THE MMA telegram

ISSUE 06 - Q2 2021

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

Accreditation of the MMA Academy

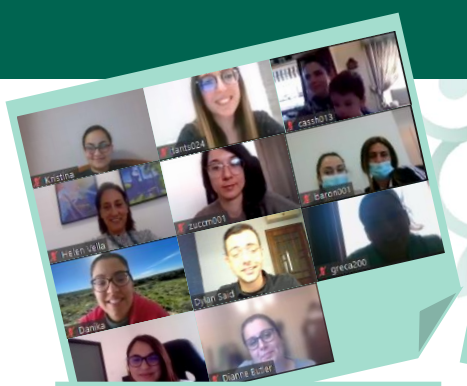
The Academy for Patient Centred Excellence and Innovation in Regulatory Sciences of the Malta Medicines Authority (MMA) is now a licensed Higher Education Institution.

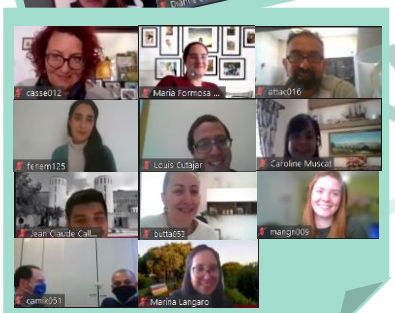
EVENTS

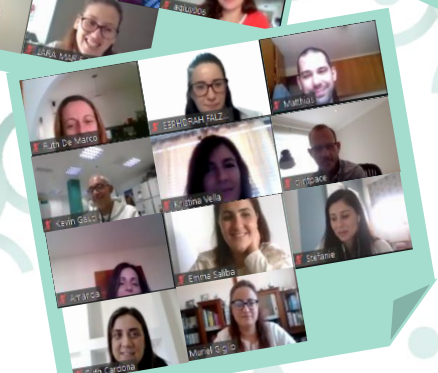
Virtual Staff Meeting

During the virtual staff meeting, held on 7 April 2021, the Chairperson of the MMA highlighted the main areas which need to be addressed in the post-COVID era. In such challenging times, the virtual team building activity was important for the organisation since it served as a communication interface between employees at all levels, augmenting the synergism and the effectiveness of work outputs. The Chairperson thanked all the employees for their extraordinary contribution which has ensured the continuity of the work towards the availability of safe, quality and effective medicines.

THE MMA WOULD LIKE TO CONGRATULATE THE WINNERS OF THE TEAM BUILDING ACTIVITY!







GENERAL UPDATES

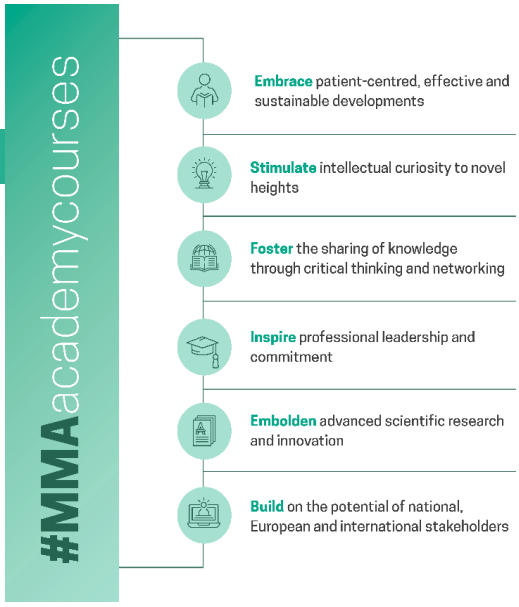
Internal Quality Assurance (IQA) Policy for the MMA Academy

The MMA Academy functions in line with an Internal Quality Assurance (IQA) Policy which attests the commitment for provision of high-quality education, continuous enhancement and accountability. The contribution of the MMA towards excellence and innovative developments is aligned with applicable requirements and regulations to ascertain that accredited programmes meet and exceed participants' expectations whilst bridging knowledge gaps identified through educational needs analysis. The ethos of critical reflection, collegiality and stakeholder engagement are considered as key drivers for the identification of opportunities for improvement.

