Annual Report 2016

MALTA MEDICINES AUTHORITY

CONTENTS

Message by the Minister

The Malta Medicines Authority is a key entity under my portfolio and I am proud to have witnessed this National Competent Authority positioning itself as a best-in-class regulator in Malta. Its commitment to protect and enhance the effective, safe and rational use of quality medicinal products has rendered the Authority to be an efficient entity of people development and sustainable growth.

The relocation of the Malta Medicines Authority to the Life Sciences Park is the result of good planning and an appraisal of options to find cost-effective premises for Malta's key regulatory and scientific competent authority in the pharmaceutical sector. The prestigious location of the Authority was achieved with savings of about a quarter of a million Euros on rent and bills over a period of three years.

What matters most for the public is not the building but what goes on inside it where patients remain at the heart of the Authority's work. Opportunities for open dialogue and transparent collaboration between the international scientific, regulatory and medical sectors are created, encouraging the exchange of knowledge in a harmonic design to ensure accessibility to authorised medicinal products.

The Malta Medicines Authority has launched an effective Traineeship Programme. The Authority invests heavily in its people and in capacity building of the Maltese pharmaceutical sector. Ten percent of its budget is dedicated to training and International and EU exposures. The investment in training and development ensures maintaining the high standards of the functions of the Medicines Authority.

The healthy financial position established by the Authority through its European and International new income-generating activities has led to a significant contribution for the consolidation of expertise on emerging and challenging topics related to innovative therapies and technologies. The growing interest in Malta as a centre for medical research, the supply of quality healthcare and the further expansion of the pharmaceutical industry presents many opportunities for growth for the Malta Medicines Authority. It places a greater onus on the Authority as a regulator and active stakeholder within the national health policy framework.

Building on the achievements and in response to the challenges and opportunities envisaged, five goals were identified for the Medicines Authority Strategy 2016 – 2020. These include optimised regulatory systems, better informed users, access to medicinal products, supporting innovation and organisational development.

A central initiative is the hosting of twenty-two meetings during the Maltese Presidency in 2017 and a number of International conferences. The meetings are significant to promote the quality, safety and efficacy of medicines.

It is a pleasure to see that the team at the Malta Medicines Authority leads an excellent organisation hosting highly motivated individuals committed to protecting public health. The journey of the Authority shall continue to be one of evolution and growth in a rapidly changing international, scientific and technological landscape.

Dr Helena Dalli

Minister for Social Dialogue, Consumer Affairs and Civil Liberties

Message by the Chairperson

The Malta Medicines Authority has undergone a major transformation to position itself as an independent science and health oriented public entity. The improvements have been embedded into a new strategy for 2016-2020. The strategy is a key milestone and a result of intensive and holistic consultation with all stakeholders.

Fulfilling the mission of the Medicines Authority requires a knowledge-based approach. The Authority is investing extensively capacity building. This shows the commitment of the management to promote people development and sustainable growth in regulatory sciences.

We operate in a proactive environment to meet the dynamics of scientific development, new legislation and stakeholder needs. The Medicines Authority has a track record of assessing over three hundred medicinal products as Reference Member State. The number of authorised medicinal products exceeds 5000 medicinal products, increasing access to medicines and competition on the local market. A team of competent inspectors carry out Good Manufacturing Practice third country inspections. Through this process, the Authority is attaining revenue from outside Europe while facilitating the prospect of more companies importing medicinal products embracing the strong regulatory framework of the European Union.

Practical initiatives, such as the evolvement of the Medicines Intelligence and Access Unit and proactive pharmacovigilance, are an excellent example of how competent authorities can strengthen their regulatory role whilst providing an outstanding service to the community. The price reductions for medicinal products – over 140 during the last 4 years - mark the growing success being achieved through constant dialogue with stakeholders.

On relocating to the Malta Life Sciences Park, the Medicines Authority has moved towards more electronic records. The strategic and scientific environment of the new premises provides the Authority with an ideal workplace to achieve further value, service and excellence.

The Authority has strengthened collaboration with other National Competent Authorities in the EU. The provision of scientific expertise by employees of the Authority to the Medicines Evaluation Board (Netherlands) was expanded and the Authority is in the final stages of implementing a new IT system following an agreement with the Health Products Regulatory Agency (Ireland).

I would like to acknowledge the commitment and professional competence of the personnel at the Authority and the Ministry for Social Dialogue, Consumer Affairs and Civil Liberties whose active contribution, complemented by the added support from all stakeholders, was fundamental to accomplish the achievements of 2016. In 2017 we aim to bolster research and innovation. An exciting year is approaching - we are eager to host European and International colleagues for the Maltese Presidency and create lasting results for the benefit of patients and consumers. We are planning unique events which shall have an impact on the history of regulatory sciences in the EU.

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 2016 the Malta Medicines Authority established a 2016-2020 Strategy. The initiative followed a strategic review carried out in 2015 and was based on over twenty workshops with internal and external stakeholders. The strategy is entrenched on five strategic goals:

- Optimised regulatory systems
- Better informed users
- Access to medicinal products
- Supporting innovation
- Organisational development

Open communication, collaboration and stakeholder engagement were strengthened and the Authority organised its second annual structured stakeholder meeting to share achievements and better understand the needs and expectations of its clients.

1.2 Capacity

The number of persons employed by the Malta Medicines Authority at the end of 2016 was forty nine (49) (Table 1).

	Female	Male
Management	4	5
Professional and technical	21	11
Administration	6	2
Total	31	18

Table 1: Employees at the Malta Medicines Authority

1.3 Learning and Development

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 2016, Malta Medicines Authority's employees attended and successfully completed thirty (30) 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 2016, the Malta Medicines Authority also supported its employees to read postgraduate studies through a flexible approach. Over thirty per cent of employees are currently undergoing Masters or Doctoral studies and ten per cent (10%) completed a Diploma in Leadership and Management. During 2016 the Authority achieved its target that all employees have at least a Level 5 qualification.

The Authority re-launched a traineeship programme to support individuals undergoing level eight studies (doctoral) in an effort to build a new generation of pharmaceutical leaders. Eighteen (18) professionals participated in this programme to date.

1.4 Quality, Simplification and Better Regulation

The Malta Medicines Authority processed a total of sixteen (16) policies and forty-four (44) 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 2016 in line with the four-year audit strategy. A total of thirteen (13) internal audits were performed in 2016 on the internal processes which resulted in a number of quality improvements. A total of thirty-one (31) quality improvements were processed by the Malta 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. Twenty-nine per cent (29%) 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, 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 a number of action points translating into continuous improvement and the continued suitability, adequacy, and effectiveness of the Quality Management System.

Four (4) simplification actions were prioritised for 2016. These were identified and prioritised in line with customer feedback. The first action was the introduction of new IT system for financial statements. The statements are now being sent automatically, thus reducing the processing time, risk of human errors and debtors are receiving the invoice according to ageing periods. The second action was to eliminate the requirement for submission of type IA_{IN} variations related to Qualified Person Responsible for Pharmacovigilance (QPPV) and location of Pharmacovigilance system master file (PSMF) as these can be reported through the Article 57 database of the European Medicines Agency. The third action was the introduction of the joint Direct Healthcare Professional Communications (DHPC). In this process, when more than one marketing authorisation holder is obliged to circulate the same DHPC or more than one product is the subject of a DHPC, then Marketing Authorisation Holders may request the service of the Authority to circulate the letter on their behalf. This results in reduction in processing and approval time of the communication letters and the medicinal product can be made available on the market in lesser time with the updated information. The fourth action was the scanning project, were all the Authority's documentation are now scanned. This is leading to easier access to information which is resulting in reduction of processing time. Further enhancement in the receipt of electronic submissions with the reduction in paper submissions was achieved. Applicants are being encouraged as much as possible to use the Common European Submission Portal (CESP) and no paper submissions are being requested.

All four actions are within timelines and budget and have led to simplification for the benefit of stakeholders.

1.5 Active Participation at EU and International Level

During 2016, the Malta Medicines Authority has participated actively in European and International fora. Malta Medicines Authority officers participated in one hundred and seventy one (171) 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.

In 2016, the Malta Medicines Authority strengthened its participation in an EU Funded Project. The Project entitled Strengthening Collaboration for Operating Pharmacovigilance in Europe (Scope) Joint Action 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 2016, the Authority followed up data at EU level and actively participated in a project status update.

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 an abstract of the audited financial statements to enhance openness and transparency.

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

2.1 Scientific Advice

In 2016, Malta was the Rapporteur evaluating a type II variation of an authorised medicinal product for a new significant orphan indication. This variation took into consideration the Scientific Advice provided by the Malta Medicines Authority in 2015. The Authority is open to extend its scientific advice function.

