MALTA
MEDICINES
AUTHORITY

ANNUAL REPORT

2021

Total number of employees

108

Total number

73 **Females**

35 **Males**

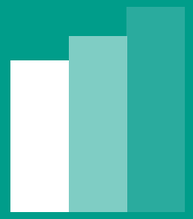
Academic qualifications of MMA employees

106

Total number

72 **Females**

34 **Males**



24 **Lvl 6**

46 **Lvl 7**

25 **Lvl 8**

MQF levels

Total number of training opportunities attended by employees to enhance professional development

366

22

Students

Total number of students who engaged in the International Fellowship Programme

14

Research publications and presentations

Total number of internal documents related to the QMS (SOPs, Policies and Guidelines)

231

Total number of new medicinal products authorised in 2021

by end of 2021

724

5 of which have been withdrawn

120

Procedures with MT acting as RMS in MRP/DCP procedures

MT acting as rapporteur in centralised procedures

4 **as rapporteur only**

The number of scientific advice for human medicines

21 (1) **National Scientific Advice Procedure**

EMA SAWP Procedures

Individual Case Safety Reports registered

3001

912

Reports of suspected ADRs associated with the use of human medicines

43

EU GMP Inspections

49

EU GDP Inspections

82 **Individual queries handled by the MIAU**

Total number of medicine price reductions and new medications on the local market

Price Reductions

42 **Medicinal Products**

29 **Generic Medicines**

9 **New Medicines**

New medications on the local market

40

Free sale certificates for medical devices

Number of cannabis-based products serialised with tamper-evident labels for controlled access on the local market

31,600

2021
Statistics at a Glance

ACRONYMS

AA	Authorisation according to Article 126(a)
ADR	Adverse Drug Reaction
AG	Attorney General
AI	Artificial Intelligence
API	Active Pharmaceutical Ingredient
BCC	Borderline Classification Committee
BSI	British Standards Institution
CAP	Centrally Authorised Product
CBD	Cannabidiol
CMDh	Co-Ordination Group for Mutual Recognition and Decentralised Procedure Human
CMS	Concerned Member State
COVID-19	Coronavirus Disease
CPSU	Central Procurement and Supplies Unit
CTR	Clinical Trial Regulation
DCP	Decentralised Procedure
DG INTPA	Director General for International Partnership
DHPCs	Direct Healthcare Professional Communications
DPU	Data Protection Unit
EC	European Commission
EEA	European Economic Area
EMA	European Medicines Agency
EMRN	European Medicines Regulatory Network
EU	European Union
EUCD	EU Coordination Department
EU-GMP	European Union Good Manufacturing Practice
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	Freedom Of Information Coordinate Unit
FSCA	Field Safety Corrective Actions
GACP	Good Agricultural and Collection Practices
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GMO	Genetically Modified Organ
GMP	Good Manufacturing Practice
HERA	Health Emergency Preparedness and Response Assessment
HMA	Heads of Medicines Agencies
HTA	Health Technology Assessment
IACS	International Academic Conference Scheme
ICSRs	Individual Case Summary Reports
ICT	Information and Communications Technology
ICP	International Collaboration Programme
IFP	International Fellowship Programme
INCB	International Narcotic Control Board
IPAS+	Internationalisation Partnership Awards Scheme Plus
IPS	Institute of Public Service
IQA	Internal Quality Assurance
IRG	Inspections Review Group
ISO	International Organization for Standardization
IVD	In-Vitro Diagnostic
IVDR	In-Vitro Diagnostic Device Regulation
LA	Licensing Authority
MA	Marketing Authorisation
MAH	Marketing Authorisation Holder
MBR	Malta Business Registry
MCAST	Malta College of Arts, Science and Technology
MCCAA	Malta Competition and Consumer Affairs
MDCG	Medical Device Coordination Group
MDR	Medical Devices Regulation
MEB	Medicines Evaluation Board
ME	Malta Enterprise
MFHEA	Malta Further & Higher Education Authority
MLN	Malta Laboratories Network
MMA	Malta Medicines Authority
MPF	Malta Police Force
MQF	Malta Qualifications Framework
MRP	Mutual Recognition Procedure
MRR	Mutual Recognition Regulation
NAT/LE	National and Line Extension
NB	Notified Body
NCA	National Competent Authority
OMCL	Official Medicines Control Laboratory
PAES	Post-Authorisation Efficacy Studies
PASS	Post-Authorisation Safety Studies
PDPID	Policy Development and Programme Implementation Directorate
PI	Parallel Import
PSUR	Periodic Safety Update Report
PSUSA	Periodic Safety Update Report Single Assessment
PSWG	Prescription Status Working Group
PPP	Pregnancy Prevention Programmes
PSR	Product Safety Recall
QI	Quality Improvement
QM	Quality Management
QMS	Quality Management System
QP	Qualified Person
RA	Rapid Alert
RAT	Rapid Antigen Test
RMM	Risk Minimisation Measure
RMP	Risk Minimisation Programmes
RMS	Reference Member State
RUP	Repeat Use Procedure
SAWP	Scientific Advice Working Party
SDGR	Single Digital Gateway Regulation
SOC	System Organ Class
SOP	Standard Operating Procedures
SPH	Superintendence of Public Health
SSI	Safety Signal Investigations
SWOT	Strengths, Weaknesses, Opportunities, and Threats
THC	Tetrahydrocannabinol
TOPRA	The Organisation for Professionals in Regulatory Affairs
UK	United Kingdom
UOM	University of Malta
VPN	Virtual Private Network
WHO	World Health Organisation

CONTENTS

Page 3 **Message from the Chairperson**

Page 4 **1. About the Malta Medicines Authority**

6 Main Roles and Responsibilities
8 Mission and Vision
8 Values
10 Strategic Goals and Objectives
12 Business Continuity and Regulatory Considerations amid the Coronavirus Disease (COVID-19) Pandemic
13 Quality Management, Simplification Measures and Good Governance
16 Organogram

Page 18 **2. Organisational development, A Positive Working Environment, a Patient-centred Ethos and a Proactive Approach**

20 People Management
21 Education and Professional Development
24 A European and Global Player

Page 28 **3. Quality, Safety, Efficacy: The 3 Pillars of an Effective Medicines Regulator**

30 Assessment and Licensing of Medicinal Products
30 European Cooperation on Training and Assessments
31 Applications for Marketing Authorisations
32 Malta as a Lead in European Procedures
35 Malta as a Contributor in European Procedures
37 Post-authorisation Procedures
42 Impact of Brexit on the Malta Medicines Authority
42 Committees, Working Groups and National Advisory Services
43 Pharmacovigilance Activities
48 Clinical Trials
48 Advertising of Medicinal Products
48 Medicines Intelligence and Access
49 Regulating Medical Devices
49 Stakeholder Focus
50 Vigilance
51 Authorisation Activities
51 COVID-19 Impact
51 Pharmaceutical Collaboration

Page 54 **4. Maintaining the Highest Standards for Pharmaceutical Inspections in the Best Interest of Patient Safety**

56 Pharmaceutical Inspections: Manufacturing, Importation and Distribution
57 Third Country Inspections
59 Pharmacies, Pharmacovigilance and Surveillance of the Local Market
60 Granting of Qualified Persons Status and Certification of Pharmaceutical Products

Page 62 **5. Translating Regulation into a Patient-Centred Science**

66 Cannabis for Medicinal and Research Purposes
68 Academy for Patient Centred Excellence and Innovation in Regulatory Sciences

Page 70 **6. Publications and Presentations**

MALTA MEDICINES AUTHORITY

Message from the Chairperson

The Malta Medicines Authority is recognised for its excellence in ensuring the quality, safety and efficacy of medicines. In the past year the Authority has established a Directorate for medical devices. In line with its key values of people, innovation and integrity, the Authority is planning to achieve the same high standards it has set for medicinal products in the regulation of medical devices. While maintaining successful and stable management, the Authority has kept patients at the centre of its agenda. Scientific rigour and good governance remain the tools underlying its decisions. The Authority takes pride in considering the social, legal and economic aspects of its operations. This year the Malta Medicines Authority has launched a strategic plan leading to 2025. The Authority has set up this strategic plan in consultation with stakeholders and, more importantly, intends to carry out this plan in regular consultation with the stakeholders.

The future for the Malta Medicines Authority looks bright in that the Authority has developed resilience against current and potential market disruptors such as the challenges brought about by the COVID-19 pandemic and Brexit. All these challenges could affect the accessibility to medicines and medical devices and could pose a threat to the robustness of a regulatory system that has to ensure the availability of good quality, safe and effective medicines, and medical devices at all times. Despite the pandemic, the Malta Medicines Authority has continued the process of awarding Good Manufacturing Practice certification to third countries. In this way, Malta has made an extraordinary contribution to continue maintaining Europe's access to medicines from third countries. The Malta Medicines Authority has also increased its role in drug registrations by taking on significant work previously carried out by the United Kingdom when it was a member of the European Union. There has been an increase in rapporteurship on medicines to make these medicines accessible in Europe. Pharmacovigilance of medicines, including COVID-19 vaccines, is regularly carried out to safeguard the efficacy, safety and quality of these products after they are licensed.

The excellence of service shown by the Malta Medicines Authority has been indicated by the pharmaceutical industry as a primary attraction and reason for the industry to directly invest in Malta. The key to this success is directly related to the personnel working at the Malta Medicines Authority having a high scientific and academic base. This is shown in its highly qualified persons and in the experience obtained through international collaborations. In the European scenario, the Malta Medicines Authority contributes to the work of the Pharmaceutical Strategy for Europe, the European Medicines Agency and the work programmes established by the Heads of Medicines Agencies. The Authority is working in line with international obligations to continue to attract competent industry with the intention of expanding into more scientific endeavours, research and education.

This year the Academy for Excellence and Innovation in Patient-Centred Regulatory Sciences, established within the Malta Medicines Authority, has been licensed as a Higher Education Institution by the Malta Further and Higher Education Authority. This represents an important milestone in the recognized work of the Authority, which serves to showcase the impetus, vision and commitment to excellence in advanced sciences. Such concrete developments are offering high-level networking, exchange of collaborations and advanced learning in innovative areas of regulatory sciences.

The collaboration with other entities, especially with the Superintendent of Public Health, has been instrumental for the Malta Medicines Authority to meet its mission to protect and enhance public health through the regulation of medicinal products, medical devices and pharmaceutical activities. The Authority's track record demonstrates that it is well equipped with the necessary skills and expertise to take on challenges and transform them into opportunities for success, whilst protecting the interests of patients.

Professor Anthony Serracino-Inglott
Chairperson, Malta Medicines Authority

ABOUT THE MALTA MEDICINES AUTHORITY

1

The Malta Medicines Authority (MMA) was established by virtue of the Medicines Act 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 established by six (6) 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, the Regulatory Operations, Medicines Intelligence and Access Directorate and the Medical Devices, Pharmaceutical Collaboration and Entrepreneurship Directorate. Their core work is supported by thirteen (13) Units, namely the Finance and Corporate Services Unit, the Information and Communications Technology Unit, the Quality, Continuous Improvement and Internal Audit Unit, the Legal Unit, the Regulatory Project Leader Unit, the Pharmacovigilance Unit, the Inspectorate and Enforcement Unit, the Research, Scientific Affairs and Innovation Unit, the Educational Planning and Academic Development Unit, the Medicines Intelligence and Access Unit, the Operations and Data Interpretation Unit, the People Management Unit and the Medical Devices Unit.

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.

MAIN ROLES AND RESPONSIBILITIES

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.

