ANNUAL REPORT 2017

MALTA MEDICINES AUTHORITY

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Message by the

Parliamentary Secretary

The function of the Malta Medicines Authority is based on the values of people, innovation, quality and integrity. These values are practised by the Authority being a forward looking regulator working in transparent dialogue with all stakeholders. The Authority works through four directorates, namely Licensing, Post-Licensing, Inspectorate and Enforcement, and Strategy, Operations and Regulatory Affairs, and five headships – ICT, Finance and Corporate Services, Medicines Intelligence and Access, Quality, International and EU Affairs, and Research, Scientific Affairs and Innovation. All these areas performed successfully in 2017 by working in unity.

The Licensing increased significantly the number of registered medicinal products in Malta. The Post-Licensing excelled in pharmacovigilance activities. The Inspectorate and Enforcement increased its third country inspections. The Strategy, Operations and Regulatory Affairs was instrumental in gaining European and international recognition and spearheading change initiatives in tandem with Finance to ensure the sustainability of the Authority. ICT was pivotal in moving towards an agile entity. The Medicines Intelligence sustained a reduction in the price of a number of medicinal products and facilitated access to medicines. The Quality management piloted the high standards achieved and ISO recertification. The Research promoted in a tangible manner the remarkable scientific image witnessed this year. The Malta Medicines Authority has achieved recognition within the European regulatory network and in 2017 by the US Food and Drug Administration. GMP inspections that are performed by the Malta Medicines Authority are now recognised by the US FDA. The Malta Medicines Authority reviewed the potential impact that UK's referendum decision to exit the EU could have on the various aspects of regulatory work and strengthened collaboration with other European regulatory authorities. Agreements for sustainable collaboration were made with the Medicines Evaluation Board (Netherlands), Agenzia Italiana del Farmaco (Italy) and Infarmed (Portugal) aiming to accelerate the scientific development of professionals at the Authority and enhancing access to medicine.

The team at the Malta Medicines Authority show constant commitment to enable patient access to good quality, safe and efficacious medicinal products and this is achieved through continuous education. The pharmaceutical stakeholders also give their valuable input to sustain the excellence of the Malta Medicines Authority. The rolling outcome is not only the advanced regulation of medicines, but the expansion of the educational and scientific initiatives while boosting innovation and progress of the pharmaceutical sector and life sciences in our country.

Dr Deo Debattista
Parliamentary Secretary for
Consumer Protection and Valletta 2018

Message by the

Chairperson

The year 2017 was a fruitful albeit challenging year for the Malta Medicines Authority. The Authority excelled in the European networking commitment by hosting 24 meetings of European committees and working groups as part of the Maltese Presidency of the Council of the European Union. Rare diseases, paediatric medicines, law enforcement and safety of medicines were among the discussions addressed during these meetings. One of the priorities of the Maltese Presidency was International Collaboration in line with one of the key business priorities of the Heads of Medicines Agency Multi-Annual Work Plan. Experts from the European Medicines Agency and regulators from seventeen African countries participated in the summit 'Making Article 58 and other EMA outputs more relevant for non-EU regulators' to discuss significant achievements and advances in the pharmaceutical industry. We are working with global partners to address problems which require a consistent and collaborative approach focused on the needs and expectations of citizens and consumers.

The Malta Medicines Authority has undergone successfully intensive inspections and assessments by the Joint Audit Programme involving the United States FDA, the rigorous Benchmarking of European Medicines Agencies and the recertification of ISO 9001:2015. These bear evidence to the commitment to quality management, good governance and management structures. The success of the Authority is attributed to the motivated professional employees that have the skills and mindset necessary to transpire the strategic function of the Authority in the regulatory sciences sector while incorporating a patient-centred approach. Thirty percent of the employees are following Masters and Doctorate programmes, carrying out research in innovative and advanced aspects of the pharmaceutical sciences. This year four scientific professionals have excelled in their advanced research on biosimilars, innovative medicines, stem cells and safety of medicines and graduated with a Doctorate in Pharmacy. The expertise obtained is key to expand the Malta Medicines Authority portfolio. The research, scientific affairs and innovation unit was launched in 2017 with the aim to strengthen the collaboration of the Authority with academia and pharmaceutical entities in the local and international scenario. Research leads to an innovative approach towards achieving excellence in regulatory sciences. The regulatory role of the Malta Medicines Authority continues to evolve in line with national and European legislation. The Authority is responsive to challenges and developments in the ever-changing operating environment.

Professor Anthony Serracino Inglott
Chairperson, Malta Medicines Authority

1.
Achieving Results through People, Good Governance and Innovation

1.1 Leadership, Decision Making and Communication

During 2017 the Malta Medicines Authority focused on the implementation of the 2016-2020 Strategy whilst taking the lead on key initiative for the pharmaceutical sector in Malta.

Open communication, collaboration and stakeholder engagement were strengthened and the Authority organised its third annual structured stakeholder meeting to share achievements and better understand the needs and expectations of its clients. The stakeholder meeting was carried out as part of the Presidency Programme and interested parties had the opportunity to partake in discussions relevant to European citizens, healthcare professionals and industry.

The Authority participated in a number of National initiatives to enhance visibility of regulatory work. Initiatives included proactive participation in events related to World Pharmacist Day, Consumer Conference, Science in the City and Science in the Citadel.

1.2 Capacity

The number of persons employed by the Malta Medicines Authority at the end of 2017 was fifty seven (57) (Table 1).

	Female	Male
Management	5	5
Professional and technical	22	12
Administration	9	4
Total	**36**	**21**

Table 1: Employees at the Malta Medicines Authority

1.3 Learning and Development

The Malta Medicines Authority understands that the fulfilling of its mission requires a knowledge-based approach. The accomplishment of the Authority's role is achievable only if its employees are motivated and have the necessary skills and competences to perform their duties. The Malta Medicines Authority therefore ensures that its employees are offered the possibility to develop their skills and competences through ongoing training and professional development.

In 2017, Malta Medicines Authority's employees attended and successfully completed thirty three (33) courses. These courses, which were offered either internally or externally, dealt with a variety of topics, including sterile manufacturing, radiopharmaceuticals, stem cells research and innovative products.

During 2017, the Malta Medicines Authority supported its employees to read postgraduate studies through a flexible approach. Over thirty per cent of employees are currently undergoing Masters or Doctoral studies. Following the target achieved in 2016 that employees have a minimum of Level 5 qualification, the Authority continued investing in its employees to reach Level 7 qualifications of the Malta Qualifications Framework.

In view of the positive results gained with the Traineeship Programme, in 2017 the Authority rebranded the initiative as the Malta Medicines Authority International Fellowship Programme. The initiative was enhanced to support professionals undergoing level eight studies (Doctoral), level 7 studies (Masters) and level 5 studies (Diploma) in an effort to build a new generation of pharmaceutical leaders and promote further education. Nine (9) professionals participated in this programme during 2017.

1.4 Quality, Simplification and Better Regulation

The Malta Medicines Authority is fully committed towards quality improvement and continuous improvement. A total of Fourteen (14) policies and Thirty-four (34) standard operating procedures. The process incorporated changes in policies as well as quality for improvements identified through implementation of operations, internal audits and Management Review.

The Authority implemented the audit programme for 2017 in line with the five-year audit strategy. A total of thirteen (13) internal audits were performed in 2017 on the internal processes which resulted in a number of quality improvements. A total of twenty-eight (28) quality improvements were processed by the Medicines Authority. These related to internal operations and resulted in the setting up/review of policies, standard operating procedures and amendments to standard documentation with the aim of continuously improving the internal operations towards increasing effectiveness and efficiency of its internal operations. Forty-three per cent (43%) of the quality improvements identified resulted from internal / external audits. The implementation of all quality improvements is monitored centrally.

An annual Management Review was performed, which involved review of the operations of each Directorate and Unit within the Medicines Authority, evaluation of results of stakeholder (internal and external) feedback, including complaints, evaluation of results of previous audits (internal and external) and analysis of quality improvements. This resulted in action points translating into continuous improvement and the continued suitability, adequacy, and effectiveness of the Quality Management System.

Five (5) simplification actions were prioritised for 2017. These were identified and prioritised in line with stakeholder feedback. The first action dealt with the collaboration between the National Competent Authorities of Malta and Ireland on establishing an electronic licensing management system, the second measure was to initiate a planning strategy on extending the scope of the electronic system to inspectorate and enforcement activities. In its commitment to become a paperless agency, the Authority has vested capacity in continuing the scanning of documents into a central virtual locator for facilitated retrieval and enhanced accessibility of structured information for our stakeholders. The Medicines Act (Chapter 458 of the Laws of Malta) was amended in 2013 resulting in discrepancies with the Special Procedure (Penalties in Respect of the Medicines Act) Regulations. The fourth simplification measure was aimed at spurring a legislative process of

aligning the Special Procedure with provisions in the Medicines Act and to introduce the possibility of paying administrative fines and closing current pending cases in an accountable, transparent, proportional and consistent manner. The legal notice for the proposed streamlining is in its advanced stages of approval. In fulfilment of the Authority's strategic goal of better informed users, an initiative has been undertaken to facilitate information on pharmacy access to the public. A link to a geoserver on the Authority's website has been published displaying licensed pharmacies plotted across Malta and Gozo, together with relevant details for each pharmacy. Another action concerned facilitated electronic payments by applicants to the Authority. This method simplifies transactions between both parties, expediting the application process. An automated transaction system also allows applicants to revise outstanding balances and review payment history. The Authority is now accepting direct payments for all the services provided.

1.5 Active Participation at EU and International Level

2017 was the European year for the Malta Medicines Authority in view of the active commitment to deliver a holistic programme for Malta's Presidency if the Council of the EU. The Authority delivered approximately ten percent (10%) of the Presidency meetings held in Malta. The programme included the established meetings normally delivered by incumbent Presidencies and innovative initiatives targeting to set Malta as a centre of excellence for pharmaceuticals and life sciences.

The innovative aspects of the Presidency Programme included a summit on continuous manufacturing in collaboration with the International Institute for Advanced Pharmaceutical Manufacturing within Rutgers University (USA) and a unique high level conference on rare diseases to discuss the development and access of medicinal products for rare disease. This conference convened the European Organisation for Rare Diseases (EURORDIS), EU Health Ministers, experts from the Committee of Orphan Medicinal Products (COMP), BBMRI-ERIC, Malta Alliance for Rare Diseases and the members of the Innovative Medicines Initiative (IMI).

A pivotal summit organised by the European Medicines Agency and hosted by the Malta Medicines Authority was 'Making European Medicines Agency scientific outputs more relevant for non-EU regulators'. The meeting was funded the Bill and Melinda Gates Foundation and was a first for Europe in bring EU member states close to seventeen African countries to enhance international collaboration to improve patient access to medicines.

