MALTA
MEDICINES
AUTHORITY

ANNUAL REPORT 2024

MALTA
MEDICINES
AUTHORITY

2024 Statistics at a Glance

Number of Employees

128

107 Technical

21 Administrative

237

QMS Internal Documents

12 Internal Audits Performed

MQF Levels

Lvl 6: 18

Lvl 7: 63

Lvl 5: 6

Lvl 8: 32

Academic qualifications of MMA employees

31

Finalised MRP/DCP procedures with MT acting as RMS

29 IFP Fellows

10 Research Publications

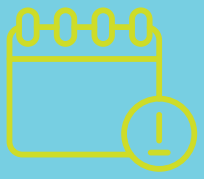
Scientific Advice

3 EMA SAWP Procedures

108 ICSR registered

Local 32 23 3rd Country

55 EU-GMP Inspections



272 Number of adverse events reported

67 Approved Cannabis-Based Products

3 Purified Extract

37 Dried Flowers

27 Oil

Formulations of Approved Cannabis-Based Products

25

EU-GDP Inspections

38 Free Sale Certificates for MDs

1273 MD Notifications Received

51 Strategic & Scientifc EU Participations

18 Certified QPs

719 Article 20 Exemption Requests Approved

ACRONYMS

µ	Micro
AA	126(a)
ADR	Adverse Drug Reaction
AE	Adverse Event
AI	Artificial Intelligence
AMA	African Medicines Agency
AMR	Antimicrobial Resistance
ANSM	Agence Nationale de Sécurité du Médicament et des produits de santé
API	Active Pharmaceutical Ingredient
ASID	Advanced Scientific Initiatives Directorate
ASR	Annual Safety Report
CAs	Competent Authorities
CAB	Conformity Assessment Bodies
CAPA	Corrective and Preventive Action
CAPs	Centrally Authorised Products
CBD	Cannabidiol
CEO	Chief Executive Officer
CHMP	Committee for Human Medicinal Products
CInMED	Institute for Medicines and Medical Devices of Montenegro
CMRU	Cannabis for Medicinal and Research Purposes Unit
CMS	Concerned Member State
COMP	Committee for Orphan Medicinal Products
COVID-19	Coronavirus Disease
CPPs	Certification of Pharmaceutical Products
CPSU	Central Procurement and Supplies Unit
CTD	Clinical Trials Directive
CTIS	Clinical Trials Information System
CTR	Clinical Trial Regulation
DC	Decentralised
DCP	Decentralised Procedure
DE	Germany
DHPCs	Direct Healthcare Professional Communications
DPU	Data Protection Unit
DSUR	Development Safety Update Report
EAHP	European Association of Hospital Pharmacists
EC	European Commission
EDQM	European Directorate for the Quality of Medicines and Healthcare
EEA	European Economic Area
EL	Greece
EMA	European Medicines Agency
EMRN	European Medicines Regulatory Network
EPAD	Educational Planning and Academic Development
EQF	European Qualifications Framework
ES	Spain
EU	European Union
EU-IN	EU Innovation Network
EUCD	EU Coordination Department
EU-GDP	European Union-Good Distribution Practice
EU-GMP	European Union-Good Manufacturing Practice
EU-NTC	European Union-Network Training Centre
EURD	European Union Reference Dates
EVDAS	EudraVigilance Data Analysis System
FCS	Finance and Corporate Services Unit
FEBS	Federation of European Biochemical Societies
FIP	International Pharmaceutical Federation
FOI	Freedom of Information
FOICU	FOI Coordination Unit
FR	France
FRCS(Ed)	Felowship of Royal College of Surgeons in Edinburgh
FSCA	Field Safety Corrective Actions
FSN	Field Safety Notices
GACP	Good Agricultural and Collection Practices
GCP	Good Clinical Practice
GDP	Good Distribution Practice
GMP	Good Manufacturing Practice
HCPs	Healthcare Professionals
HMA	Heads of the Medicines Agencies
HPRA	Health Products Regulatory Authority
ICO	Inspection Coordination Office
ICSRs	Individual Case Summary Reports
ICT	Information and Communications Technology
IE	Ireland
IED	Inspectorate and Enforcement Directorate
IFP	International Fellowship Programme
IMDRF	International Medical Device Regulation Forum

IPAS+	Internationalisation Partnership Awards Scheme Plus
IQA	Internal Quality Assurance
IRG	Inspections Review Group
ISO	International Organization for Standardization
IT	Italy
IVDR	In Vitro Diagnostics
IVDR	In Vitro Diagnostics Regulation
JAMS	Joint Action on Reinforced Market Surveillance of Medical Devices and In Vitro Medical Devices
LA	Licensing Authority
LD	Licensing Directorate
MA	Marketing Authorisation
MAH	Marketing Authorisation Holder
MCST	Malta Council for Science and Technology
MD	Medical Doctor
MDH	Mater Dei Hospital
MDITF	Medical Devices Inspector Task Force
MDMS	Medical Device Management System
MDPCD	Medical Devices and Pharmaceutical Collaboration Directorate
MDR	Medical Device Regulation
MDRP	Medical Device Registered Person
ME	Malta Enterprise
MFHEA	Malta Further and Higher Education Authority
MHRA	Medicines and Health Regulatory Agency
MIA	Manufacturer's/Importation Authorisation
MIAU	Medicines Intelligence and Access Unit
MMA	Malta Medicines Authority
MNAT	Multinational Team
MPhil	Masters of Philosophy
MQF	Malta Qualifications Framework
MOU	Memorandum of Understanding
MR	Mutual Recognition
MRP	Mutual Recognition Procedure
MRCS	Membership of The Royal College of Surgeons
MSSG	EU Executive Steering Group on Shortages of Medicines and Medical Devices
MT	Malta
NCA	National Competent Authority
NCPE	National Commission for the Promotion of Equality
NPB	Named Patient Basis
OMCL	Official Medicines Control Laboratory
PAES	Post-Authorisation Efficacy Studies
PASS	Post-Authorisation Safety Studies
PDPID	Policy Development and Programme Implementation Directorate
PhV	Pharmacovigilance
PIC/S	Pharmaceutical Inspection Co-operation Scheme
PLD	Post-licensing Directorate
PMU	People Management Unit
PT	Portugal
PPP	Pregnancy Prevention Programmes
PSURs	Periodic Safety Update Reports
PSUSAs	Periodic Safety Update Report Single Assessments
QIFs	Quality Improvements Form
QMS	Quality Management System
QP	Qualified Person
RMMs	Risk Minimisation Measures
RMPs	Risk Minimisation Programmes
RMS	Reference Member State
RO	Romania
ROMAD	Regulatory Operations, Medicines Intelligence & Access Directorate
RPL	Recognition of Prior Learning
SAWP	Scientific Advice Working Party
SMART	Specific, Measurable, Attaonable, Relevant, and Time-bound
SMS	Short Message Service
SO	Strategy and Operations Unit
SOC	System Organ Class
SOPs	Standard Operating Procedures
SPH	Superintendence of Public Health
SPOC	Single Point of Contact
STEM	Science, Technology, Engineering, Mathematics
SUSARs	Suspected Unexpected Serious Adverse Reactions
SVP-LTCF	St. Vincent de Paul Long Term Care Facility
THC	Tetrahydrocannabinol
VARS	Variations
UHM	Unjoni Haddiema Maghqudin
UK	United Kingdom
USA	United States of America
UM	University of Malta
WHO	World Health Organisation

CONTENTS

Foreword from the Minister

It is with pleasure that I address you in this annual report, reflecting on the progress and achievements of the Malta Medicines Authority (MMA) over the past year. The Authority demonstrates its pivotal role in safeguarding public well-being through regulatory excellence, scientific innovation, and proactive engagement with stakeholders.

This year has been one of remarkable progress and steadfast commitment. The MMA has continued to build on its reputation as a centre of excellence in regulatory sciences, a leader in medicinal product safety, and an advocate for patient-centric healthcare. I would like to take this opportunity to highlight some key accomplishments that have defined the Authority's journey over the past year.

First and foremost, the Authority has upheld its mandate to ensure the quality, safety, and efficacy of medicines available in Malta. With the increasing complexity of global supply chains, the proactive management of regulatory signals has become critical. The Authority's implementation of innovative tools for signal detection and quality assurance demonstrates its forward-thinking approach to adapting to emerging challenges in pharmaceutical regulation.

The Authority's emphasis on fostering collaboration has been instrumental in achieving these milestones. Partnerships with international regulatory bodies, academia, and industry stakeholders have strengthened Malta's position as a hub for pharmaceutical innovation. Initiatives such as joint inspections, knowledge-sharing platforms, and capacity-building programs have not only enhanced regulatory oversight but have also contributed to Malta's growing influence in the global healthcare landscape.

The Authority has also prioritised public engagement and education, recognising that an informed society is key to achieving sustainable healthcare outcomes. Campaigns aimed at promoting rational medicine use, combating antimicrobial resistance, and addressing deception have empowered citizens to make informed decisions in the remit of medicinal products and medical devices.

As Minister for Health and Active Ageing, I am deeply appreciative of the efforts of the Malta Medicines Authority and its dedicated workforce. Your hard work and vision ensure that Malta continues to meet the highest standards in regulatory practice while prioritising patient health.

Looking ahead, the challenges in the healthcare sector remain dynamic and multifaceted. I am confident that the Malta Medicines Authority, with its expertise and resilience, will continue to address these challenges head-on. Let us commit to building on the successes of 2024, fostering a culture of excellence, and ensuring that Malta's regulatory framework remains robust, agile, and innovative.

I extend my heartfelt gratitude to every member who has contributed to the Authority's achievements. Your dedication not only safeguards public health but also strengthens Malta's standing as a leader in pharmaceutical regulatory sciences.

As a unified force, we will continue to drive progress in healthcare, foster innovation, and enhance well-being, always keeping patients at the heart of our mission and activities.

Hon Jo Etienne Abela MD MPhil MRCS FRCSEd FEBS MP
Minister, Ministry for Active Aging

Message from the Chief Executive Officer

As the Chief Executive Officer (CEO) of the Malta Medicines Authority, I am pleased to share our achievements and strategic initiatives from 2024, reflecting our unwavering commitment to regulatory excellence and patient care.

In 2024, we continued to focus on regulatory sciences, expanding our capacities beyond standard compliance. This forward-thinking approach is crucial for staying ahead in the rapidly evolving pharmaceutical field.

Shortages of medicines continued to be a growing public health concern affecting countries in the European Union (EU) and globally. We adopted a strategic and proactive approach to reduce the risk of unmet patient needs, aiming for a more robust supply of medicines that aligns with developments in the pharmaceutical field. Collaboration with manufacturers, distributors, healthcare professionals, and regulators was paramount in tackling these challenges effectively.

To foster a mutually beneficial relationship with stakeholders, we hosted the annual stakeholder meeting and welcomed requests for one-to-one discussions. This transparent and inclusive approach strengthens trust and relationships.

The MMA invested in continuous training for our workforce to ensure competence, independence, and efficiency in this ever-changing regulatory environment. This investment is vital for maintaining high standards in regulatory practices.

Patient safety and transparency remain at the forefront of our goals, contributing to our strong reputation in issuing marketing authorisations, granting EU Good Manufacturing Practice (EU-GMP) certifications, and administering pharmacovigilance activities. This dedication led to the award of the Twinning Project with Montenegro.

The MMA invested in the regulation of medical devices to the benefit of promoting the availability of good quality medical devices. This adaptability and readiness to tackle new challenges are significant steps forward.

Through seminars and courses organised in 2024, the MMA highlighted current challenges like antimicrobial resistance and shared expert insights. We also emphasised the dissemination of knowledge about recent advances, including the emergence of Artificial Intelligence (AI).

The MMA maintains a prudent and steadfast approach to AI implementation, balancing innovation with data safety concerns. AI is broadly implemented in pharmacovigilance, and the MMA looks forward to expanding it to other regulatory fields.

The MMA will continue to aim for improvement in all facets and enhance collaboration with stakeholders to maintain our patient-centred approach. Malta faces unique challenges as a small member state, but it will continue to be a leader in regulatory excellence.

All stakeholders are invited to join us in our mission to improve patient care and regulatory excellence. Together, we can overcome challenges and achieve great success.

Professor Anthony Serracino-Inglott
Chief Executive Officer, Malta Medicines Authority

Remarks from the Directors

In 2024, the Office of the CEO worked towards promoting operational excellence, transparency, and accountability to fulfil the Malta Medicines Authority's regulatory mandate.

This year has been marked by a renewed commitment to raising standards through enhanced collaboration and robust stakeholder engagement. Our team has actively participated in the EU and international forums, sharing our expertise and incorporating global best practices to elevate pharmaceutical regulation and public health initiatives.

We have streamlined processes by reviewing and refining Policies and Standard Operating Procedures (SOPs), effectively reducing bureaucratic delays and ensuring that our regulatory framework remains both agile and efficient. The successful recertification to International Organization for Standardization (ISO) 9001 demonstrates our dedication to quality management systems and continuous improvement.

By addressing a wide range of legal and regulatory queries, spanning from procedural guidance to operational issues, we have sustained stakeholder confidence through clear and timely communications.

In addition, the Authority has made notable progress in key areas, such as the cannabis sector for medical use, where nearly 40,000 units have been domestically commercialised, outpacing international benchmarks.

Strategic initiatives in AI have also been launched, further modernising our operational landscape and paving the way for innovative regulatory practices.

Finally, our record financial collection of late fees underscores the strength of our enforcement mechanisms and commitment to fiscal responsibility.

Overall, 2024 has been a transformative year for the Authority, characterised by dynamic growth, strategic innovation, and a steadfast commitment to regulatory excellence.

Dr Annalise Attard
Director, Management Support

Pharmacovigilance (PhV) is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problems. Pharmacovigilance is an ongoing endeavour that requires a proactive, risk-proportionate and patient-centred approach.

Following authorisation, all medicines must be monitored throughout their lifecycle for safety issues that emerge with widespread, real-world use. Spontaneous reporting of adverse reactions by vigilant healthcare professionals and consumers is the cornerstone of safety monitoring systems of medicines. The Post-licensing Directorate (PLD) manages the national adverse drug reaction reporting system and supports reporters through the provision of guidance and educational initiatives. Once safety issues are identified, they are assessed, and when required, regulatory action is taken to protect patient and public health.

The MMA strives to provide timely, objective, and unbiased safety information to help prescribers, healthcare professionals, and patients make informed decisions on the choice and use of medicines. Through such activities, the MMA contributes to the rational and safe use of medicines, both nationally and in the EU. In 2025, patient safety will continue to be a priority area for the MMA, with plans to improve incoming Adverse Drug Reaction (ADR) data quality and promote the national reporting system.

Prof John Joseph Borg
Director, Post-licensing

Over the past year, our team has remained committed to ensuring the timely and thorough evaluation of medicinal products, aligning with both national and EU regulatory standards. This report highlights our key achievements, challenges, and ongoing efforts to enhance the quality, safety, efficacy, and accessibility of medicines for patients.

At the Licensing Directorate (LD), we collaborate closely with our stakeholders to ensure that medicinal products meet rigorous scientific and ethical standards. We are committed to transparency, efficiency, and continuous improvement in our processes to support the swift yet thorough evaluation of medicines.

Our team is dedicated to fostering an environment of excellence in regulatory practice, and we take great pride in contributing to the overall safety and well-being of patients. As we look ahead, we remain dedicated to upholding the highest principles of regulatory rigour and patient-centred care.

Ms Helen Vella
Director, Licensing

The Inspectorate and Enforcement Directorate (IED) continued successfully supporting the local stakeholders, especially the local manufacturing industry, including the ever-increasing demand for third-country inspections. Third-country inspections are not only essential for our local pharma industry, especially in the sector of import and batch release which is the sector that saw the most increase in local investment in recent years, but are also important for increasing access and availability of more affordable medicinal products to all patients within the EU, whilst at the same time proving to be an important revenue generation and source of income for the MMA. The challenges throughout 2025 thus remain the continuous upkeep in performance with requests for these third-country inspections, whilst at the same time increasing support to the EU network through further collaboration in GxP inspections for Centrally Authorised Products (CAPs).

I would like to conclude this short remark-note with the following thought: While several potentially disruptive global forces could impact the life sciences industry in 2025, including the pharma industry, digital transformation is expected to have a major impact on pharma companies' strategies and development in the ensuing years. Therefore, digital transformation remains a key focus in the pharma industry, driven by advancements in cloud computing, generative AI, and other digital technologies. These innovations provide the pharma industry with new opportunities to enhance its products, operations, and strategic decision-making. I remain optimistic that in 2025 and beyond, regulators, together with all stakeholders, will be able to make great strides in this area for the general benefit of the pharma industry and, ultimately, to the benefit of patients.

Dr Mark Cilia
Director, Inspectorate and Enforcement

Our responsibilities to public health call for a regulatory ecosystem that engages with a broad range of stakeholders dedicated to acting in the best interests of patients. Whilst anticipating further alignment of regulatory provisions and industry incentives to public health needs through revision of the pharma legislation, it is understood that, as a standalone, this may not provide a definite solution to all concerns. Whether it's lessening administrative burdens and streamlining processes, facilitating access to information and a stronger voice for patients, limiting dependencies and enhancing competitiveness, supporting innovation and security of supply, or addressing antimicrobial resistance and unmet medical needs, it all hinges on what each of us is willing to contribute for effective collaborative efforts.

Multifaceted dynamics demand bridge-building at all levels while fostering needs-driven talent and professional networking as key elements for strategic development. The Advanced Scientific Initiatives Directorate (ASID) encompasses the functions of research strategy, innovative growth, and regulatory response, along with educational planning and academic development. This symbiosis is intended to have regulatory sciences expertise and competency cascading seamlessly between the learning context and the performance context.

During the period under review, multiple initiatives were sustained to advance research and education in priority areas, support timely interventions for evolving needs and establish constructive multinational connections, whilst prioritising the MMA Academy for Patient-Centred Excellence and Innovation in Regulatory Sciences as a central interface for meeting training needs and business requirements. A win-win scenario unfolds, where stakeholders may contribute to our market demand analysis and gaps are addressed. Such experience-informed practices are being further leveraged in leading actions of other significant EU-funded projects, including capacity building of the EU medicines regulatory network and prospectively expanding into the strengthening of regulatory systems in Sub-Saharan Africa.

Dr Luana Mifsud-Buhagiar
Director, Advanced Scientific Initiatives

In the ever-evolving landscape of medical products, regulatory authorities face ongoing challenges in ensuring compliance with pharmaceutical regulations and safeguarding patient safety. Within the Regulatory Operations, Medicines Intelligence, and Access Directorate (ROMAD), we lead patient-focused regulatory operations and best practices to improve access to medicines.

The Strategy and Operations (SO) plays a crucial role in continuously assessing and optimising performance by evaluating key performance indicators in alignment with the Authority's vision, mission, values, and strategic objectives. This includes regulating community pharmacies, coordinating communication initiatives, managing EU and international regulatory affairs and projects, and driving public relations and stakeholder engagement.

Our approach remains proactive and patient-centred, with the Medicines Intelligence and Access Unit (MIAU) working to bridge the gap between regulatory requirements and patient needs. By compiling real-time medicines intelligence, offering targeted recommendations, and collaborating with stakeholders, we ensure the continuous availability of medicines across both public and private sectors.

Innovation and adaptability are at the heart of our operational strategies, ensuring we effectively manage organisational change and adapt regulatory frameworks to support the growth of pharmaceutical advancements. The People Management Unit (PMU) fosters a positive organisational culture that encourages development, innovation, integrity, equal opportunities, and enhanced capacity to support the strategic goals of the Authority in an increasingly dynamic environment.

Dr Caroline Muscat
Director, Regulatory Operations, Medicines Intelligence and Access

As the world moves towards pharma industry 5.0, which is increasingly revolving around big data, robotics and Artificial Intelligence, medical devices are becoming more innovative whilst continuing to play a pivotal role across the continuum of care, from prevention to diagnosis, treatment, monitoring, rehabilitation, and palliative care. The Medical Devices and Pharmaceutical Collaboration Directorate (MDPCD) continues its unwavering commitment to supporting stakeholders through active communication at national and international levels. The Directorate believes that this supportive approach ensures increased assistance towards facilitating and ensuring the availability of safe, effective, and high-quality medical devices on the market, aligning to enhance patient outcomes. The Directorate's key accomplishments include strengthening the expertise and technical capacity to ensure a robust infrastructure capable of addressing the dynamic needs of the health care landscape in addition to a sustained and responsive approach to challenges within the Notified Bodies (NBs) aspect. In leading the Work Package 5 of the JAMS 2.0 on vigilance in medical devices, the Directorate has established itself as a focal point in signal detection, working with other member states to put forward best practices in vigilance and patient safety. It is actively shaping training modules for continuous professional development at the European level as part of Work Package 8 of the JAMS 2.0. To support inspections as a strategy to assist medical device stakeholders in keeping with the EU legislation, the team is actively involved in national and European joint inspections, contributing our expertise in the area through a positive patient-centred approach.

Through its collaborative arm, the Directorate is actively working to break down silos within healthcare and beyond fostering innovative ideas for the mutual benefit of the MMA and society at large. As we look ahead to 2025, the Directorate remains enthusiastically committed to forthcoming challenges to assist stakeholders in embracing excellence and the highest standards in medical device and pharmaceutical regulation. A testament to this is our unwavering commitment to remaining close to our stakeholders' needs and our scientific dedication to establishing Malta as a hub for clinical investigations within medical devices, allowing innovation and patient safety to entwin together against practical EU legislation.

Dr Louise Grech
Director, Medical Devices and Pharmaceutical Collaboration

The Stakeholders Conference

The Malta Medicines Authority (MMA) held the 2024 Stakeholders Conference on 5 June 2024 at Villa Arrigo, Naxxar. The conference brought together leaders and professionals from healthcare, academia, and regulatory sciences under the central theme “Excellence Beyond Compliance.”

The conference was addressed by the Honourable Dr Jo Etienne Abela, Minister for Health and Active Ageing, and by Mr Joseph Chetcuti, Permanent Secretary. Both speakers emphasised the importance of stakeholder collaboration in advancing Malta’s healthcare and regulatory frameworks.

The morning plenary featured a series of high-level presentations by distinguished speakers:

- Professor Charmaine Gauci, Superintendent of Public Health addressed regulatory best practices in the post-pandemic landscape, highlighting resilience, adaptability, and forward-looking strategies.
- Professor Anthony Serracino-Inglott, Chief Executive Officer of the MMA explored evolving standards of excellence within the healthcare sector and the Authority’s commitment to continuous improvement.
- Professor Lilian M Azzopardi, Head of the Pharmacy Department University of Malta, discussed the integration of digital tools in pharmacy practice, emphasising their transformative role in enhancing service delivery.
- Dr Luana Mifsud Buhagiar, Director of the Advanced Scientific Initiatives Directorate underscored the critical role of collaboration in fostering scientific innovation and progress.
- Dr Caroline Muscat, Director of the Regulatory Operations Medicines Intelligence and Access Directorate, provided a strategic update on the MMA’s priorities and initiatives leading up to 2025, aligning with both national and European regulatory developments.

The conference transitioned into four parallel break-out discussions with stakeholders, each centred on key strategic themes:

1. Balancing Compliance with Compassion – examining the human-centric aspects of regulatory adherence and adopting regulatory flexibilities, to address healthcare needs.

2. Fostering Innovation through Science – identifying pathways to accelerate scientific research and innovation, whilst advancing regulatory norms which adapts to today's realities.

3. Maintaining High Standards in Medicinal Products – focusing on regulatory quality, safety, and efficacy of medicinal products.

4. Advancing Medical Devices through Pharmaceutical Collaboration – exploring synergies between pharmaceutical and medical device sectors and addressing stakeholder needs.

These sessions provided an interactive platform for participants to exchange expertise and formulate actionable insights. The breakouts culminated in a plenary session, where representatives shared consolidated takeaways, promoting cross-disciplinary dialogue.

The event concluded with closing remarks, followed by a networking lunch, offering delegates the opportunity to foster professional connections and explore future avenues for collaboration.

The MMA Stakeholders Conference 2024 reaffirmed the Authority's dedication to advancing regulatory excellence and fostering stakeholder engagement in alignment with the evolving healthcare objectives in Malta.