2.2 Assessment and Licensing

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

During 2016, the Malta Medicines Authority continued with activities towards national and European procedures for the registration of new medicinal products. It has enhanced its activities within the European network by increasing the number of procedures where Malta has a lead role. The overall number of these pre-authorisation procedures in 2016 was thirty nine (39) with an increase in the Mutual Recognition and Decentralised Procedures (MRP/DCP) and a slight decrease as rapporteur in the Centralised procedure (Figure 1). Post-authorisation activities also increased in number. It is planned to continue to increase the numbers of these procedures as Malta focuses to attract more applicants to choose it as a Reference Member State. With planned enhanced capacity and the focus on the competence of its staff, the Authority will be able to carry out these procedures for a more diverse range of medicinal products. Experienced assessors and other staff have been recruited for the technical coordination and assessment of dossiers for these procedures to ensure adequate capacity to handle more procedures. Additionally, experienced experts have been included in the Authority database to cover certain areas where further competence is required.

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. Each procedure is also presented at the Medicines Review Committee, where technical or regulatory decisions are endorsed for a final position for Malta. There was an increase of five per cent (5%) in the number of new applications received through European procedures with Malta as Reference Member State or rapporteur in 2016. Since 2009, a slow but steady increase with some fluctuations was reported in the total number of procedures where Malta is lead member state. This was followed by a marked increase in 2014 and continued increase thereafter in the number of submissions (Figure 1). This fact has also resulted in a continuous increase in the volume of post-authorisation procedures for these marketing authorisations (Figure 2). It is envisaged that the number of post-authorisation procedures will increase over the next years as the number of new applications finalised increases. 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. It has also helped to enhance the competence of the Malta Medicines Authority assessors, whilst giving some insight into how other competent authorities manage their processes and resources. During 2016, more procedures, including assessment of new dossiers was taken up by the Maltese assessors on behalf of the MEB. New Maltese assessors are being trained by Dutch assessors to enhance their competence.

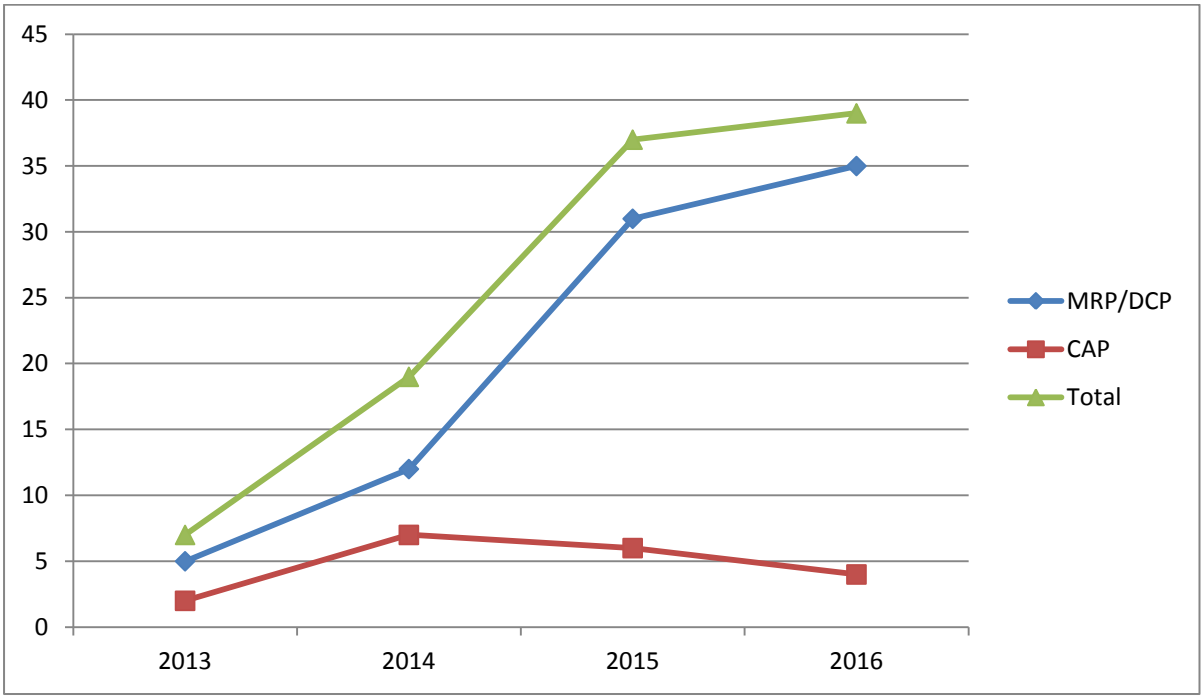

Figure 1: Number of procedures received by the Malta Medicines Authority with Malta as Reference Member State or rapporteur in the period 2013-2016

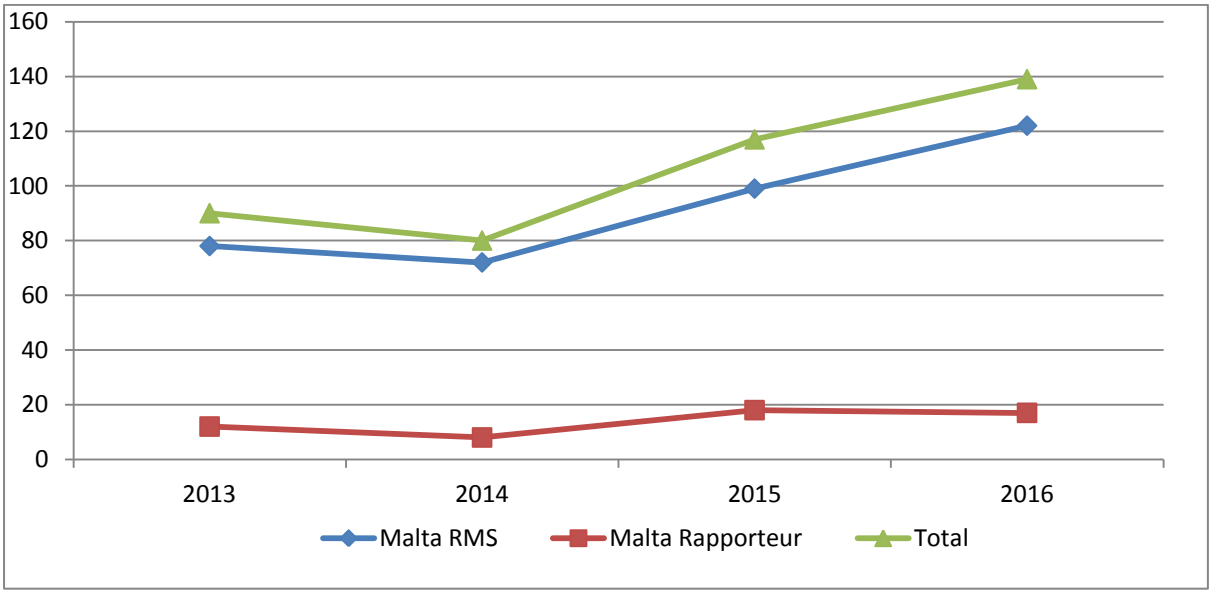

Figure 2: Number of variations received for European procedures with Malta as Reference Member State or rapporteur in the period 2013 – 2016

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

The numbers of applications for new national authorisations for the approval of new products received and finalised are shown in Figure 3. These submissions include marketing authorisations, authorisations in accordance with article 126a and parallel import licences.

2.2.3 Post authorisation procedures

Nationally authorised products

A number of post-authorisation procedures are received each year including variations, notifications, renewals and withdrawals. The information in Figure 4 refers to withdrawal applications for authorisations and licences.

Figures 5 and 6 include other national post-authorisation procedures, including variations, notification in accordance with article 61(3) and other notifications of change.

