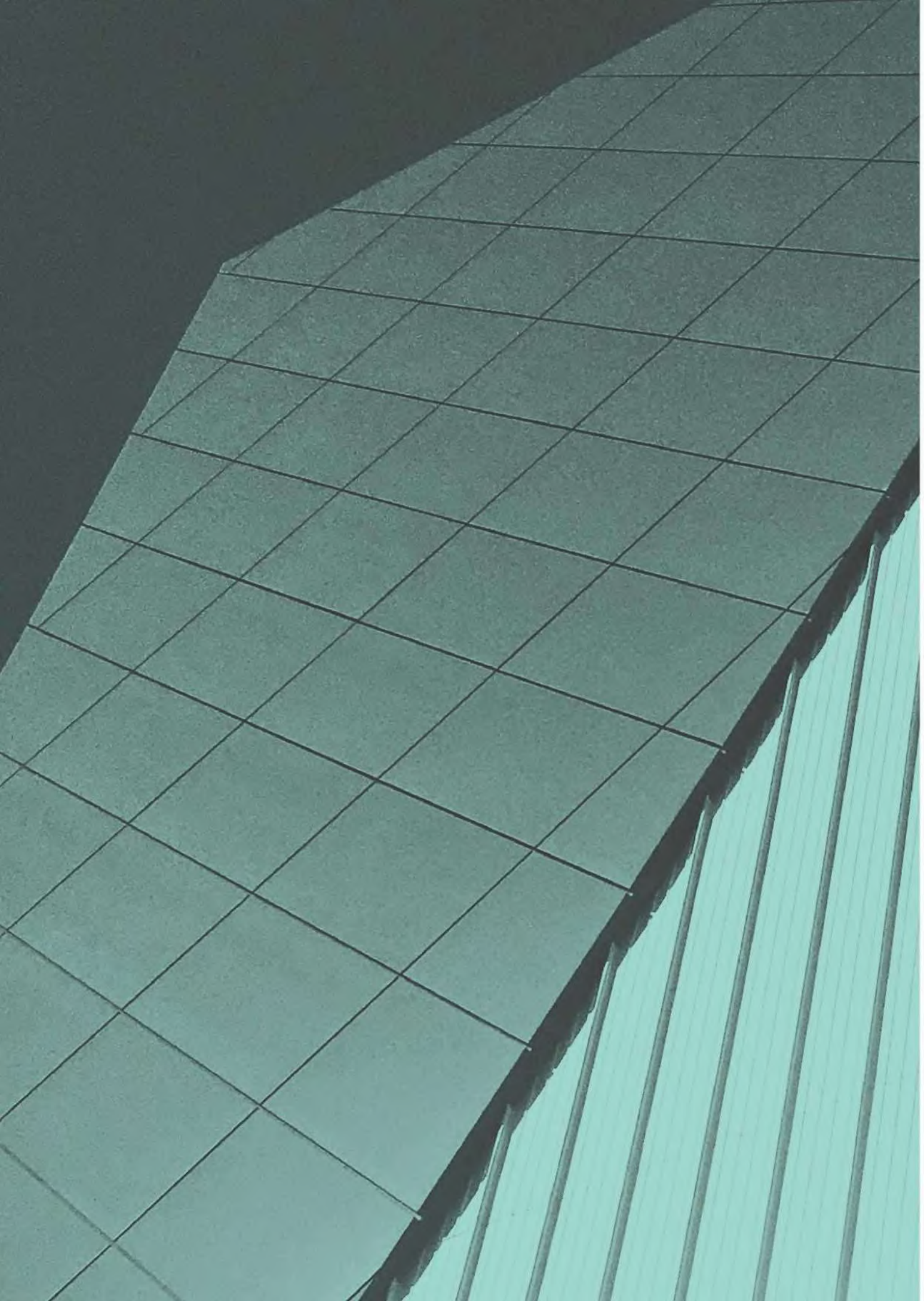
MALTA
MEDICINES
AUTHORITY

ANNUAL REPORT

2019



Content

Foreword by the Parliamentary Secretary

The Malta Medicines Authority continuously commits to fulfil its mission of protecting and enhancing public health through the regulation of medicinal products and pharmaceutical activities. The foundation of the Authority's successes is the possession of a professional workforce with a high scientific aptitude and personal motivation. Emphasis is placed on optimal resource allocation to ensure sustainability in operational and organisational functions whilst engaging in advanced initiatives that strengthen stakeholder collaboration and safeguard the patient's wellbeing.

Positive disruptive approaches towards established regulatory systems are characteristic of a forward-looking organisation. The launch of the Academy for Patient Centred Excellence and Innovation in Regulatory Sciences in 2019 has introduced a didactic framework intended for internal and external stakeholders to be equipped with a skillset that meets developments in the pharmaceutical arena. Ancillary measures were rolled out in the past year to streamline and bolster processes, including an analysis to introduce risk-based pharmacy inspections, the preparation and publication of a template to widen the collaborative network of the Authority and the investment in capacity building to consolidate third country Good Manufacturing Practice (GMP) inspections performed by the Authority for the European Union (EU). Outcomes from research projects led by the Authority in collaboration with academia were presented in a number of fora convening global professionals exchanging knowledge and expertise.

The Malta Medicines Authority is instrumental for Malta in navigating through regulatory challenges, brought about by Brexit and the enforcement of new European regulations, to allow a steady supply of medicinal products to the local market. Malta ranks among the top EU Member States as lead in assessment procedures for the authorisation of medicines. This advanced work in assessment serves as a testimony to the scientific acumen of the Authority. Effective interventions through intelligence and information gathering assist consumers and other stakeholders with concerns related to medicines accessibility. Throughout the year 2019, substantial interaction was noted between the Authority and its legal, academic, clinical and industrial partners on regulatory aspects as applicable to cannabis for medicinal and research purposes to uphold due diligence in this area.

The endeavours mentioned in this annual report pave the way for future paradigms to align with technological and scientific advancements related to the advent of biopharmaceutics, genomics, artificial intelligence, big data and novel R&D models adopted by industry. The landscape of pharmaceutical regulation is ever-evolving and the Authority has the right elements to harness this change. The Authority is preparing to assume the new role as competent authority for medical devices in 2020.

Dr Deo Debattista
Parliamentary Secretary for Consumer Protection and Public Cleansing

Message from the Chairperson

In recent years, regulatory affairs have evolved in line with the pharmaceutical sciences to include scientific principles in all processes of medicines development. The scientific intelligence remodelled regulatory affairs into regulatory sciences and this ranges from analysing guidelines to tracking a recall, to batch release of medicinal product.

The Malta Medicines Authority which performs sterling work in safeguarding the quality, safety and efficacy of medicines for patients in the European framework recognised the importance of setting up the Academy for Patient Centred Excellence and Innovation in Regulatory Sciences. Inaugurated on 20 November 2019, the Academy merges research and education into regulatory sciences and strengthens the contribution that Malta is delivering in the area of research and innovative developments. The Academy coordinates the interactive advanced level courses on diverse aspects of regulatory sciences meeting the needs of stakeholders. The leadership course on medical devices was a prime example of how the Academy is spearheading innovative research initiatives and establishing national, European and international collaborations to share ideas, discuss opportunities and overcome challenges in a holistic approach.

The portfolio of the Malta Medicines Authority is expanding towards patient-centred functions, namely in the assessments of medicinal products, inspections and pharmacovigilance that regulate medicines to advanced scientific initiatives. New functions for the Authority include the regulation of cannabis for medicinal and research purposes and medical devices. The Authority is consolidating the new European regulations for medical devices at national level to ensure patient safety and enhanced public health protection.

The successful work strategy of the Malta Medicines Authority is interlinked to the empowered professionals and the continuous cooperation with all stakeholders who keep the best interest of the patient at the centre of all activities. The Authority promotes the well-being, motivation and ongoing professional development of every member through several opportunities which include family-friendly measures and educational and training opportunities to achieve higher academic levels.

The year 2019 was characterised by innovation and advances of scientific regulatory practices. These prove to be an asset in the dynamic fora of the pharmaceutical sciences and render the Malta Medicines Authority a best in class regulator.

Professor Anthony Serracino-Inglott
Chairman of the Malta Medicines Authority

The Malta Medicines Authority

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

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

What we do

The Malta Medicines Authority 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.

Ensure that medicinal products have a favourable risk to benefit profile through independent, science-based assessments, post-authorisation activities and participation in decision-making at the European level

Ensure that medicinal products marketed and supplied in Malta and the European Union are of good quality, safety and efficacy

Perform functions as delegated by the Licensing Authority

Assist and advice the Licensing Authority

Monitor and enforce the relevant legislation

Monitor the safety of medicinal products

Investigate potential breaches of regulations

Provide objective and unbiased information to help prescribers, healthcare professionals and patients make informed decisions on the choice and use of medicines

Enhance the effective, safe and rational use of medicinal products

Provide high quality monitoring and inspection services for pharmaceutical activities

Scientifically evaluate requests and monitor clinical trials carried out in Malta

Support the availability of medicinal products on the local market

Support competitiveness in the local market through scientific and regulatory advice

Assess and ensure the quality, safety and efficacy of medicinal products and pharmaceutical activities

Enhance the standard of medicinal products and pharmaceutical activities through the sustained capacity building of our workforce

Actively participate in European and International fora

Collaborate with stakeholders to maximise access to medicinal products

Spearhead collaborative research and innovation activities, including academic development

Act as a Reference Member State or Concerned Member State and rapporteur for European procedures

Steer the progress of regulatory sciences through advanced initiatives aligned to our strategic priorities

Promotes continuous learning, research and innovation

Lead advancements in the regulation of cannabis for medicinal use

Our Mission and Vision

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

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

Our Values

PEOPLE

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

QUALITY

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

INTEGRITY

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

INNOVATION

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

Strategic Goals and Objectives

1. Optimised Regulatory Systems

- To strengthen the effectiveness of surveillance systems for medicinal products
- To ensure appropriate national regulation of medicinal products and contribute to national health policy
- To enhance the Malta Medicines Authority's commitment to strengthening the European and International regulatory network

2. Better informed users

- To promote rational and safe use of medicinal products
- To promote greater engagement in the role of the Malta Medicines Authority
- To ensure public awareness and knowledge of the Malta Medicines Authority

3. Access to medicinal products

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

4. Supporting innovation

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

5. Organisational development

- To ensure that optimal workplace and organisational structure is in place
- To appropriately manage finances and human resource
- To enhance quality management systems
- To further develop ICT systems

Quality Management, Simplification Measures and Good Governance

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

By the end of 2019, the foundation of the quality management system at the Authority, which ensures uniform and high-quality operations, consisted of thirty-four (34) policies, one hundred and eight (108) standard operating procedures (SOPs) and twenty-one (21) guidelines. In 2019, seventeen (17) policies, forty-seven (47) SOPs, and thirteen (13) guidelines were revised through the annual management review process and periodic internal audits which are both an integral part of the ongoing efforts to continuously improve the Malta Medicines Authority's quality management system (Figure 1).

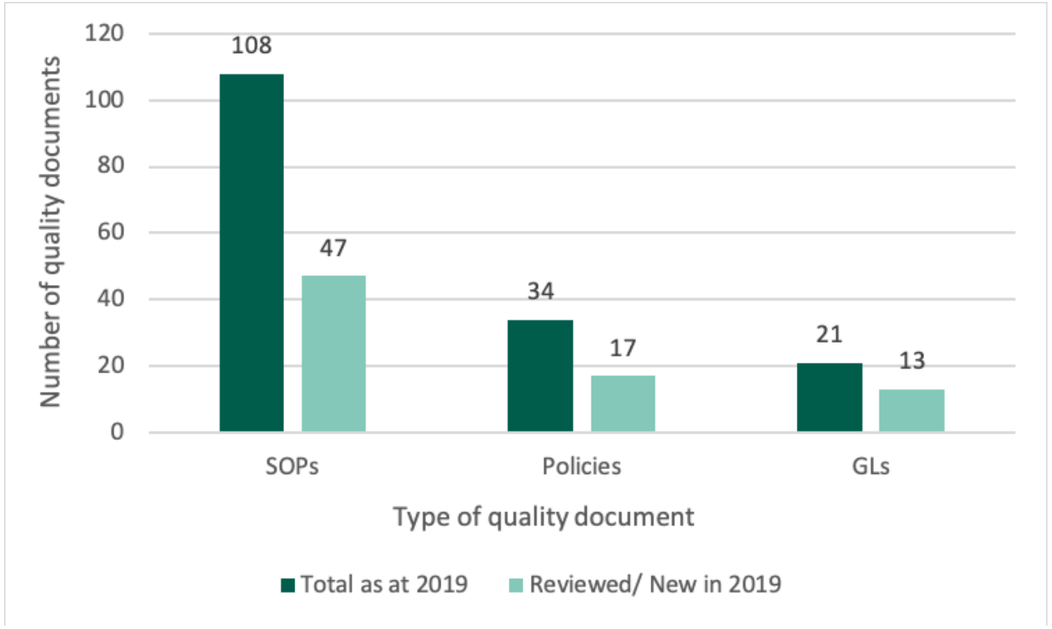


Figure 1: Standard Operating Procedures (SOPs), policies and guidelines of the Malta Medicines Authority

