2020

MALTA
MEDICINES
AUTHORITY

ANNUAL REPORT

ACRONYMS

ADR	Adverse Drug Reaction
AESI	Adverse Events of Special Interest
ASHP	American Society of Health System Pharmacists
BCC	Borderline Classification Committee
CBD	Cannabidiol
CMDh	Coordination Group for the Decentralised and Mutual Recognition Procedure (Human)
CMS	Concerned Member State
COVID-19	Coronavirus Disease
CTMS	Corporate Travel Management System
CTR	Clinical Trial Regulation
DCP	Decentralised Procedure
DHPCs	Direct Healthcare Professional Communications
DPU	Data Protection Unit
DSUR	Development Safety Update Report
EAFP	European Association of Faculties of Pharmacy
EC	European Commission
EMA	European Medicines Agency
EMRN	European Medicines Regulatory Network
EU	European Union
EUCD	EU Coordination Department
EU-IN	EU Innovation Network
EU-NTC	EU Network Training Centre
EURD	European Union Reference Dates
EVDAS	EudraVigilance Data Analysis System
FMD	Falsified Medicines Directive
FOI	Freedom of Information
FOICU	FOI Coordination Unit
GACP	Good Agricultural and Collection Practices
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GMOs	Genetically Modified Organisms
GMP	Good Manufacturing Practice
HMA	Heads of Medicines Agency
IACS	International Academic Conference Scheme
ICSRs	Individual Case Summary Reports
ICT	Information and Communications Technology
IFP	International Fellowship Programme
IPAS+	Internationalisation Partnership Awards Scheme Plus
IQA	Internal Quality Assurance
IRG	Inspections Review Group
ISO	International Organisation for Standardisation
IVD	In-Vitro Diagnostic
IVDR	In-Vitro Diagnostic Device Regulation
MAH	Marketing Authorisation Holder
MCCAA	Malta Competition and Consumer Affairs Authority
MDR	Medical Devices Regulation
MEB	Medicines Evaluation Board
MFHEA	Malta Further & Higher Education Authority
MMA	Malta Medicines Authority
MRP	Mutual Recognition Procedure
NAO	National Audit Office
NCA	National Competent Authority
NCFHE	National Commission for Further and Higher Education
OMCL	Official Medicines Control Laboratory
PAES	Post-Authorisation Efficacy Studies
PASS	Post-Authorisation Safety Studies
PDPID	Policy Development and Programme Implementation Directorate
PPP	Pregnancy Prevention Programmes
PSR	Product Safety Recall
PSUR	Periodic Safety Update Report
PSUSA	Periodic Safety Update Report Single Assessment
PSWG	Prescription Status Working Group
QMS	Quality Management System
QP	Qualified Person
RA	Rapid Alert
RMM	Risk Minimisation Measure
RMP	Risk Minimisation Programmes
RMS	Reference Member State
RP	Responsible Person
SAWP	Scientific Advice Working Party
SOC	System Organ Class
SOP	Standard Operating Procedures
SSI	Safety Signal Investigations
THC	Tetrahydrocannabinol
UK	United Kingdom
WHO	World Health Organisation

Table of **Content**

Foreword by
the Parliamentary Secretary

The Malta Medicines Authority is internationally recognised as an efficient sustainable entity at the forefront of regulatory science embracing innovation and excellence by inherently adopting quality and scientific principles for the benefit of patients and stakeholders. It strives to fulfil its mission of protecting and enhancing public health through the regulation of medicinal products, medical devices, and pharmaceutical activities on the national and EU markets. The Authority ensures steady commitment towards the realisation of its vision and is a model of people development and continued professional maturity.

The year 2020 was characterised by changes and challenges brought about mainly by Brexit and COVID-19 pandemic. This scenario added further strain on the supply chain particularly because of Malta's small market volume. The Malta Medicines Authority professional experts worked relentlessly in collaboration with other national and international institutes, organisations and entities rising to the occasion to ensure the continuous provision of safe, effective, and high-quality medicines and medical devices during these challenging times. The Authority's dynamic, diligent, and proactive characteristics were acknowledged in a report published by the National Audit Office (NAO) following an audit on performance management and cost-effectiveness. The NAO acclaimed the Authority as an organisation which has been re-engineered to enable it to broaden its scope of operations, fulfil new obligations and cope with the increasing volume of activity. This re-modelling exercise has extended to both administrative and pharmaceutical arms for the Authority to be able to respond with agility to a fluid regulatory environment, in a patient-centred manner.

The designation of the Malta Medicines Authority as the Competent Authority for medical devices in 2020 is a noteworthy milestone towards safeguarding the patient's wellbeing by means of a strengthened regulatory framework for such products. Human and financial resources have been channelled in this regulatory niche to allow the Authority to prepare for a national centralised management system which will carry out the registration of local economic operators, list medical devices placed on the local market and incorporate a reporting system for medical device incident reports. Capacity building for site audits and inspections of local medical device operators, together with competence development required for the designation of Notified Bodies, has been initiated in 2020 to ensure compliance with applicable EU legislation.

In 2020, the Authority continued to embrace investment and initiatives to establish Malta as a centre for educational development, scientific research, and innovation in regulatory sciences, considering national and global exigencies and emerging circumstances. The groundwork for the accreditation of the Academy for Patient Centred Excellence and Innovation in Regulatory Sciences as a Higher Education Institution necessitated intensive preparations in terms of documentation to be integrated in the Medicines Authority Quality Management System.

The Malta Medicines Authority actively assists other government entities by regularly contributing to enhance accessibility to medicines and medical devices. This is achieved through various approaches such as the identification of strategies to ensure that medicines are not out of stock and to enhance fair and equitable pricing of medicines.

The year 2020 has shown that the Malta Medicines Authority is well equipped with the necessary expertise and skills to confidently take on any challenge and overturn it into an opportunity of success whilst keeping the patient at the centre of its endeavours. Through my encouragement and in line with the Government's vision of continuous advancement in innovation and excellence, the Authority is analysing the sustainability of taking up other scientific projects such as in the areas of vaccines, radiopharmaceuticals, Notified Bodies for medical devices, assessments of advanced medicinal products, the setting up of a post-doctorial fellowship scheme and an Official Medicines Control Laboratory (OMCL) laboratory.

The Authority has completed the strategic goals set out for the period 2016-2020 and triggered the planning process for a new strategy. The Malta Medicines Authority Strategy to 2025 shall serve as an essential roadmap which paves the way for a resilient and sustainable vision for the Authority in the next five years.

Dr Deo Debattista
Parliamentary Secretary for Consumer Protection and Public Cleansing

Message from
the Chairperson

The Malta Medicines Authority regulates medicines and medical devices based on the core principles of safety, efficacy and quality. The Authority forms part of the European medicines regulatory network. Through this European commitment, the MMA actively participates in the Management Board of the European Medicines Agency (EMA) and all EMA committees regarding matters such as licensing and granting of marketing authorisations and pharmacovigilance activities. The obligations towards public health are carried out by the MMA through its core Directorates, mainly those of Licensing, Post-Licensing and Inspectorate and Enforcement, and also now through its more recently established Directorates and Units which include the Advanced Scientific Initiatives Directorate, which incorporates the Academy for Patient Centred Excellence and Innovation in Regulatory Sciences and the Research, Scientific Affairs and Innovation Unit, as well as the Medical Device Unit. The work carried out by the Medicines Intelligence and Access Unit has contributed significantly to societal needs, especially following the adoption of the reduction in the price of medicines within its realm. These were all coordinated through the capable management in pharmaceutical areas of the Scientific and Regulatory Operations Directorate.

In 2020, the MMA was at the forefront of the largest public health emergency in recent times. As the local, and global, population struggled with the COVID-19 pandemic, the staff at the MMA got to grips with the necessity to continue to meet patients' needs, both with the exigencies demanded by the COVID-19 pandemic, but also by continuing to ensure the uninterrupted supply of medicines for other medical needs. The pandemic began just as the MMA was responding to the effects of Brexit on the accessibility to medicines. The MMA worked swiftly to adapt to the new scenario in processing the registration of medicines rapidly, responding to the demands for medicines, especially from the national health service. Staff at the Authority had to do this whilst adapting to performing in a virtual environment. One could state here that one of the lessons learnt from the pandemic is how efficiently and effectively the MMA staff acclimatised to working mostly from home, with the advantages and disadvantages that such a situation presents. The Authority ensured that facilities would be afforded to all staff, in every line of regulatory science, to be able to continue their business efficiently. The pandemic has also underlined the need and the advantages of efficient engagement with all stakeholders and partners involved in the accessibility of medicines, compliance with local legislation and EU Regulations and Directives, and in general in acting as guardians of medicines in Malta and in the EU. It is worth mentioning that in some instances the Inspectorate team proceeded with their evaluations of the pharmaceutical manufacturing industry within third countries, such as through its inspections in Turkey, to aid with the availability of medicines from third countries through EU GMP certification. The Authority has also assisted with the availability and accessibility of COVID-19 vaccines and therapies, and several other medicines and medical devices at an unprecedented pace, without compromising its high standards of safety, efficacy and quality. I must say how impressed and proud one and all ought to be of the endurance and rigour shown by all the staff at the Authority and the support received from the Ministry, especially through the fatherly care and advice given by the Parliamentary Secretary for Consumer Protection and Public Cleansing, Dr. Deo Debattista.

Amid this public health challenge, the Authority has cooperated and collaborated on a daily basis with the Superintendent of Public Health who very often found the MMA to be a pillar by virtue of its wealth of knowledge, innovative ideas, scientifically evidence-based advice and intelligence, obtained through its continuous contact with the European Medicines Agency, the European Network of Medical Competent Authorities and other expertise derived from international entities and the pharmaceutical industry. We cannot say that the Medicines Authority did not have to work under tremendous pressure this past year but thanks to the excellent cooperation and collaboration, and the flexibility and wisdom of the staff, this has led to a very memorable and successful year. This demonstrates that the Authority will be able to face challenges in years to come and, in alignment with other European countries, perform its strategy for the advancement of medicines in the foreseeable future.

Professor Anthony Serracino-Inglott
Chairman of the Malta Medicines Authority

1

The Malta Medicines Authority

The Malta Medicines Authority (MMA) was established in 2003 and has developed into an autonomous body that implements scientific decisions in the best interest of patients. It is committed to provide high quality licensing, pharmacovigilance, pharmaceutical inspections and enforcement services to its stakeholders for the ultimate benefit of the public.

The MMA is made up of five Directorates under the guidance of the Executive Chairman. These are the Licensing Directorate, the Post-Licensing Directorate, the Inspectorate and Enforcement Directorate, the Advanced Scientific Initiatives Directorate and the Scientific and Regulatory Operations Directorate. Their core work is supported by seven units, namely the Finance and Corporate Services Unit, the Information and Communications Technology Unit, the Medicines Intelligence and Access Unit, the Quality, Continuous Improvement and Internal Audit Unit, the Research, Scientific Affairs and Innovation Unit, the Educational Planning and Academic Development Unit and the Operations and Data Interpretation Unit.

The MMA works to sustain its reputation as a recognised centre of excellence for European regulatory sciences through the highest quality and scientific rigour with which it undertakes the core functions outlined below in a patient-centred approach.

WHAT **WE DO**

- Perform functions as delegated by the Licensing Authority
- Assist and advice the Licensing Authority
- Ensure that medicinal products marketed and supplied in Malta and the European Union (EU) are of good quality, safety and efficacy
- Ensure that medicinal products have a favourable benefit-to-risk profile through independent, science-based assessments, post-authorisation activities and participation in decision-making at the European level
- Scientifically evaluate requests and monitor clinical trials carried out in Malta
- Provide high quality monitoring and inspection services for pharmaceutical activities
- Monitor the safety of medicinal products
- Monitor and enforce the relevant legislation
- Investigate potential breaches of regulations
- Enhance the effective, safe and rational use of medicinal products and medical devices
- Provide objective and unbiased information to help prescribers, healthcare professionals and patients make informed decisions on the choice and use of medicines
- Support the availability of medicinal products on the local market
- Support competitiveness in the local market through scientific and regulatory advice
- Enhance the standard of medicinal products and pharmaceutical activities through the sustained capacity building of our workforce
- Actively participate in European and International fora
- Collaborate with stakeholders to maximise access to medicinal products
- Act as a Reference Member State (RMS) or Concerned Member State (CMS) and rapporteur for European procedures
- Promote continuous learning, research and innovation
- Steer the progress of regulatory sciences through advanced initiatives aligned to our strategic priorities
- Spearhead collaborative research and innovation activities, including academic development
- Lead advancements in the regulation of cannabis for medicinal use

OUR **MISSION AND VISION**

"Our mission is to protect and enhance public health through the regulation of medicinal products and pharmaceutical activities."

"Our vision is to be a centre of excellence in advancing effective and innovative regulation and promoting quality and scientific rigour in the work we do. We strive to be a best in class regulator for the benefit of patients and stakeholders. We endeavour to be an internationally recognised, efficient entity and promoter of people development and sustainable growth."

OUR **VALUES**

People

Our people are our most valued resource. We are committed to sustain our ongoing efforts to improve our workforce through educational advancements and most importantly a healthy work life balance.

Quality

We are committed to provide high quality licensing, pharmacovigilance, inspections, enforcement, and advisory services to our stakeholders in the best interest of consumers.

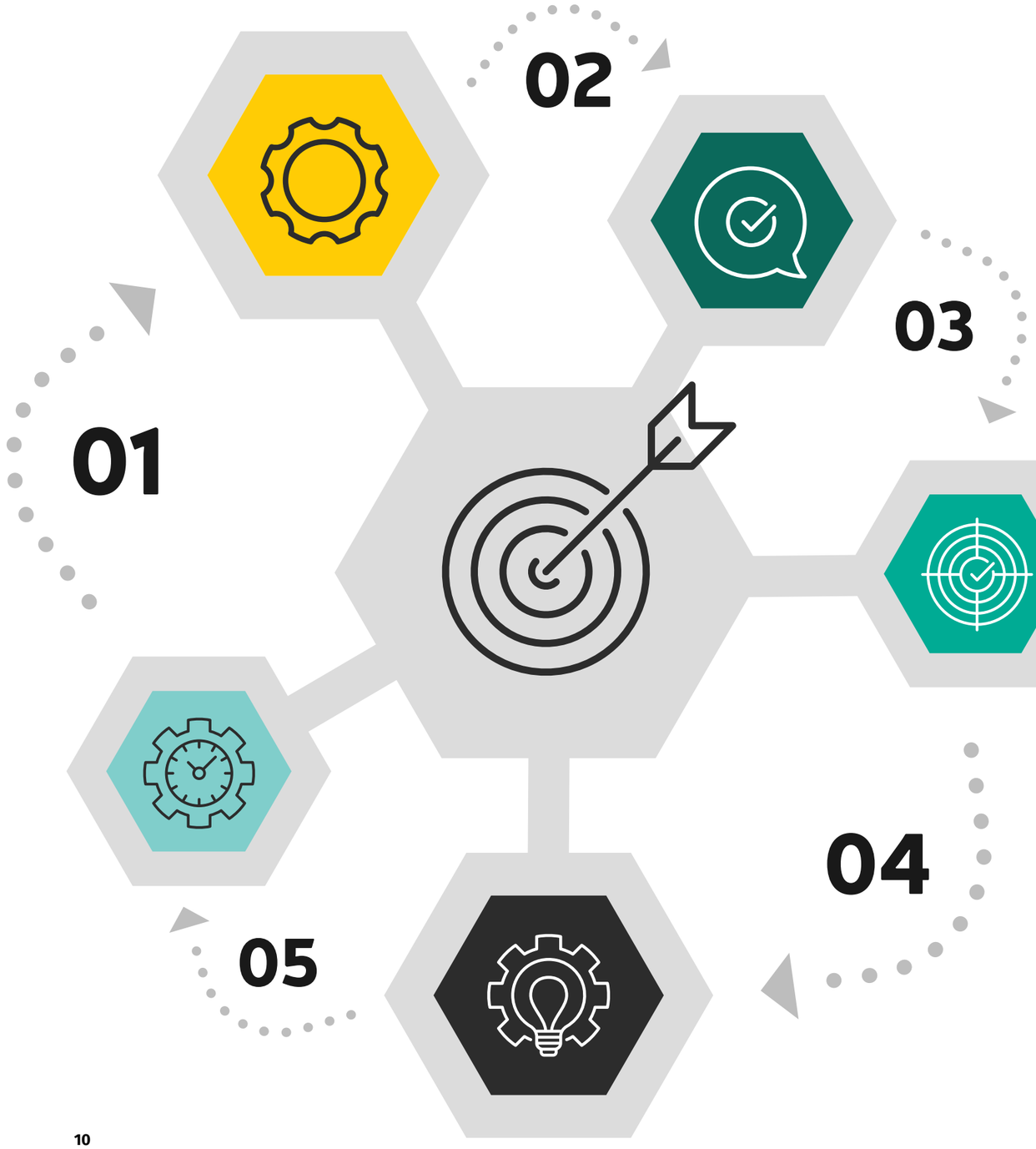
Integrity

Discpiline and fairness are the utmost principles which guide us to do what is right. The intergity of our officers lies at the very heart of our mission to uphold the best interests of Maltese consumers and beyond.