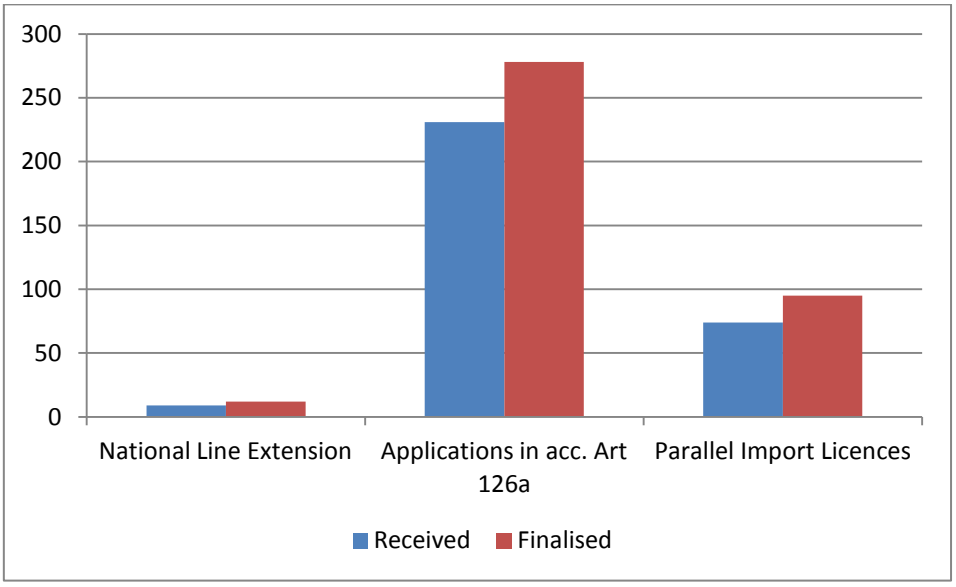

Figure 3: National applications received and finalised in 2016

Figure 4: Withdrawal applications for marketing authorisations and licences

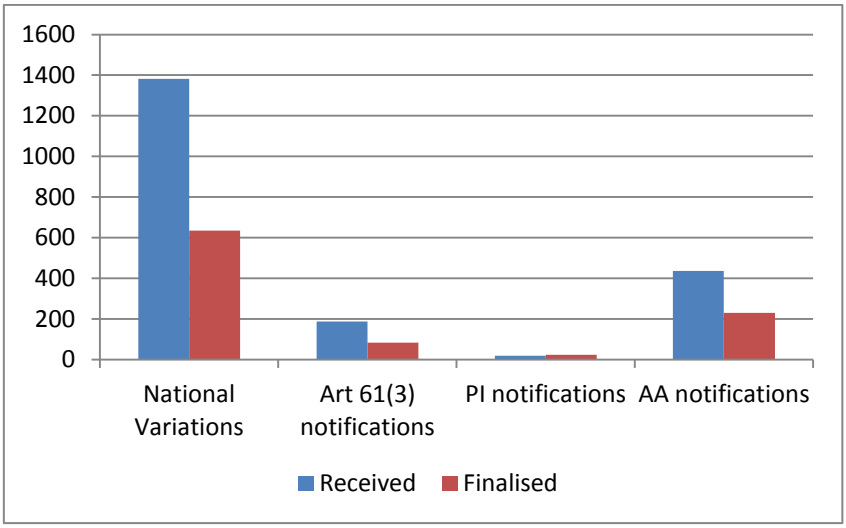

Figure 5: National variations and notifications

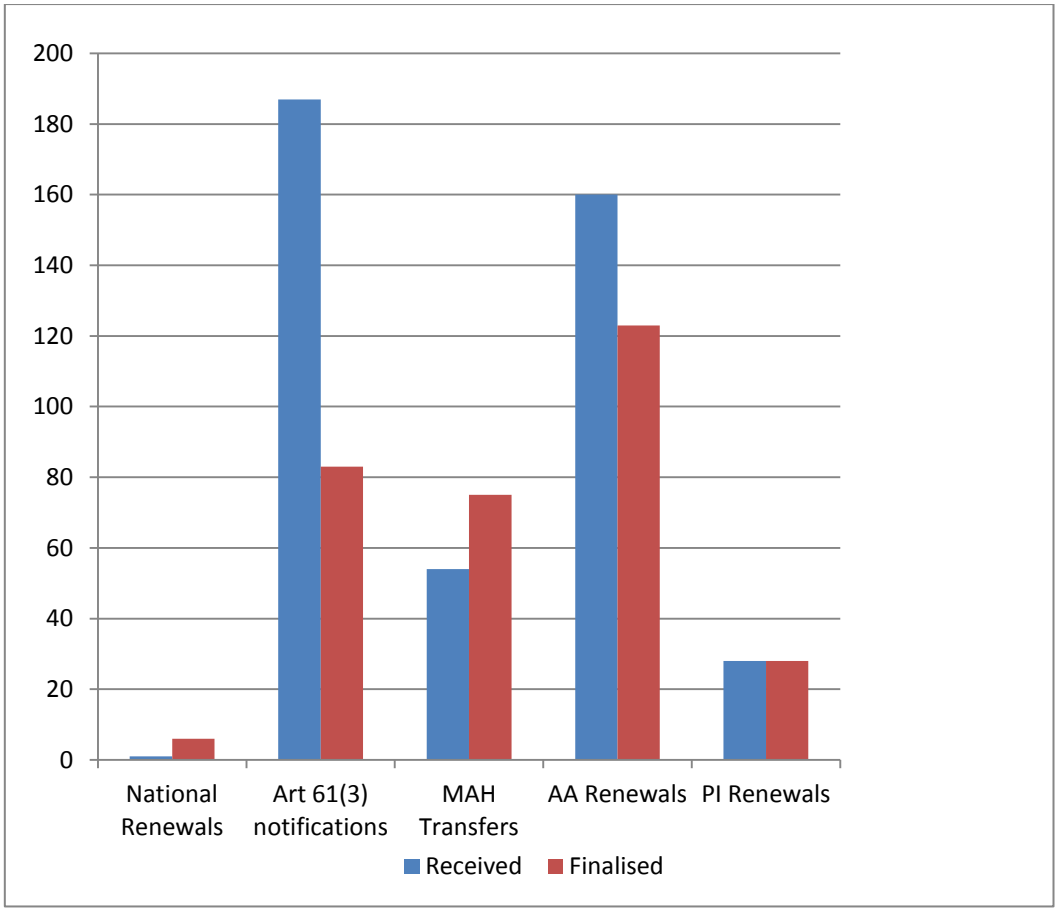

Figure 6: National post-authorisation procedures (other)

Products authorised through the Mutual Recognition and Decentralised procedures

Marketing authorisations as a result of Mutual Recognition Procedures and Decentralised procedures with Malta as Concerned Member State are shown in Figure 7.

European Post-authorisation procedures

Variations, renewals and notifications for procedures received through the European procedure route are shown in Figures 8 and 9.

Paediatric Data Assessment (Article 45 and Article 46 of the Paediatric Regulation)

During 2016, Malta was rapporteur for two European work-sharing procedures in accordance with article 45 of European Regulation 1901/2006. This resulted in changes to the information on the products, including the package leaflet of medicines, to enhance safe use in children.

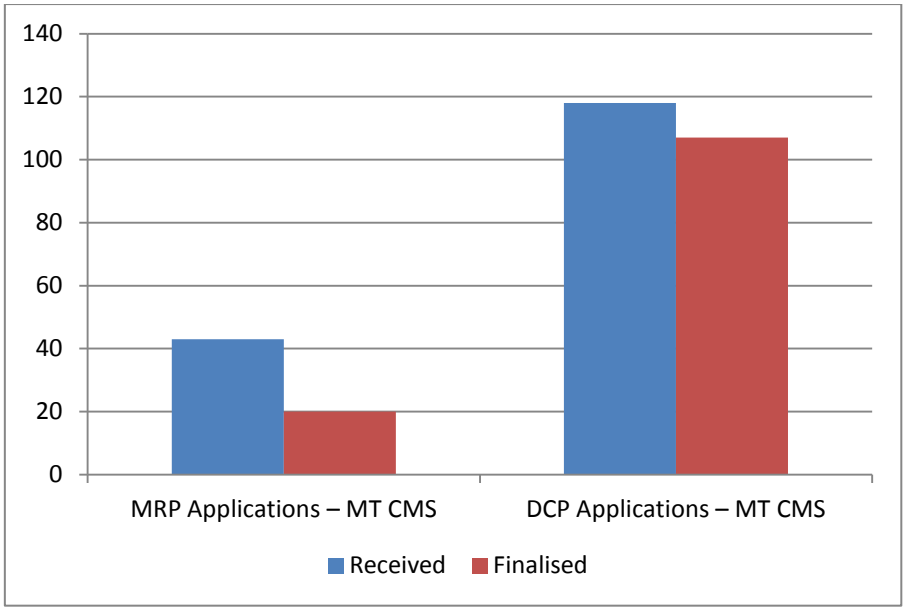

Figure 7: Number of MAs as a result of MRP and DCP (MT CMS)

Figures 8 and 9: Post-authorisation procedures and Variation applications received and finalised through European procedures (MT CMS)

2.2.4 The Medicines Review Committee

The Medicines Review Committee within the Malta Medicines Authority continued to meet regularly to discuss regulatory and technical issues relating to ongoing applications for marketing authorisations for medicinal products, both national and European. These include applications for marketing authorisation and post-authorisation activities (e.g. variations, renewals, pharmacovigilance issues) as well as clinical trial applications and European work-sharing procedures. Other items presented include feedback from external technical and regulatory meetings attended by members of the Medicines Review Committee and other staff members (e.g. Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh), Pharmacovigilance Risk Assessment Committee (PRAC), Paediatric Committee (PDCO) and Committee for Medicinal Products for Human Use (CHMP) and its working parties) Issues relating to the local market, such as safety issues following on from European referrals are discussed. Meetings are held on a monthly basis.

2.2.5 Prescription Status Working Group

During 2016, the Prescription Status Working Group continued to work on the harmonisation of legal classification (prescription versus non-prescription of medicinal products). Therapeutic groups prioritised for harmonisation included pain relief products including non-steroidal anti-inflammatory drugs, mucolytics, cold and flu products and antihistamines. The work will continue during 2017 for other therapeutic groups where harmonisation is required. This is to ensure that products that are similar in indications, posology, and other criteria for establishing legal status are harmonised.