The IQA Policy evolves on the basis of a quality cycle and is constantly reviewed, both internally and externally, to attest fitness for purpose. The standards outlined in the National Quality Assurance Framework for Further and Higher Education are addressed, including:

- Appropriate learning resources and student support
- Collection, analysis and use of relevant information for the effective management of programmes and other activities
- Public information
- On-going monitoring and periodic review of programmes
- Cyclical external quality assurance
- Set-up and publication of an effective policy for quality assurance
- Financial and institutional probity
- Design and approval of programmes
- Student-centred learning, teaching and assessment;
- Regulations for student admission, progression, recognition and certification
- Competence and effectiveness of teaching staff

The IQA Policy is available on the intranet (LinkLibrary).
MMA Academy public information is accessible through the following link on the MMA website: medicinesauthority.gov.mt/academyforregulatorysciences



Regulatory experience of handling Risk Management Plans (RMPs) for medicinal products in the EU

The Authority contributed to a publication entitled 'Regulatory experience of handling Risk Management Plans (RMPs) for medicinal products in the European Union (EU)'. RMPs are a requirement in all new applications for medicinal products in the EU, both for the centrally and nationally authorised medicinal products. These aim to optimise the safety profile of medicinal products. Findings from different regulatory authorities indicate that different RMP requirements and risk minimisation measures (RMM) aim to protect and enhance public health. This review analysed the different RMP assessments carried out by the European Medicines Agency, US Food and Drug Administration and Japan's Pharmaceuticals and Medical Devices Agency, and safety communications issued by Malta and the US.

Publication accessible through the following URL:
https://www.researchgate.net/publication/350796393_Regulatory_experience_of_handling_Risk_Management_Plans_RMPs_for_medicinal_products_in_the_EU

GENERAL UPDATES

Reduction in the Price of Medicines, Introduction of New Generics and New Medicines on the Maltese Market

On 29 April 2021, the Minister for Tourism and Consumer Protection, Mr Clayton Bartolo, and the Parliamentary Secretary for Consumer Protection and Public Cleansing, Dr Deo Debattista, announced reduction in the price of medicines and introduction of new medicinal products and generics on the Maltese market. Forty-two (42) medicines price reductions indicated in hypertension, hypercholesterolaemia, anxiety, osteoporosis, neurological conditions, skin conditions and coronary heart disease, were announced with the highest price reduction of up to €24.45 (60% reduction on the original price). Twenty-nine (29) generic medicines indicated for conditions related to prostate, inflammation, neuropathic pain and depression, that conform with EU Quality Standards, were introduced on the local market, with a reduction in price of 73% when compared to alternative medicines which are already available on the market. Additionally, nine (9) new medicines, including 2 (two) new types of oral contraceptives and memantine in liquid form, were also introduced on the local market. Medicinal price reductions and introduction of new medicines and generics enhance accessibility and affordability of medicinal products for the ultimate benefit of the patient.

Recognition of Good Practice

During the Public Service Week awards ceremony held on 4 June 2021, the MMA was recognised as an innovative public entity that worked to sustain, protect and enhance public health through the regulation of medicinal products, medical devices and pharmaceutical activities by optimising its core operations.

The MMA received the Good Practice Award by the President of Malta, His Excellency Dr George Vella.

The Good Practice Award acknowledges the remodelling practices that have been scientifically and structurally adopted by the Authority to meet its vision as a centre of excellence, which were confirmed by the Auditor General.

Training Course on Good Distribution Practice for Medical Devices

On 29 and 30 April 2021, the Parliamentary Secretary for Consumer Protection and Public Cleansing, Dr Deo Debattista launched the interactive online training course which was organised by the Malta Laboratories Network (MLN) in conjunction with the MMA Medical Devices Unit. The course aimed to provide knowledge about changes in EU Regulations and their impact on practice. The course discussed innovation with traceability of medical devices, field safety corrective actions and incidence reporting, all within the context of Good Distribution Practice (GDP) and the requirements and obligations that the new EU legislation brings to stakeholders in this area.

GENERAL UPDATES

EU Immunisation Awareness Week

The MMA participated in the European Immunisation Week, held between 26 April and 2 May 2021. This awareness week is organised every year to inform the general public and healthcare professionals on the importance of immunisation in preventing and controlling infectious disease outbreaks. Furthermore, the campaign increases vaccination coverage, which is vital to achieve optimal health and protect and promote healthy lives. Apart from promoting the importance of routine immunisation, the campaign also focused on building solidarity and trust in the COVID-19 vaccination.

European Immunization Week

Prevent Protect Immunize

EMA Committees

The MMA actively participates in different scientific committees and working parties of the European Medicines Agency (EMA) to ensure the quality, safety and efficacy of medicines on the Maltese Market and across Europe. The EMA has seven scientific committees (CHMP, PRAC, CVMP, COMP, HMPC, CAT and PDCO) and a number of working parties and related groups which conduct the scientific work of the Agency. The EMA adopts an opinion for the authorisation of medicines in the EU by evaluating the Marketing Authorisation (MA) applications which are submitted through the centralised procedure. The committees and working parties also contribute to the development of medicines and medicines regulation by preparing scientific and regulatory guidelines and provide scientific advice to assist pharmaceutical developers in the research and development phases of medicinal products in the pipeline. The EMA aims to sustain the harmonisation of regulatory requirements in the EU and internationally.