Innovation

In an everchanging environment, innovation is what drives us forward and keeps us up to speed with the constant technological and scientific advancements. This ensures we remain both valid and effective.

Strategic **Goals and Objectives**



1. Optimised Regulatory Systems

1.1. To strengthen the effectiveness of surveillance systems for medicinal products
1.2. To ensure appropriate national regulation of medicinal products and contribute to national health policy
1.3. To enhance the MMA's commitment to strengthening the European and International regulatory network

2. Better informed users

2.1. To promote rational and safe use of medicinal products
2.2. To promote greater engagement in the role of the MMA
2.3. To ensure public awareness and knowledge of the MMA

3. Access to medicinal products

3.1. To work with national agencies and European regulators to address the challenges of medicines shortages
3.2. To optimise the use of the current regulatory system to maintain authorised products on the market in Malta at reasonable prices
3.3. To protect supply chain integrity

4. Supporting innovation

4.1. To support research and development in the Maltese life-sciences sector
4.2. To look for opportunities to build an innovative portfolio

5. Organisational development

5.1. To ensure that optimal workplace and organisational structure is in place
5.2. To appropriately manage finances and human resource
5.3. To enhance quality management systems
5.4. To further develop Information and Communications Technology (ICT) systems

In view of the expansion of its regulatory portfolio, the MMA was re-engineered to enable the broadening of its scope of operations, fulfil new obligations and cope with the increasing volume of activity, entailing the Authority to sustainably invest in manpower. Committed action led to the realisation of key corporate and regulatory targets outlined in the 2016-2020 strategic framework; such achievements founded the successful outcomes of a National Audit Office (NAO) audit on human resources and cost-effectiveness of the MMA, which concluded that the Authority's "strategic direction placed it on a sound foundation to fulfil its stated vision as a centre of excellence." To sustain its vision of prosperity, during the previous year of operation the Authority initiated works on designing a forward-looking, innovative and robust Strategy leading to 2025 for the regulation of medicines, medical devices and pharmaceutical activities which embraces the principles of public health protection and societal wellbeing.

The Coronavirus Disease (COVID-19) Pandemic

Business Continuity and Regulatory Considerations

During 2020, in view of the COVID-19 pandemic, the MMA has ensured the continuity of business operations and safeguarded the health and safety of the workforce by communicating timely decisions in tandem with direction issued by local health Authorities. The Authority was proactive in addressing the holistic well-being of its staff amid the pandemic through several support measures, including the provision of health and hygiene products and the organisation of virtual counselling sessions.

Given that the COVID-19 pandemic extended the scope of employee remote working, the Authority was fully equipped to support users by way of laptops, virtual private networks, interaction platforms and facilitated document exchange systems.

In line with the strategic vision to foster research and excellence in regulatory sciences, the Authority collaborated with other entities on projects within the scope and focus of the COVID-19 R&D Fund which may translate into innovative approaches related to the current and potential future pandemics. The MMA considered prospective collaboration with stakeholders that meet the eligibility criteria for participation issued by the Malta Council for Science and Technology and Malta Enterprise Corporation in the National Rules COVID-19 Fund.

The MMA monitored closely developments related to the pandemic and where necessary contributed to and communicated about regulatory discussions and decisions. The Authority participated in virtual meetings with the European Medicines Regulatory Network (EMRN) to discuss current affairs related to the COVID-19 pandemic, including the review of authorised and unauthorised vaccines and therapeutics indicated in COVID-19. Salient discussion points included the development and supply aspects of vaccines against COVID-19, such as parameters related to logistics, safety, quality and efficacy and national preparations for the roll-out of vaccination programmes.

The MMA pledges its commitment to sustain its parallel work with health Authorities and stakeholders by offering regulatory support and to ensure continuous accessibility to vaccines and therapeutics required to alleviate the pandemic situation.

Quality Management, Simplification Measures and Good Governance

As an internationally certified institution according to ISO 9001, the MMA upholds the highest standards of governance and is fully committed towards improved quality management.

By the end of 2020, the foundation of the quality management system at the Authority, which ensures uniform and high-quality operations, consisted of thirty-eight (38) policies, one hundred and fourteen (114) Standard Operating Procedures (SOPs) and thirty-three (33) guidelines. In 2020, eighteen (18) policies, forty-six (46) SOPs, and eighteen (18) guidelines were revised or introduced through the annual management review process and periodic internal audits which are both an integral part of the ongoing efforts to continuously improve the MMA's Quality Management System (QMS) **(Figure 1.1).**

Figure 1.1: Standard Operating Procedures (SOPs), policies and guidelines of the Malta Medicines Authority that were revised or introduced in 2020

SOPs: Standard Operating Procedures, GLs: Guidelines

The MMA implemented eleven (11) internal audits throughout 2020, in line with the five (5)-year audit strategy which was extended to a six (6)-year programme due to COVID-19 interruptions.

Overall, a total of one-hundred and four (104) quality improvement forms were submitted to the Quality, Continuous Improvement and Internal Audit Unit. These quality improvement forms arose from internal audits and other internal initiatives by the respective Directorates and Units. Consequently, this led to the introduction of new policies and standard operating procedures or the systematic review of existing ones with a cross-cutting aim of reducing red tape and unnecessary bureaucracy.

The annual Management review examined the operations of each Directorate and the respective Units within the MMA, evaluated the results of stakeholder (internal and external) feedback, analysed the results of previous audits (internal and external) and studied the outcome of the previously identified quality improvements, in a comprehensive exercise to strengthen the QMS.

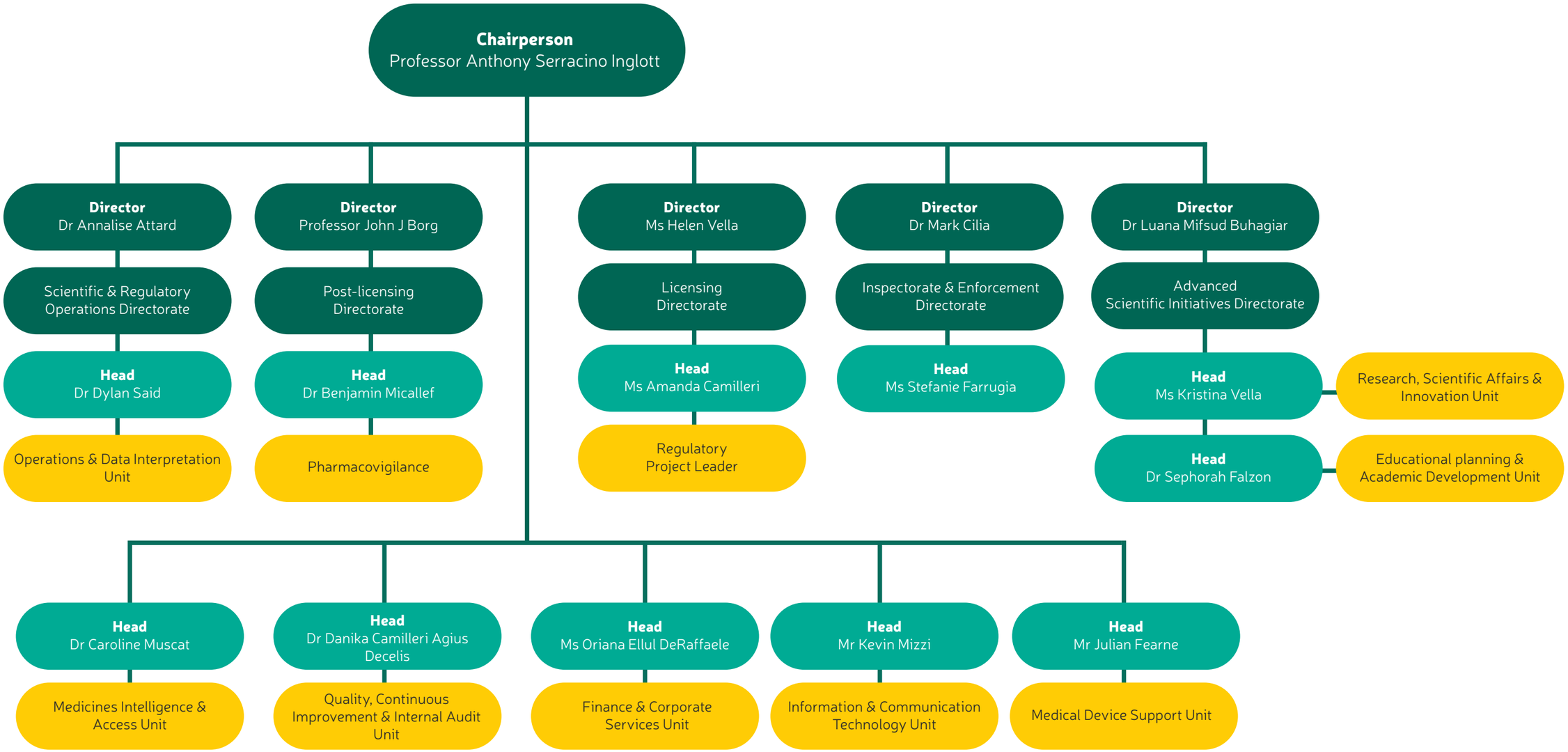
In line with the MMA's commitment to simplify its systems and processes, two (2) simplification measures were identified and successfully implemented in 2020. The first concerned an internal exercise to simplify the Periodic Safety Update Report (PSUR) submission frequency for nationally authorised products which have been locally marketed for ten (10) years or more and registered no safety issues. A successful pilot led to the identification of six (6) medicinal products benefitting from this measure which translates to a reduction of PSUR submissions, and hence bureaucracy and administrative burden, for pharmaceutical stakeholders. The second measure related to the introduction of the Corporate Travel Management System (CTMS) which is an electronic platform serving as a storage and notification database for the purposes of transactions for duty travel. The system is intended to increase processing efficiency whilst securing greater conformity and accountability in travel administration at the Authority.

Looking forward, the MMA for another year 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. The deployment of a national electronic database for medical devices shall constitute the simplification measure for 2021 and will be developed to store information and facilitate transactions with economic operators. This measure will ensure conformity to local and European regulations through a robust registration process of medical devices with the National Competent Authority (NCA). The database shall interface with the Authority's website where economic operators can directly access the registration platform for devices. The development of this database is intended to instil greater confidence in the operations involved in the regulation of medical devices. In its endeavour to continue to secure the protection and safety of consumers of medicines, the MMA has pledged to a budgetary commitment which shall

explore the feasibility of setting up a national reference laboratory for the purpose of ensuring the quality of medicinal products on the market.

The MMA attaches utmost importance to good governance practices which are embodied in three primary measures of transparency based on information disclosure, clarity and accuracy. In compliance with the Freedom of Information (FOI) Act, categories of documents and manuals held by the Authority together with the full audited financial statements were published on the Authority's official website. Privacy by design is a concept brought about by data protection regulations which is fully embedded within the Authority's operational framework for processes handling personal data. The MMA continued to process FOI and data protection access requests and queries in a timely and supportive manner, where necessary liaising with the Government Data Protection Unit (DPU) and FOI Coordination Unit (FOICU). Members of the public can submit their FOI requests through the portal www.freedomofinformation.gov.mt and forward any queries related to data protection on communications.medicinesauthority@gov.mt.

ORGAN**OGRAM**


Chairperson
Professor Anthony Serracino Inglott
Director
Dr Annalise Attard
Director
Professor John J Borg
Director
Ms Helen Vella
Director
Dr Mark Cilia
Director
Dr Luana Mifsud Buhagiar
Scientific & Regulatory Operations Directorate
Post-licensing Directorate
Licensing Directorate
Inspectorate & Enforcement Directorate
Advanced Scientific Initiatives Directorate
Head
Dr Dylan Said
Head
Dr Benjamin Micallef
Head
Ms Amanda Camilleri
Head
Ms Stefanie Farrugia
Head
Ms Kristina Vella
Research, Scientific Affairs & Innovation Unit
Operations & Data Interpretation Unit
Pharmacovigilance
Regulatory Project Leader
Head
Dr Sephorah Falzon
Educational planning & Academic Development Unit
Head
Dr Caroline Muscat
Head
Dr Danika Camilleri Agius Decelis
Head
Ms Oriana Ellul DeRaffaele
Head
Mr Kevin Mizzi
Head
Mr Julian Fearne
Medicines Intelligence & Access Unit
Quality, Continuous Improvement & Internal Audit Unit
Finance & Corporate Services Unit
Information & Communication Technology Unit
Medical Device Support Unit

2

A Positive Working Environment, a Patient-centred Ethos, and a Proactive Approach

Throughout 2020, the MMA maintained its focus on the implementation of the 2016-2020 Strategy as well as the National Framework for Education Strategy 2014-2024. This was achieved through a cross-cutting patient-centred approach across all Directorates and their respective Units.

Team-building activities, capacity building courses and sustained work-life balance measures all contributed towards a positive working environment without which we would not have reached the highest goals which are expected of a reputable scientific regulatory authority. It is such a positive working environment which equips the MMA's officers with the best tools to implement our patient-centred ethos which does not exist in a vacuum. Rather, it is the basis upon which each and every decision is made.

This solid internal structure and philosophy enabled the MMA to improve its engagement with all stakeholders and the public in general through several meetings, seminars, conferences, social media campaigns, and the distribution of informative material on a wide spectrum of topics, ranging from the use of Cannabis for medicinal and research purposes to the introduction of Regulations related to falsified medicines and the availability and accessibility of medications.

Brexit preparedness together with the COVID-19 pandemic were two major challenges which the Authority successfully managed throughout 2020 and will continue over the following weeks to ensure the smoothest outcome for both consumers and the industry at large. In this regard, the MMA will stand as one with the Maltese Government to overcome the threats and maximise the potential of these unique international scenarios.

Human **Resources**

By the end of 2020, the Malta Medicines Authority employed ninety-two (92) officers **(Figure 2.1)**. This represents an increase of 127% from the year 2015 **(Figure 2.2)** which effectively caters for the increased regulatory activities.