- To perform duties delegated to the MMA by the Licensing Authority (LA) through the Medicines Act.
- To assist and advise the Licensing Authority on any matter relating to the regulation of medicinal products, medical devices (MD) and related activities.
- To ensure in so far as possible and consistent with current medical and scientific knowledge, that medicinal products and medical devices marketed in Malta and the European Union (EU) are of good quality and have a favourable risk-to-benefit profile through independent, science-based assessment, post-authorisation activities and participation in decision-making at European level.
- To scientifically evaluate requests and monitor clinical trials carried out in Malta.
- To ensure, that the medicines and medical devices supplied on the local market through the regulated supply chain are of good quality, safe for the public, and as per the intended use.
- To provide high-quality monitoring and inspection services for pharmaceutical activities, local medical device economic operators, and the performance of Notified Bodies (NBs) registered in Malta.
- To monitor the safety of medicinal products and medical devices.
- To monitor and enforce the relevant legislation through investigation of potential breaches of regulations and a range of measures.
- To enhance the effective, safe and rational use of medicinal products and medical devices through the provision of objective and unbiased information which helps prescribers, healthcare professionals and patients make informed decisions on the choice and use of medicines.
- To support the availability of medicinal products and medical devices on the local market.
- To support the competitiveness of the local market through scientific and regulatory advice and the implementation of principles of SMART Regulation.
- To utilise and develop tools, standards, and approaches to assess and ensure the safety, quality and effectiveness of medicinal products, medical devices, and pharmaceutical activities.
- To enhance the standard of medicinal products and pharmaceutical activities for medicines for human use in Malta.
- To manage developments related to scientific research, innovation, and academic initiatives, in line with the strategy of the MMA.
- To support the regulation of cannabis for medicinal and research purposes through guidance, technical review, and stakeholder engagement among other areas.
- Process and investigate complaints received regarding advertised medicinal products and provide guidance as laid down in the advertising regulations.
- To participate on European fora of the European Medicines Agency (EMA), Council, working groups, and the Commission and perform assessment and give scientific and regulatory positions in various areas.

MISSION AND VISION

"Our mission is to protect and enhance public health through the regulation of medicinal products, medical devices 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."

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

Discipline and fairness are the utmost priciples 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

The Authority sustained its vision of prosperity through the design of a forward-looking, innovative, and robust MMA Strategy to 2025 for the regulation of medicines, medical devices, and pharmaceutical activities, which was launched during a stakeholders conference with the theme 'Science Meets Practice'.

During the planning and development stages of the MMA Strategy to 2025, the Strengths, Weaknesses, Opportunities, and Threats (SWOT) approach was employed and six (6) overarching goals were identified as the core areas to be addressed by the MMA throughout the next five (5) years. A set of objectives corresponding to each goal were subsequently developed, through which the Authority aims to reinforce its power to navigate through market challenges and continue contributing towards a level of excellence in medicines, medical devices and pharmaceutical regulation and ultimately, the protection of public health.

The MMA aims to sustain its contribution towards the implementation of the European Commission (EC) Pharmaceutical Strategy and the European Medicines Agency and Heads of Medicines Agencies (HMA) work programmes, arising from the Joint HMA-EMA network strategy to 2025.

The new strategic goals and objectives of the MMA include:

1. Resilience against current and potential market disruptors

1.1. *To act in coherence with partners in designing supply chain strategies*
1.2. *To optimise the allocation of the Authority's resources in response to major events*
1.3. *To monitor developments related to the COVID-19 pandemic*
1.4. *To sustain support structures in the areas of Brexit and falsified medicines*

2. Enhancing the accessibility framework

2.1. *To gather intelligence systematically and expediently*
2.2. *To operate in a global context to address shortages*
2.3. *To maintain current regulatory approaches to accessibility*

3. A robust regulatory system that adapts to new realities

3.1. *To further bolster the surveillance for the safety and quality of medicines*
3.2. *To spur initiatives related to the clinical development of medicinal products*
3.3. *To reinforce the regulation of medical devices*
3.4. *To instil change in pharmacy practice*

4. Organisational growth and sustainability

4.1. *To offer workspaces with in-built ergonomics*
4.2. *To monitor performance targets and achieve proper people and financial management*
4.3. *To continue acting as a global player*
4.4. *To implement a forward-looking Information and Communications Technology (ICT) Governance system*
4.5. *To enhance the Quality Management System and auditing functions*

5. Leading through science, innovation, and expertise

5.1. *To intensify the research arm by leveraging on collaborations*
5.2. *To instil a professional acumen in tomorrow's pharmaceutical leaders*
5.3. *To venture further into the Authority's innovative regulatory activities*

6. Advancing communication norms

6.1. *To implement internal engagement initiatives*
6.2. *To uphold professional communication approaches with external stakeholders*
6.3. *To enhance public knowledge on the MMA and the appropriate use of medicines*

BUSINESS CONTINUITY AND REGULATORY CONSIDERATIONS AMID THE CORONAVIRUS PANDEMIC

During 2021, in view of the COVID-19 pandemic, the MMA ensured the continuity of business operations and safeguarded the health and safety of the workforce by communicating timely decisions in tandem with directions issued by local health Authorities. Through several support measures, including the provision of health and hygiene products and the organisation of virtual counselling sessions, the Authority was proactive in addressing the holistic well-being of its staff amid the pandemic.

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 (VPN), interaction platforms, and facilitated document exchange systems.

The MMA monitored closely developments related to the pandemic and where necessary contributed to and communicated decisions during regulatory discussions. The Authority followed the EMA regular press briefings and participated in 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, which are indicated for the prevention and/or treatment of the COVID-19 virus. 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 International Organization for Standardization (ISO) 9001:2015, the MMA upholds the highest standards of governance and is fully committed to improved Quality Management (QM).

By the end of 2021, the foundation of the Quality Management System at the Authority, that ensures uniform and high-quality operations, consisted of thirty-nine (39) Policies, one hundred and nineteen (119) Standard Operating Procedures (SOPs) and thirty (30) Guidelines. In 2021, ten (10) Policies, forty-four (44) SOPs, and fifteen (15) Guidelines were revised or introduced through the annual Management Review (MR) 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)**.

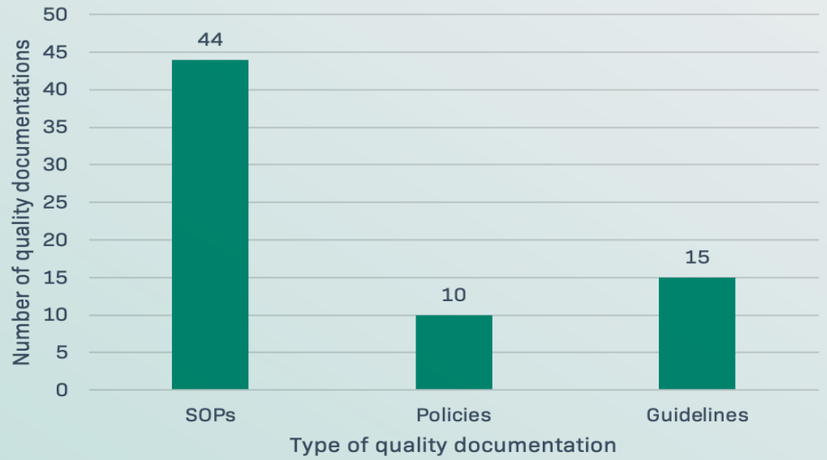


Figure 1.1:
Standard Operating Procedures, Policies and Guidelines of the Malta Medicines Authority

The MMA implemented fifteen (15) internal audits throughout 2021, in line with the five-year audit strategy which was extended to a six (6) year programme due to COVID-19 interruptions.

Seventy-six (76) Quality Improvements (QIs) were identified through internal audits and other internal initiatives by the respective Directorates and Units, which jointly oversee the implementation of all QIs. Some improvements led to the introduction of new Policies and SOPs or the systematic review of existing ones with a cross-cutting aim of reducing red tape and unnecessary bureaucracy.

The annual MR 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 QIs, in a comprehensive exercise to strengthen the QMS.

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

In line with the MMA's commitment to simplify its systems and processes, one (1) simplification measure was identified. This includes the deployment of a national electronic database for medical devices to store information and facilitate transactions with economic operators. This measure ensures 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 that explores the feasibility of setting up of a national reference laboratory by the MMA, for the purposes of monitoring and testing the quality of medicinal products on the market. The planning and development of the national laboratory involve important considerations including logistical matters as well as financial, technical, legal, and quality issues.

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 the General Data Protection Regulation (GDPR) 2016/679/EU 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.

ORGANOGRAM

Chairperson
Professor Anthony Serracino Inglott

Director
Dr Louise Grech

Medical Devices, Pharmaceutical Collaboration & Entrepreneurship Directorate

Senior Head
Mr Julian Fearne

Medical Devices

Director
Dr Caroline Muscat

Regulatory Operations, Medicines Intelligence & Access Directorate

Head
Dr Dylan Said

Operations & Data Interpretation

Head
Ms Emma Saliba

People Management

Acting Head
Ms Jessica Zarb

Medicines Intelligence & Access

Director
Professor John J Borg

Post-licensing Directorate

Head
Dr Benjamin Micallef

Pharmacovigilance

Head
Dr Danika Camilleri Agius Decelis

Quality, Continuous Improvement & Internal Audit

Director
Ms Helen Vella

Licensing Directorate

Head
Ms Amanda Camilleri

Regulatory Project Leader

Head
Ms Oriana Ellul DeRaffaele

Finance & Corporate Services

Director
Dr Mark Cilia

Inspectorate & Enforcement Directorate

Head
Ms Stefanie Farrugia

Inspectorate & Enforcement Directorate

Head
Ms Kristina Vella

Research, Scientific Affairs & Innovation

Head
Mr Kevin Mizzi

Information & Communication Technology

Chairperson
Professor Anthony Serracino Inglott

Director
Dr Luana Mifsud Buhagiar

Advanced Scientific Initiatives Directorate

Head
Dr Sephorah Falzon

Educational planning & Academic Development

Head
Dr Sonia Consiglio

Legal

2 ORGANISATIONAL DEVELOPMENT, A POSITIVE WORKING ENVIRONMENT, A PATIENT-CENTRED ETHOS AND A PROACTIVE APPROACH

Throughout 2021, the Authority maintained its focus on the implementation of the MMA Strategy to 2025 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. The positive working environment equips employees of the MMA with the best tools to implement our patient-centred ethos, where the patient is put at the core of each and every decision made.

The 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, Regulation related to falsified medicines, the availability and accessibility of medications, the Medical Device Regulation (MDR) and accredited courses which are organised by the MMA.

Brexit preparedness together with the COVID-19 pandemic were two major challenges which the Authority successfully managed throughout 2021, and will continue to strive for improvement 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.

PEOPLE MANAGEMENT

By the end of 2021, one hundred and eight (108) employees were engaged, with the MMA **(Figure 2.1)**. This represents an increase of 67% from the year 2013 **(Figure 2.2)** which effectively caters for the increased regulatory activities.

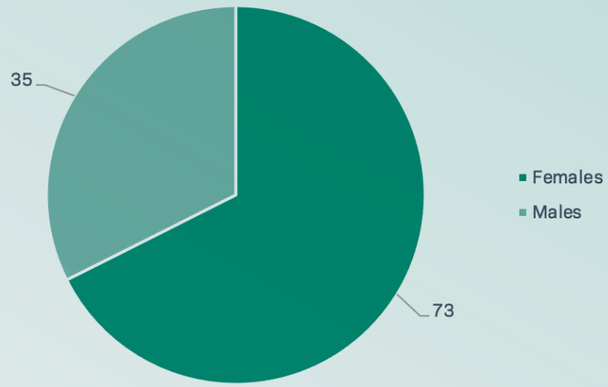


Figure 2.1:
Total number of employees at the Malta Medicines Authority at the end of 2021 (N=108)

Figure 2.2:
Number of employees at the Malta Medicines Authority (2013-2021)

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 2021, its employees successfully attained four hundred and fifty-nine (459) certificates related to training initiatives which were offered internally (n=270) and externally (n=189). These comprised a wide range of subjects including pharmacovigilance, regulatory sciences related to good practice and biopharmaceutical manufacturing **(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.

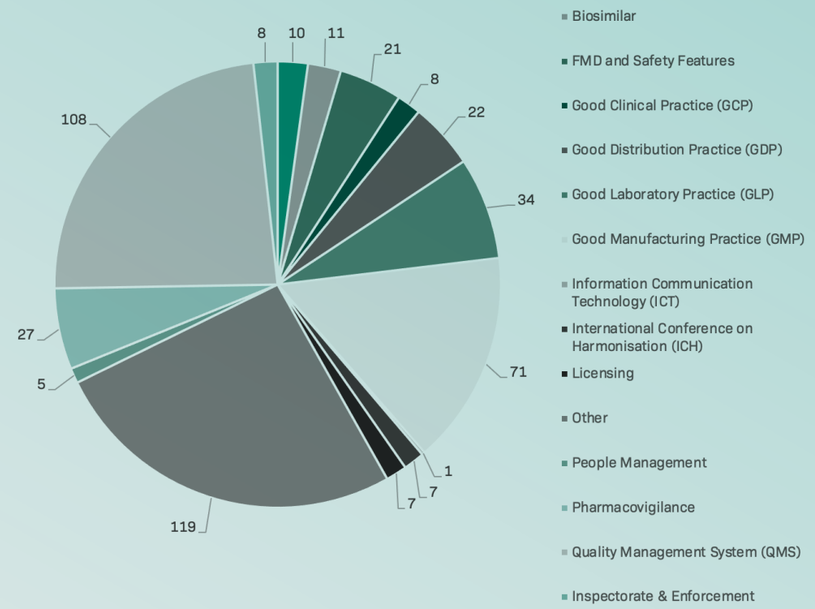


Figure 2.3:
Number of training certificates attained by employees at the Malta Medicines Authority

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 are a fine example of the above-mentioned commitment. This is clearly portrayed in the number of employed graduates in 2021, whereby three (3) 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 that attracts local and foreign students to join the MMA's team while reading for a Doctorate, Master or a comparable and equivalent qualification in line with the Malta Qualifications Framework (MQF) in Pharmacy, Leadership, Management, Administration, and Finance.