ACRONYMS: Committee for Medicinal Products for Human Use (CHMP), Pharmacovigilance Risk Assessment Committee (PRAC), Committee for Medicinal Products for Veterinary Use (CVMP), Committee for Orphan Medicinal Products (COMP), Committee on Herbal Medicinal Products (HMPC), Committee for Advanced Therapies (CAT), Paediatric Committee (PDCO)

Participation in the HMA WGCP Virtual Meeting

On 6 April 2021, the MMA participated in the Heads of Medicines Agency (HMA) Working Group of Communication Professionals (WGCP) virtual meeting. The MMA is involved in different HMA working groups including the WGCP, with the aim of developing and co-ordinating good practices in communications across the HMA network by sharing insights and harmonising actions for its engagement with stakeholders. Whilst supporting the work of the European Regulatory Medicines Network (EMRN) regarding public health and animal health and welfare, the HMA WGCP fosters specialised communication between the EMRN, its stakeholders and the public.

A representative from the Authority, Dr Dylan Said, delivered a presentation entitled 'Communication in Regulatory Data Management' which focused on the importance of data-driven regulation ultimately leading to innovation and informed decision-making. The model adopted by the MMA for coordinating the collation and processing of data was outlined, highlighting the fact that data is processed with integrity and accountability according to National and EU regulations.

DID YOU KNOW?

Fun Facts!

Did you know that exercising boosts your self- confidence? Exercising can help ease your mind and rejuvenate your body.

So Remember, exercise more if you want to boost your confidence!

Standards of Good Practice

Good 'x' (any type of practice) Practice (GxP) is a collection of quality guidelines and regulations created to ensure the safety, quality and efficacy of medicinal products and medical devices. In any regulated organisation, including the pharmaceutical and medical devices industries, GxP guidelines focus on the traceability, accountability and the integrity of data for the ultimate benefit of the end-users.

Standards of Good Practice (GxP)	Description	Requirements for the GxP standard	Legal/ Reference guidelines
Good Documentation Practice (**GDocP**)	The standard that ensures all records, both paper and electronic, allow the full reconstruction and traceability of GXP activities.	• Data accuracy; • Data integrity/ validation; • Contemporaneous record-keeping; • Legibility; • Identifiable.	N/A
Good Laboratory Practice (**GLP**)	Set of rules and criteria for a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, reported and archived.	• Quality standards should be in place.	Directive 2004/9/EC; Directive 2004/10/EC
Good Manufacturing Practice (**GMP**)	The minimum standard that a medicines manufacturer must meet in their production processes.	• High quality medicines appropriate for their intended use; • Meet the requirements of the marketing authorisation or clinical trial authorisation.	Regulation No. 1252/2014 and Directive 2003/94/EC, applying to active substances and medicines for human use Directive 2001/83/EC; Directive 2001/82/EC
Good Distribution Practice (**GDP**)	The minimum standards that a wholesale distributor must meet to ensure that the quality and integrity of medicines is maintained throughout the supply chain.	• Authorisation of medicine in accordance with EU legislation; • Storage of medicines in their appropriate conditions at all times, including during transportation; • Avoidance of contamination of the products; • The medicines should reach the right recipient within an acceptable timeframe.	Directive 2001/83/EC; Directive 2001/82/EC
Good Clinical Practice (**GCP**)	An international ethical and scientific quality standard for designing, recording, and reporting trials that involve the participation of human subjects.	• Assurance of the public that the trial subjects are fully protected and that their rights are reserved; • Credibility of the clinical trial data.	Directive 2001/20/EC; Directive 2005/28/EC
Good Pharmacovigilance Practice (**GVP**)	A set of measures drawn up to facilitate the performance of pharmacovigilance in the EU. GVP apply to marketing-authorisation holders, the European Medicines Agency (EMA) and medicines regulatory authorities in EU Member States. They cover medicines authorised centrally via the Agency as well as medicines authorised at national level.	• Preventing harm from adverse reactions in humans arising from the use of authorised medicinal products; • Promoting the safe and effective use of medicinal products.	Directive 2012/26/EU
Good Pharmacy Practice (**GPP**)	The standard ensures that all pharmacists practising their profession provide a high quality service for the public and private sector.	• Pharmacist's first concern must be the welfare of the patient in all settings; • Supply medications of assured quality; • Appropriate information and advice for the patient; • Promotion of rational and economic prescribing.	Joint FIP/WHO guidelines on good pharmacy practice: standards for quality of pharmacy services