Medicines Authority

Annual report and financial statements

for the year ended 31 December 2015

Contents

Medicines Authority

Report of the Chairperson/Chief Executive Officer for the year ended 31 December 2015

The Chairperson/Chief Executive Officer presents his report and the audited financial statements of the Medicines Authority for the year ended 31 December 2015.

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/CEO 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/CEO, Directors and Managers 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 2015, the Authority sustained a surplus of EUR 996,857 when compared to a surplus of EUR265,767 in 2014. The increase in surplus of EUR 731,090 is mainly due to an increase in income of EUR 905,533.

Medicines Authority

Report of the Chairperson/Chief Executive Officer for the year ended 31 December 2015 (continued)

Auditors

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

Approved by the Chairman / Chief Executive Officer on 12 February 2016.

Anthony Serracino Inglott
Chairman / Chief Executive Officer

203, Level 3,
Rue D'Argens,
Gzira
Malta

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

Report on the financial statements

We have audited the accompanying financial statements of the Medicines Authority ("Authority") set out on pages 5 to 17 which comprise the statement of financial position as at 31 December 2015, 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.

Chairperson/CEO's responsibility for the financial statements

As described on page 1, the Chairperson/Chief Executive Officer ("CEO") is responsible, for the preparation and fair presentation of the financial statements in accordance with the Medicines Act, 2003 (Cap 458) and International Financial Reporting Standards as adopted by the EU, and for such internal control as the Chairperson/CEO determines to be necessary to enable the preparation of financial statements that are free from material misstatements, whether due to fraud or error.

Auditors' responsibility

Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with International Standards on Auditing. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgement, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal controls relevant to the Authority's preparation and fair presentation of the financial statements 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. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the Chairperson/CEO, as well as evaluating the overall presentation of the financial statements. We believe that the audit evidence obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

In our opinion, the financial statements give a true and fair view of the financial position of the Authority as at 31 December 2015 and of its financial performance and its cash flows for the year then ended in accordance with International Financial Reporting Standards as adopted by the EU.

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

Emphasis of matter

Without qualifying our opinion, we draw attention to note 15 to the financial statements whereby in January 2010 the Courts of Malta condemned an officer who had occupied the position of Director Corporate Services within the Authority in 2006 of misappropriation of funds totalling EUR 165,000. The latter was ordered to reimburse the funds to the Authority, however as at 31 December 2015 the case was still under appeal.

Report on other legal and regulatory requirements

In our opinion, the financial statements have been properly prepared in accordance with the provisions of the Medicines Act, 2003 (Cap 458).

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

Mazars Malta
Certified Public Accountants
Attard

12 February 2016

Medicines Authority

Statement of comprehensive income
For the year ended 31 December 2015

	Notes	2015 EUR	2014 EUR
Income	5	**2,828,519**	1,922,986
Expenditure			
Staff costs	6	**(1,297,743)**	(1,190,207)
Amortisation and depreciation		**(23,733)**	(11,467)
Audit fee		**(2,360)**	(2,360)
Finance costs		**-**	(366)
Other operating expenses		**(507,826)**	(452,819)
Operating surplus for the year before taxation		**996,857**	265,767
Income tax expense	7	**-**	-
Surplus for the year		**996,857**	265,767
Other comprehensive income for the year		**-**	-
Total comprehensive income for the year		**996,857**	265,767

The notes on pages 9 to 17 are an integral part of these financial statements.

Medicines Authority

Statement of financial position
As at 31 December 2015

	Notes	2015 EUR	2014 EUR
ASSETS			
Non-current assets			
Intangible assets	8	**13,366**	17,595
Tangible assets	9	**199,075**	10,415
		212,441	28,010
Current assets			
Trade and other receivables	10	**754,437**	450,836
Cash and cash equivalents		**1,153,226**	570,108
		1,907,663	1,020,944
Current liabilities			
Trade and other payables	11	**751,925**	677,632
Net current assets		**1,155,738**	343,312
Net assets		**1,368,179**	371,322
RESERVES			
Accumulated fund		**1,368,179**	371,322

The notes on pages 9 to 17 are an integral part of these financial statements.

The financial statements on pages 5 to 17 were approved by the Chairman / Chief Executive Officer on 12 February 2016;

Anthony Serracino Inglott
Chairman / Chief Executive Officer

Medicines Authority

Statement of changes in equity
For the year ended 31 December 2015

	Accumulated fund EUR
Balance at 1 January 2014	**105,555**
Changes in equity for 2014	
Surplus for the year	265,767
Balance at 31 December 2014	**371,322**
Changes in equity for 2015	
Surplus for the year	996,857
Balance at 31 December 2015	**1,368,179**

The notes on pages 9 to 17 are an integral part of these financial statements.
Acknowledgements

Medicines Authority

Statement of cash flows
For the year ended 31 December 2015

	Notes	2015 EUR	2014 EUR
Cash flows from operating activities			
Surplus before tax		**996,857**	265,767
Amortisation		**8,721**	7,598
Depreciation		**15,012**	3,869
Provision for bad debts		**13,516**	16,128
Movement in working capital:			
Trade and other receivables		**(317,117)**	(244,772)
Trade and other payables		**74,293**	177,213
Net cash generated from operating activities		**791,282**	225,803
Cash flows from investing activities			
Purchase of intangible assets		**(4,492)**	(9,602)
Purchase of tangible fixed assets		**(203,672)**	(4,830)
Net cash used in investing activities		**(208,164)**	(14,432)
Net movement in cash and cash equivalents		**583,118**	211,371
Cash and cash equivalents at the beginning of the year		**570,108**	358,737
Cash and cash equivalents at the end of the year	12	**1,153,226**	570,108

The notes on pages 9 to 17 are an integral part of these financial statements.