Till the end of 2021, twenty-two (22) students from across the globe were following the MMA's IFP **(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.

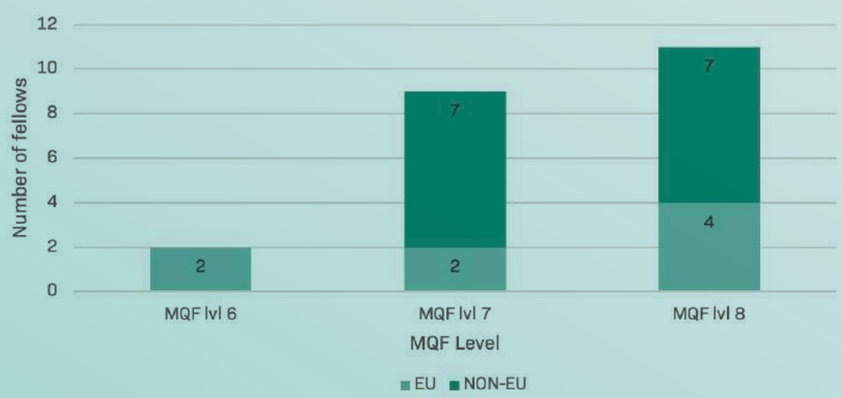


Figure 2.4:
Number of students following the International Fellowship Programme in 2021 (N=22)

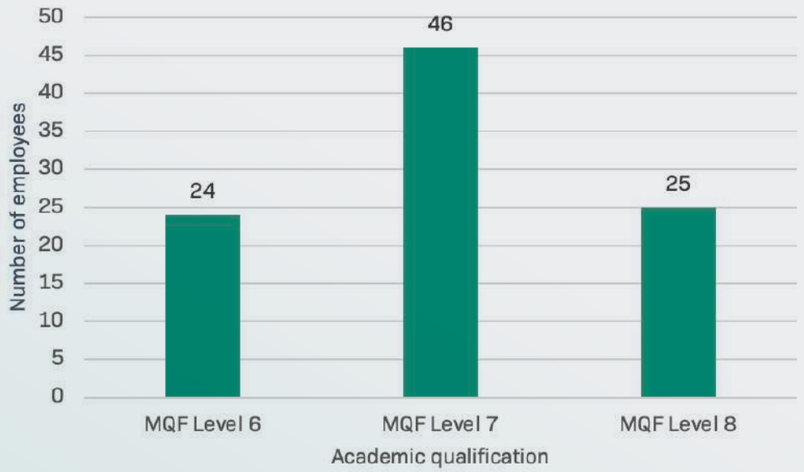


Figure 2.5:
Academic qualifications for employees at the Malta Medicines Authority in 2021 (N=95)

The above represents a concerted effort to improve the overall capacity of the MMA while reinforcing its scientific prowess. As it currently stands, twenty-five (25) employees hold Doctoral degrees, whilst forty-six (46), nearly half of the Authority's workforce, hold an academic qualification at a Master 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 (UOM) by hosting student placements. In 2021, the Authority also welcomed students on summer placements from the Malta Enterprise (ME) 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 (MCAST) and the University of Illinois in Chicago.

A **EUROPEAN AND** GLOBAL PLAYER

Throughout 2021, 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-five (45) strategic and scientific expert groups, committees and boards **(Figure 2.6)**.

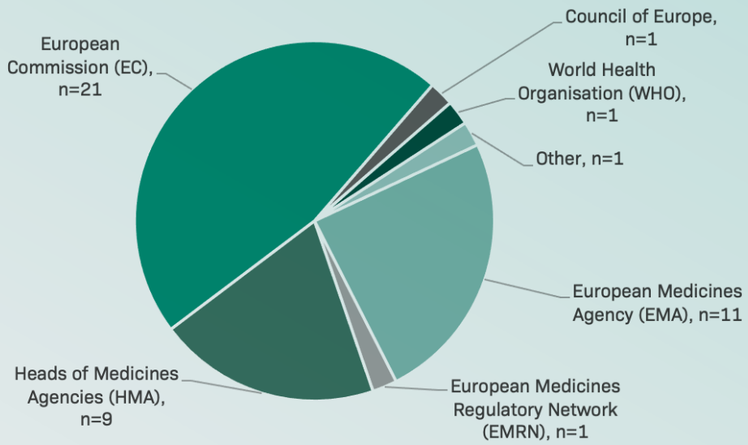


Figure 2.6:
Representation by the Malta Medicines Authority in European institutions and professional bodies

The MMA was consulted on a number of established and proposed EU legislative files and any relevant outputs from the EU institutions, 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 following the necessary internal and external consultations 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:
EU legislative files and any relevant outputs from the EU institutions on which the Malta Medicines Authority was consulted in 2021.

The United Kingdom's withdrawal from the European Union and the potential ramifications on pharmaceutical supply chains has drawn much attention from NCAs 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 opportunities to exchange best practices.

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. An update to this Notice was published in December 2021, where the Authority provided regulatory support to stakeholders in view of the derogations introduced with the revised version of 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 through a number of networking initiatives that consolidate the role of Malta as a global player. The Authority interfaced with officials from the Commission Directorate General for International Partnerships (DG INTPA) to identify emerging opportunities for collaboration with African states. The Authority also contributed to Council discussions regarding the Commission non-paper on the sixth EU-African Union Summit. Moreover, the Authority contributed towards the Malta Government Policy Framework for collaboration for the regions of Asia, Oceania and countries of the Gulf. Bilateral collaborations were tabled with India and Cuba on sharing scientific insights and possible capacity building in the area of COVID-19 vaccine development.

Through these agreements, the Authority foresees 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 Practices (EU-GMP) certification. The agreements are also intended to promote collaboration on capacity building with regards to pharmaceutical product registration, pharmaceutical quality control, and pharmacovigilance.

In accordance with the COVID-19 Business Continuity Plan released in September 2020 by the European Medicines Regulatory Network (EMRN), 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 into 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.

QUALITY, SAFETY, EFFICACY: 3 THE 3 PILLARS OF AN EFFECTIVE MEDICINES 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 Maltese patients. In addition, 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, for both healthcare professionals and patients.

Amid Brexit, it has also been a priority for the Licensing Directorate to assist stakeholders in ensuring continuity of supply by providing support in carrying out the necessary regulatory changes in line with the EU legislation.

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 an assessment of applications on behalf of MEB to enable registration of new medicinal products both for the Dutch and the European market. This alliance has been mutually beneficial and has helped the MMA to consolidate the expertise of its assessors. The Authority seeks to have this collaboration with other Member States to improve its relationship within the network, contribute to the assessment work and its assessors to gain more experience in innovative areas of expertise. Staff within the MMA also benefited from other various training initiatives organised by the MEB through the International Collaboration Programme (ICP). Areas of training included toxicological qualification of impurities, downstream and upstream processing, product manufacturing and testing and validation. A refresher course for the new assessors was also organised.

The Licensing Directorate has worked to improve the capacity to be able to assess other types of products as Rapporteur and Reference Member State (RMS). With a view to increasing the range of types of applications to be handled by the Authority, training opportunities were explored in different areas.

Furthermore, the MMA continued to strengthen its team of external assessors to handle more challenging procedures, whereby in 2021 the Authority explored assessments of different pharmaceutical forms.

APPLICATIONS FOR MARKETING AUTHORISATIONS

The number of applications for authorisations received through all routes for the approval of new products in 2021 is shown in **Figure 3.1.** These submissions include national Marketing Authorisations (MAs) as a result of national procedures (n=10), authorisations in accordance with Article 126(a) of Directive 2001/83/EC (n=343), and Parallel Import (PI) licences (n=194). A total of five hundred and forty-seven (547) authorisations for new products were issued in 2021. A total of three hundred and twelve (312) Marketing Authorisation applications were received as a result of European procedures with Malta as Reference Member State (n=178) and Concerned Member State (CMS) (n=134).

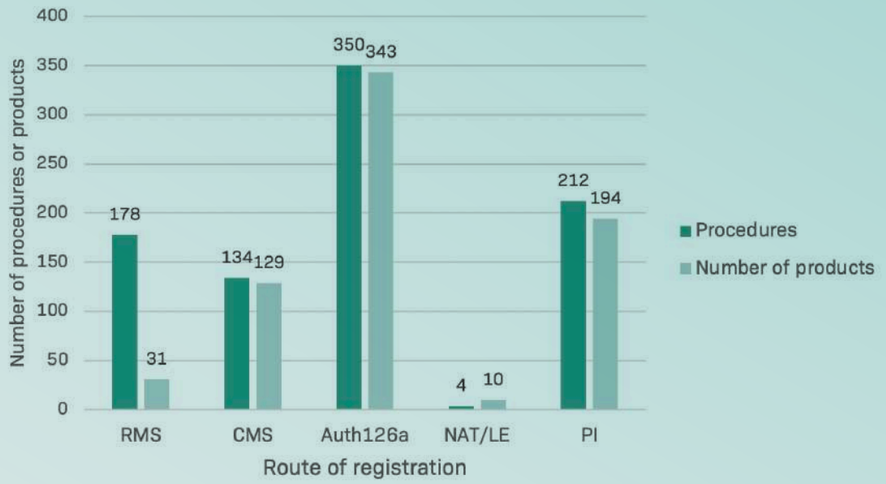


Figure 3.1:
Total number of product applications and product authorisations through all routes in 2021 (N=547)
[NAT/LE: National and Line Extension]

The total number of authorisations in accordance with Article 126(a) of Directive 2001/83/EC standing at the end of 2021 were one thousand, nine hundred and ninety-seven (1,997).

In late 2020, an Advisory Committee was set up by the Chairman of the Authority, with the main function being that of discussing applications in accordance with article 126(a) or through any other unlicensed routes. The Advisory Committee discusses the public health reason given by the applicants and/or reasons given for not applying for a marketing authorisation through the established registration routes. Wherever this is possible, companies are invited to use the Mutual Recognition Procedure (MRP) to place their products on the Maltese

Market. The Advisory Committee, together with the Medicines Intelligence and Access Unit (MIAU) also discuss each application and investigates the availability of other authorised products on the market. The Advisory Committee met forty-two (42) times in 2021 to discuss these applications. The agendas and relevant outcomes from the discussions are published on the MMA website for enhanced transparency.

MALTA AS A LEAD IN EUROPEAN PROCEDURES

During the year under review, the MMA unequivocally faced challenges in relation to licensing of medicinal products, mainly in view of 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 RMS via the European Decentralised Procedure (DCP) and the MRP, or by acting as Co-/Rapporteur/Part of a Multinational team in European centralised authorisation procedure.

In 2021, Malta was rapporteur for four (4) 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. Malta also participates in multi-national teams with other Member States which enhances collaboration with other European countries and allows for internal and external experts in the organisation to work with counterparts in other agencies.

Malta started acting as RMS in 2007 and contributed to the authorisation of six hundred and eighty-two (682) products. The number of authorisation procedures started by Malta as RMS received in 2021 was eighty-two (82) procedures.

By the end of 2021, Malta ranked seventh (7th) and eleventh (11th) as a RMS respectively for the number of started and finalised MRPs and DCPs **(Figure 3.2, Figure 3.3)**.

