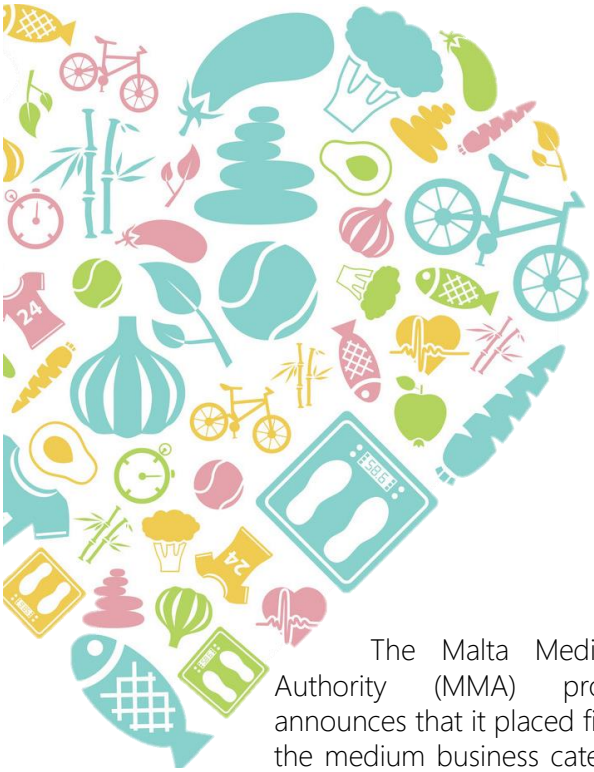
THE MMA
telegram

ISSUE 03 – Q3 2020

GENERAL UPDATES



During the last three months, the MMA engaged post-secondary and post-graduate students including ten (10) summer students, three (3) students through the Institute of Public Service (IPS) scheme and nineteen (19) fellows, who were stationed among different areas of competencies within the Authority. The engagement of students and fellows is a worthwhile endeavour which mutually benefits the parties involved.

'The expert in anything, was once a beginner'
-Helen Hayes

The Malta Medicines Authority (MMA) proudly announces that it placed first in the medium business category of the Workplace Health Initiative Competition 2020 which was organised by the Health Promotion and Disease Prevention Directorate. The Authority contributed towards the following activities:

✓Offered its employees herb-infused water, fresh fruit salad and healthy yoghurts;

✓Affixed health awareness messages to prominent areas in the workplace;

✓Organised yoga, a circuit training session, and a 6 km walk;

✓Organised a nutritional talk;

✓Organised health checks (blood pressure and blood glucose monitoring) to its employees;

✓Staff members developed a healthy recipe book.