1 The Malta Medicines Authority Background

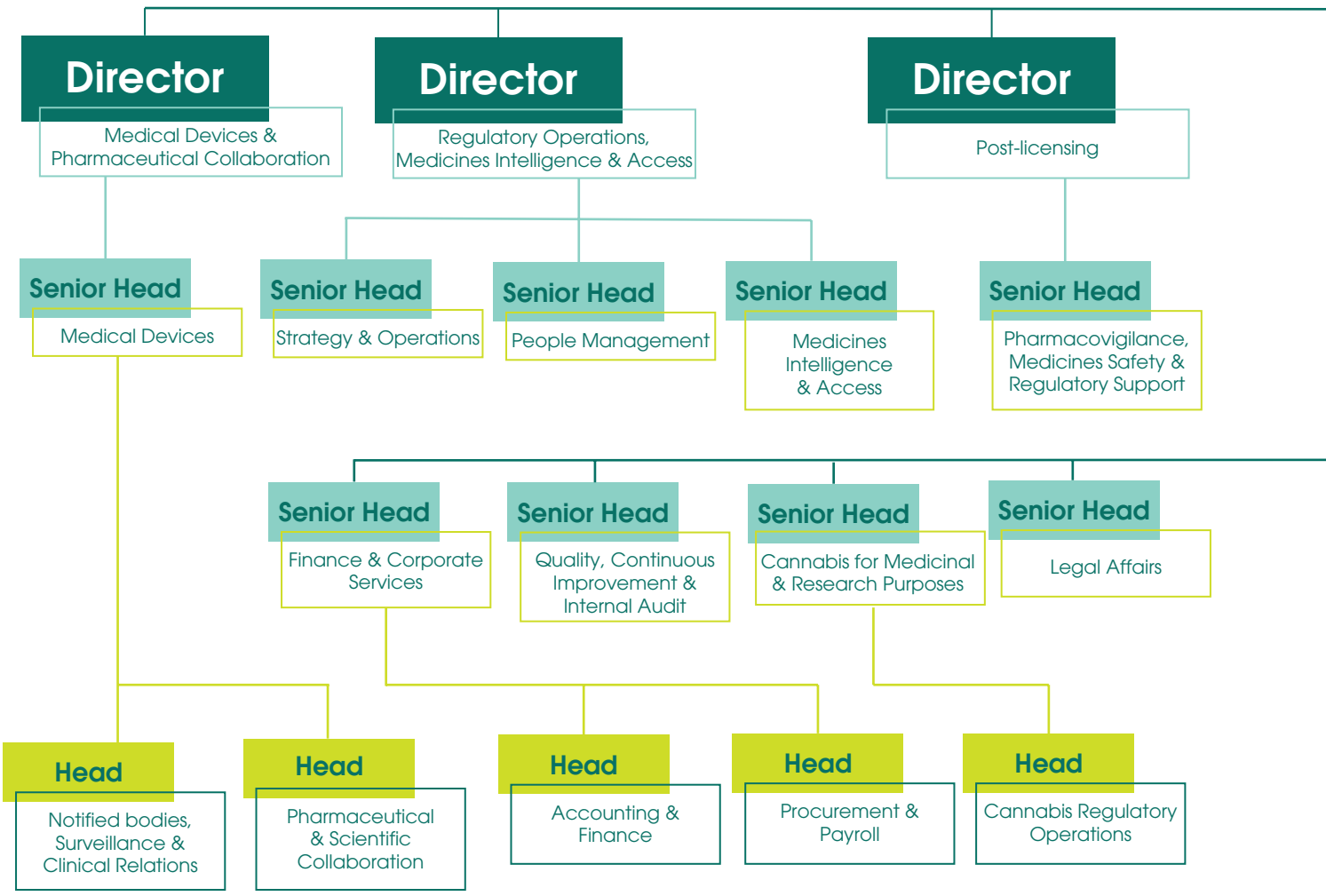
The MMA was established by the Medicines Act 2003 and has developed into an autonomous body that implements scientific decisions with a patient-centred approach. It is committed to providing high-quality services through its functions of licensing, pharmacovigilance, pharmaceutical inspections, and enforcement services to its stakeholders for the ultimate benefit of patients.

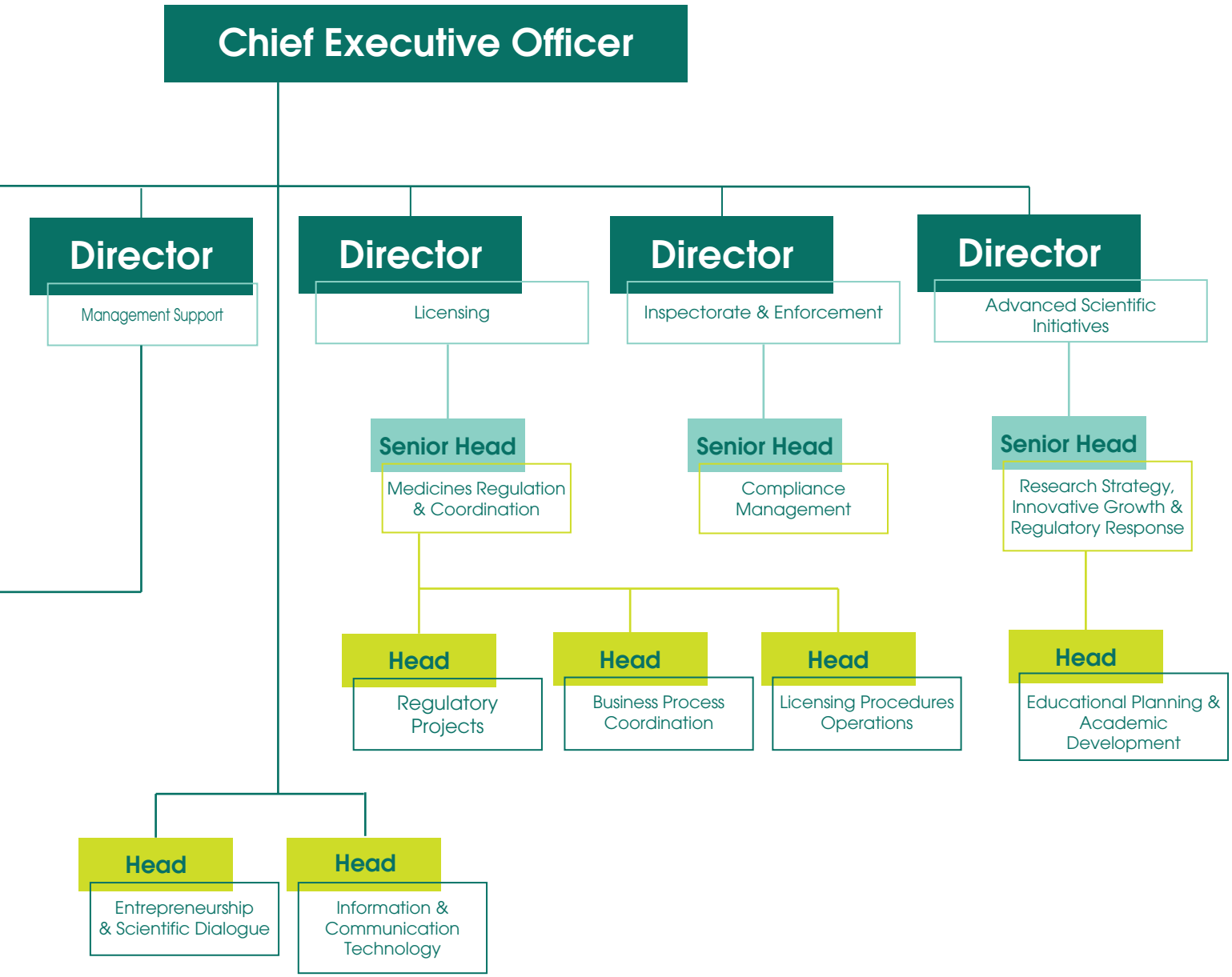
The MMA is established by seven (7) Directorates under the guidance of the Chief Executive Officer. These are the Licensing Directorate, the Post-licensing Directorate, the Inspectorate and Enforcement Directorate, the Advanced Scientific Initiatives Directorate, the Regulatory Operations, Medicines Intelligence and Access Directorate, the Management Support Directorate and the Medical Devices and Pharmaceutical Collaboration Directorate.

The Authority is also supported by the continuous collaboration of six (6) Units that fall within the Office of the Chief Executive Officer, namely the Finance and Corporate Services Unit (FCS), the Information and Communications Technology Unit (ICT), the Quality, Continuous Improvement and Internal Audit Unit, the Legal Affairs Unit, the Entrepreneurship and Scientific Dialogue Unit, and the Cannabis for Medicinal and Research Purposes Unit (CMRU).

Given 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 invest in manpower sustainably.

Organogram


Director
Medical Devices & Pharmaceutical Collaboration
Director
Regulatory Operations, Medicines Intelligence & Access
Director
Post-licensing
Senior Head
Medical Devices
Senior Head
Strategy & Operations
Senior Head
People Management
Senior Head
Medicines Intelligence & Access
Senior Head
Pharmacovigilance, Medicines Safety & Regulatory Support
Senior Head
Finance & Corporate Services
Senior Head
Quality, Continuous Improvement & Internal Audit
Senior Head
Cannabis for Medicinal & Research Purposes
Senior Head
Legal Affairs
Head
Notified bodies, Surveillance & Clinical Relations
Head
Pharmaceutical & Scientific Collaboration
Head
Accounting & Finance
Head
Procurement & Payroll
Head
Cannabis Regulatory Operations


Chief Executive Officer
Director
Management Support
Director
Licensing
Director
Inspectorate & Enforcement
Director
Advanced Scientific Initiatives
Senior Head
Medicines Regulation & Coordination
Senior Head
Compliance Management
Senior Head
Research Strategy, Innovative Growth & Regulatory Response
Head
Regulatory Projects
Head
Business Process Coordination
Head
Licensing Procedures Operations
Head
Educational Planning & Academic Development
Head
Entrepreneurship & Scientific Dialogue
Head
Information & Communication Technology

Participation in EU-funded projects

Twinning Light Project

In 2024, the MMA embarked on a collaboration with the Institute for Medicines and Medical Devices of Montenegro (CInMED) as part of an EU-funded Twinning Light Project, enabling Montenegro to develop a robust pharmaceutical regulatory framework that is in line with the EU pharmaceutical acquis in preparation for the EU accession process.

This project aims to support and develop the necessary expertise required by Montenegrin experts to carry out activities in line with EU pharmaceutical regulatory standards for medicines and medical devices. As part of this project CInMED will receive guidance on several aspects of pharmaceutical regulation including Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP) inspections, management of medicine shortages, medical device market surveillance, monitoring of rapid alerts and medicine quality defects, and assessment of quality, safety, efficacy, and administrative documentation of generic medicines. The MMA and CInMED will also collaborate to review and compare Montenegrin laws on medicines and medical devices with current EU regulations. This joint effort will result in recommendations for CInMED to harmonise its legislation with the EU acquis.

EU4Health Projects

The MMA is actively participating in the Joint Action on Reinforced Market Surveillance of Medical Devices and In Vitro Medical Devices (JAMS 2.0), an initiative co-funded by the EU under the EU4Health Programme. This project aims to enhance the market surveillance of medical devices and in vitro diagnostic medical devices (IVDs) across EU member states. By fostering increased coordination and dialogue among Competent Authorities (CAs), JAMS 2.0 seeks to ensure the availability of safe, effective, and high-quality medical devices. The initiative includes eight (8) work packages, with the MDPCD taking the lead on Work Package 5, which focuses on signal detection in vigilance and developing a harmonised framework for medical devices vigilance signal detection. Additionally, the Directorate is involved in Work Package 6, which centres on inspections, and Work Package 8, which focuses on academic training for experts in the field of medical devices and IVDs.

The MMA is also participating in IncreaseNET, the EU4Health Joint Action on increasing the capacity building of the EU Medicines Regulatory Network (EMRN). Officers of the MMA are actively contributing to the Programme by leading Working Package 3 of this Joint Action on the overall coordination, monitoring and reporting of the key tasks and activities.

Support for the Establishment of the African Medicines Agency

The MMA has been chosen to participate in the European Medicines Agency (EMA) project to support regulatory systems at the national and regional level in Africa, and particularly, for the setting up of the African Medicines Agency (AMA). The MMA has been granted financial support through the EMA for developing and delivering a training programme aimed at regulatory professionals in Sub-Saharan African National Competent Authorities (NCAs).

Funded by the European Union

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.

i. To perform duties delegated to the MMA by the Licensing Authority (LA) through the Medicines Act,
ii. To assist and advise the Licensing Authority on any matter relating to the regulation of medical products and related activities,
iii. To ensure in so far as possible and consistent with current medical and scientific knowledge, that medical products marketed in Malta and the 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,
iv. To scientifically evaluate requests and monitor clinical trials carried out in Malta,
v. To ensure that the medical products supplied on the local market through the regulated supply chain are of good quality, safe for the public, and as per the intended use,
vi. To provide high-quality monitoring and inspection services for pharmaceutical activities, local medical device economic operators and notified bodies registered in Malta,
vii. To monitor the safety of medical products,
viii. To monitor and enforce the relevant legislation through investigation of potential breaches of regulations and a range of measures,
ix. To enhance the effective, safe, and rational use of medical products through the provision of objective and unbiased information that helps prescribers, healthcare professionals (HCPs) and patients make informed decisions on the choice and use of medicines,
x. To support the availability of medical products on the local market,
xi. To support the competitiveness of the local market through scientific and regulatory advice and the implementation of principles of Scientific Measurable Attainable Relevant Time-bound (SMART) regulation,
xii. To utilise and develop tools, standards, and approaches to assess and ensure the safety, quality and effectiveness of medical products and pharmaceutical activities,
xiii. To enhance the standard of medical products and pharmaceutical activities in Malta,
xiv. To manage developments related to scientific research, innovation, and academic initiatives, in line with the strategy of the MMA,
xv. To support the regulation of cannabis for medicinal and research purposes through guidance, technical review, and stakeholder engagement,
xvi. To process and investigate complaints received regarding advertised medicinal products and provide guidance as laid down in the advertising regulations,
xvii. To participate in European fora of the 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 safeguard public health through the regulation of medical products, and pharmaceutical activities for human use.”

“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

INTEGRITY

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

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.

INNOVATION

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

QUALITY

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

Strategic Goals and Objectives

The MMA strategic goals and objectives to 2025 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 man agement.
4.3 To continue acting as a global player.
4.4 To implement a forward-looking Information and Communications Technology governance system.
4.5 To enhance the Quality Management System (QMS) and auditing functions.

5. Leading through science, innovation, and expertise

5.1 To intensify the research arm by leveraging 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 of the MMA and the appropriate use of medicines.

2 Organisational Development: a Positive Working Environment, a Patient-Centred Ethos and a Proactive Approach

Throughout 2024, 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 is achieved through a cross-cutting patient-centred approach across all Directorates and 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 expected of a reputable scientific regulatory authority. The positive working environment equips the employees of the MMA with the best tools to implement our patient-centred ethos, where the patient is put at the core of 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 including safety of medicines and medical devices, and accredited courses organised by the Academy for Patient Centred Excellence and Innovation in Regulatory Sciences.

Quality Management and Good Governance

As an institution that is internationally certified according to the ISO 9001, the MMA upholds the highest governance standards and is fully committed to improved Quality Management.

By the end of 2024, the foundation of the QMS at the Authority, which ensures uniform and high-quality operations, consisted of hundred forty-seven (147) SOPs, forty-six (46) policies, and forty-four (44) guidelines. In 2024, sixty-one (61) SOPs, seventeen (17) policies, and twenty (20) guidelines were revised or introduced through the annual Management Review process and periodic internal audits. These form an integral part of the ongoing efforts to continuously improve the MMA's QMS **(Figure 2.1)**.

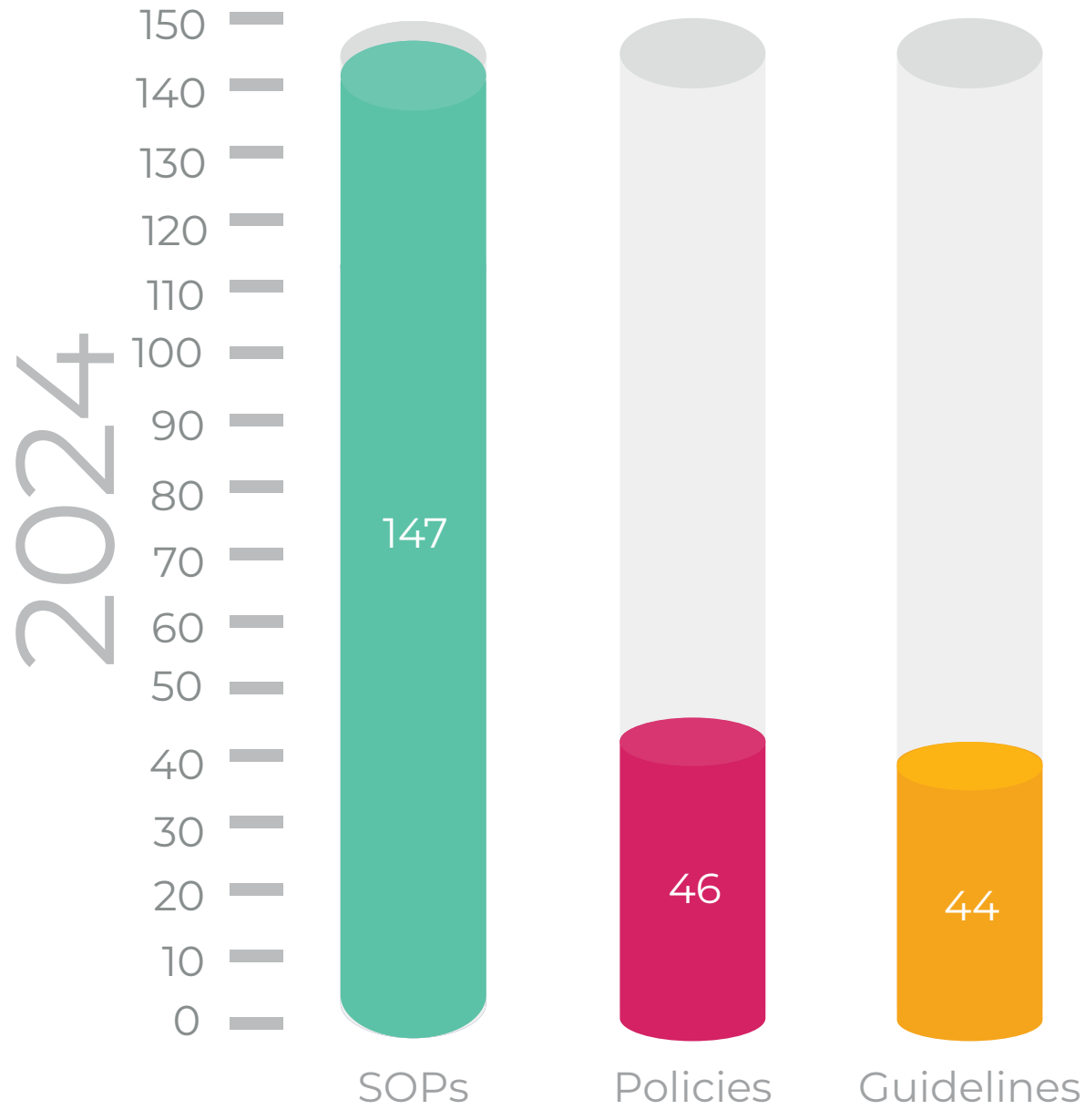


Figure 2.1: SOPs, Policies and Guidelines of the MMA that were revised or introduced in 2024

The MMA conducted twelve (12) internal audits throughout 2024, in line with the five (5)-year audit strategy. Overall, one hundred eight (108) Quality Improvement Forms (QIFs) were submitted to the Quality, Continuous Improvement, and Internal Audit Unit. These QIFs arose from internal audits and other internal initiatives by the respective Directorates and Units. Consequently, this 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 Management Review examined the operations of each Directorate and the respective Units, 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 QIFs in a comprehensive exercise to strengthen the QMS.

The MMA endured its commitment to the budgetary measure BM 69 (2021) studying the feasibility of setting up a national reference laboratory in Malta, which was concluded in March 2024. The Official Medicines Control Laboratory (OMCL) is considered essential for a country to safeguard the quality and safety of medical products placed on the local market, the vigilance and enforcement of medicines, medical devices, and medicinal cannabis, and for collaboration with other institutes such as the forensic and health laboratories. The planning and development of the OMCL covers essential considerations, including logistical matters as well as financial, technical, legal, and quality issues. The cost of the budgetary measure is funded at a national level.

The MMA attaches utmost importance to good governance practices embodied in five (5) 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, are published on the Authority's official website. Privacy by design is a concept brought about by the Data Protection Regulation that is fully embedded within the Authority's operational framework for processes handling personal data. Throughout 2024, the MMA continued to process FOI requests and promptly provide support regarding data protection access requests and queries, 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 to **communications.medicinesauthority@gov.mt.**

Our People

Throughout 2024, the People Management Unit made significant strides in human resource management. Maintaining effective human resource management, including staff recruitment for Directorates and Units, and preparing the Authority for the effective execution of its responsibilities were our top priorities.

Employee engagement is an ongoing priority for the MMA. In 2024, employee engagement and appointments were maintained in line with the approved capacity building, availability of funds and the MMA's operational requirements. A total of sixteen (16) employees were recruited.

Figure 2.2 represents the total number of employees engaged in full-time (n=125) and part-time (n=3), which increased by 68% between 2015 and 2024.

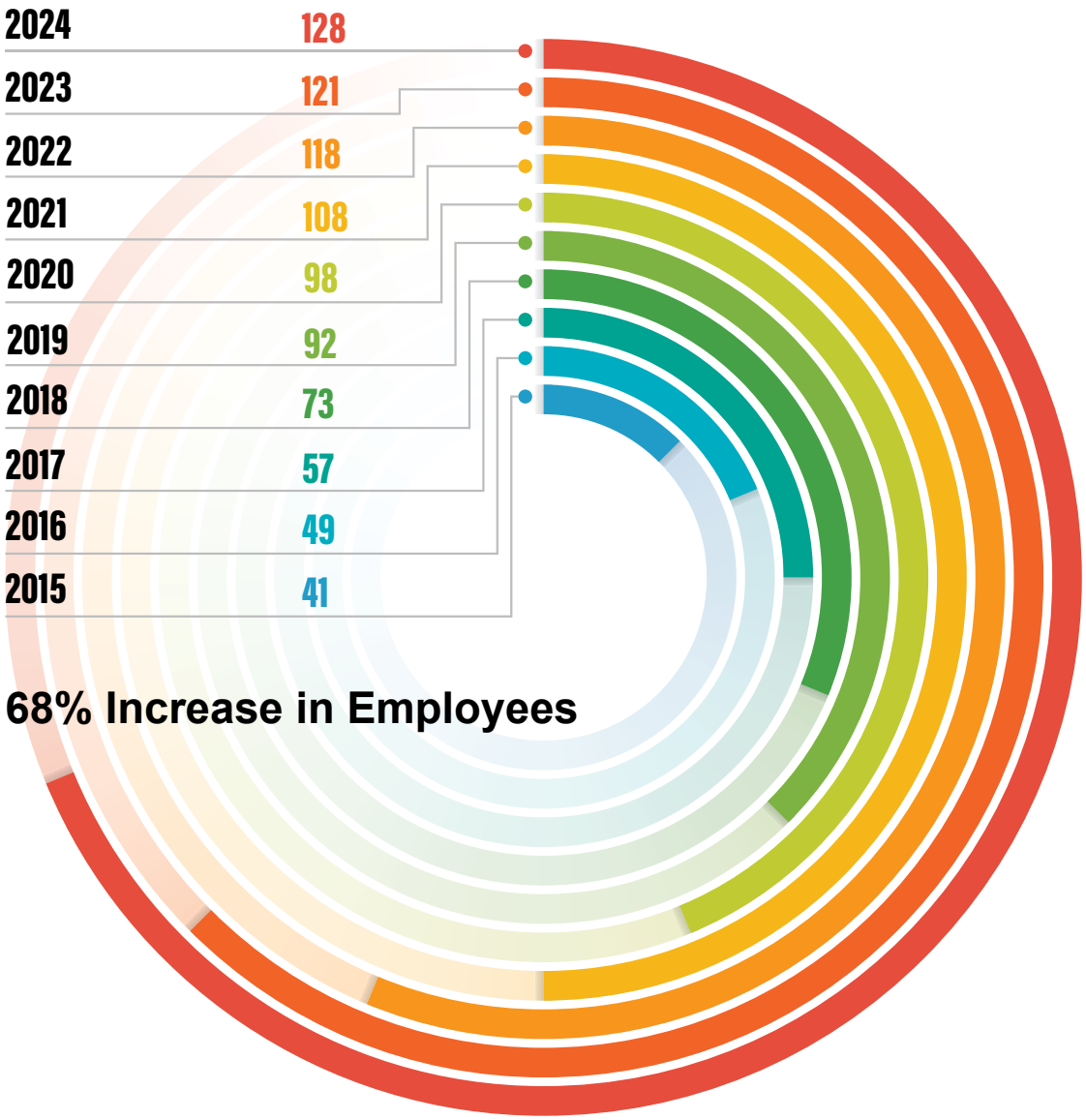


Figure 2.2: Number of employees at the MMA (2015-2024)

The MMA Collective Agreement

The new MMA- UHM Collective Agreement covering the period from 2022 to 2027 was signed after fruitful negotiations and collaborative efforts between the UHM Voice of the Workers, the People and Standards Division and the MMA. This comprehensive agreement brings forth numerous improvements including salary increments, performance bonus and the introduction of additional allowances. The new collective agreement paves the way for enhanced career progression for both scientific and administrative staff whilst ensuring the Authority's sustainability.

Employee Wellbeing

The MMA recognises that employee motivation is crucial in fulfilling its objectives and ensuring overall productivity. Thus, the Authority remains committed to maintaining an environment that brings out the best in each employee.

In 2024, the People Management Unit organised various engaging team-building events and provided a variety of courses focused on enhancing employees' physical health, safety, and mental well-being. These initiatives aim to foster stronger connections, promote wellness, and ensure a supportive and thriving work environment for all employees. Throughout the year, several key team-building activities were held **(Figure 2.3)**, each contributing to the development of a collaborative and resilient workplace culture.