STARTED Procedures – MRP/DCP per CMS
Total: 366 MRP and 1144 DCP (regarding 703 and 2342 products respectively)

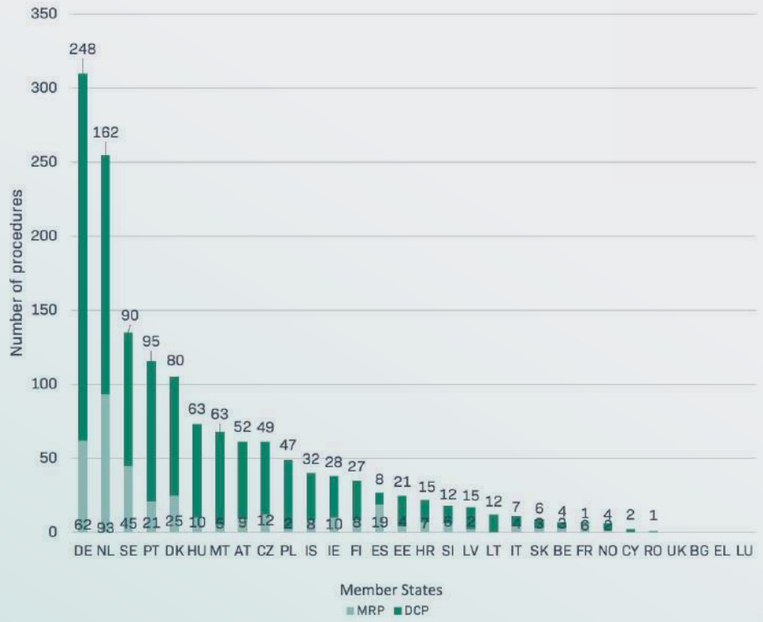


Figure 3.2:
The number of Mutual Recognition Procedures (MRPs) and Decentralised Procedures (DCPs) started in 2021 by The number of Mutual Recognition Procedures and Decentralised Procedures started in 2021 by Reference Member States (N=366 MRP, N=1144 DCP) (source: CMDh 2021 Statistics)

FINALISED Procedures - MRP/DCP per CMS
Total: 354 MRP and 954 DCP (regarding 722 and 1943 products respectively)

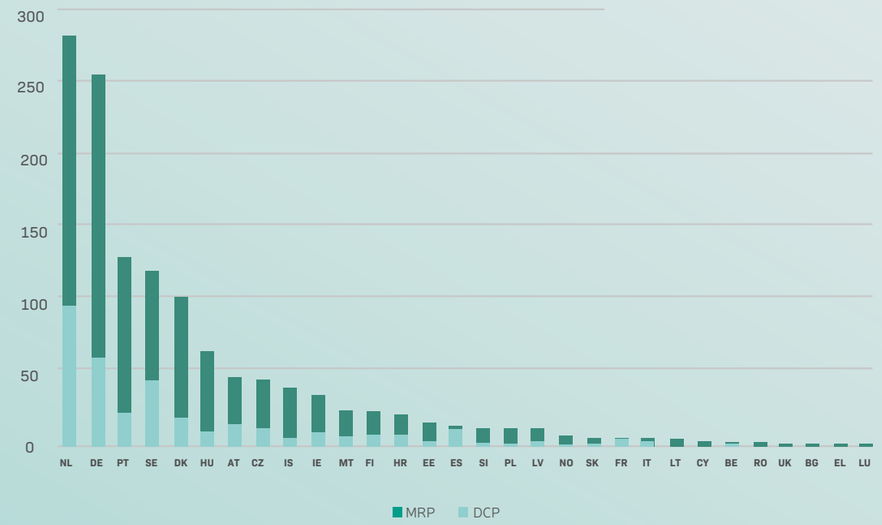


Figure 3.3:
The number of Mutual Recognition Procedures and Decentralised Procedures started in 2021 by Reference Member States (N=366 MRP, N=1144 DCP) (source: CMDh 2021 Statistics)

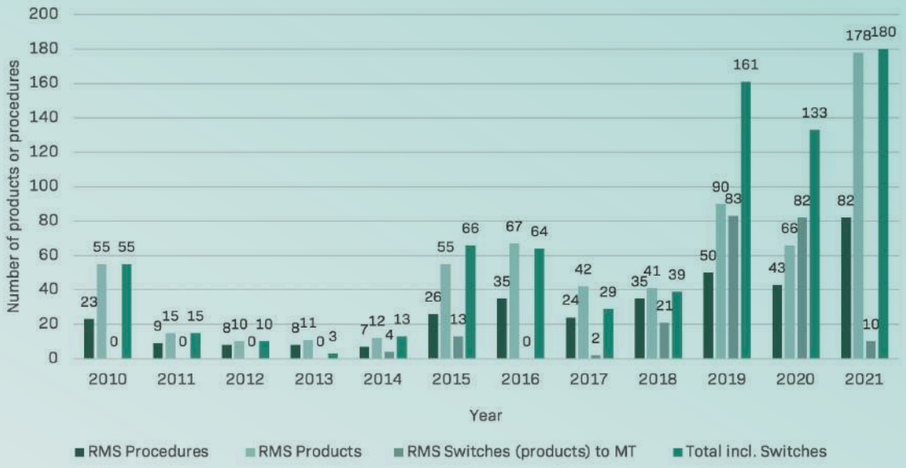


Figure 3.4:
A cumulative overview of applications as number of procedures (and resulting product authorisations) with Malta as Reference Member State, inclusive of RMS switches (2010-2021)

In 2021, one hundred and seventy-eight (178) applications were submitted with Malta as RMS whereby seventy-eight percent (78%, n=139) were duplicate applications, seventeen percent (17%, n=30) were Lead Procedures and five percent (5%, n=9) were Repeat Use Procedures (RUP) **(Figure 3.5).** 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 2022. In 2021 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.

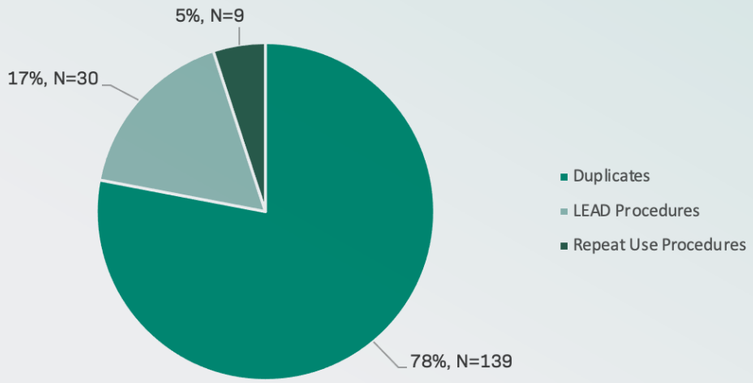


Figure 3.5:
Types and number of procedures with Malta as Reference Member State (N=178)

MALTA AS A CONTRIBUTOR IN EUROPEAN PROCEDURES

The number of MA applications in the MRP and DCP received in 2021 with Malta as CMS (n=162 products) resulted in the granting of eighty-two (82) MAs. **Figure 3.6** and **Figure 3.7** show the applications started and finalised by Malta through this route compared to other Member States. As can be seen from both figures, the size of the market and economies of scale determine the extent that smaller Member States are included as CMS in European procedures by pharmaceutical companies. However, during year 2021, there has been an increasing use of the Day 0 MRP by companies, following discussions between the MMA, stakeholders, and other NCAs to facilitate this procedure and make it more feasible for companies to include Malta in European procedures for products that have already been authorised in another Member State.

STARTED Procedures – MRP/DCP per CMS
Total: 366 MRP and 1144 DCP (regarding 703 and 2342 products respectively)

Figure 3.6:
Applications started by all Member States as Concerned Member State, including Malta, in Mutual Recognition Procedures/Decentralised Procedures in European Union in 2021 (N=366 MRP, N=1144 DCP) (source: CMDh statistics)

FINALISED Procedures - MRP/DCP per CMS
Total: 354 MRP and 954 DCP (regarding 722 and 1943 products respectively)

Figure 3.7:
Applications finalised by all Member States as Concerned Member State, including Malta, in Mutual Recognition Procedures/Decentralised Procedures in European Union in 2021 (N=354 MRP, N=954 DCP) (source: CMDh statistics)

Figure 3.8:
An overview of applications for procedures (and resulting product authorisations) with Malta as Concerned Member State

Figure 3.9 gives an overview of the registration of medicinal products over the period 2010-2021 by the MMA. The relatively constant number of authorised products, in spite of the loss of medicinal products that were withdrawn because of Brexit, was mainly due to an increase in the number of MRP and authorisations in accordance with Article 126(a) of Directive 2001/83/EC (AA), especially during 2021.

Figure 3.9:
An 11-year overview of products registered in Malta by route of registration.

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. In 2021, the Malta Medicines Authority has also received a substantially higher number of batch specific requests to cover exemptions needed to maintain as many products on the market as possible, particularly from issues related to Brexit.

Post-authorisation activities, especially for procedures where Malta is a RMS, maintained consistent numbers, 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 three hundred and seven (307) variation applications in this category with resulting changes to five hundred and ninety-seven (597) products in procedures where Malta is the RMS.

Figure 3.10:
An 11-year overview of the number of variation applications (with resulting product changes) received for procedures with Malta as Reference Member State

The portfolio of procedures where Malta is the rapporteur or co-rapporteur in the centralised procedures continues to increase as Malta takes on new procedures each year. Thirty-three (33) post-authorisation activities for centralised procedures where Malta is rapporteur were reported for 2021. Twenty-four (24) were variations, including Type 1B and Type II variations, while nine (9) were renewal of MAs **(Figure 3.11)**.

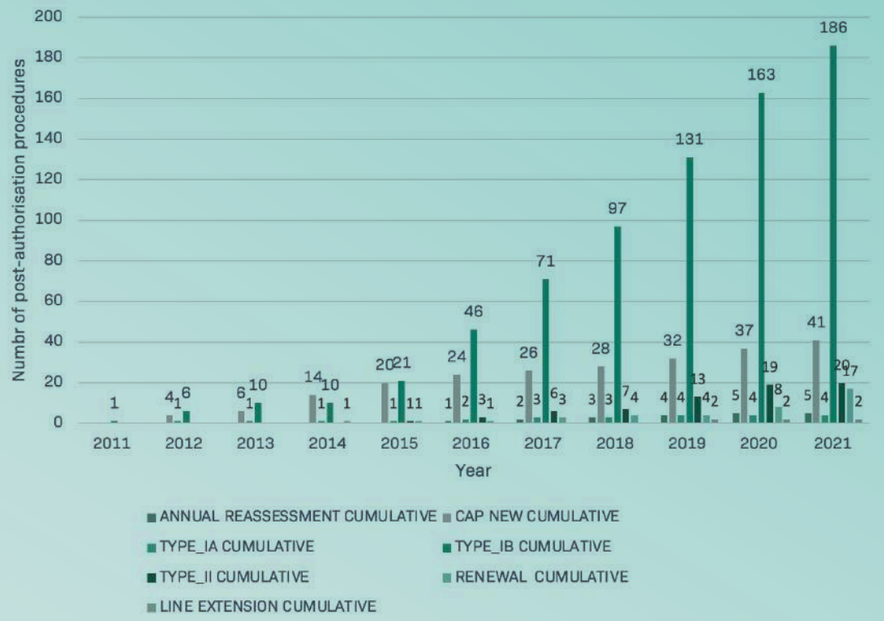


Figure 3.11:
Cumulative number of procedures with Malta as co-/rapporteur in the centralised procedure

In 2021, the MMA as Concerned Member State, received three thousand, six hundred and fifty-two (3,652) MRP variation applications and other post-authorisation procedures including one hundred and fifteen (115) renewals and one hundred and seven (107) Article 61(3) notifications **(Figure 3.12)**.

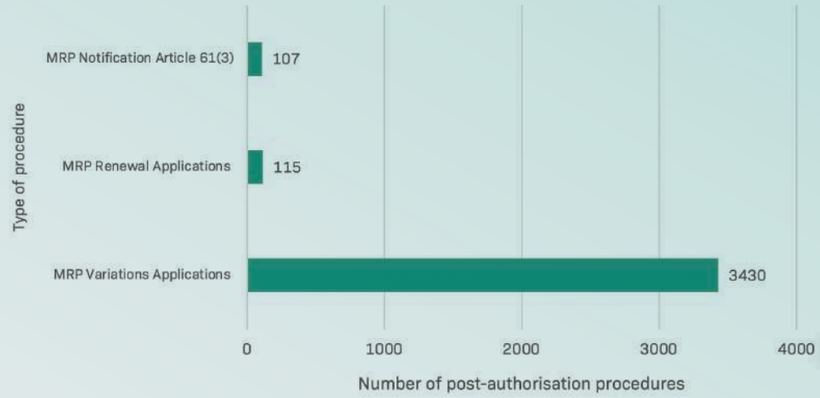


Figure 3.12:
Post-authorisation procedures received by Malta as Concerned Member State in the Mutual Recognition Procedure

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.