2.3 Pharmacovigilance

Safety of medicines is a priority area for the 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 Medicines Authority. The 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 2016, an additional staff member obtained the necessary E.U. certification to enable input of Adverse Drug Reactions (ADR) within the Eudravigilance database as well as 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 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 2016, the Authority worked to provide a web based side effect reporting form for patients and consumers. This reporting form is hosted on the Malta Medicines Authority's website.

In 2016, the MMA finalised a new two (2) year ADR promotion strategy. As part of this strategy, the first output was a social media campaign to promote reporting of suspected medicines side effects. This campaign was part of an EU-wide awareness initiative and helped to strengthen the system of ADR reporting in Malta. Another output was the updating of the national Guideline for pharmacovigilance obligations, which is targeted to be finalised in Q1 2017. In relation with ADR reporting, 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 2016. This measure continued to reduce the administrative burden of parallel reporting for Marketing Authorisation Holders and the Medicines Authority.

The Malta Medicines Authority has also published a review in Expert Opinion on Drug Safety. This review maps the implementation of pharmacovigilance activities in Malta since accession in the EU in mid 2004 and discusses the challenges encountered while setting up adequate and effective systems to fulfil its legal mandate. Areas reviewed are those around ADR reporting, promotion and safety communications including rapid alerts and recalls, direct healthcare professional communications, risk minimisation measures and safety circulars and quality systems. Overall, within a ten year period, 3 EU directives on pharmacovigilance were implemented by our agency. Despite limitations to resources, based on a

prioritised implementation, the legislation provisions are now fully operational with a good level of sustainability. Lessons learnt from this process were also discussed. Another output was the analysis of the promotional efforts carried out by the Authority on the ADR reporting system within the Medical School in 2015. In addition in 2016, feedback was obtained from stakeholders through a survey on opinions of doctors and pharmacists regarding factors leading to medication errors. This survey is part of the Authority's attempt to improve the medication error reporting system of the Medicines Authority.

A total of one hundred and eighteen (118) Individual Case Summary Reports (ICSRs) were registered over 2016. Each of these cases detailed at least one adverse drug reaction to the medicinal product concerned thus resulting in a total of six hundred and thirteen (613). Figure 10 gives a breakdown of these adverse drug reactions according to system organ classification. Each case report received at the 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 2016) 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 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.

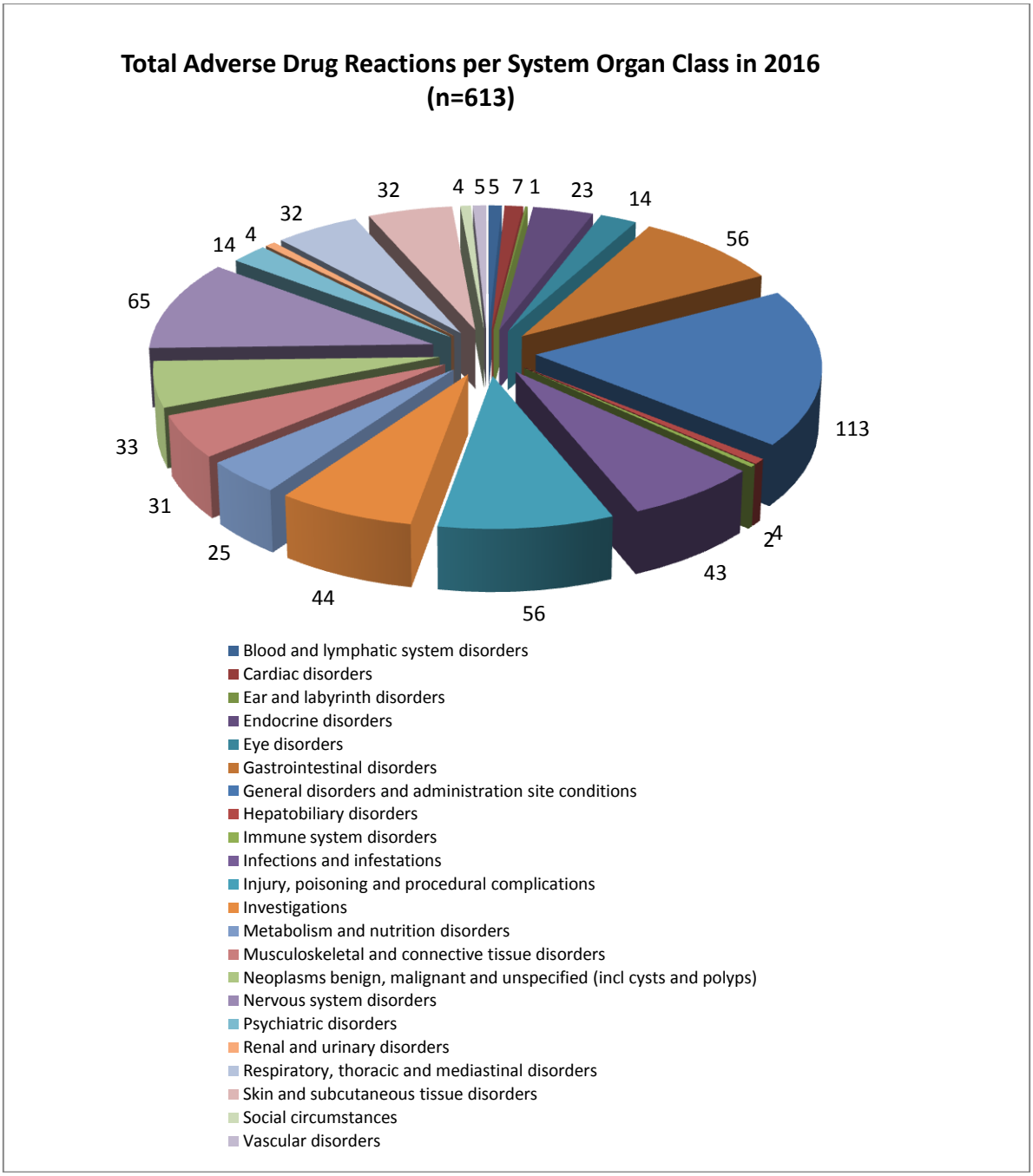

Figure 10: Distribution of Adverse Drug Reactions according to System Organ Classification in 2016

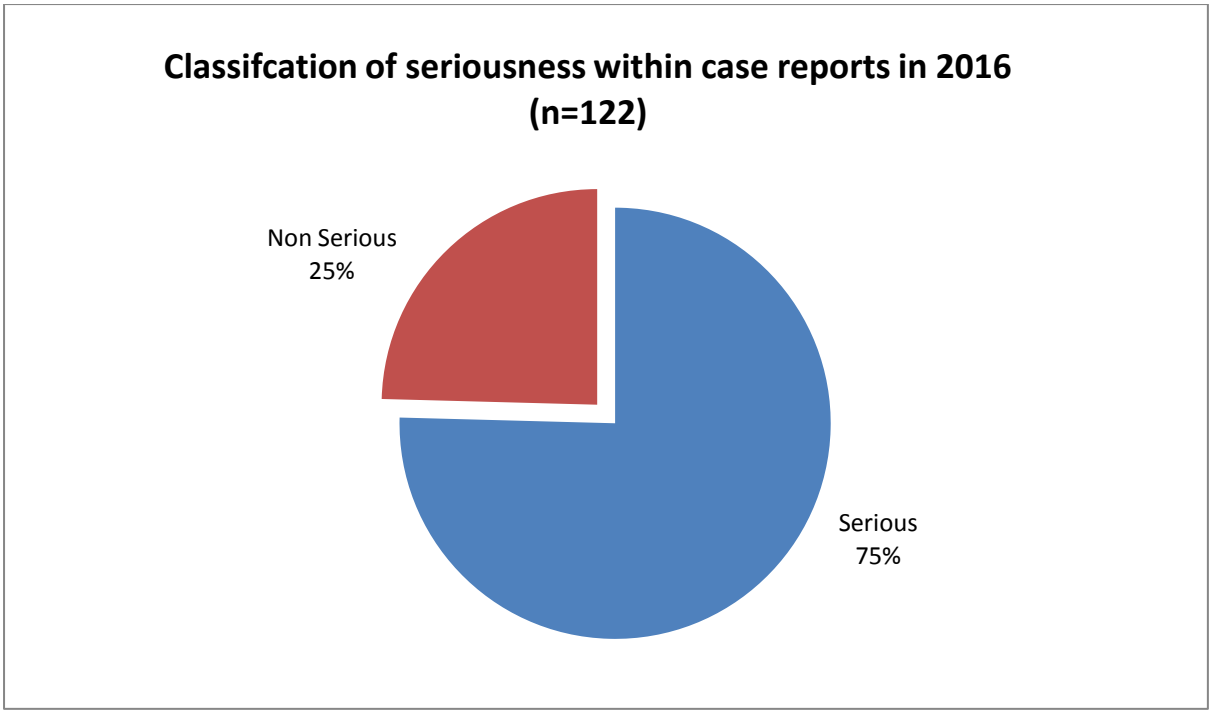

Figure 11: Frequency of ICSRs according to seriousness in 2016 (n=122)

