THE MMA telegram

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Welcome dear colleagues to our first e-newsletter for year 2022!

In this Issue

A look back at 2021...

The Malta Medicines Authority (MMA) upheld its mission to protect and enhance public health through the regulation of medicinal products, medical devices and pharmaceutical activities amid the challenges imposed by the COVID-19 pandemic and BREXIT. Prominent events of year 2021 include:

Enhancing the Accessibility Framework

- BREXIT: Licensing virtual seminar
- Supply of medicines used in ART services in Mater Dei Hospital: MIAU virtual seminar
- Price reductions:
  - 42 medicinal products
- New medicines on the local market:
  - 29 generic medicines
  - 9 new medicines
- Article 20 exemption requests assessments and recommendations
- Approval of the draft Commission Notice: Extension of derogations for human medicines impacted by BREXIT

Sustainable Operations Management & Effective Communications

- Good Practice Award
- 2 virtual Staff Meetings
- Preparations for ISO Certifications on Information Security Management
- Stakeholders conference for the launch of MMA Strategy to 2025
- EU immunisation awareness week
- Breast cancer awareness week
- Participation in the #MedSafetyWeek 2021 campaign

Research, Development & Innovative Educational Initiatives

- Accreditation of the MMA Academy
- Internal Quality Assurance Policy for the MMA Academy
- 2 MMA Academy accredited courses: Award in GMP and Award in Medical Devices
- MMA Academy seminar on biosimilars
- 14 research publications and presentations

A Robust Regulatory System

- EUDAMED Actor registration module: Medical Devices virtual seminar
- Online training course on GDP for medical devices
- Inauguration of the Medical Devices, Pharmaceutical Collaboration and Entrepreneurship Directorate
- Visit from the Medicines Evaluation Board, Netherlands

Award in Good Distribution practice

The MMA Academy for Patient Centred Excellence and Innovation in Regulatory Sciences organised a four-day virtual course which focused on core aspects of Good Distribution Practice (GDP). Ms Madeline Ault and Ms Mariam Naqesh Bandi, both pharmaceutical consultants and former MHRA GDP inspectors, were the keynote speakers of the course. Ms Stefanie Farrugia and Dr Dylan Said were representative speakers from the MMA. All speakers presented extensive knowledge and understanding of GDP to stakeholders in the pharmaceutical industry.

This course gave a comprehensive overview of GDP as applicable to pharmaceutical products which enabled participants to:

- ✓ Understand the legal basis and quality management of GDP;
- ✓ Determine the storage requirements in the supply chain;
- ✓ Expand knowledge on import and export of pharmaceutical products;
- ✓ Understand the importance of maintaining the integrity and security throughout the pharmaceutical supply chain;
- ✓ Gain insights on several processes related to GDP including deviations, complaints, returns, recalls and self-inspection practices, whilst maintaining favourable interactions with the licence holder and regulator;
- ✓ Apply key GDP concepts, roles and responsibilities into day-to-day practices and;
- ✓ Support the transformation of potential challenges into opportunities in key areas of GDP.

Seminar on the Medical Device Organisation Registration and MDRP Applications

The MMA has launched a series of guidance documents and applications on the Good Distribution Practice and registration of medical devices. Two virtual seminars were organised for stakeholders on 21 and 28 March to increase awareness and visibility on the medical devices sector in Malta.

Seminar on Vaccinology as relevant to COVID-19

On the 9 March, the MMA Academy organised a *Seminar On Vaccinology As Relevant To COVID-19*, which targeted healthcare professionals, policy makers, academics, students, researchers and representatives from industry, scientific and regulatory operations.

Dr Marco Cavaleri, Head of Biological Health Threats and Vaccine Strategy at the European Medicines Agency (EMA), was the keynote speaker addressing the seminar which focused on the current landscape of COVID-19 vaccines.

This included the development process of vaccines, regulatory considerations, therapeutics, vaccination during childhood, safety monitoring and adaptations to variants, evaluation of vaccines that are under investigation and approved for use in the EU.

Local challenges and confidence in COVID-19 vaccines, alongside response to the pandemic and future perspectives and preparedness, were also addressed. The seminar was followed by a networking dinner to promote the exchange of knowledge amongst professionals with an interest in the dynamic sphere of COVID-19 vaccines.

