

**Medicines Authority**  
**Annual report and financial statements**  
**for the year ended 31 December 2016**

## Contents

Report of the Chairperson/Chief Executive Officer

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

Statement of comprehensive income

Statement of financial position

Statement of changes in equity

Statement of cash flows

Notes to the financial statements

The Chairperson/Chief Executive Officer presents his report and the statements of the Medicines Authority for the year ended 31 December 20

## **Functions of the Medicines Authority**

The functions of the Medicines Authority ("Authority") are specified in Medicines Act, 2003 (Cap 458). They include assistance and provision Licensing Authority on matters relating to the regulation of medicinal pharmaceutical activities; the establishment of procedures and undertaking assessment of medicinal products; the inspection of pharmaceutical r distributing activities and monitoring the use of medicinal products in line standards of quality, efficacy and safety in order to make recommendation 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 and performance of the Authority.

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

## **Management of the Authority**

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

## **Results**

The results for the year are as shown in the statement of comprehensive income. During 2016, the Authority earned a surplus of EUR 1,601,499 when compared with a surplus of EUR 996,857 in 2015. The increase in surplus of EUR 1,601,499 is due to an increase in income of EUR 1,126,654, partly due to a one-off circumstance

**Auditors**

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

**Approved by the Chairman / Chief Executive Officer on 9<sup>th</sup> February**



**Anthony Serracino Inglott  
Chairman / Chief Executive Officer**

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

## Consumer Affairs and Civil Liberties (continued)

### *Responsibilities of the Chairperson/Chief Executive Officer*

The Chairperson/Chief Executive Officer is responsible for the preparation of 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 controls 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 error or fraud.

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 any 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, 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. This is a high level of assurance but is not a guarantee that an audit conducted in accordance with ISAs will detect all material misstatements 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 to address those risks, and obtain audit evidence that is sufficient and appropriate to support 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, intentional omissions, misrepresentations, or the override of internal controls.
- Obtain an understanding of internal control relevant to the audit in order to design procedures that are appropriate in the circumstances, but not intended to express 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.

## **Report on the Audit of the financial statements**

We have audited the accompanying financial statements of the 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 equity and statement of cash flows for the year then ended and a summary of accounting policies and other explanatory notes.

### *Opinion*

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

### *Basis for Opinion*

We conducted our audit in accordance with International Standards on Auditing (ISAs) which are applicable to the audit of the Financial Statements section of our report. We are also required to apply the International Ethics Standards Board for Accountants' (IESBA) Code of Ethics for Professional Accountants together with the ethical requirements of the Accountancy Profession Act 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, 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, we are not responsible for reading the other information and, in doing so, considering whether the other information is materially inconsistent with the financial statements or our audit, or otherwise appears to be materially misstated.

With respect to the Chairperson/Chief Executive Officer's Report, whether the Report includes the disclosures required by Article 19 of the 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 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).

# 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 going concern basis of accounting and based on the audit evidence material uncertainty exists related to events or conditions that may call into question the Authority's ability to continue as a going concern. If we conclude that such uncertainty exists, we are required to draw attention in our auditors' report to the disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained in the course of our audit. However, future events or conditions may cause the company 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 transactions and events in a manner that achieves fair presentation.

We communicate with the Chairperson/Chief Executive Officer regarding 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.

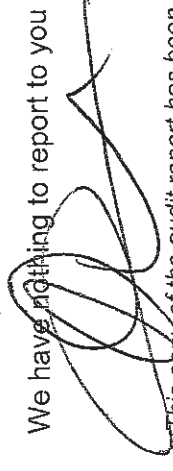
We also provide those charged with governance with a statement that we have considered relevant ethical requirements regarding independence, and to communicate with them any relationships and other matters that may reasonably be thought to create a potential conflict of interest, and where applicable, related safeguards.

## Report on Other Legal and Regulatory Requirements

Under the Maltese Companies Act (Cap. 386) we are required to report on other legal and regulatory requirements:

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

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

	Notes	2019 EUR
<b>Income</b>	5	3,955,173
<b>Expenditure</b>		
Staff costs	6	(1,542,765)
Amortisation and depreciation		(61,087)
Audit fee		(2,360)
Other operating expenses		(747,462)
<b>Operating surplus for the year before taxation</b>		<b>1,601,499</b>
Income tax expense	7	-
<b>Surplus for the year</b>		<b>1,601,499</b>
Other comprehensive income for the year		-
<b>Total comprehensive income for the year</b>		<b>1,601,499</b>