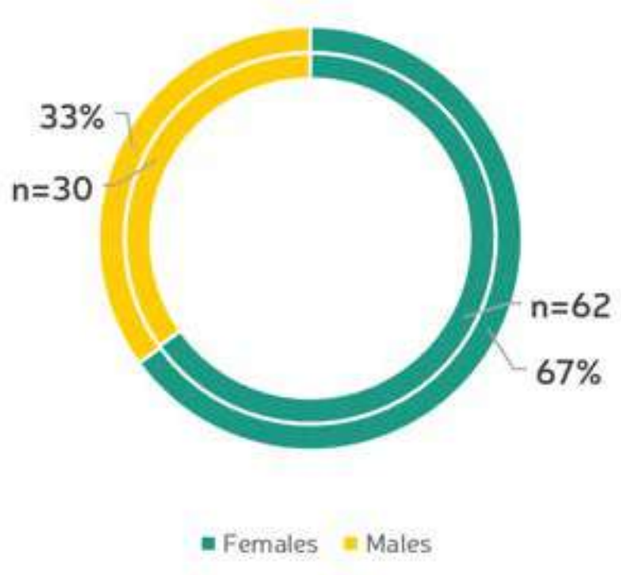


Figure 2.1: Total number of employees at the Malta Medicines Authority at the end of 2020 (N=92)

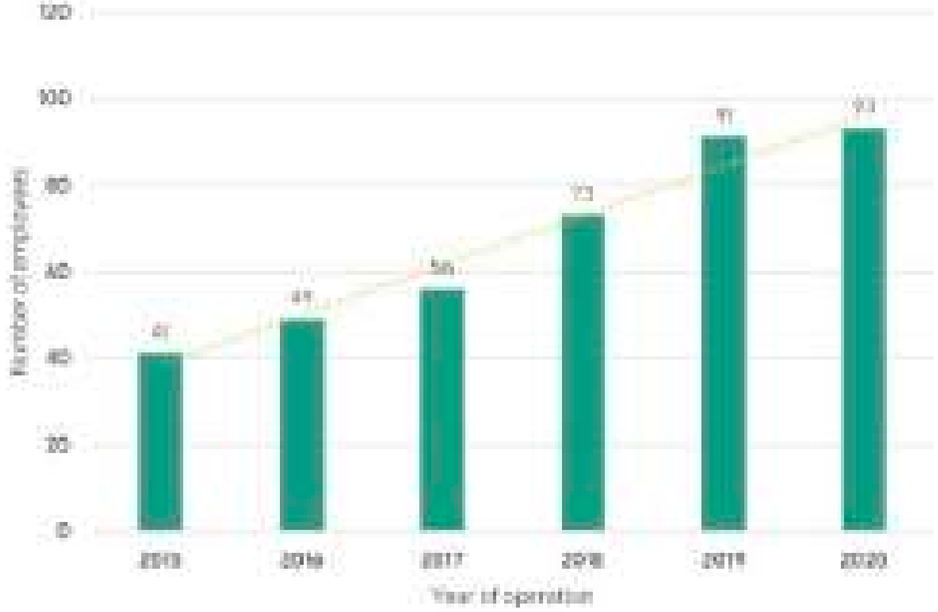


Figure 2.2: Number of employees at the Malta Medicines Authority (2015-2020)

Education and **Professional Development**

The education and professional development of the MMA's workforce is the key towards its continued regeneration and relevance to the ever-evolving pharmaceutical industry. In 2020, its employees successfully attained one hundred and eighty-seven (187) certificates related to training initiatives which were offered internally (n=120) and externally (n=67). These comprised a wide range of subjects inter alia pharmacovigilance, regulatory sciences related to cannabis-based products, biopharmaceutical manufacturing, cyber security awareness and the Medical Devices Regulation (MDR) **(Figure 2.3)**. A number of senior staff members continued pursuing a high-level managerial programme coordinated by the Institute of Public Service (IPS) which targets several aspects related to management in the public administration.

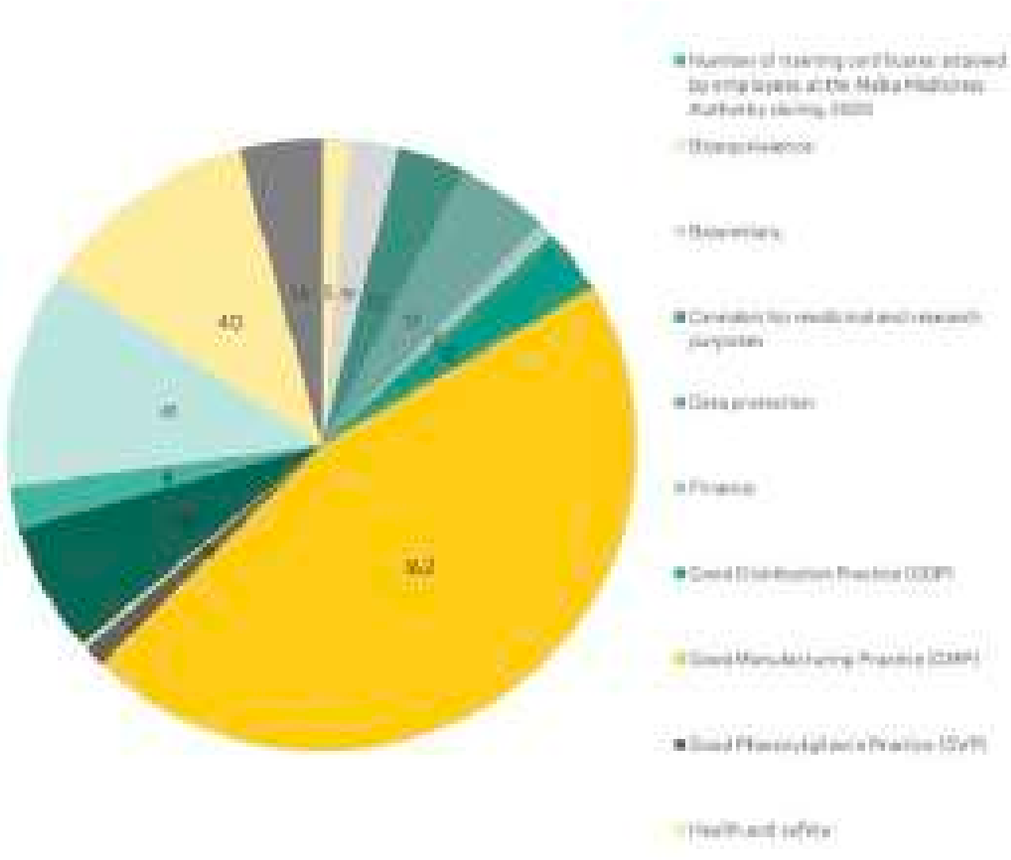


Figure 2.3: Number of training certificates issued by the Malta Medicines Authority in 2020

Besides the ongoing internal training across all the respective scientific fields of operation, the MMA spearheads various initiatives which continuously strengthen its most valued resource.

The flexible working conditions for officers undergoing scientific and corporate studies is a fine example of the above-mentioned commitment. This is clearly portrayed in the number of employee graduates in 2020, whereby four (4) employees attained the Doctorate in Pharmacy degree.

The MMA offers the new International Academic Conference Scheme (IACS) whereby employees tap into financial support to attend international conferences. This scheme further enhances the scientific image of the Authority through the presentation of papers as listed in Section 6.

The International Fellowship Programme (IFP) may be described as a flagship initiative which attracts local and foreign students to join the MMA's team while reading for a Doctorate or Master or a comparable and equivalent qualification in line with the Malta Qualifications Framework in pharmacy, leadership, management, administration, and finance.

Nearly 30% of the graduates were engaged on a full-time contract with the MMA following their successful completion of the International Fellowship Programme **(Figure 2.4)**. Through this initiative, which is intended to overcome skills mismatches in the local pharmaceutical sector by increasing the capacity and level of research, young professionals actively contribute to the ongoing functions and day-to-day running of the Authority in exchange for a financial grant which covers the tuition fee or facilitates the living expenses of the participants. Graduates are often engaged on a full-time contract with the MMA following their successful completion of the Fellowship Programme.

Figure 2.4: Number of students following the International Fellowship Programme in 2020 (N=23)

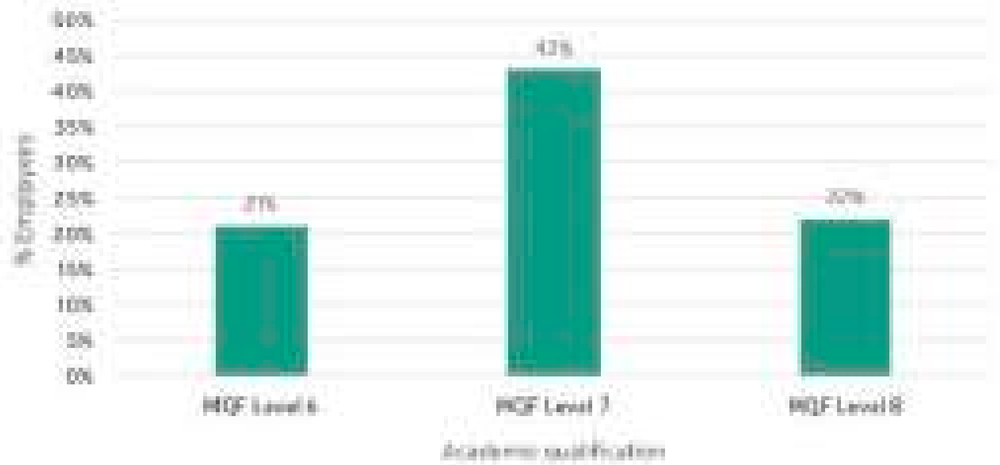


Figure 2.5: Academic qualifications for employees at the Malta Medicines Authority 2020

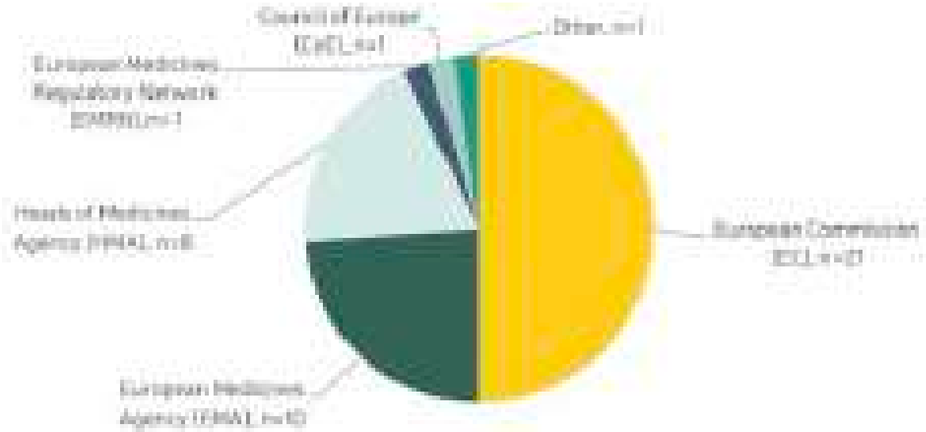


Figure 2.6: Representation by the Malta Medicines Authority in European institutions and professional bodies

The above represents a concerted effort to improve the overall capacity of the MMA while reinforcing its scientific prowess. As it currently stands, twenty-two percent (22%) of employees hold Doctoral degrees, whilst forty-three percent (43%), nearly half of the Authority's workforce, hold an academic qualification at a Master's level **(Figure 2.5)**.

The MMA's commitment towards the professional development of its human resources was augmented by the increased investment in cross-border opportunities for its employees, allowing the exchange of best practices with European and International bodies. Such professional exposure secures the Authority's ability to adapt to the constantly-evolving landscape of pharmaceutical regulation.

Furthermore, the MMA maintains strong ties with the University of Malta by hosting student placements. In 2020, the Authority also welcomed students on summer placements from the Malta Enterprise and through the Institute for Public Service trainee scheme. Such initiatives set the benchmark for future cooperation with other national and international institutions such as the Malta College of Arts, Science and Technology and the University of Illinois in Chicago.

A European **and Global Player**

Throughout 2020, the MMA maintained its active role at the highest European and international fora, with officers participating in diverse technical and management meetings, conferences and training opportunities. Despite challenges brought about by the previous year of operation, the extent of the Authority's representation in professional bodies was not only sustained but surpassed. By the end of year, MMA delegates were involved in a total of forty-two (42) strategic and scientific expert groups, committees and boards **(Figure 2.6)**.

The MMA was consulted on a number of established and proposed EU legislative files which mostly concern the regulation of medicines, medical devices and pharmaceutical activities. In liaison with the line Ministry Policy Development and Programme Implementation Directorate (PDPID), the Government EU Coordination Department (EUCD) and the Permanent Representation of Malta to the EU, the Authority provided feedback on diverse regulatory policy areas **(Figure 2.7)**, keeping the interest and safety of patients and consumers at the core of all positions put forward.

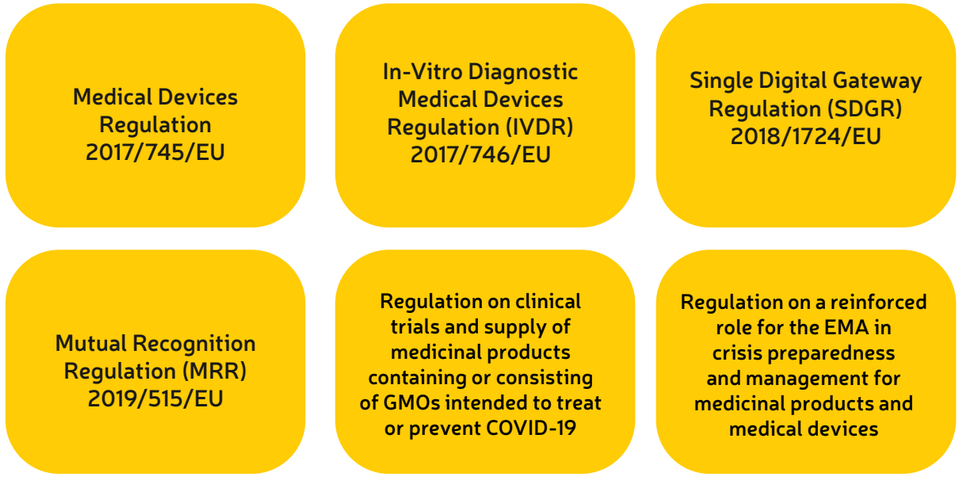


Figure 2.7: Examples of EU legislative files on which the Malta Medicines Authority was consulted in 2020.

The United Kingdom's withdrawal from the European Union and the potential ramifications on pharmaceutical processes has drawn much attention from NCA's across the EU. On its part, the MMA Brexit task force continued its work to mitigate the impact of Brexit on the Authority's operations and the Maltese and EU public at large. Actions were delivered in line with contingency measures specified in the Authority's Brexit Plan. The Authority participated in European expert technical seminars and workshops on Brexit's impact on the availability of authorised medicines. These were deemed fundamental in gaining foresight on the situation and served as opportunistic to exchange best practices.

The Authority provided the necessary feedback on Brexit preparedness notices formulated by the EU Commission concerning medicinal products for human use. These notices were discussed in a virtual tour des capitales in July 2020 and the final versions communicated with relevant stakeholders to direct resources into operational and logistical readiness in view of the approaching end of transition. During the same period, a report was compiled by the Authority delineating the key actions and contingency measures undertaken to circumvent possible consequences associated with a no-deal Brexit scenario. Towards the end of 2020, the EU Commission issued a notice on the application of the pharmaceutical acquis in markets historically dependent on medicines supply from or through Great Britain after the end of the transitional period. The Authority responded by initiating works on a framework to collect the information needed from local operators to fulfil the conditions attached with the measures highlighted in the notice.

Through the tenets of knowledge dissemination and training in advanced pharmaceutical research, the MMA reaches out to its counterparts in third country states with the objective of consolidating the quality of medicines imported in the EU and to spur the accessibility of medicinal products. The Authority has sustained the impetus in the area of international affairs by joining a Maltese delegation in a trade mission to Ghana to strengthen the mutual areas of cooperation between both sides. Moreover, in line with the series of meetings held between line Ministry and ambassadors from the states of Greece, France, Austria, Israel and Spain, the Authority has expressed its interest to extend cooperative discussions and strengthen collaborative efforts in the areas of medical devices and notified bodies, cannabis for medicinal and research purposes, third country inspections, accessibility to medicines, as well as academic initiatives.

These agreements foresee the development of industrial cooperation between pharmaceutical bodies of participating countries and the eventual exchange of experience and knowledge. The Authority has also pledged its support to the pharmaceutical sector in these international states by providing training to obtain EU Good Manufacturing Practice (GMP) certification. The agreements are also intended to promote collaboration on capacity building with regards to pharmaceutical products registration, pharmaceutical quality control and pharmacovigilance.

The EMRN released the Network's COVID-19 Business Continuity Plan in September 2020 and since then the Authority has, in partnership with the Network, been involved in regular discussions on a consistent approach for the best utilisation of resources and prioritisation of regulatory activities in the context of the pandemic. Members of the Authority have also contributed in other related platforms, including the EU Executive Steering Group on Shortages of Medicines Caused by Major Events and the EMA/HMA COVID-19 Communications Working Group, on the impact of accessibility to medicines caused by and communication updates related to COVID-19.

3

Quality, Safety, Efficacy: The 3 Pillars of an Effective Scientific Regulator

Assessment **and Licensing of Medicinal Products**

One of the priorities of the MMA is that of ensuring that a comprehensive range of medicinal products are authorised and accessible to the Maltese patients. Through life-cycle management, the Authority ensures that the information for all authorised medicinal products available in Malta is always updated and in line with scientific advancements.

European Cooperation on **Training and Assessments**

Through the collaboration agreement with the NCA of The Netherlands, the Medicines Evaluation Board (MEB), which was signed in 2014, the MMA has continued to carry out assessment of applications on behalf of MEB to enable registration of new medicinal products both for the Dutch and the European market.