Notes to the financial statements
For the year ended 31 December 2015

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 5 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:

Refurbishment of new premises	-	33% per annum
Furniture and fittings	-	10% per annum
Office and computer equipment	-	25% per annum
Motor vehicles	-	20% 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 2015:

- Annual improvements to IFRSs 2010-2012 Cycle and 2011 – 2013 Cycle *(applicable for financial period beginning in or after 1 July 2014)*

  The application of the amendments has had no impact on the disclosures or amounts recognised in the Authority's financial statements.

IAS 19 Amendments – Defined Benefit Plans: Employee Contributions *(applicable for financial period beginning in or after 1 July 2014).*

The Authority does not make contributions to a defined benefit plan

The adoption of the above new and amended standards and IFRIC interpretations did not have an impact on the financial position or performance of the Authority.

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 up to 31 December 2015

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. The Chairperson/CEO anticipates that the adoption of International Financial Reporting Standards that were in issue at the date of authorisation of these financial statements, but not yet effective, will have no impact on the financial statements of the Authority in the period of initial application. These are as follows:

- IFRIC 19: (Amendments arising from IFRS9) – Extinguishing Financial Liabilities with Equity Instruments (*effective on adoption of IFRS 9*)
- IAS 1 Amendments – Disclosure Initiative (effective from 1 January 2016)
- Annual Improvements to IFRSs 2012 – 2014 Cycle (effective from 1 January 2016)
- IAS 27 Amendments – Equity Method in Separate Financial Statements (effective from 1 January 2016)
- IAS 16 and IAS 41 Amendments – Bearer Plants (effective from 1 January 2016)
- IAS 16 and IAS 38 Amendments – Clarification of Acceptable Methods of Depreciation and Amortisation (effective from 1 January 2016)
- IFRS 11 Amendments – Accounting for Acquisition of interest in Joint Operations (effective from 1 January 2016)

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

- IFRS 9 – Financial Instruments
- IFRS 14 – Regulatory Deferral Accounts
- IFRS 15 – Revenue from Contracts with Customers
- IFRS 10, IFRS 12 and IAS 28 Amendments – Investment Entities: Applying the Consolidation Exemption
- IFRS 10 and IAS 28 Amendments – Sale or Contribution of Assets between an Investor and its Associate or Joint Venture

The Chairperson/CEO 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.

6 Employee information

The average weekly number of persons employed by the Medicines Authority during the year was 41 (2014: 40). Staff costs for the year comprised: -

	2015 Number	2014 Number
Management	**7**	7
Technical staff	**25**	24
Administration	**9**	9
	41	40

	2015 EUR	2014 EUR
Management	**238,981**	233,731
Wages and salaries	**983,132**	884,015
Social security costs	**75,630**	72,461
	1,297,743	1,190,207

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 31 December 2014	30,390
Additions	4,492
At 31 December 2015	**34,882**
Amortisation	
At 31 December 2014	12,795
Charges for the year	8,721
At 31 December 2015	**21,516**
Net book value	
At 31 December 2015	**13,366**
At 31 December 2014	17,595

9 Plant and equipment

	Furniture & fittings	Office and computer equipment	Motor Vehicles	Total
	EUR	EUR	EUR	EUR
Cost				
At 1 January 2014	25,121	10,906	-	36,027
Additions	4,029	801	-	4,830
At 31 December 2014	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**
Depreciation and impairment				
At 1 January 2014	18,502	8,071	-	26,573
Charges for the year	2,690	1,179	-	3,869
At 31 December 2014	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**
Net book value				
At 31 December 2015	**8,059**	**27,976**	**13,040**	**49,075**
Net book value				
At 31 December 2014	7,958	2,457	-	10,415

There was a deposit of EUR 150,000 on refurbishment of new premises. Since the Authority has not yet moved in the new premises, depreciation is not charged in the current year.

10 Trade and other receivables

	2015	2014
	EUR	EUR
Trade receivables	**576,413**	295,843
Prepayments	**113,404**	32,995
Accrued income	**29,364**	121,998
Guarantee on rental agreement	**35,256**	-
	754,437	450,836

Trade receivables are stated net of provisions for bad debts amounting to EUR 231,937.

Other receivables are stated net of provisions for bad debts amounting to EUR NIL.

11 Trade and other payables

	2015 EUR	2014 EUR
Trade payables	**53,199**	178,838
Other payables	**217,632**	
Accruals	**169,630**	163,638
Deferred income	**311,464**	335,156
	751,925	677,632

12 Cash and cash equivalents

	2015 EUR	2014 EUR
Cash at bank and in hand	**1,153,226**	570,108

13 Commitments

	2015 EUR	2014 EUR
Non-cancellable operating commitments:		
Less than one year	**23,908**	123,611

14 Financial instruments

Fair values of financial assets and financial liabilities

At 31 December 2015 and 2014 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.

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.

14 Financial instruments (continued)

Credit risk (continued)

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 Chief Executive Officer manages the Authority's capital structure and makes adjustments to it, in light of changes in economic conditions.

15 Contingency

In January 2010 the Courts of Malta condemned an officer who had occupied the position of Director Corporate Services within the Authority in 2006 of misappropriation of funds totaling EUR165,000. The latter was ordered to reimburse the funds to the Authority, however as at 31 December 2015 the case was still under appeal.