Article 126a Stakeholders Webinar

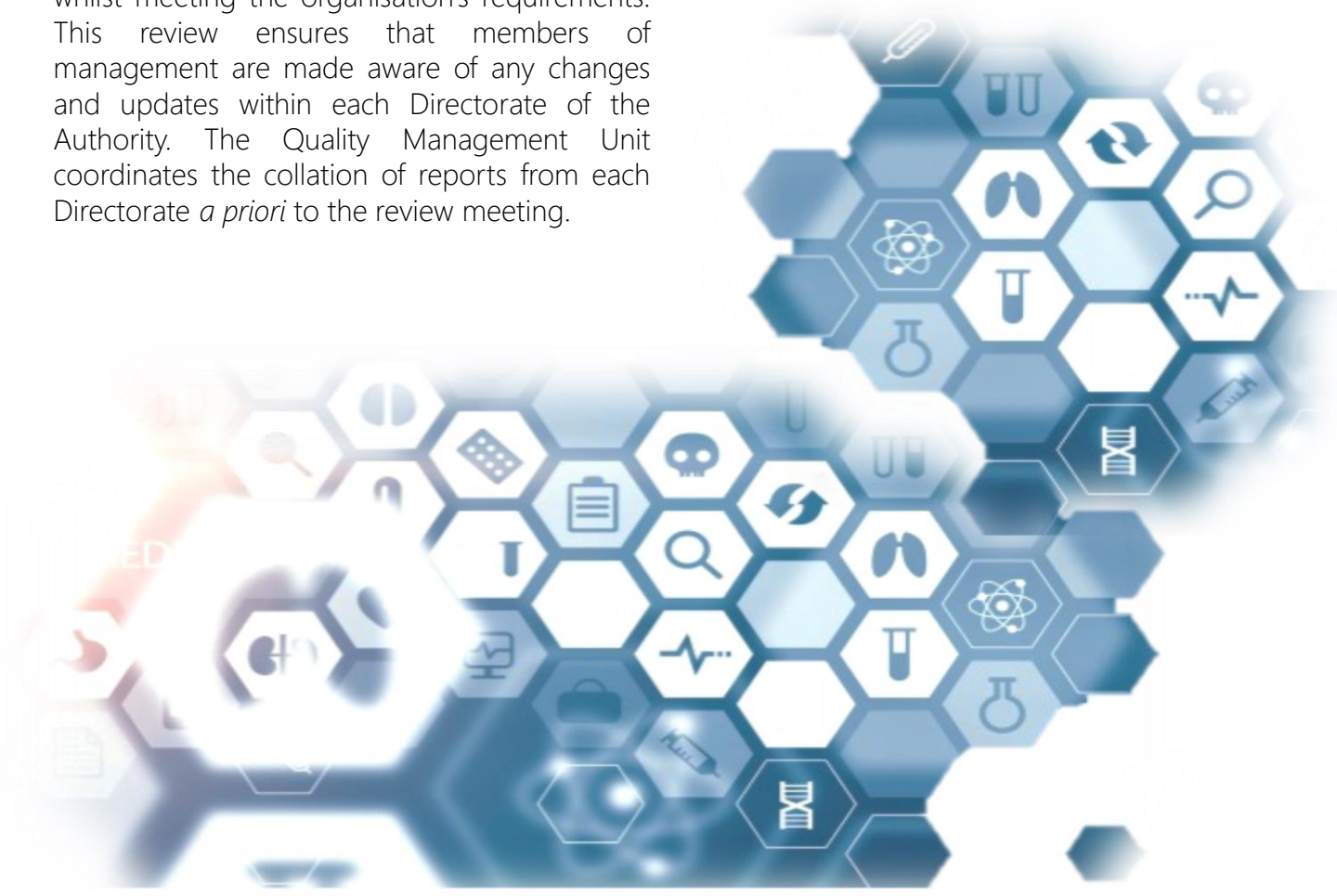
On 29 July 2020, the MMA organised a webinar to concerned stakeholders to discuss the new process which the Authority intends to implement regarding the process for the application for an authorisation in accordance with Article 126a of Directive 2001/83/EC. In order to enhance the transparency of the procedure, the Authority revised the application form and informed the stakeholders that any applications submitted from 1 October 2020 must be submitted using the new application form.

Management Review Meeting

The annual management review meeting 2019-2020, which will take place on 7 October 2020, is a formal, structured meeting that involves Directors and Heads as members of the Management team. The main purpose of this yearly meeting is to review and evaluate the effectiveness of the Authority's deliverables whilst meeting the organisation's requirements. This review ensures that members of management are made aware of any changes and updates within each Directorate of the Authority. The Quality Management Unit coordinates the collation of reports from each Directorate *a priori* to the review meeting.

Transfer of Remit of Medical Devices to the MMA

In July 2020, a stakeholders meeting regarding the transfer of remit of medical devices to the MMA was organised. The MMA was designated as the competent authority for medical devices. The function of the national competent authority for medical devices and in-vitro diagnostic medical devices was transferred from the Malta Competition and Consumer Affairs (MCCAA) to the MMA. As with the regulation of medicinal products, the Regulation for medical devices aims to safeguard the safety, quality and efficacy of medical devices on the local market. This transfer falls within act VII of 2020 to amend the Medicines Act (Cap 458 of the laws of Malta), and its subsidiary legislation Legal Notices 318-321 of 2020. In order to ensure a smooth transition, both authorities are working in tandem keeping the patient at the core of activities.



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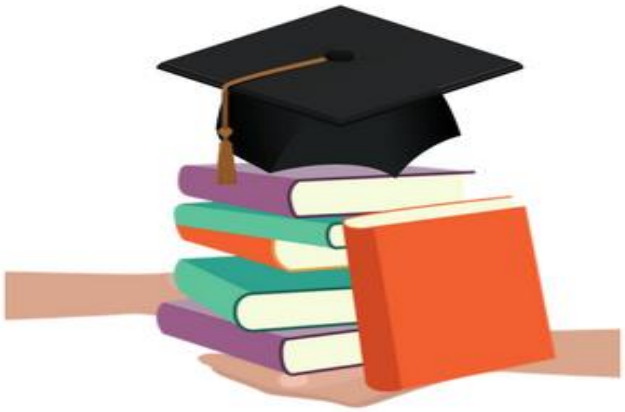
ISO 9001:2015 Re-Certification Audit

In August, the ISO 9001:2015 re-certification audit was carried out. The ISO 9001:2015 is an international standard which stipulates the requirements for the quality management system where processes are outlined within the institution. It aims to retain all documented information to make sure that the procedures are carried out as planned. The scope of the re-certification audit is to establish whether the management system implemented is still appropriate in the organisation.

