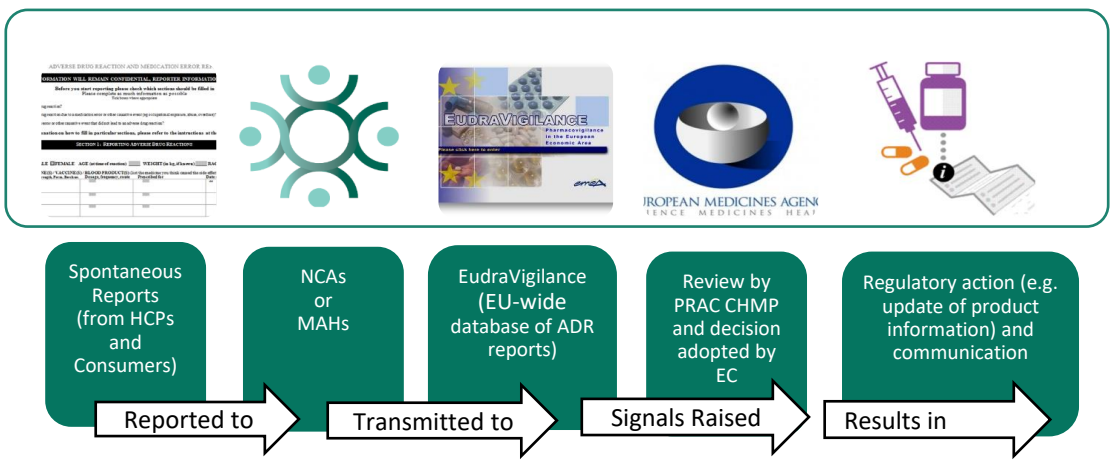


Figure 2: The European Union system for the monitoring of adverse drug reactions

Acronyms: HealthCare Professionals (HCPs), National Competent Authorities (NCAs), Marketing Authorisation Holders (MAHs), Pharmacovigilance Risk Assessment Committee (PRAC), Committee for Medicinal Products for Human Use (CHMP), European Commission (EC).

The MMA is responsible to monitor the safety and enhance the safe and rational use of vaccines and medicinal products locally. The Authority manages adverse drug reactions (ADRs) and raises potential safety signals to the Pharmacovigilance Risk Assessment Committee (PRAC). The PRAC is the European Medicines Agency (EMA) committee responsible for assessing and monitoring the safety of human medicines. The Authority participates in EU decision-making on regulatory actions, communicates on safety issues via direct healthcare professional communication (DHCPs) and safety circulars, and approves Risk Minimisation Measures.

Wishing your hard work and dedication to pay off well!

May the year 2022 be the most prosperous one filled with
success,
happiness
and
laughter