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



**ASSETS**

**Non-current assets**

Intangible assets  
Tangible assets

8 7,73  
9 157,02  
164,75

**Current assets**

Trade and other receivables  
Cash and cash equivalents

10 1,628,54  
2,677,70  
4,306,25

**Current liabilities**

Trade and other payables

11 1,501,33

**Net current assets**

2,804,92

**Net assets**

2,969,67

**RESERVES**

Accumulated fund

2,969,67

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  
Officer on 9<sup>th</sup> February 2017;



Anthony Serracino Inglott  
**Chairman / Chief Executive Officer**

**Balance at 1 January 2015**

*Changes in equity for 2015*  
Surplus for the year

**Balance at 31 December 2015**

*Changes in equity for 2016*  
Surplus for the year

**Balance at 31 December 2016**

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

<b>Cash flows from operating activities</b>	
Surplus before tax	1,601,499
Amortisation	9,751
Depreciation	51,336
Provision for bad debts	27,474
Movement in working capital:	
Trade and other receivables	(901,585)
Trade and other payables	749,406
<i>Net cash generated from operating activities</i>	<b>1,537,881</b>
<b>Cash flows from investing activities</b>	
Purchase of intangible assets	(4,121)
Purchase of tangible fixed assets	(9,283)
<i>Net cash used in investing activities</i>	<b>(13,404)</b>
<b>Net movement in cash and cash equivalents</b>	<b>1,524,477</b>
<b>Cash and cash equivalents at the beginning of the year</b>	<b>1,153,220</b>
<b>Cash and cash equivalents at the end of the year</b>	<b>2,677,703</b>

12

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

## 1 Basis of preparation

The financial statements have been prepared on the historical cost basis 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 are set out below.

## 2 Significant accounting policies

### *Intangible assets*

#### *Website*

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

Intangible assets are subsequently carried at cost less any accumulated impairment losses. Amortisation is calculated to write down the 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 date that the asset is classified as held for sale (or included in a disposal group 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 will flow to the Authority and the cost of the item can be measured reliably. The cost of an item will flow to the Authority and the cost of the item can be measured reliably only when 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 the disposal of an item represent the difference between the net disposal proceeds, if any, and the carrying amount of the asset and are included in profit or loss in the period of derecognition.

Depreciation commences in the year when the depreciable assets are available for use. Depreciation 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 basis:

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 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. Financial assets and 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 financial assets and financial liabilities 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 the obligation is extinguished. This occurs when the obligation specified in the contract is cancelled or expires.

#### (i) Trade and other receivables

Trade and other receivables are classified with current assets and are measured at nominal value. Appropriate allowances for estimated irrecoverable amounts are recognised in profit or loss when there is objective evidence that the assets will not be recovered.

#### (ii) Trade and other payables

Trade and other payables are classified with current liabilities and are measured at 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's best estimate of the expenditure required to settle the present obligation at the reporting date. If the effect of the time value of money is material, provisions are discounted to their present value.

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, 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 carrying amount does not exceed the carrying amount that would have been had no impairment loss been recognised for the asset in prior years. Impairment loss is 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 the asset was previously recognised in profit or loss.

#### *Revenue recognition*

Revenue is measured at the fair value of the consideration received or receivable for the services provided in the normal course of business net of discounts, rebates and other incentives. 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 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 3<sup>rd</sup> 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 receipt basis.

#### *Leases*

Leases are classified as finance leases whenever the terms of the lease agreement substantially transfer all the risks and rewards incidental to ownership to the lessee. Leases are classified as operating leases unless the lease agreement is such that it is substantially a finance lease. 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 commencement of the lease. The classification of the lease is not reassessed unless there is a change in the principal provisions of the lease.

The financial statements of the Authority are presented in its functional currency being the currency of the primary economic environment in which the Authority operates. Transactions denominated in currencies other than the functional currency are translated into the functional currency at the exchange rate ruling on the date of transaction. Monetary assets and liabilities denominated in currencies other than the functional currency are re-translated into the functional currency at the exchange rate ruling at year-end. Exchange differences 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 estimation uncertainty**

#### *Judgements in applying accounting policies*

In the process of applying the Authority's accounting policies, management may be required to make 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 carrying amounts of assets and liabilities 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 reporting period except as follows:

The Authority has adopted the following new and amended IFRS and IFRICs 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 any impact on the Authority's financial statements.

- Annual Improvements to IFRSs 2012 – 2014 Cycle (effective from 1 January 2015)

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

The amendments to IFRS 5 introduce specific guidance in IFRS 5 for the disposal of an asset (or disposal group) from held for sale to held for sale.

