



Welcome dear colleagues for our 4th e-newsletter for year 2023!

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MED-IN PHARMA 2023 SYMPOSIUM | OCTOBER 2023

The Med-In Pharma 2023 Symposium presented an opportunity for discussions on policy making and regulation, health inquiry, medical innovation, and patient-focused technology. Poster presentations of research projects carried out by MMA employees were presented as part of the conference proceedings for discussion with stakeholders.



MEDICINE PRICE REDUCTIONS | NOVEMBER 2023

In view of the electoral manifesto measure “*Għażla wiesgħa ta’ mediċini bi prezzijiet affordabbli*”, the MIAU, the MCCA and pharmaceutical stakeholders are working in synergy to enhance access to medicines. During a press conference, the Minister for Active Ageing, Dr Jo-Etienne Abela and the Minister for Inclusion, Social Wellbeing and Voluntary Organisations, Ms Julia Farrugia Portelli presented a list of price reductions of 54 medicinal products and 10 new generic medicines which were introduced on the Maltese market.



JOINT ACTION ON MARKET SURVEILLANCE OF MEDICAL DEVICES | NOVEMBER 2023

As part of the “EU4Health” Programme, the EU JAMS 2.0 project brings together 24 NCAs to collaborate on joint inspections, signal detection operations and harmonised market surveillance campaigns to reinforce Market Surveillance of MDs and IVDs. The Medical Devices and Pharmaceutical Collaboration Directorate, as leader of Working Package 5, successfully hosted the first meeting on signal detection and vigilance, which was addressed by the Minister for Active Ageing, Dr Jo-Etienne Abela.



Get ready for

#MedSafetyWeek
6–12 November 2023

Advise how to prevent or manage side effects

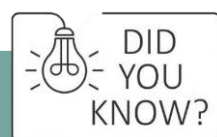
Communicate the importance of reporting side effects

Adjust therapies or dosage if needed

#MEDSAFETYWEEK 2023

The #MedSafetyWeek 2023 campaign which took place between 6 and 12 November, aimed to increase awareness among stakeholders, including patients and healthcare professionals, to report suspected side effects from medicines. A total of 4836 accounts were reached via MMA social media throughout the campaign.

Humans share 60% of their DNA with bananas



PEOPLE MANAGEMENT EVENTS

During the *Breast Cancer Awareness* month an interactive and informative session was delivered to MMA employees to emphasise the importance of breast screening and monitoring for signs and symptoms.



The *Award in Communication Skills* (MQF Level 4) course was organised in collaboration with Jobsplus. The course was open to all MMA employees and aimed to enhance effective communication inside and outside the office.



To mark *November*, educational activities were organised to raise awareness about men's health.



The second *Staff Meeting of 2023* was organised on 21 November at Esplora. The achievements and targets of each Directorate over the past year were presented and teambuilding activities were organised.



Thank you to all employees who participated in the Christmas fundraising initiatives and contributed to the collection of:

- €220.50 during the Poinsettia Sale in aid of the MCCF
- €1000 during the Cuti Raffle in aid of Puttinu Cares
- 62 presents for children as part of the 'Fondazzjoni Sebħ' Wishlist
- Gifts, toys, socks, and food items in aid of Disneyland Ward at Mater Dei Hospital, Caritas, and Foodbank Lifeline Malta.



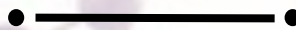
EMA alerts EU patients on reports of falsified Ozempic pens | OCTOBER

Fraudulent pre-filled pens labelled as Ozempic were identified at wholesaler level in the EU and UK. Investigations at EU level concluded that there is no evidence that any falsified pens were dispensed from licensed pharmacies and no patient harm was made.



Steps taken to address critical medicine shortages in the EU | OCTOBER

The EMA-MSSG published a toolkit including recommendations for monitoring supply and demand, collaboration with stakeholders, and implementation of regulatory flexibilities. This is part of a solidarity mechanism, which allows Member States to obtain medicine stocks from other Member States in case of critical medicine shortages.



Lowest level of antimicrobial consumption reached in Europe | NOVEMBER

The consumption of antibiotic medicines indicated for human use has decreased. This includes 3rd and 4th generation Cephalosporins (49%), Polymyxins (81%), and Fluoroquinolones (25%). The sales of veterinary antibiotics have significantly declined (53%), leading to a reduced risk of bacteria developing resistance in humans and animals.



Reflection on lessons learnt from COVID-19 | DECEMBER

EMA and HMA issued a joint report evaluating the EMRNs response to the COVID-19 pandemic. The main lessons for any future health crises, unexpected challenges faced by the network, actions that ensured effective response to the COVID-19 emergency and recommendations on improvements required were highlighted in the report.