During 2017, the Malta Medicines Authority has participated actively in European and International fora. Malta Medicines Authority officers participated in one hundred and sixty two (162) meetings/training sessions at EU and international level. Most of these initiatives were primarily funded by the EU and resulted in increased public health impact, participation in revenue generating procedures, active participation in policy development at European level and the possibility of sharing work and best practices with other agencies, resulting in increased efficiency and maximisation of resources.

The Malta Medicines Authority strengthening its European co-operation by means of four new technical agreements. The agreements were signed with the National Competent Authorities of Italy, the Netherlands, Iceland and Portugal. The agreements focused on facilitating access to medicines, capacity building for the Authority, research co-operation and dissemination, increase of joint work and outsourcing of assessment duties to the Maltese agency.

In 2017, the Authority continued consolidating its participation in the project entitled Strengthening Collaboration for Operating Pharmacovigilance in Europe (Scope) Joint Action. The project aims to support Medicines regulators to operate pharmacovigilance systems in line with the EU legislative requirements. The Authority is collaborating with other agencies within the EU to improve skills and capability which will help in safeguarding public health. During November 2017, the Authority participated in an EU wide information campaign which resulted in upsurge of one hundred and seventy two percent (172%) in adverse drug reaction reporting when compared to the preceding months.

1.6 Transparency

The Malta Medicines Authority prioritised measures that encouraged transparency and freedom of information. Audit reports were shared with the Internal Audit and Investigation Directorate within the Office of the Prime Minister to strengthen transperancy and information was published on the website on a regular basis. The Authority is publishing the full audited financial statements to enhance openness and transparency (Appendix 1 refers).

Captured moments during the Malta Medicines Authority programme for the Council of the European Union Presidency in Malta.

2.
Safe, Efficacious and High Quality Medicines for the Benefit of the Patients

2.1 Assessment and Licensing

2.1.1 Malta as Reference Member State and rapporteur in European registration procedures

During 2017, the Malta Medicines Authority through the coordination of procedures in the Licensing Directorate continued with activities towards national and European procedures for the registration and continued life-cycle management of medicinal products. This is one of the priorities of the Medicines Authority, ensuring that a comprehensive range of medicinal products are authorised for the Maltese patients and making sure that the product information remains updated for the benefit of health care professionals and patients.

With the activities towards European procedures the Medicines Authority, as a Reference Member State (RMS) or rapporteur, also plays a role in the registration of products also for other European countries. This is one of the most important activities for the Medicines Authority whereby it plays a part in the European network for the regulation of medicines and also provides for more products authorised for use in patients in the European Union.

The overall number of authorisation procedures in 2017 with Malta in the lead role was twenty six (26) (Table 2). In 2017, Malta ranked 11th out of the 28 Member States, in the number of procedures finalised and started with the role of Reference Member State (Figures 1 and 2).

With planned enhanced capacity and the focus on the competence of its staff, the Authority is carrying out these procedures for a more diverse range of medicinal products. New pharmacists and assessors have been recruited and external experts engaged to complement the existing experienced team for the technical coordination and assessment of dossiers for these procedures. This ensures adequate capacity to handle more procedures. Additional resources are planned for 2018 as the work in these activities increases.

For procedures for which Malta is Reference Member State or rapporteur, team meetings are organised for each procedure to discuss the progress of the procedures and for a consolidated and fact-based decision to be taken at each step of the procedure. This ensures consistency and fairness for the pharmaceutical industry, and makes sure that standards and guidelines are followed.

Post-authorisation activities increased in number as a result of the increasing number of procedures over the years with Malta in a lead role in the European procedures (Figure 3). This is envisaged to increase further as more procedures get concluded over the years. Post-authorisation procedures make sure that life-cycle management of products is continuous and the latest information on the quality, safety and efficacy of all products is available at all times to the Authority.

2.1.2 European cooperation

Through the continued collaboration with the Medicines Evaluation Board (MEB, The Netherlands) signed in 2014, the Malta Medicines Authority has continued to carry out assessment of applications for the Dutch competent authority. This has been a successful cooperation for both entities and there is an ongoing request for the Medicines Authority to increase this collaboration both in terms of quantity and diversity of work. This alliance has been mutually beneficial and has helped to enhance the competence of the Malta Medicines Authority assessors, whilst assisting the MEB in their work. During 2017, the Medicines Authority assessed variations and new procedures for the MEB.

At the end of 2017 further meetings were held with the MEB to discuss concrete proposals on how to extend this cooperation further and a three year plan has been drawn up.

2.1.3 Applications for new authorisations through various routes resulting in national authorisations

The number of applications for national authorisations for the approval of new products received and finalised in 2017 are shown in Figure 4. These submissions include national marketing authorisations (as a result of national and European procedures), authorisations in accordance with article 126(a) of Directive 2001/83 /EC, and parallel import licences. A total of six hundred and sixty (660) new products were authorised in 2017. This brings the total number of all authorised products as at the end of 2017 to five thousand four hundred and fifty nine (5459). The number of products by route of registration is shown in Figure 5.

2.1.4 Herbal and homeopathic medicinal product registrations

In 2017, the Medicines Authority received the first national application for the authorisation of a traditional herbal medicinal product.

2.1.5 Post authorisation procedures

Nationally authorised products

A number of post-authorisation procedures are received each year including variations, notifications, renewals and withdrawals. These constitute a considerable workload for the directorate.

Figures 6 and 7 include the number of national post-authorisation procedures, including renewals, variations, Marketing Authorisation Holder transfers and notifications in accordance with article 61(3) of Directive 2001/83/EC.

The information in Figure 8 refers to withdrawal applications for authorisations and licences.

European post-authorisation procedures

Variations, renewals and notifications for procedures received through the European procedure route where Malta is Concerned Member State (CMS) are shown in Figure 9. Variations remain high in number with only a very slight decrease from last year.

2.1.6 Paediatric Data Assessment

Malta also participated in the assessment of paediatric data in accordance with article 45 of European Regulation 1901/2006 for the safer use of medicines in children. During 2017, Malta was rapporteur for one European work-sharing procedure.

2.1.7 Prescription Status Working Group

During 2017, the Prescription Status Working Group (PSWG) worked on the harmonisation of the legal classification of a number of medicinal products (prescription versus non-prescription). Further work on the harmonisation of the therapeutic groups identified for prioritisation during 2016 was done by the group. Apart from the therapeutic groups, a number of high priority products were discussed on a case by case basis to improve availability for the patients in community settings. A number of meetings were set up with individual stakeholders to support them with regulatory advice when it was considered appropriate to change the status of some particular products from prescription only to non-prescription status.

2.1.8 Borderline Classification Committee

The Borderline Classification Committee (BCC) of the Malta Medicines Authority classifies products into medicinal products and non-medicinal products when requests for classification are received from companies and from other sources. The Committee meets regularly and feedback is sought from all members as well as the herbals expert in line with an updated simplified and shorter process. In 2017, nineteen (19) applications for classification of borderline products were received, out of which seventy nine per cent (79%), were considered as non-medicinal, eleven per cent (11%), were considered medicinal and another eleven per cent (11%), were considered as illegal in Malta at the end of the reporting period.

2.2 Scientific Advice

The Malta Medicines Authority started a process to expand its remit for scientific advice. There were no requests for structure scientific advice during 2017.

The values, 2016-2020 strategic goals, mission and vision of the Malta Medicines Authority.

	2017
Mutual Recognition Procedure (MRP)/Decentralised Procedure (DCP)	24
Centralised Authorisation Procedure (CAP)	2
Total	**26**

Table 2: Number of procedures received with Malta as RMS or rapporteur in 2017

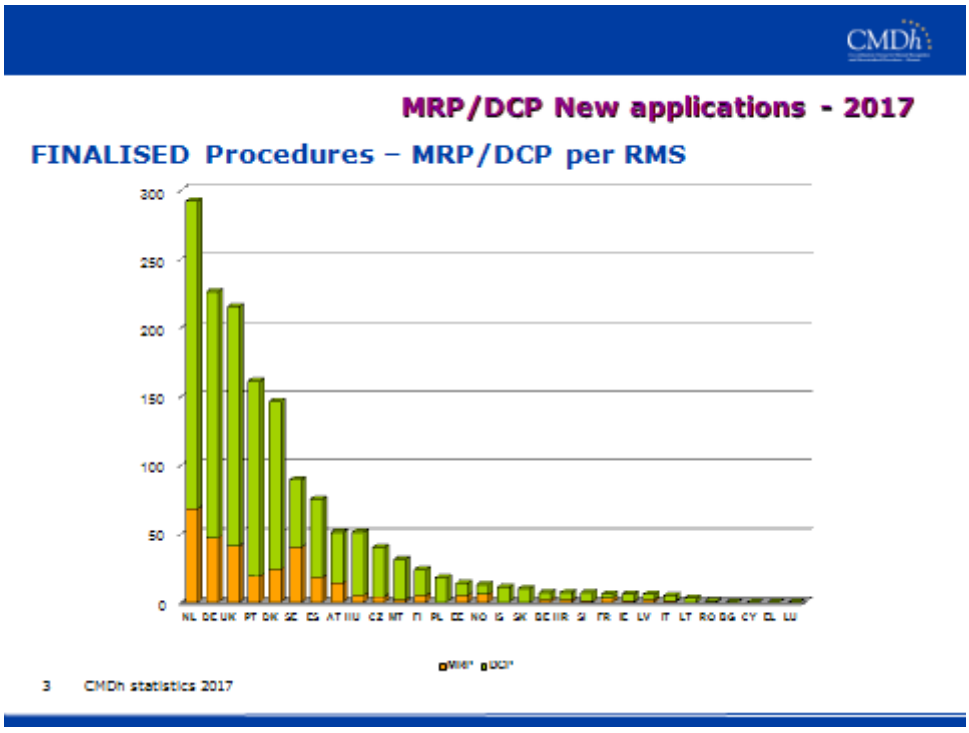


Figure 1: Finalised MR/DC procedures with EU Member States as Reference Member State