The Malta Medicines Authority Budgetary and Simplification Measures for Year 2022

For another year, the MMA has risen to the occasion of acting as a model entity by proposing and devising the frameworks of simplification and budgetary initiatives aimed at contributing towards the consolidation of service delivery of the Authority and the public administration altogether.

Measure	Description
Budgetary Measure 2021 - 2026	National Reference Laboratory The MMA has pledged to a budgetary commitment which explores the feasibility of setting up of a national reference laboratory by the MMA, for the purposes of monitoring and testing the quality of medicinal products on the market. The planning and development of the national laboratory involve important considerations including logistical matters as well as financial, technical, legal, and quality issues.
Simplification Measure 2020 - 2022	National Electronic Database for Medical Devices This measure includes the deployment of a national electronic database for medical devices to store information and enable economic operators to directly access the registration platform for devices from the MMA's website.
Simplification Measure 2021 - 2022	Standard Operating Procedure (SOP) and/or Guidelines for Article 20 Requests This measure includes the development and validation of an SOP and/or guidelines to formalise the application process and the evaluation of requests based on the Article 20. The main aim is to process applications more expeditiously by reducing the amount of clarifications between the Authority and the concerned public and private stakeholders during the vetting process, for the ultimate benefit of the patient.

Table 1: Budgetary and Simplification Measures for Year 2022

Stakeholders invited to connect with the Malta Medicines Authority Academy

Stakeholders, including representatives of the pharmaceutical industry, healthcare professionals and the general public, are encouraged to engage and connect with the MMA Academy with the aim of enhancing the relationship with the Authority ultimately leading to long-term sustainability and an increase in educational success. The engagement of stakeholders enables the identification of educational needs for the development of programmes which meet evolving needs and requirements.

The Legal Notice Amending Subsidiary Legislation 458.28 – Pharmacy (Opening Hours) Rules

The Legal Notice amending Subsidiary Legislation 458.28 – Pharmacy (Opening Hours) Rules, issued under the Medicines Act (Cap. 458) of 2003 was enacted on 7 February to optimise patient accessibility to community pharmacies on Sundays and public holidays. The amended S.L. 458.28 extended the minimum required opening hours on Sundays and public holidays to 9:00 till 12:00 and 16:00 till 19:00 in accordance with the roster.

GENERAL EUROPEAN UPDATES

The European Medicines Agency statistics at a glance for Year 2021:

In 2021, the European Medicines Agency (EMA) recommended ninety-two (92) medicines for marketing authorisation, out of which fifty-three (53) had a new active substance which was never authorised in the EU. Figure 1 shows the number of the EMA's recommendations on the authorisation of new medicines and a selection of new treatments in the EU that represent significant progress in their therapeutic areas which are essential to advancing public health as they provide new opportunities to treat certain diseases.