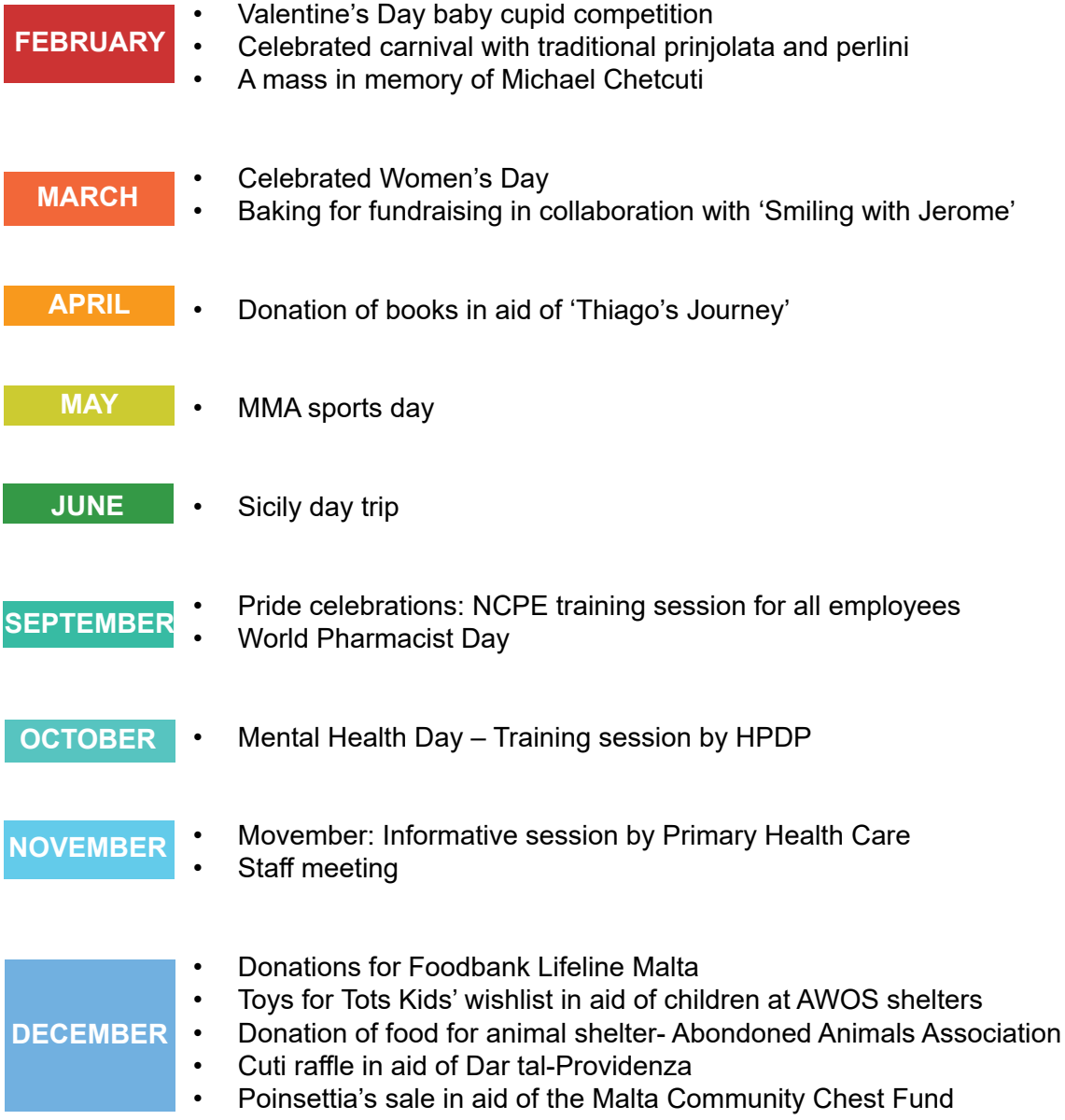


Figure 2.3: Timeline of the prominent events of the PMU for 2024

“These activities provide the opportunity to foster unity and strengthen collaboration”

The MMA’s International Fellowship Programme

The MMA’s International Fellowship Programme (IFP) is offered to prospective and current individuals to pursue further levels of academic research. The objectives of the Programme are to strengthen skills in the pharmaceutical and life sciences sector, to increase competence on topics relevant to innovative therapies and technologies and to expand the capacity and level of research and development activity.

Figure 2.4 illustrates the number of new fellows who enrolled for Malta Qualifications Framework MQF Level 7 and MQF Level 8 degrees between 2014 and 2024.

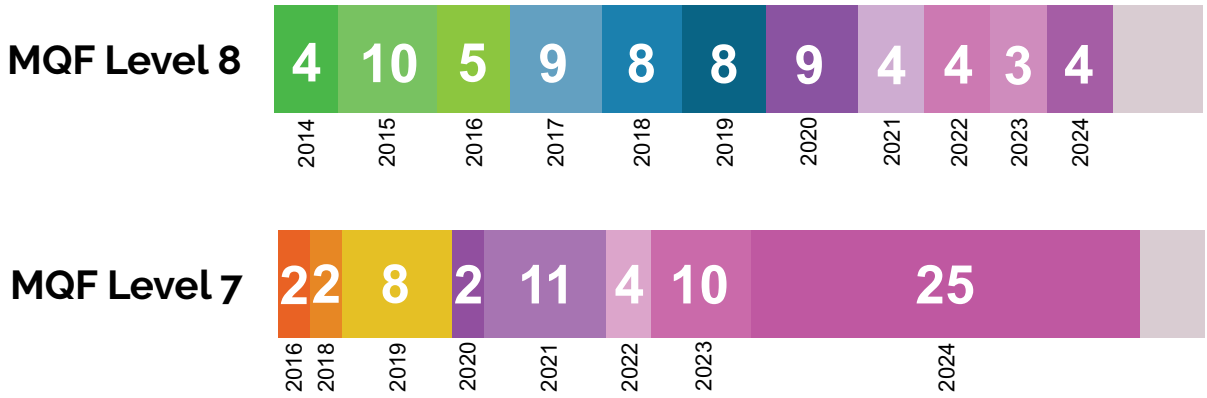


Figure 2.4: New fellow students subdivided per year and MQF level

Educational and Professional Development

The MMA acknowledges that education and professional development allow employees to learn and apply new knowledge and skills that can help them perform better at work.

In terms of self-development, in 2024, its employees successfully attained five hundred thirty-eight (538) certificates related to training initiatives offered internally and externally.

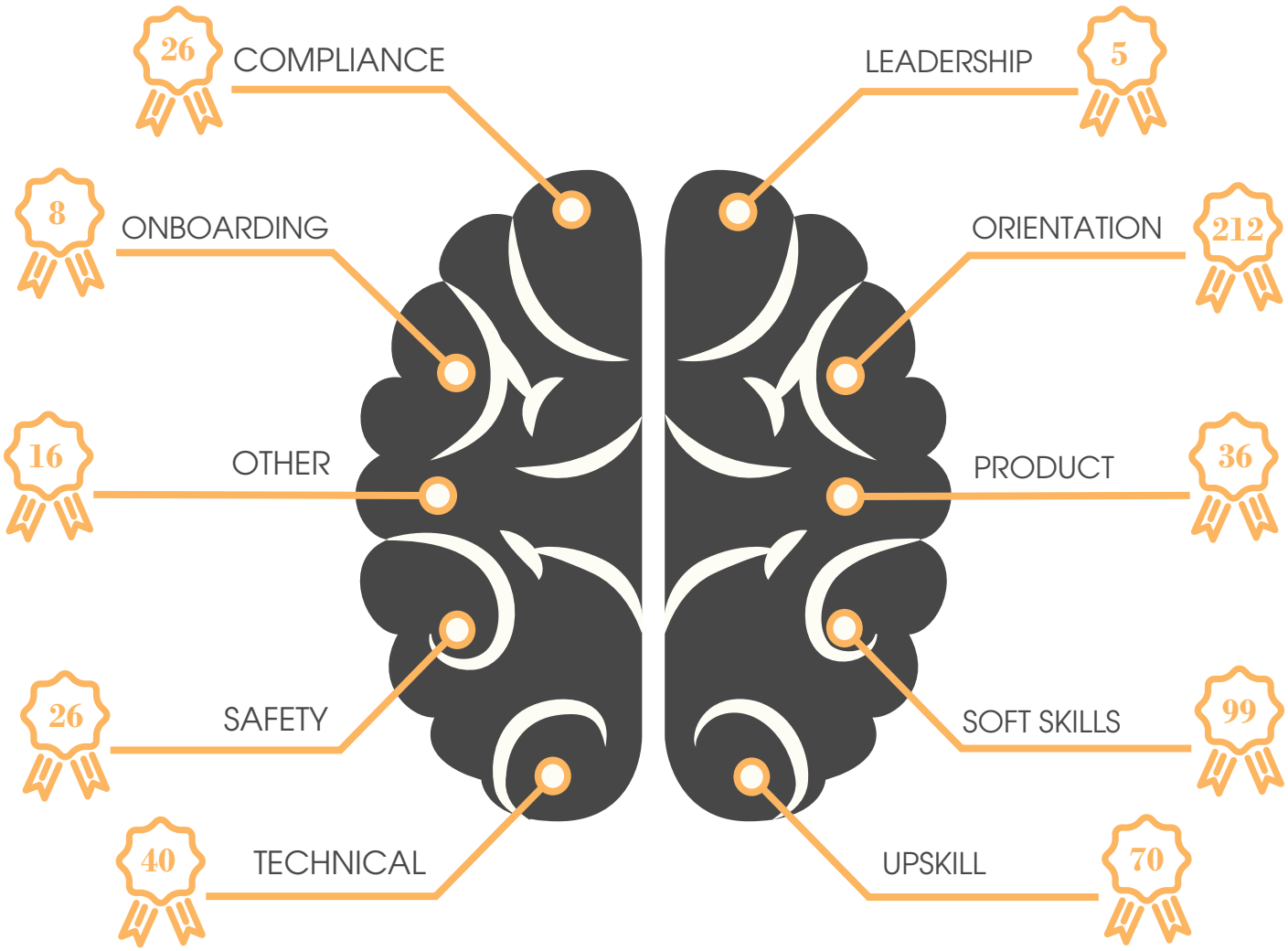


Figure 2.5: Number of training certificates attained by employees at the MMA (N=538)

A European and Global Player

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. During 2024, the extent of the Authority's representation in professional bodies was sustained. By the end of the year, MMA delegates were involved in a total of fifty-one (51) strategic and scientific expert groups, committees, and boards **(Figure 2.6)**.

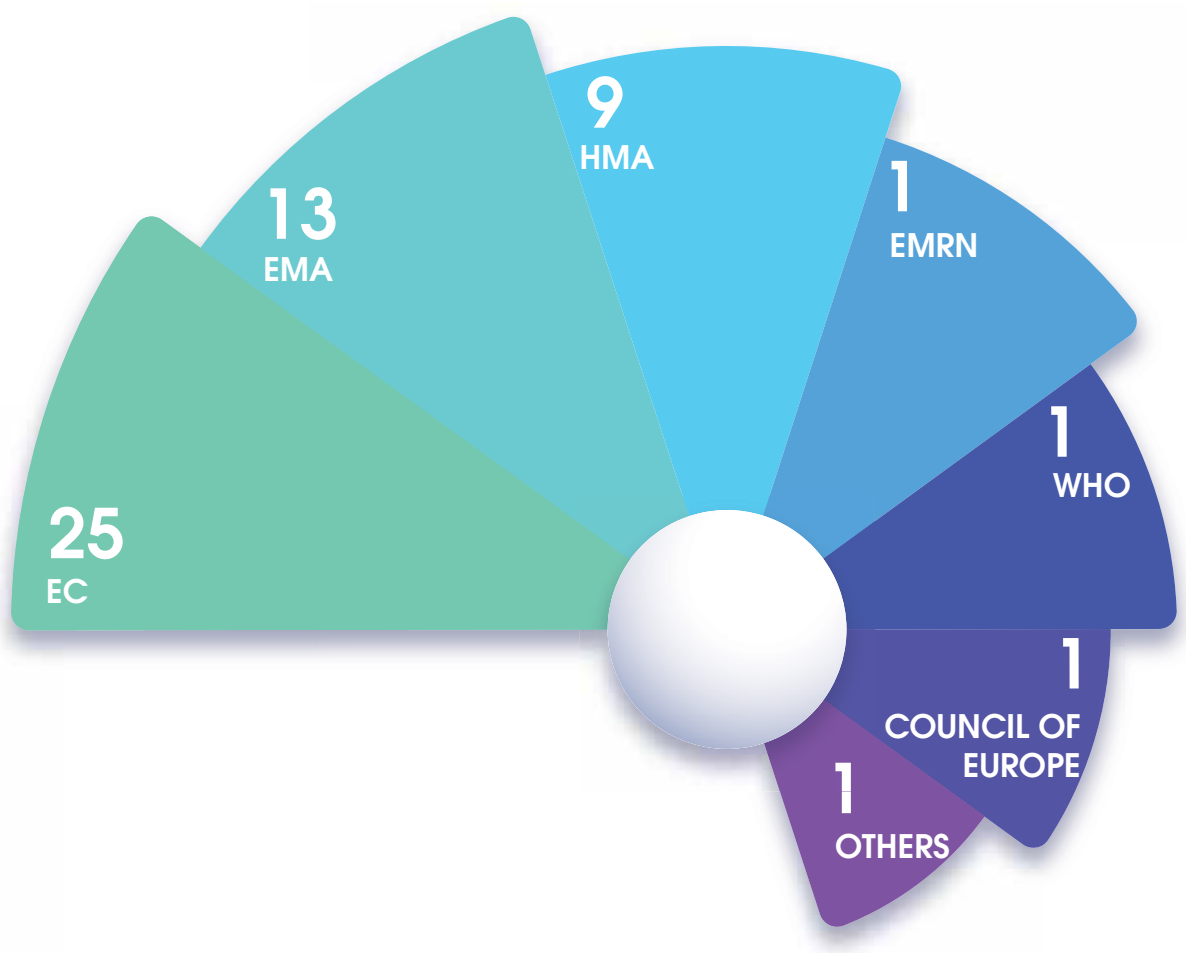


Figure 2.6: Representation by the MMA in European institutions and professional bodies (N=51)

The MMA had hundred ninety-eight (198) requests for action or feedback through 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 dossiers on which the MMA provided feedback in 2024

Through the tenets of knowledge dissemination and training in advanced pharmaceutical research, the MMA reaches out to its counterparts in third-country states, intending to consolidate the quality of medicines and medical devices imported into the EU and spur the accessibility of medical products in the Maltese islands. The Authority has sustained the impetus in international affairs through several networking initiatives that consolidate the role of Malta as a global player. The MMA was consulted on several bilateral collaborations including Qatar, Libya, Saudi Arabia, Ghana, India, Kyrgyzstan, and Algeria. In 2024, the MMA reaffirmed its continuous collaboration with Montenegro to provide support in the alignment process to European standards with relevance to medicinal products, medical devices, and pharmaceutical activities. To strengthen its commitment towards this agreement, the MMA submitted a proposal for a Twinning Light Project with Montenegro, which was awarded in June 2024.

In 2024 the MMA continued the strengthening of a collaborative relationship between the MMA and the French Agence Nationale de Sécurité du Médicament et des produit de santé. A MoU between the entities is being drafted to foster cooperation in multinational teams (MNAT) in the context of applications assessed through the centralised procedure and optimising use of expertise to assessments and inspections on medicinal products' manufacturing and clinical trials, cannabis for medicinal and research purposes and medical devices. 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 certification. The agreements are also intended to promote collaboration on capacity building concerning pharmaceutical product registration, pharmaceutical quality control, and pharmacovigilance.

Members of the Authority have also contributed to other related platforms, including the EU Executive Steering Group on Shortages of Medicines and Medical Devices (MSSG) and the EMA / Heads of Medicines Agencies (HMA) Communications Working Group, on the impact of accessibility to medicines and communication updates.

Stakeholders Synergy and Entrepreneurship

The Entrepreneurship and Scientific Dialogue Unit spearheads initiatives aimed at fostering collaboration among key stakeholders in pharmaceutical regulatory sciences, such as:

- Pharmaceutical entities,
- Regulatory authorities,
- Healthcare providers,
- Government departments, and
- Academic institutions such as the University of Malta (UM).

The Unit serves as a hub for promoting scientific dialogue and advancing pharmaceutical entrepreneurship, with a focus on patient-centred, evidence-based approaches.

In 2024, the Unit engaged in thirty-five (35) stakeholders' meetings to:

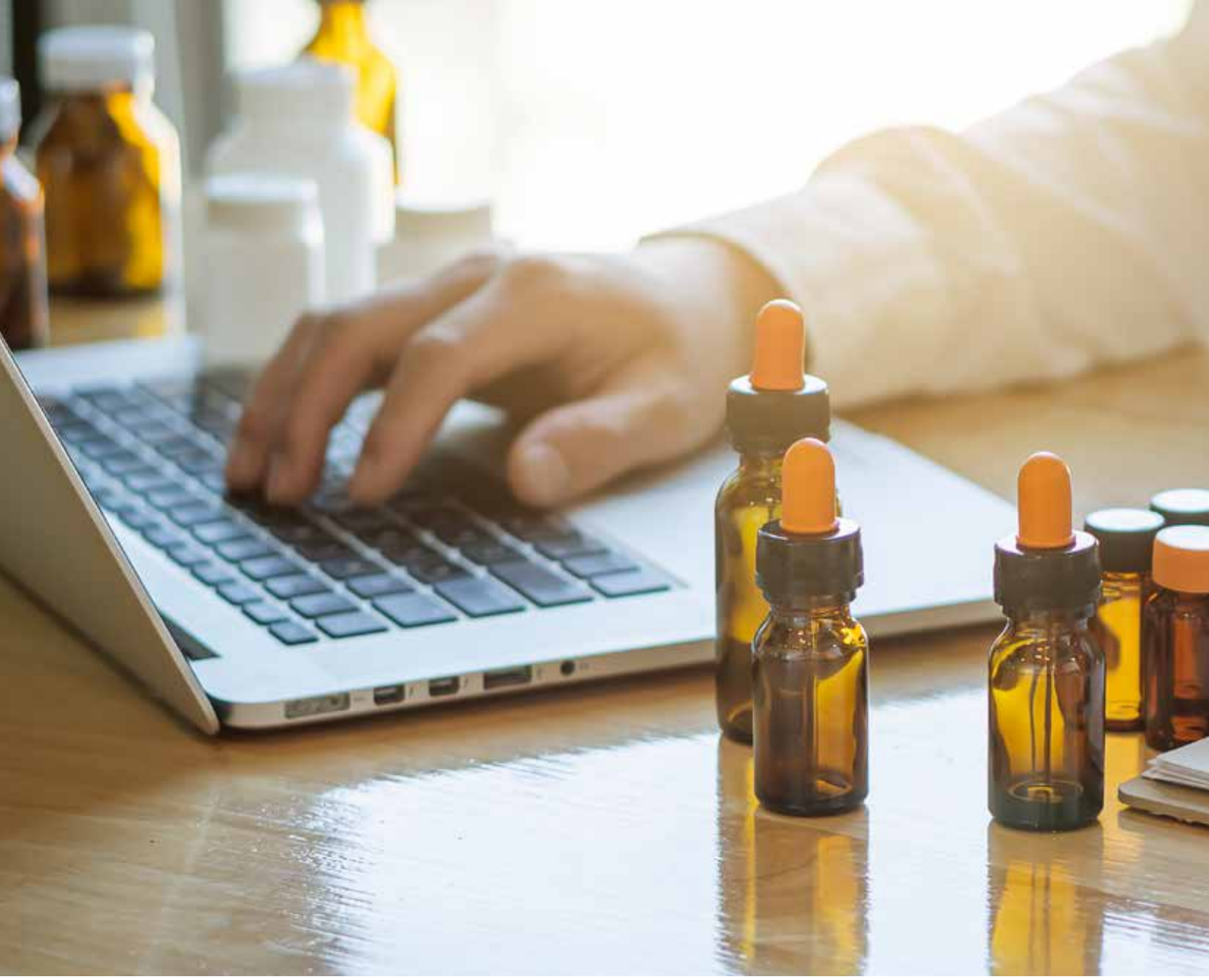
- Advance pharmaceutical entrepreneurship initiatives,
- Addressing the needs of special patient groups,
- Advancing research and development in advanced therapies,
- Strengthening industrial growth, and
- Providing scientific advice to start-ups.

The Unit explores innovative strategies to enhance the MMA's reputation, focusing on research-driven activities such as signal detection for quality assurance, online dispensing practices, and strengthening collaboration with Malta Enterprise (ME).

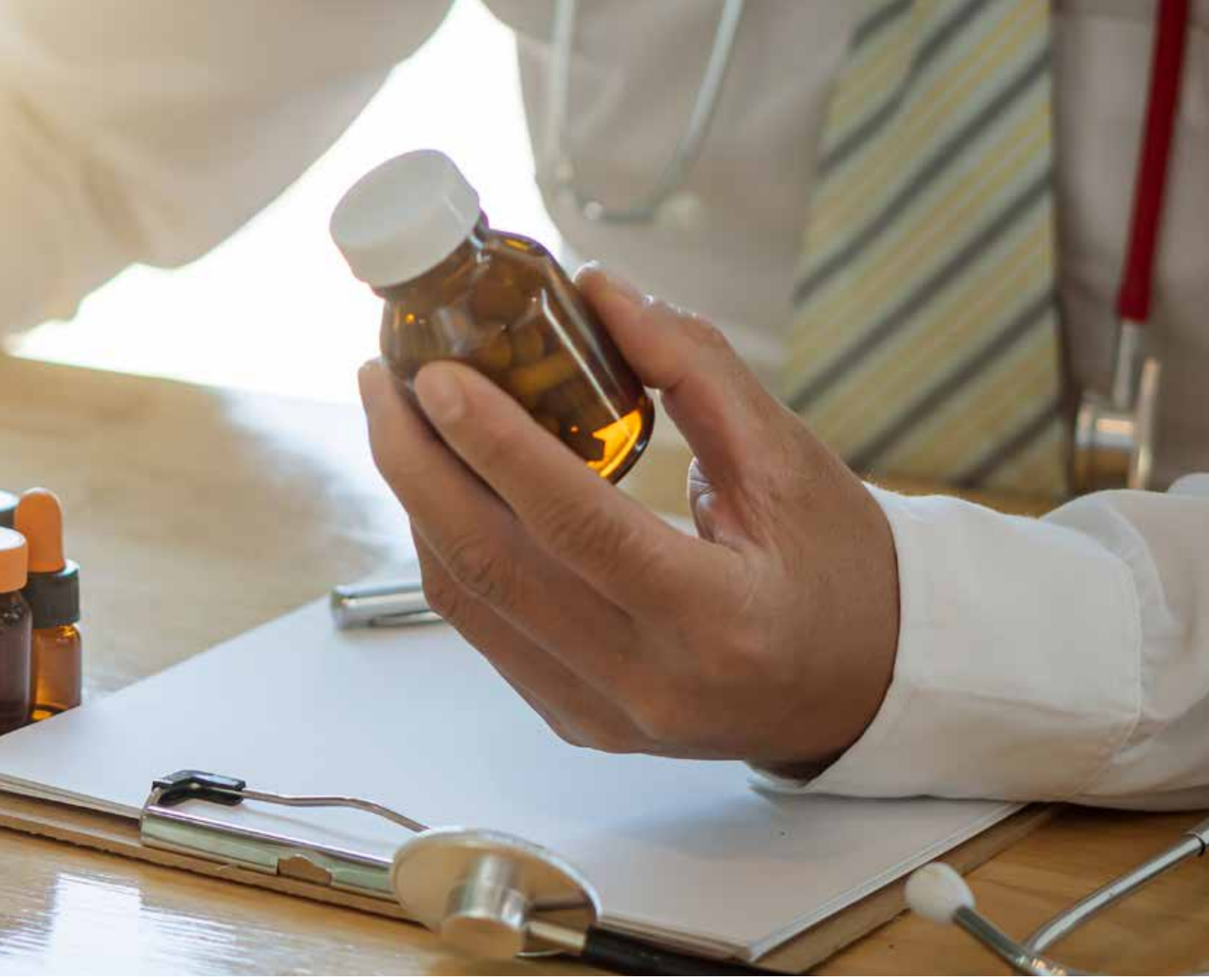
The Unit operates with a futuristic evolving vision, emphasising data-driven approach to sustainability and entrepreneurship. Through active participation in international fora and scientific networks, the Unit continues to extend the MMA's capabilities, ensuring its prominence in regulatory sciences.

The Unit integrates entrepreneurial acumen into its routine communication activities, aligning with the Authority's patient-centred and collaborative ethos. These initiatives contribute to participation in strategic engagements, including advisory committees on medical devices, the organisation of an international conference on pharmaceutical technologies, and technical discussions on key developments such as e-labelling and the procurement of essential medicinal products.

Strategically, the Unit supports internal collaboration in streamlining activities with the Office of the CEO in its dedication to expand the role of the MMA in engaging in the STEM disciplines. These efforts are pivotal to ensuring the availability of highly skilled professionals for the pharmaceutical and regulatory sectors. By cultivating expertise and fostering metamorphic changes, the Unit aims to support the continued growth and impact of the MMA within the regulatory and healthcare landscapes.



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



The MMA plays a critical role in ensuring that medicinal products available to the public meet the highest standards of quality, safety, and efficacy. As a regulatory body, the MMA is responsible for evaluating marketing authorisation applications, overseeing the post-authorisation lifecycle of medicines, and ensuring that patients have access to safe and effective treatments. In 2024, the Licensing Directorate continued to enhance its regulatory framework, optimising its capacity to handle a growing portfolio of products while adhering to the required standards.

This report outlines the key developments, regulatory achievements, and challenges faced by the Licensing Directorate over the past year, including the impact of Brexit, staffing improvements, and Malta's expanded role within the European Medicines Regulatory Network.

Assessment of Marketing Authorisation Applications

In 2024, the MMA successfully granted nine hundred ninety-six (996) new medicinal product authorisations through the following licensing regulatory procedures:

- National Marketing Authorisations (MAs): The MMA received four (4) purely national marketing authorisation applications

- European Procedures: The MMA acted as a Reference Member State (RMS) and Concerned Member State (CMS) in Decentralised (DC) and Mutual Recognition Procedures (MR) procedures, resulting in three hundred twenty (320) new marketing authorisations

- Article 126(a) Authorisations: A total of five hundred eighty (580) products were authorised in accordance with the legal basis of Article 126(a) of Directive 2001/83/EC, enabling the marketing of products already authorised in other EU member states

- Parallel Import Authorisations: The MMA approved ninety-six (96) medicinal products through parallel import applications.

Figure 3.1 illustrates the number of new medicinal product applications received and the number of authorisations granted through the different licensing routes throughout 2024. **Figure 3.2** provides a 10-year overview of registration processes for the authorisation of medicinal products in Malta via different registration procedures. The relatively constant number of authorised products was due to an increase in the number of MR and DC procedures and authorisations in accordance with Article 126(a) of Directive 2001/83/EC.