The National Audit Office (NAO) HR Cost-effectiveness Audit

The NAO HR cost-effectiveness audit promotes accountability, propriety and best practices in organisations while assessing whether the resources and funds are used effectively, efficiently and economically. Throughout August and September 2020, in an extensive, cross-directorate collaborative exercise, the MMA compiled several documentation and trends on key deliverables from the Authority's regulatory portfolio covering the period 2012 till present. Corporate statistics, strategic documents, financial statements, business plans and audit reports were among the records submitted to the NAO in the final package. The Authority is currently awaiting the formal communication and outcome for this external audit.



MMA Academy

Further to the launch of the Academy for Patient-Centred Excellence and Innovation in Regulatory Sciences in November 2019, the MMA is following the NCFHE process to register as a Further & Higher Education Institution. The Academy, within the Advanced Scientific Initiatives Directorate, manages the design, development and delivery of multidisciplinary educational initiatives, encompassing the pertinent elements of innovation, optimisation and accreditation, to translate regulatory standards of good practice into day-to-day excellence. Upcoming programmes include Awards in Good Distribution Practice (GDP), Good Manufacturing Practice (GMP) and Medical Devices.

Operational Review

In line with keeping the Government organisations in peak performance, operational reviews of the MMA have been carried out which mainly focused on the financial and operational aspect of the Authority. The MMA was asked to prepare documents related to contracts of service of all senior employees, contractual obligations with suppliers, bank statements, financial and HR quality documents, audited financial statements, budget or forecasts and a comprehensive list of tenders issued by the Authority.

MMA On-Boarding to the Malta Medicines Verification System (MaMVS)

In liaison with the Malta Medicines Verification Organisation (MaMVO), the National Competent Authority (NCA) MaMVS on-boarding application has been completed and the NCA Terms & Conditions have been reviewed and endorsed. The MMA has registered its MaMVS account and now has access to national repository data in line with Article 37(g) and Article 39 of the Commission Delegated Regulation (EU) 2016/161. This will enable the Authority to generate reports related to the supervision of the functioning of the repository system, to investigate potential incidents of falsification and to verify the compliance of pharmaceutical stakeholders to the requirements of the Regulation.

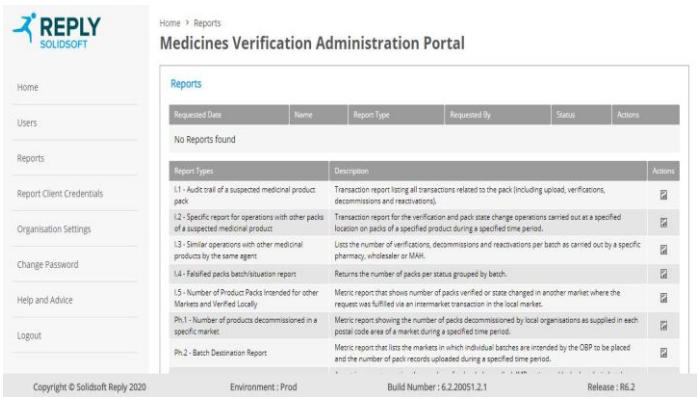
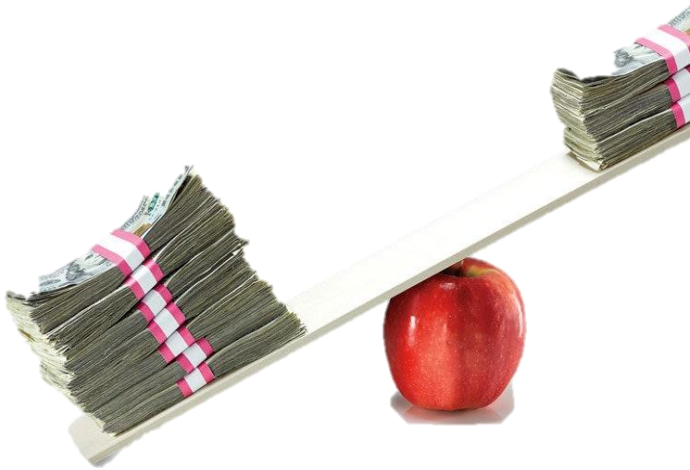


Figure 1: MaMVS portal screenshot.

Consolidation of MMA FOI Services

The MMA has consolidated its Freedom of Information (FOI) services by developing an internal structure consisting of an FOI officer, alternate officer and validator for the handling of FOI requests in line with direction provided by the Government FOI Coordination Unit (FOICU). Members of the public can submit their FOI requests through the portal https://freedomofinformation.gov.mt/, which are then processed internally by the Authority and the outcome relayed back to the client by means of a seamless, track-and-trace web-based backend system.



