MALTA
MEDICINES
AUTHORITY

# ANNUAL REPORT 2018

# CONTENTS

# FOREWORD BY THE PARLIAMENTARY SECRETARY

The Malta Medicines Authority has fostered scientific excellence in the field of the regulatory sciences through its mission to protect human health by safeguarding the quality, safety and efficacy of medicines for patients in the European framework. The success of the Malta Medicines Authority is attributed to the motivated professional employees that operate in a proactive environment to meet with advances in the regulatory sciences, stakeholder needs and local and European regulatory requirements.

The key to success is invariably linked to scientific research and professional educational development. The Malta Medicines Authority is pioneering the encouragement of its team to further their studies and research to Master and Doctorate levels. The Fellowship programme offered in collaboration with the University of Malta has reached international dimensions and professionals from several countries are enrolled. The expertise attained from these scientific endeavours provides a solid foundation that strengthens the knowledge-based approach adopted to respond to challenges and developments in the dynamic environment of the scientific regulatory sciences.

Patients are the core of the regulatory systems at the Malta Medicines Authority. Noteworthy initiatives are being implemented across all areas within the remit of the Medicines Authority to ensure that patients receive timely access to affordable, high-quality medicines that meet their medical needs. These include enhanced patient safety through increased awareness of reporting of adverse drug reactions, improved accessibility to medicines through added value interventions and regulation of new advanced scientific areas.

The legalisation of medicinal cannabis and the launch of GMP-certified medicinal cannabis products on the local market was a key milestone of 2018. The outstanding scientific and robust work carried out by the Malta Medicines Authority in the application of regulatory sciences to cannabis for medicinal use sets the tone for advanced and innovative tasks to be assumed by the Authority. These include regulation of medical devices, stem cell therapy and clinical trials.

The collective effort, cooperation and coordination of best practices between all professional employees and stakeholders has positioned the Malta Medicines Authority as a forward-looking best in class regulator. The journey of excellence of the Malta Medicines Authority shall continue to evolve in the rapidly changing international, scientific and technological fora.

Dr Deo Debattista
Parliamentary Secretary for Consumer Rights, Public Cleansing and Support for the Capital City



# MESSAGE BY THE CHAIRPERSON

The Malta Medicines Authority is recognised internationally for its reliable, high quality patient-centred work in the regulation of medicines. The accomplishments achieved in 2018 include all aspects of medicines assessments, GMP inspections, pharmacovigilance and advanced scientific initiatives. The regulation of cannabis for medicinal and research purposes established this year through the introduction of the appropriate legislation positioned Malta as a leader in the dynamic regulatory sciences.

Research, training and education are key factors of the continued growth, progress and success of the Malta Medicines Authority. The Authority works in collaboration with the Superintendence of Public Health, the Malta Enterprise, the University of Malta and European National Competent Authorities. The scientific development of professionals is supported by the Medicines Evaluation Board (MEB) in the Netherlands, the Italian Medicines Agency (AIFA), the Health Products Regulatory Agency (HPRA) in Ireland and Infarmed, the regulatory agency in Portugal. The professionals at the Malta Medicines Authority engage in network-led partnerships with academia to undertake ground-breaking research in strategic areas of the regulatory sciences. To this end, the Medicines Authority is a proactive member of the STARS (Strengthening Training of Academia in Regulatory Science) EU initiative. On this line, the coordinator of the STARS consortium and Vice president of the BfArM, the regulatory agency in Germany, Professor Julia Stingl stated, 'The comprehensive and sustainable implementation of regulatory science and support in Europe has a great potential to significantly increase the benefits for patients arising from academic driven research.'

The Malta Medicines Authority is looking forward to development in the academia in respect to the regulatory science in postgraduate courses namely the Master of Science and the Doctorate in Pharmacy programmes. The Authority is examining the possibility of launching within its structure a regulatory science academia which will be responsible for the training of professionals and also for establishing Malta as a centre for educational development, research and innovation.

During 2018, the strategy of the Medicines Authority was to consolidate its functions as an independent, scientific, patient-centred regulator. The sustainable success of the Medicines Authority can be attributed to the continuous communication and cooperation with all stakeholders with the common aim of keeping the best interests of the patient at the centre of all its activities while enhancing the support given to all personnel to reach their aspirations by giving consideration to the need of family-friendly measures in a spirit of equality.

Professor Anthony Serracino Inglott
Chairperson of the Malta Medicines Authority

# 1 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 interests of patients. It is committed to providing high quality licensing, pharmacovigilance, inspection 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 four 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, and the Research, Scientific Affairs and Innovation Unit.

**THE MALTA MEDICINES AUTHORITY:**

i) Performs functions delegated to it by the Licensing Authority in accordance with the Medicines Act;

ii) Assists and advises the Licensing Authority on any matter relating to the regulation of medicinal products and related activities;

iii) Ensures, in line with current medical and scientific knowledge, that medicinal products marketed and supplied in Malta and the European Union are of good quality and have a favourable risk to benefit profile through independent, science-based assessments, post-authorisation activities and participation in decision-making at the European level;

iv) Scientifically evaluates requests and monitors clinical trials carried out in Malta;

v) Provides high quality monitoring and inspection services for pharmaceutical activities;

vi) Monitors the safety of medicinal products;

vii) Monitors and enforces the relevant legislation through investigation of potential breaches of regulations;

viii) Enhances the effective, safe and rational use of medicinal products through the provision of objective and unbiased information which helps prescribers, healthcare professionals and patients make informed decisions on the choice and use of medicines;

ix) Supports the availability of medicinal products on the local market;

x) Supports competitiveness in the local market through scientific and regulatory advice and the implementation of principles of smart regulation, that is delivering results in the least burdensome way;

xi) Develops tools and standards to assess and ensure the quality, safety and efficacy of medicinal products and pharmaceutical activities;

xii) Enhances the standard of medicinal products and pharmaceutical activities for medicines for human use in Malta through the sustained capacity building of our workforce;

xiii) Actively participates in the major European fora, namely the European Medicines Agency, the Council of the European Union, and the European Commission through the sharing of scientific and regulatory positions in various policy areas;

xiv) Collaborates with stakeholders including government entities, manufacturing industries, healthcare professionals, and research communities, to maximise patients' access to medicinal products;

xv) Acts as a Reference Member State or Concerned Member State and rapporteur for European procedures; authorisation and approval functions;

xvi) Promotes continuous learning, research and innovation.

The Malta Medicines Authority will pursue its efforts 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 above in a patient-centred approach.



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



# STRATEGIC GOALS AND OBJECTIVES

**1. Optimised Regulatory Systems**

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

**2. Better informed users**

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

**3. Access to medicinal products**

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

**4. Supporting innovation**

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

**5. Organisational development**

- 5.1. To ensure that optimal workplace and organisational structure is in place
- 5.2. To appropriately manage finances and human resource
- 5.3. To enhance quality management systems
- 5.4. To further develop 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.

In 2018, ten (10) policies, thirty-five (35) standard operating procedures, and four (4) 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.

The Malta Medicines Authority implemented seven (7) internal audits throughout 2018, in line with the five-year audit strategy. These resulted in a total of fifty-five (55) 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 sixty-seven (67) quality improvements were identified through other internal initiatives by the respective Directorates, which jointly oversee the implementation of all quality improvements.

