THE MMA telegram

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GENERAL UPDATES

MMA: A Centre of Excellence

The National Audit Office (NAO) Human Resources (HR) Cost-effectiveness Audit at the Malta Medicines Authority (MMA) entitled 'Performance Audit: An analysis of MMA recruitment process', concluded that the 'MMA's strategic direction placed it on a sound foundation to fulfil its stated vision as a centre of excellence'. The report highlights good practices at the MMA namely the sustainable recruitment process, the various technical audit reports affirming the high-quality management system embedded at the Authority and the MMA as a financially self-thriving entity.

The full report, together with its press release may be accessed from the NAO website: www.nao.gov.mt

Launch of the MMA Newly Designed Website

The MMA announces the launch of its newly-designed website interface. The main drivers for the re-branding initiative of the MMA's website are to improve its functionality, corporate appearance and to meet changing expectations including its relevance, the speed of page loading, ease of use and security. The upgrade enhances user experience by making it interactive with the aim of promoting an enhanced and seamless communication with stakeholders. The website is designed to adjust dynamically for multiple types of electronic devices. A note of gratitude goes to the content writers for their contribution during the migration and quality verification phases of the new website.

www.medicinesauthority.gov.mt

Malta Medicines Authority

Key Operational Data

2015-2019

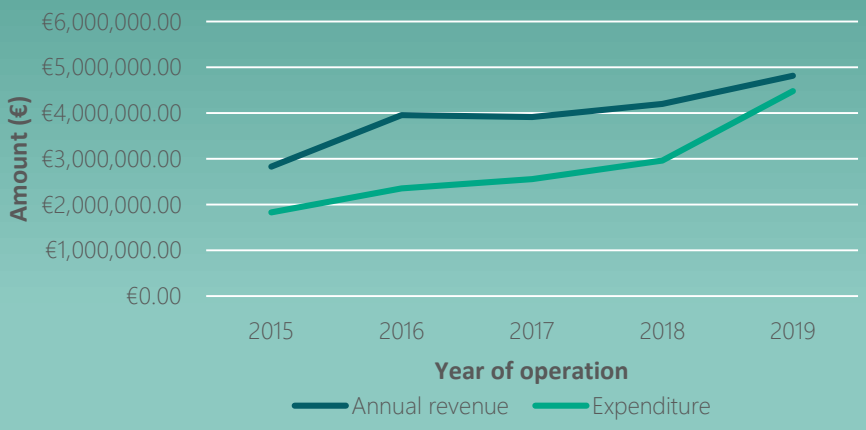


Figure 1: Total annual revenue and expenditure at the Malta Medicines Authority, 2015-2019

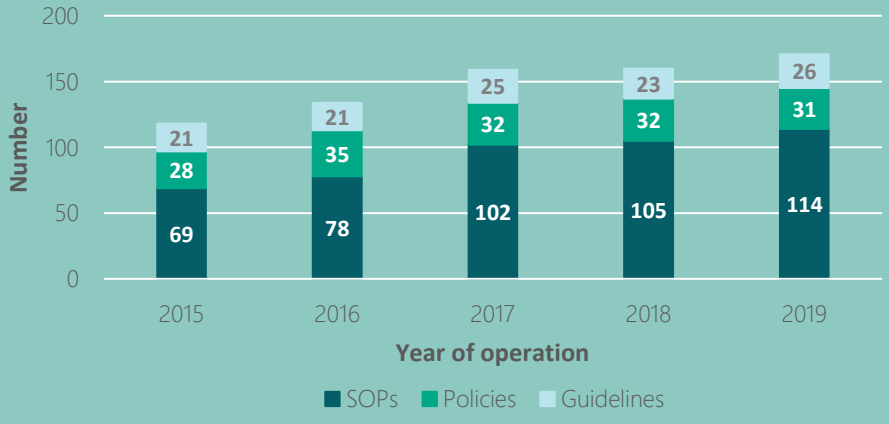


Figure 2: Total number of standard operating procedures (SOPs), policies and guidelines standing per year at the Malta Medicines Authority, 2015-2019