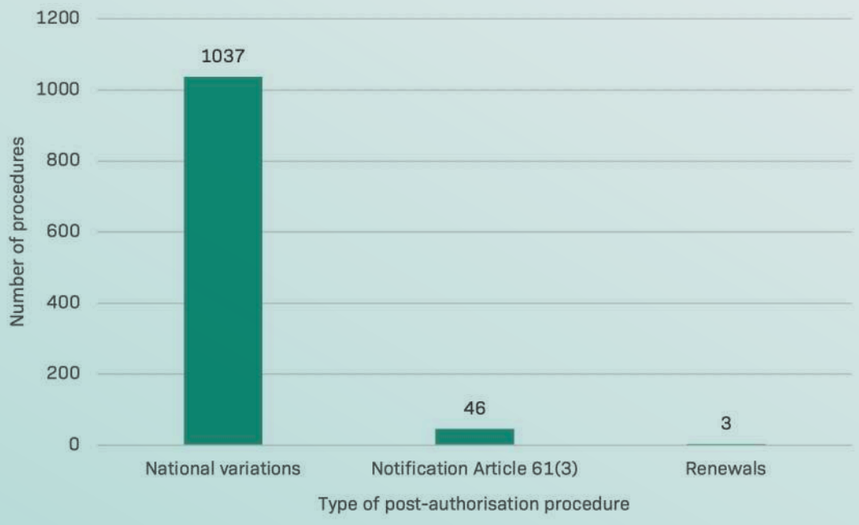


Figure 3.13:
Number of post-authorisation procedures for national Marketing Authorisations in 2021 (N=1086)

In 2021, three hundred and thirty-four (334) post-authorisation procedures were carried out in accordance with Article 126(a) of Directive 2001/83/EC. **Figure 3.14** show the number of post-authorisation procedures for parallel import licences, including renewals and variations.

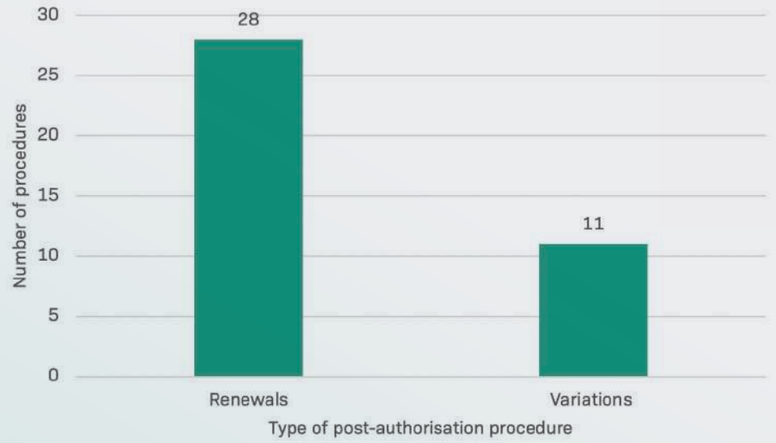


Figure 3.14:
Number of post-authorisation procedures for parallel import licences in 2021 (N=39)

Figure 3.15 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 where possible. Where there are no alternatives, the MMA engages with the company requesting the withdrawal and tries to find a way to maintain the product on the market.

Figure 3.15:
Number of withdrawal applications for Marketing Authorisations and licences received in 2021 (N=443)

IMPACT OF BREXIT ON THE MALTA MEDICINES AUTHORITY

In 2021, Brexit continued to be a distinct challenge. Through coordinated endeavours, the MMA continued to support public and private pharmaceutical stakeholders to proactively address the implications of Brexit on the availability of medicines on the local market. The Authority had several meetings with individual companies to assist in the registration of products, particularly by encouraging companies to use the Day 0 Mutual Recognition Procedure. Meetings with a number of European NCAs were also held to discuss how these agencies can support Malta by agreeing to be more active as RMS for day 0 procedures and to revise fees for this practically administrative procedure. This procedure is particularly useful for products that are already authorised in one or more European countries where a company would not otherwise find it feasible to run another MR procedure for a small country like Malta. The number of day 0 procedures in 2021 increased by 57% from year 2020.

Following discussions and bilateral meetings regarding the accessibility and availability of medicines in Malta, the EC published the Commission Notice on the Application of the Union's pharmaceutical acquis in markets historically dependent on medicines supply from or through parts of the United Kingdom (UK) other than Northern Ireland. This will give some additional time for companies to move their activities from the UK to the EU whilst also allowing the supply of products from the UK in case of challenges with availability and shortage issues.

COMMITTEES, WORKING GROUPS AND NATIONAL ADVISORY SERVICES

During 2021, the Prescription Status Working Group (PSWG) continued to work on the harmonisation of the legal classification of medicinal products (prescription versus non-prescription). 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 2021, forty-five (45) applications for the classification of borderline products were received, out of which twenty-five (25) were considered as non-medicinal and seven (7) 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 advice regarding the development of medicinal products through the participation in the Scientific Advice Working Party (SAWP) of the EMA. In 2021, the MMA fully participated in twenty-one (21) scientific advice requests through the SAWP and one (1) national scientific advice procedure was received and finalised.

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 of the MMA 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 2021, 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 2021, included the participation in two (2) online webinars for healthcare professionals as well as the sixth annual ADR awareness week campaign (#MedSafetyWeek) held between 1 and 7 of November 2021 with the aim to raise awareness and encourage healthcare professionals and the public to report suspected side effects related to vaccines. During this week humorous animations (sample animations **Figure 3.16**), videos, infographics and other material were uploaded to the Authority's social media platforms.

Figure 3.16:
Sample animations used for the social media campaign on Adverse Drug Reaction reporting held during November 2021.

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 nine hundred and twelve (912) Individual Case Summary Reports (ICSRs) were registered in 2021. These cases detailed at least one (1) ADR to the medicinal product concerned and together these 912 ICSRs resulted in three thousand and one (3001) suspected ADRs. **Figure 3.17** gives a breakdown of these ADRs according to System Organ Class (SOC) classification.

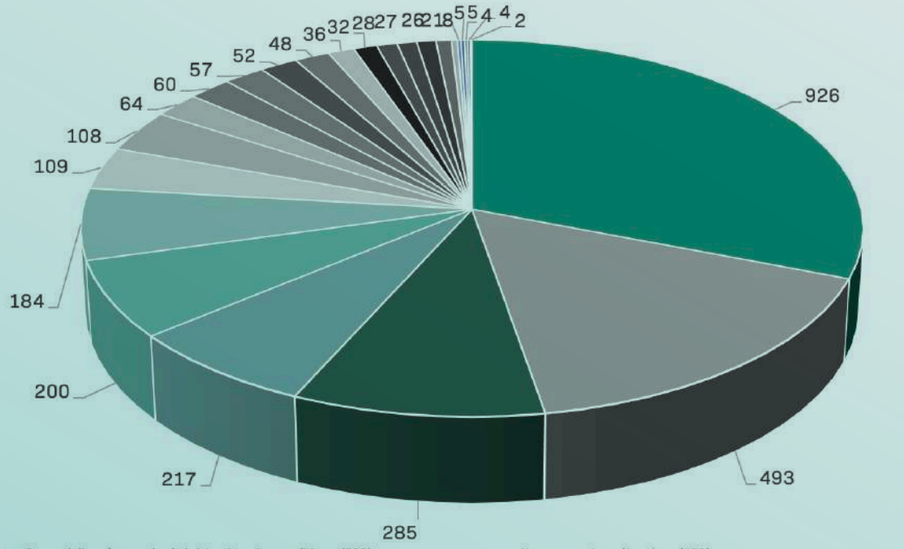


Figure 3.17:
Distribution of Adverse Drug Reactions according to System Organ Classification in 2021 (N=3001)

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 3.18 and **3.19** further classify the adverse ICSRs (as received over 2021) 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.

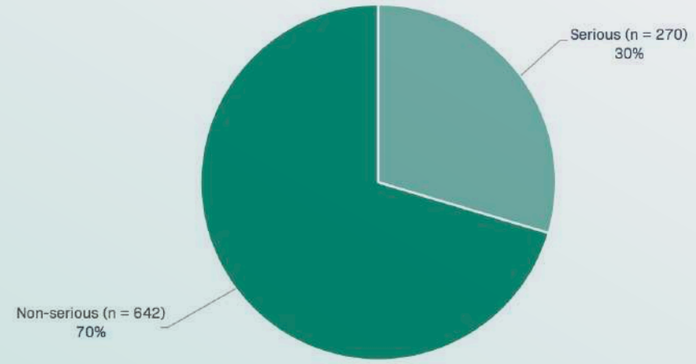


Figure 3.18:
Frequency of Individual Case Summary Reports according to seriousness in 2021 (N=912)

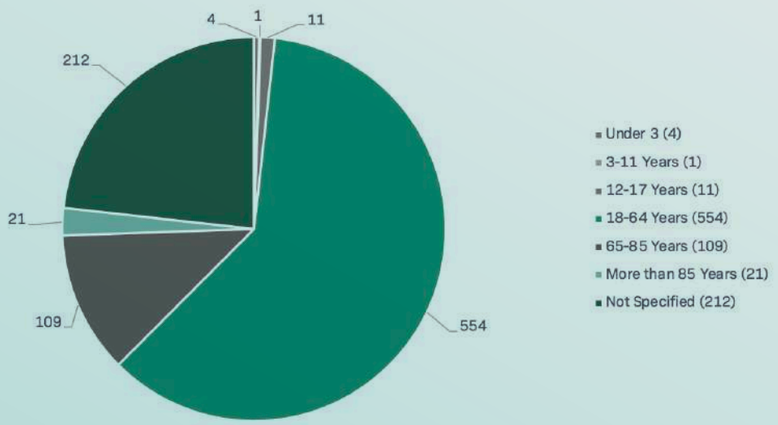


Figure 3.19:
Distribution of Individual Case Summary Reports according to patient age in 2021 (N=912)

In addition to the management of ADRs, several other activities were undertaken nationally by the Authority in 2021 for purposes of attaining effective product safety surveillance. Such activities (amongst others) include the:

(1) 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;

(2) 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);

(3) 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;

(4) 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 2021 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;

(5) Initiation and subsequent approval of variations to scientific medicinal product information relating to identified novel or increased risk (Urgent Safety Restrictions) and assessment of Periodic Safety Update Reports (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 Periodic Safety Update Report Single Assessments (PSUSAs) work-sharing at an EU level.

Table 3.1 below gives the distribution of Safety Communications and Risk Minimisation Measures (RMMs) approvals which the MMA handled over 2021.

Activity	Number of safety communications and RMM approvals
Direct Healthcare Professional Communications	8
Joint DHPCs	11
Safety Circulars	10
Risk Minimisation Measures	93

Tabel 3.1:
Safety Communications and Risk Minimisation Measures approvals in 2021

Area Queried		Number (n)
1	Submission requirements of PSURs / PSUSAs	8
2	National Pharmacovigilance legislation and requirements locally	7
3	Literature monitoring requirements	5
4	RMPs / RMMs / Educational Material	5
5	ADR Reporting / ICSR transmission requirements	4
6	Qualified Person for Pharmacovigilance/Local Contact Person for pharmacovigilance	4
7	Request for Information for research	3
8	Safety Signal Detection	2
9	Others	2
10	Post-Authorisation Efficacy Studies (PAES) and Post-Authorisation Safety Studies (PASS)	1
11	Data Protection and Pharmacovigilance	1
Total		**42**

Tabel 3.2:
Pharmacovigilance related queries in 2021 (N=42)

An additional stakeholder service performed by the MMA is that of responding to any queries related to Pharmacovigilance activities in a timely manner. In 2021, queries received were mostly related to submission requirements of PSURs/PSUSAs, national pharmacovigilance legislation and requirements locally, and literature monitoring requirements **(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 2021, 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 and national legislation that was put in place to implement the Directive.

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. For 2021, no advertising complaint procedures are pending.

MEDICINES INTELLIGENCE AND ACCESS

The Medicines Intelligence and Access Unit leads noteworthy initiatives to enhance access to medicines through a proactive patient-centred approach.