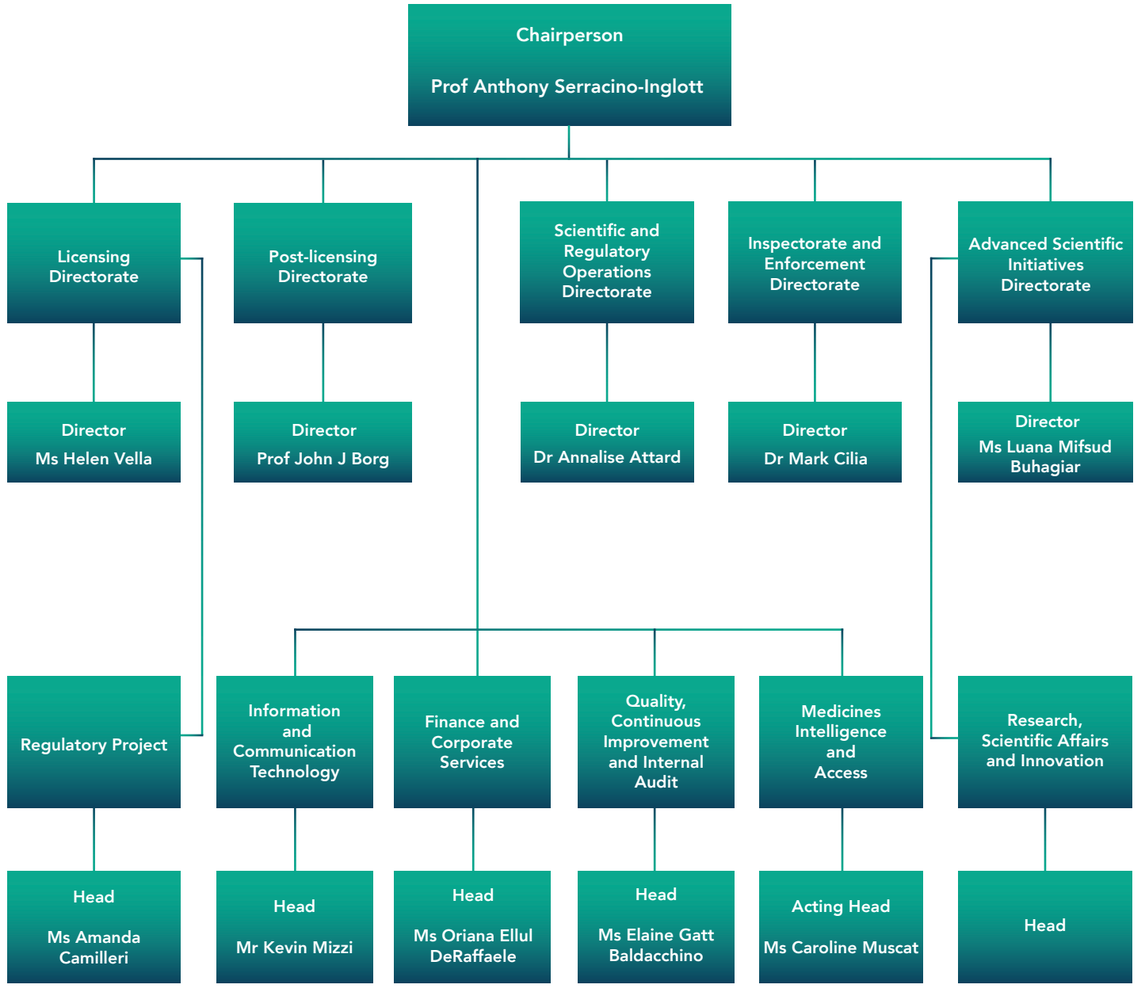
The annual management review examined the operations of each Directorate and the respective Units within the Malta Medicines Authority, evaluated the results of stakeholder (internal and external) feedback, analysed the results of previous audits (internal and external) and studied the outcome of the 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, three (3) simplification measures were identified and successfully implemented in 2018. The first measure pursued sustained collaboration with the Irish National Competent Authority towards establishing an electronic licensing management system for inspectorate and enforcement activities. This measure will be fully implemented by the end of 2019. The second measure targeted the alignment of the discrepancies between the penalties established in the Medicines Act and those foreseen by the Special Procedure Regulations. To this end, the Malta Medicines Authority submitted proposed amendments to the legal text following consultation with stakeholders. The final measure concerned the introduction of an electronic payment system which facilitated payment processes in an efficient and transparent manner.

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 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.



# ORGANOGRAM



# 2 A POSITIVE WORKING ENVIRONMENT, A PATIENT-CENTRED ETHOS, AND A PRO-ACTIVE APPROACH

Throughout 2018, 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 two new Directorates which further enhanced the scientific image and reputation of the Authority, namely the Advanced Scientific Initiatives Directorate and the Scientific and Regulatory Operations Directorate.

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 valsartan saga to the introduction of cannabis for medicinal purposes.

Brexit preparedness was another challenge which the Authority successfully endured throughout 2018 and this 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 2018, the Malta Medicines Authority employed seventy-one (71) officers (Figure 2.1). This represents an increase of 115% from the year 2013 (Figure 2.2) which effectively caters for the increased regulatory activities.

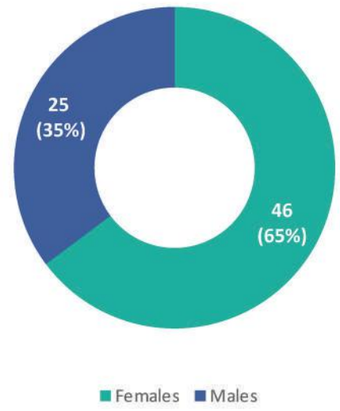



*Figure 2.1: Total number of employees at the Malta Medicines Authority at the end of 2018*

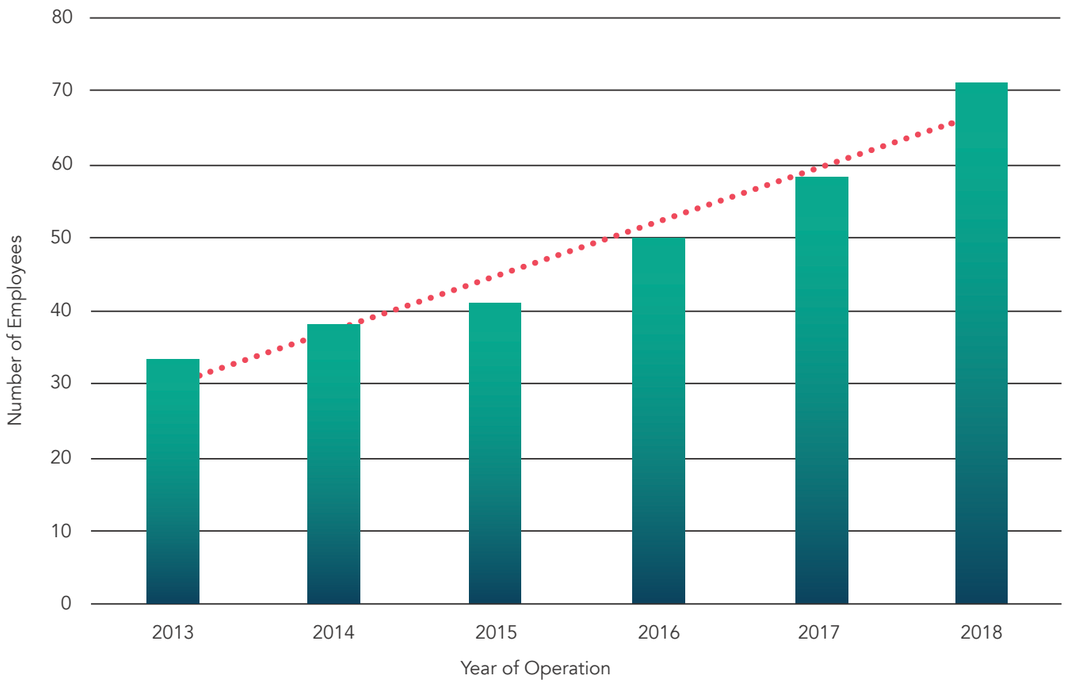



*Figure 2.2: Number of employees at the Malta Medicines Authority 2013-2018*

## 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 2018, its employees successfully completed fifty-nine (59) certified training initiatives which were offered internally (26), externally (24), and internationally (9). These comprised a wide range of subjects inter alia sterile manufacturing, radiopharmaceuticals, stem cells research and innovative products.

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 2018, whereby three (3) employees attained the Doctorate in Pharmacy degree, twelve (12) employees obtained a Master degree, and four (4) employees graduated with a Diploma.



Furthermore, in 2018 the Malta Medicines Authority introduced a new International Academic Conference Scheme which employees may tap into for financial support to attend such 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, Master, or Diploma or a comparable and equivalent qualification in line with the Malta Qualifications Framework in Pharmacy, Leadership, Management, Administration, and Finance.

In 2018 alone, fifteen (15) students from across the globe registered for the Malta Medicines Authority's Fellowship Programme (Figure 2.3). 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.

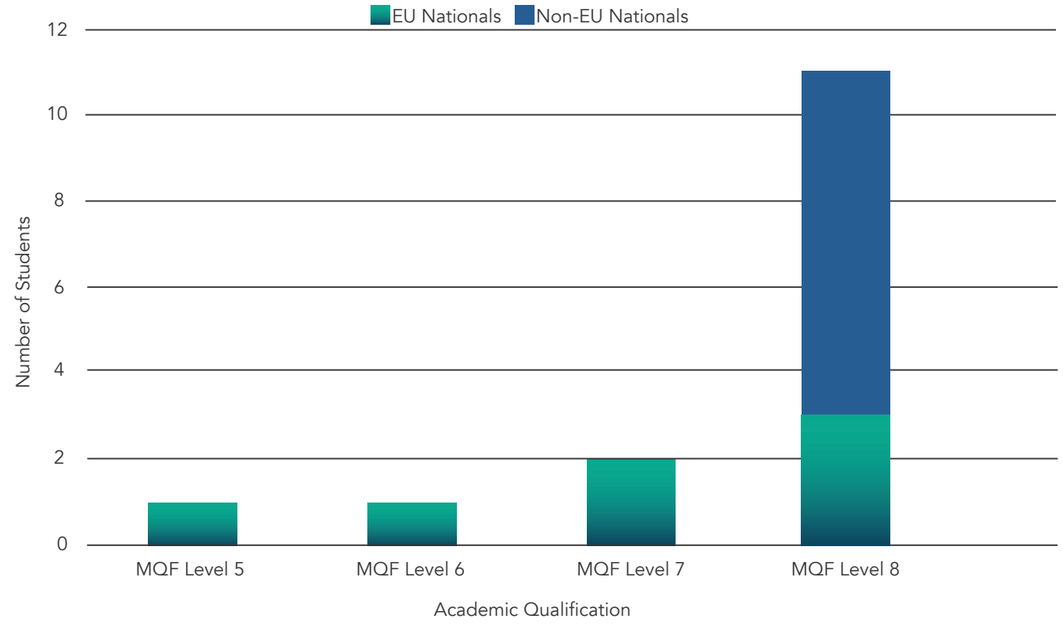



*Figure 2.3: Number of students following the International Fellowship Programme in 2018*

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, thirteen per cent (13%) of employees hold Doctoral degrees, whilst over half (54%) of the Authority's workforce hold an academic qualification at a Master's level (Figure 2.4).

