

**MEDICINES AUTHORITY**

**Annual Report and Financial Statements  
31 December 2018**

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

The Chairperson/Chief Executive Officer presents his report and the audited financial statements of the Medicines Authority for the year ended 31 December 2018.

### **Functions of the Medicines Authority**

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

### **Statement of Chief Executive Officer's Responsibilities**

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

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

### **Management of the Authority**

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

### **Results**

The results for the year are as shown in the statement of comprehensive income on page 7. During 2018, the Authority generated a surplus of €1,241,583 (2017: €1,356,461).

**Report of the Chairperson/Chief Executive Officer - continued**

**Auditors**

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

Approved by the Chairperson/Chief Executive Officer on 8 February 2019.



Anthony Serracino Inglott  
Chairperson/Chief Executive Officer

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



# GCS Malta

## *Independent auditors' report*

To the Ministry for Justice, Culture and Local Government

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

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#### *Our opinion*

In our opinion:

- Medicines Authority's financial statements give a true and fair view of the Authority's financial position as at 31 December 2018, and of the Authority's financial performance in accordance with the International Financial Reporting Standards (IFRSs) as adopted by the EU; and
- the financial statements have been prepared in accordance with the requirements of the the International Financial Reporting Standards (IFRSs) as adopted by the EU.

#### **What we have audited**

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

- the statement of financial position as at 31 December 2018;
- the statement of comprehensive income for the year then ended;
- the statement of changes in equity for the year then ended;
- the statement of cash flows for the year then ended;
- the notes to the financial statements, which include a summary of significant accounting policies.

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#### *Basis for opinion*

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

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

#### **Independence**

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

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#### *Other information*

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

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



## GCS Malta

### *Independent auditors' report* - continued

To the Ministry for Justice, Culture and Local Government

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

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

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

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

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#### *Auditors' responsibilities for the audit of the financial statements*

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

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

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



## GCS Malta

### *Independent auditors' report* - continued

To the Ministry for Justice, Culture and Local Government

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

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

### *Report on other legal and regulatory requirements*

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#### *Other matters on which we are required to report by exception*

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

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

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

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

115A, Floor 1,  
Msida Valley Road  
Birkirkara BKR 9024  
Malta

8 February 2019

## Statement of financial position

		As at 31 December	
		2018	2017
		€	€
	Notes		
<b>ASSETS</b>			
<b>Non-current assets</b>			
Intangible asset	4	2,413	4,932
Property, plant and equipment	5	177,304	132,522
Total non-current assets		179,717	137,454
<b>Current assets</b>			
Trade and other receivables	6	1,562,048	1,551,412
Cash and cash equivalents	7	5,701,359	4,391,625
Total current assets		7,263,407	5,943,037
<b>Total assets</b>		<b>7,443,124</b>	<b>6,080,491</b>
<b>CAPITAL AND LIABILITIES</b>			
<b>Capital and reserves</b>			
Accumulated reserves		5,567,722	4,326,139
<b>Total capital and reserves</b>		<b>5,567,722</b>	<b>4,326,139</b>
<b>Current liabilities</b>			
Trade and other payables	8	1,875,402	1,754,352
<b>Total liabilities</b>		<b>1,875,402</b>	<b>1,754,352</b>
<b>Total capital and liabilities</b>		<b>7,443,124</b>	<b>6,080,491</b>

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

The financial statements on pages 6 to 19 were approved by the Chairperson/Chief Executive Officer on 8 February 2019:



Anthony Serracino Inglott  
Chairperson/Chief Executive Officer



## Statement of comprehensive income

	Notes	Year ended 31 December	
		2018 €	2017 €
Revenue	9	4,201,470	3,914,163
Administration expenses	10	(2,959,887)	(2,557,702)
<b>Surplus before tax</b>		<b>1,241,583</b>	<b>1,356,461</b>
Tax expense	12	-	-
<b>Surplus for the year – total comprehensive income</b>		<b>1,241,583</b>	<b>1,356,461</b>

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

**Statement of changes in equity**

	<b>Accumulated reserves €</b>	<b>Total €</b>
Balance at 1 January 2017	2,969,678	2,969,678
Surplus for the year	1,356,461	1,356,461
<b>Balance at 31 December 2017</b>	<b>4,326,139</b>	<b>4,326,139</b>
Balance at 1 January 2018	4,326,139	4,326,139
Surplus for the year	1,241,583	1,241,583
<b>Balance at 31 December 2018</b>	<b>5,567,722</b>	<b>5,567,722</b>