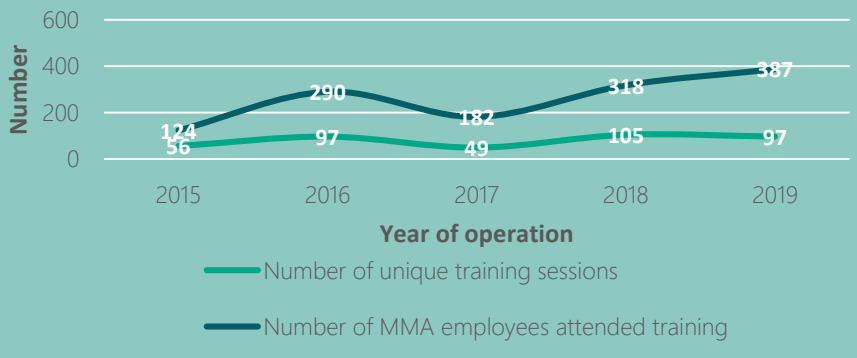


Figure 3: Total number of training opportunities attended by employees of the Malta Medicines Authority per year, 2015-2019

The MMA Strategy to 2025

The MMA is developing its corporate strategy leading to 2025. A Strategy Task Force, established by the Scientific and Regulatory Operations Directorate, serves as a reference group to discuss, guide and provide recommendations.

A roadmap document forms the basis for a pre-strategy framework. The planning of the MMA Strategy to 2025 is two-fold where one facet will identify the internal views on the organisational and regulatory priorities and the other aspect will take into consideration the external stakeholder needs.

A series of one-to-one virtual meetings were organised with line Directors, Heads of Units and representatives from the Medical Devices Support Office in order to gain insights on the priority areas for the strategic planning of the MMA.

The external component in strategic development shall be targeted by means of virtual consultation fora, an online stakeholders satisfaction survey and a comparative analysis of strategies published by members of the European Medicines Regulatory Network and counterpart agencies internationally.

All contributions are conducive to formulate the landscape of the Authority for the next five (5) years within the current and evolving contexts.

#MedSafetyWeek 2020

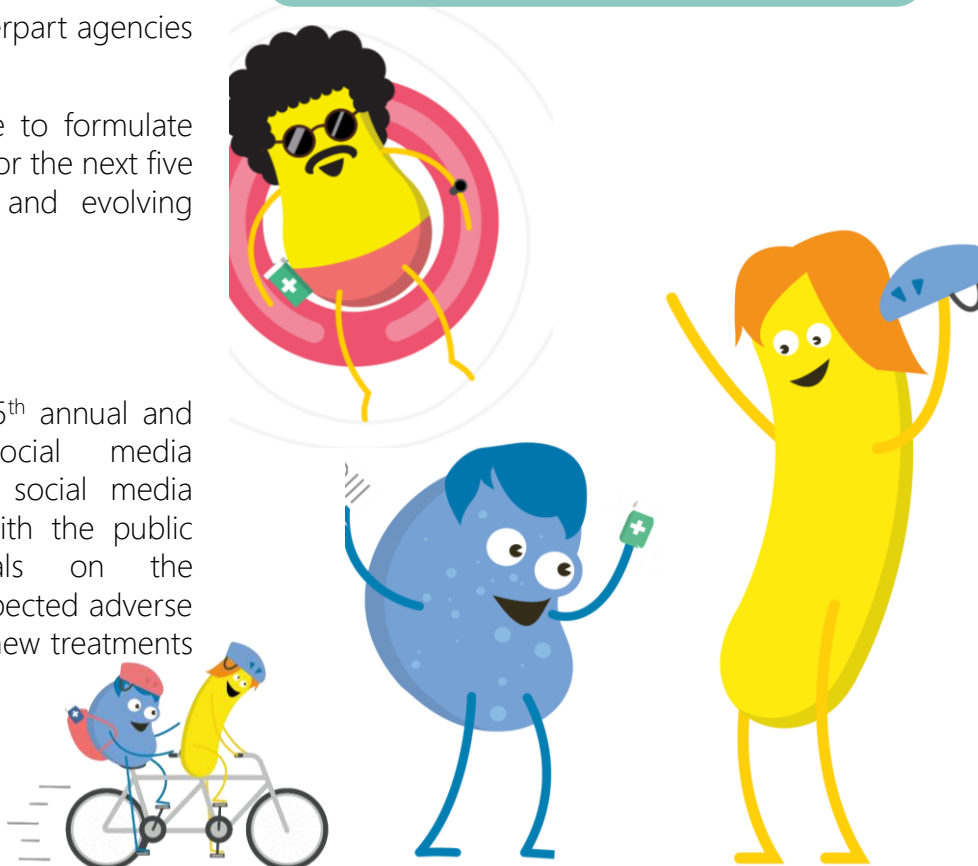
The MMA participated in the 5th annual and global #MedSafetyWeek social media campaign. The MMA shared social media material to raise awareness with the public and healthcare professionals on the importance of reporting all suspected adverse drug reactions, especially with new treatments and experimental medications.