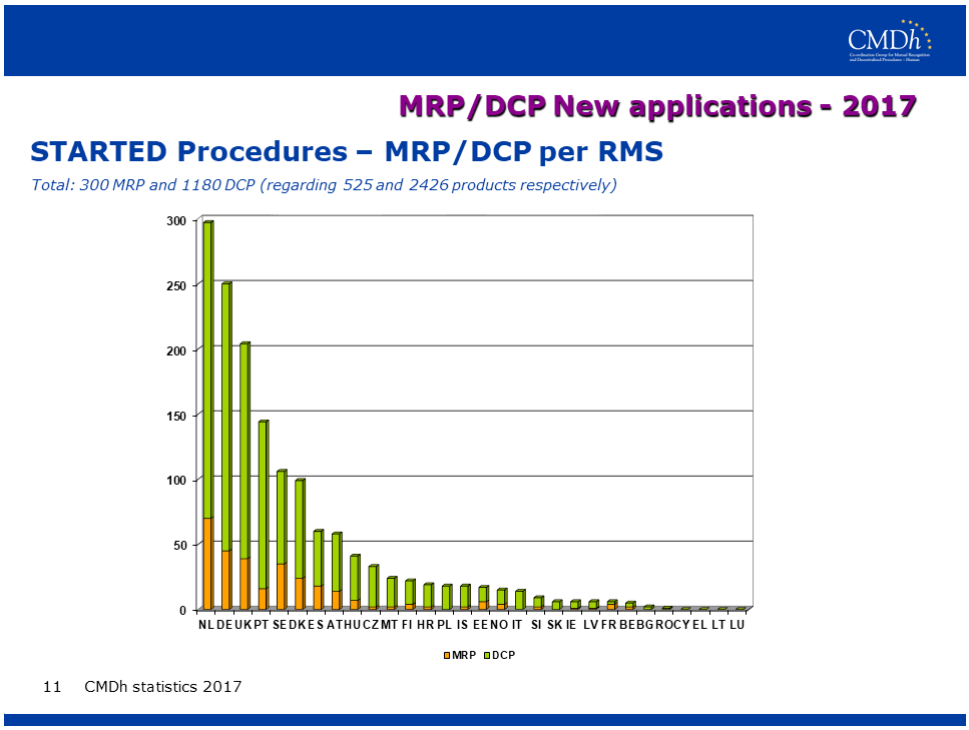


Figure 2: Started MR/DC procedures with EU Member States as Reference Member State

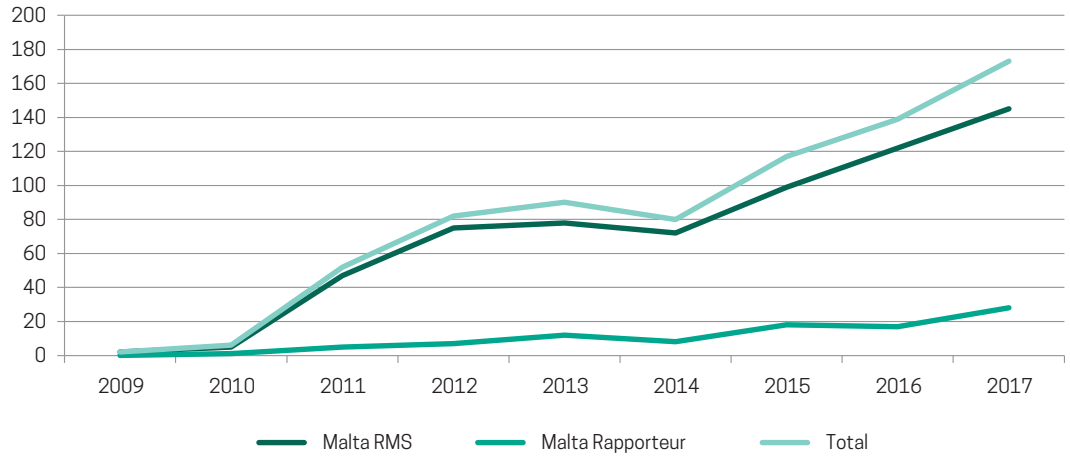


Figure 3: Number of variations received for European procedures with Malta as Reference Member State or rapporteur in the period 2013 – 2017

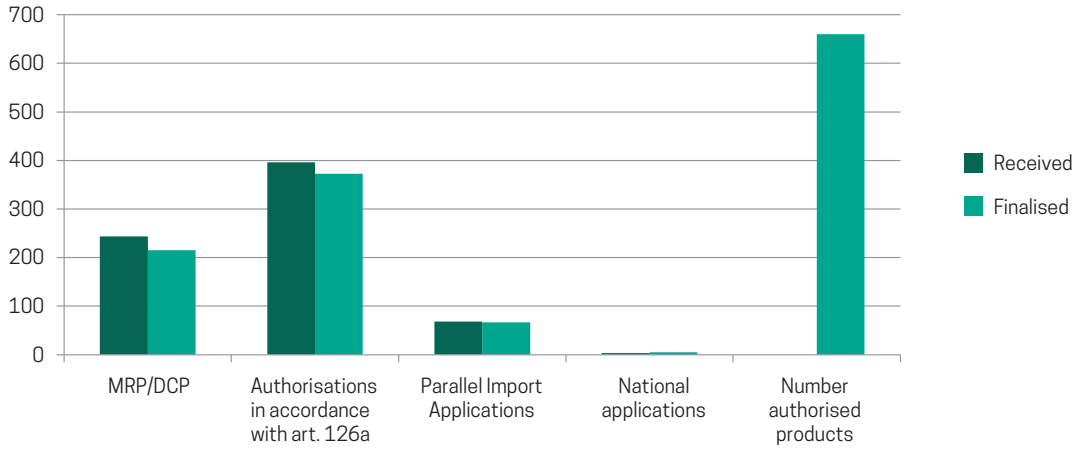


Figure 4: Number of new authorisation applications (different routes) received and finalised in 2017

Figure 5: Authorised products at end 2017 by route of authorisation

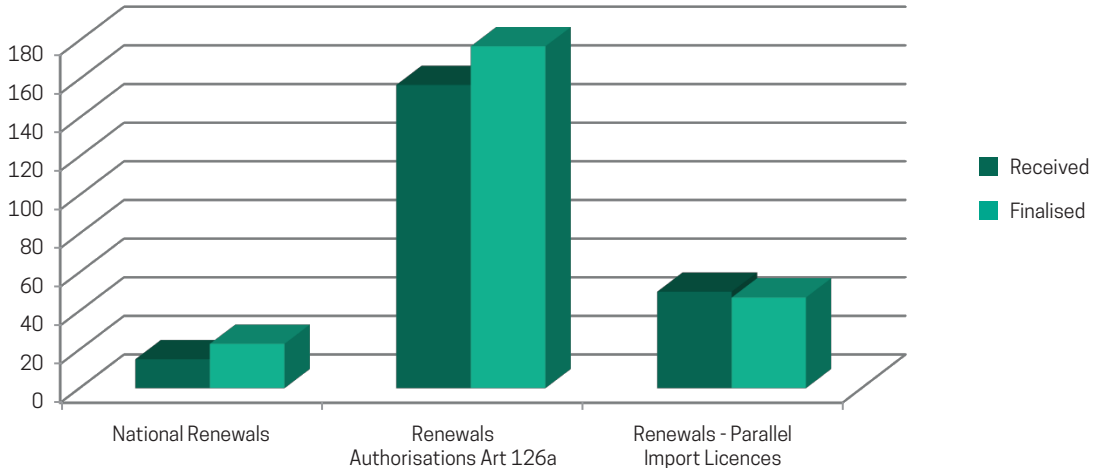


Figure 6: Number of applications for renewals of authorisations/licences received and finalised in 2017