The Licensing Directorate has worked to improve the capacity to be able to assess other types of products as rapporteur and Reference Member State. With a view to increasing the range of types of applications to be handled by the Authority, training opportunities were explored in different areas. The collaboration with the Dutch MEB for quality assessment continued in 2020 – a collaboration that is mutually useful for both agencies. Staff within the MMA also benefits from other various training initiatives organised by the MEB.

This alliance has been mutually beneficial and has helped the MMA to consolidate the expertise of its assessors. There is an ongoing request from the MEB for the MMA to enhance this successful collaboration both in terms of quantity and diversity of its work.

Furthermore, the MMA continued to strengthen its team of external assessors to handle more challenging procedures, whereby in 2020 the Authority explored assessments of different pharmaceutical forms.

Applications for **National Authorisations**

The number of applications for authorisations for the approval of new products finalised in 2020 is shown in **Figure 3.1**. These submissions include national Marketing Authorisations (MAs), as a result of national procedures (n=6), authorisations in accordance with Article 126(a) of Directive 2001/83 /EC (n=839), and parallel import licences (n=115). A total of nine hundred and sixty (960) authorisations and licences for new products were issued in 2020.

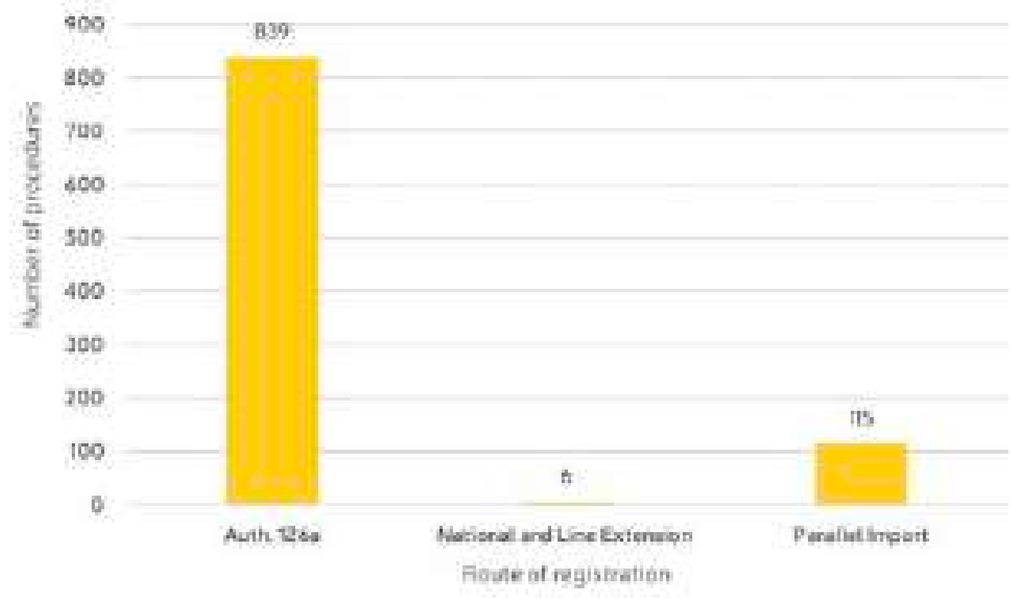


Figure 3.1: Total number of product authorisations through all routes in 2020 (N=960)
Auth. 126(a): authorisations in accordance with Article 126(a) of Directive 2001/83 /EC

The total number of authorisations in accordance with Article 126(a) of Directive 2001/83/EC standing at end 2020 were two thousand, six hundred and thirty-eight (2,638). Fifty-five percent (55%, n=1,453) of the authorised products were registered by a holder from Malta.

Malta as a Lead **in European Procedures**

During the year under review, the MMA unequivocally faced challenges in relation to licensing of medicinal products, namely Brexit, obligations related to Regulations on falsified medicines and the COVID-19 pandemic, which required capacity building and updates to internal quality documentation. The MMA overcame its challenges and sustained its reputation as a key player in the European network for the regulation of medicinal products to provide greater accessibility of medical products for patients in Malta and beyond. This was primarily achieved through its role as a RMS via the European Decentralised Procedure (DCP) and the Mutual Recognition Procedure (MRP), or by acting as co-/rapporteur in European centralised authorisation procedure.

Malta started acting as RMS in 2007 and contributed to the authorisation of five-hundred and fifty-seven (557) products. The number of authorisation procedures led by Malta as RMS which were processed in the last quarter of 2019 and in 2020 was forty (40) procedures **(Figure 3.2, Figure 3.3).** These procedures resulted in the authorisation of fifty-three (53) new MAs for Malta and other EU countries.

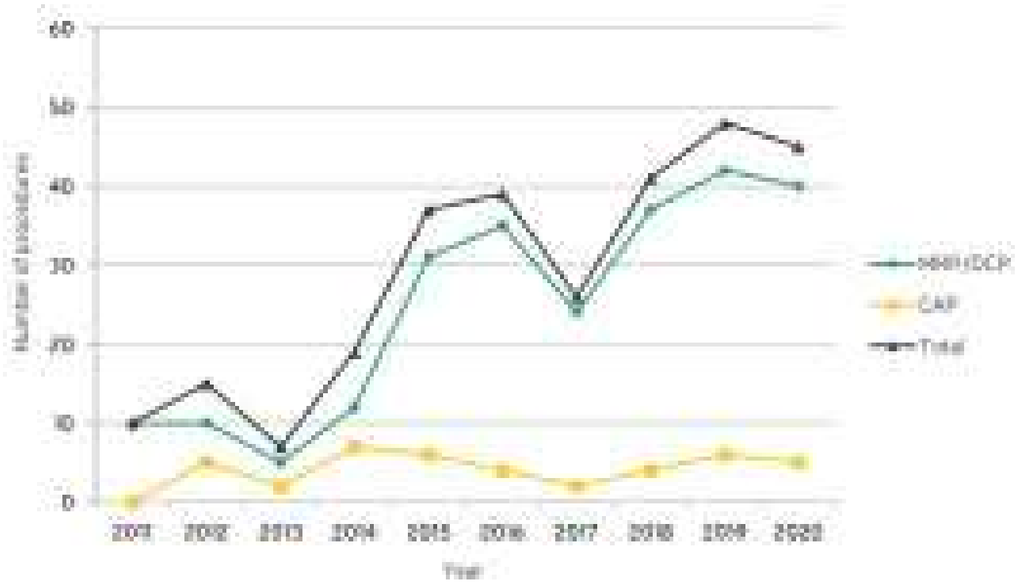


Figure 3.2: Number of procedures received with Malta as Reference Member State (RMS) or co-/rapporteur in the last 10 years

CAP: Centralised Authorisation Procedure, DCP: Decentralised Procedure, MRP: Mutual Recognition Procedure

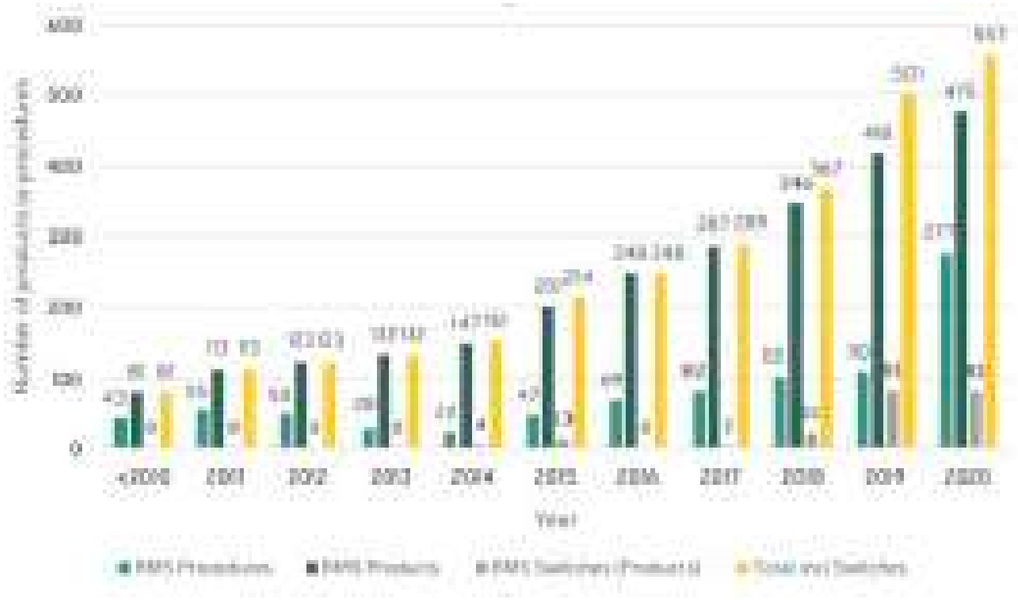


Figure 3.3: A cumulative overview of applications for procedures (and resulting product authorisations) with Malta as Reference Member State (RMS)

RMS: Reference Member State

By the end of 2020, Malta ranked ninth (9th) and eighth (8th) as a RMS respectively for the number of started and finalised MRPs and DCPs **(Figure 3.4, Figure 3.5)**.

MRP/DCP **New applications - 2020**

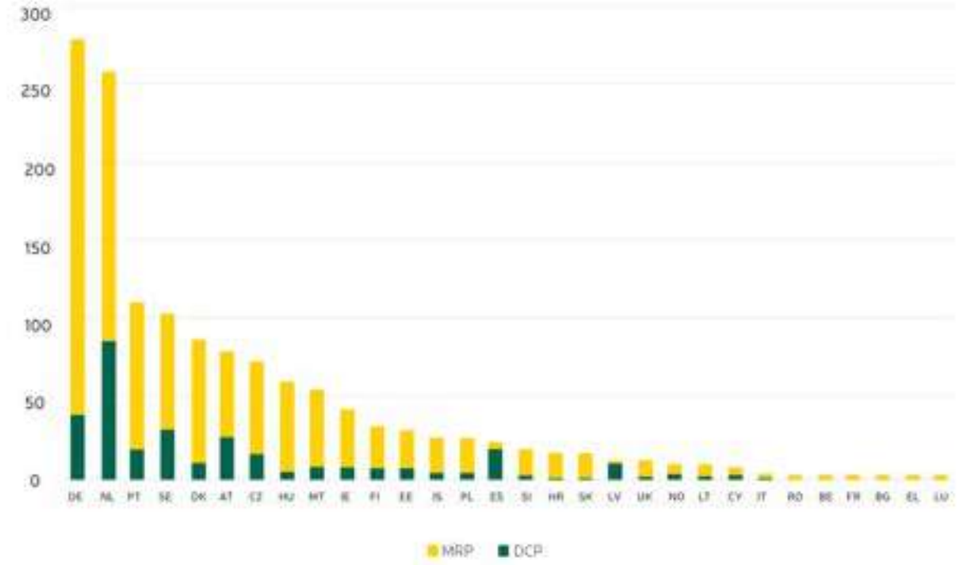


Figure 3.4: The number of Mutual Recognition Procedures (MRPs) and Decentralised Procedures (DCPs) started in 2020 by Reference Member States (RMSs) (N=310 MRP, N=1006 DCP) (source: CMDh 2020 Statistics)

MRP: Mutual Recognition Procedure, DCP: Decentralised Procedure, RMS: Reference Member State
Glossary of Member State country codes:
https://ec.europa.eu/eurostat/statistics-explained/index.php/Glossary:Country_codes

FINALISED Procedures - MRP/DCP per CMS
Total: 296 MRP and 856 DCP (regarding 569 and 1793 products respectively)

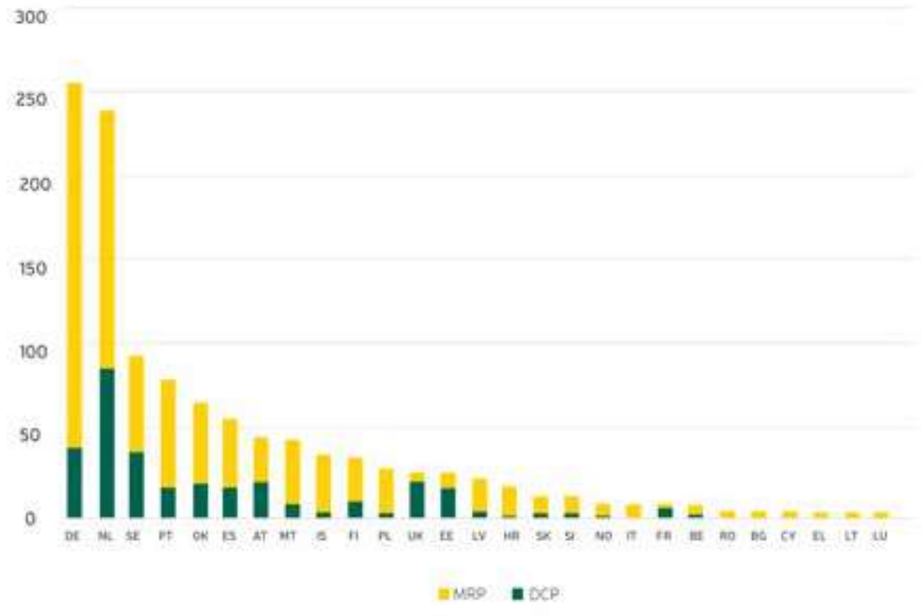


Figure 3.5: The number of Mutual Recognition Procedures (MRPs) and Decentralised Procedures (DCPs) finalised in 2020 by Reference Member States (RMSs) (N=296 MRP, N=856 DCP) (source: CMDh 2020 Statistics)

MRP: Mutual Recognition Procedure, DCP: Decentralised Procedure, RMS: Reference Member State
Glossary of Member State country codes:
https://ec.europa.eu/eurostat/statistics-explained/index.php/Glossary:Country_codes

In 2020, Malta was rapporteur for five (5) applications submitted to the EMA for central authorisation, leading assessments of medicinal products eligible for a single authorisation throughout the EU. This set the tone for more involvement in such assessments in the future which will effectively enable the MMA to expand its visibility as a reputable scientific body while improving its expertise in this field of operation.

With an increasing number of procedures, the number of European project management staff within the MMA has also increased and further growth is planned for 2021. In 2020 training was provided to ensure the smooth running of procedures while improving the synergy between Malta as a RMS, the CMS, and the MA applicants.

Malta as a Contributor **in European Procedures**

During 2020, a procedure with legal basis Article 8(3) of Directive 2001/83/EC was assessed for the first time by the MMA in the DCP with Malta as RMS. The number of MA applications in the MRP and DCP received in 2020 with Malta as CMS (N=102) resulted in the granting of one hundred and seventy-one (171) MAs **(Figure 3.6)**. **Figure 3.7** and **Figure 3.8** show the applications started and finalised by Malta through this route compared to other Member States.