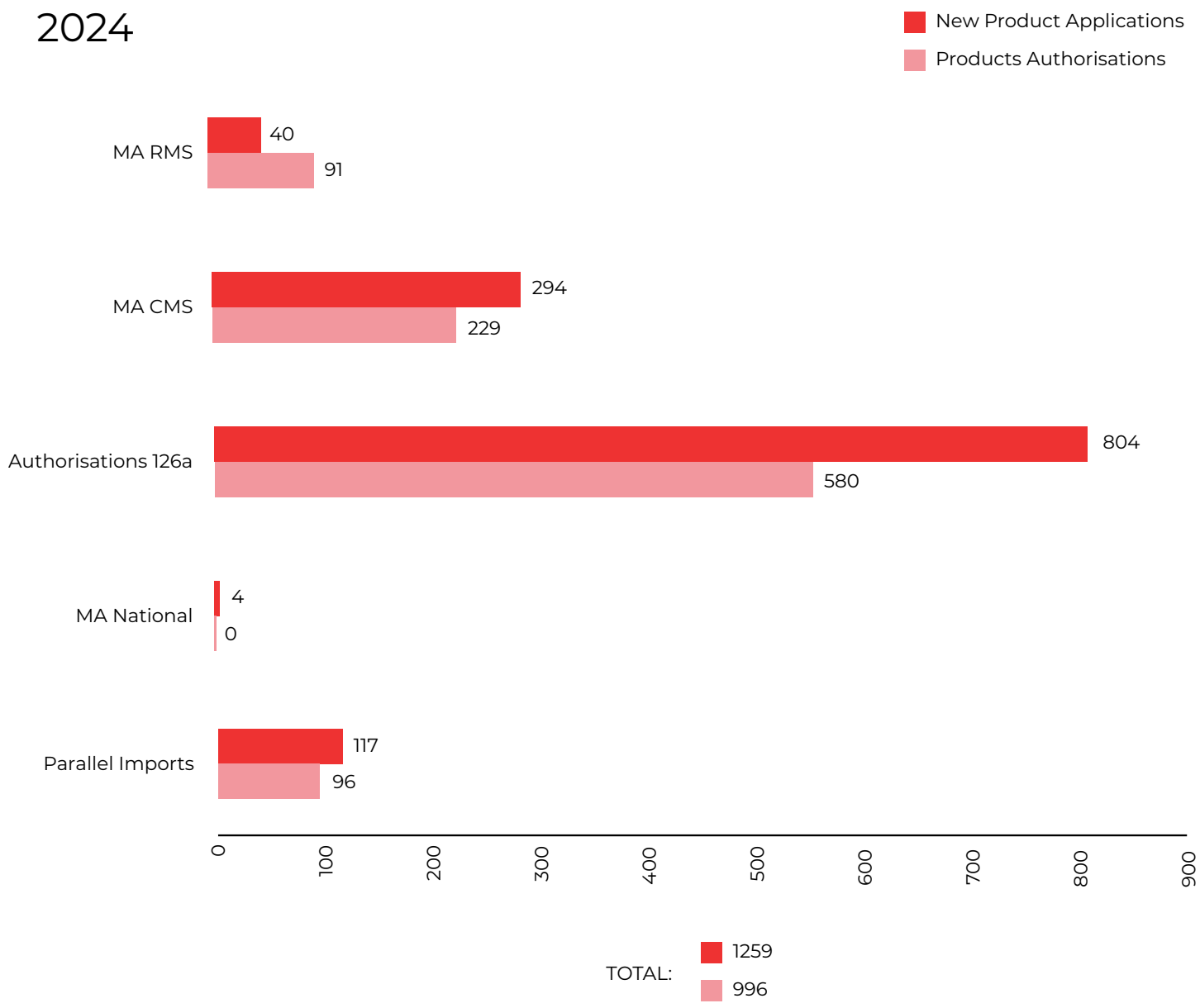


Figure 3.1: Total number of product applications and resulting product authorisations through all routes in 2024

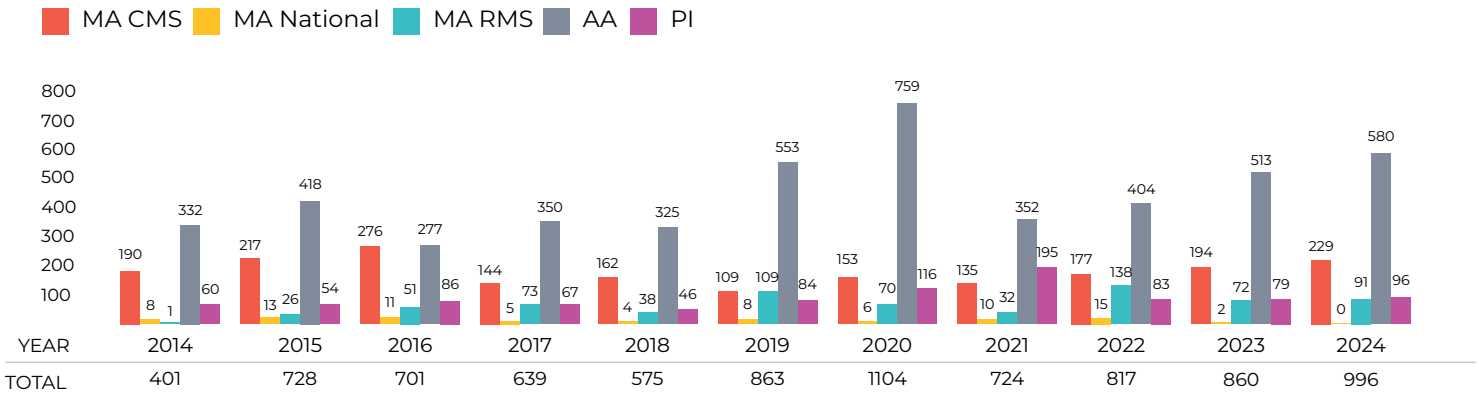


Figure 3.2: A 10-year overview of products registered annually in Malta by route of registration

Malta's Leadership Role in European Regulatory Procedures

Malta as a Reference Member State

In 2024, Malta solidified its position as a key player in the European regulatory framework. As a Reference Member State, Malta took the lead in forty (40) Decentralised Procedures (DCPs), resulting in ninety one (91) Marketing Authorisations across the EU **(Figure 3.3).** This contribution underscores Malta's growing interest in handling various regulatory dossiers, reaffirming its standing as a reliable scientific authority.

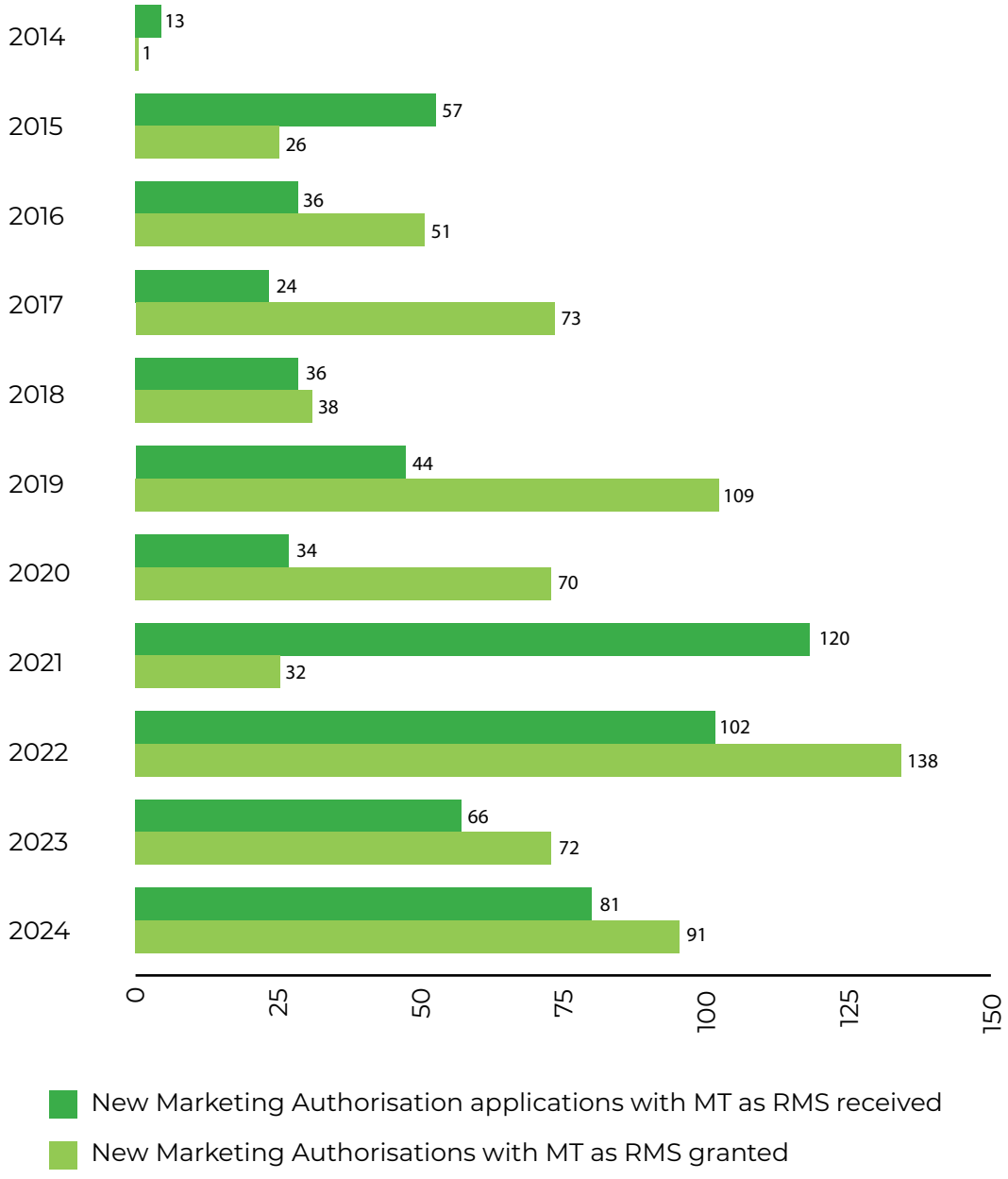


Figure 3.3: Number of applications with Malta as RMS and resulting Marketing Authorisations

Figures 3.4 and **3.5** give an overview of procedures started and finalised in the EU per RMS country.

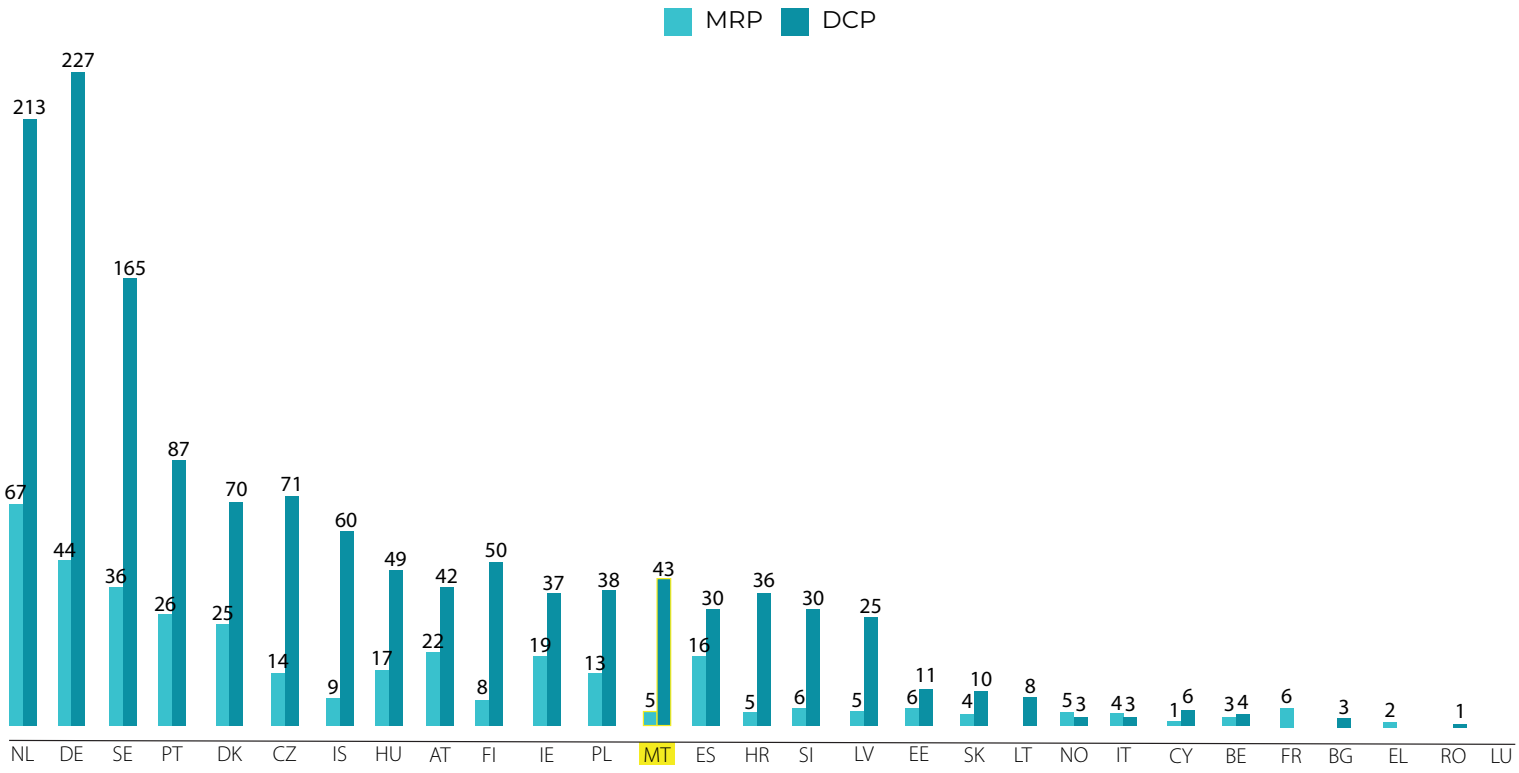


Figure 3.4: Total number of started procedures MRP/DCP per RMS

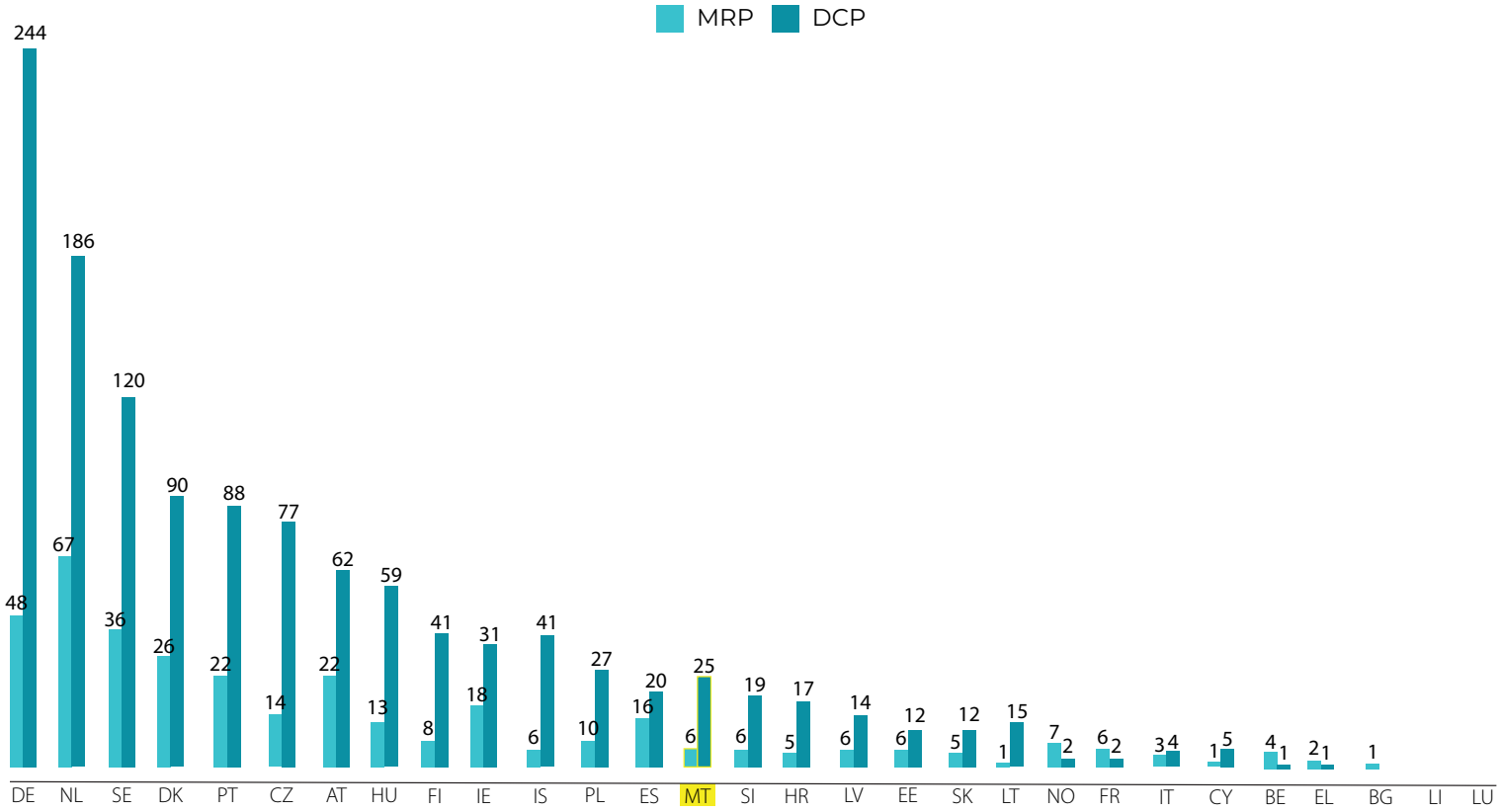


Figure 3.5: Total number of finalised procedures MRP/DCP per RMS

Malta as a Concerned Member State

The number of Marketing Authorisation applications received in 2024 as MR and DC procedures with Malta as CMS was two hundred ninety-four (294), whilst two hundred twenty-nine (229) new Marketing Authorisations were granted. **Figures 3.6** and **3.7** demonstrate the marketing authorisation applications that Malta started and finalised through this route compared to the other Member States. As can be seen, the size of the market and economies of scale determine the extent to which smaller Member States are included as CMS in European procedures by pharmaceutical companies. This has been an ongoing challenge for Malta, where companies choose not to include Malta in European procedures, the main reason being the market size. Meetings are conducted with companies to understand the issues and provide guidance on regulatory matters.

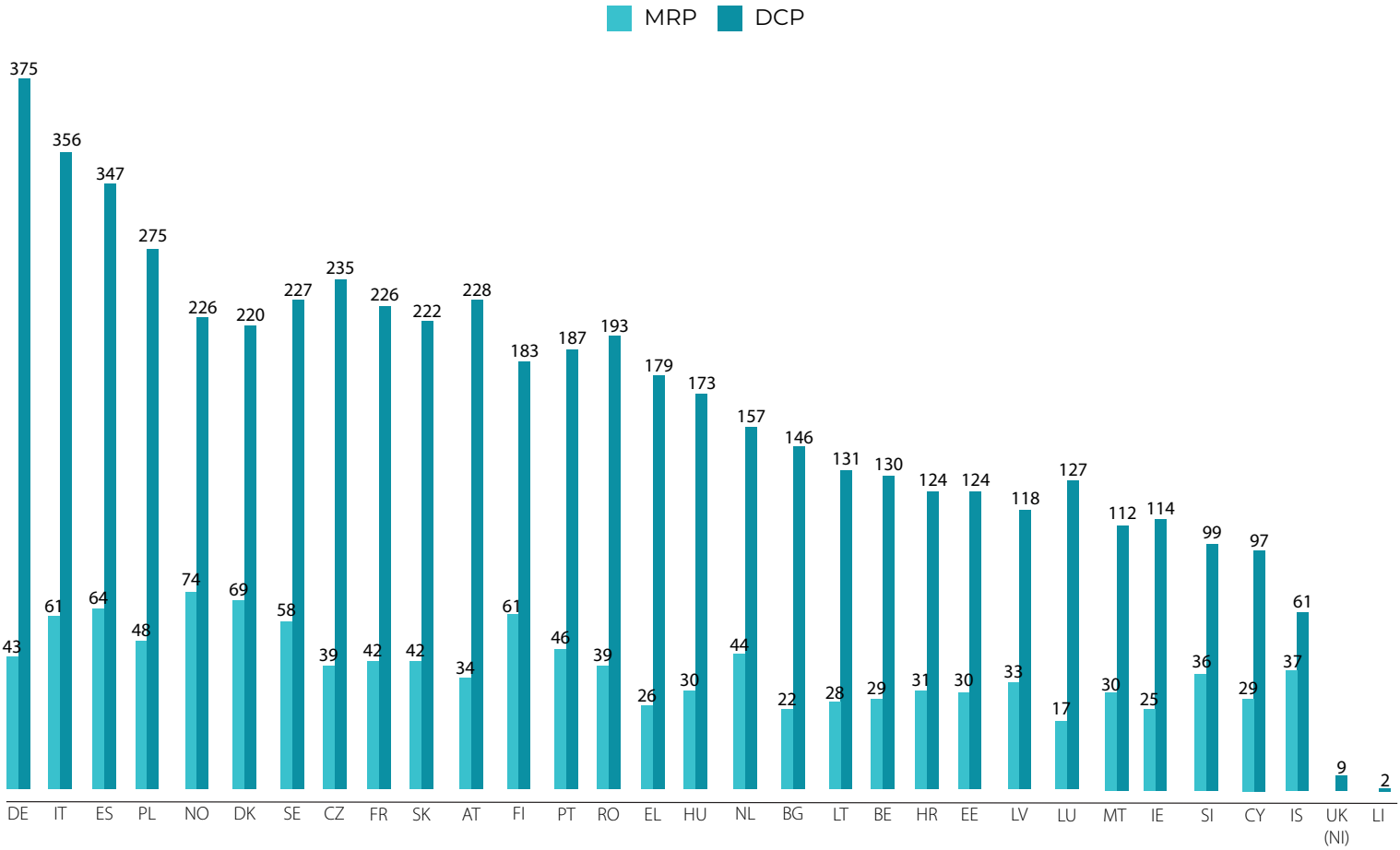


Figure 3.6: Total number of started procedures MRP/DCP per CMS

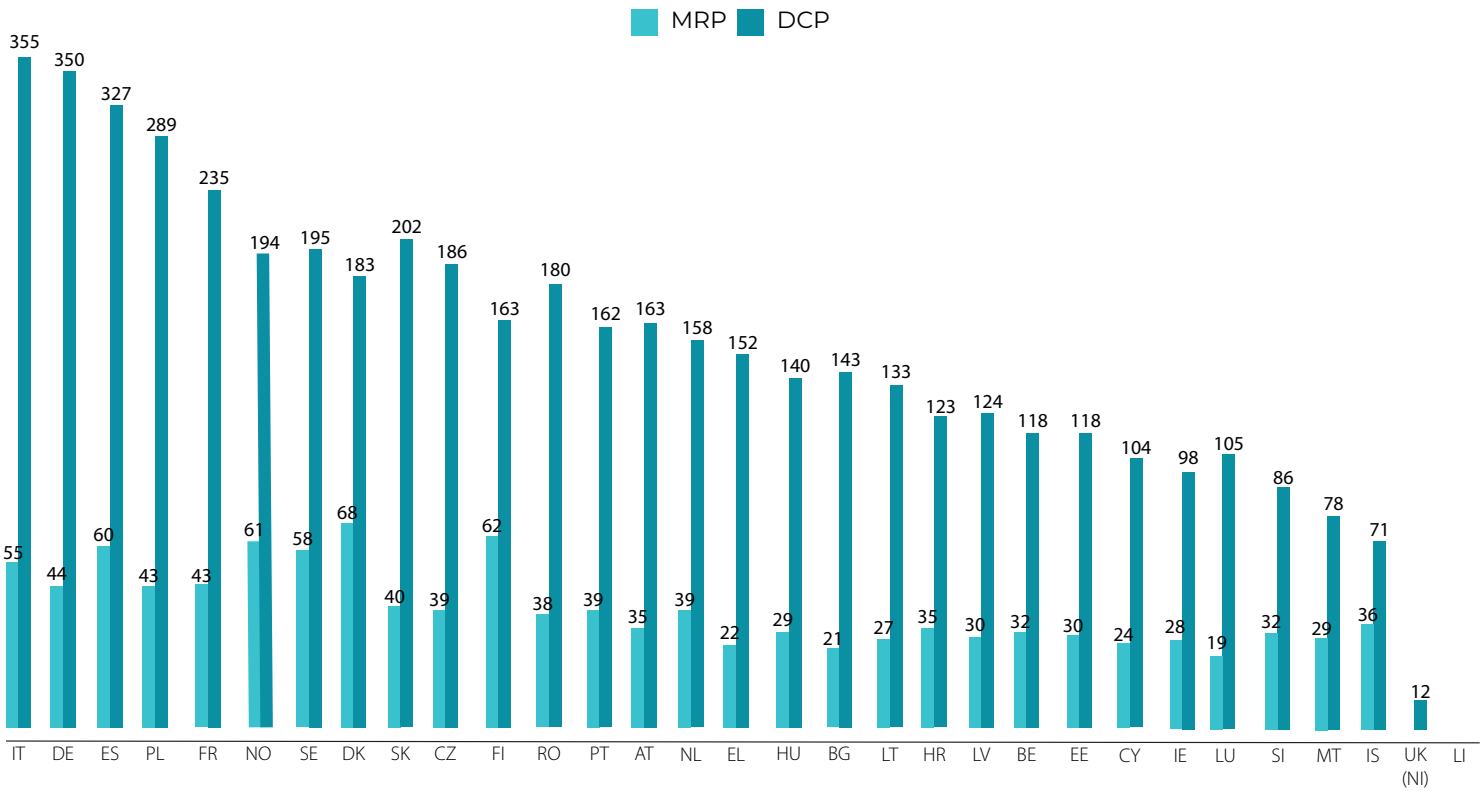


Figure 3.7: Total number of finalised procedures MRP/DCP per CMS

Malta as rapporteur in the centralised procedure

In addition to its involvement in DCPs, Malta served as the rapporteur for three (3) new centralised applications, expanding its role in evaluating products that require EU-wide authorisation. In these procedures, Malta was part of an Multinational Assessment Teams (MNAT), providing expertise mainly in the clinical and non-clinical assessment sections of the dossier. This brings Malta's total number of centralised procedures, where it has acted as rapporteur or co-rapporteur, to thirty-seven (37) active procedures, further enhancing its visibility and improving its expertise in this field of operation.