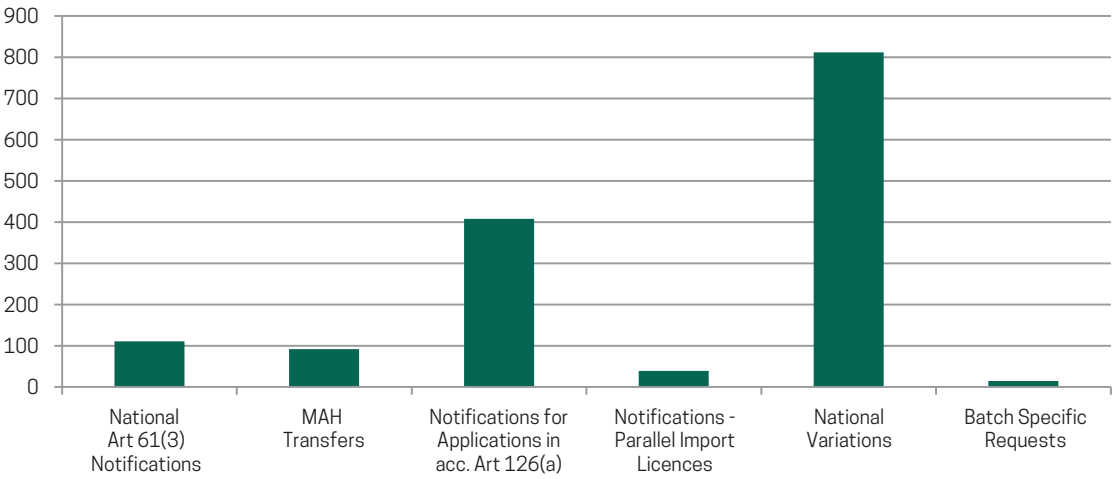


Figure 7: Number of national post-authorisation procedures received in 2017

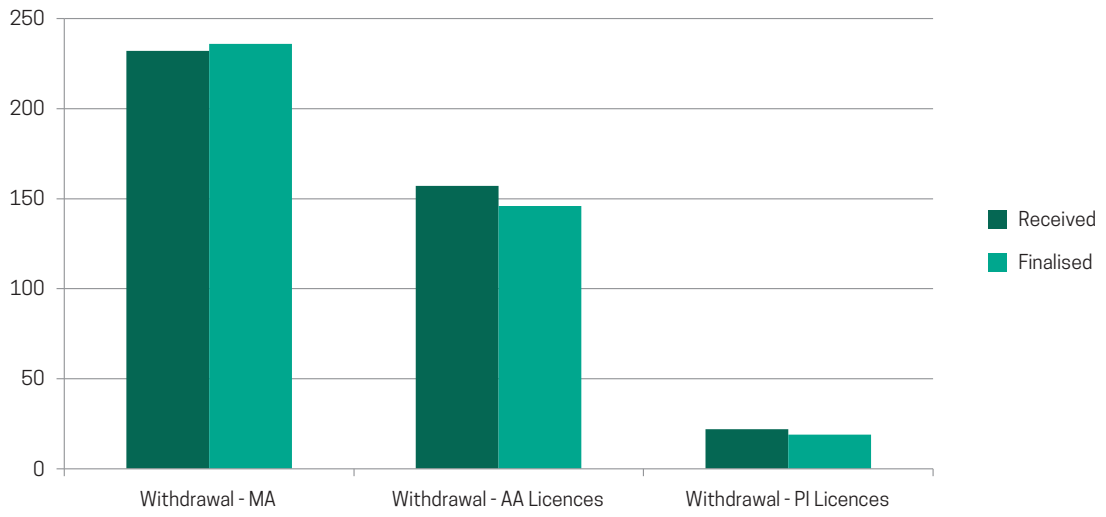


Figure 8: Withdrawal applications for marketing authorisations and licences

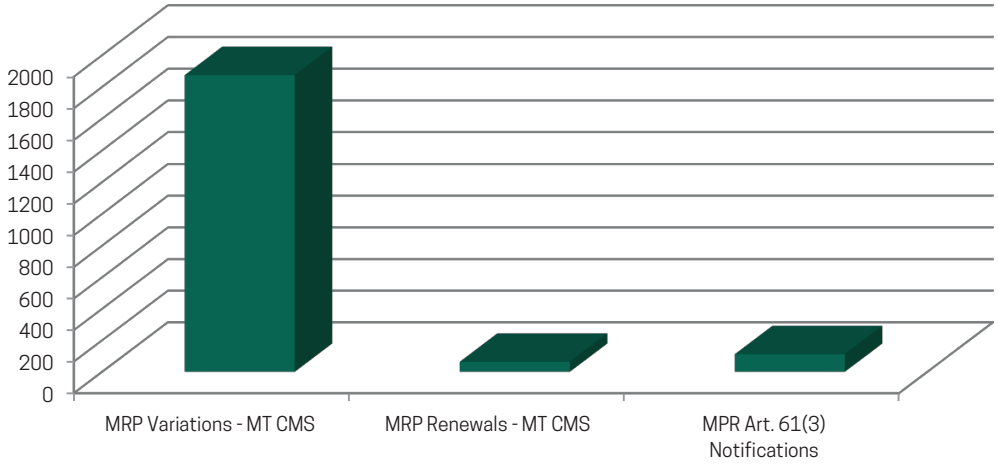


Figure 9: Post-authorisation EU procedures where MT is CMS

2.3 Pharmacovigilance

Safety of medicines is a priority area for the Malta Medicines Authority and the Authority continues to strengthen its efforts to ensure the safe use of medicinal products on the local market. The main objectives of the Pharmacovigilance role of the Malta Medicines Authority includes 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 Authority has in the past year, maintained its active role in Pharmacovigilance.

2.3.1 National Pharmacovigilance Activities

The Malta Medicines Authority participates in a number of activities to help ensure that only safe medicinal products are kept on the Maltese market. The collection, investigation and reporting of drug safety information (the Spontaneous Reporting System) in accordance with European requirements comprises one such major Pharmacovigilance activity carried out by the Malta Medicines Authority. The Malta Medicines Authority requests the implementation of risk minimisation measures that are conditions of marketing authorisations from marketing authorisation holders as well as the approval of Direct Healthcare Professional Communications (DHPC) informing of key messages to prescribers and suppliers of medicinal products for human use.

The Authority requests modifications to be implemented to medicinal product information following safety signal detection activities by the European Medicines Agency and the opinions adopted by its Committees. Safety information updates as supplied by the medicinal products' Marketing Authorisation Holders are also assessed and followed up at a local level. These may sometimes also result in the implementation of product safety recalls in an effort to ensure public safety. The Authority assesses and monitors risk management programmes as proposed by Marketing Authorisation Holders or as recommended at a European level. The Authority also participates in discussions related to safety of medicinal products at European level.

The Malta Medicines Authority utilises a number of European information technology application systems and networks for the implementation of the above-mentioned activities. The collection of safety information from local healthcare professionals comprises the major and most basic Pharmacovigilance activity and this is furthered by the collation of these reports using these European IT applications such as EudraVigiliance (EV) and EV Data Analysis System (EV DAS). In the second part of 2017, two staff members received training and were certified by the European Medicines Agency on the new version of the EudraVigilance System that went live in November 2017. The new EudraVigilance system 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.

Staff who obtained the necessary E.U. certification enable theinput of Adverse Drug Reactions (ADR) within the new version of the Eudravigilance database and further strengthen established in-house training on ADR assessments.

Reports detailing occurrence of adverse drug reactions to medicinal products available on the market or at hospital are regularly submitted to the Authority for review and assessment. Such adverse drug reaction reports are mainly compiled and reported by healthcare professionals or the local Marketing Authorisation Holder (MAH) representatives for the medicinal product.

Wherever medicines are being used, there should be a readiness to observe and report unwanted and unexpected medical events.

The Authority strives to foster an attitude of participation by promoting the need for drug safety monitoring in all its collaborations with MAHs as well as healthcare professionals. The MMA hosts the report form for ADRs and medication errors (MEs) online at: www.medicinesauthority.gov.mt/adrportal

Healthcare professionals are encouraged to use this form to submit ADR reports as per S.L.458.35, 3 (4). In 2017, the Authority maintained it's web based side effect reporting form for patients and consumers. This reporting form is hosted on the Malta Medicines Authority's website at: http://medicinesauthority.gov.mt/form-details?sID=35&cat=3

In 2017, the Malta Medicines Authority continued to implement the two (2) year ADR promotion strategy which was finalised in 2016. As part of this strategy, an interactive conference for consumers was organised to promote the safe and rational use of medicines. All talks were delivered by Authority's staff and external speakers in Maltese. Topics included the importance of ADR reporting, safety of herbal medicinal products, product labelling, medicines for children and patient rights amongst others. To complement the success of online campaigns and to sustain ADR reporting levels, a proposal for face-to-face seminars on ADR reporting for healthcare professionals was approved in 2017. The first initiative was held in Cottonera in 2017 and another seminar will be held in 2018. Such initiatives help to strengthen the system of ADR reporting in Malta.

The direction for Marketing Authorisation Holders to send ADRs directly to the EU database to which the Medicines Authority has direct access for signal detection activities has been kept during 2017. This measure continued to reduce the administrative burden of parallel reporting for Marketing Authorisation Holders and the Malta Medicines Authority.

The Malta Medicines Authority has published a research article on opinions of Maltese doctors and pharmacists on medication errors, in the International Journal of Risk & Safety in Medicine. This publication is a result of the promotional efforts carried out by the Authority on the ADR reporting system and medication errors reporting. Feedback on medication errors was obtained from stakeholders during the Malta Medical School Conference of 2015 and through a survey targeting doctors and pharmacists carried out in 2016. The study identified that, increasing technical resources and keeping knowledge up-to-date, addressing overwork and high patient workloads, and avoiding distractions and interruptions as important areas when looking to reduce medication errors.

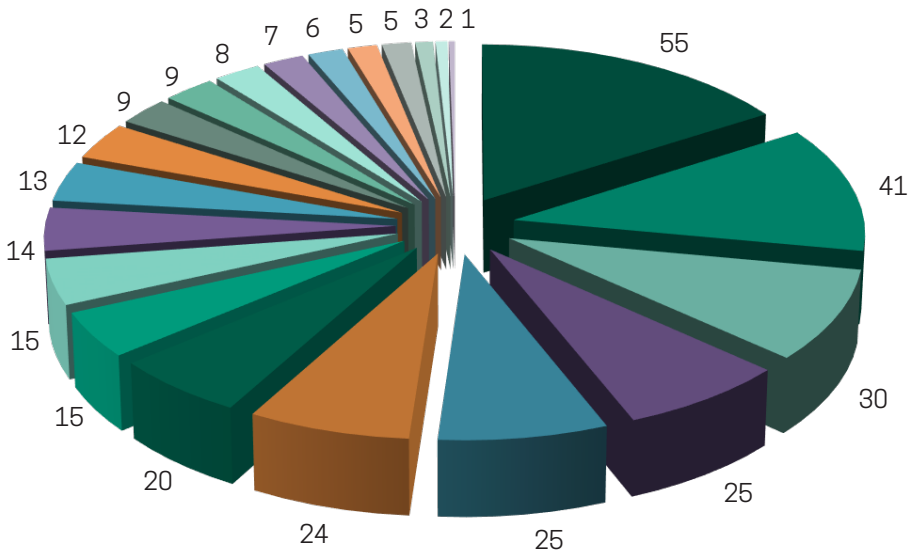
A total of one hundred and eighty five (185) Individual Case Summary Reports (ICSRs) were registered over 2017. Each of these cases detailed at least one adverse drug reaction to the medicinal product concerned thus resulting in a total of Three hundred and forty four (144). Figure 10 gives a breakdown of these adverse drug reactions according to system organ classification. 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 adverse drug reaction repositories. Adverse drug reaction databases maintained at these organisations typically comprise essential medicinal product safety monitoring tools which allow for the identification of potential/novel safety signals associated with the use of specific drugs particularly when these are

administered at certain doses and/or to distinct patient categories.

Figures 11 and 12 further classify the adverse drug reaction case reports (as received over 2017) according to seriousness and patient age respectively. The severity of the adverse drug reaction reports 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.

The establishment and maintenance of a viable electronic reporting system with the European Medicines Agency and the World Health Organisation has comprised a major Pharmacovigilance endeavour necessary for the reporting of adverse drug reactions according to European legislative requirements.

Total Adverse Drug Reactions per System Organ Class in 2017 (n=344)



- General disorders and administration site conditions
- Nervous system disorders
- Gastrointestinal disorders
- Injury, poisoning and procedural complications
- Respiratory, thoracic and mediastinal disorders
- Skin and subcutaneous tissue disorders
- Infections and infestations
- Investigations
- Psychiatric disorders
- Musculoskeletal and connective tissue disorders
- Vascular disorders
- Cardiac disorders
- Blood and lymphatic system disorders
- Eye disorders
- Renal and urinary disorders
- Reproductive system and breast disorders
- Immune system disorders
- Metabolism and nutrition disorders
- Product issues
- Hepatobiliary disorders
- Social circumstances
- Pregnancy, puerperium and perinatal conditions

Figure 10: Distribution of Adverse Drug Reactions according to System Organ Classification in 2017 (n=344)

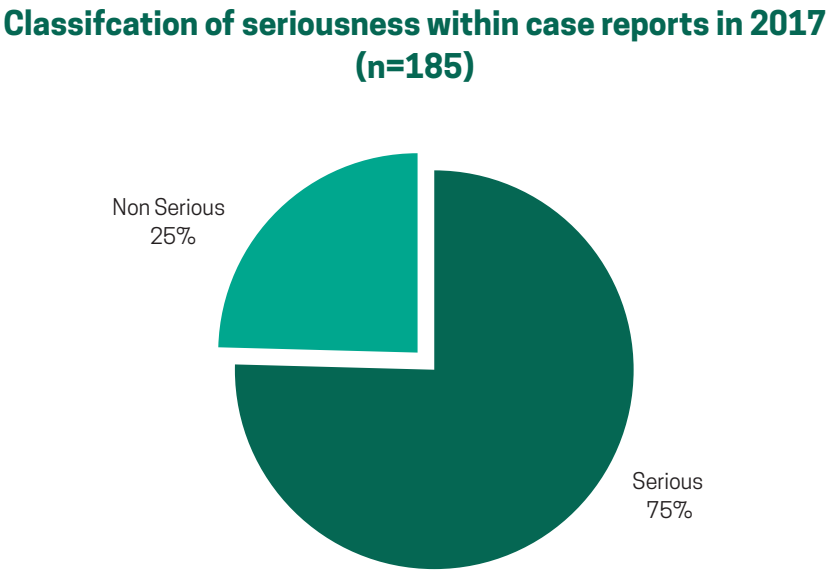


Figure 11: Frequency of ICSRs according to seriousness in 2017 (n=185)