The MIAU intervenes to support consumers, healthcare professionals and patient organisations in their enquiries related to availability of medicines on the local market and supports stakeholders by assisting in the sourcing of medicines in demand. In 2021, the Medicines Intelligence and Access Unit handled on an individual basis eighty-two (82) queries related to medicine shortages, pharmacoeconomic, registration and safety issues **(Figure 3.20)**.

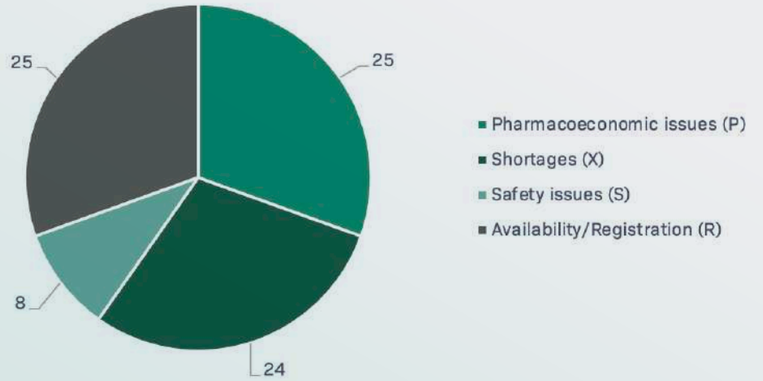


Figure 3.20:
Number of interventions by the MIAU in 2021 (N=82)

In 2021, COVID-19 and Brexit continued to be a distinct challenge. Through coordinated endeavours, the MIAU supported public and private pharmaceutical stakeholders to facilitate the continuous provision of medicines. The Licensing Authority delegated the assessment of Article 20 exemption requests to the MMA, where the latter has invested in a competence infrastructure within the MIAU to fulfil these duties. The Authority liaises with the concerned public and private partners during the vetting process and following a thorough review, it issues a recommendation to the Licensing Authority to grant or refuse the request, together with conditions attached to the approval.

An exemption in accordance with Article 20 of the Medicines Act (Chapter 458 of the Laws of Malta) may be considered by the Licensing Authority to place a medicinal product on the Maltese market in the absence of a Marketing Authorisation in response to exceptional and justified public health reasons. The Article 20 exemption is reserved solely as an interim measure when all the options to register the medicinal product through a Marketing Authorisation, authorisation in line Article 126(a) of Directive 2001/83/EC and parallel importation have been exhausted as possible sourcing routes to supply the medicinal product.

In 2021, 368 Article 20 exemption requests were approved. Figure 3.21 describes the classification of medicines approved through Article 20 exemption according to therapeutic class.

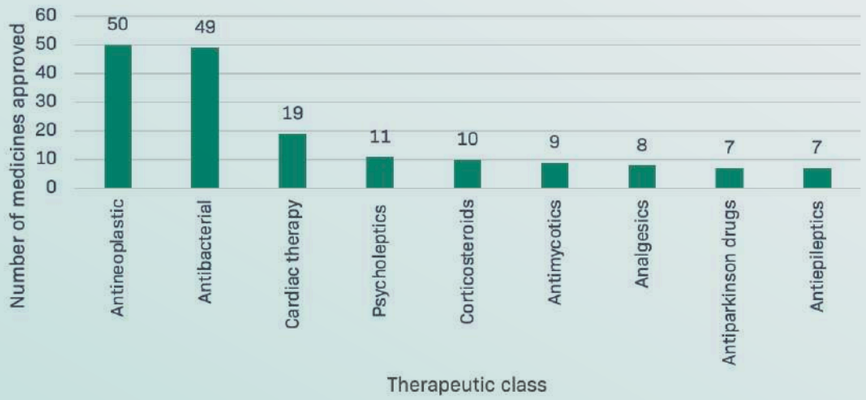


Figure 3.21:
The number of prominent therapeutic classes according to the number of medicines approved by Article 20 exemption in 2021

The reliance of the availability of medicines on the Maltese market which are sourced from the UK is depicted in **Figure 3.22**. This dependence is multifactorial and could be the result of the lack of interest from EU pharmaceutical operators to market their products in small Member States like Malta, but also due to issues of labelling where packs sourced with product information in the English language are deemed acceptable for the local market without the need of over/re-labelling. Only 26.5% of the approved Article 20 requests are sourced from EU markets **(Figure 3.22)** which aligns with principles of best regulatory practice to promote the registration of products on the market prior to resorting to the Article 20 exemption.

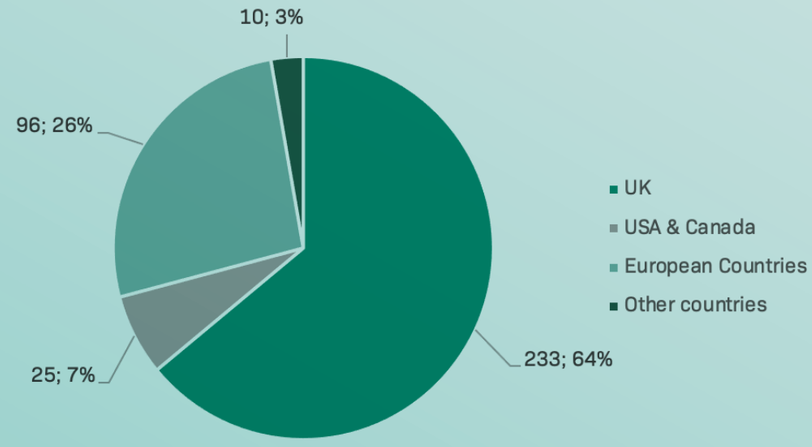


Figure 3.22:
The country of source of medicines approved by Article 20 exemption in 2021 (N=364)

REGULATING MEDICAL DEVICES

The Medical Device Unit was upgraded to a Directorate in November 2021 reinforcing the commitment of the MMA in placing patient safety at the centre of all its regulatory activities by applying the robust regulatory principles to the field of medical devices. The pharmaceutical activities of the new Directorate were broadened to incorporate collaborative and entrepreneurship initiatives to further assure the safety, quality and efficacy of medicinal products and medical devices on the Maltese market whilst advancing the sharing of expertise at an international level. In view of this, ten (10) sessions for internal training were held during the year and eight (8) sessions were held for external stakeholders. Staff was given preference and priority for attendance in external sessions to further increase opportunities.

One of the roles of the MMA as the NCA for medical devices is to designate and continuously monitor the performance of NBs registered in Malta. In Q1 2021, the MMA received the second application for the designation as a NB under the Medical Device Regulation (MDR) 745/2017 reflecting the need for Malta's contribution to the area of designation of NBs given the lack of notified bodies for medical devices.

STAKEHOLDER FOCUS

The Medical Devices, Pharmaceutical Collaboration and Entrepreneurship Directorate staff were directly involved in raising awareness and increasing the knowledge of stakeholders on their legal obligations pertaining to the new regulations, by proactively participating in seminars and training sessions as speakers, in collaboration with the MMA Academy and the Malta Laboratories Network (MLN). The staff in the Directorate participated in a total of eighty (80) International Medical Device Coordination Group (MDCG) meetings and European Commission working groups and one hundred and ninety-three (193) meetings held locally involving local governmental entities, such as Central Procurement and Supplies Unit (CPSU), Mater Dei Hospital, the line ministry and meetings with stakeholders involved in the medical devices industry both locally and internationally. Collaboration with stakeholders was also enhanced through the receipt and processing of total of two hundred and seventy-eight (278) queries received in 2021 of which two hundred and twenty-one (221) were positively closed.

VIGILANCE

A total of seventy-four (74) incident reports were received with thirty-two (32) closed and forty-two (42) ongoing investigations. A total of four hundred and seventy-five (475) Field Safety Corrective Actions (FSCA) were received with four hundred and twenty-one (421) closed and fifty-four (54) ongoing investigations **(Figure 3.23)**.

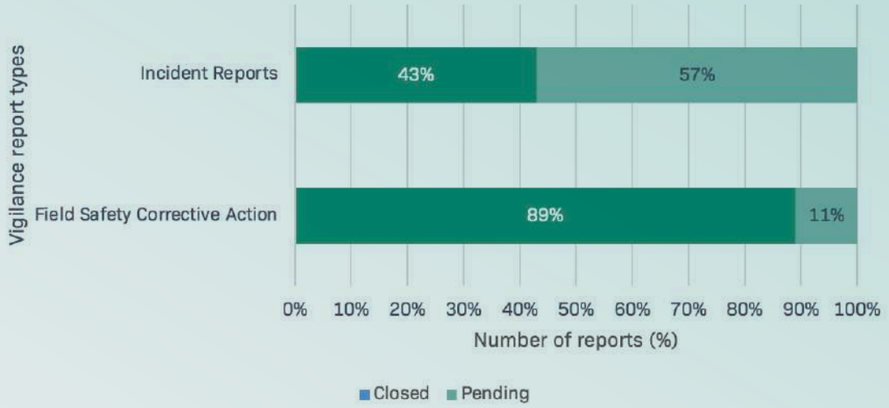


Figure 3.23:
Percentage number of incident reports and Field Safety Corrective Actions in 2021

AUTHORISATION ACTIVITIES

During the year 2021, the MMA received applications for different authorisation activities including: one (1) notified body, three hundred and forty-four (344) Medical Device registrations, one hundred and twenty (112) COVID-19 designated premises, twenty-four (24) COVID-19 RAT notifications and forty-seven (47) certificate for free sales.

COVID-19 IMPACT

The pandemic led to a significant rise in work in the area of medical devices. This included the establishment of National Legislation for testing and reporting protocols. Increased activity in market surveillance for work relating to COVID-19 testing kits, surgical masks, designation of premises and other affected In-Vitro Diagnostics (IVDs). A national list of approved RAT kits was created and maintained through a dedicated application and internal procedure. Information dissemination and seminars were held with stakeholders to respond to queries and facilitate the obligations brought by the pandemic.

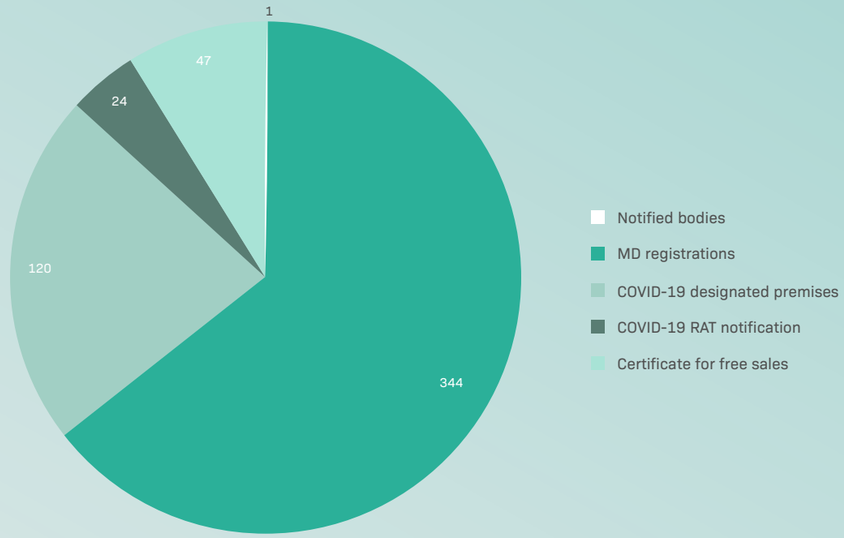


Figure 3.21:
Number of applications for different authorisation activities received in 2021

PHARMACEUTICAL COLLABORATION

The Directorate was entrusted the Budgetary measure 69 of 2021 “Ntejbu l-faċilitajiet tal-laboratorji nazzjonali, fosthom dawk għal skopijiet ta’ sorveljanza u ttestjar tal-kwalità tal-mediċini”, which involves establishing a local Official Medicines Control Laboratory (OMCL) facility. A preliminary feasibility study and a needs analysis study including a cost benefit study were carried out. The national OMCL in Malta would serve to meet threats and embrace opportunities that arose as a result of Brexit, serve more effectively and efficiently the needs currently serviced by overseas laboratory providers, reduce timeframes and cost incurred to analyse samples and provide a source of technical expertise in innovative areas.

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 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.