Participation in Multinational Assessment Teams

The MMA's engagement in Multinational Assessment Teams MNATs has enhanced the collaboration with NCAs from other EU member states, ensuring that the evaluation of medicinal products is both comprehensive and timely. The multinational collaboration maximises the use of available resources and expertise within the network and facilitates the participation of National Competent Authorities in assessments, allowing for expertise to be built up while maintaining the high-quality scientific work of the scientific committees. It can also be a useful tool for the training of in-house assessors.

Authorisations in accordance with article 126(a)

The cumulative number of authorisations in accordance with Article 126(a) of Directive 2001/83/EC (AA) standing at the end of 2024 was two thousand six hundred and seventy-one (2,671). Eight hundred and four (804) new applications were received in 2024. Five hundred eighty (580) new authorisations were granted.

Figure 3.8 illustrates the number of applications in accordance with article 126(a) received in 2024 from the main source countries.

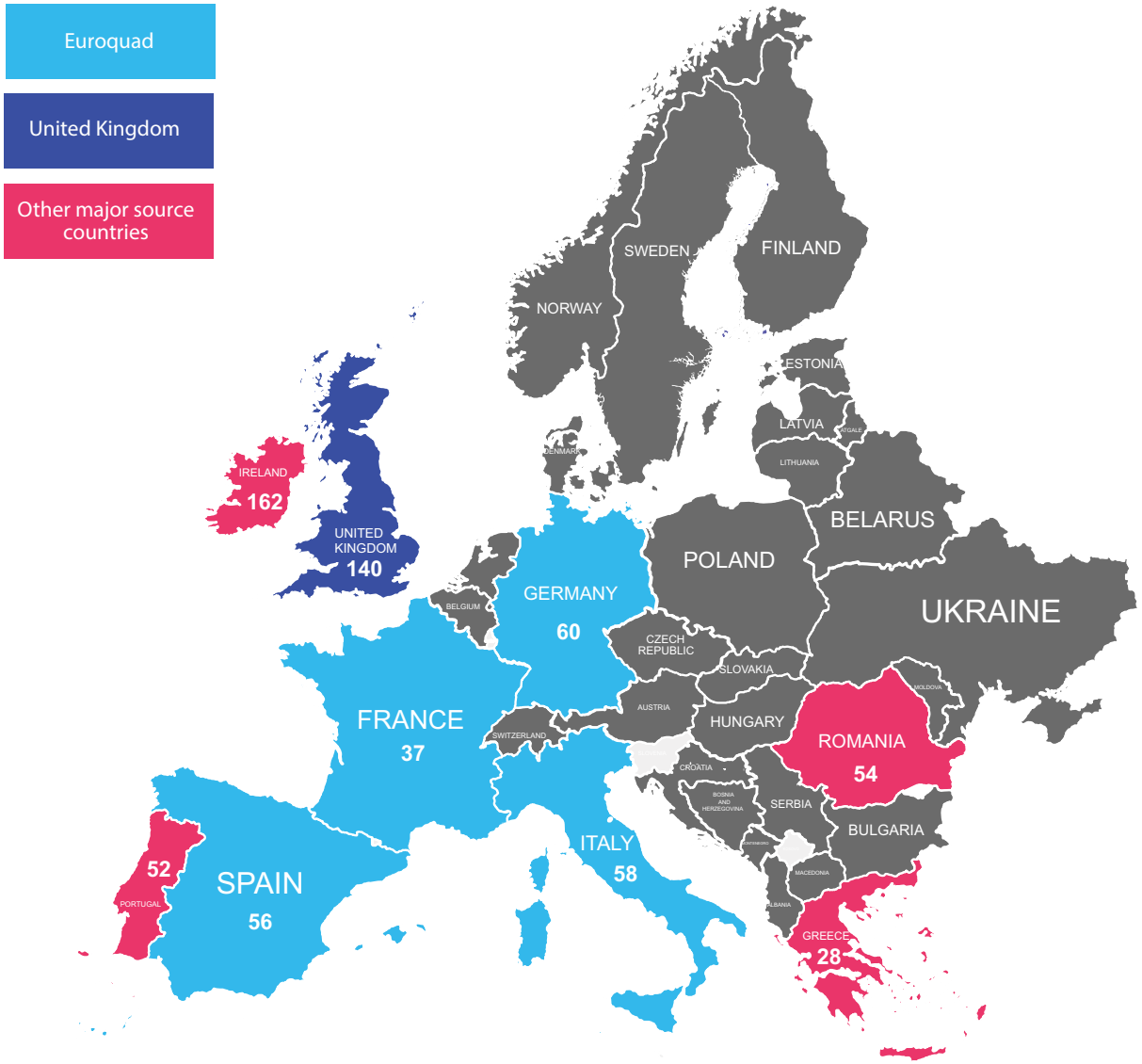


Figure 3.8 Number of applications in accordance with article 126(a) received in 2024 from the main source countries

As a result of Brexit, a shift in source countries in 2024 continued to be observed, with most products now originating from Ireland (IE), followed by Germany (DE), Italy (IT), Spain (ES), Romania (RO), Portugal (PT), France (FR), and Greece (EL). A substantial number of applications continued to be registered based on marketing authorisations in the United Kingdom (UK) for the supply of the national health service.

Companies are always supported to make use of the established European procedures, through sound regulatory advice, reduction of bureaucracy and enabling communication channels with other Competent Authorities for this route to be made more feasible. The Licensing Directorate continues to support companies in applying for MAs through the MRP. One-to-one meetings with companies are held to encourage the use of the Zero-day MR Procedure over applications in accordance with Article 126(a).

Products authorised in accordance with article 126(a) (and amended by article 126(c)) based on MAs in the United Kingdom can continue to be made available based on the derogations granted by the EC until the end of 2026, in case of shortages or lack of accessibility of alternatives from the EU.

Post-Authorisation Procedures

Overview of Post-Authorisation Work

Post-authorisation activities remain a cornerstone of the MMA's regulatory responsibilities, ensuring that authorised medicines continue to meet safety, efficacy, and quality standards throughout their lifecycle. In 2024, the MMA processed eight hundred forty-nine (849) variation applications, leading to updates for one thousand two hundred and seventy-four (1,274) products. These variations cover a range of modifications, including changes to product information, quality control measures to the drug substance and drug product, and safety monitoring.

As the number of products authorised in Malta continues to grow, the volume of post-authorisation activities has increased, underscoring the importance of efficient management in this area. Post-authorisation activities, especially for procedures where Malta is a RMS, maintained an increased average, also as a result of the additional procedures taken over by Malta from the United Kingdom. This is expected to continue in the coming years.

The portfolio of procedures where Malta is the rapporteur or co-rapporteur in the centralised procedures also continues to increase as Malta takes on more new procedures each year. Forty-eight (48) post-authorisation activities for centralised procedures where Malta is rapporteur were reported for 2024. Forty-five (45) were variations, including Type 1B and Type II variations, while two (2) were renewals of Marketing Authorisations **(Table 3.1)**.

	Annual reassessment cumulative	CAP new cumulative	TYPE_IA cumulative	TYPE_IB cumulative	TYPE_II cumulative	Renewal cumulative	Line Extension cumulative
2011	0	0	0	1	0	0	0
2012	0	4	1	6	0	0	0
2013	0	6	1	10	0	0	0
2014	0	14	1	10	0	1	0
2015	0	20	1	21	1	1	0
2016	1	24	2	46	3	1	0
2017	2	26	3	71	6	3	0
2018	3	28	3	97	7	4	0
2019	4	32	4	131	13	4	2
2020	5	37	4	163	19	8	2
2021	7	49	4	204	26	12	3
2022	8	50	4	236	28	16	3
2023	9	51	4	265	37	19	3
2024	10	53	4	301	46	21	4

Table 3.1: Cumulative number of post-authorisation procedures with MT as co/rapporteur in the centralised procedure (2011-2024)

In 2024, the MMA received:

- One thousand four hundred and sixty-eight (1468) procedural variation applications where Malta is a CMS;
- Other post-authorisation procedures, including thirty-seven (37) procedural renewals and sixty-two (62) article 61(3) notifications **(Table 3.2)** for products authorised through the MRP with Malta as CMS.

	CMS Variations	CMS Renewals	CMS Article 61(3) notifications
2010	1057	72	18
2011	1103	163	40
2012	1351	165	31
2013	1462	137	28
2014	1493	124	19
2015	1803	119	76
2016	1682	69	57
2017	1792	65	114
2018	1608	55	217
2019	1744	70	63
2020	1626	129	36
2021	1567	101	58
2022	1279	67	52
2023	1379	29	49
2024	1468	37	62

Table 3.2: Post-authorisation procedures received by MT as CMS in the MRP in 2024

The MMA has made significant strides in 2024, further establishing itself as a leader within the European Medicines Regulatory Network. Despite the ongoing challenges posed by Brexit and the expanding regulatory workload, the Licensing Directorate has remained focused on ensuring that medicines available in Malta are of the highest quality, safety, and efficacy. Looking forward, the MMA will continue to build on its leadership role within the EU, focusing on enhancing its internal processes, expanding its regulatory capacity, and maintaining robust post-authorisation monitoring to safeguard public health.

Pharmacovigilance Activities

Patient safety is a priority area for the MMA as it continues to strengthen its efforts to ensure the safe use of medicinal products on the local market. The Pharmacovigilance role includes the evaluation, monitoring, and communication of safety-related data and, where appropriate, implementation of regulatory action to maximise benefits 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. In 2024, 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 2024, included participation in two (2) face-to-face workshops targeting professionals and participation in the annual ADR awareness week social media campaign (#MedSafetyWeek). During the workshops, MMA staff instructed participants on how to report ADRs, explained the importance of good data quality in ADR reporting and discussed causality assessment as well as how ADR reporting translates into improving the safety of medicines. In 2024, #MedSafetyWeek was held between the 4th to 10th November 2024 with the aim of increasing awareness of the importance of monitoring side effects and encouraging reporting of side effects by both healthcare professionals and patients.

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

A total of hundred eight (108) Individual Case Summary Reports (ICSRs) were registered in 2024. These cases detailed at least one (1) ADR to the medicinal product concerned, and together, these hundred eight (108) reports described two hundred seventy-two (272) suspected Adverse Events (AE). **Figure 3.9** gives a breakdown of these ADRs according to the System Organ Class (SOC) classification.

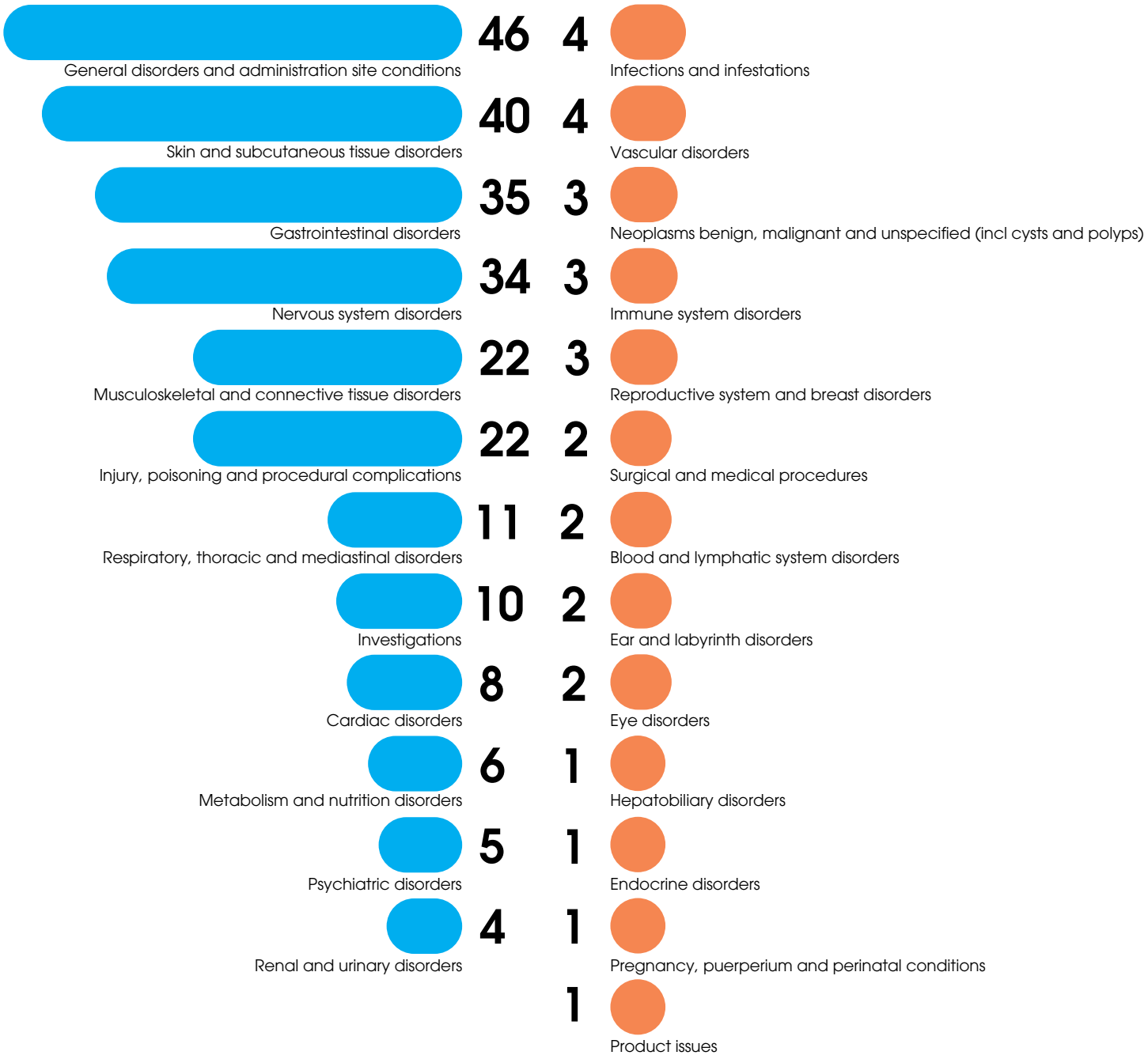


Figure 3.9: Distribution of ADRs according to SOC in 2024 (N=272)

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 the dose of the medicinal product, indication for use, concurrently administered drugs, and underlying patient disease.

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. **Figure 3.10 and Figure 3.11** further classify the adverse ICSRs (as received over 2024) according to seriousness and patient age, respectively.

Figure 3.10: Frequency of ICSRs according to seriousness in 2024 (N=108)

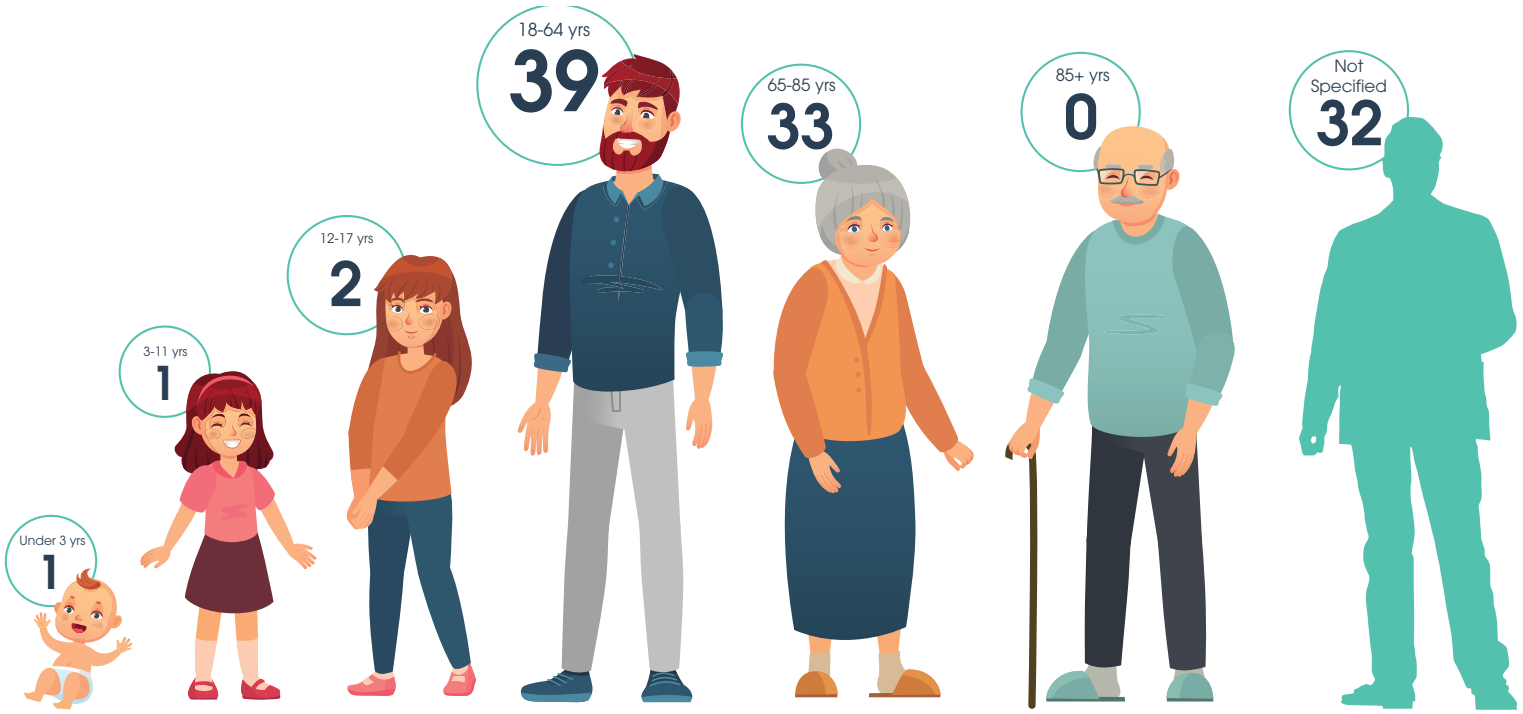


Figure 3.11: Distribution of ICSRs according to patient age in 2024 (N=108)

In addition to the management of ADRs and routine safety signal management as relevant, several other activities were undertaken nationally by the Authority in 2024 to attain effective product safety surveillance. Such activities (amongst others) include the following:

- 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,
- Investigation of newly identified emerging safety issues, rapid alerts, and product recalls which, where necessary, can lead to immediate product suspension and/or recall,
- Approval and monitoring of Risk Minimisation Measures (RMMs) and educational material relating to high-risk medicinal products as well as approving Pregnancy Prevention Programmes (PPPs) as proposed to potentially teratogenic medicinal products,
- Issue of safety circulars and media statements addressed to healthcare professionals and the public, respectively. Safety Circulars give recommendations on medicinal product use and applicable cautionary and precautionary measures. Throughout 2024, 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,
- Initiation and subsequent approval of variations to scientific medicinal product information relating to identified novel or increased risk (Urgent Safety Restrictions),
- Assessment of Periodic Safety Update Reports (PSURs) for nationally authorised products containing active substances or active substance combinations 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,
- Assessment of risk management plans during national and centralised procedures.

Figure 3.12 gives the distribution of safety communications and RMMs approvals, which the MMA handled over 2024:

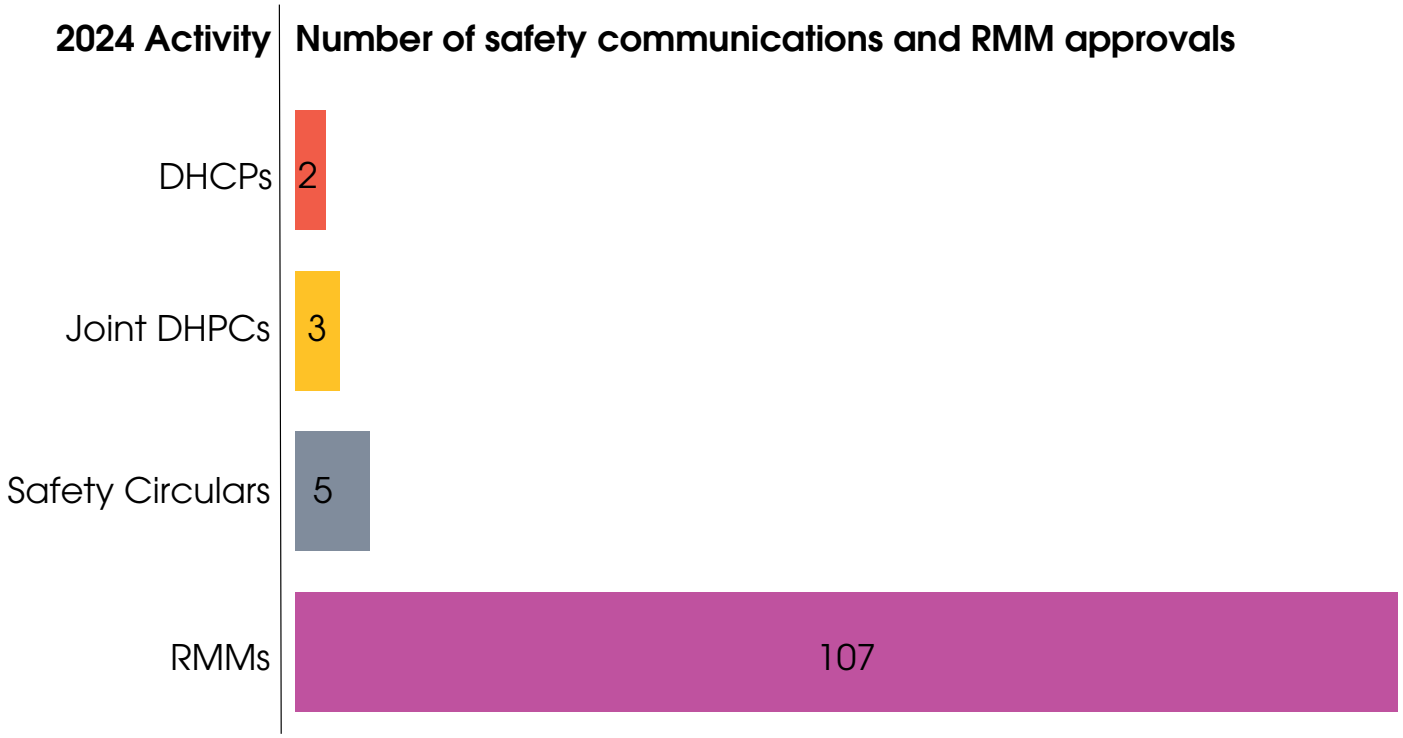


Figure 3.12: Safety Communications and RMMs approvals in 2024 (N= 117)

An additional stakeholder service performed by the MMA is that of responding promptly to any queries related to Pharmacovigilance activities. In 2024, queries received were mostly related to:

- National pharmacovigilance legislation and requirements locally, and
- Clinical trial Suspected Unexpected Serious Adverse Reactions (SUSARs), Annual Safety Reports (ASRs) and Development Safety Update Reports (DSURs) **(Figure 3.13).**

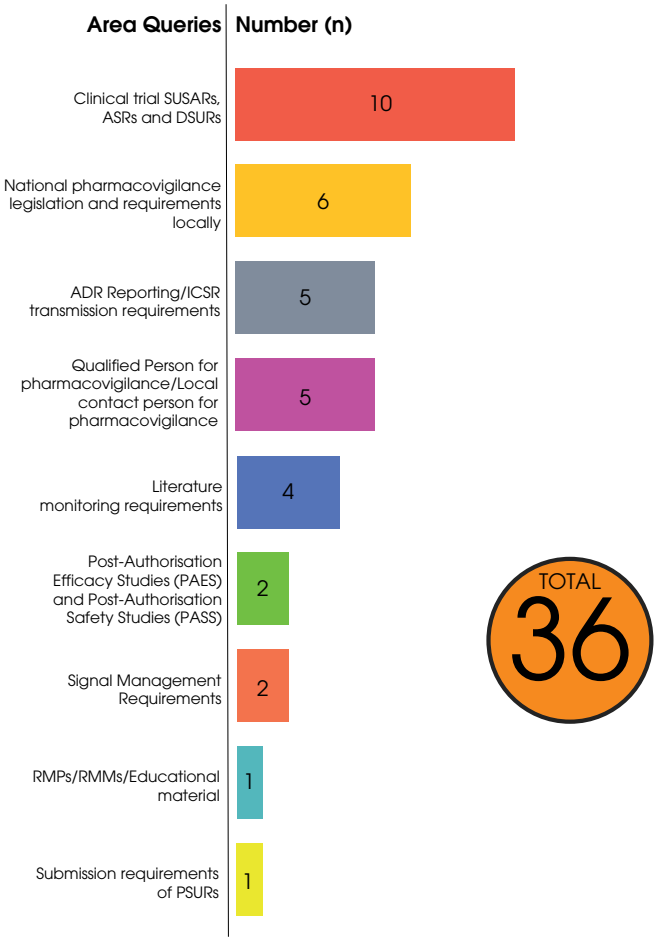


Figure 3.13: Pharmacovigilance-related queries in 2024 (N=36)

Advertising of Medicinal Products

The MMA monitors the advertising of medicinal products, and the issue of any promotional material related to such medicinal 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. Advertising and promotional material regulatory control is implemented according to the criteria set out within 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 through 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 2024, four (4) advertising complaint procedures were registered.

Clinical Trials

The role of the MMA concerning clinical trials is to evaluate both the quality of the investigation and the patient safety of clinical trials, provide recommendations to the licensing authority and provide authorisation based on the Authority's and the Health Ethics Committee's recommendations.

The Clinical Trial Regulation (CTR), Regulation (EU) No. 536/2014, came into application on 31 January 2022. The Regulation is part of a broad initiative to transform the EU/EEA clinical trials environment in support of large clinical trials in multiple European countries, to the benefit of medical innovation and patients. The Regulation introduces an authorisation procedure based on a single submission via a single EU online portal - the Clinical Trials Information System (CTIS), an assessment procedure leading to a single decision for multinational trials, improved rules on the protection of subjects and informed consent, and new transparency requirements. As of 31 January 2023, all initial clinical trial applications must be submitted through the new Clinical Trials Information System. Ongoing clinical trials currently governed by the Clinical Trials Directive (CTD) and expected to continue after 30 January 2025 will need to transition to the CTR regulatory framework. For 2024, no clinical trial assessment procedures were registered.