SOPs: Standard Operating Procedures, GLs: Guidelines

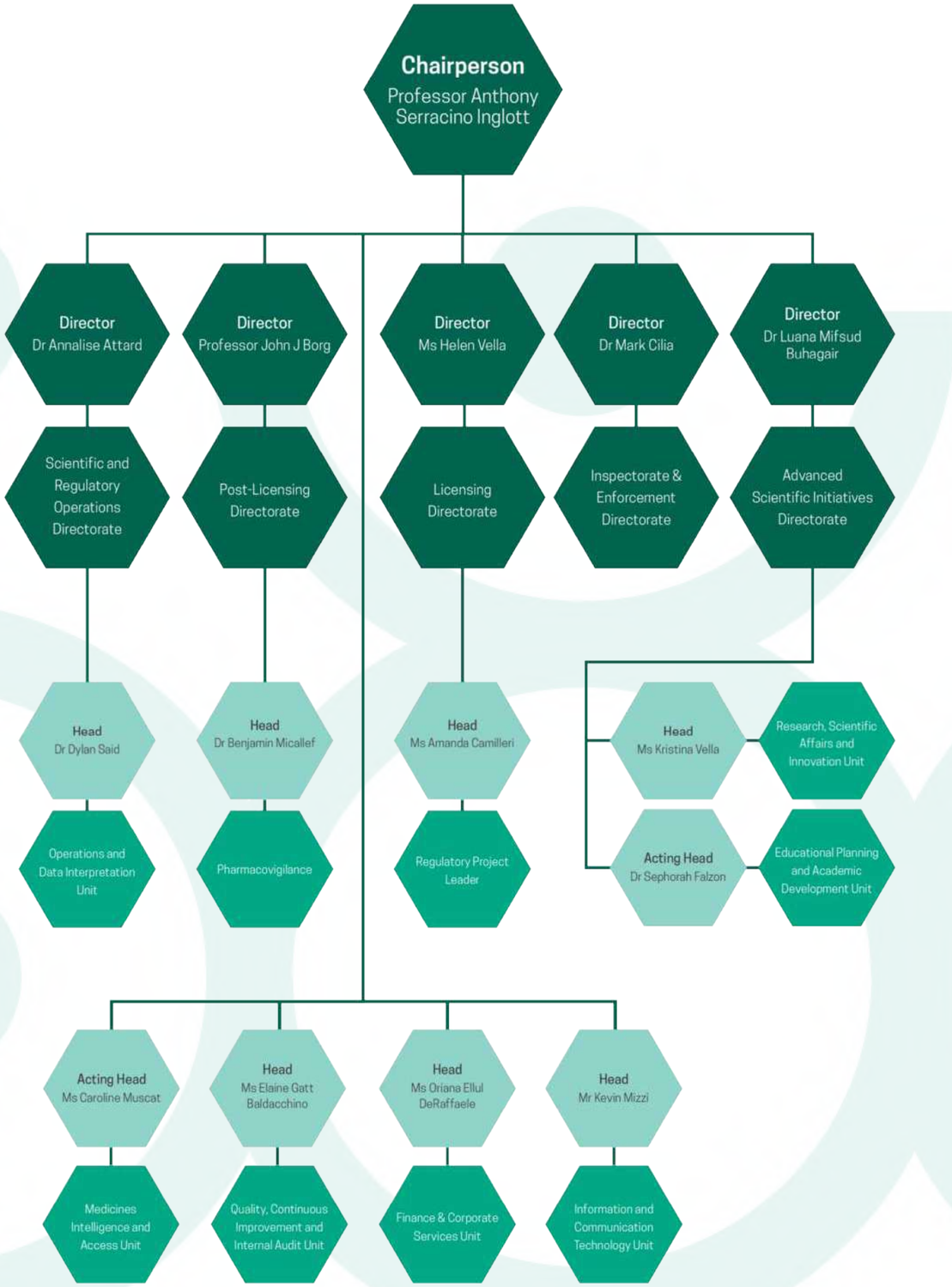
The Malta Medicines Authority implemented twelve (12) internal audits throughout 2019, in line with the five-year audit strategy. These resulted in a total of twenty-seven (27) quality improvements which led to the introduction of new policies and standard operating procedures or the systematic review of existing ones with a cross-cutting aim of reducing red tape and unnecessary bureaucracy. Another eighty-six (86) quality improvements were identified through other internal initiatives by the respective Directorates and Units, which jointly oversee the implementation of all quality improvements.

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

In line with the Malta Medicines Authority's commitment to simplify its systems and processes, four (4) simplification measures were identified and successfully implemented in 2019. The first measure pursued the establishment of an electronic licensing management system for inspectorate and enforcement activities. The second measure targeted a review for simplification of the submission process of new or updated information related to the safety of medicinal products, known as Direct Healthcare Professional Communications (DHPCs) and Risk Minimisation Measures (RMMs), by Marketing Authorisation Holders (MAHs) to the Medicines Authority for onward transmission to healthcare professionals. To this end, the Malta Medicines Authority identified, through a time and motion study, that submission by electronic mail is less bureaucratic than using electronic forms, facilitating submission for our stakeholders. The third measure involved the preparation and introduction of guidelines related to local and international collaborations, including a 'Memorandum of Understanding' template, to internally standardise and facilitate future collaborations. The final measure concerned the integration of a self-auditing system in the pharmacy inspection process which will empower pharmacists to ensure maximal conformity to regulatory requirements. The intended outcome is enhanced monitoring of the quality of service and the safety of medicinal products when compared to the traditional on-site inspections. The innovative pharmacy inspection system will also incorporate an element of risk analysis which will streamline the auditing process of pharmacies by reviewing the inspection frequency based on risk score computation.

The Malta Medicines Authority attaches great importance to good governance practices which are embodied in three primary measures of transparency based on information disclosure, clarity and accuracy. The Authority's commitment to freedom of information was fulfilled by sharing audit reports with the Internal Audit and Investigation Directorate within the Office of the Prime Minister. In compliance with the Freedom of Information (FOI) Act, categories of documents and manuals held by the Authority together with the full audited financial statements were published on the Authority's official website. Privacy by design and default is a concept brought about by data protection regulations which is fully embedded within the Authority's operational framework for processes handling personal data. In line with the FOI and data protection principles, the Authority has initiated preparatory work to become certified in the ISO27001:2013 standard on Information Security Management Systems (ISMS) which will preserve the confidentiality, integrity and availability of information by applying a risk management process.

Organogram



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

Throughout 2019, the Malta Medicines Authority maintained its focus on the implementation of the 2016-2020 Strategy as well as the National Framework for Education Strategy 2014-2024. This was achieved through a cross-cutting patient-centred approach across all Directorates and their respective Units. Such an approach was expedited by the setting up of an Academy for Patient-Centred Excellence and Innovation in Regulatory Sciences and two new Units which further enhanced the scientific image and reputation of the Authority, namely the Educational Planning and Academic Development Unit and the Operations and Data Interpretation Unit.

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

This solid internal structure and philosophy enabled the Malta Medicines Authority 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 leaflets on a wide spectrum of topics, ranging from the use of Cannabis for medicinal purposes to the introduction of the Falsified Medicines Directive.

Brexit preparedness was another challenge which the Authority successfully continued to endure throughout 2019 and will continue over the following weeks to ensure the smoothest outcome for both consumers and the industry at large. In this regard, the Malta Medicines Authority will stand as one with the Maltese Government to overcome the threats and maximise the potential of this unique international scenario.

Human Resources

By the end of 2019, the Malta Medicines Authority employed eighty-nine (89) officers (Figure 2.1). This represents an increase of 187% from the year 2013 (Figure 2.2) which effectively caters for the increased regulatory activities.

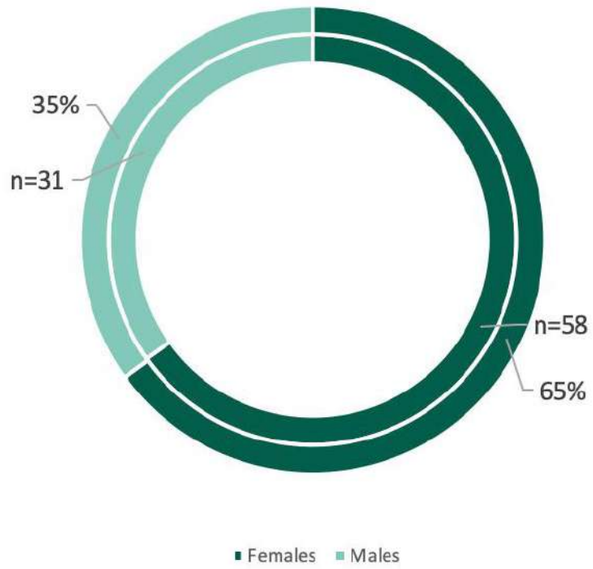


Figure 2.1: Total number of employees at the Malta Medicines Authority at the end of 2019 (N=89)

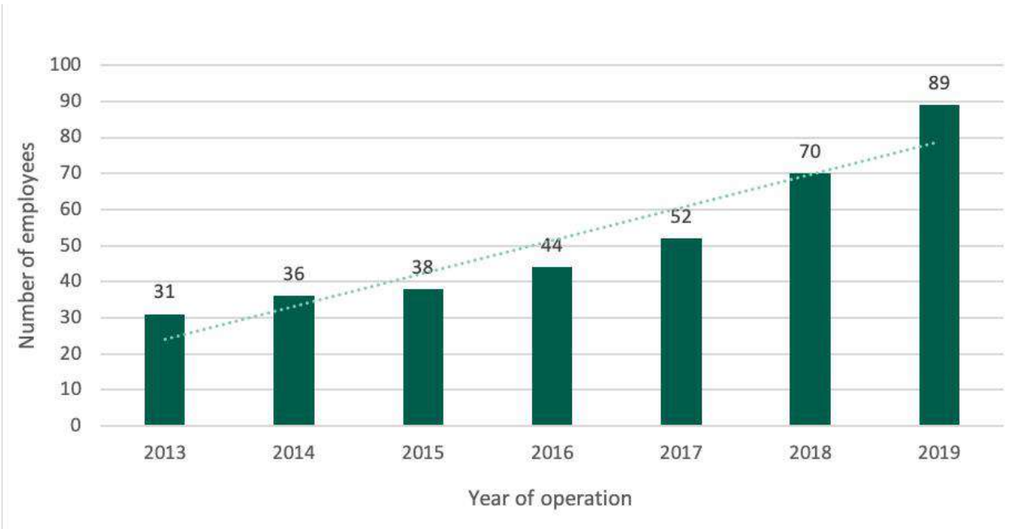


Figure 2.2: Number of employees at the Malta Medicines Authority 2013-2019

Education and Professional Development

The education and professional development of the Malta Medicines Authority's workforce is the key towards its continued regeneration and relevance to the ever-evolving pharmaceutical industry. In 2019, its employees successfully attained three hundred and sixty-two (362) certificates related to training initiatives which were offered internally (n=228) and externally (n=134). These comprised a wide range of subjects inter alia pharmacovigilance, regulatory sciences related to cannabis based products, biopharmaceutical manufacturing and medical device leadership (Figure 2.3).

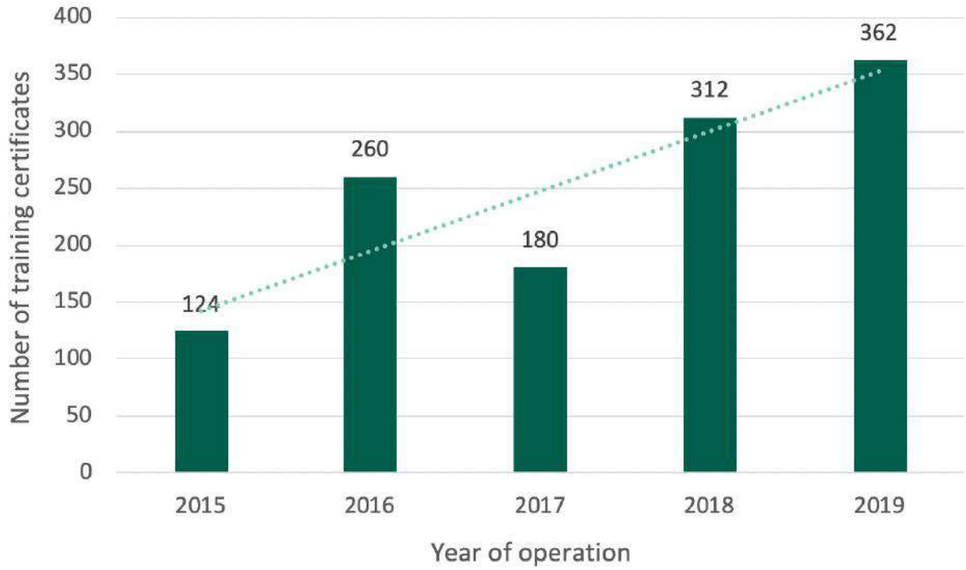


Figure 2.3: Number of training certificates attained by employees at the Malta Medicines Authority 2015-2019

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

The flexible working conditions for officers undergoing scientific and corporate studies is a fine example of the above-mentioned commitment. This is clearly portrayed in the number of employee graduates in 2019, whereby one (1) employee obtained the Doctorate in Philosophy, three (3) employees attained the Doctorate in Pharmacy degree, and one (1) employee graduated with a Diploma.

Furthermore, in 2019 the Malta Medicines Authority continued to offer the new International Academic Conference Scheme whereby employees (n=15) tapped into financial support to attend international conferences. This scheme further enhanced the scientific image of the Authority through the presentation of papers as listed in Section 6.

The International Fellowship Programme may be described as a flagship initiative which attracts local and foreign students to join the Malta Medicines Authority's team while reading for a Doctorate or Master or a comparable and equivalent qualification in line with the Malta Qualifications Framework in Pharmacy, Leadership, Management, Administration, and Finance.

In 2019, twenty (20) students from across the globe were following the Malta Medicines Authority's Fellowship Programme (Figure 2.4). Through this initiative, which is intended to overcome skills mismatches in the local pharmaceutical sector by increasing the capacity and level of research, young professionals actively contribute to the ongoing functions and day-to-day running of the Authority in exchange for a financial grant which covers the tuition fee or facilitates the living expenses of the participants. Graduates are often engaged on a full-time contract with the Malta Medicines Authority following their successful completion of the Fellowship Programme.