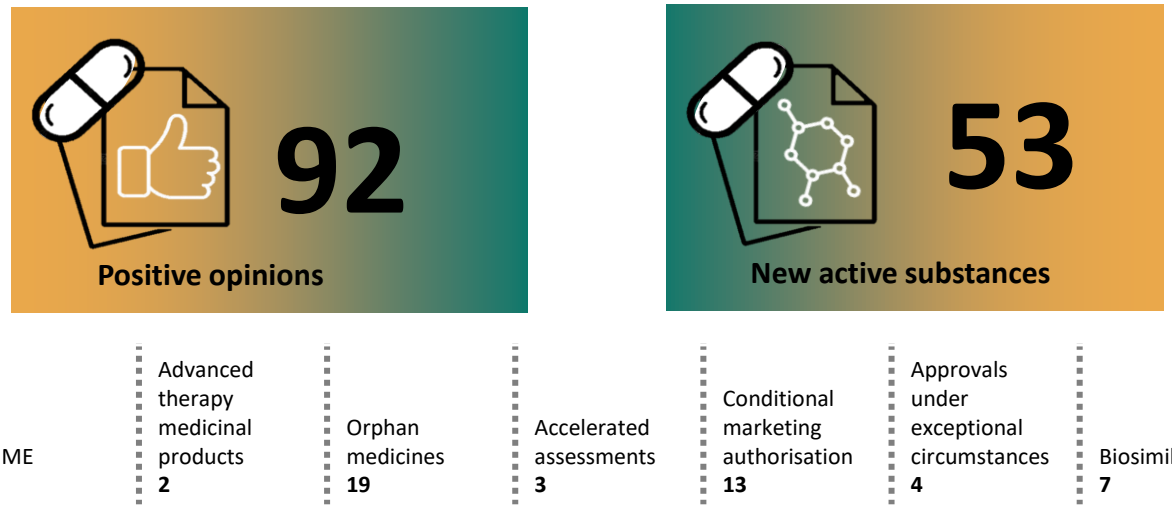

Figure 1: Key figures on the European Medicines Agency's recommendations for the authorisation of new medicines in 2021. (PRIME) Priority Medicines
Source: https://www.ema.europa.eu/en/documents/report/human-medicines-highlights-2021_en.pdf

General Updates

Clinical Trial Regulation - On the 31 January, the European Commission (EC), the Heads of Medicines Agency (HMA) and the European Medicines Agency (EMA) have jointly launched a transformation initiative, referred to as Accelerating Clinical Trials in the EU (ACT EU), that strengthened the European environment for clinical trials for the ultimate benefit of the patient. It supports transparency, medical research, and innovation through the new Clinical Trials Regulation (CTR) which regulates the harmonisation of assessment and supervision of clinical trials throughout Europe via the Clinical Trials Information System (CTIS). *(More information regarding this topic can be found in the Regulatory Sciences section of this E-newsletter)*

Reinforced Role for the EMA in Crisis Preparedness and Management for Medicinal Products and Medical Devices – Through this regulation, which was enacted on the 1 March, the EMA has been entrusted with several new tasks including the reporting and monitoring of medicines, medical devices and/or in-vitro diagnostics shortages. A pan-European network of real-world data, DARWIN EU, was established which provides EMA's scientific committees with real-world evidence from healthcare databases across the EU.

Common Standard for the electronic Product Information (ePI) on Medicines in the EU - The European Medicines Regulatory Network adopted the provision of harmonised electronic information which aims to improve the delivery of unbiased and up-to-date information on all medicines to patients and healthcare professionals across the EU.

Regulatory and Coordinating Activities Arising from the Russian Invasion in Ukraine - During the EMA Management Board meeting, the Agency gave details on their proactive approach to prepare for potential medicine-related consequences, including shortages, amid the precarious situation in Ukraine.

Updates related to the COVID-19 Pandemic

EMA ensures **regulatory alignment with global/international regulators** on response to the Omicron variant. Evidence suggests that COVID-19 vaccines remain effective against severe disease and hospitalisation caused by the Omicron variant.

Based on the latest safety data, EMA provides reassurance regarding the administration of mRNA COVID-19 vaccines (Comirnaty® and Spikevax®) during **pregnancy**.

The EMA's Committee for Medicinal Products for Human Use (CHMP) has recommended the extension of indication for the COVID-19 vaccines Spikevax® to include use in **children aged 6 to 11.**

The Pharmacovigilance Risk Assessment Committee (PRAC) has recommended the following additions to the product information: **flare-ups of capillary leak syndrome (CLS)** for Spikevax® and **small vessel vasculitis** for Janssen ®.

DID YOU KNOW?

Did you know that time management is life management?

So Remember, time management is really a misnomer, the challenge is not to manage time, but to manage ourselves!

Clinical Trials for Human Medicines – Introducing the new Clinical Trials Regulation and the Clinical Trial Information System

A clinical trial for human medicines is a research study which is performed in human subjects/volunteers, to investigate the safety and efficacy of a medicine.

Clinical trials in the European Union (EU) and European Economic Area (EEA) are governed by the new Clinical Trials Regulation (CTR) (EU No 536/2014), which became effective as of 31 January 2022. Its aims to ensure that the EU offers an attractive and favourable environment for conducting clinical research on a large scale in multiple EU Member States/EEA countries. The CTR supports high standards of public transparency whilst reinvigorating clinical research for the ultimate benefit of medical innovation and patients. The new Regulation safeguards the protection of trial subjects and ensures the reliability of the research study results.

The CTR regulates the harmonisation of the submission, assessment, and supervision of clinical trials throughout Europe through the Clinical Trials Information System (CTIS). Throughout the lifecycle of a clinical trial, the CTIS supports the flow of information and interactions between clinical trial sponsors, regulatory authorities in the EU Member states/EEA countries, and the European Commission.