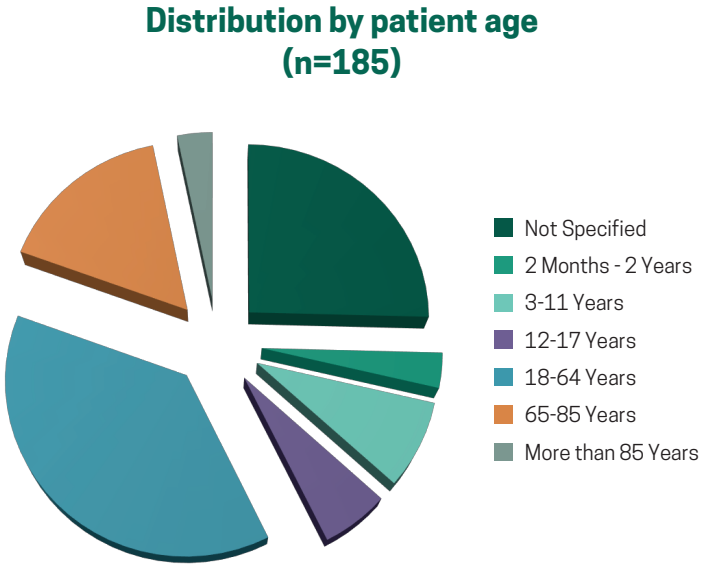


Figure 12: Percentage distribution of case safety reports according to patient age in 2017 (n=185)

The Malta Medicines Authority is responsible for ensuring medicinal product safety via the assessment and approval of circulars detailing proposals for safety updates to scientific product information. Approval of such information is normally requested by the concerned product's Marketing Authorisation Holders or its local representative. The Authority may, initiate such requests for product safety updates following toxicological signal identification and expert working party or committee decisions taken at European Medicines Agency or World Health Organisation level. Requests may also entail product suspension or recall.

Several activities are undertaken by the Medicines Authority for purposes of attaining effective product safety surveillance, amongst which are the (1) approval of Direct Healthcare Professional Communications (DHPCs) detailing safety/risk changes to scientific information and recommendations on product administration methods, (2) investigation of newly identified safety signals with immediate product suspension and/or recall as relevant (Safety Signal Investigations, Rapid Alerts and Product Safety Recalls), (3) approval and monitoring of Pregnancy Prevention Programmes as proposed in relation to potentially teratogenic medicinal products, (4) monitoring of risk minimisation programmes relating to high risk medicinal products and provision of the relevant regulatory information in order to establish such programmes, (5) issue of Safety Circulars and Media Statements addressed to healthcare professionals and the general public respectively. These documents normally give recommendations on medicinal product use and applicable cautionary and precautionary measures. Throughout 2017 the Malta Medicines Authority continued implementing the SMS notification service though a web-based Notifications Portal which replaced the old mGov Gateway in 2016. 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 (6) communication as relevant with the Department of Healthcare Services Standards on toxicological risks identified in relation to blood products (Haemovigilance), (7) initiation and subsequent approval of variations to scientific medicinal product information relating to identified novel or increased risk (Urgent Safety Restrictions), (8) investigation into locally reported incidences of severe unexpected medicinal product toxicity or any anomalous lack of efficacy following medicinal product administration (Local Product Safety Issues), (9) review of newly emergent data concerning safety evidence of a medicinal product, substance or class upon request, (10) review of queries that may be related to a possible safety issues with a medicinal product, substance or class. Table 3 below gives the distribution of reviews, communications and approvals which the Malta Medicines Authority handled over 2017.

The established joint DHPC service was maintained in 2017. In this process, when more than one marketing authorisation holder is obliged to circulate the same DHPC or more than 1 product is the subject of a DHPC, then license holders may request the service of the Malta Medicines Authority to circulate the letter on their behalf. While it is not obligatory to partake in a joint DHPC licence holders must still send the letter to the stakeholders unilaterally as the provision of new emerging safety information to doctors and other healthcare professionals by pharmaceutical companies is an obligation set by the EU's directive on pharmacovigilance, 2001/83/EC.

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. The main area of queries were those relating to; National Pharmacovigilance legislation and local pharmcovigilance requirements, collection, assessment and reporting of local adverse drug reactions including literature monitoring requirements, submission requirements for Periodic Safety Update Reports (PSURs), and Risk Minimisation Measures (RMMs) (Table 4).

An update to the Guidance Notes for Pharma-ceutical Companies on Pharma-covigilance Obligations for Medicinal Products for Human Use was not required through 2017.

The direction given to MAHs in 2016 namely in the area of PSURs submissions to a central repository and Qualified Person Responsible For Pharmacovigilance (QPPV) details directly submitted to the Article 57 database (maintained by the EMA) continue to apply. The Malta Medicines Authority has direct access to the article 57 database as the source of QPPV and Pharmacovigilance system master file (PSMF) information. The Malta Medicines Authority remains committed to updating this guidance notes document on an ongoing basis as necessary when new standards are implemented at the level of the EMA.

Documents Received	Number of submissions
Annual Reassessments	1
Direct Healthcare Professional Communications	16
Joint DHPCs	3
Safety Circulars	9
Risk Minimisation Measures	105
Rapid Alert	1 (N.B. Rapid Alert Simulation Exercise)
Non Urgent Information	12

Table 3: Pharmacovigilance and safety issue reviews and communications – 2017

	Areas Queried	Number
1	National Pharmacovigilance legislation and requirements locally	17
2	Adverse Drug Reactions (ADR) reporting	13
3	Periodic Safety Updated Reports (PSURs)	10
4	Literature Monitoring requirements	10
5	Risk Minimisation Measures(RMMs)/ Educational materials	10
6	Individual Case Safety Reports (ICSRs)	10
7	Local contact person for pharmacovigilance	8
8	Clinical Trials requirements	4
9	Direct Healthcare Professional Communication (DHPC) Distribution	4
10	Requests for ADR related data	4
11	Risk Management Plans (RMPs)	3
12	Local requirements on EudraVigilance Go-Live Plan	3
13	Pharmacovigilance fees	2
14	Pharmacovigilance System Master File	2
15	Serious Unexpected Serious Adverse Reaction (SUSARs)	2
16	Data Lock Point requirements	1
17	Periodic Safety Updated report Single Assessment (PSUSA)	1
18	Extended EudraVigilance medicinal product dictionary	1
19	Generic requirements	1
	Total	**106**

Table 4: Pharmacovigilance related queries in 2017 (n=106)

2.3.2 EU Pharmacovigilance Activities

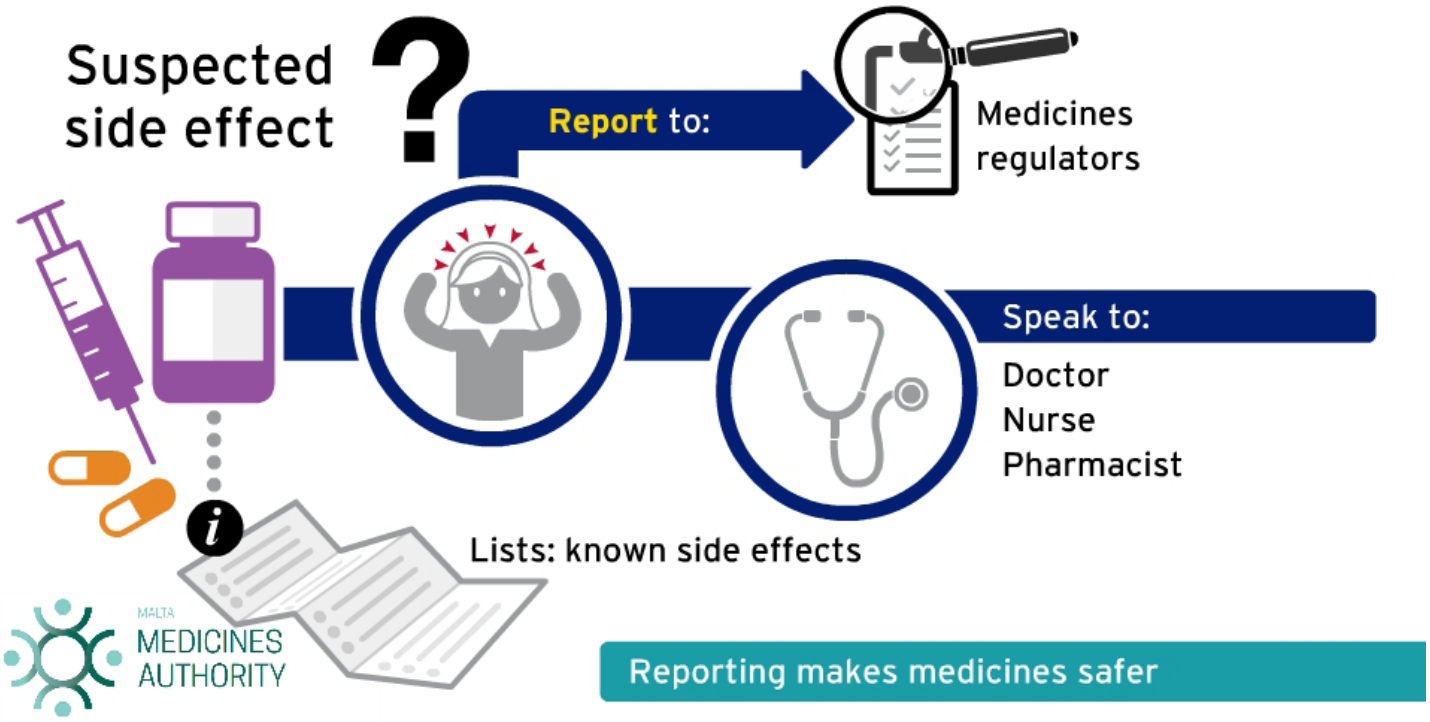
Following the 2012, Directive 2010/84/EU and commission implementing regulation 520/2012 on Pharmacovigilance which was transposed, and the preparation for the new changes, 2017 saw another year of fulfilling legislative obligations and updating procedures to maintain requirements with the new directive.

At an EU level, 2017 saw the continuation of centralised PSUSA assessments and over 2017 the Medicines Authority participated as lead member state in two (2) Period Safety Update Report Single Assessment Procedures (PSUSAs) for Ursodeoxycholic Acid and Nitrous Oxide. All submissions of PSURs became mandatory via the PSUR repository during mid 2016. The Medicines Authority accesses PSURs submissions and

transmits assessment reports following PSUR assessments via a secure interface for competent authorities within the same PSUR Repository.