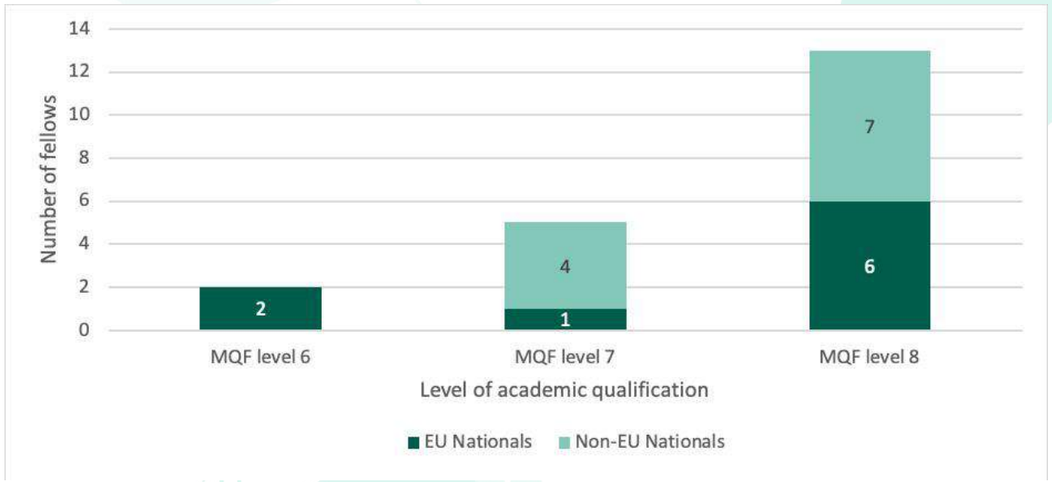


Figure 2.4: Number of students following the International Fellowship Programme in 2019 (N=20)

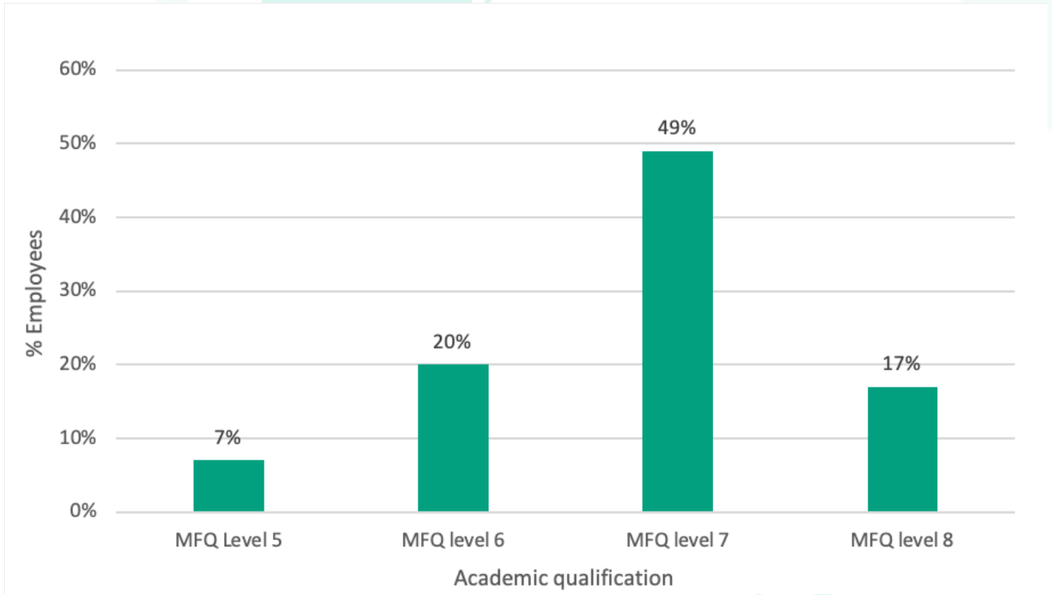


Figure 2.5: Academic qualifications for employees at the Malta Medicines Authority in 2019

The above represents a concerted effort to improve the overall capacity of the Malta Medicines Authority while reinforcing its scientific prowess. As it currently stands, seventeen percent (17%) of employees hold Doctoral degrees, whilst forty-nine percent (49%), nearly half of the Authority's workforce, hold an academic qualification at a Master's level (Figure 2.5).

The Malta Medicines Authority's commitment towards the professional development of its human resources was augmented by the increased investment in cross-border opportunities for its employees, allowing the exchange of best practices with European and International bodies. Such professional exposure secures the Authority's ability to adapt to the constantly-evolving landscape of pharmaceutical regulation. To this end, the Malta Medicines Authority has witnessed a significant expansion of 114% over the past three (3) years for the budgetary allocation to international training activities, conferences and meetings .

Furthermore, the Malta Medicines Authority maintains strong ties with the University of Malta by hosting student placements. In 2019, the Authority also welcomed students on summer placements from the Malta Enterprise and through the Institute for Public Service trainee scheme. Such initiatives set the benchmark for future cooperation with other national and international institutions such as the Malta College of Arts, Science and Technology and the University of Illinois in Chicago.

A European and Global Player

Throughout 2019, the Malta Medicines Authority maintained its active role at the highest European and International Fora, with officers participating in one hundred and eighty-eight (188) meetings, conferences and training opportunities abroad (Figure 2.6).

The extent of the Authority's representation in professional bodies has been further bolstered during the year 2019. Delegates are involved in a total of thirty-six (36) management and scientific expert groups and committees within the following organisations and institutions:

- European Medicines Agency (n=10)
- Heads of Medicines Agency (n=8)
- European Commission (n=17)
- Council of Europe (n=1)

This level of engagement allows the Authority to remain at the forefront of developments in the international pharmaceutical sphere, placing it in a position to respond promptly to global trends and strategies by taking the necessary regulatory actions.

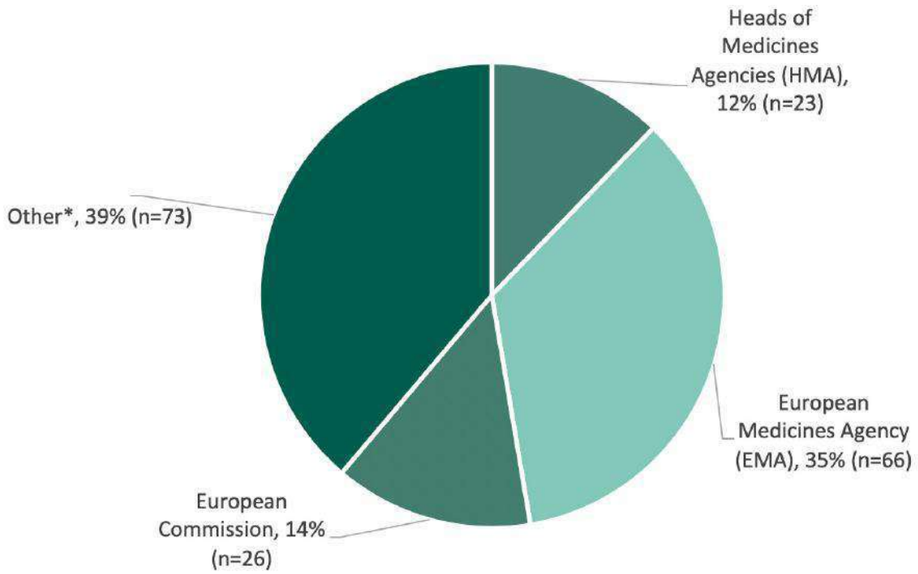


Figure 2.6: Number of cross-border meetings, conferences and training opportunities attended by delegates of the Authority, categorised by organisation/institution (N=188)

** 'Other' refers to training opportunities, international academic conferences, diplomatic missions and market research visits.*

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

In 2019, the Malta Medicines Authority was also represented in three (3) Commission Expert Group meetings on the implementation of the Delegated Regulation 2016/161/EU for safety features appearing on the packaging of medicinal products, during which the concerns of stakeholders were voiced while salient updates were subsequently disseminated to local operators and suppliers. The Authority has responded effectively to queries and clarifications presented by stakeholders on their obligations related to the Safety Features Regulation which pertained mostly to the areas depicted in Figure 2.7.

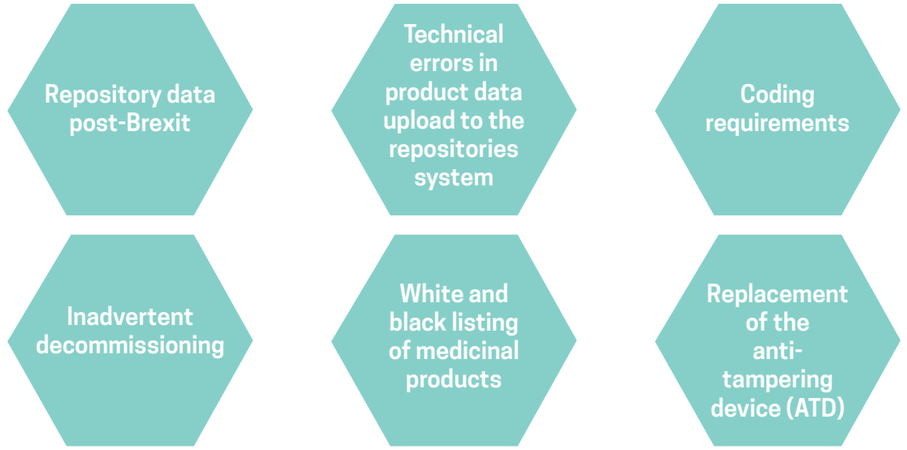


Figure 2.7: Main areas queried by internal and external stakeholders related to the Delegated Regulation 2016/161/EU for safety features appearing on the packaging of medicinal products

Through the tenets of knowledge dissemination and training in advanced pharmaceutical research, the Malta Medicines Authority reaches out to its counterparts in third country states with the objective of consolidating the quality of medicines imported in the EU and to spur the accessibility of medicinal products. The Authority has sustained the impetus in the area of international affairs by joining a Maltese delegation in a diplomatic visit to Ghana to strengthen the mutual areas of cooperation between both sides. Moreover, the Authority has also expressed its interest to tap into a new agreement with the authorities in Seychelles within a Joint Commission framework. These agreements foresee the development of industrial cooperation between pharmaceutical bodies of participating countries and the eventual exchange of experience and knowledge. The Authority has also pledged its support to the pharmaceutical sector in these international states by providing training to obtain EU Good Manufacturing Practice certification. The agreements are also intended to promote collaboration on capacity building with regards to pharmaceutical products registration, pharmaceutical quality control and pharmacovigilance.

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

Assessment and Licensing

One of the priorities of the Malta Medicines Authority is ensuring that a comprehensive range of medicinal products are authorised and accessible to the Maltese patients. Through life-cycle management, the Authority ensures that the information for all authorised medicinal products available in Malta is always updated and in line with scientific advancements. In 2019, the Malta Medicines Authority carried out seven-hundred and fifty (750) changes and updates to information of medicinal products for healthcare professionals and patients.

Malta as a Lead in European Procedures

During the year under review, the Malta Medicines Authority faced various challenges in relation to licensing of medicinal products, namely Brexit and the implementation of the Falsified Medicines Directive, which required capacity building and updates to internal Standard Operating Procedures (SOPs) and policies. The Malta Medicines Authority overcame its challenges and sustained its reputation as a key player in the European network for the regulation of medicinal products to provide greater accessibility of medical products for patients in Malta and beyond. This was achieved through its role as a Reference Member State (RMS) via the Decentralised Procedure (DCP) and the Mutual Recognition Procedure (MRP), or a Rapporteur in European Registration Procedures via the Centralised Procedure.

Malta started acting as a RMS in 2007 and contributed to the authorisation of five-hundred and forty (540) products over 13 years. The number of authorisation procedures led by Malta as RMS in 2019 was forty-two (42), whereby thirty-eight (38) were DCPs and four (4) were MRPs (Figure 3.1). These procedures resulted in the authorisation of eighty (80) new marketing authorisations (MA) for Malta and other European Union (EU) countries.

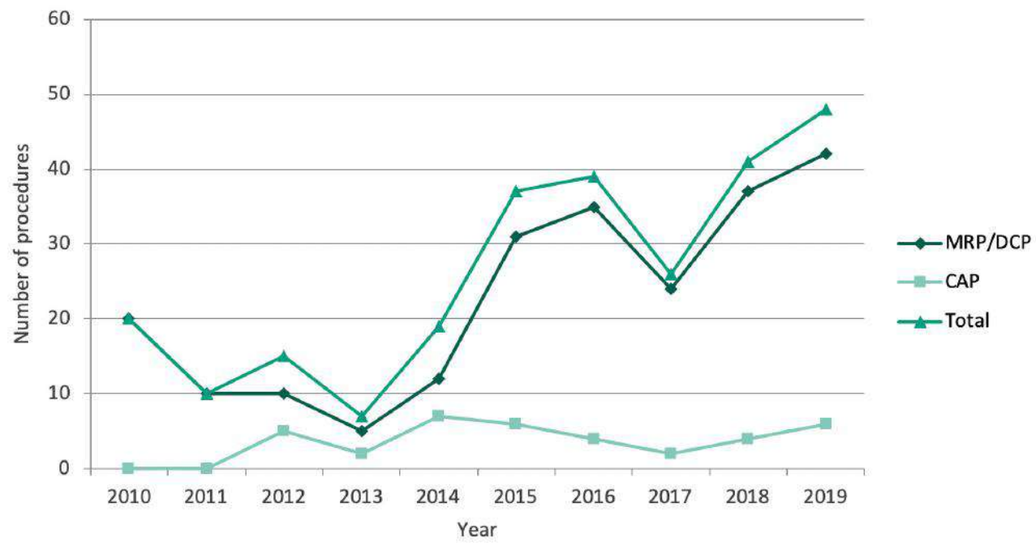


Figure 3.1: Number of procedures received with Malta as Reference Member State (RMS) or rapporteur in the last 10 years

MRP: Mutual Recognition Procedure, DCP: Decentralised Procedure, RMS: Reference Member State
CAP: Centrally Authorised Products

By the end of June 2019, Malta ranked eight (8th) as a RMS in the number of started MRPs and DCPs (Figure 3.2).