Cannabis for Medicinal and Research Purposes

Regulatory Activities

Two (2) legal frameworks principally govern the regulation of medicinal cannabis in Malta where through Article 10 of the Drug Dependence (Treatment not Imprisonment) Act (Chapter 537 of the Laws of Malta) patients may access medicinal cannabis preparations that either have an MA in line with the requirements of the Medicines Act or have been produced under EU-Good Manufacturing Practice standards, as per the relevant provisions and prescribing protocols established by the Superintendence of Public Health (SPH). The MMA reviews applications for the sourcing of finished cannabis-based products intended for the local market. Chapter 578 of the Laws of Malta provides a legal basis for the production of cannabis for medicinal and research purposes.

Production and wholesale distribution operations are regulated through a comprehensive evaluation of scientific and technical documentation, security considerations and good practices, thereby safeguarding the integrity of transacted material and products. An audit trail of the cannabis supply chain is maintained for reconciliation and traceability and to fulfil international reporting obligations. The Unit undertakes and

promotes research initiatives related to different aspects of medicinal cannabis and cannabinoids by forging multi-sectoral partnerships with diverse stakeholders.

The regulatory framework, as published in the respective MMA Guidelines, involves several 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. The total number of approved cannabis-based products standing at the end of 2024 was sixty-seven (67), where such products may have varied pack sizes and were commercialised through both wholesale and production routes; the charts in **Figure 3.14A** and **3.14B** respectively characterise their formulation and cannabinoid concentration. Most products are in the dried inflorescence formulation. Upon further stratification according to their tetrahydrocannabinol (THC) and cannabidiol (CBD) content, it is observed that nearly two-thirds of the products fall in the THC-dominant type category. The cannabinoid concentration for the approved oils and extracts ranges from 240mg/ml for most CBD-dominant products to a THC concentration of 8.7mg/10µl present in the purified extract. The most potent THC-approved flower product has a concentration of 31% w/w.

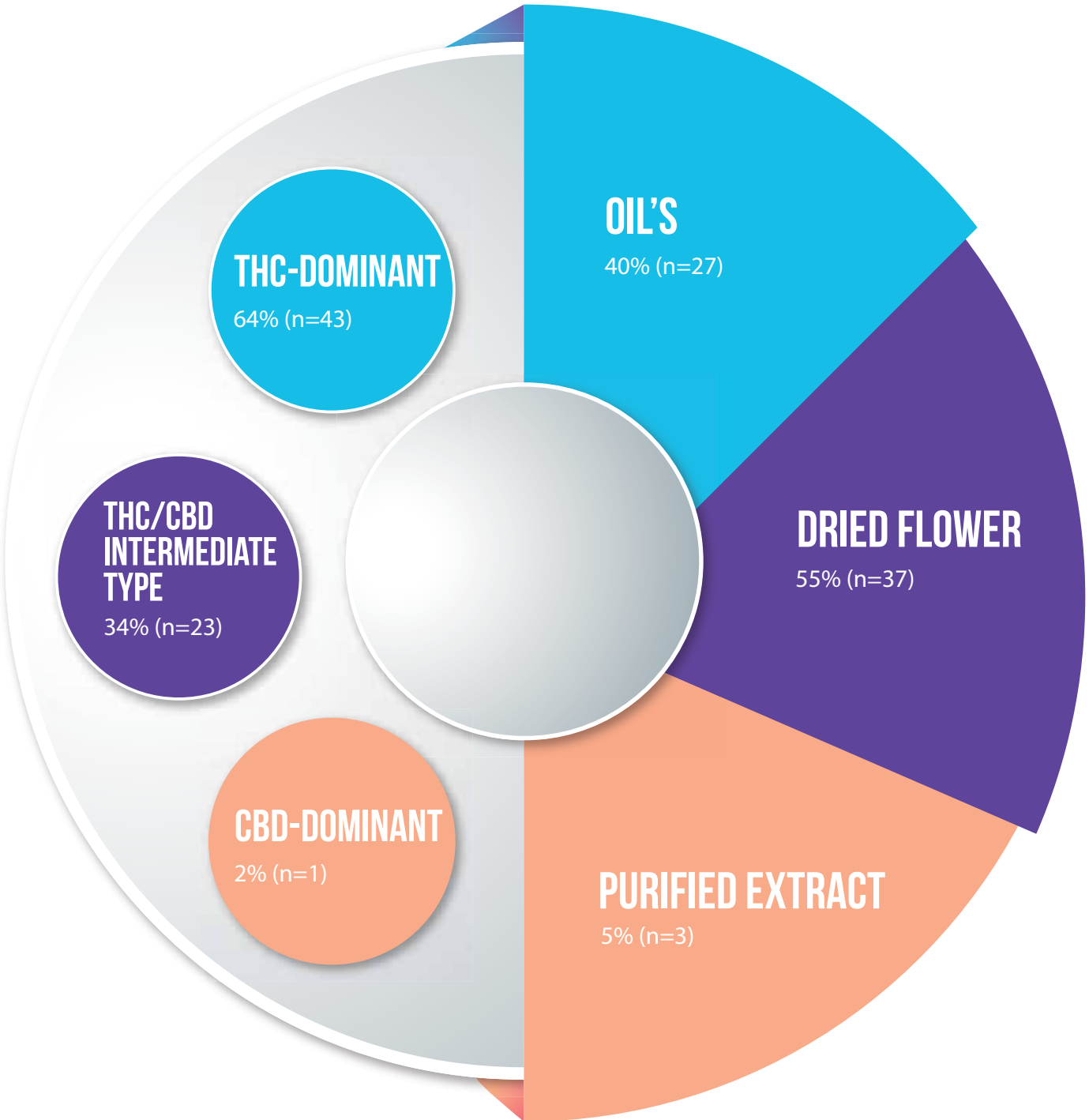


Figure 3.14A: Characterisation of the approved cannabis-based products according to their cannabinoid content (N=67)

Figure 3.14B: Characterisation of the approved cannabis-based products according to their formulation (N=67)

Reconciliation and traceability of transacted cannabis material are continuously upheld by the Authority through monitoring efforts conducted by reviewing periodic stakeholder reports. Such records enable the tracking and quantification of the movement of imported, processed, disposed and exported cannabis material from authorised suppliers to licensed clients and service providers across the supply chain.

For security and product authenticity, approved wholesalers and production licence holders are provided with unique serial numbers that are displayed on the packaging of the cannabis units. More than ninety-four thousand (94,000) serial numbers were issued by the Authority to local operators throughout 2024 for product units intended to be marketed **(Figure 3.15)**. This represents an increase of +157% in the total number of serial numbers issued throughout the year under review when compared to the preceding year. This same graph also denotes the relative proportions of serial numbers in terms of the destination market and product formulation.

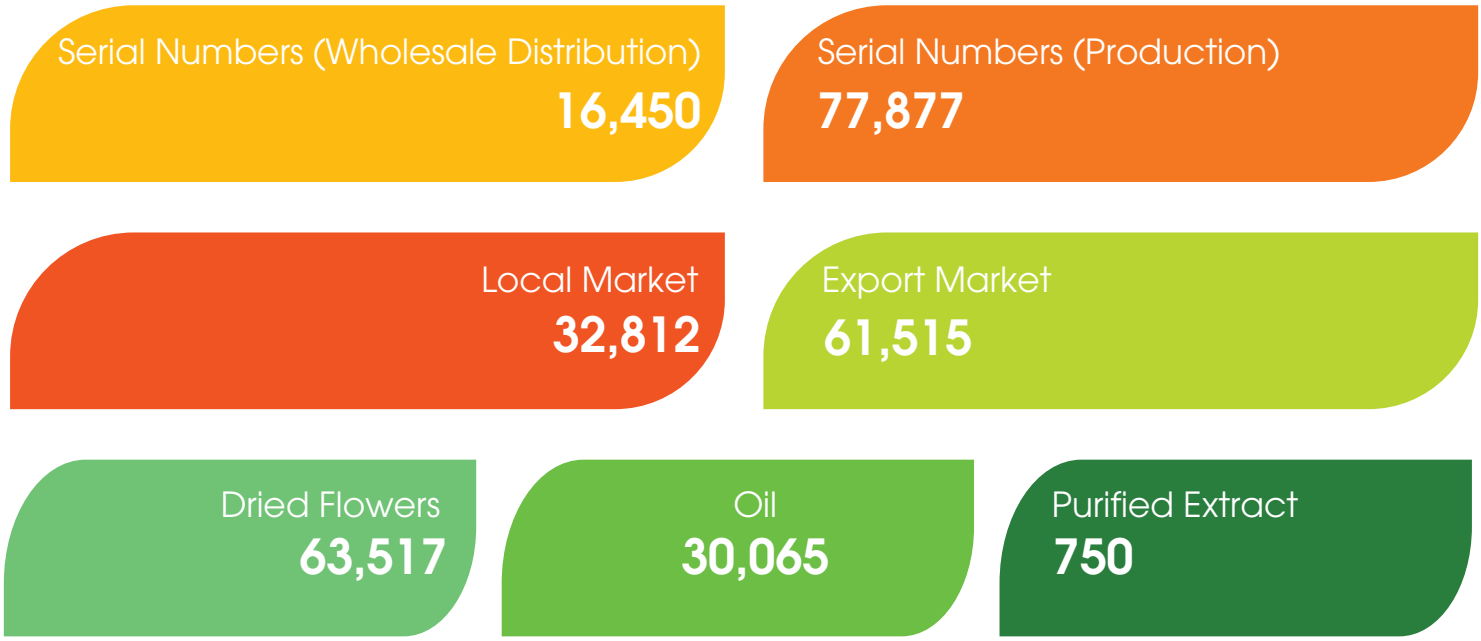


Figure 3.15: Units of cannabis-based products for medicinal use issued with a serialisation code, characterised by pharmaceutical activity, destination market and product formulation

Since the first product approval in 2018, two (2) Adverse Events were reported and assessed accordingly. The portfolio of approved cannabis-based products is followed up with an annual renewal, including a review of emerging data in updated studies.

- **Wholesale Distribution**

Till the year-end, two (2) operators are approved for wholesale distribution activities, both of which source cannabis in its dried inflorescence form. A total of twelve (12) new and eight (8) renewal applications for cannabis-based products were received and reviewed throughout 2024, for which thirteen (13) products were issued with a notification of approval.

- **Production Activities**

The number of companies issued with a positive recommendation for the grant of a licence to produce cannabis for medicinal and research purposes by the end of 2024 stood at six (6) from a total of seven (7) applications received. Two (2) renewal applications were approved in 2024, extending the licence validity for another term in line with the endorsed conditions. One (1) facility produces oils and purified extracts, another one (1) produces flowers, and a further two (2) companies manufacture products in both inflorescence and oil formulations. A total of fifty-eight (58) applications for a variation to the production licence were received throughout 2024. The main variation types that requested amendments to the licence details or proposed changes to relevant application documents are depicted in **Figure 3.16**, where almost half of the variation applications received in 2024 were of variation type A2, relating to changes in product details.

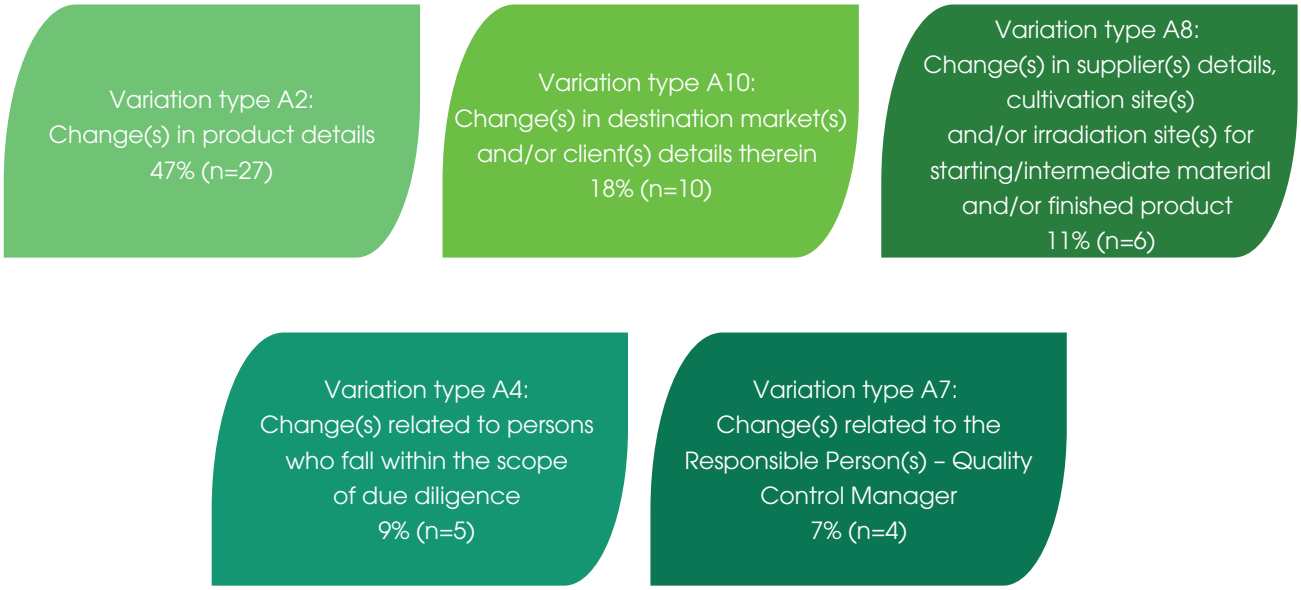


Figure 3.16: Number of VARS applications received for the main variation types (N=58)

Through liaison with relevant internal departments and external parties, five (5) local certification inspections were coordinated in 2024, including two (2) for EU-GMP and three (3) for facility/physical security. Authorised operations encompass importation, analytical testing, packaging, extraction, dilution, standardisation, and batch certification activities.

Collectively, by the end of 2024, production licence holders were authorised to produce a total of fifty-four (54) products out of which twenty-four (24) products in dried flower form, twenty-seven (27) oils and three (3) purified extracts. Thirty-eight (38) of which are intended for export in destination markets, twelve (12) for domestic consumption and four (4) can be commercialised both locally and abroad. **Figure 3.17** demonstrates the successful expansion over four years of local production companies into a diverse range of geographically distinct territories. Malta led the way with nearly 40,000 units being domestically commercialised, followed closely by Germany, showcasing strong penetration in these key markets. France accounted for over 11,000 units, demonstrating a growing presence, whilst alternative European countries like the Czech Republic and Cyprus represent promising entry points as emerging markets. This distribution underscores the increasing reach and adaptability of local producers in meeting varied market demands.

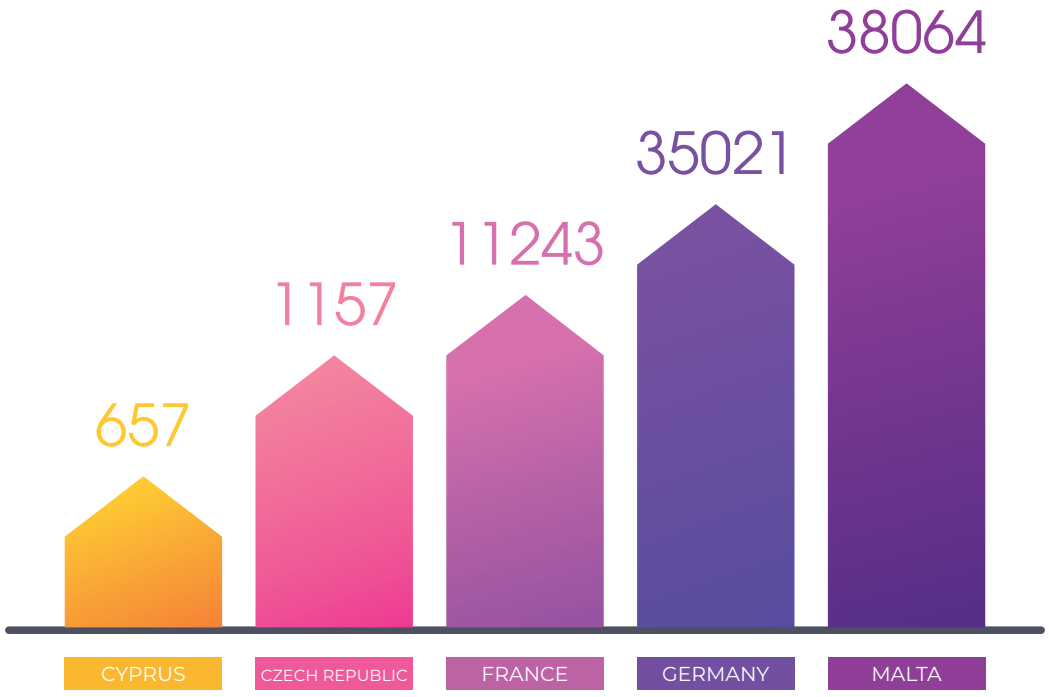


Figure 3.17: Number of commercialised locally produced cannabis-based units for medicinal and research purposes by destination market (2021* - 2024).

* The first commercial activity for local production licence holders was registered in the year 2021

Regulating Medical Devices

Authorisation Procedures

The Medical Devices and Pharmaceutical Collaboration Directorate is responsible for the regulation of medical devices and in-vitro diagnostics. The Medical Devices Registration application form pertains to the registration of medical devices placed on the EU Market through the MMA. Economic operators and entities planning to engage in activities involving medical devices and in-vitro diagnostics in Malta must register with the MMA using the Organisation Registration form. In line with national legislation, distributors and importers are required to designate a Medical Device Registered Person (MDRP) responsible for regulatory compliance, who must also be registered with the MMA via the Medical Device Registered Person application form. These processes provide easier coordination of surveillance and activity, promoting greater transparency and accountability in the field.

Certificate of Free Sales are issued by European Competent Authorities, in this case, the Malta Medicines Authority, after technical regulatory consideration upon request by a manufacturer or an authorised representative. By way of derogation from the Regulations, the Malta Medicines Authority may grant an exemption from the conformity assessment procedures set out in Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR). An exemption may be granted after having evaluated in accordance with MDR article 59 or article 97 or IVDR article 54 or article 92. The device must not pose an unacceptable risk to the health or safety of patients, users or others, or public health in general. **Table 3.3** summarises the authorisation activities processed in 2024.

Application Type	Number Received
EUDAMED actor registration processed and approved by the Authority on the European Databank	81
Medical Device Registration	85
Organisation registration	38
Certificate of free sale	38
Medical Device Registered Person Registration	36
Medical Device notification	1273
COVID-19 designated premises	3
COVID-19 test notification	6
Derogation related to MDR Article 59	1
Derogation related to MDR Article 97	1
Pre-Submission meeting	3
Clinical Investigation/notification	3
Request for Medical Device/IVD classification confirmation	3
Customs Documentation and Product Compliance Evaluation	12

Table 3.3: Applications processed in relation to stakeholders' operations within the MD and IVD field

Notified Bodies, Surveillance and Clinical Relations

The Notified Bodies, Surveillance and Clinical Relations Unit operating within the MDPCD is responsible for assessing conformity assessment bodies seeking designation as Notified Bodies for medical devices and/or in vitro diagnostic medical devices, as well as conducting their periodic reassessment. The Unit plays an active role in market surveillance and supporting economic operators. It adopts a patient-centred approach by coordinating vigilance activities, including the evaluation of reported incidents and complaints. The Unit contributes to the establishment of a clinical investigations hub in Malta by assessing applications for clinical investigations and performance studies, ensuring the safety, clinical performance, and effectiveness of devices. These efforts aim to uphold the overall safety, efficacy and quality of medical devices available in both local and European markets.

- **Designation of Notified Bodies**

The Directorate is proactively addressing the international challenge of shortages in Notified Bodies in the area of medical devices and in-vitro diagnostics in accordance with European Union regulations through its commitment to designate and continuously monitor the performance of Notified Bodies registered in Malta. Two Conformity Assessment Bodies (CABs) have ongoing applications in Malta for designation as a Notified Body. Both processes have reached the post-on-site assessment activity phase, following the two joint assessment audits undertaken, which were led by the Directorate in collaboration with the Joint Assessment Team (JAT), composed of European Commission (EC) auditors and other European member state experts. Both CABs have been provided with feedback on their submitted corrective and preventive action plans.

The feedback provided to the CAB consists of feedback from the joint assessment team and the Malta Medicines Authority team as the designating authority. Meetings were held to assist the CABs in finalising their Corrective and Preventive Actions (CAPAs). The designation processes are continued procedures set to continue in 2025 until the CABs provide satisfactory CAPAs. In 2024, two national experts within the Directorate were invited by the European Commission to participate in a medical devices training course for national experts under Regulations (EU) 2017/745 and (EU) 2017/746, which took place at the premises of the European Commission's Directorate-General for Health and Food Safety in Grange, Ireland. The course was delivered by both Commission personnel and representatives from designating authorities. The course objectives included:

i. Seeking harmonised interpretations and views on recurring shortcomings in the bodies' performance;
ii. Preparation for re-assessments;
iii. Conducting assessments for extending the scope of designation; and
iv. Promoting exchanges of experience between designating authorities.

- **Vigilance**

An effective incident reporting framework that ensures the visibility of incident reports and communication with economic operators and stakeholders is recognised as a key strategy for enhancing medical device safety. This approach aligns safety requirements with EU legislation, taking into consideration challenges encountered by end users when using medical devices that fail to perform as intended. In 2024, a total of twelve (12) Advisory Committee meetings were held. Two hundred forty-five (245) incident reports and complaints were received from healthcare professionals and the public. The incident reporting system adopts a patient-centred approach in collaboration with the Mater Dei Hospital (MDH) and the Central Procurement and Supplies Unit (CPSU) in the interest of patient safety. A total of hundred thirty (130) Field Safety Notices (FSN)/Field Safety Corrective Action (FSCA) reports were received and processed in 2024.

- **Market Surveillance**

The medical devices inspectorate team is committed to supporting other member states in conducting joint inspections in the area of medical devices and IVD. In 2024, the section carried out a total of fifteen (15) economic operator inspections, three (3) of which were conducted jointly with other EU Member States as part of the Work Package 6 of Joint Action on Reinforced Market Surveillance of Medical Devices and In Vitro Diagnostic Medical Devices (JAMS 2.0) on Inspections, where Malta is actively participating. The

remaining twelve (12) inspections took place in Malta. Inspections are carried out to assist national and European stakeholders to identify gaps in their systems and effectively resolve these gaps, thereby safeguarding patient safety through enforced adherence to EU legislation. The team actively participates in the Medical Devices Inspector Task Force (MDITF) to put forward recommendations for best practices in terms of inspections.

- **Clinical Relations: Clinical Investigations/Performance Studies**

In 2024, the Directorate's arm responsible for managing clinical investigations engaged in multiple meetings with international collaborators to explore how clinical investigations are conducted internationally. Malta also began to actively participate in an Assessors' Forum within the EU, which was set up in 2024. The team contributes to the exchange of expertise and collaboration. During this period, three pre-submission meeting requests were received and successfully processed. To further enrich our expertise, the team underwent training on clinical investigations and performance studies with the Irish competent authority for medical devices, the Health Products Regulatory Authority (HPRA).

Medical Device Management System

The MMA is developing a Medical Device Management System (MDMS), a national database encompassing all medical devices and in vitro diagnostics available on the national market. The scope of this project is to enhance the transparency and traceability of these products. The MDMS will feature key modules, namely entity/organisation registration, device notification, vigilance, market surveillance, invoicing and payments, and reporting module. By the end of 2024, the development of the system had reached its final stages, and the planning for pilot testing in 2025 was carried out.

Pharmaceutical Collaboration

The Pharmaceutical Collaboration arm within the Directorate is dedicated to fostering synergy with various entities on existing and innovative ideas for the mutual benefit of the MMA and society. The MDPCD is the lead of Work Package 5 within the Joint Action on Reinforced Market Surveillance of Medical Devices and In Vitro Diagnostic Medical Devices (JAMS 2.0). In 2024, the Pharmaceutical Collaboration section took an active role in spearheading this Work Package. As part of this initiative, the Directorate successfully hosted a working meeting between 30 and 31 October 2024. The meeting focused on vigilance and signal detection methodologies adopted by different NCAs in the medical devices framework.

During the two-day meeting, different NCAs were involved in four (4) dynamic workshops on:

- Qualitative and quantitative evaluation of incident data and reports;
- Signal management, tracking and data sharing in the signal detection process;
- Use challenges and solutions of International Medical Device Regulators Forum (IMDRF) codes; and
- Management and analysis of signals, incident reporting and vigilance.

The Directorate is actively participating in Work Package 8 of JAMS 2.0, which focuses on building medical devices and in vitro diagnostics University. As part of this Work Package, the Pharmaceutical and Collaboration section has coordinated and participated in European regulatory meetings aimed at developing academic training material for experts in the area of medical devices and in vitro diagnostics. Specifically, the section is responsible for coordinating the training material for two modules within Work Package 8 of JAMS 2.0, namely:

- Standards and common specifications for medical devices; and
- Roles and requirements of different economic operators. The section is also partaking in shaping a third module led by Ireland on the qualification and classification of medical devices.

The Pharmaceutical Collaborative arm supports the strategic partnership established between the MMA and Saint Vincent de Paul Long Term Care Facility (SVP-LTCF) to develop and implement a scientific research pilot project on clinical pharmaceutical activities and services with a focus on geriatric medicine. This initiative seeks to establish an innovative process where pharmaceutical care goes beyond the conventional provision of safe, effective, and quality medicines to the elderly but ensures that the treatment takes into consideration active ageing. In addition, the Unit contributed to a working group designated to update and publish national standards on systemic anticancer therapy.

This work supports the Superintendent of Public Health in designing and adopting patient-centred frameworks that merge regulatory sciences and clinical best practices. Collaboration with the Department of Pharmacy at the University of Malta was also sustained to advance the sharing of expertise and further contribute to the enhancement of pharmaceutical practices and services. Following the completion of a feasibility study for establishing an OMCL in Malta, the Unit is undertaking further steps to establish an OMCL in Malta, taking into consideration innovation and best practices within a sustainable framework.

4 Ensuring Patient Safety through High Standards of Pharmaceutical Activities

The Inspectorate and Enforcement Directorate is responsible for inspecting and recommending the issue of licences for manufacturers and wholesale dealers according to national legislation, EU-GMP and EU-Good Distribution Practice (EU-GDP), respectively. The IED also carries out Good Clinical Practice (GCP) inspections of clinical trials and Pharmacovigilance inspections on a risk-based approach.