Figure 3.6: A cumulative overview of applications for procedures (and resulting product authorisations) with Malta as Concerned Member State (CMS)

CMS: Concerned Member State

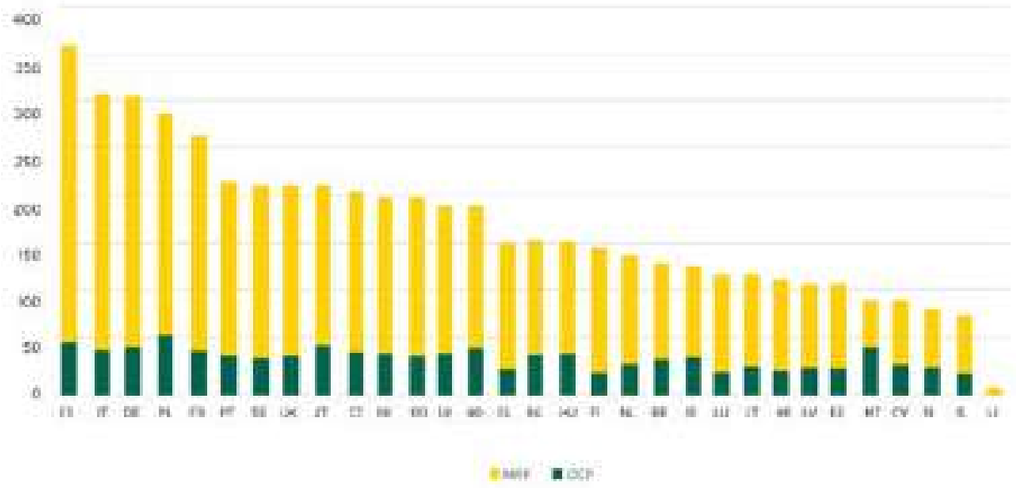


Figure 3.7: Applications started by all Member States as Concerned Member State (CMS), including Malta, in Mutual Recognition Procedures (MRPs)/ Decentralised Procedures (DCPs) in European Union (EU) in 2020 (N=310 MRP, N=1,006 DCP) (source: CMDh statistics)

MRP: Mutual Recognition Procedure, DCP: Decentralised Procedure, CMS: Concerned Member State
Glossary of Member State country codes:
https://ec.europa.eu/eurostat/statistics-explained/index.php/Glossary:Country_codes

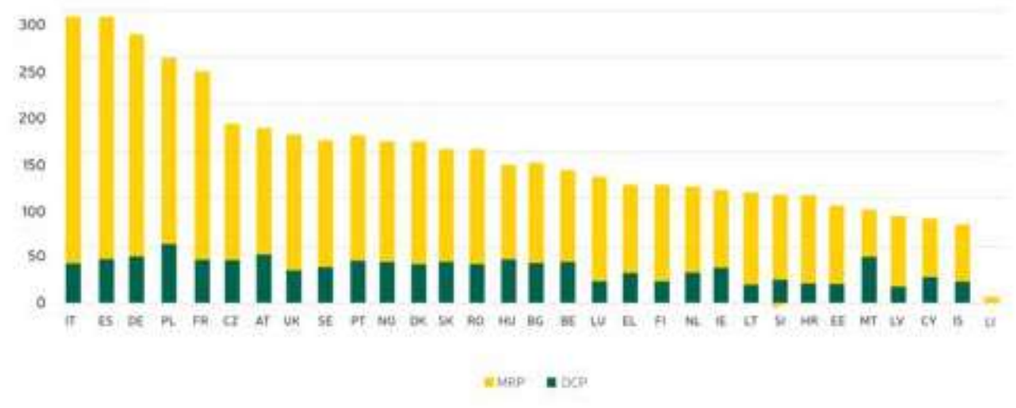


Figure 3.8: Applications finalised by all Member States as Concerned Member State (CMS), including Malta, in Mutual Recognition Procedures (MRPs)/ Decentralised Procedures (DCPs) in European Union (EU) in 2020 (N=296 MRP, N=856 DCP) (source: CMDh statistics)

MRP: Mutual Recognition Procedure, DCP: Decentralised Procedure, CMS: Concerned Member State
Glossary of Member State country codes:
https://ec.europa.eu/eurostat/statistics-explained/index.php/Glossary:Country_codes

Figure 3.9 gives an overview of the registration of medicinal products over the period 2011-2020 by the MMA. The relatively constant number of authorised products was mainly due to an increase in the number of MRP and authorisations in accordance with Article 126(a) of Directive 2001/83/EC, especially during 2020.

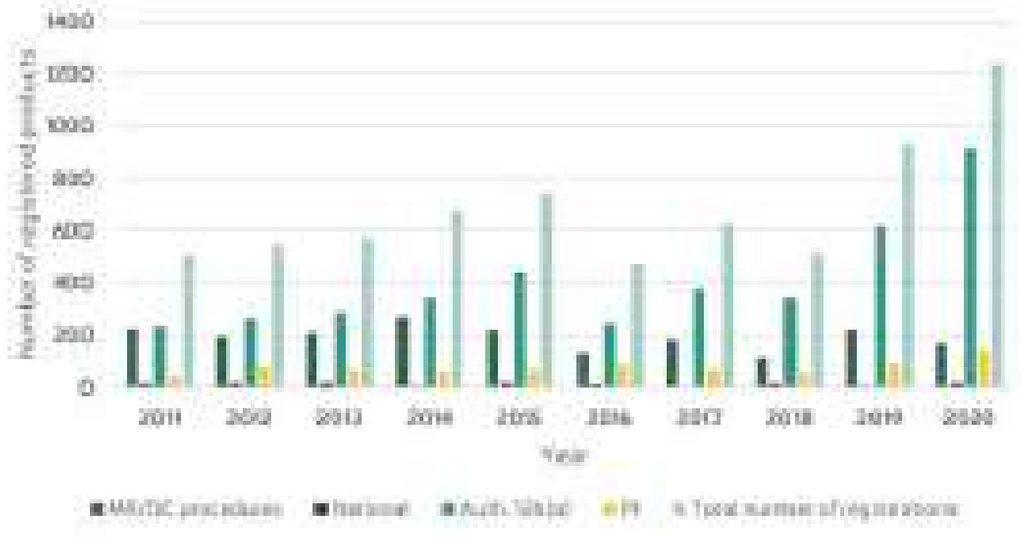


Figure 3.9: A 10-year overview of products registered in Malta by route of registration.

MR: Mutual Recognition, DC: Decentralised, Auth. 126(a): authorisations in accordance with article 126(a) of Directive 2001/83 /EC, PI: Parallel importation licences

Post-authorisation **Procedures**

Post-authorisation procedures are received each year and include variations, notifications, renewals and withdrawals. These constitute a considerable workload for the MMA and ensure that the life-cycle management of products is maintained so that the latest information with respect to quality, safety and efficacy of all products is always available to the Authority, health care professionals and patients.

Post-authorisation activities, especially for procedures where Malta is a RMS, maintained a strong increase, particularly in view of the procedures taken by Malta from the United Kingdom (UK), which is expected to subsist in the coming years **(Figure 3.10)**. The MMA received two-hundred and sixty (260) variation applications in this category with resulting changes to six-hundred and ninety (690) products in procedures where Malta is the RMS.

Figure 3.10: A 10-year overview of the number of variation applications (with resulting product changes) received for procedures with Malta as Reference Member State (RMS)

The portfolio of procedures where Malta is the rapporteur or co-rapporteur in the centralised procedures continues to increase as Malta takes on more initial and/or new procedures each year. Forty-two (42) post-authorisation activities for centralised procedures where Malta is rapporteur were reported for 2020. Thirty-eight (38) were variations, including Type 1B and Type II variations, while four (4) were renewal of MAs **(Figure 3.11).**

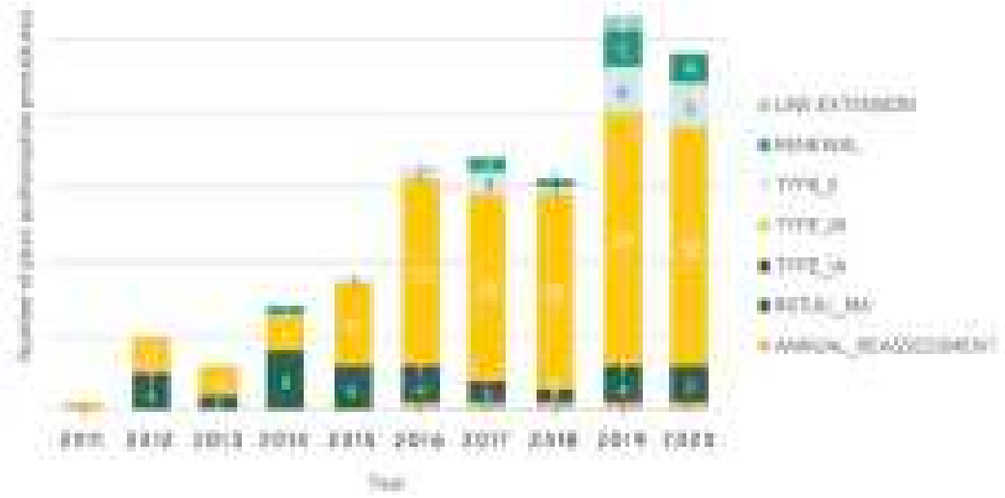


Figure 3.11: Cumulative number of procedures with Malta as co-/rapporteur in the centralised procedure

In 2020, the MMA finalised one thousand, nine hundred and sixty-four (1,964) MRP variation applications and other post-authorisation procedures including eighty-three (83) renewals and sixty-six (66) Article 61(3) notifications **(Figure 3.12)**.

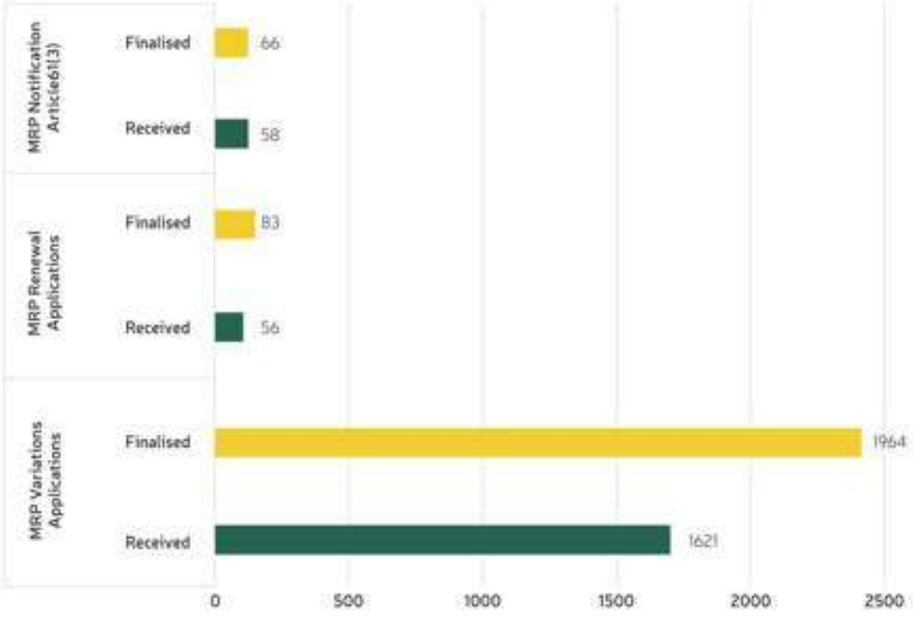


Figure 3.12: Post-authorisation procedures received and finalised by Malta as Concerned Member State (CMS) in the Mutual Recognition Procedure (MRP)

MRP: Mutual Recognition Procedure; Article 61(3) Notifications: Notifications in accordance with Article 61(3) of Directive 2001/83/EC

Figures 3.13, 3.14 and **3.15** show the number of national post-authorisation procedures, including renewals, variations, Marketing Authorisation Holder (MAH) transfers and notifications in accordance with Article 61(3) of Directive 2001/83/EC. Compared to the previous year, there were no major variances, except for batch specific exemption requests, which increased by 90% from 2019. The total number of withdrawal of authorisations and licence applications were in decline from 2019 by 20%. The number of withdrawals in the past three years exceed those of previous years mainly due to Brexit.

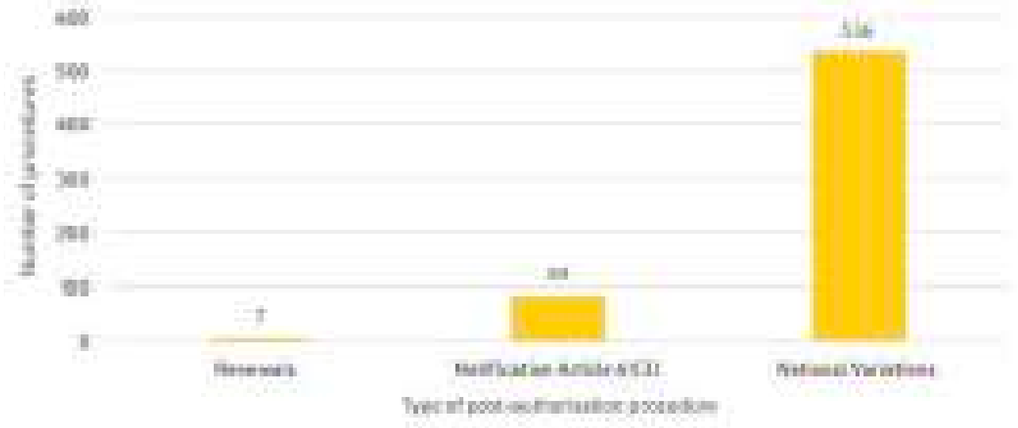


Figure 3.13: Number of post-authorisation procedures for national Marketing Authorisations in 2020 (N=627)
MAH: Marketing Authorisation Holder, Notifications Article 61(3): notifications in accordance with article 61(3) of Directive 2001/83/EC

Figures 3.14 and **3.15** show the number of post-authorisation procedures for authorisations in accordance with Article 126(a) of Directive 2001/83 /EC and parallel import licenses, including notifications of change and renewals.

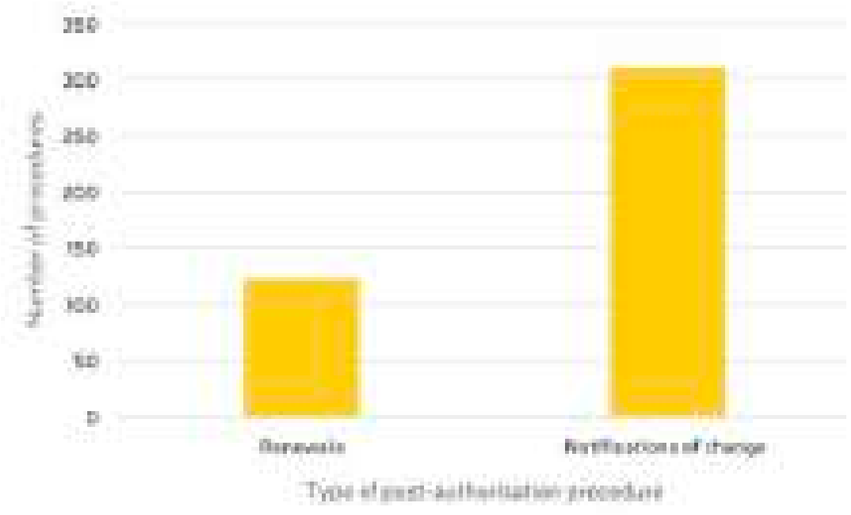


Figure 3.14: Number of post-authorisation procedures for authorisations in accordance with Article 126(a) of Directive 2001/83 /EC in 2020 (N=434

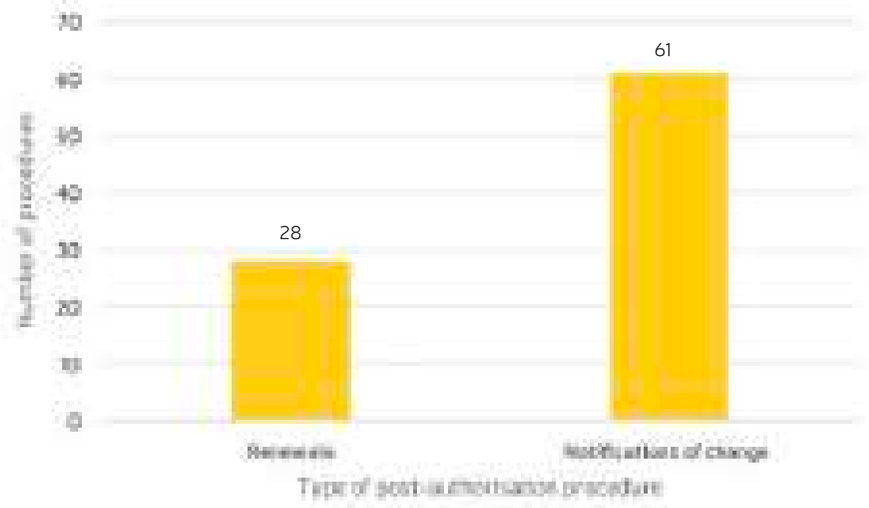


Figure 3.15: Number of post-authorisation procedures for parallel import licences in 2020 (N=89)

Figure 3.16 refers to withdrawal applications for authorisations and licences. Following the UK's decision to leave the EU, companies have been withdrawing some product licences and authorisations, particularly those which were not marketed in Malta. Such withdrawal applications are evaluated in a comprehensive exercise through which the MMA identifies alternative medicinal products. The MMA has continued to monitor all locally authorised products to ensure that UK-based companies are submitting their applications in line with the regulatory requirements, thereby maintaining as many MAs as possible.