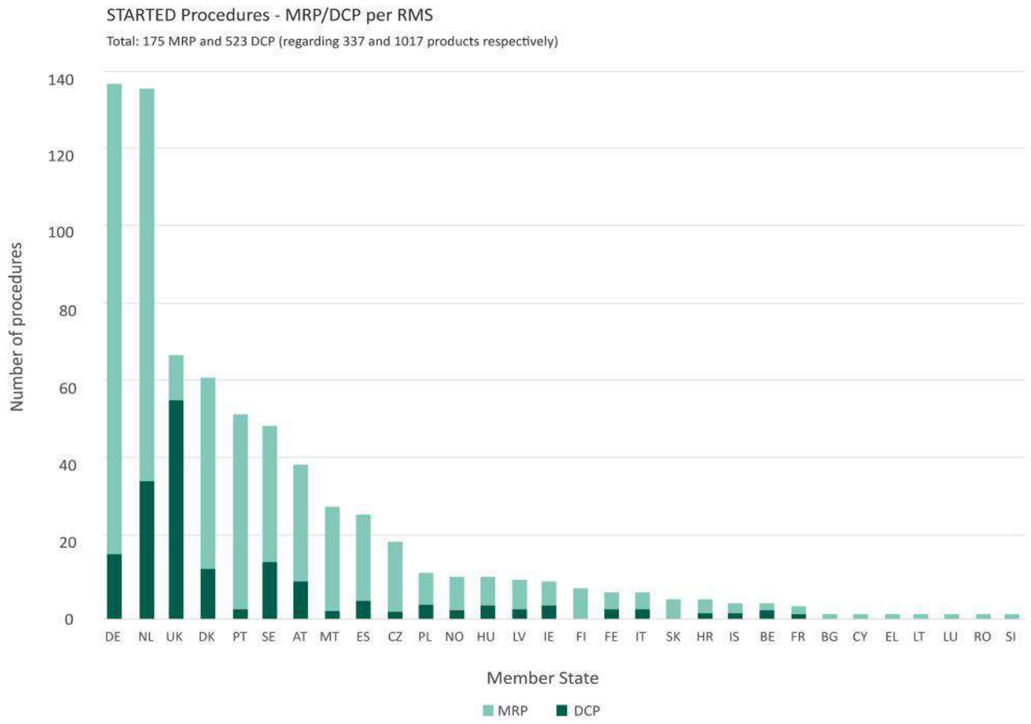


Figure 3.2: The number of Mutual Recognition Procedures (MRPs) and Decentralised Procedures (DCPs) started in the first semester of 2019 by Reference Member States (RMSs) (N=175 MRP, N=523 DCP) (source: CMDh statistics)

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

In 2019, Malta was rapporteur for six (6) applications submitted to the European Medicines Agency (EMA) for central authorisation, leading assessments of medicinal products eligible for a single authorisation throughout the EU. This sets the tone for more involvement in such assessments in the future which will effectively enable the Malta Medicines Authority to expand its visibility as a reputable scientific body while improving its expertise in this field of operation.

The Malta Medicines Authority participates in the European exercise for paediatric work-sharing which has reached Wave 41, to assess paediatric data to enhance safety of products for use in children. Malta, through its active role in the network, contributed to eleven (11) assessments of various active substances in 2019.

With an increasing number of procedures, the number of European project management staff within the Malta Medicines Authority has also increased and further growth is planned for 2020. In 2019 training was provided to ensure the smooth running of procedures while improving the synergy between Malta as a RMS, the Concerned Member States (CMS), and the MA applicants.

European Cooperation on Training and Assessments

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

Training of the Safety, Quality and Pharmacokinetic Assessors was provided by MEB during 2019 to enable the Malta Medicines Authority to participate more actively in the European network.

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

Furthermore, the Malta Medicines Authority continued to strengthen its team of external assessors to handle more challenging procedures, whereby in 2019 the Authority explored assessments of different pharmaceutical forms, namely inhalers with diverse devices.

Applications for National Authorisations

The number of applications for authorisations for the approval of new products received and finalised in 2019 is shown in Figure 3.3. These submissions include national MAs, as a result of National and European procedures (n=239), namely MRP and DCP, authorisations in accordance with article 126(a) of Directive 2001/83 /EC (n=703), and parallel import licences (n=98). A total of one thousand and forty (1040) authorisations and licences for new products were issued in 2019, an increase of eighty-two percent (82%) when compared to 2018.

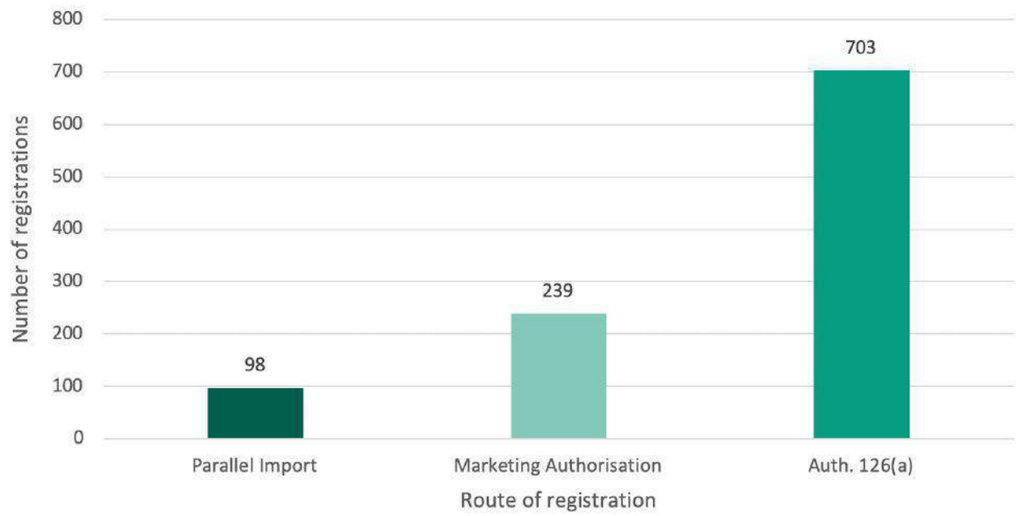


Figure 3.3: Total number of new registrations of medicinal products through all routes in 2019 (N=1040)

Auth. 126(a): authorisations in accordance with article 126(a) of Directive 2001/83 /EC

The below figure represents the authorisations in accordance with article 126(a) of Directive 2001/83 /EC (N=703) by the Anatomical Therapeutic Chemical Classification System (ATC) code and prescription status (Figure 3.4). Ninety-four percent (94%) of the authorised products had a Prescription-Only status.

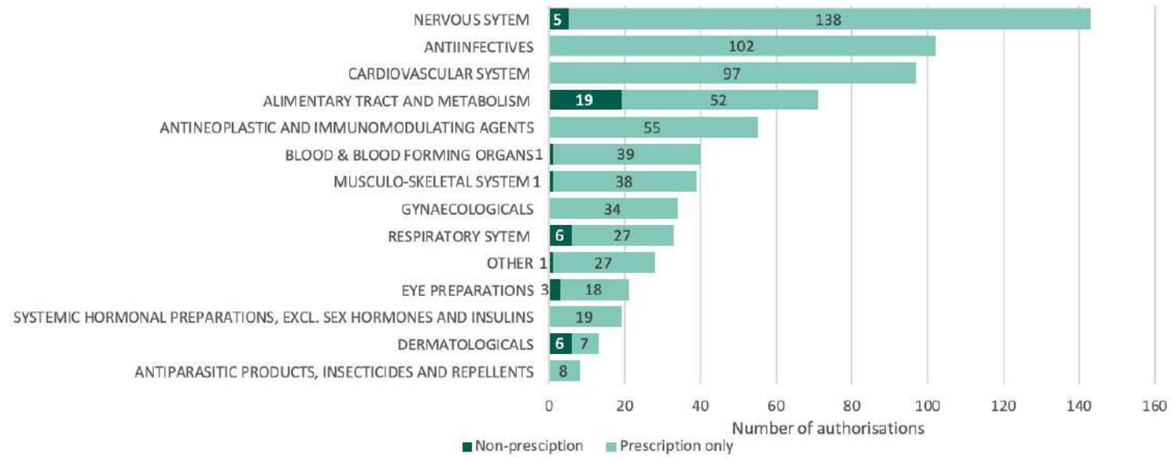


Figure 3.4: Authorisations in accordance with article 126(a) of Directive 2001/83 /EC (N=703) by the Anatomical Therapeutic Chemical Classification System (ATC) code and prescription status

Malta as a Contributor in European Procedures

The number of marketing authorisation applications received in 2019 with Malta as CMS resulted in the granting of two hundred and forty-one (241) MAs. Figure 3.5 and Figure 3.6 show the applications started and finalised by Malta through this route compared to other Member States (source of data: Coordination Group for the Decentralised and Mutual Recognition Procedure (CMDh) statistics). Malta ranked seventh (7th) as a CMS in the number of finalised MRPs and DCPs (Figure 3.6).

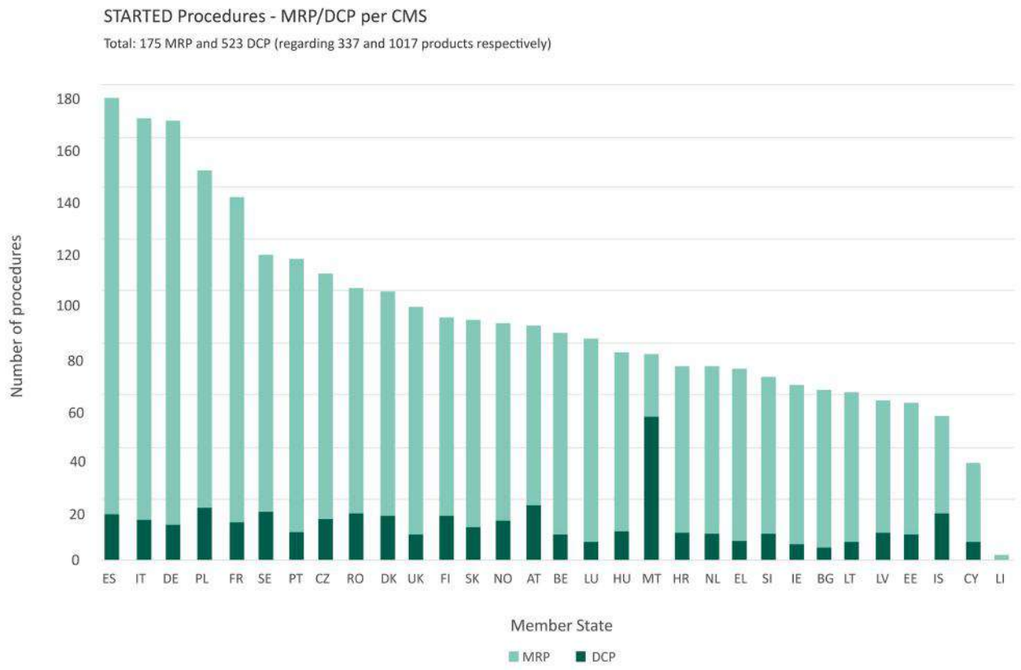


Figure 3.5: Applications started by all Member States as Concerned Member State (CMS), including Malta, in Mutual Recognition Procedures (MRPs)/ Decentralised Procedures (DCPs) in European Union (EU) in 2019 (N=175 MRP, N=523 DCP) (source: CMDh statistics)

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

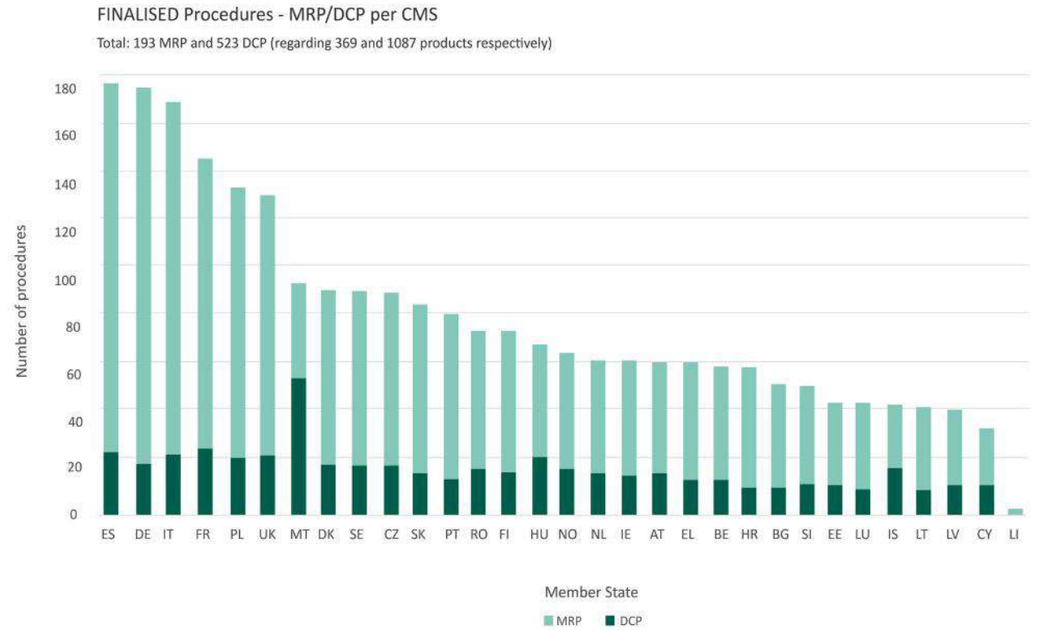


Figure 3.6: Applications finalised by all Member States as Concerned Member State (CMS), including Malta, in Mutual Recognition Procedures (MRPs)/ Decentralised Procedures (DCPs) in European Union (EU) in 2019 (N=193 MRP, N=535 DCP) (source: CMDh statistics)

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

Post-authorisation Procedures

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

Post-authorisation activities, especially for procedures where Malta is a RMS, maintained a strong increase, particularly in view of the procedures taken by Malta from the United Kingdom (UK), which is expected to subsist in the coming years (Figure 3.7).