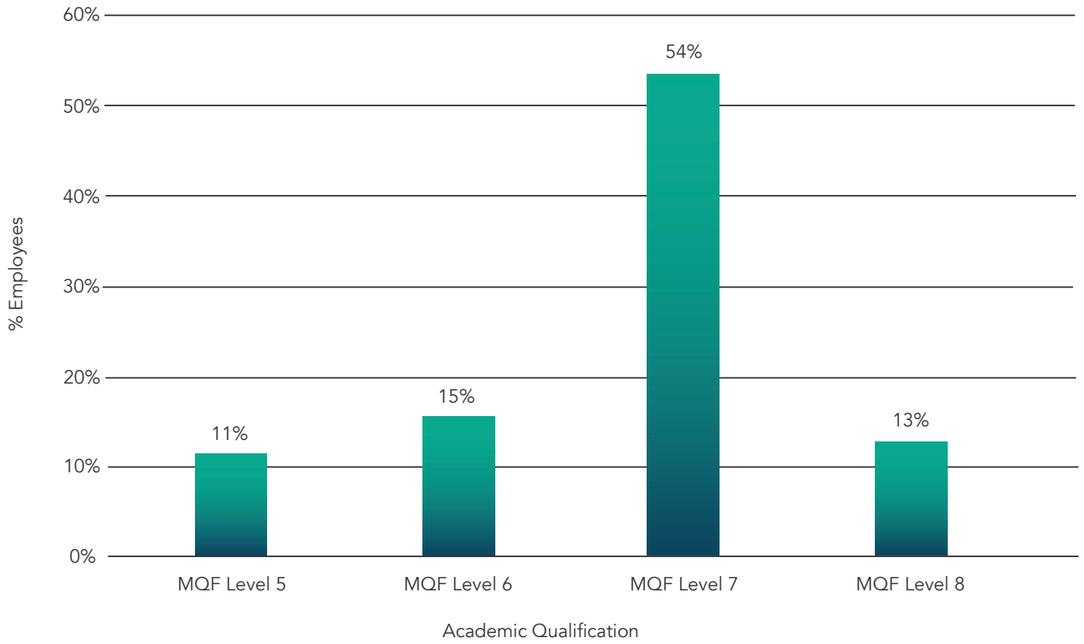



*Figure 2.4: Academic qualifications for employees at the Malta Medicines Authority in 2018*

The continued investment in education and professional development is further reflected in the upward trend for employees of the Malta Medicines Authority holding postgraduate degrees (Figure 2.5).

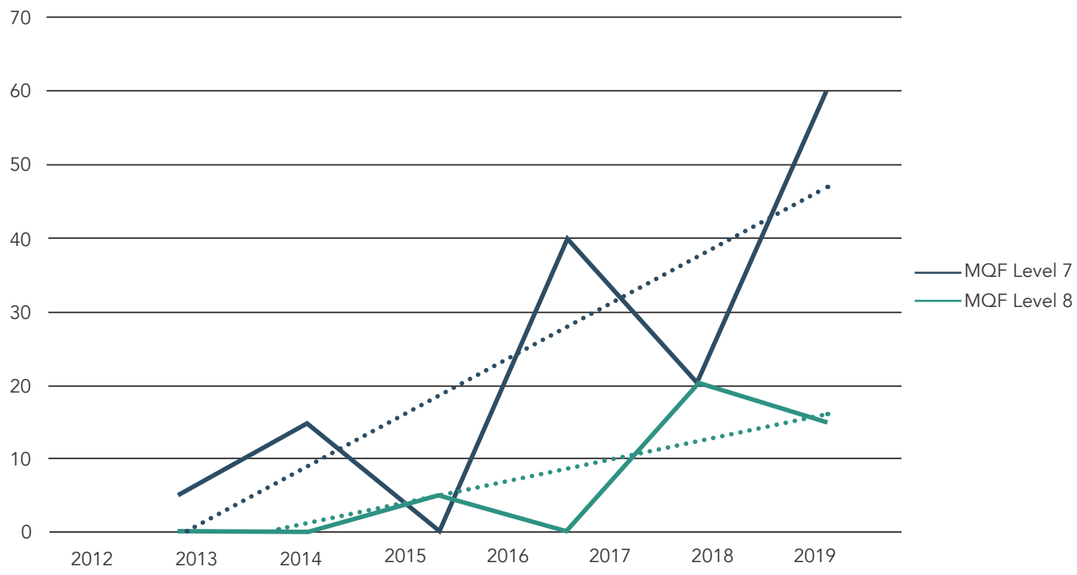



*Figure 2.5: Number of employees attaining postgraduate degrees 2013 - 2018*



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 overseen a significant expansion of 93% over the past four years for the budgetary allocation to international training activities, conferences and meetings, from €49,214.34 in 2015 to €94,929.64 in 2018 (Figure 2.6).

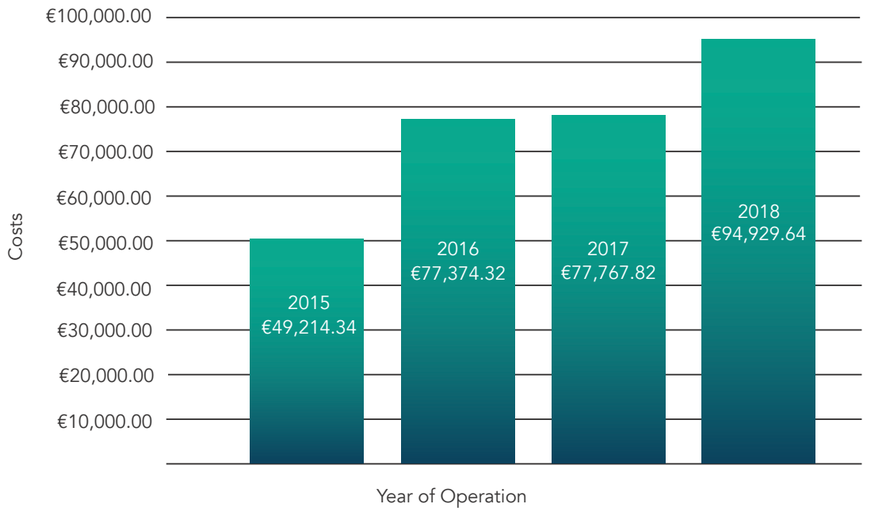



*Figure 2.6: Total travel expenses borne by the Malta Medicines Authority 2015-2018*

Furthermore, the Malta Medicines Authority maintains strong ties with the University of Malta by hosting student placements. In 2018, the Authority also welcomed students on summer placements from the Malta Enterprise. Both 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 2018, the Malta Medicines Authority maintained its active role at the highest European and International Fora, with officers participating in one hundred and seventy-two (172) meetings or training sessions.

The United Kingdom's impending 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 convened a Brexit task force which aims to mitigate the impact of Brexit on the Authority's operations and the Maltese public at large. A contingency plan was devised, with the measures contained therein outlined in subsequent sections of this Annual Report. Moreover, 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 2018, the Malta Medicines Authority was also represented in five (5) 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.

Beyond the EU, the Malta Medicines Authority strengthened its cooperation with third countries by tapping into Joint Commission Agreements between Malta and three (3) African states, namely the Republic of Ghana, the Republic of Algeria and Libya. These agreements foresee the development of industrial cooperation between pharmaceutical companies of participating countries and the eventual exchange of experience and knowledge. The Authority has also pledged its support to the pharmaceutical sector in these African states by providing training to obtain EU Good Manufacturing Practices certification. The agreements are also intended to promote collaboration on capacity building with regards to pharmaceutical products registration, pharmaceutical quality control and pharmacovigilance.

# 3 QUALITY, SAFETY, EFFICACY: THE 3 PILLARS OF AN EFFECTIVE SCIENTIFIC REGULATOR



## ASSESSMENT AND LICENSING

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

The Malta Medicines Authority is also an important player in the European network for the regulation of medicinal products and provides greater accessibility of medical products for patients in Malta and beyond. This through its role as a Reference Member State (RMS) or a Rapporteur in European Registration Procedures.