Equality Mark Certification

The MMA is re-certified by the National Commission for the Promotion of Equality (NCPE) with the Equality Mark and is granted the use of the Equality Mark logo for another period of three years. This re-certification is based on evidence that the Authority kept its commitment to implement relevant policies and practices that concern gender equality and family friendly measures at the place of work and in the access to and provision of goods and services. The MMA also demonstrated that it has the will and capacity to keep these good practices in the years to come.

Members of the MMA are referred to the Manager (People Management), Ms Emma Saliba, should they wish to discuss matters related to equality.

'Gender mainstreaming is a strategy to achieve gender equality. It should be a strategy used with special tools whenever and in whatever you do at work as a public officer'



Academia

Employees at the MMA who are following the Doctorate in Pharmacy (PharmD) programme undertake a Doctoral research dissertation related to the different branches of pharmaceutical regulatory sciences.

The following are examples of PharmD research projects which were pursued throughout the period 2018-2020.

Regulatory Framework for Community Pharmacies

- *Patient centred regulatory audits in community pharmacies*

This research has allowed for the reengineering of the pharmacy inspection process. It involved the evolvement from adopting a predominantly policing approach with forceful enforcement towards a patient-centred inspection following an innovative educational approach, where concordance between the inspector and the pharmacist is being reached to improve patient safety and care outcomes. Using punitive enforcement as a motivator induced fear and has been identified as a barrier for quality improvement. The implementation of an educational approach in inspections improved communication and cooperation between the regulator and the pharmacist, which led to increased pharmacist motivation to reach concordance on the implementation of patient-centred improvements in pharmacy practice. Inspections incorporating educational discussions are positively influencing the relationship between the regulator and the pharmacist to reach concordance on corrective and preventive actions to be implemented to improve patient safety and care outcomes.

Annalise Attard

- *Innovative regulatory framework in community pharmacy*

The innovative regulatory framework proposed the integration of a self-audit approach and a patient-based risk assessment in community pharmacy audits. The research fostered the empowerment of pharmacists and the promotion of the self-audit as a learning experience. The risk assessment of pharmacy audits contributes to patient safety through the risk-based prioritisation of audit frequency. The project promotes the evolution of pharmacy audits from the regulatory frameworks towards the integration of Good Pharmacy Practice standards and pharmaceutical care.

Marina Langaro

Emerging Patterns and Treatments for Different Disease States

- *Emerging patterns in the development of medicines in paediatric oncology*

This project reviews the clinical development programs and therapeutic indications of authorised and prospective medicinal products for childhood acute lymphoblastic leukaemia (ALL) to identify emerging patterns in drug development and future treatment protocols. Results indicate that established products are being repositioned or reformulated (e.g as liposomal, PEGylated, paediatric friendly dosage forms) for childhood ALL, while new active substances tend to target patient cohorts with poor outcomes. Results also indicate that first line treatment protocols continue to be based on multidrug chemotherapy regimens and innovative products in the pipeline are more likely to impact second line treatment protocols.