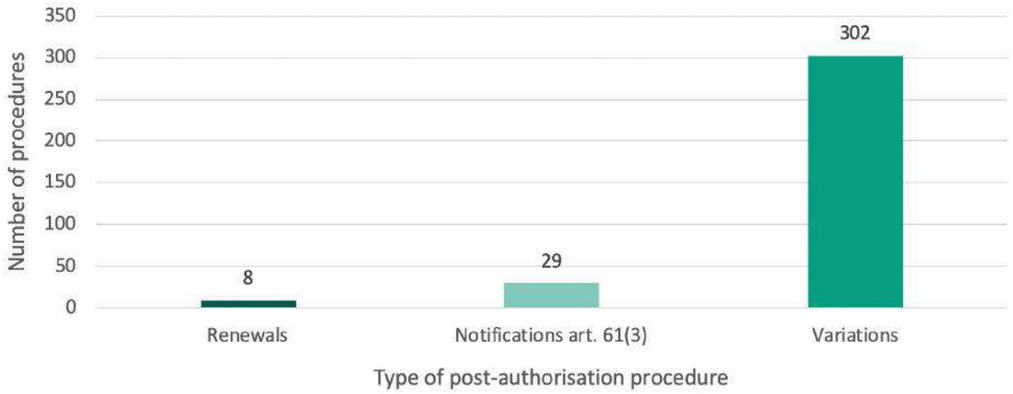


Figure 3.7: Number of post-authorisation procedures for European procedures with Malta as Reference Member State (RMS) in 2019 (N=339)

Notifications art. 61(3): notifications in accordance with article 61(3) of Directive 2001/83/EC

Twenty-one (21) post-authorisation activities for centralised procedures where Malta is rapporteur were reported for 2019. Eighteen (18) were variations while three (3) were renewal of MAs.

Figures 3.8 show the number of national post-authorisation procedures, including renewals, variations, Marketing Authorisation Holder (MAH) transfers and notifications in accordance with article 61(3) of Directive 2001/83/EC.

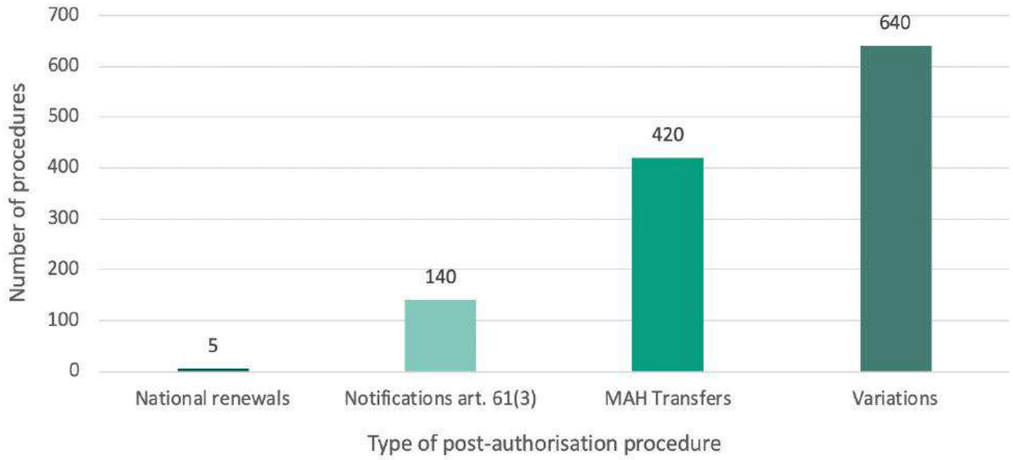


Figure 3.8: Number of post-authorisation procedures for national Marketing Authorisations (MAs) in 2019 (N=1205)

MAH: Marketing Authorisation Holder, Notifications art. 61(3): notifications in accordance with article 61(3) of Directive 2001/83/EC

In 2019, the Malta Medicines Authority has continued to monitor all locally authorised products to ensure that UK-based companies are submitting their applications in line with the regulatory requirements, thereby maintaining as many MAs as possible. As shown in Figure 3.8, four hundred and twenty (420) MAH transfers were processed in 2019 as more companies prepared to relocate from the UK. Concurrently, the Malta Medicines Authority is monitoring UK authorised products which are being withdrawn from the local market to ensure that suitable alternatives are authorised.

Figures 3.9 and 3.10 show the number of post-authorisation procedures for authorisations in accordance with article 126(a) of Directive 2001/83 /EC and parallel import licenses, including notification of changes and renewals.

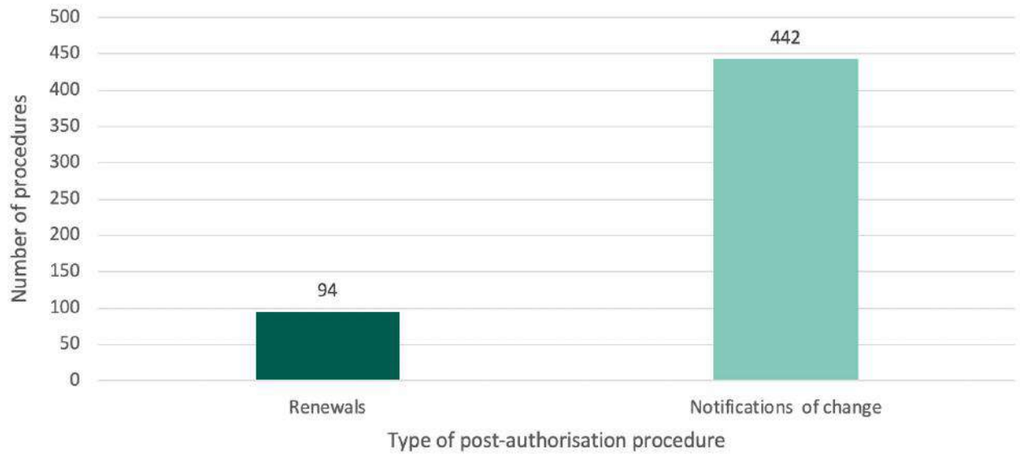


Figure 3.9: Number of post-authorisation procedures for authorisations in accordance with article 126(a) of Directive 2001/83 /EC in 2019 (N=536)

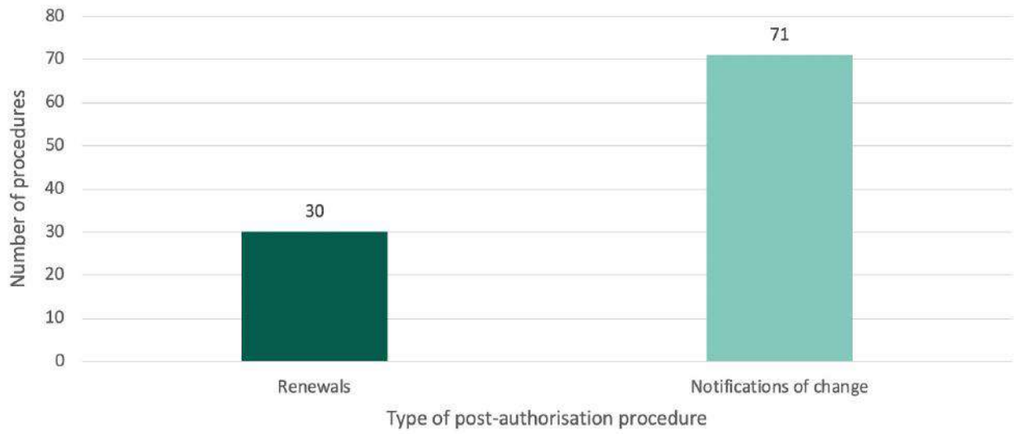


Figure 3.10: Number of post-authorisation procedures for parallel import licences in 2019 (N=101)

Figure 3.11 refers to withdrawal applications for authorisations and licences. Following the UK's decision to leave the EU, companies have been withdrawing some product licences and authorisations, particularly those which were not marketed in Malta. Such withdrawal applications are evaluated in a comprehensive exercise through which the Malta Medicines Authority identifies alternative medicinal products.

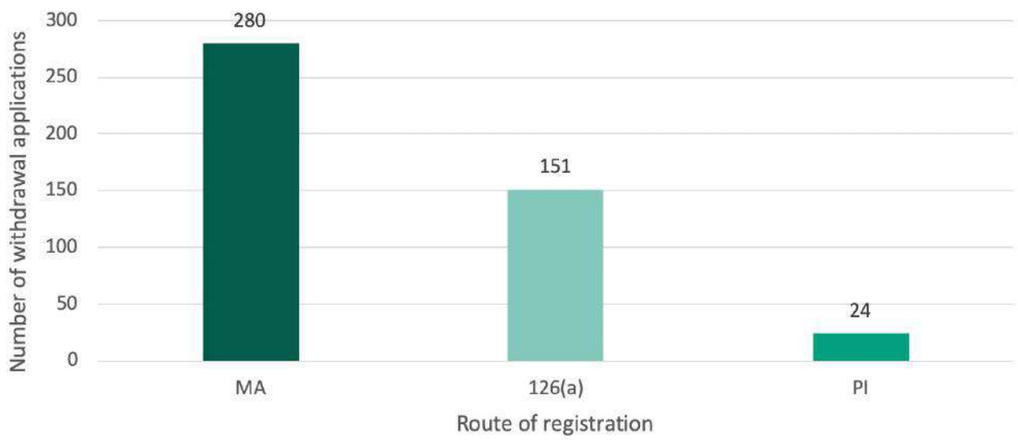


Figure 3.11: Number of withdrawal applications for Marketing Authorisations (MAs) and licences received in 2019 (N=455)

126(a): authorisations in accordance with article 126(a) of Directive 2001/83 /EC, MA: Marketing Authorisations, PI: Parallel Import Licenses

Committees, Working Groups and National Advisory Services

During 2019, the Prescription Status Working Group continued to work on the harmonisation of the legal classification of medicinal products (prescription versus non-prescription). Several meetings were held with individual stakeholders to support with regulatory advice when it was considered appropriate to change the status of some products from prescription only status to non-prescription status. Apart from the legal classification of medicinal products, the Prescription Status Working Group, worked to harmonise classification by therapeutic class and discussed several cases relating to the availability of medicinal products in view of the new requirements of prescription-only medicinal products due to the Falsified Medicines Directive.

The Borderline Classification Committee of the Malta Medicines Authority classifies products into either medicinal products or non-medicinal products when requests for classification are received from companies or from other sources. The Committee meets regularly, and feedback is sought from all members as well as the herbal expert in line with an updated simplified and shorter process. In 2019, twenty-four (24) applications for the classification of borderline products were received, out of which seventeen (17) were considered as non-medicinal and five (5) were considered medicinal. The Borderline Classification Committee provided recommendations regarding the use for four (4) requests where classification was deemed to be non-medicinal.

At the national front, the Malta Medicines Authority is continuously seeking to expand its remit as a reputable scientific advisory centre. In 2019, one (1) request for national scientific advice was received via the centralised procedure.

At an EU level, the Malta Medicines Authority is involved in scientific affairs regarding the development and licensing of medicinal products through the participation in the Scientific Advice Working Party (SAWP) of the EMA. In 2019, the Malta Medicines Authority provided nineteen (19) scientific advices related to chemical products in the area of quality (n=17), pharmacokinetics (n=1), preclinical (n=1) and both preclinical and quality (n=1).

Impact of Brexit on the Malta Medicines Authority

In 2019, Brexit was a distinct challenge. Through coordinated endeavours, the Malta Medicines Authority supported public and private pharmaceutical stakeholders to proactively address the implications of Brexit on the availability of medicines on the local market. The Authority:

- Initiated discussions between several pharmaceutical stakeholders outside the UK and local distributors to establish alternative supply routes to the local market;
- Provided its expertise to support the Central Procurement and Supplies Unit in an extensive operation to analyse and identify new sources for eight hundred and thirty-three (833) medicinal products that were being procured from the UK. Twelve thousand, five hundred and thirty-four (12,534) alternative suppliers were identified and contacted to establish a supply route to Malta;
- Put forward a proposal as a no deal Brexit contingency initiative to counteract the event of shortages of medicines;
- Continuously provided updated information on the website in line with the EMA and European Commission discussions and publications;
- Participated in all EU Brexit meetings and was represented at high level meetings with the purpose of ensuring accessibility to medicinal products to local patients;
- Worked in close collaboration with patients and the national health service, and addressed various issues concerning access to medicinal products. This service will be extended throughout 2020.

Through the Coordination Group for the Decentralised and Mutual Recognition Procedure (CMDh), the EU Member States have been monitoring the situation of medicinal products with the UK as a RMS. By the end of 2019, one hundred and four (104) procedures were officially switched from UK as RMS to Malta (Figure 3.12). This positive trend is expected to climax after the first month of 2020.