The number of authorisation procedures led by Malta in 2018 was thirty-eight (38), representing an increase of twelve (12) procedures from the year 2017 (Figure 3.1).


*Figure 3.1: Number of procedures received with Malta as RMS or rapporteur in the period 2009-2018*

*MRP: Mutual Recognition Procedure, DCP: Decentralised Procedure, CAP: Centrally Authorised Products*

In 2018, Malta was part of a multinational assessment team on one of the centrally authorised products (CAPs). This set the tone for more involvement in such teams 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.

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 2019. In 2018 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 Marketing Authorisation (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.

The newly recruited Safety, Quality and Pharmacokinetic Assessors were trained during 2018 to enable the Malta Medicines Authority to participate more actively in the European network. Quality Assessors were trained by experienced trainers from this Agency, whereby one MEB Quality Assessor spent three (3) months in Malta providing high quality training to enable staff to attain the necessary competence to carry out quality assessment.

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.

## APPLICATIONS FOR NEW AUTHORISATIONS

The number of applications for authorisations for the approval of new products received and finalised in 2018 are shown in Figures 3.2 and 3.3. These submissions include national MAs, as a result of National and European procedures, namely Mutual Recognition Procedure (MRP) and Decentralised Procedure (DCP), authorisations in accordance with article 126(a) of Directive 2001/83 /EC, and parallel import licences. A total of five hundred and seventy-two (572) authorisations and licences for new products were issued in 2018.



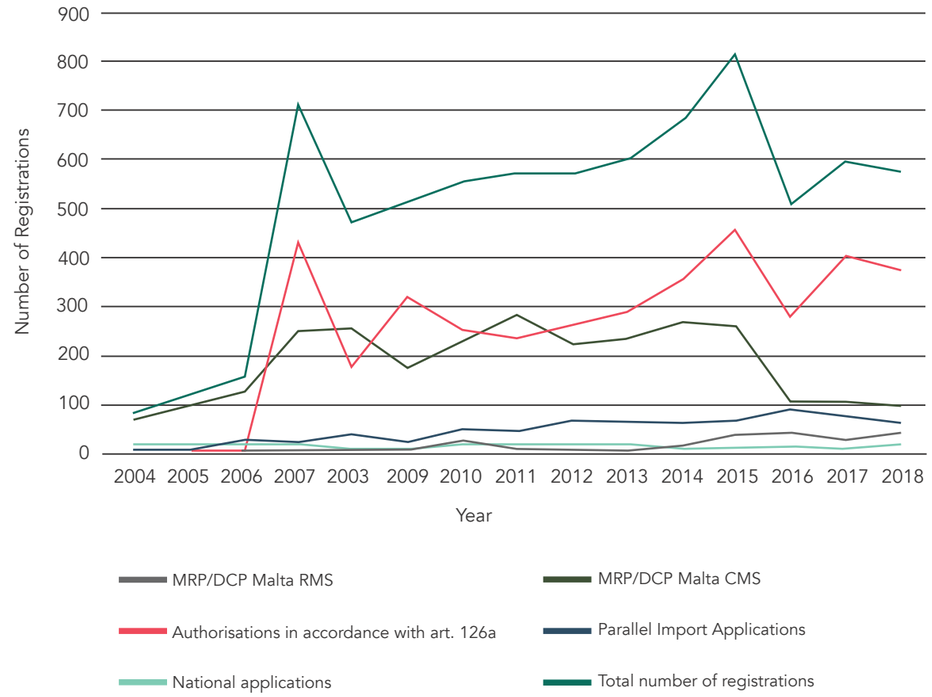



*Figure 3.2: Total number of new registrations of medicinal products through all routes throughout the years*

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

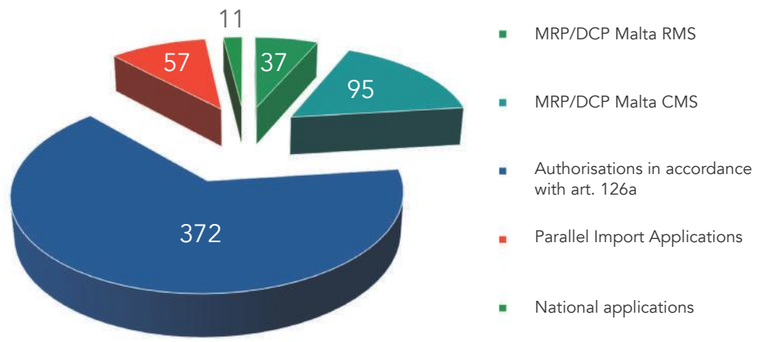



*Figure 3.3: Authorised products at end 2018 by route of authorisation*

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

## 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 post-2014, which is expected to subsist in the coming years (Figure 3.4).

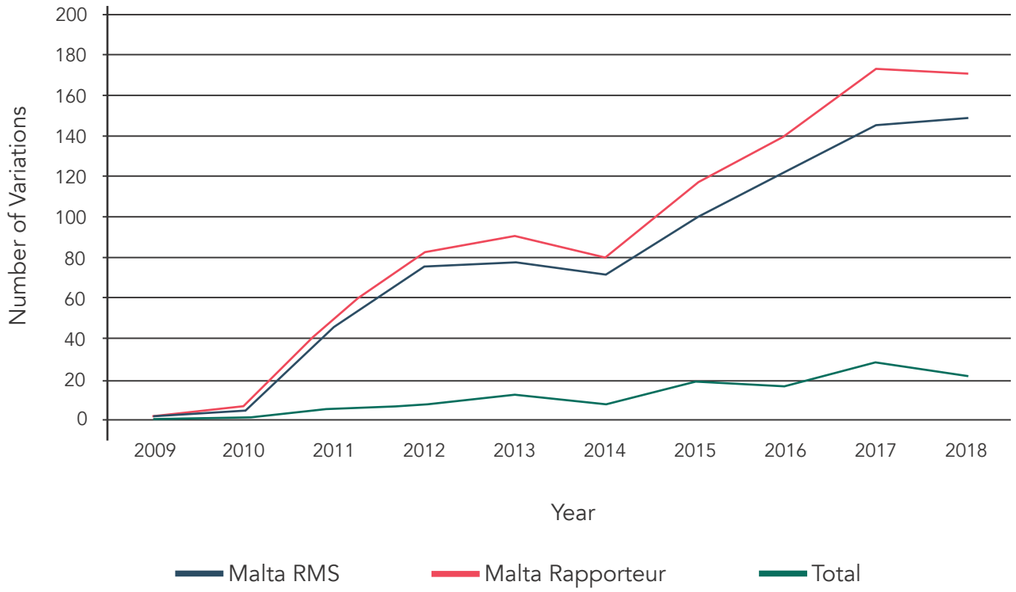



*Figure 3.4: Number of variations received for European procedures with Malta as Reference Member State or rapporteur in the period 2009 – 2018*

*RMS: Reference Member State*

Figures 3.5 and 3.6 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.



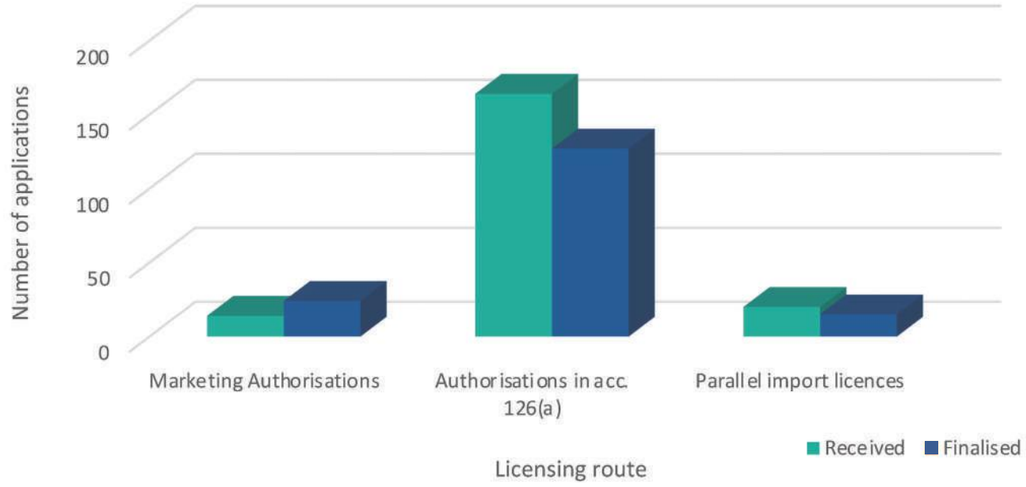
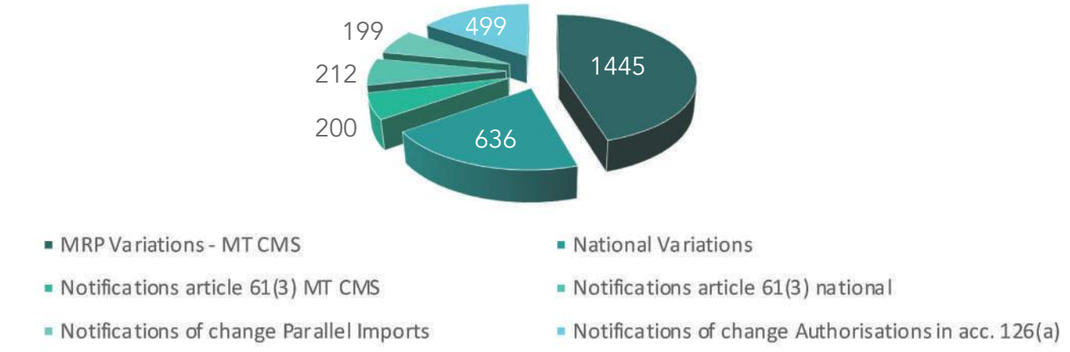