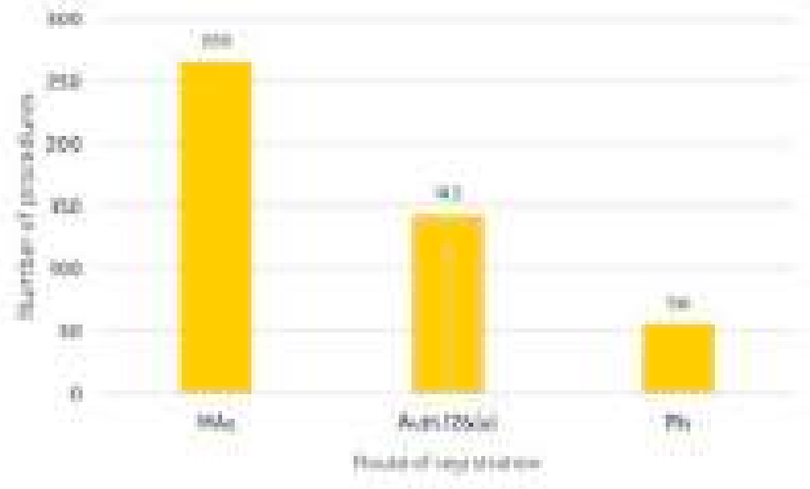


Figure 3.16: Number of withdrawal applications for Marketing Authorisations (MAs) and licences received in 2020 (N=464)
Auth. 126(a): authorisations in accordance with article 126(a) of Directive 2001/83 /EC, MA: Marketing Authorisations, PI: Parallel Import licenses

Committees, Working Groups **and National Advisory Services**

During 2020, the Prescription Status Working Group (PSWG) continued to work on the harmonisation of the legal classification of medicinal products (prescription versus non-prescription). Several meetings were held with individual stakeholders to support with regulatory advice when it was considered appropriate to change the status of some products from prescription-only status to non-prescription status. Apart from the legal classification of medicinal products, the PSWG, worked to harmonise classification by therapeutic class and discussed several cases relating to the availability of medicinal products in view of the new requirements of prescription-only medicinal products due to the Falsified Medicines Directive (FMD).

The Borderline Classification Committee (BCC) of the MMA classifies products into either medicinal products or non-medicinal products when requests for classification are received from companies or from other sources. The Committee meets regularly, and feedback is sought from all members including experts such as herbal and paediatric experts in line with an updated simplified and shorter process. In 2020, fifty-five (55) applications for the classification of borderline products were received, out of which forty (40) were considered as non-medicinal and two (2) were considered medicinal.

At the national front, the MMA is continuously seeking to expand its remit as a reputable scientific advisory centre.

At an EU level, the MMA is involved in scientific affairs regarding the development and licensing of medicinal products through the participation in the Scientific Advice Working Party (SAWP) of the EMA In 2020, the MMA fully participated in SAWP activities and no procedures are pending.

Impact of Brexit on **the Malta Medicines Authority**

In 2020, Brexit was a distinct challenge. Through coordinated endeavours, the MMA supported public and private pharmaceutical stakeholders to proactively address the implications of Brexit on the availability of medicines on the local market. The Authority:

- **Rolled out quarterly communication mailshots to all MAHs to request submission of necessary regulatory applications to bring MAs in line with the EU acquis;**
- **Continued discussions between several pharmaceutical stakeholders outside the UK and local distributors, including one-to-one meetings, to establish alternative supply routes to the local market and how to maintain their marketing authorisations valid;**
- **Engaged with other NCAs to facilitate the use of the Day 0 MRP for companies in order to make more products available locally through this route;**
- **Encouraged applicants to include Malta in new procedures and discussed the MMAs flexibility with regards to joint packs, multilingual packs and allowing re-labelling of products locally to ensure that products from other markets can be made available locally;**
- **Updated the information on the website continuously in line with the EMA and European Commission (EC) discussions and publications;**
- **Participated in all EU Brexit meetings and was represented at high level meetings with the purpose of ensuring accessibility to medicinal products to local patients;**
- **Worked in close collaboration with patients and the national health service, and addressed various issue concerning access to medicinal products. This service will be extended throughout 2021.**

Through the Coordination Group for the Decentralised and Mutual Recognition Procedure (CMDh), the EU Member States have been monitoring the situation of medicinal products with the UK as a RMS. Up to the first month of 2020, one hundred and four (104) procedures were officially switched from UK as RMS to Malta. This positive trend climaxed as expected throughout 2020.

Pharmacovigilance **Activities**

Patient safety is a core priority of the MMA as it continues to strengthen its efforts to ensure the safe use of medicinal products on the local market. The Pharmacovigilance role foresees the evaluation, monitoring and communication of safety related data and, where appropriate, implementation of regulatory action to maximise benefit and minimise risks associated with medicinal products.

The collection, investigation and transmission of Adverse Drug Reaction (ADR) reports to Eudravigilance comprises a major Pharmacovigilance activity carried out by the MMA. In 2020, the Authority continued to receive ADR reports from local healthcare professionals as well as from patients and consumers.

The Authority continued the implementation of its ADR promotion strategy, which for 2020, included the fifth annual ADR awareness week campaign (#MedSafetyWeek) held between 2nd and 8th November 2020 with the aim to raise awareness and encourage healthcare professionals and the public to report suspected side effects from medicines. During this week humorous animations (sample animations **Figure 3.17**), videos, infographics and other material were uploaded to the Authority's social media platforms.

Figure 3.17: Sample animations used for the social media campaign on Adverse Drug Reaction (ADR) reporting held during November 2020.

The MMA has direct access to all reports in the EU EudraVigilance database for signal detection activities. Furthermore, European IT applications such as EudraVigilance Data Analysis System (EVDAS) allows for detailed analysis of ADR data.

A total of one hundred and forty-seven (147) Individual Case Summary Reports (ICSRs) were registered in 2020. These cases detailed at least one (1) ADR to the medicinal product concerned and together these 147 ICSRs resulted in two hundred and sixty-nine (269) suspected ADRs. **Figure 3.18** gives a breakdown of these ADRs according to System Organ Class (SOC) classification.

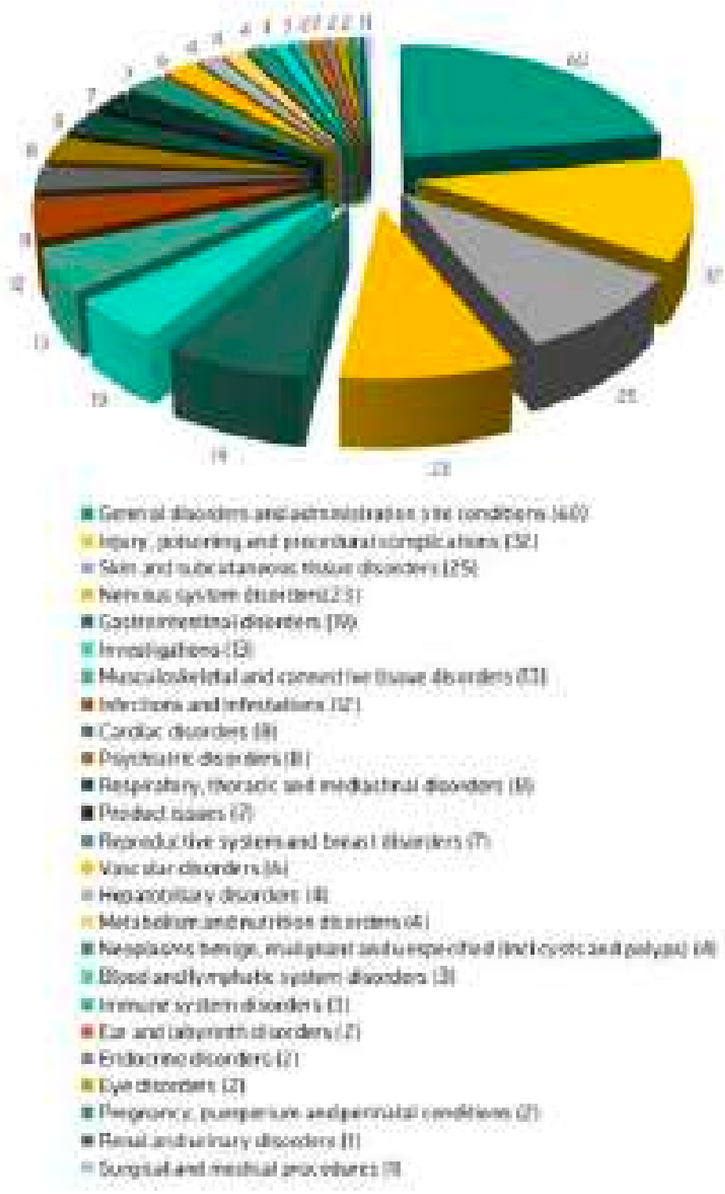


Figure 3.18: Distribution of Adverse Drug Reactions (ADRs) according to System Organ Classification (SOC) in 2020 (N=269)

Each case report received at the MMA was assessed and reported electronically to the EMA and the World Health Organisation (WHO) as the central ADR repositories.

Figures 3.19 and **3.20** further classify the adverse ICSRs (as received over 2020) according to seriousness and patient age respectively. The severity of the adverse reaction is normally assigned by the reporting healthcare professional or by the MMA following careful assessment and consideration of applicable factors such as dose of the medicinal product, indication for use, concurrently administered drugs and underlying patient disease.

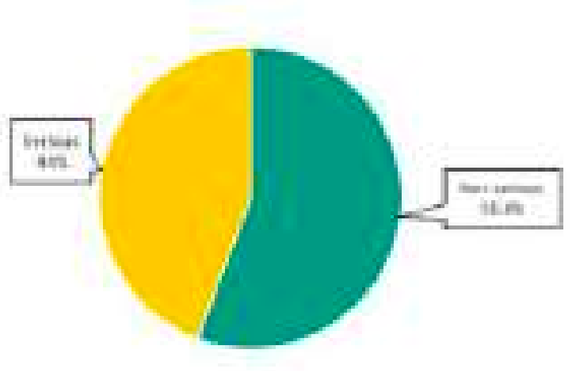


Figure 3.19: Frequency of Individual Case Summary Reports (ICSRs) according to seriousness in 2020 (N=1,47)

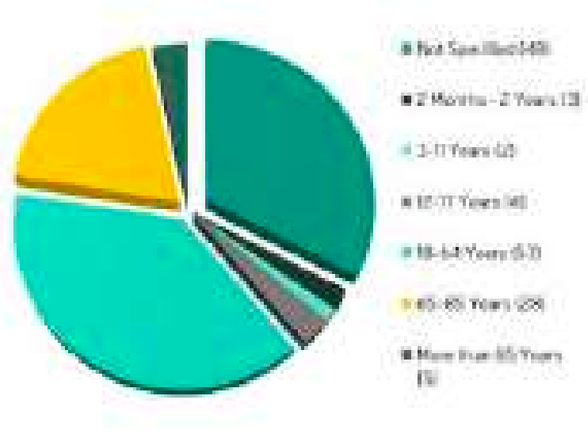


Figure 3.20: Distribution of Individual Case Summary Reports (ICSRs) according to patient age in 2020 (n=147)

In addition to the management of ADRs, several other activities were undertaken nationally by the Authority in 2020 for purposes of attaining effective product safety surveillance. Such activities (amongst others) include the:

01 approval of Direct Healthcare Professional Communications (DHPCs) detailing safety/risk changes to scientific information and recommendations on product administration methods, and where necessary co-ordinating joint DHPCs when several MAHs are involved;

02 investigation of newly identified safety signals with immediate product suspension and/or recall as relevant (Safety Signal Investigations (SSIs), Rapid Alerts (RAs) and Product Safety Recalls (PSRs);

03 approval and monitoring of Risk Minimisation Programmes (RMPs) and educational material relating to high risk medicinal products as well as approving Pregnancy Prevention Programmes (PPPs) as proposed in relation to potentially teratogenic medicinal products;

04 issue of Safety Circulars and Media Statements addressed to healthcare professionals and the general public respectively. Safety Circulars give recommendations on medicinal product use and applicable cautionary and precautionary measures. Throughout 2020 the Authority continued implementing the SMS notification service that allows subscribed medical and healthcare professionals to receive alerts and links to the safety circulars as soon as they are published on the website;

05 initiation and subsequent approval of variations to scientific medicinal product information relating to identified novel or increased risk (Urgent Safety Restrictions) and

06 assessment of PSURs for nationally authorised products containing active substances or active substance combination not included in the list of European Union Reference Dates (EURD list) and hence such product PSURs are assessed at a national level.

Table 3.1 below gives the distribution of Safety Communications and Risk Minimisation Measures (RMMs) approvals which the MMA handled over 2020.

Activity	Number of assessments, reviews, communications and approval
Direct Healthcare Professional Communications	11
Joint DHPCs	4
Safety Circulars	15
Risk Minimisation Measures	90

Table 3.1: Safety Communications and Risk Minimisation Measures approvals in 2020

DHPCs: Direct Healthcare Professional Communications, PSUR: Periodic Safety Updated Reports

	Area Queried	Number (n)
1	ADR Reporting / ICSR transmission requirements	13
2	National Pharmacovigilance legislation and requirements locally	9
3	RMPs / RMMs / Educational Material	9
4	Submission requirements of PSUR / PSUSAs	6
5	Literature monitoring requirements	5
6	Qualified Person for Pharmacovigilance/Local Contact Person for pharmacovigilance	5
7	DHPC submission and dissemination	3
8	Development Safety Update Report (DSUR) / ADR reporting requirements in Clinical Trials	3
9	Pharmacovigilance information on MMA Website	2
10	Pharmacovigilance Quality Systems and Pharmacovigilance document control	2
11	Post-Authorisation Efficacy Studies (PAES) and Post-Authorisation Safety Studies (PASS)	2
12	Requests for MMA contact points for pharmacovigilance	2
13	Controlled distribution systems	1
14	Medicinal product suspensions	1
	Total	63

Table 3.2: Pharmacovigilance related queries in 2020 (n=63)

An additional stakeholder service performed by the MMA is that of responding to any queries related to Pharmacovigilance activities in a timely manner. In 2020, queries received were mostly related to ADR reporting and ICSRs transmission requirements, national pharmacovigilance legislation and requirements locally, RMPs, RMMs and Educational Material and the submission of PSURs and Periodic Safety Update Report Single Assessments (PSUSAs) **(Table 3.2)**.

Clinical **Trials**

The role of the MMA with respect to clinical trials is to evaluate both the quality of the investigation and the patient safety of clinical trials. It provides recommendations to the Licensing Authority who provides authorisation based on the Authority's and the Health Ethics Committee's recommendations. For 2020, no clinical trial assessment procedures are pending.

The way clinical trials are conducted in the EU will undergo a major change when the new Clinical Trial Regulation (CTR) (Regulation (EU) No 536/2014) comes into application. The Regulation harmonises the assessment and supervision processes for clinical trials throughout the EU. When the Regulation becomes applicable, it will repeal the existing EU Clinical Trial Directive (EC) No. 2001/20/EC.

Advertising of **Medicinal Products**

The MMA monitors the advertising of medicinal products and the issue of any promotional material related to such products being presented either to the public or to healthcare professionals. Regulation of promotional material such as the provision of medicinal product samples to healthcare professionals and the sponsoring of promotional activities or scientific congresses is also regularly undertaken, in accordance with the Medicinal Products (Advertising) Regulations. Control of advertising material is also implemented via the ad hoc selection and investigation of local advertisements as presented within the major media formats. This activity principally aims at ensuring public health protection via the affirmation that the applicable legislation is constantly being upheld and rigorously adhered to. Monitoring is mainly implemented via the application in accordance with European legislation of a self-regulatory approach whereby medicinal product advertising complaints as reported by external stakeholders are assessed and investigated in detail for purposes of verifying claims of breaches to the Advertising Regulations.

Medicines Intelligence **and Access**

Access to medicines continues to be a complex, multifaceted challenge which has gained more importance globally in view of the ongoing disruptions. The Medicines Intelligence and Access Unit provides individualised added value interventions for queries received to support consumers, healthcare professionals and patient organisations in accessibility to medicines. A risk-based scientific framework to detect, address and mitigate access issues based on medicines intelligence and risk identification was developed to proactively enhance access to medicines in a patient-centred approach. The framework involves classification of the query under the category representing the barrier to access (availability, pharmacoeconomic, safety, shortages) and risk identification, where the query is assessed in terms of the risk on patient medicines needs (critical, major or other). As a result, queries are prioritised according to the implications on patient health outcomes and timely actions are taken. In 2020, the MMA handled on an individual basis one hundred and twenty-three (123) queries related to medicine availability (n=215), shortages (n=86), pharmacoeconomic (n=147) and safety issues (n=201).