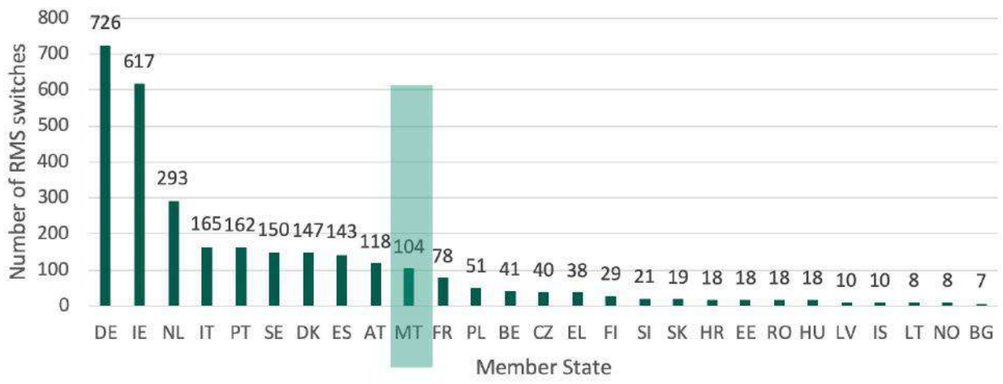


Figure 3.12: Reference Member State (RMS) switches received from the United Kingdom since 01/04/2017 (N=3057) (Source: EMA statistics)

RMS: Reference Member State,
Glossary of Member State country codes: https://ec.europa.eu/eurostat/statistics-explained/index.php/Glossary:Country_codes

Pharmacovigilance Activities

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

In 2019, the Malta Medicines Authority maintained its web-based side effect reporting form for patients and consumers. Moreover, the Authority continued the implementation of its adverse drug reaction (ADR) promotion strategy which included the organisation of five (5) workshops on quality in ADR reporting for medical practitioners with the aim to improve the overall pharmacovigilance system locally and to further facilitate the rapid and scientific identification of post-marketing safety issues through good quality ADR reports. During the workshop, participants were asked to fill an ADR form following the presentation as a practical case example, whereby the positive and constructive feedback received, is being considered for the planned 2020 workshops for healthcare professionals.

The fourth ADR awareness week campaign was held between 25 and 29 November 2019, focused on the importance of reporting side effects when taking multiple medicines, known as polypharmacy. During this week humorous animations (sample animations Figure 3.13), videos, infographics and other material were uploaded to the Authority's social media platforms.

Figure 3.13: Sample animations used for a global social media campaign during November 2019 on adverse drug reaction (ADR) reporting

Additional measures to reduce the administrative burden of ADRs transmission of parallel reporting for MAHs and the Malta Medicines Authority were implemented in 2019, in line with the simplified reporting rules rolled out across the EU during 2018. MAHs now have access to Individual Case Summary Reports (ICSRs) by means of the revised EudraVigilance access policy.

A total of one hundred and eighty-nine (189) ICSRs were registered in 2019. These cases detailed at least one (1) ADR to the medicinal product concerned and resulted in three hundred and twenty-eight (328) suspected ADRs. Figure 3.14 gives a breakdown of these ADRs according to system organ classification.

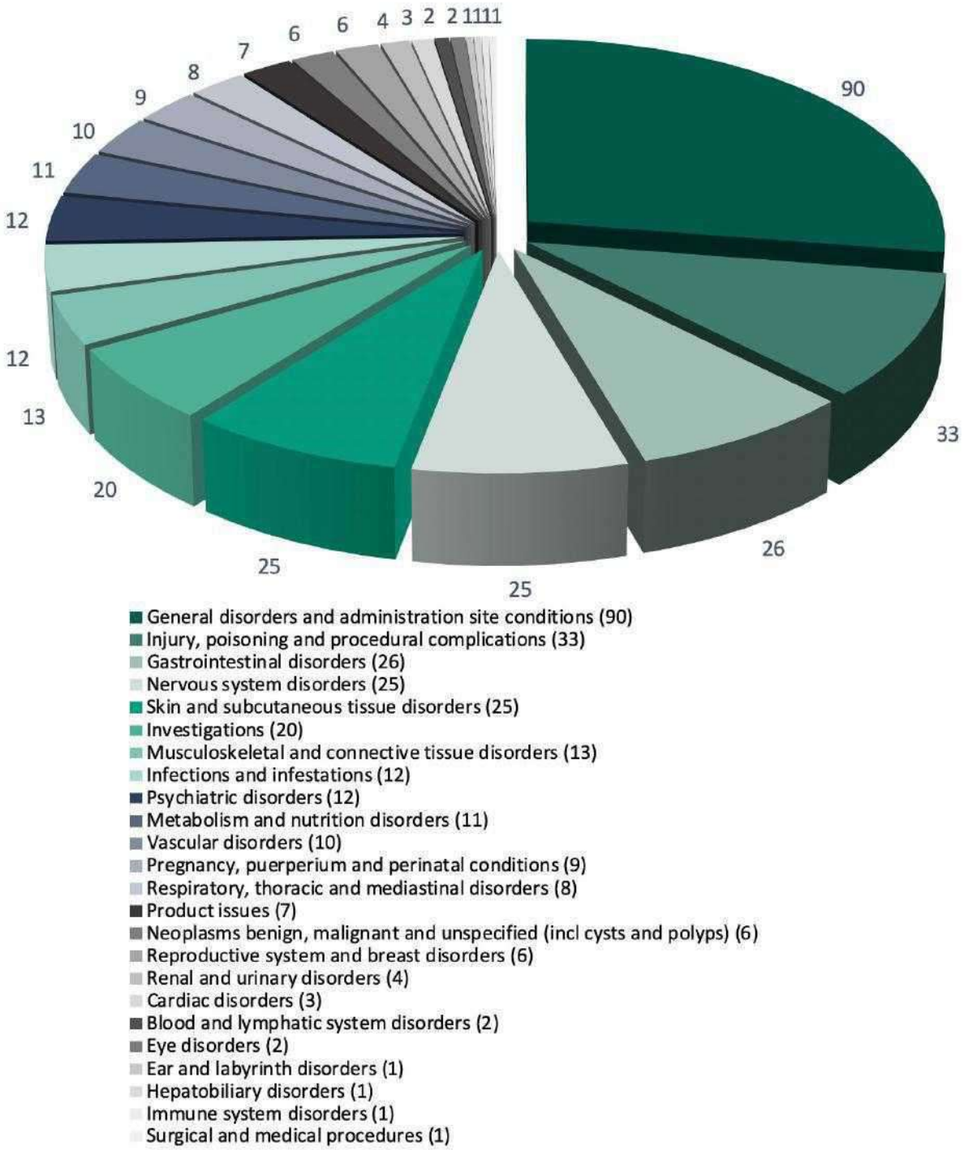


Figure 3.14: Distribution of Adverse Drug Reactions (ADRs) according to System Organ Classification in 2019 (N=328)

Each case report received at the Malta Medicines Authority was assessed and reported electronically to the European Medicines Agency and the World Health Organisation as the central ADR repositories.

Figures 3.15 and 3.16 further classify the adverse ICSRs (as received over 2019) according to seriousness and patient age respectively. The severity of the ICSRs is normally assigned by the reporting healthcare professional or by the Malta Medicines Authority following careful assessment and consideration of applicable factors such as dose of the medicinal product, indication for use, concurrently administered drugs and underlying patient disease.

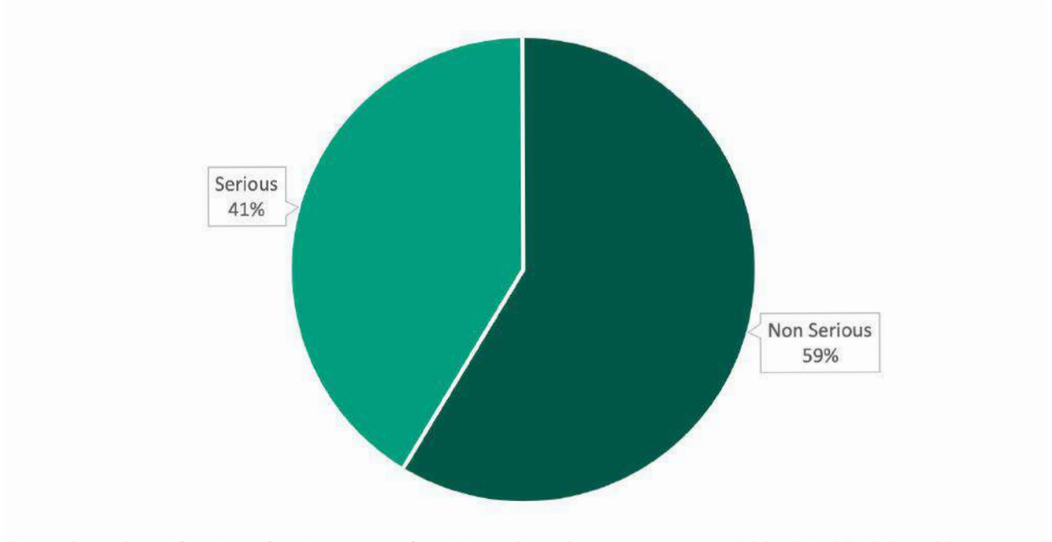


Figure 3.15: Classification of seriousness of Individual Case Summary Reports (ICSRs) in 2019 (N=189)

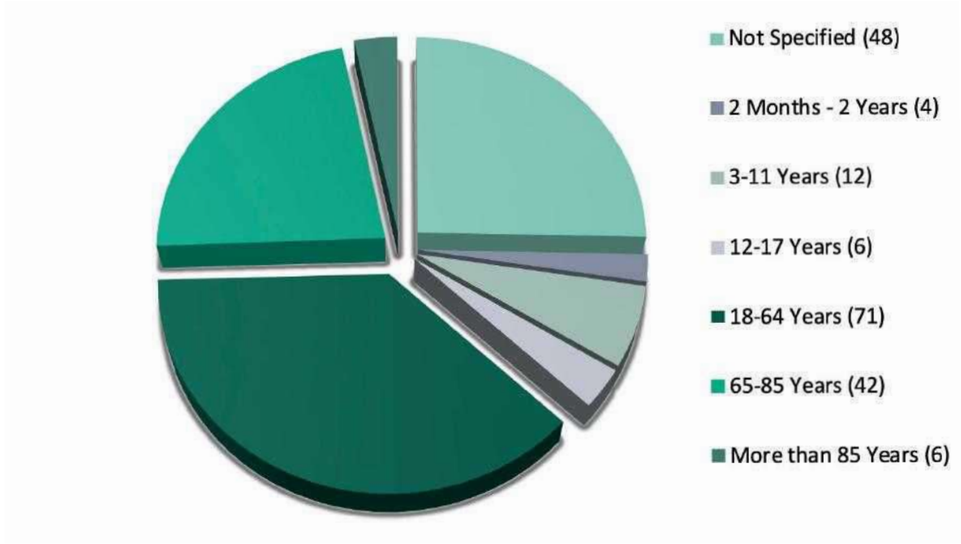


Figure 3.16: Percentage distribution of Individual Case Summary Reports (ICSRs) according to patient age in 2019 (N=189)

Throughout 2019 the Malta Medicines Authority continued implementing the SMS notification service though a web-based Notifications Portal supplied by the Malta Information Technology Agency. This service allows subscribed medical and healthcare professionals to receive alerts and links to the safety circulars as soon as they are published on the website.

Table 3.1 below gives the distribution of assessments, reviews, communications and approvals which the Malta Medicines Authority handled over 2019.

Activity	Number of assessments, reviews, communications and approval
Direct Healthcare Professional Communications	13
Joint DHPCs	7
Safety Circulars	15
Risk Minimisation Measures	116
Rapid Alert	0
Non-Urgent Information	3
National PSUR assessments	2

Table 3.1: Pharmacovigilance and safety issue reviews and communications in 2019 (N=156)

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

An additional stakeholder service performed by the Malta Medicines Authority is that of responding to any queries related to Pharmacovigilance activities in a timely manner. Queries received were related to; national legislation and requirements, collection, assessment and reporting of local ADRs and medication errors and submission requirements for Periodic Safety Updated Reports (PSURs) and Periodic Safety Update Report Single Assessments (PSUSAs) and ICSRs transmission requirements (Table 3.2).

	Area Queried	Number
1	ADR reporting/ICSR transmission requirements	13
2	Literature Monitoring requirements	10
3	Submission of PSURs/PSUSAs	9
4	National Pharmacovigilance legislation and requirements locally	7
5	RMMs/Educational Material	6
6	Qualified Person for Pharmacovigilance/Local Contact Person for pharmacovigilance	5
7	Pharmacovigilance information on Medicines Authority Website	3
8	Requests for local Adverse Reaction Data from students and researchers	2
9	DHPC dissemination	2
10	Pharmacovigilance requirements for Medical Devices	1
11	Safety Signal Notification requirements	1
12	Submission of Development Safety Update Reports	1
13	PSMF	1
14	Pharmacovigilance requirement in view of Brexit	1
	Total	62

Table 3.2: Pharmacovigilance related queries in 2019 (N=62)

ADR: Adverse Drug Reaction, ICSR: Individual Case Summary Report, DHPC: Direct Healthcare Professional Communication, RMM: Risk Minimisation Measure, PSMF: Pharmacovigilance System Master File, PSUSA: Periodic Safety Update Report Single Assessment, PSUR: Periodic Safety Updated Report

At an EU level, the Malta Medicines Authority continued to implement the centralised PSUSA, which in 2019 amounted to one (1) PSUSA procedures for lubiprostone. The Malta Medicines Authority is also involved in signal management work-sharing activities. In 2019, Malta maintained appointment as lead Member State to monitor data in EudraVigilance, validate and confirm signals for twenty-five (25) active substances and active substance combinations.