Benjamin Micallef

- *Evidence generation in the clinical development of medicines for leukaemia*

Leukaemia accounts for the highest age-standardised mortality rate among haematological malignancies in Europe. Evidence of efficacy for antineoplastic agents may be valued differently by regulatory and health technology assessment (HTA) bodies in the European Union (EU), impacting decision-making and access to novel medicines. The study analyses the evolvement of efficacy parameters studied in leukaemia clinical trials (CTs), explores scientific expert opinions on evidence generated and clinical assessments for antineoplastic therapies and determines core efficacy outcomes prioritised by EU decision-makers for leukaemia CTs. Through a methodology comprising of data mining and e-Delphi tools, the study identified a core set of 6 efficacy outcomes that may potentially optimise CT data packages for regulatory and reimbursement approvals. This research also inferred that biomarker-based endpoints are emerging as primary efficacy measures of choice in leukaemia CTs and deduced that perspectives on the quality of evidence generated for antineoplastic therapy are statistically different between both groups of decision-makers.

Dylan Said

- *Emerging treatments for Leber's Hereditary Optic Neuropathy and Retinitis Pigmentosa*

Leber's Hereditary Optic Neuropathy (LHON) and Retinitis Pigmentosa (RP) are two rare diseases which affect the eye. Raxone (idebenone) is the only medicinal product (MP) approved for LHON and Luxturna (voretigene neparvovec) is the only MP approved for RP. The study aimed to detect emerging patterns pursued by companies when developing MPs to treat LHON and RP. Results showed that several MPs with different mechanism of actions are being studied these two rare diseases.

Marta Zuccarelli

Regulation of Medicinal Products

- *Assessment of medicinal products: A comparative study between Europe and United States of America*

This study sought to compare evaluation practices for the registration of medicinal products in Europe and the United States. A tool was developed, validated by 6 experts and used to compare assessment outcomes of 27 cardiology-related medicinal products evaluated by the European Medicines Agency (1995-2006) to reviews of their US counterparts carried out by the Food & Drug Administration. Lack of harmonisation between assessment outcomes and approved product information was observed. This may lead to differences in clinical guidelines, pricing policies and drug use. A framework which ensures enhanced collaboration between the agencies and the pharmaceutical industry is thus necessary in order to reduce discrepancies in medicine regulation.

Matthew Camilleri

Medical Devices

- *Regulation of medical devices*

The study focused on (1) the set-up of a medical device (MD) database and (2) improving the current incident reporting system for medical devices. Recommendations for the setup of MD databases were drawn up based on systems used throughout the EU/EEA. A new Medical Device Incident Reporting Form was proposed following the analysis of incident reports submitted at the national healthcare system by healthcare professionals in 2019.

Paula Cardona Xuereb

Access to Medications

- *Drug intelligence and access to medicine*

Access to safe, effective and good quality medicines is an evolving, complex and multifactorial challenge. The research identified the significance of a proactive personalised-patient approach to bridge the gap between patients and the regulatory and healthcare systems in order to enhance access to medicines. A scientific framework based on assessing access implications on patient health outcomes, obtaining and applying medicines intelligence in a risk-based approach was established as an innovative framework to detect, address and mitigate issues compromising access to medicines in order to provide a rational and prompt medicines accessibility strategy that meets patient needs.

Caroline Muscat

Veterinary Pharmaceutical Sciences

- *Regulatory policies, education and training in veterinary pharmaceutical sciences*

Education and training on veterinary pharmaceutical sciences empowers pharmacists to become active participants in the different areas within the veterinary field. A training programme for pharmacists in veterinary pharmaceutical sciences was developed, different systems and resources of different EU competent authorities that regulate veterinary medicines were analysed and a framework for a support office within an entity specialised in human medicinal products to extend its services to veterinary medicinal products was proposed.

Dianne Butler


2021
Happy New Year!