Regulation of Pharmaceutical Activities

Manufacturing and Importation

All medicinal products for human use manufactured or imported into Malta and the EU, including medicinal products intended for export, are to be manufactured following the principles and guidelines of the EU-GMP. The IED manages and currently maintains a portfolio of ninety-three (93) licensed/certified entities, locally and in third countries, involved in the manufacturing, importation or other GMP related activities of medicinal products for human use.

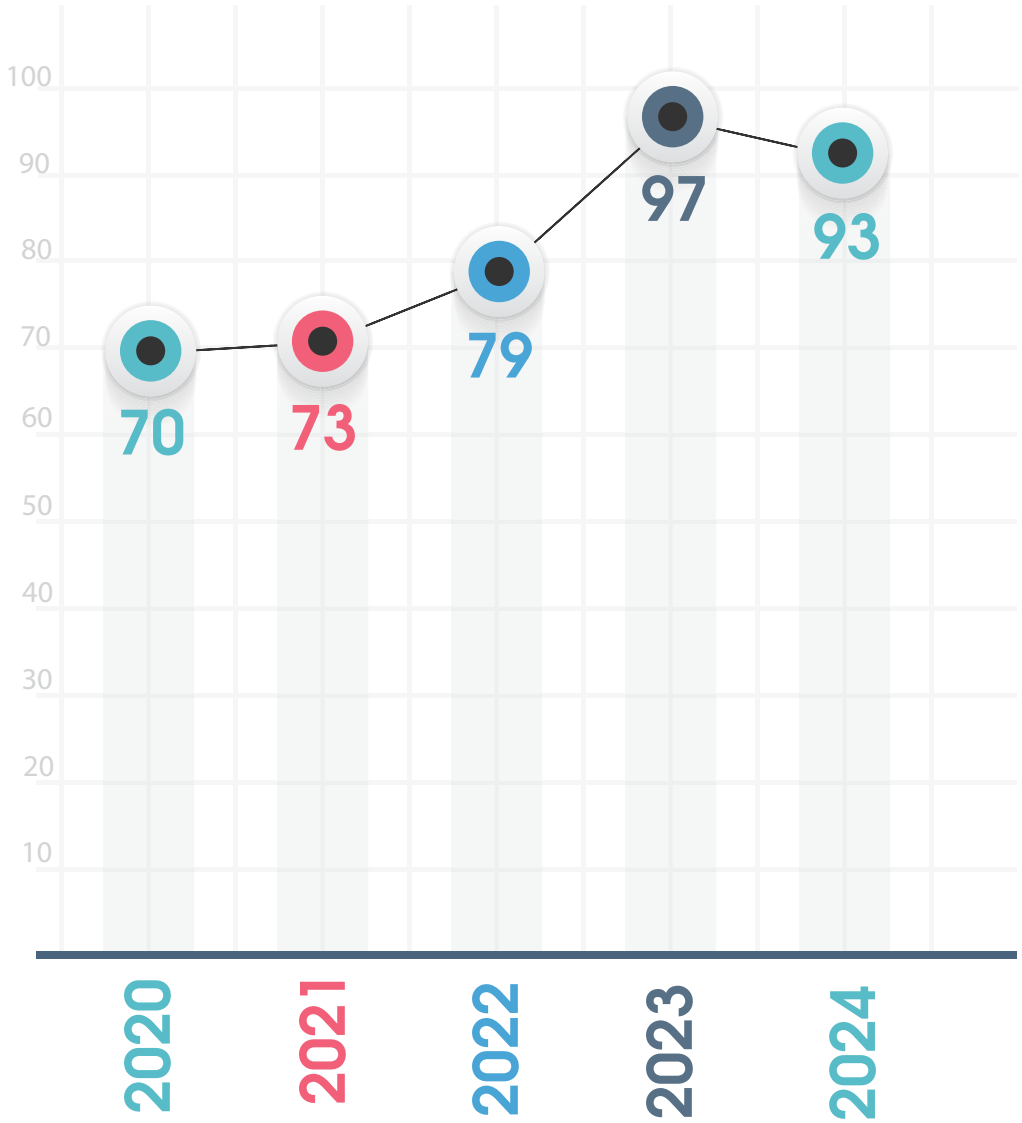


Figure 4.1: Manufacturing and importing entities supported by IED

During 2024, the IED carried out thirty-two (32) local GMP inspections for new, renewal, or variation of follow-up of GMP licences/certificates. These included:

- Five (5) inspections of full-line non-sterile dosage forms manufacturer,
- Two (2) inspections of medicinal gases dosage forms,
- One (1) laboratory providing testing services for the pharmaceutical industry,
- One (1) inspection of an APIs manufacturer,
- Two (2) inspections of cannabis products for medical use manufacturers,
- Three (3) inspections for a manufacturing authorisation of repackaging and re-labelling/partial manufacturing operations, and
- Eighteen (18) inspections for Manufacturer's/Importation Authorisation (MIAs) of importation and/or batch release activities.

A total of fifty-six (56) MIA variation applications were processed in 2024, out of which fifty-three (53) were administrative variations, whilst the other three (3) application variations required an onsite GMP inspection.

Ten (10) Inspections Review Group (IRG) meetings were held throughout 2024, during which nine (9) cases were discussed and decided upon.

During 2024, the IED received four hundred thirty-nine (439) rapid-alerts, quality defects and GMP non-compliance notifications (a 160% increase from 2020), which were investigated and out of which seven (7) resulted in a recall of medical products from the local market.

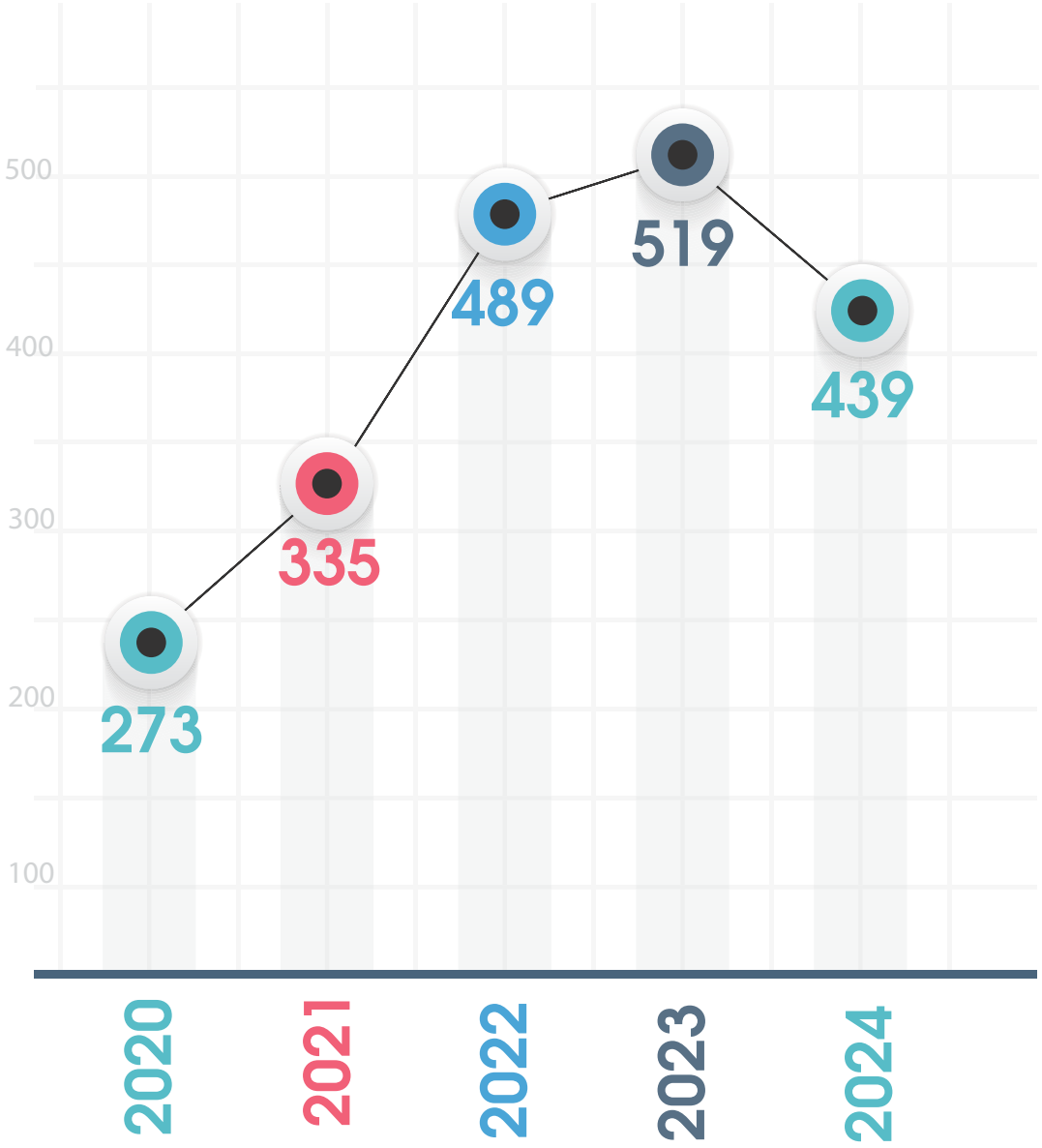


Figure 4.2: Rapid alerts trend

Distribution

Distributors of medicinal products are required to follow a good practice guideline known as GDP to source products within the EU/EEA. These standards ensure that the quality of the medicinal products is not compromised in the supply chain and to be able to carry out a recall of any defective product. The IED currently manages and maintains a portfolio of hundred nine (109) licensed/certified local entities involved in wholesale-dealing and brokering activities of medicinal products for human use and of APIs distribution and importation, the same number of sites as that in the year 2023.

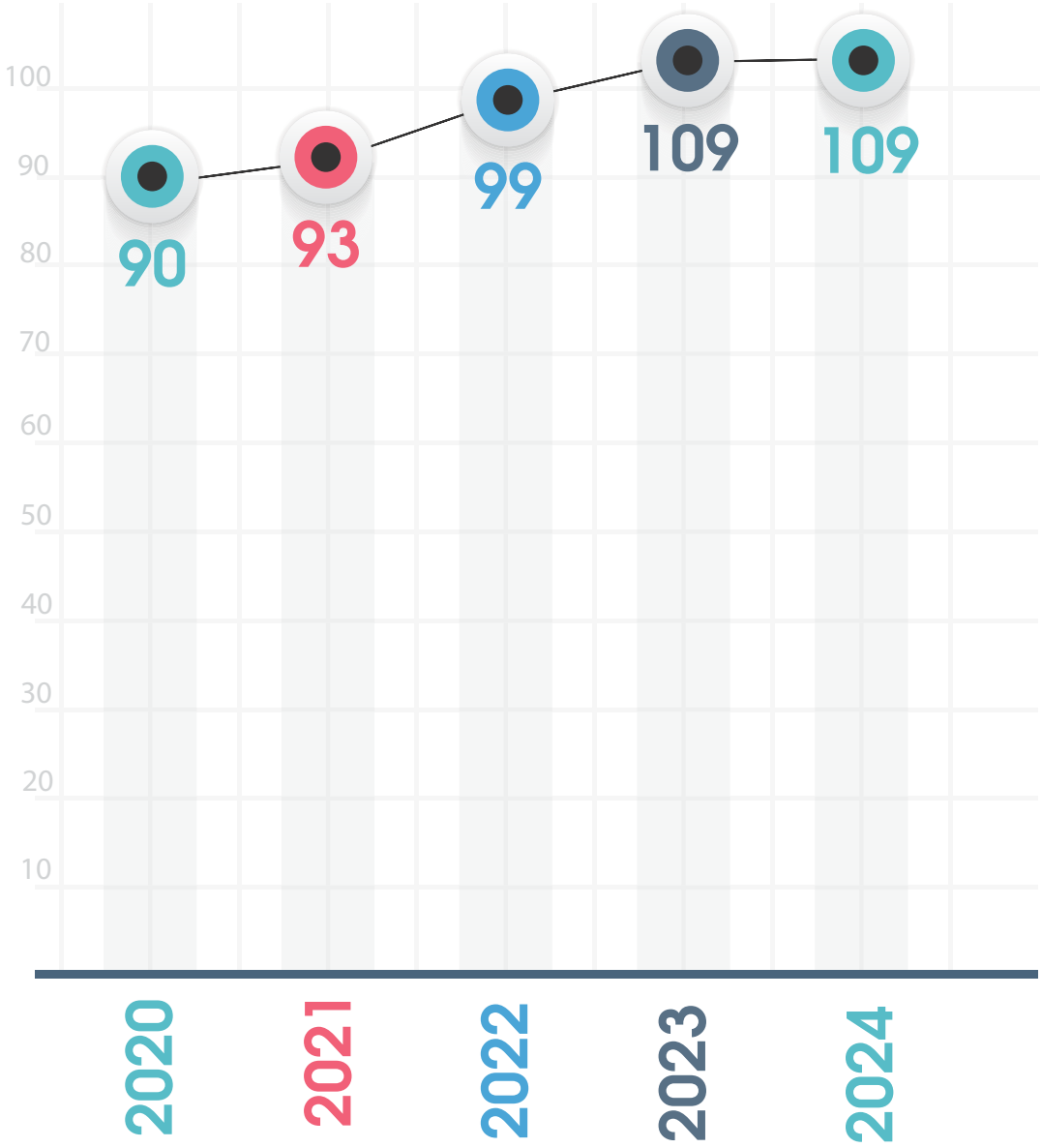


Figure 4.3: Wholesale and distribution entities supported by IED

During 2024, the IED fulfilled its GDP inspection plan, where twenty-five (25) GDP inspections were carried out. By the end of the year, seven (7) new wholesale dealing licences were processed and issued. Fifty-three (53) variation applications for wholesale dealing authorisations were processed, out of which five (5) required an onsite inspection.

Clinical Trials and Pharmacovigilance Inspections

In 2024, no new clinical trial applications were submitted to the MMA so there was no need for any inspections related to this activity.

A pharmacovigilance inspection was conducted at a Marketing Authorisation Holder (MAH) that operated a local PhV system for CAPs. This PhV inspection was performed as requested by the Committee for Human Medicinal Products (CHMP) at the EMA.

Third Country Inspections

During the year under review, the IED carried out twenty-three (23) GMP Inspections in countries outside the EU. The MMA is facilitating companies to import medicinal products within the EU whilst supporting the local industry where products coming from third countries are imported and batch-released by local companies. Additionally, these procedures attract new revenue to the Authority and provide exposure for the medicine inspectors of the MMA to different manufacturing facilities, thus increasing the collective corporate knowledge and experience.

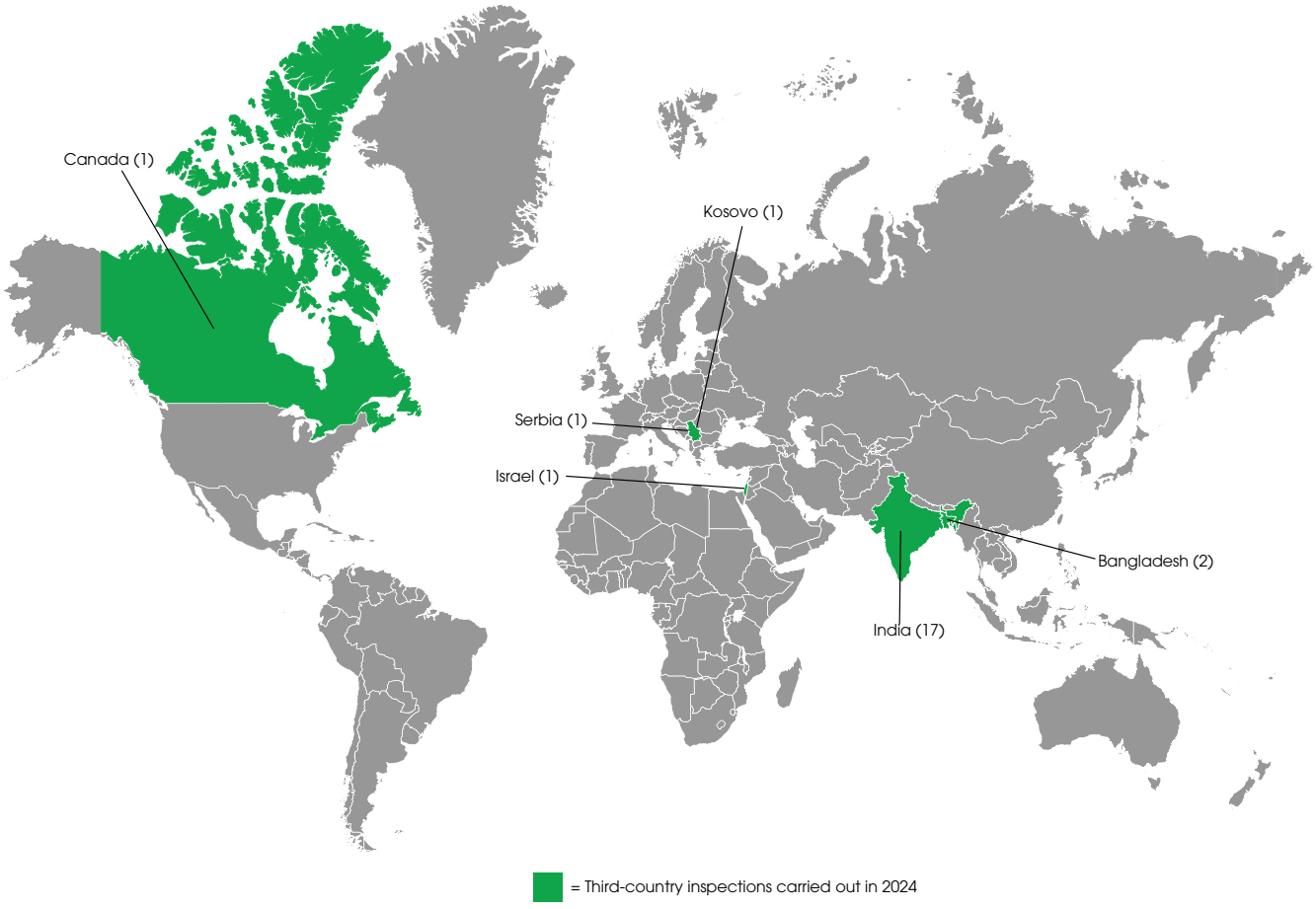


Figure 4.4: Number of third-country EU-GMP inspections carried out in 2024 (N=23)

Granting of Qualified Persons Status and Certification of Pharmaceutical Product

In 2024, the MMA received twenty-eight (28) new applications for the Qualified Person (QP) status eligibility, which were processed. Twenty-two (22) applicants were interviewed during 2024, with eighteen (18) eventually being approved as eligible for QP status.

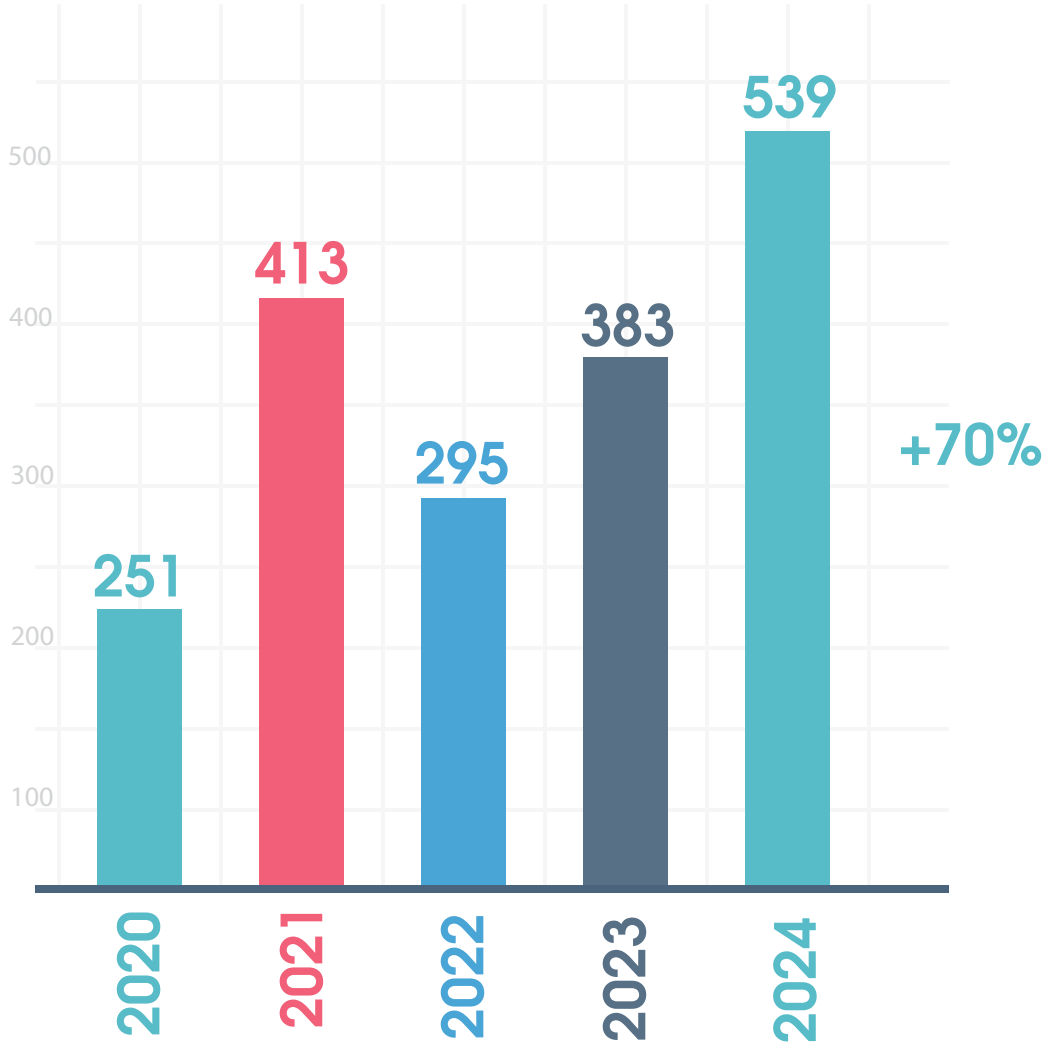


Figure 4.5: Certification of Pharmaceutical Products

IED also supports the local pharmaceutical and manufacturing industry exporting their products to developing countries which do not possess a robust regulatory framework for medicinal products, through the issuance of Certificates of Pharmaceutical Products (CPPs) based on the World Health Organisation (WHO) template and system. During the year 2024, five hundred and thirty-nine (539) Certificate of Pharmaceutical Products applications were received and processed, with all certificates being issued, a 70% increase over the previous year (2023).

Surveillance of the Local Market

The MMA collaborates with the Medicines and Healthcare Regulatory Agency (UK) (MHRA) so that the latter carries out testing in an OMCL for the MMA. In this regard, the Local Market Surveillance Plan for 2024 was closed positively. Six (6) Active Pharmaceutical Ingredients (APIs) were identified for sampling from the three (3) local API manufacturers under the national Market Surveillance plan for 2024, and two (2) medicinal products under the European Market Surveillance plan were additionally sampled from the local market under the co-ordinated of the European Directorate for Quality of Medicines and Healthcare (EDQM).

Pharmacy Practice

The Strategy and Operations Unit within the Regulatory Operations, Medicines Intelligence and Access Directorate regulates and manages a portfolio of two hundred fifty-eight (258) licensed pharmacies, which include two hundred thirty-nine (239) pharmacies serving patients in the community, eleven (11) hospitals, four (4) special licenses, and four (4) government pharmacies.

In 2024, two (2) spot-check pharmacy inspections were carried out, three (3) pharmacy relocations were inspected and approved, two (2) new pharmacy licences were issued, and seventy-seven (77) administrative variations for pharmacy licences were processed. A total of fifty-six (56) routine inspections were carried out in community and hospital pharmacies. Following the evaluation of the inspection findings, a risk assessment is performed, which allows for an impartial risk-based prioritisation of inspections. Through this approach, the safety of medicinal products and patients in the Maltese islands is assured.

As part of the government reform on inspections, the MMA continued its collaboration with the Inspection Coordination Office (ICO) towards the automation of a risk assessment model and the implementation of the Certificate of High Standard of Compliance in community pharmacies. This project ensures a coordinated approach between inspectorates and proposes a competitive scheme to uplift the standards of services provided.

Collegiality and regulatory transparency contribute to upholding the Authority's dedication to patient-centred practices. During 2024, three (3) circulars to community pharmacies were issued to assist the MMA stakeholders in improving their services. This constitutes the initial step towards the development of a strong supportive framework, which will provide regulatory guidance and simplify everyday functions in community pharmacy practice.

Continuous revision and updates to inspection processes aim at improving and standardising regulatory procedures. This complements an educational approach that aims at implementing measures that uphold the Authority's reputation. These measures include:

- Outlining process-oriented standards for hospital pharmacies, storage and dispensing of medical gases, requirements for relocation or structural changes to licensed premises and addition of a pharmacy store,
- Proactively addressing regulatory lacunae to optimise the monitoring of the supply chain up to the patient level, and
- Timely response of fifty-seven (57) regulatory queries on general procedures related to pharmacy licence, pharmacy standards and services provided in the community.

Enforcement of Legislation and Judiciary Actions

In 2024, the IED worked on three (3) enforcement cases/investigations related to receiving complaints. The Enforcement Committee, which is chaired by the Licensing Authority and addresses such cases, did not convene in 2024, and no court case sittings involved IED.

Legal Affairs

During the year under review, the Legal Affairs Unit addressed numerous queries, covering regulatory clarifications, procedural guidance, and operational issues. Effective communication with stakeholders ensured accurate information, compliance, and timely resolution of concerns, fostering smooth operations and stakeholder confidence.

The Unit was involved in various legal matters, including court cases, appeals, and formal injunctions, safe guarding interests through coordination with legal professionals, and adherence to regulatory standards.

Correspondence efforts focused on addressing licensing issues, payment demands, and compliance concerns. Communications covered documentation requests, financial dispute resolutions, and regulatory matters, including medical device fees and renewal processes. Most communications were delivered on time, ensuring critical responses.