Figure 3.21: Number of interventions between 2014-2020 (N=524)

The MMA proactively addresses emerging medical needs by assisting in the sourcing and supply of medicines. Through medicines intelligence the need to source famotidine was identified to address the lack of access to histamine-2 blockers caused by the recall of ranitidine formulations. In liaison with pharmaceutical stakeholders, famotidine 20mg tablets were introduced on the local market in 2020 along with three (3) new oral contraceptive pills.

In 2020, the COVID-19 pandemic and Brexit foisted disruptions in accessibility to medicines.

Through coordinated endeavours, the MMA supported public and private pharmaceutical stakeholders to proactively address the implications of major events on the availability of medicines on the local market.

The interventions of the MMA regarding the COVID-19 pandemic as regards accessibility to medicines included:

i. Continuous dialogue with eighty- nine (89) Responsible Persons (RPs) to identify potential disruptions or shortages of medicines. The RPs were asked to notify any confirmed supply disruption due to the coronavirus outbreak, potential disruptions and to list specific medicines at risk.

ii. Adoption of the WHO Model List of Essential Medicines to identify which medicines are of essential importance and need to be available in the local private and public sectors. The stock position of one hundred and thirty-four (134) active pharmaceutical ingredients determined to be essential in the Maltese private market were evaluated. Twenty-five (25) local wholesale distributors were contacted to compile stock levels of medicinal products containing the essential active pharmaceutical ingredients.

iii. Provision of assistance to the health authorities in the sourcing of medicines and medical devices including surgical masks and medicines that were being investigated in the therapy of COVID-19 infections.

iv. Evaluation of the impact of export bans on medicines and active pharmaceutical ingredients imposed by several countries including India.

Regulating **Medical Devices**

During the year 2020, the function of the NCA for medical devices and In-Vitro Diagnostic (IVD) medical devices was transferred from the Malta Competition and Consumer Affairs Authority (MCCAA) to the MMA. 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. To this effect, the MMA was designated as the competent authority for medical devices.

As with the regulation of medicinal products, the regulation for medical devices aims to safeguard the safety, quality and effectiveness of medical devices on the local market. In order to ensure a smooth transition, both Authorities worked in tandem keeping the patient at the core of the activities. In view of this, the Medical Devices Support Office was formed with the aim to ensure the quality, efficacy and safety of medical devices on a National and European level. In 2020, the MMA became an active member of the EU Committees and Medical Device Coordination Groups.

One of the main roles of the MMA as the NCA for medical devices is to designate and continuously monitor the performance of Notified Bodies registered in Malta. The role of a Notified Body is to conduct conformity assessment under the relevant EU Directives and Regulations. Notified Bodies are also responsible for assessing medical devices and IVDs before being placed on the market. In 2020, the MMA received the first application for the designation as a Notified Body under the MDR/ IVD Regulation.

In 2020, the MMA has received over one-hundred and sixty (160) queries, fifty (50) incident reports and two-hundred and twenty (220) applications for processing. The MMA processed one hundred and seven (107) registrations and six (6) certificate of sales **(Figure 3.22)**. The MMA participated in over thirty-five (35) international and one hundred (100) local meetings relating to medical devices with various stakeholders, namely the EC and government entities **(Figure 3.22**).

Figure 3.22: The number of certificate of sales (N=6) and registrations (N=107) received and processed during 2020

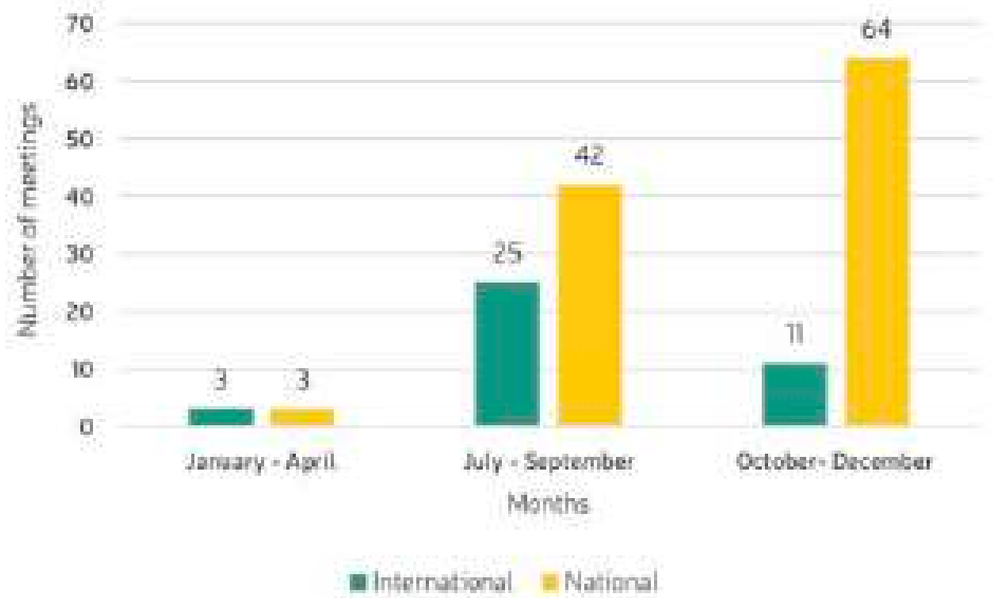


Figure 3.23: Number of international and national meetings held and attended during 2020

4

Maintaining the Highest Standards for Pharmaceutical Inspections in the Best Interest of Patient Safety

The MMA is responsible for inspecting and recommending the issue of licences for manufacturers and wholesale dealers according to national legislation, EU Good Manufacturing Practice (GMP) and EU Good Distribution Practice (GDP) respectively, while pharmacies are inspected against national legislation and standards. The MMA also carries out Good Clinical Practice (GCP) inspections of clinical trials on a risk-based approach and Pharmacovigilance inspections.

Manufacturing, Importation **and Distribution**

All medicinal products for human use manufactured or imported into Malta and the EU, including medicinal products intended for export, are to be manufactured in accordance with the principles and guidelines of GMP. The Inspectorate and Enforcement Directorate within the MMA manages and maintains a portfolio of seventy (70) licensed/certified entities, local and in third countries, involved in the manufacturing, importation or other GMP related activities of medicinal products for human use.

During 2020 the MMA, carried out eight (8) local GMP inspections for new, renewal or follow up of GMP licences/certificates. These included:

• Two (2) inspections for cannabis for medicinal or research purposes;

• Two (2) inspections for full line non-sterile solid dosage manufacturers;

• One(1) inspection for manufacturing authorisation (MAs) for repackaging and re-labelling/ partial manufacturing operations;

• One (1) inspection for MAs for repackaging and re-labelling/partial manufacturing operations;

• Three (3) applications for import activity with one (1) inspected and licence issued.

Moreover, in 2020 the MMA:

• Processed forty-three (43) MAs administrative variation applications for manufacturers and importers;

• Carried out four (4) variation inspections;

• Held eight (8) Inspections Review Group (IRG) meetings, wherein five (5) cases were discussed and decided upon; and

• Received two hundred and seventy-two (272) rapid alerts and GMP non-compliance notifications, which were investigated, two (2) of which resulted in product safety recalls from the local market.

A distributor of medicinal products sources the products one distributes from within the EU/EEA. Distributors are also required to follow good practice guidelines known as GDP in order to ensure that the quality of the medicinal products is not compromised in the supply chain and to be in a position to carry out a recall of any defective product. The Inspectorate and Enforcement Directorate within the MMA manages and maintains a portfolio of ninety (90) licensed/certified local entities involved in wholesale-dealing and brokering activities of medicinal products for human use, and of active pharmaceutical ingredients distribution and importation.

During 2020, the MMA fulfilled its GDP inspection plan through twenty-five (25) GDP inspections. During 2020, four (4) applications for new wholesale dealing licences were submitted, one (1) of which was eventually licensed after having satisfied all the criteria in a thorough inspection by the end of the year. Another application submitted in 2019 was licenced during year 2020.

Furthermore, fifty-two (52) variation applications for wholesale dealing authorisations were processed in 2020, out of which nine (9) required an inspection. Also in 2020, one (1) new application for brokerage was received, but eventually was withdrawn prior to inspection.

Third Country **Inspections**

During the year under review, the MMA carried out four (4) EU GMP Inspections in countries outside the EU in the first months of the year **(Figure 4.1)**. GMP in countries outside the EU however had to be interrupted due to COVID-19 pandemic travel restrictions. Incoming applications were however still validated and put on hold so as these can be processed, and inspections carried out when travel restrictions will be uplifted, according to priorities at that time. Through this process, the MMA is facilitating the possibility that more companies would be in a better position to import medicinal products within the EU. Additionally, these procedures attract new revenue to the MMA and provide exposure to different manufacturing facilities to the inspectors of the MMA.

Figure 4.1: Number of third country European Union (EU) Good Manufacturing Practice (GMP) inspections carried out in 2020 (N=4)

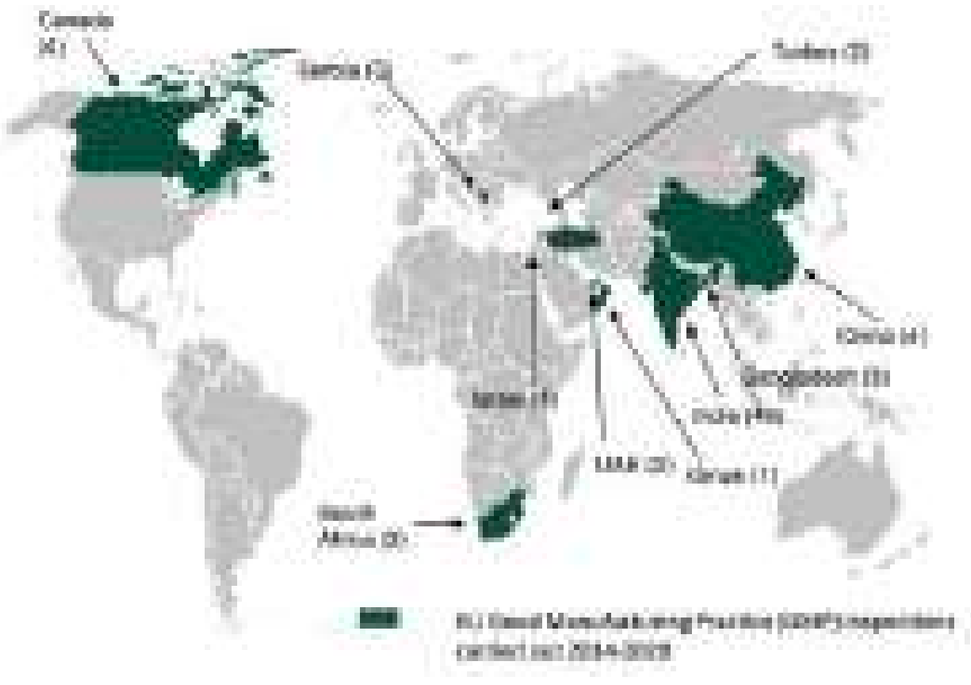


Figure 4.2: EU Good Manufacturing Practice inspections carried out 2014-2020

Pharmacies, Pharmacovigilance and **Surveillance of the Local Market**

The Scientific and Regulatory Operations Directorate within the MMA manages and maintains a portfolio of two hundred and thirty (230) licensed pharmacies.

Due to the outbreak of the COVID-19 pandemic, the MMA continued to inspect pharmacies on a two (2) year cycle up to the first quarter of year 2020, reaching forty-nine (49) routine pharmacy inspections. During the second and third quarter of year 2020, the MMA launched an innovative self-audit approach for routine pharmacy inspections. The self-audit checklist with the criteria for which evidence was requested, was sent to the pharmacies according to an inspection plan and a desk review was performed upon receipt of the report. The smooth introduction of the K2 online software for self-auditing purposes was ensured and the risk score of each inspected pharmacy was determined to calculate the next inspection date. Five (5) spot-check pharmacy inspections were carried out, and fifty (50) administrative variations for pharmacy licences were processed. Six (6) pharmacovigilance inspections were performed in 2020 for local manufacturers.

Moreover, in 2020 the MMA pursued its collaboration with the UK's NCA so that the latter carried out testing in an Official Medicines Control Laboratory (OMCL) for medicinal products under surveillance of the MMA. In this regard, the Local Market Surveillance Plan for 2020 was closed positively.

During 2020 the MMA worked on one (1) enforcement case/investigations which was related to a complaint. The Enforcement Committee (a specific committee which discusses enforcement cases, chaired by the Licensing Authority) was not required to meet in 2020.

In 2020, the MMA attended two (2) court case sittings concerning enforcement cases in which the authority's employees were summoned as witnesses.

Granting of Qualified Persons Status **and Certification of Pharmaceutical Products**

In 2020, the MMA received twenty-four (24) new applications for the Qualified Person (QP) eligibility status. Fifteen (15) applicants were interviewed during 2020, eleven (11) of whom were granted a QP status. Four (4) other applicants that submitted the application in 2019 were interviewed and approved in 2020. The Authority also received and processed two hundred and fifty one (251) applications which satisfied the required criteria and were granted the Certificate of Pharmaceutical Product.

5

Translating Regulation into a Patient-Centred Science

The MMA is committed to sustain a strong knowledgebase, enhance the scientific acumen, share best practices and embrace continuous improvement, catalysing the progress from regulatory affairs to regulatory sciences. The Advanced Scientific Initiatives Directorate, established in line with MMA strategic goals and objectives, strengthens the contribution of the Authority towards research, development and innovation. The outputs of the MMA have expanded through significant increases in peer-reviewed publications, together with enhanced representations in scientific fora and committees, as well as active participation in the EU Innovation Network (EU-IN) and the EU Network Training Centre (EU-NTC), facilitating horizon scanning and re-engineering through collaboration and stakeholder engagement. Through 2020, the MMA sustained liaison with external experts and relevant bodies (e.g. SPH, AG, MPF, ME, MCCAA, MBR, UOM, MLN, Ministries, INCB, and regulatory counterparts), alongside continuous interaction with around 200 Maltese and International stakeholders, healthcare professionals, patient groups, consultancy firms, legal advisors, and company representatives intending to invest in the medicinal cannabis industry.

The MMA leads functions related to the regulation of cannabis for medicinal and research purposes, including scientific/technical evaluations, review and follow-up of processes (importation/wholesale/production), management of procedures related to compliance, due diligence, security and serialisation, as well as inter- and intra-departmental liaison, to ensure that activities meet requirements in terms of accuracy, completeness, timeliness and financial planning. The Research, Innovation and Scientific Affairs Unit, within the Advanced Scientific Initiatives Directorate upholds consultations on scientific matters related to medicinal cannabis and established the innovation office within the national regulatory agency, in line with the HMA/EMA Joint Strategy. The Authority encourages research, thought and analysis, whilst contributing to the consolidation of EU expert views on emerging topics relevant to innovative therapies and technologies.

The drive of the MMA towards continued education, professional development and scientific exposures is enabling the identification of innovative strategic areas and tapping into funding opportunities, while supporting academic initiatives that enhance internal competence and meet stakeholder needs. Advancements are leveraged in the provision of high-level programmes that have already attracted a considerable number of local and international participants, while enabling the strengthening of internal competence as capacity building exercises. The Educational Planning and Academic Development Unit, established within the Advanced Scientific Initiatives Directorate, focuses on the design, development and delivery of multidisciplinary academic activities. The positive response and outcomes from initiatives which have unfolded to date, augur well for the Academy for Patient Centred Excellence and Innovation in Regulatory Sciences. International collaboration with academia is encouraged through the fellowship programme and the promotion of local stakeholders' involvement in research opportunities. The research output of the MMA is coordinated for the dissemination of knowledge through publications, workshops, and similar ventures.