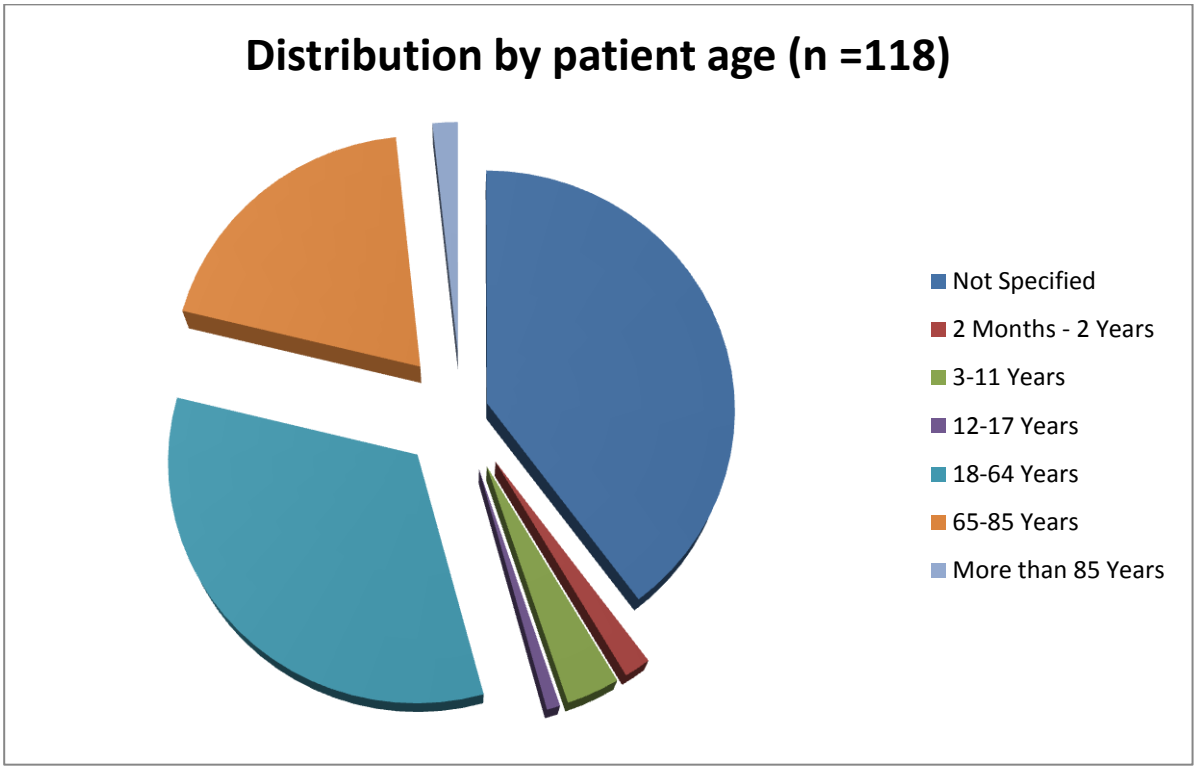

Figure 12: Percentage distribution of case safety reports according to patient age in 2016 (n=118 patients)

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 2016 the Malta Medicines Authority continued implementing the SMS notification service (a migration in IT platform was carried out in 2016 to deliver this service) whereby subscribed medical and healthcare professionals can 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 2 below gives the distribution of reviews, communications and approvals which the Medicines Authority handled over 2016.

The joint DHPC focussing on initiating a new procedure for a joint DHPC service was maintained in 2016. 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 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 the collection, assessment and reporting of local adverse drug reactions, and submission requirements for Periodic Safety Update Reports (PSURs), ADR reporting requirements and Risk Minimisation Measures (RMMs) (Table 3).

In March 2016, the Malta Medicines Authority worked in updating its Guidance Notes document following new standards that have been implemented at the level of the EMA (namely in the area of PSURs and QPPV details which are directly submitted to the EMA from MAHs and directly accessed by the Medicines Authority from the article 57 database).

At an EU level, 2016 saw the continuation of centralised PSUSA assessments and over 2016 the Medicines Authority was involved in a PSUSA evaluation for Nitrous Oxide. All submissions of PSURs became mandatory via the PSUR repository during mid 2016. The Medicines Authority accesses PSURs via the competent authority interface to carry out PSUR assessments.

Documents Received	Number of submissions
Annual Reassessments	1
Direct Healthcare Professional Communications	19
Joint DHPCs	2
Safety Circulars	17
Risk Minimisation Measures	108
Rapid Alert	0
Non Urgent Information	8

Table 2: Pharmacovigilance and safety issue reviews and communications - 2016

		Number
1	**PSURs**	34
2	**ADR reporting**	24
3	**National PhV legislation and requirements locally**	11
4	**RMMs / Educational material**	10
5	**Local contact person for Pharmacovigilance**	5
6	**Literature monitoring requirements**	4
7	**RMP submissions**	4
8	**QPPV**	3
9	**Article 57 database**	3
10	**DHPC distribution**	3
11	**Queries related to relocation of premises**	3
12	**Clinical Trials Requirements**	2
13	**Requests for ADR related data**	2
14	**DSURs**	1
15	**Outsourcing of pharmacovigilance activities**	1
16	**Pharmacovigilance Fees**	1
17	**XEVMPD**	1
18	**Safety Circulars**	1
19	**Pharmacovigilance of Medical devices**	1
	Total	114

Table 3: Pharmacovigilance related queries in 2016 (n=114)

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, 2016 saw another year of fulfilling legislative obligations and updating procedures to maintain requirements with the new directive.

In 2016, Malta participated as lead member state in a Period Safety Update Report Single Assessment Procedure (PSUSA).

2.4 Classification of Borderline Products

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 BCC meets as required and feedback is sought from all members as well as the herbals expert in line with an updated simplified process. In 2016, seventeen (17) applications for classification of borderline products were received, out of which fifteen (15), eighty eight per cent (88%), were considered as non-medicinal, one (1), six per cent (6%), was considered medicinal and one (1) application, six per cent (6%) was still being reviewed at the end of the reporting period.

During 2016, the BCC continued to work with the Malta Consumer and Competition Affairs Authority (MCCAA) to strengthen the system for the classification of products. This included an updated list of herbal preparations which was prepared by the Malta Medicines Authority and published on the MCCAA website to help companies determine whether their products fell in the medicinal or non-medicinal product category. This was done to reduce the bureaucracy for companies when seeking an opinion on the classification of products before placing them on the market in Malta. Companies can refer to the list and decide whether to go directly to the MCCAA in the case it is clearly a food supplement and to the Malta Medicines Authority if it was clearly a medicinal product. In case of doubt, cases were referred to the BCC.

2.5 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 2016, two (2) advertising complaints were registered with the Authority.

3. Medicines Intelligence and Access

3.1 Medicines Intelligence and Access

The Malta Medicines Authority expanded proactively its activities with the strengthening of the Medicines Intelligence and Access Unit. 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 will also have access to essential medicines with a reasonable price when compared to other countries. This is leading to a reduction in prices of medicines for the benefit of consumers which in 2016 has led to twenty-nine (29) medicines price reduction.

During 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 2016, a list of thirty-three (33) generic medicines has been published for the consumers.

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 Authority also 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 2016 the Malta Medicines Authority carried out 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; four (4) for non sterile solid dose manufacturers; two (2) for medicinal gases manufacturers; one (1) GMP certified laboratory; six (6) inspections for manufacturing authorisation (MAs) for repackaging and re-labelling / partial manufacturing operations; five (5) inspections for MAs of importation activity.

A total of forty two (42) MAs administrative variation applications were processed in 2016 for manufacturers and importers. Two (2) variations with inspection were carried out. There were three (3) Inspections Review Group meeting held throughout 2016 where three (3) cases were discussed and decided upon.

During 2016, the Malta Medicines Authority received one hundred and fifty four (154) rapid alerts and GMP non- compliance notifications, which were investigated and out of which nine (9) resulted in recall of medicinal products from the local market.

During the year under review, the MMA continued to carry out Good Manufacturing Inspections in countries outside the European Union. Seven (7) inspections have been carried out throughout 2016. Another two (2) applications which were processed and prepared for inspection in 2016, were postponed by the applicant for 2017. Through this process, the MMA is facilitating the possibility that more companies would be in a better position to import medicinal products within the European Union. Additionally, these procedures attract new revenue to the Authority and provide exposure to different manufacturing facilities to the inspectors of the MMA.

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 2016, the MMA has also fulfilled its Good Distribution Practice (GDP) inspection plan where fifty five (55) GDP inspections were carried out. During 2016, eight (8) applications for new wholesale dealing licences were submitted, which were all inspected and eventually licensed. Thirty seven (37) variation applications for wholesale dealing authorisations were

processed in 2016, out of which six (6) required an inspection. In 2016, there were five (5) inspections for active pharmaceutical ingredients importers and distributors out of which two (2) were new applications.