PHARMACEUTICAL 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-three (73) 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 2021, the MMA carried out twenty-seven (27) local GMP inspections for new, renewal or follow up of GMP licences/certificates. These included:

- Three (3) inspections for cannabis for medicinal or research purposes;
- One (1) inspection for sterile dosage forms;
- Five (5) inspections for full-line non-sterile solid dosage forms manufacturers;
- One (1) inspection for Active Pharmaceutical Ingredients (APIs) manufacturers;
- Two (2) inspections for medicinal gases manufacturers;
- One (1) inspection for a GMP-certified laboratory;
- Two (2) inspections for MAs of repackaging and re-labelling/partial manufacturing operations;
- Twelve (12) inspections for Mas of import activity' to Twelve (12) inspections for MAs of import activity.

Moreover, in 2021 the MMA:

- Processed forty-two (42) MAs administrative variation applications for manufacturers and importers;
- Processed three (3) application variations which required a GMP inspection.
- Held seven (7) Inspections Review Group (IRG) meetings, wherein four (4) cases were discussed and decided upon; and
- Received three hundred and thirty-five (335) rapid alerts and GMP non-compliance notifications, which were investigated, four (4) 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 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-three (93) 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 2021, the MMA fulfilled its GDP inspection plan by carrying out thirty-eight (38) GDP inspections. Nine (9) applications for new wholesale dealing licenses were submitted, two (2) of which were licensed after having satisfied all the criteria in a thorough inspection by the end of the year. Another three (3) applications submitted in 2020 were licensed during the year 2021.

Furthermore, fifty (50) variation applications for wholesale dealing authorisations were processed in 2021, out of which nine (9) required an inspection. In 2021, two (2) new applications for brokerage activity were received, out of which one (1) was eventually registered.

THIRD COUNTRY INSPECTIONS

During the year under review, the MMA carried out three (3) onsite GMP Inspections in countries outside the EU, whilst another four (4) GMP inspections in countries outside the EU were carried out through distant assessment/virtual inspections due to safety and travel restrictions being in place because of the ongoing COVID-19 Pandemic **(Figure 4.1)**. These distant assessment/virtual inspections were carried out for sites already previously inspected in order to vary or renew existing GMP certificates issued by the MMA. Good Manufacturing Inspections in countries outside the EU were generally interrupted due to COVID-19 pandemic travel restrictions. Incoming applications were still validated and put on hold so as these can be processed, and inspections carried out onsite 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 Authority and provide exposure to different manufacturing facilities to the inspectors of the MMA.

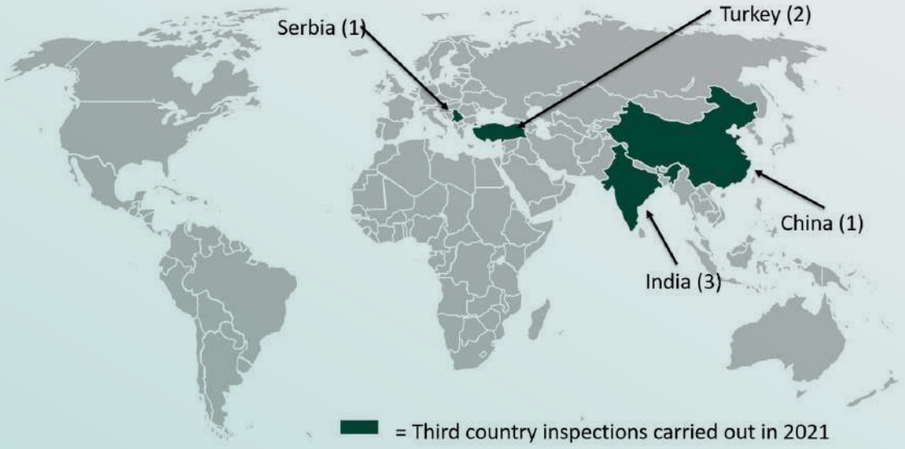


Figure 4.1:
Number of third country European Union Good Manufacturing Practice inspections carried out in 2021 (N=7)

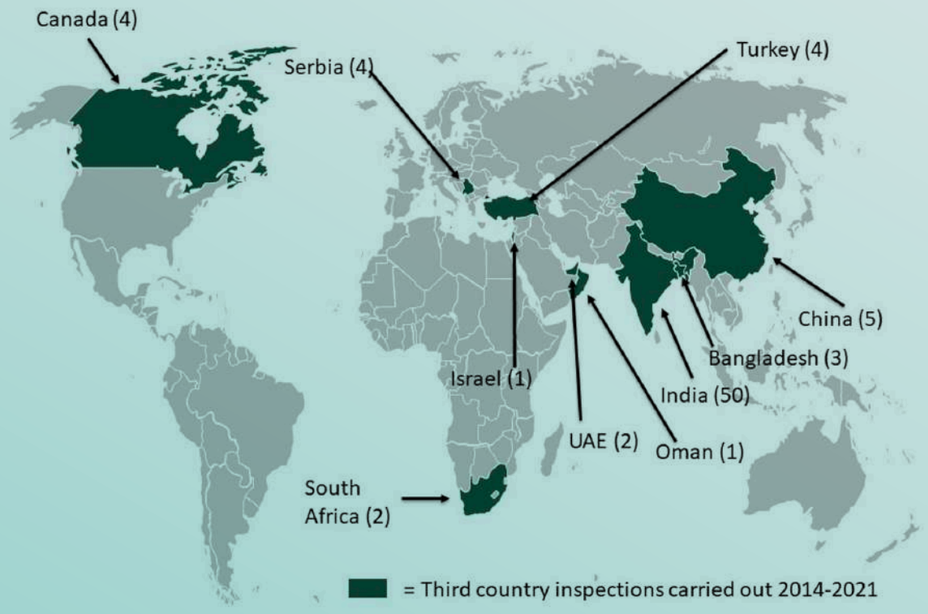


Figure 4.2:
Good Manufacturing Practice third country inspections carried out over a 6-year period (2014-2021), (N=76)

PHARMACIES, PHARMACOVIGILANCE AND SURVEILLANCE OF THE LOCAL MARKET

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

During the COVID-19 pandemic, the MMA continued to inspect pharmacies with an innovative approach of the self-assessment which incorporates the element of risk analysis which streamlines the inspection process of pharmacies by reviewing the inspection frequency based on risk score computation. The self-audit checklist with the criteria for which evidence was requested, was sent to the pharmacies according to an inspection plan whereby two hundred (200) desk reviews were performed upon receipt of the report. According to the new risk assessment, collaboration with the Inspection Coordination Office continued towards the launch of the Certificate of High Standard of Compliance for the upcoming year.

During 2021, five (5) spot-check pharmacy inspections were carried out, nine (9) pharmacy relocations were approved, two (2) new pharmacy licences were issued and forty-eight (48) administrative variations for pharmacy licences were processed. Seven (7) pharmacovigilance inspections were performed in 2021 for local manufacturers.

Moreover, in 2021 the MMA pursued its collaboration with the UK's NCA so that the latter carried out testing in an OMCL for medicinal products under surveillance of the MMA. In this regard, the Local Market Surveillance Plan for 2020 was closed positively. In 2021, seven (7) products were sampled from the local market and were sent for analysis for the Market Surveillance.

During 2021 the MMA worked on six (6) enforcement cases/investigations which were related to complaints. The Enforcement Committee (a specific committee which discusses enforcement cases, chaired by the Licensing Authority) was not required to meet in 2021.

In 2021, the MMA attended two (2) court cases sittings in which the Authority's employees were summoned as witnesses.

GRANTING OF QUALIFIED PERSONS STATUS AND CERTIFICATION OF PHARMACEUTICAL PRODUCTS

In 2021, the MMA received eighteen (18) new applications for the Qualified Person (QP) eligibility status. Seven (7) applicants were interviewed and granted a QP status. Four (4) other applicants that submitted the application in 2020 were interviewed and approved in 2021. The Authority also received and processed four hundred and thirteen (413) applications which satisfied the required criteria and were granted the Certificate of Pharmaceutical Product.

TRANSLATING REGULATION INTO A PATIENT-CENTRED SCIENCE

5

The MMA is a key European and International player in regulatory sciences, engaging in the exchange of best practices and guiding policies, with all efforts concerted in the best interest of patients. To uphold the recognised successes and support innovative growth, the Authority continues to advance its armamentarium of skills and competences which mature to be able to respond to global dynamics in regulation.

In its efforts to strengthen proficiency in regulatory sciences, the MMA fosters investment in continuing professional training and development as well as participation in European and international fora. One noteworthy example is the EU Network Training Centre (EU-NTC) through which a varied array of courses are accessed annually by MMA professionals. The MMA has not only embraced the national drive towards advanced education, innovative research and sustainable development internally within the organisation, but is inviting stakeholders to join in picking up momentum on a mission for mutual benefit. The consolidated expertise and experience is being leveraged in the design and delivery of interactive courses that engage stakeholders in our approach to enhance competence for sustainable progress in the life sciences sector.

The Academy, under the auspices of the MMA, marks another achievement in the strides made by the Authority's professional workforce, in collaboration with pertinent national and international bodies, sustaining the Authority's commitment to progress research, training and education, embraced as key elements in the MMA's portfolio and forward-looking strategy. In an ever-evolving context, it seeks to adapt whilst learning from the environment to recognise need for change and encouraging ongoing training at all levels to support a high-performance culture. The MMA, through its Academy, is fostering positive engagement for a 'patient-centred' approach which is endeavoured to disseminate widely, with the understanding that is being served to the patient. The diverse group of stakeholders, including patient groups, healthcare professionals, industry, academia, government and non-governmental organisations, may create challenges. The Academy shall serve to create a community in which team members are committed to putting the patient's interest first, inspire innovation, and serve one another to achieve their goals which will in turn translate to quality services, efficiencies and outcomes.

The MMA Academy invites the involvement of stakeholders to further identify educational needs for the development of programmes, prospectively even online, that address emerging expectations. A number of programmes are being planned in response to stakeholder feedback, covering the areas of pharmacovigilance, medicinal cannabis, as well as quality systems and auditing in a pharmaceutical environment. Through these courses, the Academy seeks to provide a forum where national and international participants share ideas, discuss opportunities and overcome challenges. Projects of this kind, spearheaded by the Advanced Scientific Initiatives Directorate, strengthen the sustainability of the Authority while boosting the progress of the pharmaceutical sector and life sciences in our country.

The continuation to pursue an inherent philosophy is focused on conscious choice that service to others, whether they are employees, stakeholders or the community at large, is crucial to achieving a realistic service of excellence. This is embedded in the collaborative spirit and resilience of the MMA, particularly in unpredictable contexts that require us to confidently step out of the status quo to overcome challenges and embrace new opportunities.

Undoubtedly, this year, COVID-19 vaccines have dominated the scene of scientific innovation. The MMA is constantly exploring ways to renew its operations, including studies which are exploring the sustainability of advanced activities in the field of vaccines. In collaboration with competent authorities in the EU, discussions have been launched to assess the feasibility of initiatives leading to greater accessibility of quality, effective and safe vaccines for all. Preliminarily, the MMA is aiming at identifying the scientific needs and technical resources needed to meet current and future needs pertaining to a pandemic scenario. Such work may pave the way for extensions to vaccine-specific regulatory capacities and possibly lead to the expansion of the Authority's portfolio to include biological products. These approaches for spurring economic growth, meeting medical needs, and strengthening areas of scientific excellence represent the core impetus shared by the MMA through stakeholder engagement to embark, with trust, on a journey of mutual concern to deliver, genuinely and efficiently, to our patients.

The Advanced Scientific Initiatives Directorate upholds sustained liaison with external experts and relevant bodies (including Superintendence of Public Health (SPH), Attorney General (AG), Malta Enterprise, Malta Competition and Consumer Affairs (MCCAA), Malta Business Registry (MBR), UOM, MLN, International Narcotic Control Board (INCB), Malta Police Force (MPF), Customs Department, Ministries, regulatory counterparts, and the newly established Malta Chamber Medical Cannabis Business Section) as well as continuous interaction with consultancy firms, legal advisors, and company representatives intending to invest in the medicinal cannabis industry. Through 2021, the Research, Scientific Affairs and Innovation Unit pursued with work related to cannabis for medicinal and research purposes. The regulation of medicinal cannabis in Malta follows systems comparable to those implemented for the pharmaceutical industry, with particular emphasis on quality standards and established manufacturing practices. In recent months, two new licenses were issued for local commercial production, while there have been substantial developments in the activities of other applicants in the licensing process. Meanwhile, there are five approved cannabis-based products in Malta, while evaluations of other products are continuing to ensure patient access to preparations which are stable throughout their shelf-life, free of contaminants, pesticides, bacteria, fungi and heavy metals. The MMA's work on Perspectives in quality control of cannabis for medicinal purposes was presented at the 12th World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology in May 2021, while further research is ongoing including doctoral projects by professionals affiliated to the MMA studying analytical aspects and laboratory considerations for the regulation of cannabis-based products and the implications of cannabis for medicinal purposes.