Professionals within the MMA actively engage in European Commission expert groups, training opportunities and collaborative initiatives with a number of competent authorities, alongside diplomatic missions and international academic conferences. Examples of 2020 exposures for internal staff included advanced training in Good Agricultural and Collection Practices (GACP)/GMP for cannabis, the types of herbal preparations and consequences for the control strategy, as well as participation in the first International ISO International Workshop for agreement on the safety, security and sustainability of cannabis facilities and operations. Invited contributions in international fora relevant to medicinal cannabis during the past year include the GCI Virtual Summit (Malta's medical market and their focus on quality, November 2020), Medical Cannabis Network Quarterly (Translating medicinal cannabis regulation into a patient-centred science, October 2020), Open Access Government (Malta's stance on cannabis for medicinal and research purposes, March 2020), and Health Europa (MMA: cannabis for medicine and research, February 2020). The MMA also presented in the 2020 American Society of Health System Pharmacists (ASHP) Clinical Meeting – 'Cannabis for medicinal purposes: Legislative, Regulatory and Clinical implications', and 'Perspectives in quality control of cannabis for medicinal purposes' shall feature in the upcoming World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology.

Cannabis for Medicinal **and Research Purposes**

Medico-legal realities pertaining to cannabis are evolving worldwide, marked by considerations of safety and therapeutic potential, emerging perceptions and scientific evidence, as well as accessibility and harmonisation matters across jurisdictions. In Malta, the Drug Dependence (Treatment Not Imprisonment) Act permits medical practitioners to prescribe cannabis-based products, licensed under the Medicines Act or produced under EU Good Manufacturing Practice, subject to a number of provisions. The MMA 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, labelling criteria, stability data, and other analytical parameters such as assays, heavy metals, pesticides, aflatoxins, and microbiology.

A total of twenty-one (21) 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), were reviewed by December 2020, alongside seven (7) renewal applications. A notification of approval was issued for four (4) dried flower products, 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 products through the controlled supply chain. 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; one (1) adverse reaction report was received and assessed in 2020 **(Figure 5.1)**.

Applications for prospective local medicinal cannabis manufacturing operations are reviewed in line with Chapter 578 of the Laws of Malta and its subsidiary legislation, alongside the MMA Guidelines on the production of cannabis for medicinal and research purposes. The developed framework covers diverse areas, such as cultivation, production, analytical considerations, licensing, due diligence, security, and reporting measures, enabling the implementation of a transparent approach, as well as monitoring and control. The quality culture within the MMA supports ongoing optimisation of established procedures, considering internal systems and processes, and external factors such as contextual developments and stakeholder engagement that empower scientific innovation and address risk-management while strategically balancing short/long term patient-centred objectives.

A total of six (6) applications for the production of cannabis for medicinal and research purposes were submitted to the MMA by end 2020. In tandem to developments within the industry, five (5) local inspections were co-ordinated, including two (2) for EU-GMP and three (3) for facility/physical security, through liaison with relevant bodies. The first licence for the production of medicinal cannabis was issued in December 2020, portending availability of two (2) products in dried flower form manufactured in Malta.

Since the implementation of the legislative measures in 2018, having regulated cannabis for medical use on the market in Malta has 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 by professionals affiliated to the MMA include the study of analytical aspects and laboratory considerations for the regulation of cannabis-based products, the implications of cannabis for medicinal purposes and use in rare diseases, whilst the MMA welcomes other proposals for collaborative initiatives.

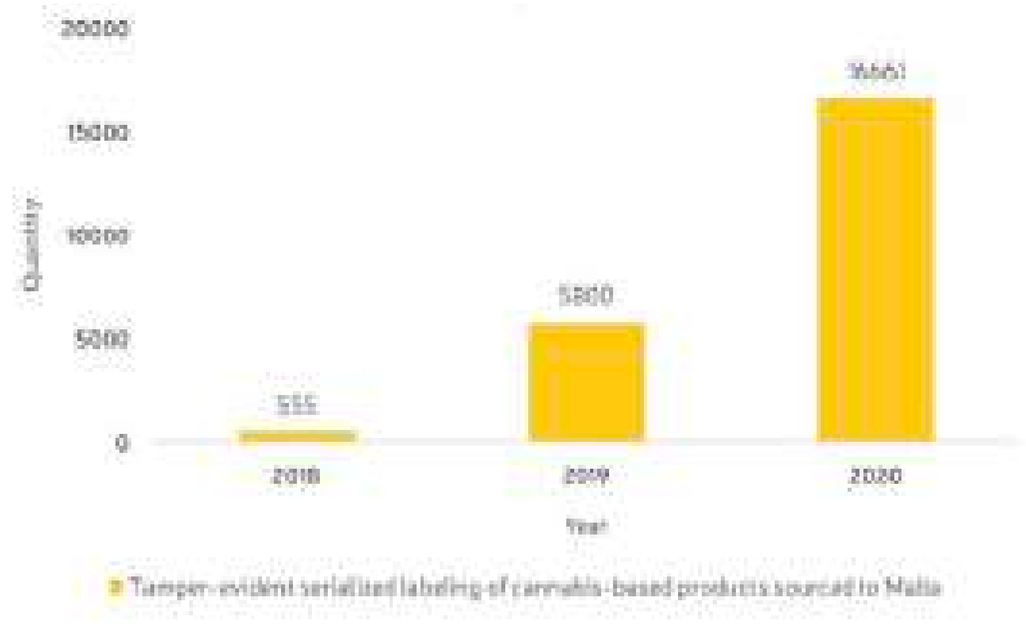


Figure 5.1: Number of cannabis-based products serialized with tamper-evident labels for controlled access on the local market (2018-2020)

Academy for Patient Centred Excellence **and Innovation in Regulatory Sciences**

The contribution of the MMA towards sustainable development and innovation is strengthened by the merging of research, training and education into the regulatory environment. The academic platform within the MMA serves for the delivery of multidisciplinary programmes that are tailored to evolving needs of stakeholders and that translate regulatory standards of good practice into day-to-day tangible outcomes. In 2020, the Authority prioritised the groundwork for registration of the MMA Academy for Patient Centred Excellence and Innovation in Regulatory Sciences as a Further and Higher Education Institution through the Malta Further & Higher Education Authority (MFHEA), formerly the National Commission for Further and Higher Education (NCFHE). In tandem to the development of an Internal Quality Assurance (IQA) Policy and the corresponding compilation of QMS documents, prospective collaborations were co-ordinated in relation to upcoming courses, designed to cover diverse areas, including GMP, GDP, and medical devices. The established framework, encompassing the pertinent elements of innovation, optimisation and accreditation, shall portend mutual benefits to regulators, policy makers, industry, professionals and society at large.

Circumstantial exigencies and impending national, international and organisational priorities influence the activities of the MMA in this dynamic area. The unprecedented COVID-19 pandemic

prompted an initiative intended to support preparedness for addressing the global health emergency. In February 2020, the Novel Coronavirus Seminar for Healthcare Professionals, organised in collaboration with the Health Promotion and Disease Prevention Directorate, brought together over one hundred professionals working in the public and private health sectors for interdisciplinary exchange of expertise, response plans and sharing of concerns. Aspects considered include the presentation of the infection, containment measures, intricacies involved in laboratory analysis and clinical diagnosis, infection prevention and control, use of personal protective equipment and procedures to be followed in case of suspected infection. Outcomes were disseminated at the virtual European Association of Faculties of Pharmacy (EAFP) 2020 Conference.

Market availability of COVID-19 vaccines within 12-18 months in lieu of the regular 10-15 years presented the need for developing a research protocol aimed at determining background incidence rates of Adverse Events of Special Interest (AESI) in Malta. In the absence of background incidence rates of AESI, the occurrence of adverse health outcomes following mass vaccination may be inadvertently interpreted as an indication of a causal relation with vaccination. Data, generated from studies being spearheaded by the MMA, shall be crucial for monitoring the benefit-risk profile of marketed COVID-19 vaccines and aid in separating legitimate safety concerns from events that are temporarily associated with but not caused by vaccination. The anticipated publication of results, may also serve as baseline to construe the impact of the COVID-19 infection, future waves or future pandemics.

Going forward, the MMA will be delivering another two educational initiatives for which grants, through the Internationalisation Partnership Awards Scheme Plus (IPAS+), were awarded in 2020. Following evaluation of proposals submitted to The Malta Council for Science and Technology (MCST), funding was secured for the organisation of a Workshop on Dimensions of Cannabis for Medicinal and Research Purposes and a Seminar on Biosimilar Medicines. These initiatives are intended for international and local experts to join forces, steering motivation and resilience, whilst fostering collaborative impetus towards patient-centred, efficient and sustainable developments.

Figure 5.2: Tamper evident labels for serialization of cannabis-based products.

Figure 5.3: Seminar 1 on Covid-19

Figure 5.4: Seminar 2 on Covid-19

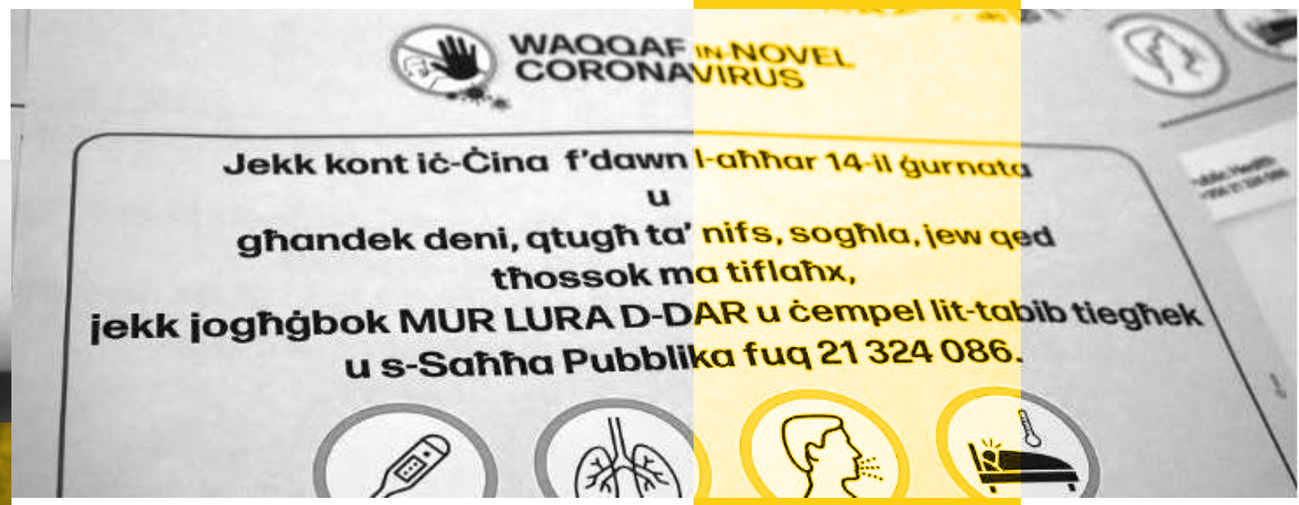


Figure 5.5: Seminar 3 on Covid-19

6

Publications and Presentations

PUBLICATIONS

Azzopardi LM, Serracino-Inglott A. An inter-professional approach towards understanding the science, myths and realities of COVID-19 pandemic. Pharmacy Education. 2020. 20(2) 33 - 34, https://doi.org/10.46542/pe.2020.202.3334.

Azzopardi LM, Serracino-Inglott A. Clinical pharmacy education and practice evolvement in Malta. Journal of the American College of Clinical Pharmacy. 2020. DOI: 10.1002/jac5.1280.

Sammut Bartolo N, Azzopardi LM, Serracino-Inglott A. Pharmaceuticals and the environment. Early Human Development. 2020 https://doi.org/10.1016/j.earlhumdev.2020.105218

Sammut Bartolo N, Attard Pizzuto M, Wirth F, Vella Szijj J, Serracino-Inglott A, Azzopardi LM. The shift from class-based to online learning during COVID-19: a student and academic perception. Pharmacy Education, 20(2), 290-296.

Sammut Bartolo N, Ignas L, Wirth F, Attard-Pizzuto M, Vella Szijj J, Camilleri L, Serracino-Inglott A, Azzopardi, LM. Public perception of generic medicines in Malta. Journal of Pharmaceutical Health Services Research. 2020;11(3):295-298. DOI: doi.org/10.1111/jphs.12366.

Sammut Bartolo N, Zoidis G, Gikas E, Benaki D, Ferrito V, Serracino-Inglott A. A multi-technique analytical approach for impurity profiling during synthesis: The case of diflуprednate. J Pharm Biomed Anal. 2020;190:113483. doi:10.1016/j.jpba.2020.113483.

Zuccarelli M, Vella Szijj J, Serracino-Inglott A, Borg JJ. Treatment of Leber's Hereditary Optic Neuropathy: An Overview of Recent Developments. Eur J Ophthalmol 2020 Jun 19;1120672120936592. doi: 10.1177/1120672120936592.

PRESENTATIONS

International Pharmaceutical Federation (FIP) Virtual Conference (FIP) Virtual Conference, 2020.

Almojero DCE, Vella Szijj J, Serracino-Inglott A. Falsified Medicines Directive: Challenges Faced by Small Member States.

Amar JJ, Attard Pizzuto M, Azzopardi LM, Serracino-Inglott A. Understanding Educational Needs of Pharmaceutical Stakeholders - Pharmacy Operators.

Bereketoglu C, Sammut Bartolo N, Serracino-Inglott A. Perception of delivery systems used for Medicinal Cannabis.

Bereketoglu C, Sammut Bartolo N, Serracino-Inglott A. Systematic Reviews about Medicinal Cannabis dosage forms.

Mifsud Buhagiar L, Serracino-Inglott A, Azzopardi LM, LaFerla G. Standardised interpretation of CYP2D6 genotypes and phenotypes : from lab reports to clinical recommendations.
Butler D, Azzopardi LM, Serracino-Inglott A. Pet Owner Perception of the Role of the Pharmacist in Animal Care.

Butler D, Azzopardi LM, Serracino-Inglott A. Education and Training in Veterinary Pharmaceutical Sciences.

Cardona Xuereb P, Serracino-Inglott A. Factors Influencing Reporting of Medical Device Related Incidents in the Maltese Healthcare System.

Dusabe G, Serracino-Inglott A. Regulation of medical devices in Europe and Africa.

Gallo LL, Vella Szijj J, Serracino-Inglott A. Developing a questionnaire to analyse the use of medicinal cannabis for veterinary purpose.

Langaro M, Serracino-Inglott A. Innovative regulatory framework in community pharmacy.

Ruba JB, Grech L, Serracino-Inglott A. Analysis of Patient Drug Usage Trends in the POYC Scheme.

Serracino-Inglott A, Azzopardi LM. Navigating the Science, the Myths and the Realities of COVID-19 Pandemic.

American Society of Health-System Pharmacists (ASHP) Midyear Clinical Meeting & Exhibition

Cassar S, Azzopardi LM, Serracino-Inglott A, Camilleri L. Community pharmacists' clinical intervention to reduce pharmaceutical waste.

Falzon S, Grech L, Azzopardi LM, Serracino-Inglott A. Establishment of direct patient-pharmacist intervention within an interdisciplinary team in paediatric oncology.

Mifsud Buhagiar L, Serracino-Inglott A, Azzopardi LM, LaFerla G. Amitriptyline reconsidered The relevance of dosage regimen, serum concentrations, genotypic measures and adverse outcomes.

Mifsud Buhagiar L, Vella K, Serracino-Inglott A, Gauci C. Cannabis for Medicinal Purposes - Legislative, Regulatory and Clinical Implications.

Parnis MJ, Marmara V, Azzopardi LM, Serracino-Inglott A. Attitudes and Beliefs of Patients towards Community Pharmacy Services.

European Association of Faculties of **Pharmacy (EAFP) Virtual Conference 2020**

Attard Pizzuto M, Azzopardi LM, Serracino-Inglott A. Introducing in Pharmaceutical Studies the Risk Concept From Art to Science.

Mifsud Buhagiar L, Serracino-Inglott A, LaFerla G. Understanding Pharmacogenetics and Drug Interactions through Case-based Examples.

Serracino-Inglott A, Gauci C, Muscat C, Falzon S, Camilleri C, Vella K, Attard A, Mifsud Buhagiar L. Novel Coronavirus (2019-nCoV) Seminar for the Healthcare Professionals - An Interdisciplinary Academic Initiative.

Vella Szijj J, Attard Pizzuto M, Wirth F, Falzon S, Mifsud Buhagiar L, Gauci M, Grech L, Serracino-Inglott A, Azzopardi LM. Development of an Applied Course in Biochemistry for Pharmacy Students.

Wirth F, Azzopardi LM. Simulation-based Blood Pressure Measurement Training for Pharmacy Students.