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

## Statement of cash flows

	Notes	Year ended 31 December	
		2018 €	2017 €
<b>Cash flows from operating activities</b>			
Cash generated from operations	13	1,463,964	1,748,814
Net cash generated from operating activities		1,463,964	1,748,814
<b>Cash flows from investing activities</b>			
Purchase of intangible assets	4	-	(4,071)
Purchase of property, plant and equipment	5	(154,230)	(36,600)
Disposal of property, plant and equipment	5	-	5,779
Net cash used in investing activities		(154,230)	(34,892)
<b>Net movement in cash and cash equivalents</b>		1,309,734	1,713,922
<b>Cash and cash equivalents at beginning of year</b>		4,391,625	2,677,703
<b>Cash and cash equivalents at end of year</b>	7	5,701,359	4,391,625

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

## Notes to the financial statements

### 1. Summary of significant accounting policies

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

#### 1.1 Basis of preparation

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

During the year ended 31 December 2018, the Authority generated a surplus before tax of €1,241,583 (2017: €1,356,461).

#### 1.2 Foreign currency translation

##### (a) Functional and presentation currency

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

##### (b) Transactions and balances

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

#### 1.3 Intangible asset

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

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

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

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

**1.4 Property, plant and equipment**

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

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

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

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

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

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

**1.5 Financial instruments**

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

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

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

**(a) Trade and other receivables**

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

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

**1.5 Financial instruments - continued**

**(b) Trade and other payables**

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

**1.6 Provisions**

Provisions are recognised when the Authority has a present legal or constructive obligation as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of obligation. Provisions are measured at the Chief Executive Officer's best estimate of the expenditure required to settle the present obligation at the financial position date. If the effect of the time value of money is material, provisions are determined by discounting the expected future cash flows at a pre-tax 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.

**1.7 Impairment**

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

Where an impairment loss subsequently 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.

**1.8 Cash and cash equivalents**

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

**1.9 Offsetting financial instruments**

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

**1.10 Revenue recognition**

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

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

**1.10 Revenue recognition - continued**

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

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

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

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

(b) Government subvention

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

**1.11 Leases**

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

**1.12 Operating leases**

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

**2. Financial risk management**

At 31 December 2018 and 2017 the carrying amounts of financial assets and financial liabilities classified with current assets and current liabilities respectively approximated their fair values due to the short term maturities of these assets and liabilities. The fair values of non-current financial assets and non-current financial liabilities are not materially different from their carrying amounts.

**2.1 Financial risk factors**

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

**2. Financial risk management - continued**

**2.1 Financial risk factors - continued**

*(a) Market risk*

*(i) Foreign exchange risk*

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

*(ii) Interest rate risk*

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

*(b) Credit risk*

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

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

*(c) Liquidity risk*

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

**2.2 Capital risk management**

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

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

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



**3. Critical accounting estimates and judgements**

**3.1 Judgements in applying accounting policies**

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

**3.2 Key sources of estimation uncertainty**

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

**4. Intangible asset**

	Website €	Total €
<b>At 1 January 2017</b>		
Cost	39,003	39,003
Accumulated amortisation	(31,267)	(31,267)
Net book amount	7,736	7,736
<b>Year ended 31 December 2017</b>		
Opening net book amount	7,736	7,736
Additions	4,071	4,071
Amortisation charge	(6,875)	(6,875)
Closing net book amount	4,932	4,932
<b>At 1 January 2018</b>		
Cost	43,074	43,074
Accumulated amortisation	(38,142)	(38,142)
Net book amount	4,932	4,932
<b>Year ended 31 December 2018</b>		
Opening net book amount	4,932	4,932
Amortisation charge	(2,519)	(2,519)
Closing net book amount	2,413	2,413
<b>At 31 December 2018</b>		
Cost	43,074	43,074
Accumulated amortisation	(40,661)	(40,661)
Net book amount	2,413	2,413