Equal Pay Tool

On 31 July 2020, MMA representatives participated in a session on equal pay tool which was organised by the National Commission for the Promotion of Equality (NCPE) specifically for entities engaged in the Equal Pay Tool pilot testing exercise. This will form part of the enhanced Equality Mark Certification where organisations will be able to opt to be equal pay certified with this Equal Pay Tool. This will check that the organisation's equal pay for work is of equal value between women and men during the Equality Mark Audits. Throughout the session, the concept underlying the tool was briefly outlined and the entities' feedbacks regarding the use of the tool were discussed.

DID YOU KNOW?

Fun Facts!

If you are physically tired, the best thing to do is exercise as it will give you more energy than sitting. Studies have found that the blood and oxygen flow through the body and the increase in endorphin levels can contribute to more energy, improve your mood and promote a feeling of well-being.

So remember, tired is just a State of mind!

Cannabis for Medicinal and Research Purposes

Medicolegal realities pertaining to cannabis are evolving worldwide, marked by considerations of therapeutic potential and safety concerns, nebulous perceptions and scientific evidence, as well as accessibility issues and limited harmonisation across jurisdictions. Medicinal cannabis is largely regulated by provisions implemented on a State-by-State basis. In Malta, the March 2018 amendments to the *Drug Dependence (Treatment Not Imprisonment) Act* permit medical practitioners to prescribe cannabis-based products, licensed under the Medicines Act or produced under EU Good Manufacturing Practice (EU-GMP), if it is considered that there is no viable alternative to such prescription and provided that none of the products are intended for smoking.

The Advanced Scientific Initiatives Directorate (ASID), established within the MMA in 2018, reviews applications for sourcing to Malta cannabis-based products produced under EU-GMP, whereby licensed wholesale dealers supply local pharmacies for dispensing, as per the protocol set by the Superintendence of Public Health. The regulatory review procedure considers a number of requisites, including GMP certification, analytical parameters, stability data and labelling. ASID received nineteen (19) new applications for the importation and/or wholesale distribution of cannabis-based products, in the form of dried flowers or oils, with varying concentrations of the active cannabinoids tetrahydrocannabinol (THC) and cannabidiol (CBD). A notification of approval was issued for four (4) products, whereas one (1) product was refused and fourteen (14) are on hold, pending submission of relevant data such as certifications and test results for assays, heavy metals, pesticides, aflatoxins, and microbiology.

The approved products to date are dried flowers with concentrations of 22% THC/<1% CBD in two products, and 20% THC/<1% CBD and 6.3% THC/ 8% CBD in the two other products respectively. Individual patient packs of all products sourced for the local market are serialised with tamper-evident labels, sustaining traceability of the products through the controlled supply chain (555 products in 2018, 5800 products in 2019, and 9410 products by September 2020). Product portfolios are followed-up for additional data during the annual renewals and as may be deemed necessary, while adverse reaction reports are managed through a set procedure.

Analogously, prospective local medicinal cannabis manufacturing operations fall within the remit of the MMA. In line with Chapter 578 of the Laws of Malta and subsidiary legislation (enacted also in 2018), the MMA functions as regulatory authority for the production of cannabis for medicinal and research purposes, referred to as the Agency in the United Nations Single Convention on Narcotic Drugs (1961) articles 23 and 28.

The Advanced Scientific Initiatives Directorate developed a framework and a sustainable fee structure, alongside yearly guidance documents which provide an overview of specific procedures such as cultivation, production, analytical considerations, licensing, security and reporting measures, enabling the implementation of a transparent system throughout all processes, including due diligence and certifications relevant to manufacturing, as well as monitoring and control. To date, five (5) applications for production licences are being processed by ASID, in liaison with the Inspectorate and Enforcement Directorate and relevant bodies, portending availability of products manufactured in Malta.

Having regulated cannabis for medical use on the market in Malta translated in a number of medical practitioners considering cannabis-based products in diverse clinical presentations, ranging from anxiety, insomnia, depression and post-traumatic stress disorder to migraine, pain, fibromyalgia, multiple sclerosis and cancer. It is anticipated that advanced research shall assist policy-makers in consolidating protocols, drive industry towards the production of quality products pertinent for clinical studies, and stimulate the medical community to construe safety and efficacy evidence. Ongoing doctoral research projects include the study of analytical considerations for the regulation of cannabis-based products and the implications of cannabis for medicinal use, whilst the MMA welcomes other proposals for collaborative initiatives.