4.3 Pharmacies

Pharmacies are inspected on a two (2) year cycle. During 2016, the MMA carried out a total of seventy-eight (78) retail community pharmacy inspections, and one (1) private hospital pharmacy.

There were another eleven (11) pharmacy inspections following variation applications for pharmacy premises transfers or alterations which were carried out, whilst thirty seven (37) administrative variations for pharmacy licences were processed.

4.4 Clinical Trials and Pharmacovigilance Inspections

During 2016, in view that no new Clinical Trials applications were submitted to the Malta Medicines Authority, no inspections for this activity were required.

Two (2) Pharmacovigilance (PhV) inspections were carried out against the national and EU legislation and the Malta 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 Malta Medicines Authority. In this regard, the Local Market Surveillance Plan for 2016 was closed positively.

4.6 Enforcement of legislation

During 2016 the Malta Medicines Authority worked upon six (6) 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) met once in 2016.

In 2016 there were ten (10) court case sittings which were attended as witnesses concerning pharmacy issues, police investigations and two ongoing enforcement cases.

4.7 Granting of Qualified Persons Status

In 2016, the Medicines Authority received eight (8) new applications for the Qualified Person (QP) status. Eight (8) applicants were interviewed during 2016 and of these six (6) were approved as eligible for QP status.

4.8 Certificates of Pharmaceutical Products (CPPs)

During 2016, seventy six (76) Certificates of Pharmaceutical Products applications were received which were all issued.

Medicines Authority

Annual report and financial statements

for the year ended 31 December 2016

Contents

Medicines Authority

Report of the Chairperson/Chief Executive Officer for the year ended 31 December 2016

The Chairperson/Chief Executive Officer presents his report and the audited financial statements of the Medicines Authority for the year ended 31 December 2016.

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 medicinal products and pharmaceutical activities; the establishment of procedures and undertaking activities for the assessment of medicinal products; the inspection of pharmaceutical manufacturing and distributing activities and monitoring the use of medicinal 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.

This 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 EU.

Management of the Authority

In accordance with the Medicines Act 2003 (Cap 458) the Chairpersons/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 5. During 2016, the Authority earned a surplus of EUR 1,601,499 when compared to a surplus of EUR 996,857 in 2015. The increase in surplus of EUR 1,601,499 is mainly due to an increase in income of EUR 1,126,654, partly due to a one-off circumstance as per Note 5.

Medicines Authority

Report of the Chairperson/Chief Executive Officer for the year ended 31 December 2016 (continued)

Auditors

The auditors, Mazars Malta, have expressed their willingness to continue in office.

Approved by the Chairman / Chief Executive Officer on 9th February 2017.

Anthony Serracino Inglott
Chairman / Chief Executive Officer

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

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Independent auditors' report to the Ministry for Social Dialogue, Consumer Affairs and Civil Liberties (continued)

Responsibilities of the Chairperson/Chief Executive Officer

The Chairperson/Chief Executive Officer is responsible for the preparation of the financial statements that give a true and fair view in accordance with the International Financial Reporting Standards 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.

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Mazars Malta
Certified Public Accountants
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Independent auditors' report to the Ministry for Social Dialogue, Consumer Affairs and Civil Liberties

Report on the Audit of the financial statements

We have audited the accompanying financial statements of the Medicines Authority ("Authority") set out on pages 6 to 23 which comprise the statement of financial position as at 31 December 2016 and the statement of comprehensive income, statement of changes in equity and statement of cash flows for the year then ended and a summary of significant accounting policies and other explanatory notes.

Opinion

In our opinion, the accompanying financial statements present fairly, in all material respects, the financial position of the Authority as at 31 December 2016, and its financial performance and its cash flows for the year then ended in accordance with International Financial Reporting Standards as adopted by the EU.

Basis for Opinion

We conducted our audit in accordance with International Standards on Auditing. Our responsibilities under those standards are further described in the Auditors' Responsibilities for the Audit of the Financial Statements section of our report. We are independent of the Authority in accordance with the International Ethics Standards Board for Accountants' Code of Ethics for Professional Accountants together with the ethical requirements that are relevant to our audit of the financial statements in accordance with the Accountancy Profession Directive issued in terms of the Accountancy Profession Act (Cap. 281) in Malta, and we have fulfilled our other ethical responsibilities in accordance with these requirements and the IESBA Code. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

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. Our opinion on the financial statements does not cover this information, including the Chairperson/Chief Executive Officer's report. In connection with our audit of the financial statements, our responsibility is to read the other information 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.

With respect to the Chairperson/Chief Executive Officer's Report, we also considered whether the 's Report includes the disclosures required by Article 177 of the Maltese Companies Act (Cap. 386). Based on the work we have performed, in our opinion:

- the information given in the Chairperson/Chief Executive Officer's report for the financial year for which the financial statements are prepared is consistent with the financial statements; and
- the Chairperson/Chief Executive Officer's report has been prepared in accordance with the Maltese Companies Act (Cap.386).

In addition, in light of the knowledge and understanding of the Authority and its environment obtained in the course of the audit, we are required to report if we have identified material misstatements in the Chairperson/Chief Executive Officer's report. We have nothing to report in this regard.

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Independent auditors' report to the Ministry for Social Dialogue, Consumer Affairs and Civil Liberties (continued)

Auditors' Responsibilities for the Audit of the Financial Statements (continued)

- 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 auditors' 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 auditors' report. However, future events or conditions may cause the Authority to cease to continue as a going concern.

- 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.

We also provide those charged with governance with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

Report on Other Legal and Regulatory Requirements

Under the Maltese Companies Act (Cap. 386) we are required to report to you if, in our opinion:

- We have not received all the information and explanations we require for our audit.
- Adequate accounting records have not been kept, or that returns adequate for our audit have not been received from branches not visited by us.
- The financial statements are not in agreement with the accounting records and returns.

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

This copy of the audit report has been signed by
Anthony Attard (Partner) for and on behalf of

Mazars Malta
Certified Public Accountants
Attard

9th February 2017

Medicines Authority

Statement of comprehensive income
For the year ended 31 December 2016

	Notes	2016 EUR	2015 EUR
Income	5	**3,955,173**	2,828,519
Expenditure			
Staff costs	6	**(1,542,765)**	(1,297,743)
Amortisation and depreciation		**(61,087)**	(23,733)
Audit fee		**(2,360)**	(2,360)
Other operating expenses		**(747,462)**	(507,826)
Operating surplus for the year before taxation		**1,601,499**	996,857
Income tax expense	7	**-**	-
Surplus for the year		**1,601,499**	996,857
Other comprehensive income for the year		**-**	-
Total comprehensive income for the year		**1,601,499**	996,857

The notes on pages 10 to 23 are an integral part of these financial statements.

Medicines Authority

Statement of financial position
As at 31 December 2016

	Notes	2016 EUR	2015 EUR
ASSETS			
Non-current assets			
Intangible assets	8	**7,736**	13,366
Tangible assets	9	**157,022**	199,075
		164,758	212,441
Current assets			
Trade and other receivables	10	**1,628,548**	754,437
Cash and cash equivalents		**2,677,703**	1,153,226
		4,306,251	1,907,663
Current liabilities			
Trade and other payables	11	**1,501,331**	751,925
Net current assets		**2,804,920**	1,155,738
Net assets		**2,969,678**	1,368,179
RESERVES			
Accumulated fund		**2,969,678**	1,368,179

The notes on pages 10 to 23 are an integral part of these financial statements.

The financial statements on pages 6 to 23 were approved by the Chairman / Chief Executive Officer on 9th February 2017;

Anthony Serracino Inglott
Chairman / Chief Executive Officer

Medicines Authority

Statement of changes in equity for the year ended 31 December 2016

	Accumulated fund EUR
Balance at 1 January 2015	**371,322**
Changes in equity for 2015	
Surplus for the year	996,857
Balance at 31 December 2015	**1,368,179**
Changes in equity for 2016	
Surplus for the year	1,601,499
Balance at 31 December 2016	**2,969,678**

The notes on pages 10 to 23 are an integral part of these financial statements.

Medicines Authority

Statement of cash flows
for the year ended 31 December 2016

	Notes	2016 EUR	2015 EUR
Cash flows from operating activities			
Surplus before tax		**1,601,499**	996,857
Amortisation		**9,751**	8,721
Depreciation		**51,336**	15,012
Provision for bad debts		**27,474**	13,516
Movement in working capital:			
Trade and other receivables		**(901,585)**	(317,117)
Trade and other payables		**749,406**	74,293
Net cash generated from operating activities		**1,537,881**	791,282
Cash flows from investing activities			
Purchase of intangible assets		**(4,121)**	(4,492)
Purchase of tangible fixed assets		**(9,283)**	(203,672)
Net cash used in investing activities		**(13,404)**	(208,164)
Net movement in cash and cash equivalents		**1,524,477**	583,118
Cash and cash equivalents at the beginning of the year		**1,153,226**	570,108
Cash and cash equivalents at the end of the year	12	**2,677,703**	1,153,226

The notes on pages 10 to 23 are an integral part of these financial statements.