Advertising of Medicinal Products

The Malta Medicines Authority monitors the advertising of medicinal products and the issue of any promotional material related to such products being presented either to the public or to healthcare professionals. Regulation of promotional material such as the provision of medicinal product samples to healthcare professionals and the sponsoring of promotional activities or scientific congresses is also regularly undertaken, in accordance with the Medicinal Products (Advertising) Regulations. During 2019, no advertising complaints were registered with the Authority.

Medicines Intelligence and Access

The patient-centred ethos is the foundation of the functions of the Malta Medicines Authority, whereby in a proactive and targeted approach, it leads noteworthy initiatives that enhance access to medicines.

The Malta Medicines Authority intervenes to support consumers, healthcare professionals and patient organisations in their queries related to availability of medicines on the local market. In 2019, the Malta Medicines Authority handled on an individual basis one hundred and seven (107) queries. Over a six-year period the Authority registered a total of five hundred and twenty-four (524) queries related to shortages (n=77), pharmacoeconomic (n=121), registration (n=128) and safety (n=198) issues (Figure 3.17).

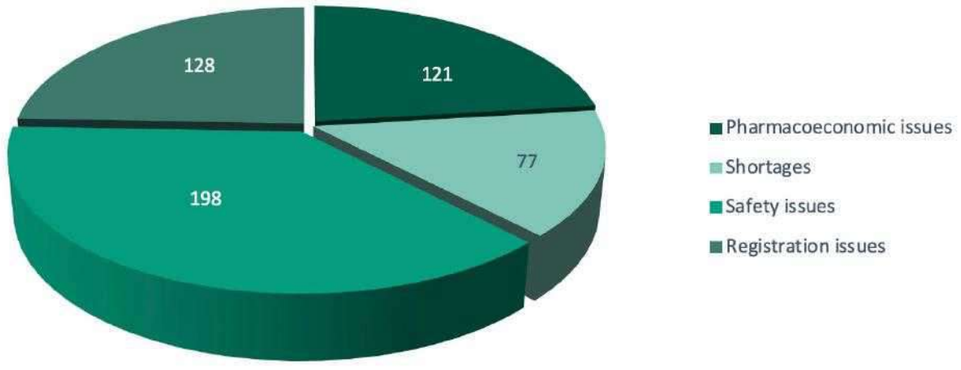


Figure 3.17: Number of interventions between 2014 and 2019. (N=524)

Medicines intelligence was promoted by engaging the general public in six (6) information seminars to raise awareness on the rational use of medicines, the influenza vaccine and the difference between over-the-counter and prescription-only medicines.

The Malta Medicines Authority is in continuous dialogue with the Malta Competition and Consumer Affairs Authority and local and international pharmaceutical stakeholders to ensure reasonable prices for medicines. In 2019, twenty-nine (29) price reductions of medicines were announced and fourteen (14) new generic medicines were introduced on the Maltese market with a price difference of up to eighty-two percent (82%) (Figure 3.18). As a result, patients have access to more affordable medicines that conform to the established European standards of quality, safety and efficacy.

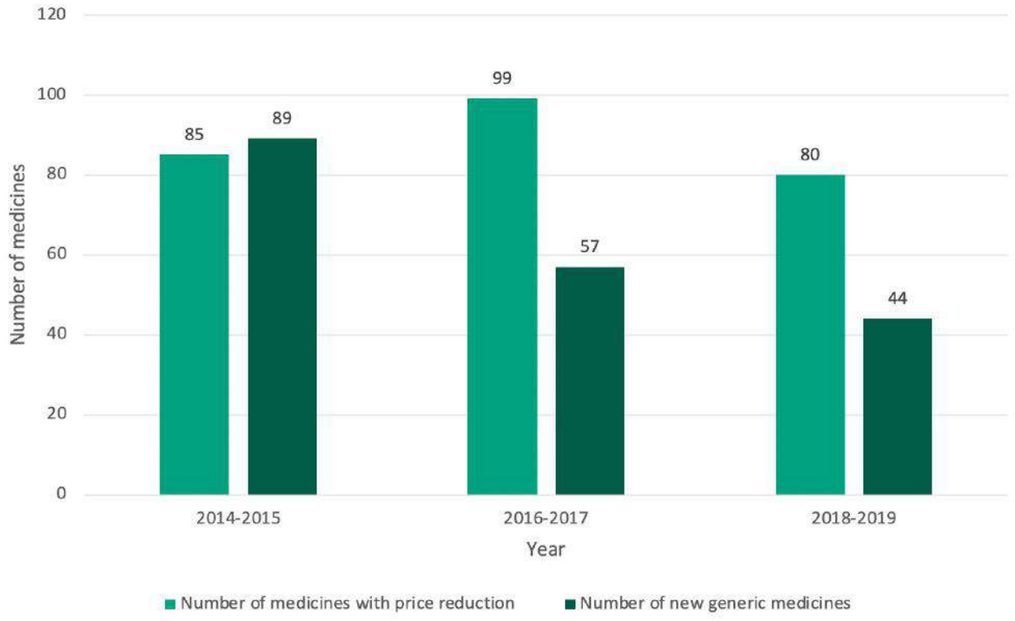


Figure 3.18: Number of medicine price reductions and new generic medicines on the Maltese market

The Malta Medicines Authority proactively addresses emerging medical needs by assisting in the sourcing and supply of new medicines with pharmacotherapeutic importance. Phenoxymethylpenicillin tablets and oral solution, a penicillin antibiotic with a low risk of resistance and emtricitabine/tenofovir tablets indicated in pre-exposure prophylaxis of Human Immunodeficiency Virus (HIV), were introduced on the local market in 2019 through close collaboration with pharmaceutical stakeholders.

Access to medicine is an evolving, multifaceted challenge that requires collective effort and cooperation between all stakeholders. The Malta Medicines Authority is supporting the health authorities and the pharmaceutical distributors with targeted recommendations to ensure business continuity and sustainable access to medicines to safeguard patients' needs in the face of geo-political challenges such as Brexit.

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

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

Manufacturing, Importation and Distribution

All medicinal products for human use manufactured or imported into Malta and the EU, including medicinal products intended for export, are to be manufactured in accordance with the principles and guidelines of GMP.

During 2019 the Malta Medicines Authority, carried out eighteen (18) local GMP inspections for new, renewal or follow up of GMP licences/certificates. These included:

- Two (2) GMP inspections for an active pharmaceutical ingredient;
- Two (2) inspections for laboratories;
- Two (2) full line non-sterile solid dosage manufacturers;
- Five (5) inspections for manufacturing authorisation (MAs) for repackaging and re-labelling/partial manufacturing operations;
- One (1) inspection for manufacturing of medicinal gases;
- Five (5) inspections for MAs of importation activity; and
- One (1) for-cause GMP inspection.

Moreover, in 2019 the Malta Medicines Authority:

- Processed thirty-nine (39) MAs administrative variation applications for manufacturers and importers;
- Carried out two (2) variation inspections;
- Held six (6) Inspections Review Group meetings, wherein five (5) cases were discussed and decided upon; and
- Received one hundred and eighty-four (184) rapid alerts and GMP non-compliance notifications, which were investigated, one (1) of which resulted in product safety recalls.

Distributors are also required to follow good practice guidelines known as GDP in order to ensure that the quality of the medicinal products is not compromised in the supply chain and to be in a position to carry out a recall of any defective product.

During 2019, the Malta Medicines Authority fulfilled its GDP inspection plan through forty-two (42) GDP inspections. During 2019, four (4) applications for new wholesale dealing licences were submitted, one (1) of which was eventually licensed after having satisfied all the criteria in a thorough inspection by the end of the year.

Furthermore, thirty-seven (37) variation applications for wholesale dealing authorisations were processed in 2019, out of which seven (7) required an inspection. Also in 2019, three (3) new applications for Active Pharmaceutical Ingredient registration were received which were processed and inspected, leading to one (1) registration by the end of the year.

Third Country Inspections

During the year under review, the Malta Medicines Authority continued to carry out GMP certification inspections in countries outside the EU. The below Figure 4.1 portrays the exponential growth of third country inspections registered over the past six years.

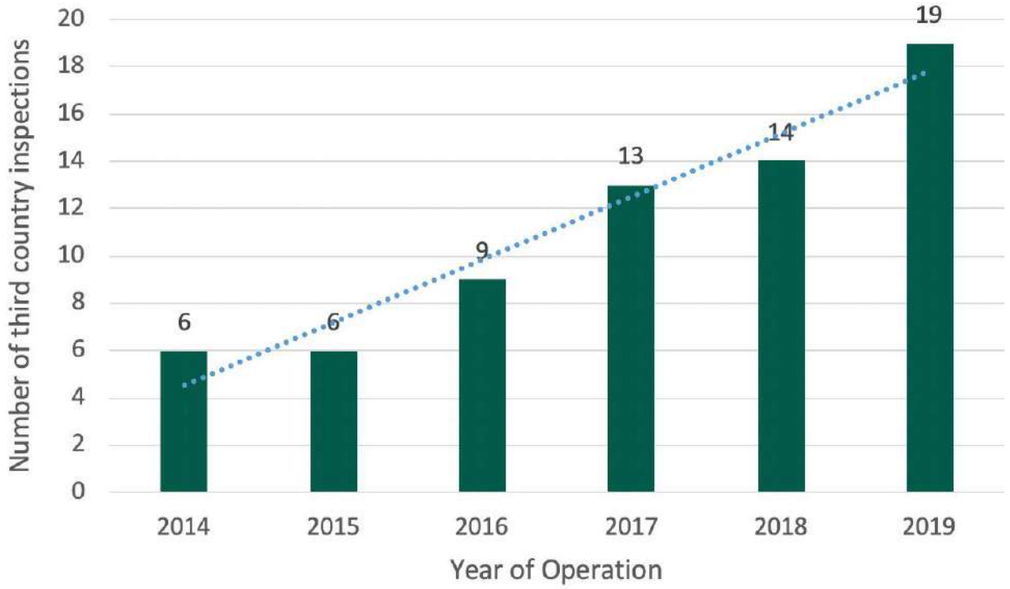


Figure 4.1: Third country inspections over a 6-year period (N=67)

A total of sixty-seven (67) third country GMP certification inspections have been carried out in various countries to date, with twenty (20) inspections being carried out in 2019 (Figure 4.2). Through this process, the Malta Medicines Authority is empowering more companies to be EU GMP certified and thus in a better position to export medicinal products to the European Single Market. Additionally, these procedures attract new revenue to the Malta Medicines Authority and provide exposure to different manufacturing facilities to the inspectors of the Malta Medicines Authority, thereby furthering the Authority's reputation as a globally-esteemed scientific regulatory institution.

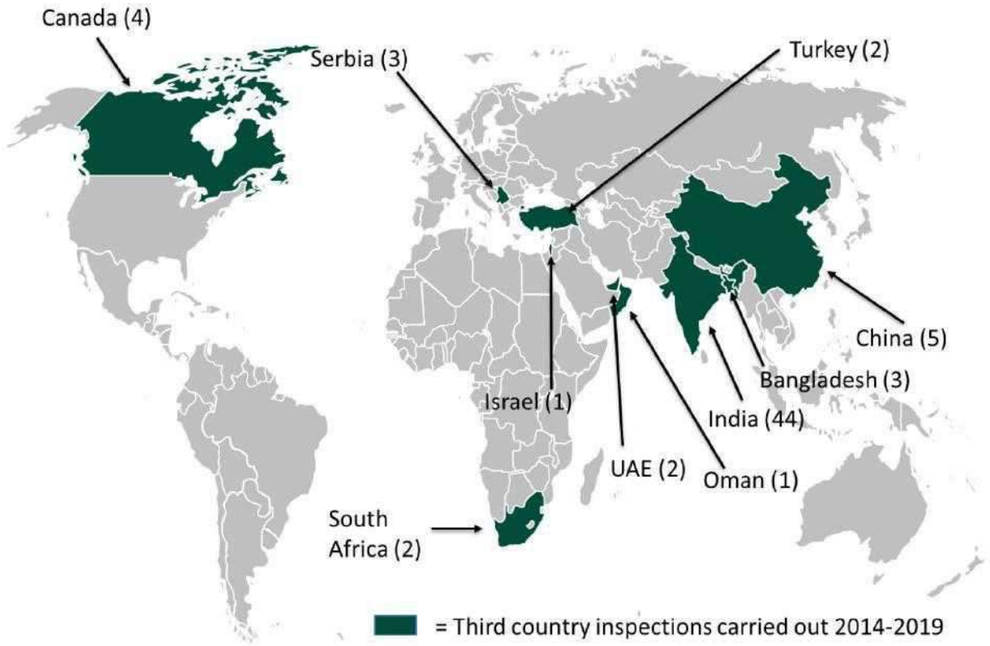


Figure 4.2: Good Manufacturing third country inspections carried out over a 6-year period (2014-2019), (N=67)

Pharmacies, Pharmacovigilance and Surveillance of the Local Market

During 2019 the Malta Medicines Authority continued to inspect pharmacies on a two (2) year cycle, reaching eighty (80) routine pharmacy inspections by the end of the year, while ensuring the smooth introduction of the K2 online software for self-auditing purposes. Nine (9) pharmacy relocation inspections and three (3) spot-check pharmacy inspections were carried out, and thirty-two (32) administrative variations for pharmacy licences were processed. Two (2) pharmacovigilance inspections were performed in 2019 for local manufacturers.

Moreover, in 2019 the Malta Medicines Authority pursued its collaboration with the UK's National Competent Authority so that the latter carried out testing in an Official Medicines Control Laboratory for medicinal products under surveillance of the Malta Medicines Authority. In this regard, the Local Market Surveillance Plan for 2019 was closed positively.

During 2019 the Malta Medicines Authority worked on seven (7) enforcement cases/investigations related to complaints and enforcement which were coordinated by the Enforcement Committee (a specific committee which discusses enforcement cases, chaired by the Licensing Authority).