2.4 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 and as being presented either to the public or to healthcare professionals. Regulation of promotional material such as the provision of medicinal product samples to healthcare professionals and the sponsoring of promotional activities or scientific congresses is also regularly undertaken. Advertising and promotional material regulatory control is implemented according to the criteria set out within the Medicinal Products (Advertising) Regulations. Control of advertising material is also implemented via the ad hoc selection and investigation of local advertisements as presented within the major media formats. This activity principally aims at ensuring public health protection via the affirmation that the applicable legislation is constantly being upheld and rigorously adhered to. Monitoring is mainly implemented via the application in accordance with European legislation of a self-regulatory approach whereby medicinal product advertising complaints as reported by external stakeholders are assessed and investigated in detail for purposes of verifying claims of breaches to the Advertising Regulations. During 2017, no advertising complaints were registered with the Authority.



Sample infographic used for an EU-wide social media campaign during November 2017 on adverse drug reaction (ADR) reporting.

3.
Medicines Intelligence and Access

3.1 Rational Use of and Access to Medicinal Products

The Medicines Intelligence and Access Unit is responsible to manage a proactive and targeted approach taking into account the expectations and needs of both patients, health care professionals and other stakeholders.

In collaboration with the Malta Competition and Consumer Affairs Authority (MCCAA), the Medicines Intelligence and Access Unit is on an ongoing process of dialogue with stakeholders in the pharmaceutical sector to ensure that the medicines remain at an affordable price for the patients, and the public has access to essential medicines with a reasonable price when compared to other countries. The process led to a reduction in prices of medicines for the benefit of consumers which in 2017 amounted to fifty-nine (59) price reduction.

Through the ongoing information campaign Mediċini: Għażla Aħjar Għalik', consumers are being informed about the choice of medicines available on the local market and the importance of discussing these choices with healthcare professionals. The Malta Medicines Authority is continuously updating lists of generic medicines which have been recently authorised and is comparing the prices of these medicines with the originators and other generics so that the consumer can use such information to decide the best treatment option. All of these generic medicines have been assessed by the Malta Medicines Authority to ensure that all medicines conform to the established standards of quality, safety and efficacy. In 2017, a list of twenty-four (24) generic medicines has been published for the consumers.

During 2017 the Malta Medicines Authority carried out planning initiatives with regards to the approach to potential Brexit scenarios and to understand the concerns and requirements of all stakeholders. Together with other Member States and the European Medicines Agency, the Malta Medicines Authority has taken a proactive stance to support stakeholders in their business continuity for the benefit of patients. The Authority is undergoing capacity building to deal with the increased demands for its services and is providing targeted advice and training.

4.
Ensuring High Standards for Pharmaceutical Activities

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

4.1 Manufacturing and Importation

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

During 2017 the Medicines Authority carried out ten (10) local Good Manufacturing Practice (GMP) inspections for new, renewal or follow up of GMP licences/certificates. These included: one (1) GMP inspection for an active pharmaceutical ingredient; ond (1) inspection for manufacturing authorisation (MAs) for repackaging and re-labelling / partial manufacturing operations; two (2) inspection for both repackaging and importation, five (5) inspections for MAs of importation activity and one (1) for sterile dosage forms manufacturing in collaboration with the Italian Medicines Agency (AIFA). The MMA also carried out an audit of the UK MHRA laboratory which is used under contract for testing of medicinal products selected for the annual local market surveillance program.

A total of forty five (45) MAs administrative variation applications were processed in 2017 for manufacturers and importers. Two (2) variations with inspection were carried out.

There were two (2) Inspections Review Group meeting held throughout 2017 where three (3) cases were discussed and decided upon.

During 2017 the Medicines Authority received one hundred and forty three (143) rapid alerts and GMP non-compliance notifications, which were investigated and out of which three (3) resulted in recall of medicinal products from the local market.

During the year under review, the Malta Medicines Authority continued to carry out Good Manufacturing Inspections in countries outside the European Union. Thirteen (13) inspections have been carried out throughout 2017. Through this process, the Medicines Authority is facilitating the possibility that more companies would be in a better position to import medicinal products within the European Union. These procedures attract new revenue to the Authority and provide exposure to different manufacturing facilities to the inspectors.

4.2 Distribution

A distributor of medicinal products sources the products one distributes from within the EU/ EEA. Distributors are required to follow good practice guidelines known as Good Distribution Practice (GDP) in order to ensure that the quality of the medicinal products is not compromised in the supply chain and in order to be in a position to carry out a recall of any defective product.

During 2017 the Malta Medicines Authority has fulfilled its Good Distribution Practice (GDP) inspection plan where fourty two (42) GDP inspections were carried out. During 2017 seven (7) applications for new wholesale dealing licences were submitted, which were all inspected and eventually three (3) were licensed. Thirty five (35) variation applications for wholesale dealing authorisations were processed in 2017, out of which four (4) required an inspection. In 2017, one (1) application for registration of a broker of medicinal products in the distribution chain was received, processed and inspected, with the applicant being registered as a broker. In 2017, two (2) application for API registration were received out of which one (1) was processed and inspected.

4.3 Pharmacies

Pharmacies are inspected on a two (2) year cycle. During 2017 the Malta Medicines Authority carried out a total of eighty five (85) retail community pharmacy inspections, eight (8) Government pharmacies in the National Health Service, three (3) private hospital pharmacies and one (1) pharmacy for medicinal gases.

There were another six (6) pharmacy inspections following variation applications for pharmacy premises transfers or alterations which were carried out and thirty five (35) administrative variations for pharmacy licences were processed.

4.4 Clinical Trials and Pharmacovigilance Inspections

During 2017 in view that no new Clinical Trials applications were submitted to the Malta Medicines Authority, no inspections for this activity were required.

No Pharmacovigilance (PhV) inspections were carried out in 2017, with two being prioritised for 2018 against the national and EU legislation and the Medicines Authority Pharmacovigilance obligations.

4.5 Surveillance of the local market

The Malta Medicines Authority collaborates with the Medicines and Healthcare Regulatory Agencies (UK) so that the latter carried out testing in an Official Medicines Control Laboratory for the Medicines Authority. In this regard, the Local Market Surveillance Plan for 2017 was closed positively.

4.6 Enforcement of legislation

During 2017 the Malta Medicines Authority worked upon four (4) enforcement cases/ investigations which were related to complaints and enforcement. The Enforcement Committee (a specific committee which discusses enforcement cases, chaired by the Licensing Authority) was not required to meet in 2017.

In 2017 there were ten (10) court case sittings concerning pharmacy issues and IED staff attended three (3) court sessions regarding enforcement as witnesses.

4.7 Granting of Qualified Persons Status

In 2017 the Malta Medicines Authority received fourteen (14) new applications for the Qualified Person (QP) status. Twelve (12) applicants were interviewed during 2017 and of these eight (8) were approved as eligible for QP status.

4.8 Certificates of Pharmaceutical Products (CPPs)

During 2017 one hundred and twenty six (126) Certificate of Pharmaceutical Products applications were received and processed and all were issued.

Workshop on the EU Falsified Medicines Directive hosted in August 2017 by the Malta Medicines Authority and industry stakeholders.

MEDICINES AUTHORITY

Annual Report and Financial Statements
31 December 2017

Report of the Chairperson/Chief Executive Officer

The Chairperson/Chief Executive Officer presents his report and the audited financial statements of Medicines Authority for the year ended 31 December 2017.

Functions of the Medicines Authority

The functions of the Medicines Authority ("Authority") are specified in article 6(1) of the Medicines Act, 2003 (Cap 458). They include assistance and provision of advice to the Licensing Authority on matters relating to the regulation of medical products and pharmaceutical activities; the establishment of procedures and undertaking activities for the assessment of medical products; the inspection of pharmaceutical manufacturing and distributing activities and monitoring the use of medical products in line with established standards of quality, efficacy and safety in order to make recommendations to the Licensing Authority in relation to licensing and standards.

Statement of Chief Executive Officer's Responsibilities

The Chairperson/Chief Executive Officer ("CEO") is responsible for the overall management and performance of the Authority.

The responsibility includes ensuring that the Authority keeps proper books of account in such manner as required by the Medicines Act, 2003 (Cap 458) and in accordance with the International Financial Reporting Standards, as adopted by the EU.

Management of the Authority

In accordance with the Medicines Act 2003 (Cap 458) the Chairperson/Chief Executive Officer shall be appointed by the Minister responsible for Public Health from amongst persons who are suitably qualified and experienced in the medical, pharmaceutical or medical science sector. The Medicines Act, 2003 (Cap 458) also provides that the Authority shall establish such Directorates as may be deemed necessary for its proper function. The management team consists of the Chairperson/Chief Executive Officer, Directors and Heads within the Authority. Regular meetings of the management team are held and corporate issues are discussed at these meetings.

Results

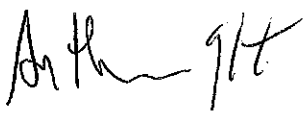
The results for the year are as shown in the statement of comprehensive income on page 7. During 2017, the Authority generated a surplus of €1,356,461 (2016: €1,601,499).

Report of the Chairperson/Chief Executive Officer - continued

Auditors

GCS Assurance Malta Limited, Certified Public Accountants and Registered Auditors, have indicated their willingness to continue in office.

Approved by the Chairperson/Chief Executive Officer on 12 March 2018.



Anthony Serracino Inglott
Chairperson/Chief Executive Officer

Registered office
Sir Temi Zammit Buildings,
Malta Life Sciences Park
San Gwann SGN 3000
Malta

GCS Malta

Independent auditors' report

To the Ministry for Social Dialogue, Consumer Affairs and Civil Liberties

Report on the audit of the financial statements

Our opinion

In our opinion:

- Medicines Authority's financial statements give a true and fair view of the Authority's financial position as at 31 December 2017, and of the Authority's financial performance in accordance with the International Financial Reporting Standards (IFRSs) as adopted by the EU; and
- the financial statements have been prepared in accordance with the requirements of the the International Financial Reporting Standards (IFRSs) as adopted by the EU.

What we have audited

Medicines Authority's financial statements, set out on pages 6 to 19, comprise:

- the statement of financial position as at 31 December 2017;
- the statement of comprehensive income for the year then ended;
- the statement of changes in equity for the year then ended;
- the statement of cash flows for the year then ended;
- the notes to the financial statements, which include a summary of significant accounting policies.