*Figure 3.5: Number of applications for renewals of authorisations/licences received and finalised in 2018*




*Figures 3.6: Number of post-authorisation procedures received in 2018*

*MT: Malta, MRP: Mutual Recognition Procedure, CMS: Concerned Member State*

Figure 3.7 refers to withdrawal applications for authorisations and licences. Following the UK's decision to leave the European Union (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.

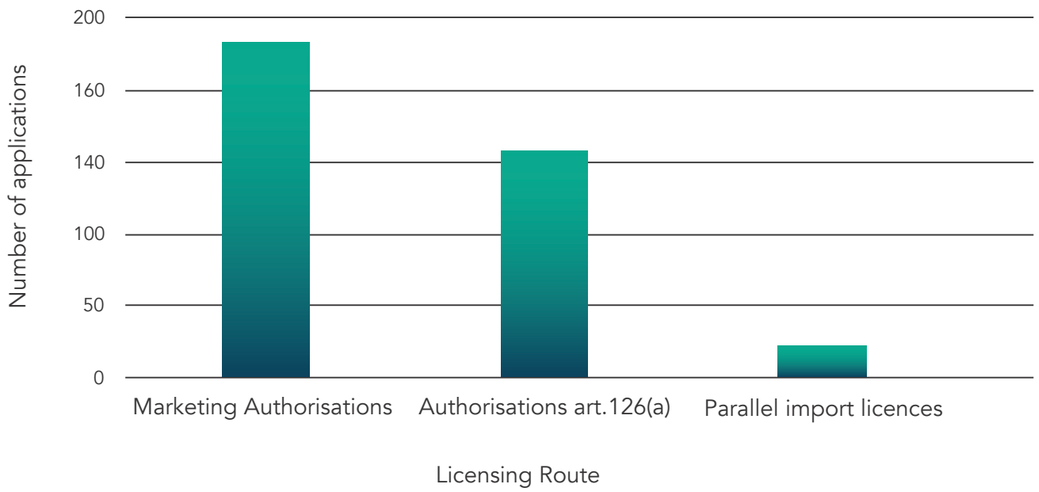



*Figure 3.7: Number of withdrawal applications for marketing authorisations and licences received in 2018*

## COMMITTEES, WORKING GROUPS AND NATIONAL ADVISORY SERVICES

During 2018, 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 to non-prescription status.

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 2018, ten (10) applications for classification of borderline products were received, out of which ninety per cent (90%) were considered as non-medicinal and ten per cent (10%), were considered medicinal.

At the national front, the Malta Medicines Authority is continuously seeking to expand its remit as a reputable scientific advisory centre. In 2018, four (4) requests for national scientific advice were received and processed.



## BREXIT PREPAREDNESS

In line with the national Brexit contingency plan, the Malta Medicines Authority has coordinated efforts, highlighted risks and proposed mitigation measures to counter the impact of a disorderly Brexit. In parallel, the Authority identified the necessary regulatory steps that will be triggered following the withdrawal date.

To this end, a Brexit Task Force was set up in the first quarter of 2018 which held thirty-two (32) one-to-one meetings with stakeholders and representatives of local and foreign companies seeking regulatory advice for their products.

Furthermore:

- The Malta Medicines Authority has worked with the National Competent Authorities of the United Kingdom and Ireland, to encourage companies to include Malta as CMS or RMS in Decentralised and Mutual Recognition (MR) procedures;

- Companies have been encouraged to use the day 0 MR procedures to be granted MAs in Malta. Malta, together with other small EU countries, has discussed this with other Member States to encourage uptake of this procedure for the smaller Member States. Malta has also worked with other Member States for the reduction of RMS fees for these procedures;

- Malta will maintain joint labels and packaging with the UK until the latter continues to abide by European legislation. This has been discussed with the Irish National Competent Authority so that joint action can be taken on this issue;

- Registration fees for CMS procedures carried out by the Malta Medicines Authority were revised to attract more applicants from within the pharmaceutical industry (the fee is €250);

- Fees for variations/notifications for CMS procedures carried out by the Malta Medicines Authority were eliminated;

- Malta has no additional national regulatory requirements;

- Malta continues to implement the procedure for registration of products based on Article 126(a) of Directive 2001/83/EC to increase the number of authorised products and to fill therapeutic gaps for both the private market and the national health care service;

- Reduced fees have been introduced with the aim of encouraging companies to register alternatives to products currently being sourced from the United Kingdom;

- The Malta Medicines Authority's access unit works with patients and the national health service to address issue concerning access to medicinal products.

In the event of a no deal Brexit, regulatory actions required for MAs (granted through national, DC and MR procedures) before 29 March 2019 include:

- UK MAHs seeking to market their products in the EU must relocate to another Member State;
- Batch release and testing must be carried out in a EU Member State;
- UK Qualified Persons for pharmacovigilance must relocate to a EU Member State;
- The UK Pharmacovigilance System Master File must relocate to a EU Member State.

In 2018, 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 above-mentioned regulatory requirements, thereby maintaining as many MAs as possible. As shown in Figure 3.8, the number of MAH transfers has increased considerably towards the end of 2018 as more companies prepare to relocate from the UK. This trend is expected to continue in the first quarter of 2019. 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.

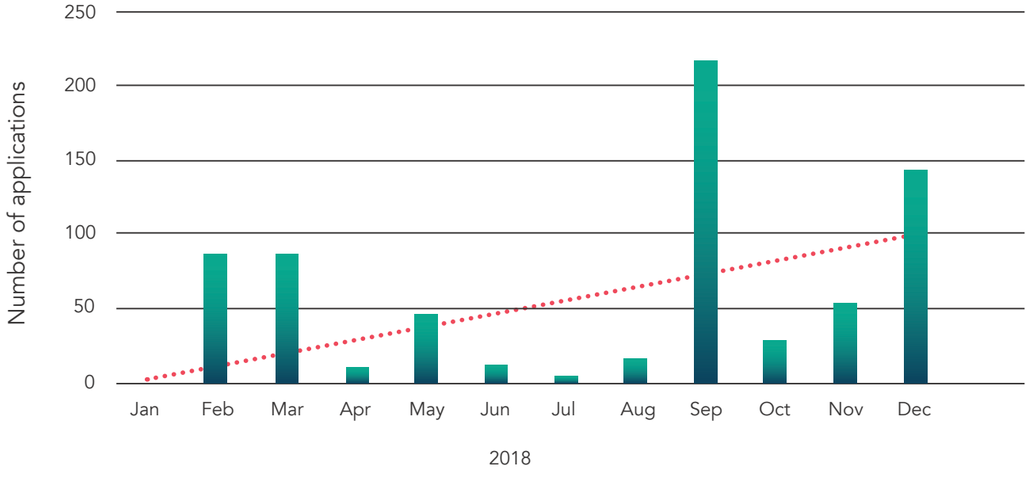



*Figure 3.8: Number of applications for the transfer of Marketing Authorisation Holder in 2018*



## IMPACT OF BREXIT ON THE MALTA MEDICINES AUTHORITY

The Malta Medicines Authority has taken up the role of a EU rapporteur for four (4) products and co-rapporteur for another four (4) products authorised through the centralised procedures for which the UK was previously the lead Member State. This means that all post-authorisation procedures for these products requiring assessment will be handled by the Malta Medicines Authority. The Malta Medicines Authority has also enhanced its capacity by increasing internal and external expertise to handle new pharmaceutical forms and therapeutic areas.

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.

In 2018 Malta became a RMS automatically on sixty-three (63) procedures on which it was the only CMS, pending the official switch that must be triggered by the Marketing Authorization Holders. This resulted from a pro-active outreach towards affected companies so that they initiate the said process. By the end of 2018, twenty-one (21) procedures were officially switched from UK as RMS to Malta (Figure 3.9). This positive trend is expected to climax as we approach the 29th of March 2019.