Notes to the financial statements for the year ended 31 December 2016

1 Basis of preparation

The financial statements have been prepared on the historical cost basis and in accordance with the requirements of the Medicines Act, 2003 (Cap 458) and International Financial Reporting Standards, as adopted by the EU. The significant accounting policies adopted are set out below.

2 Significant accounting policies

Intangible assets

Website

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 periods and is charged to profit or loss.

Plant and equipment

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

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 or loss in the period of derecognition.

2 Significant accounting policies (continued)

Depreciation

Depreciation commences in the year when the depreciable assets are available for use and is charged to profit or 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:

Furniture and fittings	-	10% per annum
Motor vehicles	-	20% per annum
Office and computer equipment	-	25% per annum
Lease hold improvements	-	33% per annum

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.

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 or loss.

Financial assets and financial 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 expires.

(i) 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.

(ii) Trade and other payables

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

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 the 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 rate 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.

2 Significant accounting policies (continued)

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 reverses, 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.

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:

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

RMS and EMA Procedures for rapporteurships for initial authorisation

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

Government subvention

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

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 lessee. 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.

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 Significant accounting policies (continued)

Currency translation

The financial statements of the Authority are presented in its functional currency, the EURO, being the currency of the primary economic environment in which the Authority operates. Transactions denominated in currencies other than the functional currency are translated at the exchange rates ruling on the date of transaction. Monetary assets and liabilities denominated in currencies other than the functional currency are re-translated to the functional currency at the exchange rate ruling at year-end. Exchange differences arising on the settlement and on the re-translation of monetary items are dealt with in profit or loss.

Cash and cash equivalents

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

3 Judgements in applying accounting policies and key sources of estimation uncertainty

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.

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 Changes in accounting policies and disclosures

The accounting policies adopted are consistent with those of the previous financial period except as follows:

The Authority has adopted the following new and amended IFRS and IFRIC interpretations as of 1 January 2016:

- IAS 1 Amendments – Disclosure Initiative (effective from 1 January 2016)

  The amendments to IAS 1 give some guidance on how to apply the concept of materiality in practice. The adoption of the amendments did not have material impact on the Authority's financial statements.

- Annual Improvements to IFRSs 2012 – 2014 Cycle (effective from 1 January 2016)

  The *Annual Improvements to IFRSs 2012-2014 Cycle* include a number of amendments to various IFRSs, which are summarised below.

  The amendments to IFRS 5 introduce specific guidance in IFRS 5 for when an entity reclassifies an asset (or disposal group) from held for sale to held for distribution to owners (or vice versa). The amendments clarify that such a change should be considered as a continuation of the original plan of disposal and hence requirements set out in IFRS 5 regarding the change of sale plan do not apply. The amendments also clarify the guidance for when held-for-distribution accounting is discontinued.

4 Changes in accounting policies and disclosures (continued)

The accounting policies adopted are consistent with those of the previous financial period except as follows: (continued)

The amendments to IFRS 7 provide additional guidance to clarify whether a servicing contract is continuing involvement in a transferred asset for the purpose of the disclosures required in relation to transferred assets.

The amendments to IAS 19 clarify that the rate used to discount post-employment benefit obligations should be determined by reference to market yields at the end of the reporting period on high quality corporate bonds. The assessment of the depth of a market for high qualify corporate bonds should be at the currency level (i.e. the same currency as the benefits are to be paid). For currencies for which there is no deep market in such high quality corporate bonds, the market yields at the end of the reporting period on government bonds denominated in that currency should be used instead.

The application of these amendments did not have a material effect on the Authority's financial statements.

- IAS 27 Amendments – Equity Method in Separate Financial Statements (effective from 1 January 2016)

The amendment to IAS 27 is a narrow-scope adjustment to restore the option to use the equity method of accounting in separate financial statements. The application of this amendment did not have a material impact on the Authority's financial statements.

- IAS 16 and IAS 41 Amendments – Bearer Plants (effective from 1 January 2016)

The amendments to IAS 16 and IAS 41 define a bearer plant and require biological assets that meet the definition of a bearer plant to be accounted for as property, plant and equipment in accordance with IAS 16, instead of IAS 41. The produce growing on bearer plants continues to be accounted for in accordance with IAS 41.

The application of these amendments to IAS 16 and IAS 41 did not have a material impact on the Authority's financial statements as the Authority is not engaged in agricultural activities.

- IAS 16 and IAS 38 Amendments – Clarification of Acceptable Methods of Depreciation and Amortisation (effective from 1 January 2016)

The amendments to IAS 16 prohibit entities from using a revenue-based depreciation method for items of property, plant and equipment. The amendments to IAS 38 introduce a rebuttable presumption that revenue is not an appropriate basis for amortisation of an intangible asset. This presumption can only be rebutted in the following two limited circumstances:

4 Changes in accounting policies and disclosures (continued)

The accounting policies adopted are consistent with those of the previous financial period except as follows: (continued)

a) when the intangible asset is expressed as a measure of revenue; or

b) when it can be demonstrated that revenue and consumption of the economic benefits of the intangible asset are highly correlated.

The amendments apply prospectively for annual periods beginning on or after 1 January 2016. Currently, the Authority uses the straight-line method for depreciation and amortisation for its property, plant and equipment, and intangible assets respectively. The Chairperson/Chief Executive Officer of the Authority believe that the straight-line method is the most appropriate method to reflect the consumption of economic benefits inherent in the respective assets and accordingly, these amendments to IAS 16 and IAS 38 had no material impact on the Authority's financial statements.

- IFRS 11 Amendments – Accounting for Acquisition of interest in Joint Operations (effective from 1 January 2016)

The amendments to IFRS 11 provide guidance on how to account for the acquisition of a joint operation that constitutes a business as defined in IFRS 3 *Business Combinations*. Specifically, the amendments state that the relevant principles on accounting for business combinations in IFRS 3 and other standards (e.g. IAS 12 *Income Taxes* regarding the recognition of deferred taxes at the time of acquisition and IAS 36 *Impairment of Assets* regarding impairment testing of a cash- generating unit to which goodwill on acquisition of a joint operation has been allocated) should be applied. The same requirements should be applied to the formation of a joint operation if and only if an existing business is contributed to the joint operation by one of the parties that participate in the joint operation.

A joint operator is also required to disclose the relevant information required by IFRS 3 and other standards for business combinations.
The amendments should be applied prospectively to acquisitions of interests in joint operations (in which the activities of the joint operations constitute businesses as defined in IFRS 3) occurring from the beginning of annual periods beginning on or after 1 January 2016. The application of these amendments to IFRS 11 had no impact on the Authority's financial statements.

- IFRS 10, IFRS 12 and IAS 28 Amendments – Investment Entities: Applying the Consolidation Exemption (effective from 1 January 2016)

The amendment clarifies that the exemption from preparing consolidated financial statements for an intermediate parent entity is available to a parent entity that is a subsidiary of an investment entity, even if that parent entity measure all of its subsidiaries at fair value. Consequently, amendments were also made to IAS 28 exemption from applying the equity method for entities that are subsidiaries and hold interest in associates and joint ventures.

4 Changes in accounting policies and disclosures (continued)

The accounting policies adopted are consistent with those of the previous financial period except as follows: (continued)

IASB also clarified that the requirements for an investment entity to consolidated a subsidiary providing services related to its investment activities applies only to subsidiaries that are not themselves investment entities.

In applying the equity method to an associate or joint venture that is an investment entity, an investor may retain the fair value measurements that the associate or joint venture used for its subsidiaries.

The IASB has clarified that an investment entity that measures all its subsidiaries at fair value should provide the disclosures required by IFRS 12, Disclosures of interest in other entities.

The amendments require retrospective application and are effective for periods beginning on or after 1 January 2016. The application of these amendments had no impact on the Authority's financial statements.

Standards, interpretations and amendments to published standards as adopted by the EU that are not yet effective for financial periods beginning on 1 January 2016

Up to the financial position date, certain new standards, amendments and interpretations to existing standards have been published but are not yet effective for the current reporting period and which the Authority has not yet adopted. These are as follows:

- IFRIC 19: (Amendments arising from IFRS9) – Extinguishing Financial Liabilities with Equity Instruments (effective on adoption of IFRS 9)
- IFRS 9 – Financial instruments (effective from 1 January 2018)

IFRS 9 issued in November 2009 introduced new requirements for the classification and measurement of financial assets. IFRS 9 was subsequently amended in October 2010 to include requirements for the classification and measurement of financial liabilities and for de-recognition, and in November 2013 to include the new requirements for general hedge accounting. Another revised version of IFRS 9 was issued in July 2014 mainly to include a) impairment requirements for financial assets and b) limited amendments to the classification and measurement requirements by introducing a 'fair value through other comprehensive income' (FVTOCI) measurement category for certain simple debt instruments.