The key benefits of the CTR and CTIS include:

- ✓ Allowing single applications for trials run in different EU countries;
- ✓ Reducing administrative burden for researchers and pharmaceutical companies;
- ✓ Facilitating patient recruitment;
- ✓ Allowing patients to learn about trials in the EU;
- ✓ Streamlining safety reporting and;
- ✓ Ensuring coordinated and faster authorisation of clinical trials.

The CTR foresees a three (3) year transition period, whereby by the 31 January 2025, all ongoing clinical trials should be transferred to the CTIS (Figure 3).

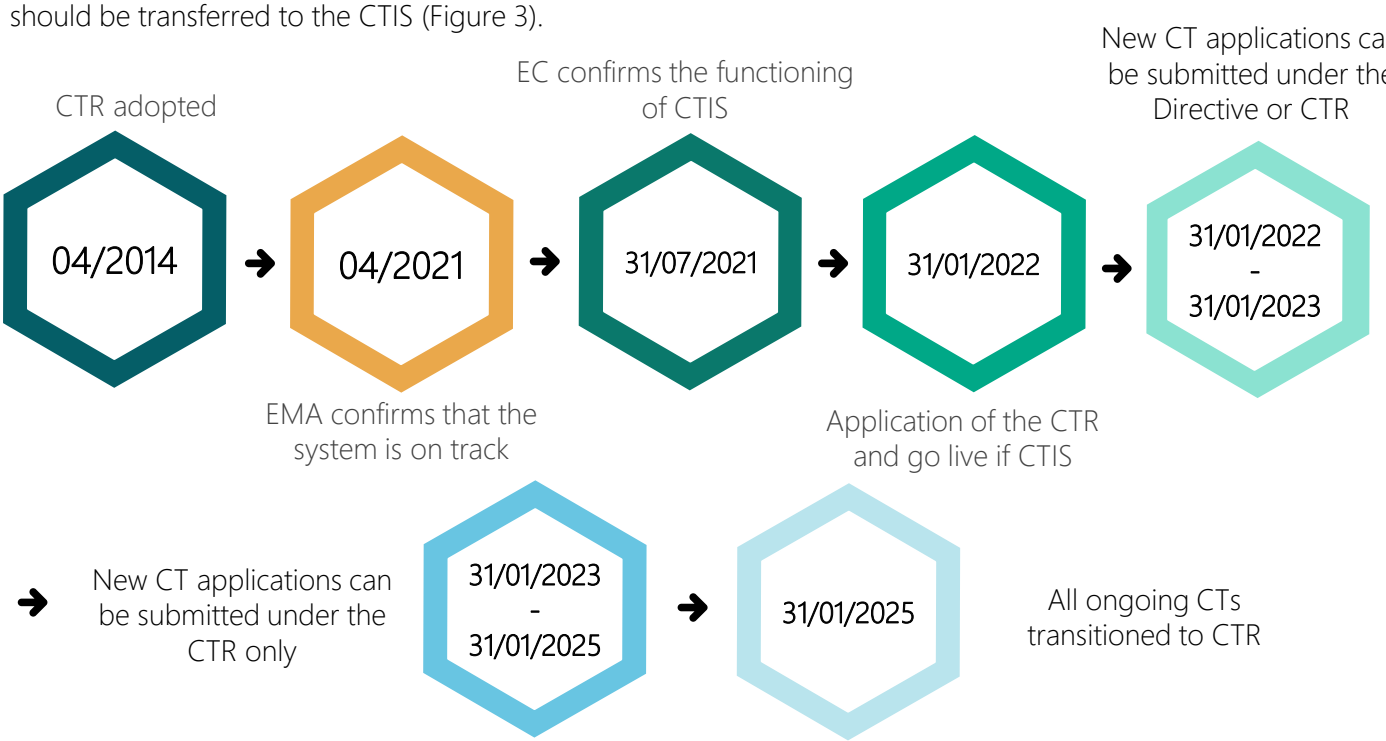

Figure 3: Timeline of the Clinical Trial Regulation
Acronyms: CT (Clinical Trial), CTR (Clinical Trial Regulation), CTIS (Clinical Trial Information System), EC (European Commission), EMA (European Medicines Agency)
Source: http://www.hpra.ie/homepage/medicines/regulatory-information/clinical-trials/clinical-trial-regulation-(regulation-(eu)-no-536-2014)