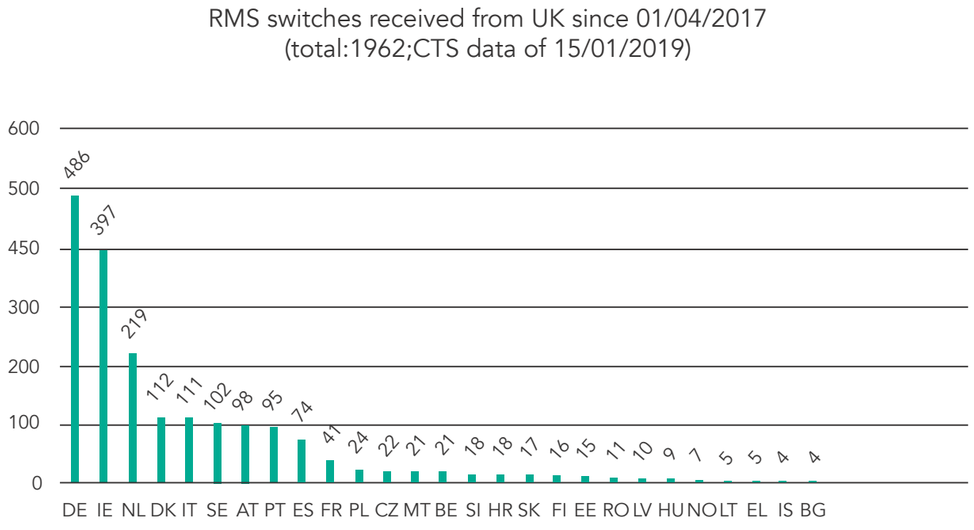



*Figure 3.9: RMS switches received from the United Kingdom since 01/04/2017 (reproduced from the Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) Brexit update November 2018*

*Available from:*
*https://www.ema.europa.eu/documents/presentation/presentation-cmdh-brexit-update-l-oliveira-h-hurts_en.pdf*

## 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.

The Malta Medicines Authority utilises several European information technology application systems and networks for the implementation of the above-mentioned functions. This was exemplified in the second half of 2018 when two (2) employees attended training and were certified by the European Medicines Agency on the latest version of the EudraVigilance System. The latter allows for the electronic reporting of individual case safety reports (ICSRs) in the ISO/ICH E2B(R3) format and has enhanced functionalities for analysing suspected adverse reactions. Besides the above, the certified employees are now enabled to conduct in-house training as the Authority continuously enhances its technical and scientific expertise.

In 2018, 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 an interactive conference for consumers and patients to promote the safe and rational use of medicines. The presentations, which were delivered by employees and external speakers, covered the importance of ADR reporting, generic medicinal products and patient rights.

The 3rd ADR awareness week campaign was held between 19-23 November 2018. During this week humorous animations (sample animations Figure 3.10), videos, infographics and other material were uploaded to the Authority's social media platforms.

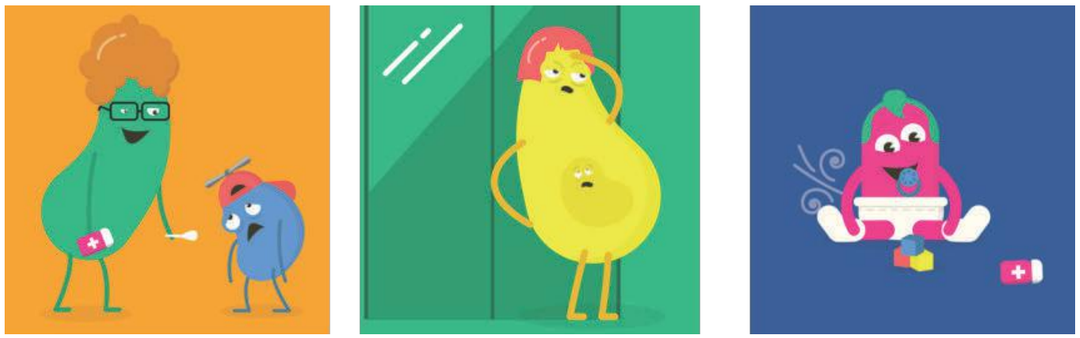


*Figure 3.10: Sample animations used for an EU-wide social media campaign during November 2018 on adverse drug reaction (ADR) reporting*

The Malta Medicines Authority also participated in the 10th Malta Medical School Conference in which the ADR reporting system was promoted through various artwork and visual means, as well as the distribution of the ADR reporting forms. Representatives of the Authority were also present to answer questions and receive feedback from medical doctors and pharmacists on the ADR reporting system.

Additional measures to reduce the administrative burden of parallel reporting for MAHs and the Malta Medicines Authority of ADRs transmission were implemented in 2018, 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 two hundred and twenty-three (223) ICSRs were registered in 2018. These cases detailed at least one ADR to the medicinal product concerned and resulted in four hundred and thirty-one (431) suspected ADRs. Figure 3.11 gives a breakdown of these ADRs according to system organ classification.

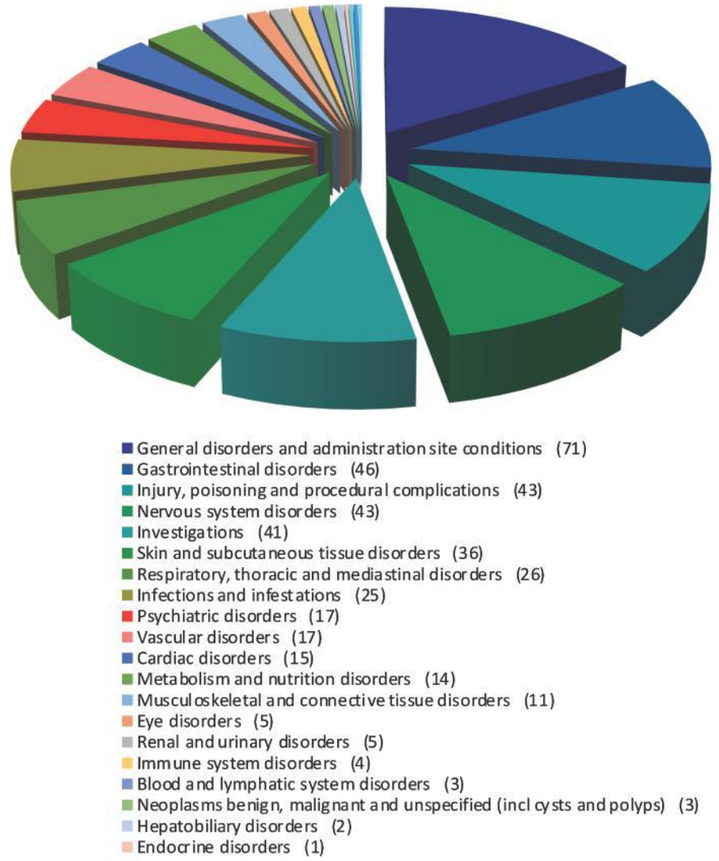



*Figure 3.11: Distribution of Adverse Drug Reactions according to System Organ Classification in 2018 (N=431)*

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 3.12 and 3.13 further classify the adverse ICSRs (as received over 2018) 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 3.12: Classification of seriousness of ICSRs in 2018 (N=223)*

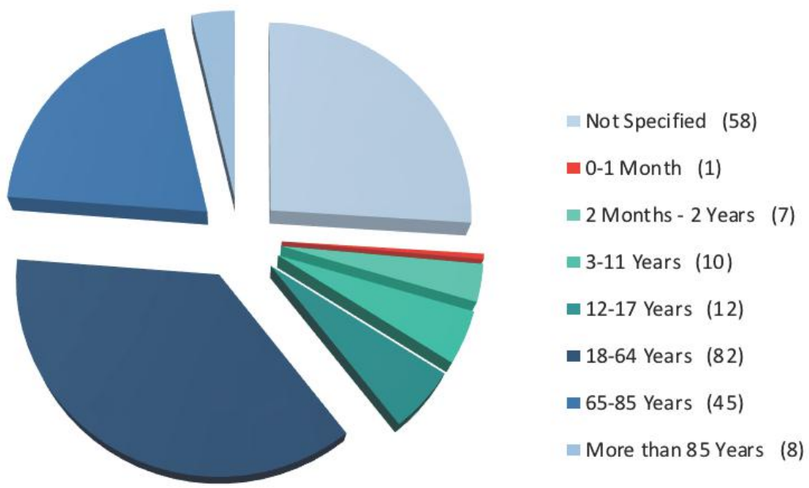



*Figure 3.13: Percentage distribution of ICSRs according to patient age in 2018 (N=223)*



Throughout 2018 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 reviews, communications and approvals which the Malta Medicines Authority handled over 2018.

| ACTIVITY | NUMBER OF ASSESSMENTS, REVIEWS, COMMUNICATIONS AND APPROVALS |
|---|---|
| Non-generic annual re-assessments under exceptional circumstances of the centralised procedure | 1 |
| Direct Healthcare Professional Communications | 14 |
| Joint DHPCs | 7 |
| Safety Circulars | 12 |
| Risk Minimisation Measures | 110 |
| Rapid Alert | 1 |
| Non-Urgent Information | 5 |