**5. Property, plant and equipment**

	Furniture & fittings €	Office and computer equipment €	Motor vehicle €	Leasehold Improvements €	Total €
<b>At 1 January 2017</b>					
Cost	74,519	92,690	34,770	51,833	253,812
Accumulated depreciation	(28,657)	(40,641)	(10,214)	(17,278)	(96,790)
<b>Net book amount</b>	<b>45,862</b>	<b>52,049</b>	<b>24,556</b>	<b>34,555</b>	<b>157,022</b>
<b>Year ended 31 December 2017</b>					
Opening net book amount	45,862	52,049	24,556	34,555	157,022
Additions	3,952	21,722	1,036	9,890	36,600
Assets written off	(5,779)	-	-	-	(5,779)
Depreciation released on disposals	4,516	-	-	-	4,516
Depreciation charge	(5,566)	(25,877)	(7,161)	(21,233)	(59,837)
<b>Closing net book amount</b>	<b>42,985</b>	<b>47,894</b>	<b>18,431</b>	<b>23,212</b>	<b>132,522</b>
<b>At 1 January 2018</b>					
Cost	72,692	114,412	35,806	61,723	284,633
Accumulated depreciation	(29,707)	(66,518)	(17,375)	(38,511)	(152,111)
<b>Net book amount</b>	<b>42,985</b>	<b>47,894</b>	<b>18,431</b>	<b>23,212</b>	<b>132,522</b>
<b>Year ended 31 December 2018</b>					
Opening net book amount	42,985	47,894	18,431	23,212	132,522
Additions	34,093	59,683	-	60,454	154,230
Depreciation charge	(14,334)	(36,492)	(7,161)	(51,461)	(109,448)
<b>Closing net book amount</b>	<b>62,744</b>	<b>71,085</b>	<b>11,270</b>	<b>32,205</b>	<b>177,304</b>
<b>At 31 December 2018</b>					
Cost	106,785	174,095	35,806	122,177	438,863
Accumulated depreciation	(44,041)	(103,010)	(24,536)	(89,972)	(261,559)
<b>Net book amount</b>	<b>62,744</b>	<b>71,085</b>	<b>11,270</b>	<b>32,205</b>	<b>177,304</b>

**6. Trade and other receivables**

	2018 €	2017 €
<b>Current</b>		
Trade receivables	1,267,265	1,378,085
Prepayments	250,733	100,069
Accrued income	44,050	73,258
	<b>1,562,048</b>	<b>1,551,412</b>

Trade receivables are stated net of provisions for bad debts amounting to €255,264 (2017: €279,324).

**7. Cash and cash equivalents**

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

	2018 €	2017 €
Cash at bank and in hand	<b>5,701,359</b>	4,391,625

**8. Trade and other payables**

	2018 €	2017 €
<b>Current</b>		
Trade payables	505,093	153,806
Accruals	302,264	227,914
Deferred income	1,068,045	1,372,632
	<b>1,875,402</b>	<b>1,754,352</b>

**9. Revenue**

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

**10. Expenses by nature**

	2018 €	2017 €
Employee benefit expense (Note 11)	2,142,563	1,807,253
Amortisation of intangible asset (Note 4)	2,519	6,875
Depreciation of property, plant and equipment (Note 5)	109,448	59,837
Professional fees	108,659	141,966
Staff training	217,656	243,237
Travel and accommodation	106,312	52,610
Computer expenses	84,860	33,929
Other expenses	187,870	211,995
<b>Total administrative expenses</b>	<b>2,959,887</b>	<b>2,557,702</b>

Auditors' fees

Fees charged by the auditors for services rendered during the financial years ended 31 December 2018 and 2017 relate to the following:

	2018 €	2017 €
Annual statutory audit	2,360	2,360

**11. Employee benefit expense**

	2018 €	2017 €
Management	537,734	486,541
Wages and salaries	1,337,699	1,113,329
Social security costs	267,130	207,383
	<b>2,142,563</b>	<b>1,807,253</b>

The average weekly number of persons employed by the Medicines Authority during the financial reporting year was 63 (2017: 56):

	2018	2017
Management	11	10
Technical staff	39	33
Administration	13	13
	<b>63</b>	<b>56</b>

**12. Tax expense**

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

**13. Cash generated from operations**

Reconciliation of surplus before tax to cash generated from operations:

	2018	2017
	€	€
Surplus before tax	<b>1,241,583</b>	1,356,461
Adjustments for:		
Amortisation of intangible asset (Note 4)	<b>2,519</b>	6,875
Depreciation of property, plant and equipment (Note 5)	<b>109,448</b>	55,321
Loss on disposal of property, plant and equipment	-	1,263
Provision for bad debts	<b>(24,060)</b>	19,913
Changes in working capital:		
Trade and receivables	<b>13,424</b>	55,960
Trade and payables	<b>121,050</b>	253,021
Cash generated from operations	<b>1,463,964</b>	1,748,814

**14. Commitments**

	2018	2017
	€	€
Non-cancellable operating commitments:		
Less than one year	<b>17,700</b>	101,316
2-5 years	-	119,024
More than five years	-	-
	<b>17,700</b>	220,340

**15. Related party transactions**

During the year ended 31 December 2018 and 2017, there were no transactions with key management personnel except for emolument payments as disclosed in Note 11.

**16. Statutory information**

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

**17. Comparative information**

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