Basis for opinion

We conducted our audit in accordance with International Standards on Auditing (ISAs). Our responsibilities under those standards are further described in the *Auditors' Responsibilities for the Audit of the Financial Statements* section of our report.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Independence

We are independent of the Authority in accordance with the International Ethics Standards Board for Accountants' Code of Ethics for Professional Accountants (IESBA Code) together with the ethical requirements of the Accountancy Profession (Code of Ethics for Warrant Holders) Directive issued in terms of the Accountancy Profession Act (Capt. 281) that are relevant to our audit of the financial statements in Malta. We have fulfilled our other ethical responsibilities in accordance with the IESBA Code.

Other information

The Chairperson/Chief Executive Officer ("CEO") is responsible for the other information. The other information comprises the Chairperson/Chief Executive Officer's report on pages 1 and 2 (but does not include the financial statements and our auditors' report thereon).

Our opinion on the financial statements does not cover the other information.

GCS Malta

Independent auditor's report - continued

To the Ministry for Social Dialogue, Consumer Affairs and Civil Liberties

In connection with our audit of the financial statements, our responsibility is to read the other information identified above and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the audit, or otherwise appears to be materially misstated.

Responsibilities of the Chairperson/Chief Executive Officer for the financial statements

The Chairperson/Chief Executive Officer is responsible for the preparation of financial statements that give a true and fair view in accordance with IFRSs as adopted by the EU, and for such internal control as the Chairperson/Chief Executive Officer determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the Chairperson/Chief Executive Officer is responsible for assessing the Authority's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Chairperson/Chief Executive Officer either intends to liquidate the Authority or to cease operations, or has no realistic alternative but to do so.

Auditors' responsibilities for the audit of the financial statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditors' report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with ISAs, we exercise professional judgment and maintain professional scepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- Obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Authority's internal control.
- Evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Chairperson/Chief Executive Officer.
- Conclude on the appropriateness of the Chairperson/Chief Executive Officer's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Authority's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Authority to cease to continue as a going concern.

GCS Malta

Independent auditor's report - continued

To the Ministry for Social Dialogue, Consumer Affairs and Civil Liberties

- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

We communicate with the Chairperson/Chief Executive Officer regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

Report on other legal and regulatory requirements

Other matters on which we are required to report by exception

We also have responsibilities under the Maltese Companies Act, 1995 to report to you if, in our opinion:

- Adequate accounting records have not been kept, or that returns adequate for our audit have not been received from branches not visited by ourselves.
- The financial statements are not in agreement with the accounting records and returns.
- We have not received all the information and explanations we require for our audit.
- Certain disclosures of Chairperson/Chief Financial Officer's remuneration specified by law are not made in the financial statements, giving the required particulars in our report.

We have nothing to report to you in respect of these responsibilities.

Christian Gravina
For and on behalf of
GCS Assurance Malta Limited
Certified Public Accountants

115A, Floor 4,
Msida Valley Road
Birkirkara BKR 9024
Malta

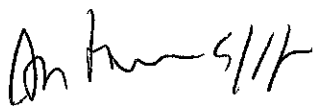
12 March 2018

Statement of financial position

	Notes	As at 31 December 2017 €	2016 €
ASSETS			
Non-current assets			
Intangible assets	4	**4,932**	7,736
Property, plant and equipment	5	**132,522**	157,022
Total non-current assets		**137,454**	164,758
Current assets			
Trade and other receivables	6	**1,551,412**	1,628,548
Cash and cash equivalents	7	**4,391,625**	2,677,703
Total current assets		**5,943,037**	4,306,251
Total assets		**6,080,491**	4,471,009
CAPITAL AND LIABILITIES			
Capital and reserves			
Accumulated reserves		**4,326,139**	2,969,678
Total capital and reserves		**4,326,139**	2,969,678
Current liabilities			
Trade and other payables	8	**1,754,352**	1,501,331
Total liabilities		**1,754,352**	1,501,331
Total capital and liabilities		**6,080,491**	4,471,009

The notes on pages 10 to 19 are an integral part of these financial statements.

The financial statements on pages 6 to 19 were approved by the Chairperson/Chief Executive Officer on 12 March 2018:



Anthony Serracino Inglott
Chairperson/Chief Executive Officer

Statement of comprehensive income

	Notes	Year ended 31 December 2017 €	2016 €
Revenue	9	**3,914,163**	3,955,173
Administration expenses	10	**(2,557,702)**	(2,353,674)
Surplus before tax		**1,356,461**	1,601,499
Tax expense	12	**-**	-
Surplus for the year – total comprehensive income		**1,356,461**	1,601,499

The notes on pages 10 to 19 are an integral part of these financial statements.

Statement of changes in equity

	Accumulated reserves €	Total €
Balance at 1 January 2016	1,368,179	1,368,179
Surplus for the year	1,601,499	1,601,499
Balance at 31 December 2016	**2,969,678**	**2,969,678**
Balance at 1 January 2017	2,969,678	2,969,678
Surplus for the year	1,356,461	1,356,459
Balance at 31 December 2017	**4,326,132**	**4,326,137**

The notes on pages 10 to 19 are an integral part of these financial statements.

Statement of cash flows

	Notes	Year ended 31 December 2017 €	2016 €
Cash flows from operating activities			
Cash generated from operations	13	**1,748,815**	1,537,881
Net cash generated from operating activities		**1,748,815**	1,537,881
Cash flows from investing activities			
Purchase of intangible assets	4	**(4,071)**	(4,121)
Purchase of property, plant and equipment	5	**(36,600)**	(9,283)
Disposal of property, plant and equipment	5	**5,779**	-
Net cash used in investing activities		**(34,893)**	(13,404)
Net movement in cash and cash equivalents		**1,713,922**	1,524,477
Cash and cash equivalents at beginning of year		**2,677,703**	1,153,226
Cash and cash equivalents at end of year	7	**4,391,625**	2,677,703

The notes on pages 10 to 19 are an internal part of these financial statements.

Notes to the financial statements

1. Summary of significant accounting policies

The principal accounting policies applied in the preparation of these individual financial statements are set out below. These policies have been consistently applied to all the years presented, unless otherwise stated.

1.1 Basis of preparation

The financial statements have been prepared in accordance with International Financial Reporting Standards (IFRSs) as adopted by the EU and in accordance with the requirements of the Medicines Act, 2003 (Cap 458). The Authority's financial statements have been prepared under the historical cost convention.

During the year ended 31 December 2017, the Authority generated a surplus before tax of €1,356,461 (2016: €1,601,499).

1.2 Foreign currency translation

(a) Functional and presentation currency

Items included in the financial statements are measured using the currency of the primary economic environment in which the entity operates ('the functional currency'). The financial statements are presented in euro, which is the Authority's functional and presentation currency.

(b) Transactions and balances

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions or valuation where items are remeasured. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognised in surplus or deficit.

1.3 Intangible Asset

An acquired intangible asset is recognised only if it is probable that the expected future economic benefits that are attributable to the asset will flow to the entity and the cost of the asset can be measured reliably. An intangible asset is initially measured at cost, comprising its purchase price and any directly attributable cost of preparing the asset for its intended use.

Intangible assets are subsequently carried at cost less any accumulated amortisation and any accumulated impairment losses. Amortisation is calculated to write down the carrying amount of the intangible asset using the straight-line method over its expected useful life. Amortisation of an asset begins when it is available for use and ceases at the earlier of the date that the asset is classified as held for sale (or included in a disposal group that is classified as held for sale) the date that the asset is derecognised.

Amortisation is based on a useful life of 4 years and is charged to profit and loss.

1. **Summary of significant accounting policies** - continued

1.4 Property, plant and equipment

The Medicines Authority's ("Authority") property, plant and equipment are classified into the following classes – furniture and fittings and office and computer equipment.

Property, plant and equipment are initially measured at cost. Subsequent costs are included in the asset's carrying amount when it is probable that future economic benefits associated with the item will flow to the Authority and the cost of the item can be measured reliably. Expenditure on repairs and maintenance of property, plant and equipment is recognised as an expense when incurred.

Property, plant and equipment are derecognised on disposal or when no future economic benefits are expected from their use or disposal. Gains or losses arising from derecognition represent the difference between the net disposal proceeds, if any, and the carrying amount, and are included in profit and loss in the period of derecognition.

Depreciation commences in the year when the depreciable assets are available for use and is charged to profit and loss so as to write off the cost less any estimated residual value, over their estimated useful lives, using the straight-line method, on the following bases:

	Years
Furniture and Fittings	10
Motor Vehicles	5
Office and computer equipment	4
Lease hold improvement	3

The depreciation method applied, the residual value and the useful life are reviewed, and adjusted if appropriate, at the end of the financial reporting period.

1.5 Financial instruments

Financial assets and financial liabilities are recognised when the Authority becomes a party to the contractual provisions of the instrument. Financial assets and financial liabilities are initially recognised at their fair value plus directly attributable transaction costs for all financial assets or financial liabilities not classified at fair value through profit and loss.

Financial assets or liabilities are offset and the net amount presented in the statement of financial position, when the Authority has a legally enforceable right to set off the recognised amounts and intends either to settle on a net basis or to realise the asset and settle the liability simultaneously.

Financial assets are de-recognised when the contractual rights to the cash flows from the financial assets expire or when the entity transfers the financial asset and the transfer qualifies for de-recognition. Financial liabilities are de-recognised when they are extinguished. This occurs when the obligation specified in the contract is discharged, cancelled or expired.

(a) Trade and other receivables

Trade and other receivables are classified with current assets and are stated at their nominal value. Appropriate allowances for estimated irrecoverable amounts are recognised in profit or loss when there is objective evidence that the asset is impaired.

1. **Summary of significant accounting policies** - continued

1.5 Financial instruments - continued

(b) Trade and other payables

Trade and other payables are classified with current liabilities and are stated at their nominal value.

1.6 Provisions

Provisions are recognised when the Authority has a present legal or constructive obligation as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of obligation. Provisions are measured at the Chief Executive Officer's best estimate of the expenditure required to settle the present obligation at the financial position date. If the effect of the time value of money is material, provisions are determined by discounting the expected future cash flows at a pre-tax rete that reflects current market assessments of the time value of money and, where appropriate, the risks specific to the liability. Provisions are not recognised for future operating losses.

1.7 Impairment

All assets are tested for impairment at each statement of financial position date, the carrying amount of assets, including cash generating units, is reviewed to determine whether there is any indication or objective evidence of impairment, as appropriate, and if any such indication or objective evidence exists, the recoverable amount of the asset is estimated.

Where an impairment loss subsequently reserves, the carrying amount of the asset is increased to the revised estimate of its recoverable amount, but so that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognised for the asset in prior years. Impairment reversals are recognised immediately in profit or loss, unless the asset is carried at a revalued amount, in which case, the impairment reversal is recognised directly in equity, unless an impairment loss on the same asset was previously recognised in profit or loss.

1.8 Cash and cash equivalents

Cash and cash equivalents comprise cash on hand and demand deposits.