*Table 3.1: Pharmacovigilance and safety issue reviews and communications – 2018*

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 in 2018 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) (Table 3.2).

| | AREAS QUERIED | NUMBERS |
|---|---|---|
| 1 | National Pharmacovigilance legislation and requirements locally | 14 |
| 2 | Adverse Drug Reaction (ADR)/ Medication errors reporting requirements | 9 |
| 3 | Submission of Periodic Safety Updated Reports (PSURs)/ Periodic Safety Update Report Single Assessments (PSUSAs) | 6 |
| 4 | Pharmacovigilance requirements during Clinical Trials | 4 |
| 5 | Direct Healthcare Professional Communication (DHPC) dissemination | 4 |
| 6 | Pharmacovigilance System Master File (PSMF) | 4 |
| 7 | E2B(R3) format of ICSRs transmission | 3 |
| 8 | Literature Monitoring requirements | 3 |
| 9 | QPPV/ Local Contact Person for pharmacovigilance | 3 |
| 10 | Risk Minimisation Measures (RMMs)/Educational Material | 2 |
| 11 | Serious Unexpected Serious Adverse Reaction (SUSARs) | 2 |
| 12 | Individual Case Safety Reports (ICSRs) | 1 |
| 13 | Development Safety Update Reports (DSURs) | 1 |
| 14 | Safety Information published on Malta Medicines Authority website | 1 |
| 15 | Pharmacovigilance fees | 1 |
| 16 | Post Authorisation Safety Studies (PASS) | 1 |
| 17 | Extended EudraVigilance medicinal product dictionary (XEVMPD) | 1 |
| 18 | Pharmacovigilance requirements for Medical Devices | 1 |
| 19 | Pharmacovigilance requirements for Veterinary Medicinal Products | 1 |
| | **TOTAL** | **63** |

*Table 3.2: Pharmacovigilance related queries in 2018 (N=63)*

At an EU level, the Malta Medicines Authority continued to implement the centralised PSUSA, which in 2018 amounted to three (3) PSUSA procedures for idebenone (non-CAP), nitrous oxide and fluorodopa (18F).

## 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 2018, no advertising complaints were registered with the Authority.

## MEDICINES INTELLIGENCE AND ACCESS

Access to medicine and the continuous supply of affordable medicines with adequate quality, safety and efficacy are principal pillars of an effective healthcare system. The Medicines Intelligence and Access Unit provides a proactive and targeted approach to increase access to medicines through added value therapeutic interventions.

This approach was imperative in the intervention to guide patients and healthcare professionals on valsartan-containing medicinal products following the international alert in July 2018. The latter indicated that valsartan-containing medicinal products may be contaminated with a genotoxic impurity, introduced during the manufacturing process of the active pharmaceutical ingredient. More than two hundred (200) queries were received and effectively followed up to ascertain patient safety. Through close collaboration with the Superintendence of Public Health and the health authorities, a strategic plan was enacted to source and supply alternative medicines on the local market.

The patient-oriented ethos within the Malta Medicines Authority is extended further through the engagement of healthcare professionals, academics, students and patients in scientific discussions. To this end, in 2018, the Authority organised three (3) seminars on pertinent pharmaceutical matters:

1. Forty-five (45) attendees participated in the interactive discussion entitled 'The Valsartan Saga: Science, Myths, Realities where a scientific examination of events related to the valsartan alert was reviewed and a rational therapeutic strategy for effected patients was discussed.

2. In the seminar Biosimilars: The Importance of Non-Proprietary Names, Professor Philip Schneider from the College of Pharmacy at the University of Phoenix, Arizona addressed the significance of biological medicines as innovative treatment options for chronic diseases.

3. In collaboration with the Malta Health Network, an information seminar addressed to patients in the community was organised to increase awareness on ADR reporting and patient safety, patients' rights in their therapeutic care and the use of generic medicines.

Accessibility to medicines with fair prices is a vital element in the continuum of healthcare provision. The Medicines Intelligence and Access Unit is in continuous dialogue with the Malta Competition and Consumer Affairs Authority and local and international pharmaceutical stakeholders to ensure reasonable prices for medicines.

Figure 3.14 illustrates the sustainable increase in price reductions of medicines and new generics introduced on the local market for the benefit of the patient. In 2018, fifty (50) price reductions of medicines were announced and thirty (30) new generic medicines were introduced on the Maltese market with a price difference of up to seventy-three percent (73%). As a result, patients have access to more affordable medicines that conform with the established European standards of quality, safety and efficacy.

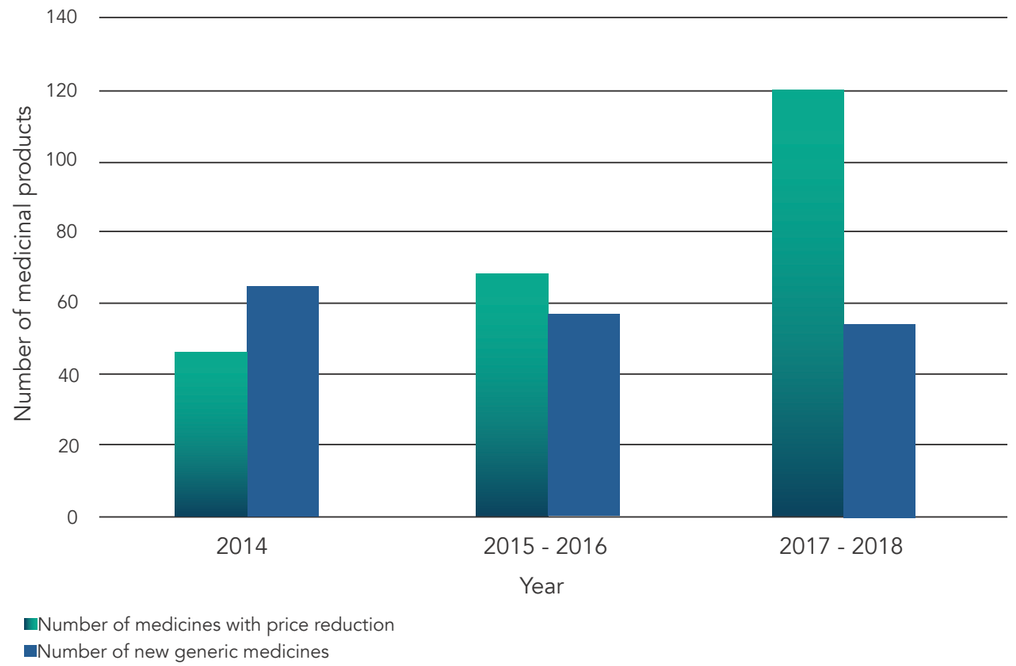



*Figure 3.14: The number of medicine price reductions and new generic medicines on the Maltese market*

Access to medicine is an evolving, multifaceted challenge that requires collective effort and cooperation between all stakeholders. The Medicines Intelligence and Access Unit 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.

# 4 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 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 2018 the Malta Medicines Authority carried out sixteen (16) local GMP inspections for new, renewal or follow up of GMP licences/certificates. These included:

- One (1) GMP inspection for an active pharmaceutical ingredient;
- One (1) inspection for homeopathic manufacturing;
- Four (4) full non sterile solid dosage manufacturers;
- Two (2) inspection for manufacturing authorisation (MAs) for repackaging and re-labelling / partial manufacturing operations;
- One (1) inspection for both repackaging and importation; and
- Seven (7) inspections for MAs of importation activity.

Moreover, in 2018 the Malta Medicines Authority's Inspectorate:

- Processed fifty-five (55) 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;
- Received one hundred and eighty four (184) rapid alerts and GMP non-compliance notifications, which were investigated, three (3) 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 2018 the Malta Medicines Authority fulfilled its GDP inspection plan through fourty (40) GDP inspections. During 2018, nine (9) applications for new wholesale dealing licences were submitted, seven (7) of which were eventually licensed after having satisfied all criteria in a thorough inspection.

Furthermore, thirty-seven (37) variation applications for wholesale dealing authorisations were processed in 2018, out of which four (4) required an inspection. Also in 2018, two (2) new applications for Active Pharmaceutical Ingredient registration were received which were processed and inspected, leading to one (1) registration.