Reflections on lessons learned from COVID-19

A joint report published by the EMA and HMA provides an analysis of the EMRN's response and underlines lessons learned guiding the management of future health crises. The report illustrates actions taken by the EMRN that contributed to an effective response to the COVID-19 pandemic and highlights areas requiring improvement which may be implemented through legislative and non-legislative actions.

COVID-19 PANDEMIC RESPONSE

HIGH PERFORMANCE AREAS	OPPORTUNITIES FOR IMPROVEMENT
<input checked="" type="checkbox"/> Accelerated procedures for the evaluation of COVID-19 vaccines and therapies	- To gather practical data for use in regulatory assessments through multiple data sources
<input checked="" type="checkbox"/> Effective collaboration between the EU international partners	- To enhance capability for a prompt organisation of large clinical trials
<input checked="" type="checkbox"/> Strengthening of the EU safety monitoring and risk management system	- To expand the size of expert groups for carrying out scientific evaluations
<input checked="" type="checkbox"/> Resource pooling for better management of increased workload and medicine shortages	- To strengthen information management, to develop innovative strategies and address misinformation

The report depicts how the EU network successfully managed the unprecedented challenges posed by the COVID-19 pandemic resulting in the authorisation of 8 vaccines in a very short timeframe as well as 8 therapies including 5 new or repurposed MABs or MAB combinations, as well as 2 new antiviral medicinal products. The network conducted procedures involving scientific advice, coordination of medicine shortages and post-marketing variations while ensuring that medicines for other diseases continued to be evaluated and supervised without delays.

The report identified the need for improved efficiency of regulatory and communication processes, strengthening cooperation with partners, and increased reserve resources in case of future crises. The leading role by EMA in crisis preparedness ensures proactivity and coordination in the network for potential public health threats.

Optimising the interplay between competent authorities and industry with a patient-first drive

DR LUANA MIFSUD BUHAGIAR, MS MARIA MAMO, DR AMAR ABBAS, PROF ANTHONY SERRACINO INGLOTT

BACKGROUND

Implementing policy mandates, overseeing compliance and taking enforcement actions are only parts of the regulation spectrum. Innovations in technologies, products, services and business models make it complex for regulators to navigate today's, and tomorrow's, challenges. Industry-led disruption can serve as an opportunity for competent authorities to rethink outreach because, with an us-versus-them approach, patients get confined in the split. Consultations and focus groups work, as do guidance and engagement exercises – people development, however, is key. The MMA, through its established Academy, is primed to deliver educational programmes that translate regulatory standards into day-to-day excellence.

SETTING AND METHOD

As of April 2023, the MMA Academy for Patient Centred Excellence and Innovation in Regulatory Sciences is licensed as a Further and Higher Educational Institution. Following 3 specialised programmes delivered at MQF Level 5, this year marked the launch of the first course accredited at MQF Level 4, targeting yet another segment of the medicinal products/devices ecosystem. The programme unfolded between 4 and 6 September, with 24 speakers and panellists engaged.

RESULTS

The course leading to an Award in Basic Regulatory Sciences was fully subscribed, with 30 participants completing the course successfully. Course evaluation was largely positive, together with several suggested topics for future educational initiatives, such as aesthetic products and AI in healthcare. Based on evolving dynamics, market demand analysis and feedback received, the MMA Academy intends to continue optimising the interface with stakeholders, through a course development approach, to further meet training needs and business requirements.

CONCLUSIONS

Collaborative efforts foster a win-win scenario where procedures can be streamlined and gaps addressed. Whilst some hesitancy about leveraging the regulator-industry interdependence persists, building a culture where the patient comes first drives all towards one mutual interest and with necessary safeguards in place, there shall be no conflict in the sharing of knowledge and best practices.



*Cheers to another year of
hard work and dedication!*

2024

MAY THE YEAR 2024 BE THE MOST
PROSPEROUS, FILLED WITH
SUCCESS, HAPPINESS AND
LAUGHTER

ACRONYMS

EMA – European Medicines Agency

EMRN – Quality Management System

EU – European Union

HMA – Heads of Medicines Agency

IVDs – In-Vitro Diagnostics

JAMS – Joint Action on Market Surveillance

MABs – Monoclonal Antibodies

MCCAA – Malta Competition and Consumer Affairs Authority

MCCF – Malta Community Chest Fund

MDs – Medical Devices

MIAU – Medicines Intelligence and Access Unit

MMA – Malta Medicines Authority

MQF – Malta Qualification Framework

MSSG – Steering Group on Shortages and Safety of Medicinal Products

UK – United Kingdom