CANNABIS FOR MEDICINAL AND RESEARCH PURPOSES – WHOLESALE DISTRIBUTION OF MEDICINAL CANNABIS

In line with Article 10 of the Drug Dependence (Treatment not Imprisonment) Act (Chapter 537 of the Laws of Malta), patients may access medicinal cannabis preparations produced under GMP, as per the relevant provisions and prescribing protocols established by the SPH. The MMA reviews applications for the sourcing of cannabis-based products, intended for the local market, ensuring the fulfilment of a number of requisites, such as EU-GMP certification, batch release specifications, certificates of analysis, stability studies and labelling.

A total of twenty-nine (29) new applications for 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 2021, alongside eleven (11) renewal applications. A notification of approval was issued for five (5) dried flower products, with two (2) products having concentrations of 22% THC/<1% CBD and the other three (3) products having concentrations of 20% THC/<1% CBD, 6.3% THC/8% CBD and 18% THC/<1% CBD respectively.

The MMA provides serialised tamper-evident labels for each individual patient pack sourced to Malta **(Figure 5.1)**, ensuring supply chain traceability from the licensed distributor(s) to the patients, to whom the products are dispensed from pharmacies. Adverse reaction reports are managed through set procedures, in liaison with clinical assessor(s), as applicable. Since the first product approval in 2018, one (1) adverse reaction report was received in 2020 and assessed accordingly. The portfolio of approved cannabis-based products is followed up with annual renewal, review of emerging data including updated studies, and reconciliation audits reflecting import permits, serialisation records, supplies/sales, expiries and destruction practices as may be applicable.

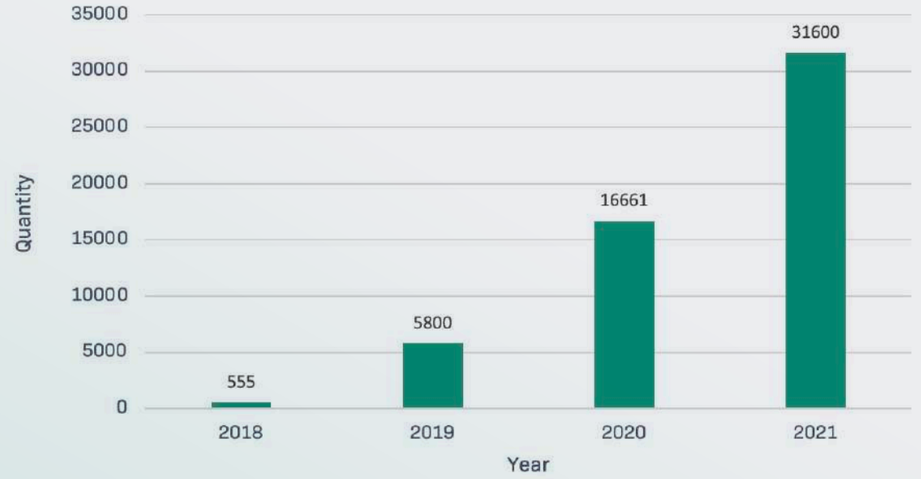


Figure 5.1:
Number of cannabis-based products serialised with tamper-evident labels for controlled access on the local market (2018-2021)

PRODUCTION OF MEDICINAL CANNABIS

In line with Chapter 578 of the Laws of Malta and its subsidiary legislation, the MMA reviews applications for the production of cannabis for medicinal and research purposes. The regulatory framework, as published in the respective MMA Guidelines, involves a number of aspects, such as EU-GMP and Good Agricultural and Collection Practices (GACP) compliance, product-specific considerations including analytical data, security screening of personnel and security audits of the manufacturing facilities.

A total of six (6) applications for the production of cannabis for medicinal and research purposes were received by the MMA to date. Through liaison with relevant bodies, ten (10) local inspections were co-ordinated, including five (5) for EU-GMP and five (5) for facility/physical security. By end 2021, a positive recommendation was issued for the granting of three (3) commercial licences, and two (2) corresponding licence variations. The licensed operations include the production of four (4) products in dried flower form and four (4) oils with a varied range of THC/CBD concentrations and pack-sizes. Individual final product packs released from the local facilities are also issued with unique randomised serial numbers; 3300 serial numbers were issued in 2021. Such practices support reconciliation exercises carried out according to international requirements, for the traceability and monitoring of cannabis material via established reporting procedures.

ACADEMY FOR PATIENT CENTRED EXCELLENCE AND INNOVATION IN REGULATORY SCIENCES

The MMA is committed to sustain a strong knowledgebase, enhance the scientific acumen, share best practices and embrace continuous improvement. In 2021, the Educational Planning and Academic Development Unit, within the Advanced Scientific Initiatives Directorate, prioritised the implementation of a sustainable framework for the MMA Academy for Patient Centred Excellence and Innovation in Regulatory Sciences, encompassing the apposite elements of accreditation, collaboration and optimization. Following a registration process through the Malta Further & Higher Education Authority (MFHEA), the MMA Academy was officially licensed as a Higher Education Institution (License No. 2021 – 004) in April 2021. This focal milestone in the recognised track-record of the MMA was pursued by development of the first three educational programmes accredited at Level 5 on the Malta Qualifications Framework.

The programme leading to an Award in GMP was held at the Malta Life Sciences Park in July 2021. Despite the global challenges brought about by the COVID-19 pandemic, the twenty-five hour face-to-face programme was enrolled by nineteen (19) local and international participants for the sharing of knowledge, strengthening collaboration, and advancing individual aptitudes in the prominent field of GMP. Topics considered included quality risk management in manufacturing operations, updates in sterile manufacturing, inspections, qualification, process validation, documentation and data integrity, and GMP as applicable to medicinal cannabis. All participants successfully completed the course and were granted a certificate.

The Award in medical devices was officially accredited in September 2021 and it was delivered via a blended mode, between November and December 2021, in collaboration with the British Standards Institution (BSI). Through this educational initiative, the twenty-seven (27) participants attained solid theoretical grounding in conjunction with practice-oriented implementation of key principles and requirements emanating from the recently established European MDR and In-Vitro Diagnostics Device Regulation (IVDR) along with recognised standards and guidelines. Specific topics considered include risk class of devices, safety and performance requirements, technical documentation, risk management, conformity assessments, post-marketing surveillance, and Good Distribution Practice. Interactive workshops on the Medical Device Management System as well as Organisation Registration and Medical Device Notification were planned, alongside a networking aspect. The uptake was remarkable, with the course being fully subscribed by national and international stakeholders, 96% of whom received certification as they successfully completed the course.

The Award in GDP, for which accreditation was granted in November 2021, is planned for online delivery in Q1 2022, through a collaborative initiative with The Organisation for Professionals in Regulatory Affairs (TOPRA). Such partnerships, alongside internal expertise and experience in the relevant fields, are enabling enrichment of programmes offered by the MMA Academy. The latter functions in line with an Internal Quality Assurance (IQA) Policy which attests the commitment to provision of high-quality education, continuous enhancement and accountability, whilst ascertaining that accredited programmes meet and exceed participants' expectations and bridge knowledge gaps identified through educational needs analysis.

The drive towards continued education, professional development and scientific exposures enables the identification of innovative strategic areas and tapping into funding opportunities, while supporting academic endeavours that enhance internal competence and meet stakeholder needs. In August 2021, the Seminar on Biosimilar Medicines spearheaded by the MMA Academy and part financed by the Internationalisation Partnership Awards Scheme Plus (IPAS+) of the Malta Council for Science and Technology, brought together over seventy (70) local and international participants working in the public and private health sectors for liaison on common grounds, consideration of current frameworks and working towards tangible progress. Keynote speaker Professor Philip James Schneider from the College of Pharmacy at the Ohio State University in Columbus, together with Dr Alex Kudrin, Biopharmaceutical Consultant from the United Kingdom and Dr Mark Cilia, Inspectorate and Enforcement Director at the MMA, delved into the rigorous requirements that must be met in the development of biosimilar medicines, pharmacovigilance aspects, prescribing and switching, economic considerations, the impact on healthcare and the future of the biosimilar medicines market. Barriers to uptake, in conjunction with factors that may contribute to the long-term sustainability of biosimilars were also considered.

Going forward, the MMA will be delivering another two educational initiatives for which grants were secured through the IPAS+ Scheme: Workshop on Dimensions of Cannabis for Medicinal and Research Purposes and Seminar on Vaccinology as relevant to COVID-19. These initiatives are intended for interested parties to join forces and proliferate further in line with the evolvement of paradigms in regulatory sciences.

PUBLICATIONS AND PRESENTATIONS

6

PUBLICATIONS

Almojero DC, Vella Szijj J, Azzopardi LM, Serracino-Inglott A. Perspectives of practices related to the implementation of the FMD. Regulatory Rapporteur. 2021; 18(7/8): 29-32.

Butler D, Vucic K, Straus S, Cupelli A, Micallef B, Serracino-Inglott A, Borg JJ. Regulatory experience of handling Risk Management Plans for medicinal products in the EU. Expert Opinion on Drug Safety. 2021; 20(7): 815-826, DOI: 10.1080/14740338.2021.1909569
Malta Medicines Authority Strategy to 2025. 2021: 1-39. file:///C:/Users/falzs066/Downloads/MMA%20Strategy%20to%202025.pdf

Sammut Bartolo N, Azzopardi LM, Serracino-Inglott A. Pharmaceuticals and the environment. Early Human Development. 2021;155:105218. https://doi.org/10.1016/j.earlhumdev.2020.105218

Serracino-Inglott, A. How to think like Francke for a global vision in challenging times. American Journal of Health-System Pharmacy. 2021.

Tejada E, Vella Szijj J, Cachia M, Falzon P, Azzopardi LM, Serracino-Inglott A. Effects of pH and amount of acetonitrile on the separation of cannabinoids. Asian J Pharm Clin Res. 2021; 14(4): 70-6.

Vella J, Attard Pizzuto M, Sammut Bartolo N, Wirth F, Grech L, Pham J, Mactal Haaf C, Lau A, Serracino-Inglott A, Azzopardi LM. A three-year post-graduate Doctorate in Pharmacy course incorporating professional, experiential and research activities: A collaborative innovative approach. MedEdPublish. 2021; 10(1): 1-14. https://doi.org/10.15694/mep.22021.000093.1

PRESENTATIONS

12th World Meeting on Pharmaceutics, Biopharmaceutics and Pharmaceutical Technology - 11-14 May 2021 (Virtual Conference)

Bezzina A, Attard Pizzuto M, Serracino-Inglott A, Azzopardi LM. Risk Assessment in Pharmaceutical Processes.

Camilleri L, Wirth F, Serracino-Inglott A, Azzopardi LM. Review of methods for TPMT biomarker genotyping in the personalisation of thiopurine therapy.

Grech S, Attard Pizzuto M, Serracino-Inglott A, Azzopardi LM. Perception of Risk Among Pharmaceutical Stakeholders.

Sammut C, Vella Szijj J, Serracino-Inglott A, Azzopardi LM. Software Validation in the Pharmaceutical Industry.

Vassallo S, Attard Pizzuto M, Serracino-Inglott A. Rare Diseases and Orphan Medicines.

Zahra M, Attard Pizzuto M, Serracino-Inglott A. Azzopardi LM. Understanding Risks in Pharmaceutical Processes.

Zuccarelli M, Borg JJ, Vella Szijj J, Azzopardi LM, Serracino-Inglott A. Emerging Treatments for Retinitis Pigmentosa.

25th EAHP Congress 23-28 March 2021 Virtual Conference

Rayner DL, Grech L, Serracino-Inglott A. The Role and Value of a Ward Based Pharmacist in the Intensive Care Unit: The Critical Care Physicians' and Nurses' Perceptions.

Vassallo S, Attard Pizzuto M, Serracino-Inglott A. Perception of Rare Diseases and Orphan Medicines.

Medicines Authority
Sir Temi Zammit Buildings, Malta Life Sciences Park
San Gwann SGN 3000, Malta

info.medicinesauthority@gov.mt