## THIRD COUNTRY INSPECTIONS

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

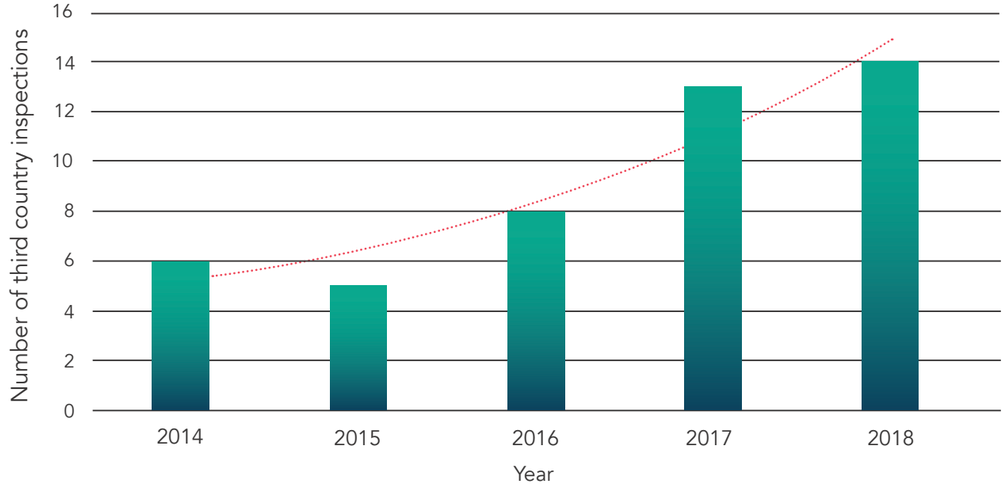



*Figure 4.1: Third country inspections over a 5-year period*

Fourteen (14) inspections were carried out in 2018 in various countries (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.



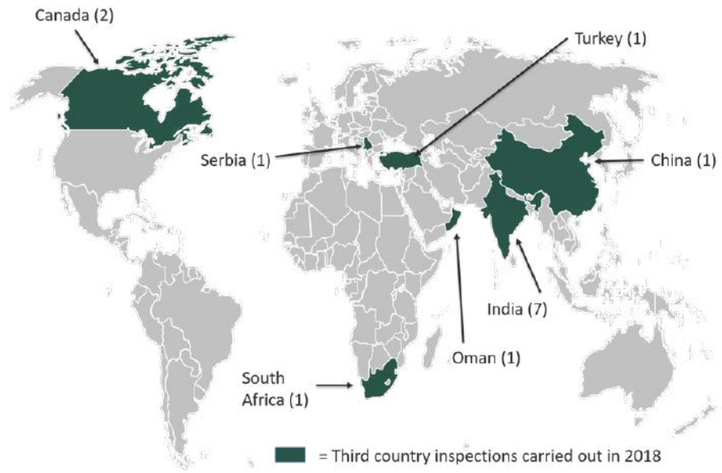



*Figure 4.2: Good Manufacturing Inspections carried out in third countries during 2018*

## PHARMACIES, PHARMACOVIGILANCE, AND SURVEILLANCE OF THE LOCAL MARKET

During 2018 the Malta Medicines Authority continued to inspect pharmacies on a two (2) year cycle. Nine (9) pharmacy relocation inspections were carried out and thirty-eight (38) administrative variations for pharmacy licences were processed. One (1) pharmacovigilance inspection was performed in 2018 for a major local company relocating its pharmacovigilance centre from the UK to Malta due to Brexit.

Moreover, in 2018 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 2018 was closed positively.

During 2018 the Malta Medicines Authority worked on four (4) enforcement cases/investigations which were related to complaints and enforcement. These were coordinated by the Enforcement Committee (a specific committee which discusses enforcement cases, chaired by the Licensing Authority), and resulted in two (2) court case sittings concerning pharmacy issues, and two other court cases in which the Authority's employees were summoned as witnesses.

## GRANTING OF QUALIFIED PERSONS STATUS AND CERTIFICATION OF PHARMACEUTICAL PRODUCTS

In 2018 the Medicines Authority received six (6) new applications for the Qualified Person (QP) eligibility status. Five (5) applicants were interviewed during 2018, four (4) of whom were granted a QP status. The Authority also processed eighty-five (85) applications seeking a Certificate of Pharmaceutical Product, out of which seventy-nine (79) satisfied the required criteria and were certified.

# 5 PROMOTING SCIENTIFIC EXCELLENCE AND INNOVATION IN REGULATION

Established in 2018, the Advanced Scientific Initiatives Directorate is responsible to steer identified scientific areas into centres of excellence and manage advanced initiatives in line with the strategy of the Malta Medicines Authority. The Directorate 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.

Following legal amendments that enable licensed medical practitioners to prescribe, not only cannabis-based products which hold a Marketing Authorisation, but also other products which are manufactured under EU-Good Manufacturing Practice, the Malta Medicines Authority implemented a process to review applications for the importation or wholesale distribution of such products, with the first application being received in March 2018. By May 2018, the first notification of approval was issued by the Superintendence of Public Health on the recommendation of the Malta Medicines Authority, with the first product being subsequently launched in Malta. Eleven (11) applications were submitted to the Malta Medicines Authority in 2018 and three (3) products have received a notification of approval.

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. Through liaison with national, European and International bodies, the Advanced Scientific Initiatives Directorate holds consultations on scientific matters related to medicinal cannabis, processes applications with pertinent experts reviewing the documentation until a recommendation is issued, co-ordinates inspections and audits as well as research and education initiatives.

The Malta Medicines Authority sustains continuous collaboration with the Superintendence of Public Health, Malta Enterprise, the University of Malta, and European counterparts, as well as networking sessions with diverse stakeholders. In November 2018, the Authority actively participated in the Medicinal Cannabis World Forum through presentations related to Science, myths and realities of medicinal cannabis and Regulatory sciences as applied to cannabis for medicinal use.



The Research, Scientific Affairs and Innovation Unit encourages research, thought, analysis, academia, knowledge dissemination, innovation and horizon scanning in collaboration with other entities such as working groups of the EU Heads of Medicines Agencies including the Network Training Centre (EU-NTC) and the Innovation Network (EU-IN). Since 2018, the Malta Medicines Authority became an active partner in the consortium of a Horizon 2020 Coordination and Support Action (CSA) and has been designated co-lead in a work package of the Strengthening Training of Academia in Regulatory Science (STARS) project.

During the past year, the Unit (Research, Scientific Affairs and Innovation) prioritised the establishment of a framework to deliver professional training to stakeholders, while enhancing competence of personnel, establishing international collaborations and imparting the scientific acumen of the Malta Medicines Authority. Through collaboration with The Organisation for Professionals in Regulatory Affairs (TOPRA), a training programme - Innovative Approaches to Excellence in Regulatory Sciences – was rolled out in March 2018. Over seventy-five (75) participants from industry and the regulatory body itself benefited from the three courses organised in line with a budgetary measure which was successfully implemented within the first half of 2018. In November, the Malta Medicines Authority participated at the 10th Malta Medical School Conference, with numerous researchers from the Authority disseminating their work through presentations delivered during the multidisciplinary meeting.

# 6 PUBLICATIONS AND PRESENTATIONS



## PUBLICATIONS


Aquilina A, Wirth F, Attard Pizzuto M, Grech L, Azzopardi LM, Camilleri L, Serracino-Inglott A. Preparing for pharmacist prescribing in Maltese Hospitals. JPHSR 2018; 9(3): 237-243.

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Mifsud E, Wirth F, Serracino-Inglott A, Azzopardi LM. Pharmacist-led medicine use review for patients on anticoagulation therapy. Int J Clin Pharm 2018; 40: 213-214.

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**2018 ACCP Global Conference on Clinical Pharmacy, Seattle, Washington, USA, October 2018:**

Abbas A, Vella Szijj J, Serracino-Inglott A. Access to Orphan Drugs and Quality of Life in Rare Disease.

Attard A, Wirth F, Serracino-Inglott A. Patient-Centred Regulatory Audits in Community Pharmacy.

Camilleri M, Borg JJ, Sammut Bartolo N, Serracino-Inglott A. A Comparison of Approved Indications between Regulatory Agencies.

Kupka JI, Zarb-Adami M, Attard Pizzuto M, Serracino-Inglott A. Risk Assessment of Prescribing Errors on Medical Prescriptions in Malta and Germany.

Mifsud Buhagiar L. Translating genomics science into personalized medicine: the regulatory aspect.

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Zuccarelli M, Borg JJ, Vella Szijj J, Serracino-Inglott A. Developing safe and effective medicinal products to treat Leber Hereditary Optic Neuropathy. Clinical and Regulatory Challenges.



**78th FIP World Congress of Pharmacy and Pharmaceutical Sciences, Glasgow, United Kingdom, September 2018:**

Abbas A, Vella Szijj J, Serracino-Inglott A. The Impact of Rare Diseases on Health Related Quality of Life.

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Attard A, Wirth F, Serracino-Inglott A. Reaching Concordance in Community Pharmacy Regulatory Audits.

Attard Pizzuto M, Sammut Bartolo N, Wirth F, Vella Szijj J. Borg KA, Grech L, Serracino-Inglott A, Azzopardi LM. Evaluation of an innovative teaching method: Buzz sessions.

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Cassar S, Wirth F, Serracino-Inglott A. Clinical practice and pricing insights into medicine access intelligence.

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