Key legislative achievements included drafting new sub-regulations, updating policies, and progressing amendments for fees and online dispensing. These initiatives involved preparing cabinet memos, explanatory notes, and user guidelines. Engagements with stakeholders, such as pharmacy representatives and government authorities, supported regulatory clarity and emerging needs.

A total of hundred forty-nine (149) scheduled meetings and seventy-nine (79) impromptu discussions were held, addressing topics such as:

- Reconciliation of financial funds
- Regulation of pharmaceutical products and activities
- Resolution of unlawful supply of medicinal products

Collaborative efforts with the Advisory Committee, other Units, and external stakeholders contributed to enhancing policies, legislation, and operations. Training sessions further supported organisational improvements.

5 Translating Regulation into Patient-Centred Science

The MMA plays a pivotal role in the regulatory landscape, facilitating the exchange of innovative strategies and shaping approaches that benefit patients. To sustain its achievements and uphold further progress, the MMA is constantly expanding its resources and capabilities to adapt to an ever-changing environment.

Advanced Scientific Initiatives

The Advanced Scientific Initiatives drives research strategy, innovative growth and regulatory response whilst steering proactive synergy through the Educational Planning and Academic Development Unit.

Horizon scanning, also within the context of the EU Innovation Network (EU-IN), supports the identification and evaluation of emerging trends and developments. Through dedicated meetings and multistakeholder fora at European level, a range of thematics were explored by the Directorate in 2024, including radiopharmaceuticals, psychedelics, pharmacogenomics, Artificial Intelligence, as well as clinical trials, paediatrics, and rare diseases. The latter represents a core focal point, whereby committed representation is sustained at the Committee for Orphan Medicinal Products (COMP), which meets monthly at the European Medicines Agency and is primarily responsible for recommending orphan designation of medicines for rare diseases.

The multitude of exercises embracing high-level exposures and stakeholder interactions often cascade into the MMA's outreach activities, as exemplified by the webinar - Stakeholder Engagement on AI in Healthcare, which was organised on 10 December 2024. This initiative, with a local and international dimension, delved into the transformative potential of AI, focusing on medical perspectives, key technical developments, and prospective applications. By bringing together experts from different fields, the webinar offered multi-disciplinary insights into the current state of play, regulation, risks related to the use of AI, ethical considerations and future trends. Eighty-nine (89) participants joined the webinar, with their areas of practice ranging across public health, industry, academia, clinical, regulatory sciences and information technology.

Earlier this year, a collaborative initiative funded by the Internationalisation Partnership Awards Scheme Plus (IPAS+) 2023 of the Malta Council for Science and Technology (MCST) was held on 30 May 2024 in the form of a seminar, entitled The Silent Threat – Antimicrobial Resistance Uncovered. Keynote speakers from Norway, Ireland, Sweden, and Malta were engaged, attracting the participation of forty-five (45) local and international attendees working in the public and private health sectors. The interactive discussions covered AMR policies, antibiotic use, surveillance systems, and recommendations for stepping up actions to combat AMR, for instance, through incentives in the revision of the EU pharmaceutical legislation package. The aim was to bridge gaps between policy frameworks, regulatory provisions, and clinical practice by sharing experiences, joint efforts and implementable approaches that may be relevant across healthcare systems. Outcomes will be presented at the 14th Pharmaceutical Care Network Europe Working Conference, being held in Innsbruck, Austria, in February 2025.

Connecting science and practice whilst encouraging collaborations enables us to prevent progress from being undone and drives us forward to continue safeguarding our patients. Such principles are distinctly manifested within the Advanced Scientific Initiatives Directorate that fosters constructive dialogue and collaborative connections with local entities such as the Malta Further and Higher Education Authority (MFHEA), XjenzaMalta (formerly MCST), Malta Enterprise, Esplora, Public Health, and the University of Malta, as well as academic and regulatory counterparts overseas, enriching all activities through a network of external and internal experts in the relevant fields.

The Advanced Scientific Initiatives Directorate is particularly active in relevant EU-funded projects in collaboration with the Office of the CEO and the Post-Licensing Directorate. For IncreaseNET, the EU4Health Joint Action on increasing capacity building of the EMRN, work is being invested in leading the evaluation work package and the corresponding deliverables. Going forward, planning ensues for another project that reaches out beyond our continent, with prospective financial support through the European Medicines Agency, for developing and delivering a training programme aimed at regulatory professionals in Sub-Saharan African national competent authorities.

Internal continued development is regularly appraised through diverse means, including active participation in the EU Network Training Centre (EU-NTC), which advances specialised training in areas such as EU procedures, scientific advice, pharmacovigilance, auditing, and data analysis. This expertise flows further through the study programmes of the MMA Academy for Patient-Centred Excellence and Innovation in Regulatory Sciences, licensed as a Further and Higher Education Institution by the MFHEA (License No. 2021-004). The MMA Academy intends to continue optimising the interface with stakeholders, particularly through an educational approach, offering accredited programmes and reflecting on the feedback of all learners - past, present, and prospective ones.

Several courses are under development to cover pertinent subjects, including Pharmaceutical Distribution Auditing, whilst actively considering updates to the Internal Quality Assurance (IQA) Policy, in liaison with the Malta Further and Higher Education Authority Adverse Events, for introducing Recognition of Prior Learning (RPL). The RPL process would enable the possibility of individuals being admitted to study programmes leading to a formal award by recognising outcomes from previous learning contexts, such as training activities undertaken in the workplace and experiential learning settings.

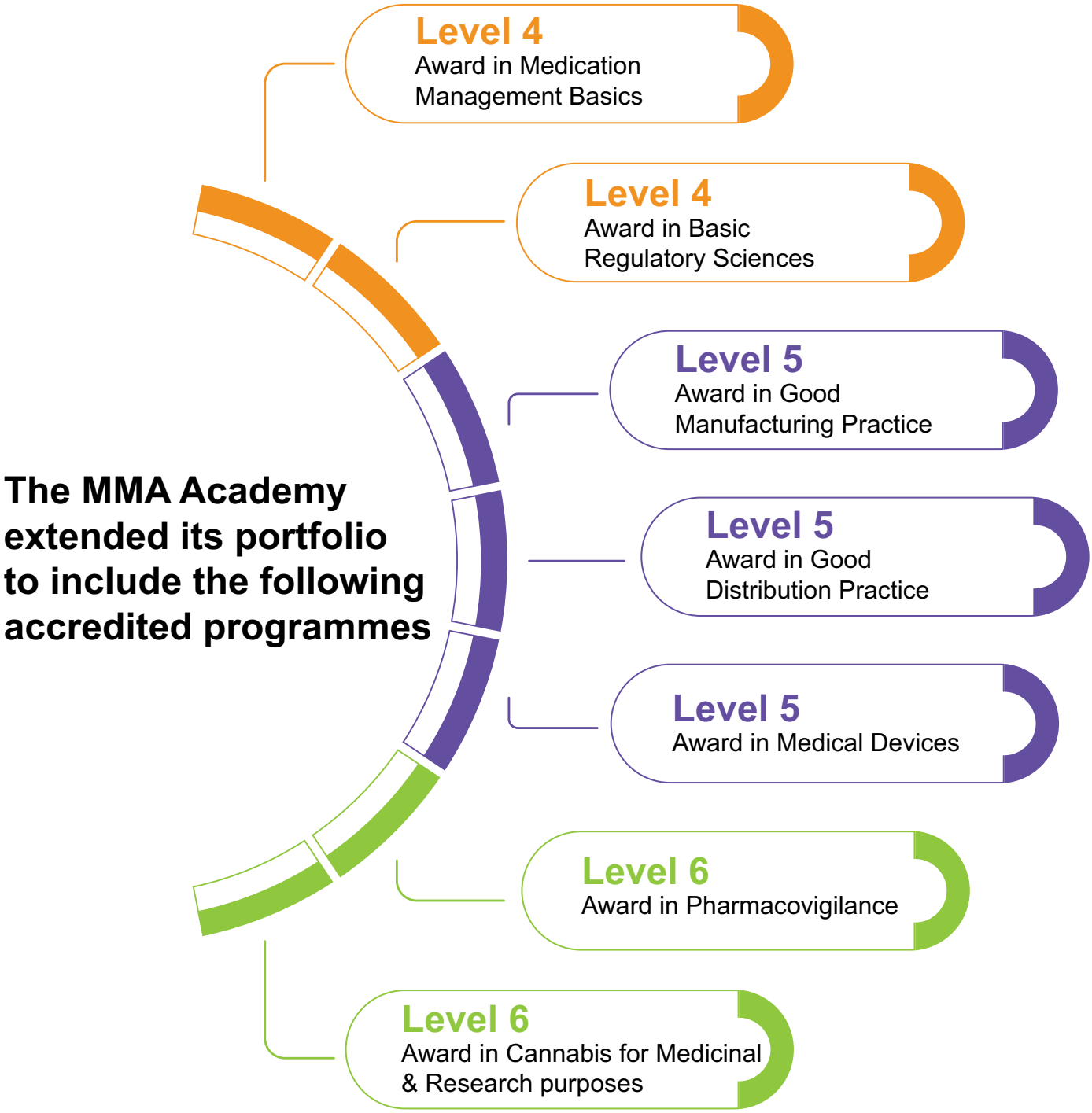


Figure 5.1: MMA Academy accredited programmes

The programme leading to an Award in Pharmacovigilance was held in January 2024 as a 25-hour face-to-face course that attracted full enrolment and successful completion by thirty-four (34) participants from diverse entities (22 private and 12 public). Sessions were delivered by an international expert and synergised with local input by representatives from the Post-Licensing Directorate at the MMA. Topics included: the EU regulatory framework and guidelines, pharmacovigilance audits and inspections, adverse drug reactions and signal detection, periodic safety update reports and post-authorisation safety studies, risk management and safety communication. All evaluation form respondents (N=22) expressed satisfaction with the course content and willingness to consider attending future educational initiatives. The keen interest observed at the registration stage, positive course outcomes and encouraging feedback underscore the exigency and applicability of such educational initiatives.

In response to stakeholder feedback, the course leading to an Award in Medical Devices was delivered for the second time in July this year. The contributions of the keynote speaker were complemented by sessions on national perspectives by representatives from the Medical Devices and Pharmaceutical Collaboration Directorate at the MMA. The three-day programme covered the legislative framework for medical devices, classification, conformity assessment, technical documentation, safety and performance requirements, incident reporting and quality management, among other matters. The course was fully subscribed with successful completion by all twenty-eight (28) participants. Reflecting on the programme's overall quality and impact, attendees indicated their willingness to recommend the programme to colleagues. Such upshots align with the MMA Academy Internal Quality Assurance (IQA) Policy in ensuring high-quality education, continuous improvement, and accountability for programmes that meet and exceed learners' expectations while addressing identified gaps.

Looking ahead, the Directorate is further intensifying its outreach through interdepartmental efforts invested in several large-scale endeavours. Through the IncreaseNET EU4Health action, the MMA is contributing to accomplishing the project objectives for strengthening competencies with the EMRN, establishing further capacities to face innovative challenges, and improving the accessibility, availability and affordability of medical products. On an international level, partnership efforts are also being expanded, with prospects of reaching Sub-Saharan Africa through European Union financing, with a grant for the delivery of pharmacovigilance training by an MMA representative, intended to strengthen on-the-ground scientific and regulatory expertise. The Malta Medicines Authority, through the Advanced Scientific Initiatives Directorate and the wide-ranging parties joining forces, is primed to continue effectively translating regulatory standards into day-to-day excellence.

Scientific Advice

Since 2018, the Authority has been engaging in EMA Scientific Advice Working Party (SAWP). A representative from the Authority attends a monthly SAWP meeting at the EMA. Each month, the Authority receives a list of procedures and bids for products it would like to review. Both external and internal assessors are engaged in assessing these products. In 2024, the Authority fully participated in SAWP activities, and twenty (20) SAWP procedures were registered.

The objective of scientific advice procedures is to discuss with the MMA scientific matters regarding the development and licensing of medicinal products. In the context of national scientific advice, applicants can obtain input concerning questions related to procedures that are within the remit of the MMA. For 2024, three (3) national scientific advice procedures were registered.

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

Medicines Intelligence and Access

The patient-centred ethos is the foundation of the functions of the Medicines Intelligence and Access Unit, where patients, healthcare professionals and patient organisations are supported in their queries with targeted recommendations to ensure sustainable access to medicines through added-value therapeutic interventions.

The MIAU handled on an individual basis hundred and sixty-seven (167) queries related to shortages, pharmacoeconomic, registration and safety issues which included cases such as the availability of sertraline syrup, the introduction of new innovative medicines and supporting the Licensing Directorate with regards to investigating the availability of medicines on the Maltese market as shown in **Figure 5.2** below. The Unit proactively addresses emerging medical needs by assisting in the sourcing and supply of new medicines. To ensure continuity of supply and access to medicines, fourteen (14) Named Patient Basis (NPB) requests were processed by the MIAU, and a positive recommendation was sent to the Licensing Authority.

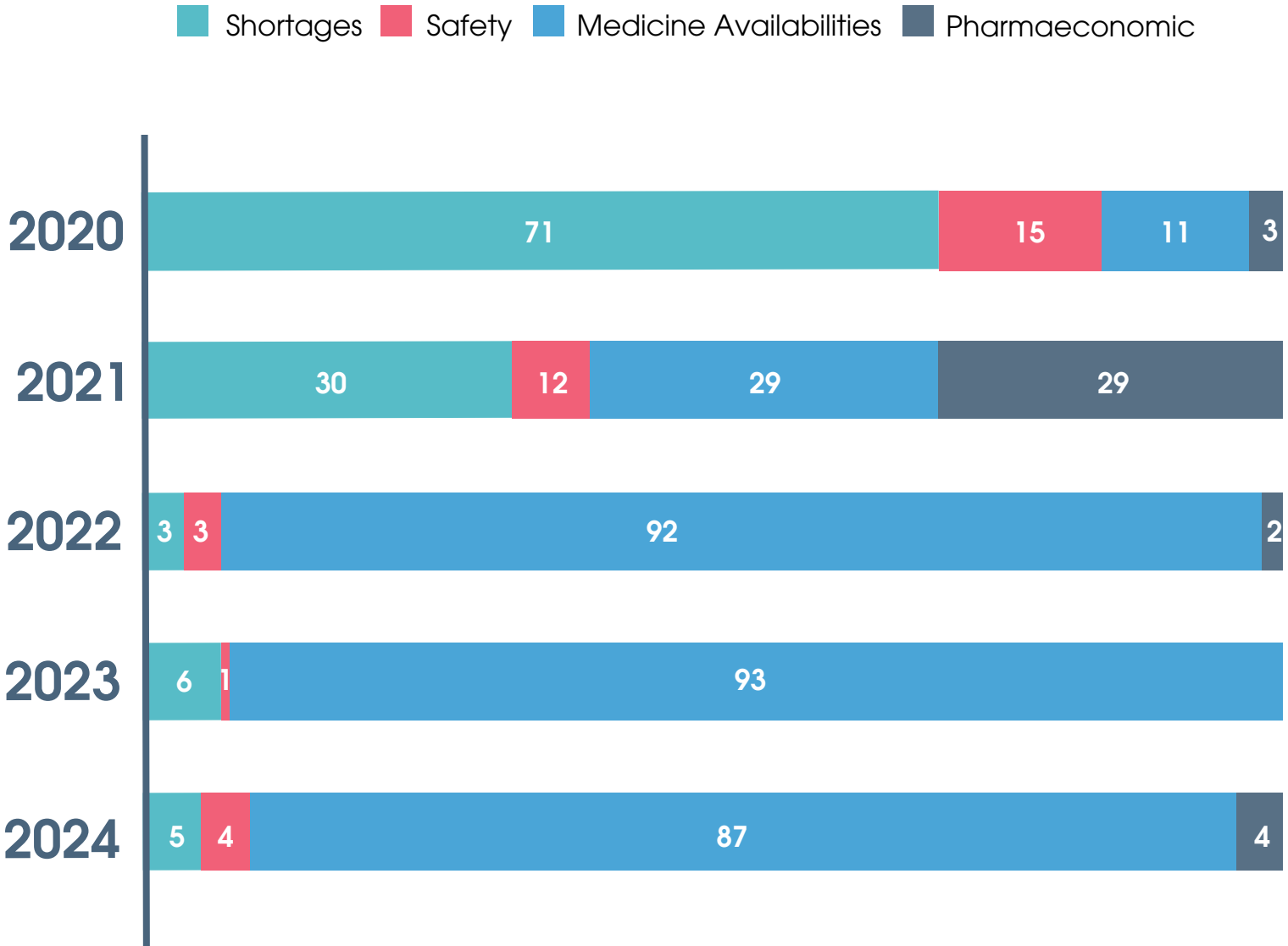
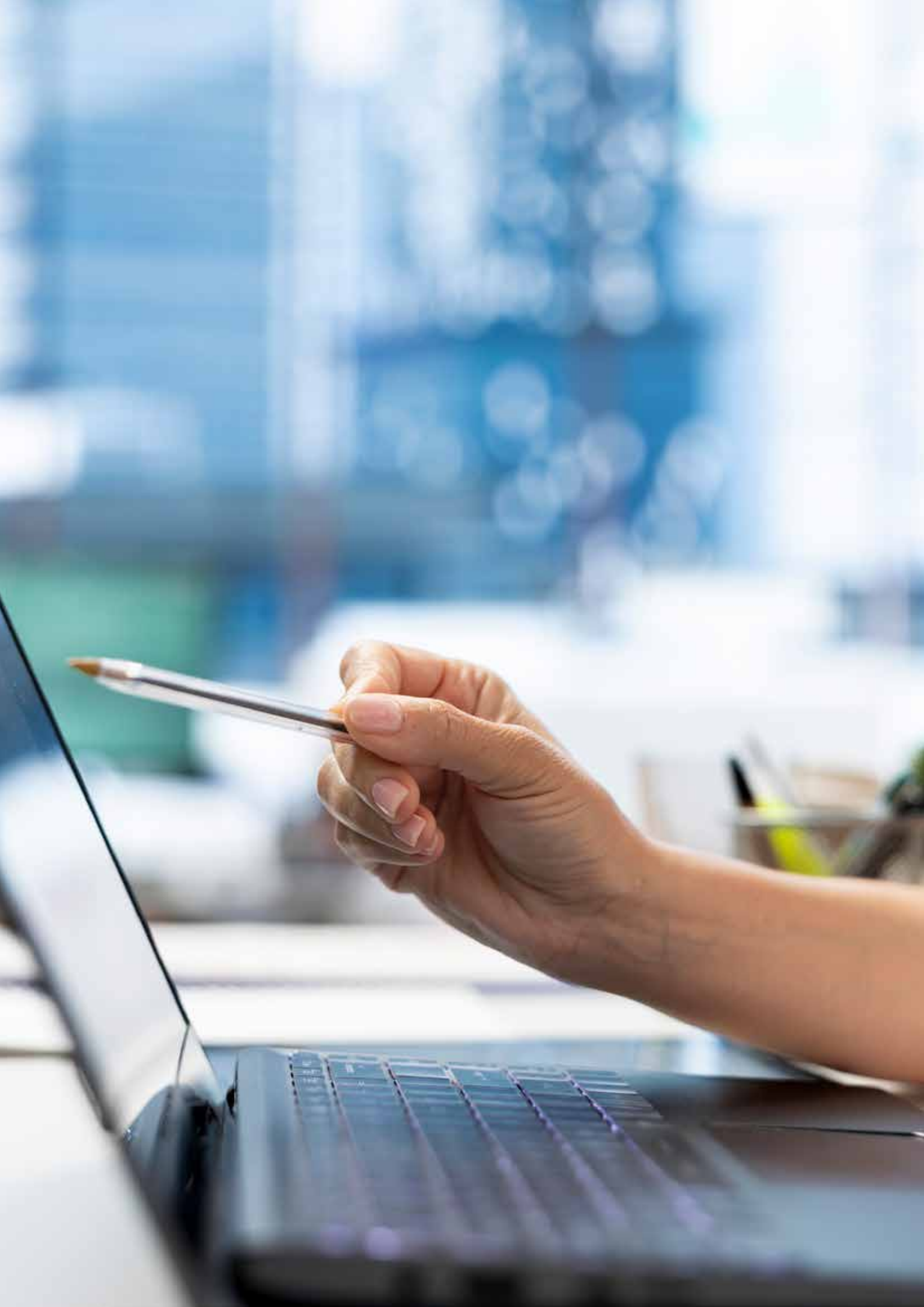


Figure 5.2: The number of interventions tackled by the MIAU between 2020 and 2024



In 2024, eight hundred eleven (811) applications requesting an Article 20 exemption were received, with seven hundred nineteen (719) applications being approved in view of a justified public health need. The Article 20 exemption is reserved solely as an interim measure to counteract the risk of shortages and maintain accessibility to medicines on the local market when registration options through a MA, authorisation in line Article 126(a) of Directive 2001/83/EC and parallel importation have been exhausted as possible registration routes. The Authority liaises with the concerned public and private stakeholders during the vetting process of Article 20 exemption requests, 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.

The extent of Malta's reliance on the United Kingdom for the availability of medicines in 2024 is depicted in **Figure 5.3** below, indicating that 45% of medicines approved under Article 20 exemptions originate from the UK. Notably, this dependence has decreased compared to the previous year. The majority (51%) of Article 20 exemption requests that were approved were sourced from EU markets, which mainly resulted from urgent interim need demands of medicines. The Article 20 exemption was also granted for certain medicines sourced from Canada, Turkey, and the United States of America (USA). These countries are members of the Pharmaceutical Inspection Co-operation Scheme (PIC/S).

Figure 5.3: Country of source of medicinal products approved under Article 20 exemption in 2024 (N=719)

The MIAU, as delegated by the Licensing Authority, has devised a subsidiary legislation (Chapter 458.63 of the Laws of Malta) to address medicine shortages and improve access within the National Health Service (NHS). In exceptional circumstances where the CPSU encounters difficulties in procuring medicines which are problematic to source, a request under the first proviso of Article 20 of the Act may be submitted, and permission may be sought from the Licensing Authority to procure and introduce an unauthorised medicinal product into the NHS following these regulations. In 2024, five (5) applications were processed and granted under the recently enacted Subsidiary Legislation.

The employees within the MIAU actively participated in thirteen (13) meetings of the Medicines Shortages Single Point of Contact (SPOC) Working Party, where intelligence on medicines, including shortages, was gathered during these meetings to prepare for disruptions in the supply of medicines that may impact Malta. The MIAU, in collaboration with fellow EU member states, engaged in a comprehensive analysis encompassing two thousand nine hundred sixty-eight (2968) active ingredients across various

pharmaceutical formulations. This exercise aimed to ascertain the market availability and criticality status of medicinal products, marking the initial phase towards establishing an EU critical medicines list. Among the examined substances, four hundred thirty-three (433) were identified as marketed, while two thousand five hundred thirty-five (2535) were not. Notably, of the marketed products, hundred ninety-six (196) were deemed critical medicines, hundred eighteen (118) were classified as medicinal products at risk, and hundred fifty-six (156) fell into the category of 'other'.

The MIAU is spearheading the supervisory role of the MMA for the National implementation of the Safety Features Regulation 2016/161/EU appearing on packs of human medicines. Ten (10) batch-specific requests for packs having safety features that do not comply with the requirements of Delegated Regulation 2016/161/EU were processed and granted to ensure the continuity of supply to patients after being evaluated and the necessary corrective and preventive actions have been implemented by the supplier.

6. Publications

Calleja JC, Debono M, Mizzi J, Langaro M, Muscat C, Serracino-Inglott A. Enhancing Pharmacy Practice: Development of an Advanced Inspection Checklist. MedTech Annual conference, Malta, 2024.

Falzon S, Gatt Baldacchino E, Galea L, Farrugia K, Fearne J, Grech L, Serracino-Inglott A. Joint Action on Reinforced Market Surveillance of Medical Devices and In Vitro Medical Devices: A European Collaborative Initiative. Poster presentation at the Med-In-Pharma Conference, Malta, November 2024.

Falzon S, Gatt Baldacchino E, Galea L, Farrugia K, Fearne J, Grech L, Serracino-Inglott A. Enhancing signal detection in the area of medical device vigilance through collaboration. Poster presentation at the Med-In-Pharma Conference, Malta, November 2024.

Mifsud Buhagiar L, Giordano L, Mamo M, Abbas A, Magri A, Grech L, Fearne J, Farrugia K, Serracino-Inglott A. Strengthening medical device practices through targeted education. Poster presentation at the Med-In-Pharma Conference, Malta, November 2024.

Mifsud Buhagiar L, Mamo M, Abbas A, Serracino-Inglott A. Advancing regulatory sciences closer to the patient care setting: a course development approach. 28th European Association of Hospital Pharmacists (EAHP) Annual Congress; 2024 Mar 20-22; Bordeaux, France.

Mifsud Buhagiar L, Mamo M, Abbas A, Serracino-Inglott A. Advancing Pharmacovigilance Practices: a collaborative approach through education. 82nd International Pharmaceutical Federation (FIP) World Congress of Pharmacy and Pharmaceutical Sciences; 2024 Sep 1-4; Cape Town, South Africa.

Tanti S, Falzon S, Grech L, Serracino-Inglott A. Clinical Investigations for Medical Devices in Small Member States. Poster presentation at the Med-In-Pharma Conference, Malta, November 2024.

Xiberras E, Grech L. Medical Devices: Awareness and Perception. Poster presentation at the Med-In-Pharma Conference, Malta, November 2024.

Publications in journals

Curtolo E, Micallef B, Szijj JV, Serracino-Inglott A, Borg JJ. An exploratory study of knowledge, attitudes, practice and barriers towards adverse drug reaction reporting among healthcare professionals in Malta. Int J Risk Saf Med. 2024;35(3):271-286. doi: 10.3233/JRS-230055.

Debono J, Balzan D, Borg JJ, Falzon S, Al-Haddad D, Micallef B, Sultana J. Nivolumab Safety in Renal Cell Carcinoma: A Case Report. J Pharm Technol. 2024 Apr;40(2):112-117. doi: 10.1177/87551225231218164.

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