Key requirements of IFRS 9:

- all recognised financial assets that are within the scope of IAS 39 Financial Instruments: Recognition and Measurement are required to be subsequently measured at amortised cost or fair value. Specifically, debt investments that are held within a business model whose objective is to collect the contractual cash flows, and that have contractual cash flows that are solely payments of principal and interest on the principal outstanding are generally measured at amortised cost at the end of subsequent accounting periods.

4 Changes in accounting policies and disclosures (continued)

Standards, interpretations and amendments to published standards as adopted by the EU that are not yet effective for financial periods beginning on 1 January 2016 (continued)

Debt instruments that are held within a business model whose objective is achieved both by collecting contractual cash flows and selling financial assets, and that have contractual terms that give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding, are generally measured at FVTOCI. All other debt investments and equity investments are measured at their fair value at the end of subsequent accounting periods. In addition, under IFRS 9, entities may make an irrevocable election to present subsequent changes in the fair value of an equity investment (that is not held for trading) in other comprehensive income, with only dividend income generally recognised in profit or loss;

- with regard to the measurement of financial liabilities designated as at fair value through profit or loss, IFRS 9 requires that the amount of change in the fair value of the financial liability that is attributable to changes in the credit risk of that liability is presented in other comprehensive income, unless the recognition of the effects of changes in the liability's credit risk in other comprehensive income would create or enlarge an accounting mismatch in profit or loss. Changes in fair value attributable to a financial liability's credit risk are not subsequently reclassified to profit or loss. Under IAS 39, the entire amount of the change in the fair value of the financial liability designated as fair value through profit or loss is presented in profit or loss;

- in relation to the impairment of financial assets, IFRS 9 requires an expected credit loss model, as opposed to an incurred credit loss model under IAS 39. The expected credit loss model requires an entity to account for expected credit losses and changes in those expected credit losses at each reporting date to reflect changes in credit risk since initial recognition. In other words, it is no longer necessary for a credit event to have occurred before credit losses are recognised; and

- the new general hedge accounting requirements retain the three types of hedge accounting mechanisms currently available in IAS 39. Under IFRS 9, greater flexibility has been introduced to the types of transactions eligible for hedge accounting, specifically broadening the types of instruments that qualify for hedging instruments and the types of risk components of non-financial items that are eligible for hedge accounting. In addition, the effectiveness test has been overhauled and replaced with the principle of an 'economic relationship'. Retrospective assessment of hedge effectiveness is also no longer required. Enhanced disclosure requirements about an entity's risk management activities have also been introduced.

4 Changes in accounting policies and disclosures (continued)

Standards, interpretations and amendments to published standards as adopted by the EU that are not yet effective for financial periods beginning on 1 January 2016 (continued)

- IFRS 15 – Revenue from contracts with customers (effective from 1 January 2018)

In May 2014, IFRS 15 was issued which establishes a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers. IFRS 15 will supersede the current revenue recognition guidance including IAS 18 *Revenue*, IAS 11 *Construction Contracts* and the related Interpretations when it becomes effective.

The core principle of IFRS 15 is that an entity should recognise revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Specifically, the Standard introduces a 5-step approach to revenue recognition:

- Step 1: Identify the contract(s) with a customer.
- Step 2: Identify the performance obligations in the contract.
- Step 3: Determine the transaction price.
- Step 4: Allocate the transaction price to the performance obligations in the contract.
- Step 5: Recognise revenue when (or as) the entity satisfies a performance obligation.

Under IFRS 15, an entity recognises revenue when (or as) a performance obligation is satisfied, i.e. when 'control' of the goods or services underlying the particular performance obligation is transferred to the customer. Far more prescriptive guidance has been added in IFRS 15 to deal with specific scenarios. Furthermore, extensive disclosures are required by IFRS 15.

The Chairperson/Chief Executive Officer of the Authority are assessing the impact that the adoption of the above standards would have on initial application.

Standards, interpretations and amendments issued by the International Accounting Standards Board (IASB) but not yet adopted by the European Union:

- IFRS 14 – Regulatory Deferral Accounts (EFRAG endorsement proves not yet launched)
- IFRS 16 - Leases
- IFRS 10 and IAS 28 Amendments – Sale or contribution of assets between an investor and its associate or joint venture (EFRAG endorsement process has been deferred indefinitely)
- IAS 12 Amendment – Recognition of deferred tax assets for unrealised losses
- IAS 7 Amendment – Disclosure initiative
- IFRS 15 Amendment – Clarification on revenue from contracts with customers

4 Changes in accounting policies and disclosures (continued)

Standards, interpretations and amendments issued by the International Accounting Standards Board (IASB) but not yet adopted by the European Union: (continued)

- IFRS 2 Amendment – Classification and measurement of share based payment transaction
- IFRS 4 Amendment – Applying IFRS 9, Financial Instruments, with IFRS 4, Insurance Contracts
- Annual improvements to IFRS Standards 2014 – 2016 Cycle
- IFRIC Interpretation 22 – Foreign currency transactions and advance consideration
- IAS 40 Amendments – Transfer of investment property

The Chairperson/Chief Executive Officer is assessing the impact that the adoption of these Financial Reporting Standards will have in the financial statements of the Authority in the period of initial application.

5 Revenue

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

Included in the 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.

6 Employee information

The average weekly number of persons employed by the Medicines Authority during the year was 48 (2015: 41). Staff costs for the year comprised: -

	2016 Number	2015 Number
Management	**9**	7
Technical staff	**29**	25
Administration	**10**	9
	48	41

	2016 EUR	2015 EUR
Management	**386,880**	238,981
Wages and salaries	**1,066,750**	983,132
Social security costs	**88,731**	75,630
	1,542,359	1,297,743

7 Taxation

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

8 Intangible asset

	Website EUR
Cost	
At 1 January 2015	30,390
Additions	4,492
At 31 December 2015	34,882
Additions	4,121
At 31 December 2016	**39,003**
Amortisation	
At 1 January 2015	12,795
Charges for the year	8,721
At 31 December 2015	21,516
Charges for the year	9,751
At 31 December 2016	**31,267**
Net book value	
At 31 December 2016	**7,736**
At 31 December 2015	13,366

9 Plant and equipment

	Furniture & fittings	Office and computer equipment	Motor Vehicles	Leasehold Improvements	Total
	EUR	EUR	EUR	EUR	EUR
Cost					
At 1 January 2015	29,150	11,707	-	-	40,857
Additions	1,816	35,556	16,300	-	53,672
At 31 December 2015	**30,966**	**47,263**	**16,300**	**-**	**94,529**
Additions	43,553	45,427	18,470	51,833	159,283
At 31 December 2016	**74,519**	**92,690**	**34,770**	**51,833**	**253,812**
Depreciation and impairment					
At 1 January 2015	21,192	9,250	-	-	30,442
Charges for the year	1,715	10,037	3,260	-	15,012
At 31 December 2015	22,907	19,287	3,260	-	45,454
Charges for the year	5,750	21,354	6,954	17,278	51,336
At 31 December 2016	**28,657**	**40,641**	**10,214**	**17,278**	**96,790**
Net book value					
At 31 December 2016	**45,862**	**52,049**	**24,556**	**34,555**	**157,022**
Net book value					
At 31 December 2015	8,059	27,976	13,040	-	49,075

10 Trade and other receivables

	2016 EUR	2015 EUR
Trade receivables	**1,386,157**	576,413
Prepayments	**45,837**	113,404
Accrued income	**124,262**	29,364
Guarantee on rental agreement	**35,256**	35,256
Other Receivables	**37,036**	-
	1,628,548	754,437

Trade receivables are stated net of provisions for bad debts amounting to EUR 259,411 (2015: EUR 231,937).

Other receivables are stated net of provisions for bad debts amounting to EUR 7,032 (2015: EUR 7,032).

11 Trade and other payables

	2016 EUR	2015 EUR
Trade payables	**24,589**	53,199
Other payables	**205,396**	217,632
Accruals	**221,604**	169,630
Deferred income	**1,049,742**	311,464
	1,501,331	751,925

12 Cash and cash equivalents

	2015 EUR	2015 EUR
Cash at bank and in hand	**2,677,703**	1,153,226

13 Commitments

	2016 EUR	2015 EUR
Non-cancellable operating commitments:		
Less than one year	**101,317**	23,908
2-5 years	**119,974**	-
More than five years	**317**	-
	221,608	23,908

14 Financial instruments

Fair values of financial assets and financial liabilities

At 31 December 2016 and 2015 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.

Financial risk management

The exposures 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.

14 Financial instruments (continued)

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 event 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 stake holders comprising the Authority's debtor base. Cash at bank is placed with reliable financial institutions. The Authority assesses the credit quality of the stake holders by taking into account their financial standing and past experience. Included in the Authority's trade receivable there are no balances which are past due and which have not been provided for.

Currency risk

Foreign currency transactions arise when the Authority buys or sells goods whose price is denominated in a foreign currency, or incurs or settles 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.

Interest rate risk

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

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.

Capital risk management

The Authority's objective when managing capital is 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 11 and items presented within equity 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.