In 2019, the Malta Medicines Authority attended five (5) court case sittings concerning pharmacy licenses, and GMP and GDP enforcement cases in which the authority's employees were summoned as witnesses.

Granting of Qualified Persons Status and Certification of Pharmaceutical Products

In 2019, the Medicines Authority received twenty-six (26) new applications for the Qualified Person (QP) eligibility status. Fourteen (14) applicants were interviewed during 2019, thirteen (13) of whom were granted a QP status. The Authority also processed one hundred and twenty-six (126) applications seeking a Certificate of Pharmaceutical Product, out of which one hundred twenty-four (124) satisfied the required criteria and were certified.

Promoting Scientific Excellence and Innovation in Regulation

The Malta Medicines Authority steers identified scientific areas into centres of excellence and manages advanced initiatives in line with the strategy. The Authority leads the development of best practice in the regulation of cannabis for medicinal and research purposes through guidance, review, technical evaluation and stakeholder engagement, among other areas. Continuous collaboration is sustained with the Superintendence of Public Health, Malta Enterprise, the University of Malta, as well as European and international counterparts.

In 2019, the Malta Medicines Authority successfully implemented the assigned budgetary measure related to cannabis for medicinal and research purposes. Continuous interaction and high-level meetings were sustained with over one hundred and fifty (150) Maltese and international stakeholders, consultancy firms, legal advisors, and company representatives intending to invest in the medicinal cannabis industry. The exchange of knowledge and experiences through delegation visits across the United States (US), European Union (EU), and the Middle East, including regulatory bodies, certified analytical laboratories for quality assurance compliance, and major universities performing cutting-edge research, has facilitated considerations for the local infrastructure pursuant to medicinal cannabis, particularly for the evaluation of the technical and scientific components, as well as the research & development aspect.

Strengthening expertise in this innovative area is pivotal for the progress of research excellence towards the production of standardised cannabis-based products that undergo clinical trials, regulatory assessment and approval. The Malta Medicines Authority participated in global conferences during the past year, presenting regulatory sciences aspects, as applicable to cannabis for medicinal and research purposes, to different fora, including the Marijuana Business Daily European Cannabis Symposium (Copenhagen, May 2019), the International Pharmaceutical Federation (FIP) World Congress of Pharmacy and Pharmaceutical Sciences (Abu Dhabi, September 2019), the Global Cannabis Institute Europe (London, November 2019) and the Medical Cannabis World Forum (Malta, November 2019).

Cannabis for Medicinal and Research Purposes

Legislative amendments in Chapter 537 of the Laws of Malta – Drug Dependence (Treatment not Imprisonment) Act – enable licensed medical practitioners to prescribe, not only cannabis-based products which hold a Marketing Authorisation (MA), but also other products which are manufactured under EU Good Manufacturing Practice (GMP). The Malta Medicines Authority implemented a process to review applications for the importation or wholesale distribution of such products. By December 2019, eighteen (18) applications were submitted to the Malta Medicines Authority and four (4) products received a notification of approval, becoming accessible to patients from local pharmacies.

The enactment of Chapter 578 of the Laws of Malta and its subsidiary legislation, as legislative measure that enables the production of cannabis for medicinal and research purposes, was followed by the publication of the Malta Medicines Authority General Guidelines on the production of cannabis for medicinal and research purposes. In December 2019, the second version of the guidelines were issued, expanding on security and analytical parameters. Five (5) applications for the production of cannabis for medicinal and research purposes were submitted to the Malta Medicines Authority in 2019. Through liaison with national, European and International bodies, the Malta Medicines Authority upholds consultations on scientific matters related to medicinal cannabis, processes applications, co-ordinates inspections and audits, as well as research and education initiatives.

Research, Scientific Affairs and Innovation

The Malta Medicines Authority encourages research, thought, analysis, knowledge dissemination, innovation and horizon scanning in collaboration with other entities, such as working groups of the EU Heads of Medicines Agencies, the Network Training Centre (EU-NTC) and the Innovation Network (EU-IN). The Malta Medicines Authority is an active partner in the consortium of a Horizon 2020 Coordination and Support Action, as co-lead in a work package (work package 2) of the Strengthening Training of Academia in Regulatory Science (STARS) project. This project aims to improve the direct regulatory impact of the results obtained in medical research and to develop a Comprehensive Inventory of existing support activities in Europe, based on a detailed analysis of the currently established programmes. This analysis will be the basis for the development of a core curriculum focused on Regulatory Sciences.

As co-lead for work package 2, the Malta Medicines Authority aims to establish and disseminate a comprehensive inventory of existing support activities for regulatory scientific advice and protocol assistance in Europe. The Comprehensive Inventory will be based on data derived from surveys targeting academic clinical centres, academic researcher groups and funding organisations active on national and European level. During 2019, the Authority was involved in drafting and implementing a set of online surveys, formulating data analysis plans and manning a telephone helpdesk where respondents called for assistance in filling in the respective surveys. The project will continue throughout 2020.

In 2019, the Malta Medicines Authority prioritised medicinal cannabis in its agenda for delivering a framework that enhances competence of personnel and stakeholders, establishing international cooperation and imparting the scientific acumen of the Malta Medicines Authority. Through collaboration with the Organisation for Professionals in Regulatory Affairs (TOPRA), a programme was organised in May 2019 – Regulatory Sciences as Applicable to Cannabis for Medicinal and Research Purposes – providing a practical overview on EU regulation of medicines and herbals, good practices, quality standards and guidance documents to local and international stakeholders, company representatives and consultancy firms. Over sixty (60) participants from Malta, Spain, UK, Slovenia, Switzerland, Israel, Canada, US, and Colombia, among others, and from the regulatory body itself, benefited from this programme. In October 2019 an educational meeting – Implications of Medicinal Cannabis: the role of Cannabidiol in the treatment of Neuropsychiatric Disorders - was organised to engage with pharmacists and medical practitioners in light of the dynamic regulatory, pharmaceutical and clinical context, related to cannabis for medicinal use.

Educational Planning and Academic Development

Established in 2019, the Academy for Patient Centred Excellence and Innovation in Regulatory Sciences, merges research, training and education into the regulatory environment, strengthening the commitment of the Malta Medicines Authority towards sustainable development and innovation. The Academy serves as a key platform within the Authority's portfolio, through which educational planning and academic development unfold.

Research, together with innovation and education, are identified as the real-world drivers for the development of regulatory sciences. The Academy for Patient Centred Excellence and Innovation in Regulatory Sciences, in collaboration with the Department of Pharmacy at the University of Malta, organizes targeted events that aim to encourage prospective students to embark on a journey in pharmacy, pharmaceutical sciences and pharmaceutical technology. Research working groups organised regularly at the Malta Medicines Authority support the progress of studies being undertaken by professionals affiliated to the Authority, including individuals within the International Fellowship Programme.

Primary initiatives of the Academy include the organisation of interactive advanced level courses on varied aspects of regulatory sciences that meet the needs of stakeholders. In October 2019, the medical device leadership course, held in collaboration with TOPRA, brought together over seventy (70) local and international participants to exchange views and overcome challenges in the evolving field of medical devices. Aspects considered include conformity assessments and technological aspects, post-marketing surveillance, risk management plans and medical device regulations. The Academy collaborated with the Malta Laboratories Network and the National Accreditation Board on courses targeting Practical Uncertainty Analysis with respect to calculation of measurement, and ISO 17025, in relation to testing and calibration laboratories. Through wide-ranging collaborations, the Academy is providing a forum for national and international participants who share a vision for excellence in patient-centred endeavours.

Publications and Presentations

Publications

Abbas A, Vella Szijj J, Azzopardi LM, Serracino Inglott A. Orphan drug policies on different countries. Journal of Pharmaceutical Health Services Research. 2019;10(3):295-302.

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Mifsud EM, Wirth F, Camilleri L, Azzopardi LM, Serracino-Inglott A. Pharmacist-led medicine use review in community pharmacy for patients on warfarin. Int J Clin Pharm. 2019.

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24th European Association of Hospital Pharmacists Congress, Barcelona, Spain, March 2019:

Attard A, Wirth F, Serracino Inglott A. Focusing Audits on Patient Safety.

Attard J, Vella Szijj, Serracino-Inglott A. 5PSQ - 107 Aspirin and Novel Oral Anticoagulants: Reporting of Adverse Drug Reactions.

Cerdá Iñesta J, Wirth F, Mifsud Buhagiar L, Zahra G, Xuereb RG, Barbara C, Serracino Inglott A. Pharmacogenetic testing for personalisation of statin therapy.

Muscat C, Attard A, Azzopardi LM, Serracino Inglott A. The valsartan saga: Pharmacists competence to resolve the therapeutic challenge.

Xuereb AM, Wirth F, Mifsud-Buhagiar L, Serracino-Inglott A. Perception of Hospital Pharmacists towards Pharmacogenetic Testing.

European Association of Faculties of Pharmacy Annual Conference, Kraków, Poland, May 2019:

Attard A, Muscat C, Mifsud Buhagiar L, Azzopardi LM, Serracino-Inglott A. Moving Towards Regulatory Sciences Through Educational Initiatives.

Attard A, Wirth F, Azzopardi LM, Serracino Inglott A. Enhancing Patient Safety Through Interactive Education.

Attard Pizzuto M, Serracino-Inglott A, Azzopardi LM. Students' Perception of Risk in Pharmaceutical Processes.

Mifsud Buhagiar L, Serracino Inglott A, LaFerla G. Empowering pharmacy students to participate in the clinical implementation of pharmacogenetics.

Muscat C, Attard A, Mifsud Buhagiar L, Serracino-Inglott A. Pharmacists' Competence to Resolve the Therapeutic Challenge of the Valsartan Saga.

Said D, Borg JJ, Attard Pizzuto M, Serracino Inglott A. Opinions of decision-makers on the clinical development and assessment of antineoplastic agents.

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Vella Szijj J, Serracino-Inglott A, Azzopardi LM. Evaluation of the Use of Case Studies to Mobilise Knowledge about Toxicology.

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Professional Society for Health Economics and Outcomes Research (ISPOR) 2019 conference, New Orleans, USA, May 2019:

Said D, Borg JJ, Attard Pizzuto M, Serracino-Inglott A. Decision-maker Perspectives on Outcomes studied in Leukaemia Clinical Trials: The Response Evaluation in Leukaemia (REVALEU) Study Protocol.

19th Asian Conference on Clinical Pharmacy, Manila, Philippines, June 2019:

Aninon AD, Wirth F, Serracino-Inglott A, Azzopardi LM. Clinical Skills Practical Sessions for Undergraduate Pharmacy Students and as a Clinical Rotation for Doctorate in Pharmacy students.

79th International Pharmaceutical Federation World Congress of Pharmacy and Pharmaceutical Sciences, Abu Dhabi, United Arab Emirates, September 2019:

Al-Haddad D, Sammut Bartolo N, Serracino-Inglott A. Nurses' perception of Intravenous Medication Administration Errors in Paediatrics.

Attard A, Muscat C, Mifsud Buhagiar L, Azzopardi LM, Serracino Inglott A. Moving towards regulatory sciences through educational initiatives.

Azzopardi Y, Wirth F, Camilleri L, Serracino-Inglott A, Azzopardi LM. Pharmacogenomics Information in Official Drug Labelling.

Baldacchino S, Muscat C, Attard A, Serracino Inglott A, Azzopardi LM. The valsartan saga: Science, Myths and Realities.

Cerdá Iñesta J, Wirth F, Serracino-Inglott A. Pharmacovigilance Analysis of Statin-Associated Muscle Symptoms.

Galea L, Attard E, Serracino-Inglott A. Physicochemical Properties Of Products Obtained From The Local Carob Tree Varieties.

Langaro M, Attard A. Serracino Inglott A. An innovative regulatory framework in community pharmacy.

Mifsud Buhagiar L, Vella K, Axisa K, Serracino Inglott A. Regulatory sciences as applied to cannabis for medicinal use.

Muscat C, Attard A, Serracino Inglott A. Pharmacists competence to resolve the therapeutic challenge of the valsartan saga.

Muscat C, Attard A, Serracino Inglott A. Application of drug intelligence to enhance access to medicines.

Muscat C, Attard A, Serracino Inglott A. Medicines Intelligence and Access.

Rapa N, Attard E, Serracino-Inglott A. Extractability of Polyphenols from Local Herbs using Traditional Extemporaneous Preparations.

Said D, Borg JJ, Attard Pizzuto M, Serracino Inglott A. Outcomes studied in leukaemia clinical trials: A need for harmonisation?

Tanti S, Attard A, Said D, Serracino Inglott A. Promoting education, quality and accessibility of vaccinations in the Maltese islands.

Xiberras M, Attard E, Sammut Bartolo N, Serracino-Inglott A. A Simple Method for the Determination of Water Content in Tetrahydrofuran.

Xuereb AM, Mifsud-Buhagiar L, Wirth F, Serracino Inglott A. Awareness and attitudes of pharmacists and physicians towards pharmacogenetic testing.

Zuccarelli M, Borg JJ, Vella Szijj J, Serracino Inglott A. Emerging treatments for Leber Hereditary Optic Neuropathy and Retinitis Pigmentosa.

European Society for Medical Oncology congress, Barcelona, Spain, September 2019:

Said D, Borg JJ, Attard Pizzuto M, Serracino Inglott A. Efficacy endpoints studied in clinical trials for early-onset leukaemia.

48th European Society of Clinical Pharmacy Symposium, Ljubjana, Slovenia, October 2019:

Wirth F, Mifsud-Buhagiar L, Xuereb AM, Serracino Inglott A. Pharmacogenetics as a tool for clinical pharmacists to promote precision medicine in a digitalised environment. (Workshop)

Xuereb AM, Mifsud-Buhagiar L, Wirth F, Serracino Inglott A. An online approach to enhance awareness on pharmacogenetics among pharmacists and physicians.