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

The amendments to IAS 19 clarify that the rate used to discount present benefit obligations should be determined by reference to market yields in the reporting period on high quality corporate bonds. The assessment of a market for high quality corporate bonds should be at the currency and same currency as the benefits are to be paid. For currencies for which there is a deep market in such high quality corporate bonds, the market yields in 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 equity method of accounting in separate financial statements. 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 the recognition of assets that meet the definition of a bearer plant to be accounted for as bearer plants in accordance with IAS 16, instead of IAS 41. The amendments to IAS 41 require bearer plants 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 Depreciation and Amortisation (effective from 1 January 2016)  
The amendments to IAS 16 prohibit entities from using a revenue-based method to determine depreciation for assets that are not bearer plants.

The amendments to IAS 16 prohibit entities from using a revenue-based method to determine depreciation for assets that are not bearer plants.



- a) when the intangible asset is expressed as a measure of revenue
- b) when it can be demonstrated that revenue and consumption of benefits of the intangible asset are highly correlated.

The amendments apply prospectively for annual periods beginning January 2016. Currently, the Authority uses the straight-line method for and amortisation for its property, plant and equipment, and intangible assets respectively. The Chairperson/Chief Executive Officer of the Authority has approved the straight-line method as the most appropriate method to reflect the economic benefits inherent in the respective assets and 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 Ventures (effective from 1 January 2016)

The amendments to IFRS 11 provide guidance on how to account for the formation of a joint operation that constitutes a business as defined in IFRS 3 *Business Combinations*. Specifically, the amendments state that the relevant accounting for business combinations in IFRS 3 and other standards shall be applied to a joint operation. *Income Taxes* regarding the recognition of deferred taxes at the time of formation of a joint operation 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 shall 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 parties that participate in the joint operation.

A joint operator is also required to disclose the relevant information regarding the joint operation and other standards for business combinations.

The amendments should be applied prospectively to acquisitions of business combinations (in which the activities of the joint operations constitute a business combination as defined in IFRS 3) occurring from the beginning of annual periods after 1 January 2016. The application of these amendments to IFRS 3 shall be applied on the Authority's financial statements.

- IFRS 10, IFRS 12 and IAS 28 Amendments – Investment Entities (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 if that parent entity is not an investment entity, even if that parent entity has a subsidiary that is an investment entity.

**period except as follows: (continued)**

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

In applying the equity method to an associate or joint venture that is an 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 assets at fair value should provide the disclosures required by IFRS 12, Disclosures of Related Parties, 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 may have an impact on the Authority's financial statements.

**Standards, interpretations and amendments to published standards as a result of EU that are not yet effective for financial periods beginning on 1 January 2018**

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

- IFRIC 19: (Amendments arising from IFRS9) – Extinguishing Financial Liabilities
- 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 and October 2013 to include requirements for financial liabilities. IFRS 9 also includes requirements for the classification and measurement of financial liabilities. IFRS 9 includes requirements for the classification and measurement of financial liabilities that are not yet effective for the current financial period. IFRS 9 includes requirements for the classification and measurement of financial liabilities that are not yet effective for the current financial period. IFRS 9 includes requirements for the classification and measurement of financial liabilities that are not yet effective for the current financial period.

**Key requirements of IFRS 9:**

- all recognised financial assets that are within the scope of IFRS 9 are measured at amortised cost or fair value. Specifically, debt investments are measured at amortised cost or fair value. Specifically, debt investments are measured at amortised cost or fair value. Specifically, debt investments are measured at amortised cost or fair value. Specifically, debt investments are measured at amortised cost or fair value.

Debt instruments that are held within a business model whose  
achieved both by collecting contractual cash flows and selling financ  
that have contractual terms that give rise on specified dates to cash  
solely payments of principal and interest on the principal amount o  
generally measured at FVTOCI. All other debt investments and equi  
are measured at their fair value at the end of subsequent account  
addition, under IFRS 9, entities may make an irrevocable elect  
subsequent changes in the fair value of an equity investment (that  
trading) in other comprehensive income, with only dividend inc  
recognised in profit or loss;