Academia - Ongoing Doctorate Level Research Projects

Medicine Shortages

Medicine shortages are a global issue primarily affecting the patient, creating obstacles for healthcare professionals and National Competent Authorities. A medicine shortage occurs "when supply does not meet demand at a national level" (EMA, HMA, 2019). Lack of economic market attractiveness, diminishing demand for medicinal products, lower profitability, policy failures and market saturation are the key concepts behind shortages present in small countries like Malta (European Healthcare Distribution Association, 2018). Malta has had to rely on Article 20 registrations in order to mitigate medicine shortages that would have a significant impact on the patient. The research focuses on assessing the impact a medicine shortage may have on the patient and the healthcare professional. Adopting a risk-based approach when granting an Article 20 registration has the potential to facilitate decision-making by policymakers, prioritising on patient safety and drug accessibility.

Jessica Zarb

Feasibility of an Official Medicines Control Laboratory (OMCL)

This study will determine how a state of the art official medicines control laboratory in a small member state like Malta, can contribute scientifically to assist and respond to the ongoing dynamic innovative evolvement of medicines and medicinal products. Special reference will be made to the present European scenario, including best practices and innovative evolvement with emphasis on the rationale of establishing an OMCL in a small member state.

Elaine Gatt Baldacchino

Development of New and Emerging Therapies

Oral Antiviral Treatment, Paxlovid™

The European Commission granted a conditional marketing authorisation for the oral antiviral medicine Paxlovid™ (nirmatrelvir (PF-07321332) and ritonavir), for the treatment of COVID-19 in adults who do not require supplemental oxygen and who are at increased risk of the disease becoming severe.

PF-07321332 is a SARS-CoV-2 protease inhibitor which inhibits viral replication at a stage known as proteolysis. Ritonavir prolongs the action of PF-07321332 enabling it to remain longer in the body at levels that affect the multiplication of the virus. Based on clinical and laboratory studies, Paxlovid™ works against the Delta, Omicron and other variants.

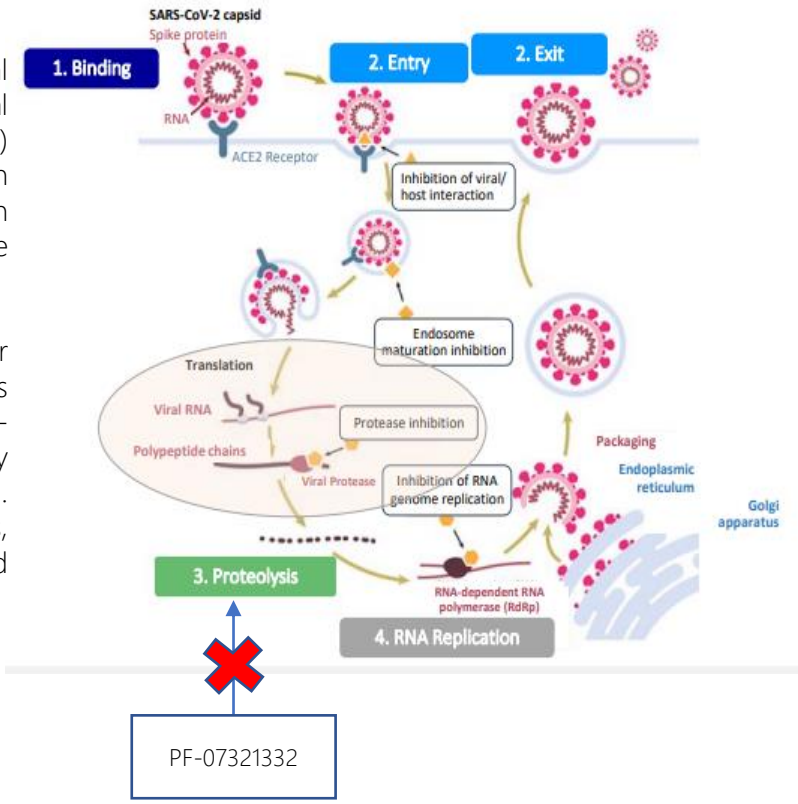

Figure 2: Schematic representation of the SARS-CoV-2 lifecycle.
Source: https://www.gov.il/BlobFolder/policy/medical-treatment/he/files_regulation_pfizer_medical_treatment_PAXLOVID.pdf