1.9 Offsetting financial instruments

Financial assets and liabilities are offset and the net amount reported in the statement of financial position when there is a legally enforceable right to set off the recognised amounts and there is an intention to settle on a net basis, or realise the asset and settle the liability simultaneously.

1.10 Revenue recognition

Revenue is measured at the fair value of the consideration received or receivable for services provided in the normal course of business net of discounts, were applicable. Revenue is recognised to the extent that it is probable that future economic benefits will flow to the Authority and these can be measured reliably. The following specific recognition criteria must also be met before revenue is recognised:

1. Summary of significant accounting policies - continued

1.10 Revenue recognition - continued

The major revenue items that are recognised on accruals basis are:

Licensing Activities – under national obligation
Inspectorate and Enforcement Activities – under national obligation
Post-Licensing Activities
EMA Linguistic Checks
Inspectorate 3rd Country Inspections

(a) RMS and EMA Procedures for rapporteurships for initial authorisation

Revenue from licensing of products falling under these categories is recognised over a period 8 months.

(b) Government subvention

Revenue from the Government of Malta budget is recognised on a cash basis on date of receipt.

1.11 Leases

Leases are classified as finance leases whenever the terms of the lease transfer substantially all the risks and rewards incidental to ownership to the lease. All other leases are classified as operating leases. Lease classification is made at the inception of the lease, which is the earlier of the date of the lease agreement and the date of commitment by the parties to the principal provisions of the lease.

1.12 Operating leases

Rentals payable under operating leases, less the aggregate benefit of incentives received from the lessor are recognised as an expense in profit or loss on a straight-line basis over the lease term.

2. Financial risk management

At 31 December 2017 and 2016 the carrying amounts of financial assets and financial liabilities classified with current assets and current liabilities respectively approximated their fair values due to the short term maturities of these assets and liabilities. The fair values of non-current financial assets and non-current financial liabilities are not materially different from their carrying amounts.

2.1 Financial risk factors

The exposure to risk and the way risks arise, together with the Authority's objectives, policies and processes for managing and measuring these risks are disclosed in more detail below. The objectives, policies and processes for managing financial risks and the methods used to measure such risks are subject to continual improvement and development.

2. Financial risk management - continued

2.1 Financial risk factors - continued

(a) Market risk

(i) Foreign exchange risk

Foreign currency transactions arise when the Authority buys or sells goods whose price is denominated in a foreign currency, or occurs or settle liabilities, denominated in a foreign currency. The risk arising from foreign currency transactions is managed by regular monitoring of the relevant exchange rates, and management's reaction to material movements thereto.

(ii) Interest rate risk

The Authority is currently not exposed to cash flow interest rate risk.

(b) Credit risk

Financial assets which potentially subject the Authority to concentrations of credit risk consist principally of receivables and cash at bank. Receivables are presented net of an allowance for doubtful debts. An allowance for doubtful debts is made where there is an identified loss even which, based on previous experience, is evidence of a reduction in the recoverability of the cash flows.

Credit risk with respect to receivables is limited due to power to take enforcement procedures and the large number of stakeholders comprising the Authority's debtor base. Cash at bank is placed with reliable financial institutions. The Authority assesses the credit quality of the stakeholders by taking into account their financial standing and past experience. Included in the Authority's trade receivables there are no balances which are past due and which have not been provided for.

(c) Liquidity risk

The Authority monitors and manages its risk to a shortage of funds by maintaining sufficient cash and by monitoring the availability of raising funds to meet commitments associated with financial instruments and by maintaining adequate banking facilities.

2.2 Capital risk management

The Authority's objectives when managing capital are to safeguard its ability to continue as a going concern.

The primary objective of the Authority's capital management is to ensure that it maintains a strong credit rating and healthy capital ratios in order to support its operations.

The capital structure of the Authority consists of cash and cash equivalents as disclosed in Note 7 and items presented within the accumulated reserve in the statement of financial position. The Authority's Chairperson/Chief Executive Officer manages the Authority's capital structure and makes adjustments to it, in light of changes in economic conditions.

3. Critical accounting estimates and judgements

3.1 Judgements in applying accounting policies

In the process of applying the Authority's accounting policies, management has made no judgements which can significantly affect the amounts recognised in the financial statements.

3.2 Key sources of estimation uncertainty

At the financial position date, there were no key assumptions concerning the future, or any other key sources of estimation uncertainty, that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year.

4. Intangible assets

	Website €	Total €
At 1 January 2016		
Cost	34,882	34,882
Accumulated amortisation	(21,516)	(21,516)
Net book amount	13,366	13,366
Year ended 31 December 2016		
Opening net book amount	13,366	13,366
Additions	4,121	4,121
Amortisation charge	(9,751)	(9,751)
Closing net book amount	7,736	7,736
At 1 January 2017		
Cost	39,003	39,003
Accumulated amortisation	(31,267)	(31,267)
Net book amount	7,736	7,736
Year ended 31 December 2017		
Opening net book amount	7,736	7,736
Additions	4,071	4,071
Amortisation charge	(6,875)	(6,875)
Closing net book amount	**4,932**	**4,932**
At 31 December 2017		
Cost	43,074	43,074
Accumulated amortisation	(38,142)	(38,142)
Net book amount	**4,932**	**4,932**

5. Property, plant and equipment

	Furniture & fittings €	Office and computer equipment €	Motor vehicle €	Leasehold Improvements €	Total €
At 1 January 2016					
Cost	30,966	47,263	16,300	-	94,529
Accumulated depreciation	(22,907)	(19,287)	(3,260)	-	(45,454)
Net book amount	8,059	27,976	13,040	-	49,075
Year ended 31 December 2016					
Opening net book amount	8,059	27,976	13,040	-	49,075
Additions	43,553	45,427	18,470	51,833	159,283
Depreciation charge	(5,750)	(21,354)	(6,954)	(17,278)	(51,336)
Closing net book amount	45,862	52,049	24,556	34,555	157,022
At 1 January 2017					
Cost	74,519	92,690	34,770	51,833	253,812
Accumulated depreciation	(28,657)	(40,641)	(10,214)	(17,278)	(96,790)
Net book amount	45,862	52,049	24,556	34,555	157,022
Year ended 31 December 2017					
Opening net book amount	45,862	52,049	24,556	34,555	157,022
Additions	3,952	21,722	1,036	9,890	36,600
Assets written off	(5,779)	-	-	-	(5,779)
Depreciation released on disposals	4,516	-	-	-	4,515
Depreciation charge	(5,566)	(25,877)	(7,161)	(21,233)	(59,837)
Closing net book amount	**42,985**	**47,894**	**18,431**	**23,212**	**132,522**
At 31 December 2017					
Cost	72,692	114,412	35,806	61,723	284,633
Accumulated depreciation	(29,707)	(66,518)	(17,375)	(38,511)	(152,111)
Net book amount	**42,985**	**47,894**	**18,431**	**23,212**	**132,522**

6. Receivables

	2017 €	2016 €
Current		
Trade receivables	**1,378,085**	1,386,157
Prepayments	**100,069**	45,837
Accrued income	**73,258**	124,262
Guarantee on rental agreement	**-**	35,256
Other receivables	**-**	37,036
	1,551,412	1,628,548

Trade receivables are stated net of provisions for bad debts amounting to €279,324 (2016: €259,411).

In 2016, other receivables are stated net of provisions for bad debts amounting to €7,032.

7. Cash and cash equivalents

For the purposes of the statement of cash flows, cash and cash equivalents comprise the following:

	2017 €	2016 €
Cash at bank and in hand	**4,391,625**	2,677,703

8. Payables

	2017 €	2016 €
Current		
Trade payables	**153,806**	24,589
Other payables	**-**	205,396
Accruals	**227,915**	221,604
Deffered income	**1,372,632**	1,049,742
	1,754,353	1,501,331

9. Revenue

Revenue represents licensing, post-licensing, inspectorate and enforcement fees, third country inspections and government funds.

Included in 2016 revenue is a one-off income of €721,972 that arose due to a change in policy as an improvement of debt control. This change in policy has been implemented as a simplification measure with the aim of increasing transparency and good governance through which invoices are being issued in advance rather than in arrears. This will improve predictability of financial budgeting thereby enhancing the accessibility of medicinal products in the local market.

10. Expenses by nature

	2017 €	2016 €
Employee benefit expense (Note 11)	**1,807,253**	1,542,359
Amortisation (Note 4)	**6,875**	9,751
Depreciation (Note 5)	**59,837**	51,336
Professional fees	**135,966**	101,700
Staff training	**243,237**	210,267
Travel and accommodation	**52,610**	80,707
Computer expenses	**33,929**	53,872
Other expenses	**211,995**	303,682
Total administrative expenses	**2,557,702**	2,353,674

Auditor's fees

Fees charged by the auditor for services rendered during the financial years ended 31 December 2017 and 2016 relate to the following:

	2017 €	2016 €
Annual statutory audit	**1,950**	2,360

11. Employee benefit expense

	2017 €	2016 €
Management	**486,541**	386,880
Wages and salaries	**1,113,329**	1,066,748
Social security costs	**207,383**	88,731
	1,807,253	1,542,359

The average weekly number of persons employed by the Medicines Authority during the financial reporting year was 56 (2016: 48):

	2017	2016
Management	**10**	9
Technical staff	**33**	29
Administration	**13**	10
	56	48

12. Tax expense

The Authority is exempt from the payment of Income Tax in terms of Article 13 of the Medicines Act, 2003 (Cap 458).

13. Cash generated from operations

Reconciliation of surplus before tax to cash generated from operations:

	2017 €	2016 €
Surplus before tax	**1,356,461**	1,601,499
Adjustments for:		
Amortisation of intangible asset (Note 4)	**6,875**	9,751
Depreciation of property, plant and equipment (Note 5)	**55,322**	51,336
Loss on disposal of property, plant and equipment	**1,263**	-
Provision for bad debts	**19,913**	27,474
Changes in working capital:		
Trade and receivables	**55,960**	(901,585)
Trade and payables	**253,022**	749,406
Cash generated from operations	**1,748,815**	1,537,881

14. Commitments

	2017 €	2016 €
Non-cancellable operating commitments:		
Less than one year	**101,316**	101,317
2-5 years	**119,024**	119,974
More than five years	**-**	317
	220,340	221,608

15. Related party transactions

During the year ended 31 December 2017 and 2016, there were no transactions with key management personnel except for emolument payments as disclosed in Note 11.

16. Statutory information

Medicines Authority is a State-owned Authority. The Authority's ultimate controlling party is the Ministry for Justice, Culture and Local Government on behalf of Government of Malta, the registered office is 30, Old Treasury Street, Valletta, Malta.

17. Comparative information

Comparative figures disclosed in the main components of these financial statements have been reclassified to conform with the current year's presentation format for the purpose of fairer presentation.