- with regard to the measurement of financial liabilities designated  
through profit or loss, IFRS 9 requires that the amount of change in  
the financial liability that is attributable to changes in the credit risk c  
presented in other comprehensive income, unless the recognition c  
changes in the liability's credit risk in other comprehensive income  
enlarge an accounting mismatch in profit or loss. Changes in fair va  
to a financial liability's credit risk are not subsequently reclassified  
Under IAS 39, the entire amount of the change in the fair value  
liability designated as fair value through profit or loss is presented in
- in relation to the impairment of financial assets, IFRS 9 requires an  
loss model, as opposed to an incurred credit loss model unde  
expected credit loss model requires an entity to account for expect  
and changes in those expected credit losses at each reporting  
changes in credit risk since initial recognition. In other words,  
necessary for a credit event to have occurred before credit losses  
and
- the new general hedge accounting requirements retain the three  
accounting mechanisms currently available in IAS 39. Under  
flexibility has been introduced to the types of transactions el  
accounting, specifically broadening the types of instruments that q  
instruments and the types of risk components of non-financi  
eligible for hedge accounting. In addition, the effectiveness  
overhauled and replaced with the principle of an 'econon  
Retrospective assessment of hedge effectiveness is also no

EU that are not yet effective for financial periods beginning on 1 January 2014 (continued)

- IFRS 15 – Revenue from contracts with customers (effective from 1 January 2014)

In May 2014, IFRS 15 was issued which establishes a single comprehensive standard for revenue recognition 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 the extent that it has transferred to customers the promised goods or services 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 performance obligation is transferred to the customer. Far more prescriptive disclosures are required by IFRS 15 to deal with specific scenarios. Furthermore, the Standard requires more detailed disclosures.

The Chairperson/Chief Executive Officer of the Authority are assessing the impact of 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 process launched)
- IFRS 16 - Leases
- IFRS 10 and IAS 28 Amendments – Sale or contribution of associate or joint venture and its associate or joint venture (EFRAG endorsement process launched indefinitely)
- IAS 12 Amendment – Recognition of deferred tax assets for unrealised losses

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

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

## 5 Revenue

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

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

## 6 Employee information

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

	2016 Number
Management	9
Technical staff	29
Administration	10
	48

2016  
EUR

Management

386,880

**8 Intangible asset**

**Cost**

At 1 January 2015  
Additions

At 31 December 2015  
Additions

**At 31 December 2016**

**Amortisation**

At 1 January 2015  
Charges for the year

At 31 December 2015  
Charges for the year

**At 31 December 2016**

**Net book value**

**At 31 December 2016**

At 31 December 2015

	EUR	equipment EUR	EUR
<b>Cost</b>			
At 1 January 2015	29,150	11,707	-
Additions	1,816	35,556	16,300
<b>At 31 December 2015</b>	<b>30,966</b>	<b>47,263</b>	<b>16,300</b>
Additions	43,553	45,427	18,470
<b>At 31 December 2016</b>	<b>74,519</b>	<b>92,690</b>	<b>34,770</b>
<b>Depreciation and impairment</b>			
At 1 January 2015	21,192	9,250	-
Charges for the year	1,715	10,037	3,260
<b>At 31 December 2015</b>	<b>22,907</b>	<b>19,287</b>	<b>3,260</b>
Charges for the year	5,750	21,354	6,954
<b>At 31 December 2016</b>	<b>28,657</b>	<b>40,641</b>	<b>10,214</b>
<b>Net book value</b>			
<b>At 31 December 2016</b>	<b>45,862</b>	<b>52,049</b>	<b>24,556</b>
Net book value			
At 31 December 2015	8,059	27,976	13,040

## 10 Trade and other receivables

Trade receivables	1,386	20
Prepayments	45,1	E
Accrued income	124,4	
Guarantee on rental agreement	35,4	
Other Receivables	37,4	
	<u>1,628,4</u>	

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 7,032).

Trade payables	24,585
Other payables	205,396
Accruals	221,600
Deferred income	1,049,744
	<u>1,501,330</u>

## 12 Cash and cash equivalents

Cash at bank and in hand	2,677,700
--------------------------	-----------

## 13 Commitments

Non-cancellable operating commitments:	201
Less than one year	101,310
2-5 years	119,970
More than five years	310
	<u>221,600</u>

## 14 Financial instruments

### *Fair values of financial assets and financial liabilities*

At 31 December 2016 and 2015 the carrying amounts of financial assets and liabilities classified with current assets and current liabilities respectively are fair values due to the short term maturities of these assets and liabilities. Non-current financial assets and non-current financial liabilities are not measured at fair value from their carrying amounts.

### *Financial risk management*

The exposures to risk and the way risks arise, together with the Aut. policies and processes for managing and measuring these risks are disclosed below. The Aut. policies and processes for managing financial risk