MEDICINES AUTHORITY

Annual Report and Financial Statements
31 December 2019

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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 2019.

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

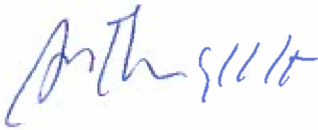
The results for the year are as shown in the statement of comprehensive income on page 7. During 2019, the Authority generated a surplus of €1,105,747 (2018: €1,241,583).

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 18 February 2020.



Anthony Serracino Inglott
Chairperson/Chief Executive Officer

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

ASSURANCE

Independent auditors' report

To the Ministry for Tourism and Consumer Protection

Report on the audit of the financial statements

Our opinion

In our opinion:

- Medicines Authority's financial statements give a true and fair view of the Authority's financial position as at 31 December 2019, 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 26, comprise:

- the statement of financial position as at 31 December 2019;
- the statement of comprehensive income for the year then ended;
- the statement of changes in equity for the year then ended;
- the statement of cash flows for the year then ended;
- the notes to the financial statements, which include a summary of significant accounting policies.

Basis for opinion

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

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

Independence

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

Other information

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

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

ASSURANCE

Independent auditors' report - continued

To the Ministry for Tourism and Consumer Protection

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

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

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

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

Auditors' responsibilities for the audit of the financial statements

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

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

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

ASSURANCE

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

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

Report on other legal and regulatory requirements

Other matters on which we are required to report by exception

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

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

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

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

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

18 February 2020

Statement of financial position

	Notes	As at 31 December 2019 €	2018 €
ASSETS			
Non-current assets			
Intangible asset	5	**1,390**	2,413
Property, plant and equipment	6	**135,920**	177,304
Right-of-use assets	7	**400,164**	-
Total non-current assets		**537,474**	179,717
Current assets			
Trade and other receivables	8	**1,572,972**	1,562,048
Cash and cash equivalents	9	**7,345,737**	5,701,359
Total current assets		**8,918,709**	7,263,407
Total assets		**9,456,183**	7,443,124
CAPITAL AND LIABILITIES			
Capital and reserves			
Accumulated reserves		**6,673,469**	5,567,722
Total capital and reserves		**6,673,469**	5,567,722
Liabilities			
Non-current liabilities			
Lease liabilities	10	**263,585**	-
Current liabilities			
Lease liabilities	10	**147,248**	-
Trade and other payables	11	**2,371,881**	1,875,402
Total current liabilities		**2,519,129**	1,875,402
Total liabilities		**2,782,714**	1,875,402
Total capital and liabilities		**9,456,183**	7,443,124

The notes on pages 10 to 26 are an integral part of these financial statements.

The financial statements on pages 6 to 26 were approved by the Chairperson/Chief Executive Officer on 18 February 2020:

Anthony Serracino Inglott
Chairperson/Chief Executive Officer

Statement of comprehensive income

	Notes	Year ended 31 December 2019 €	2018 €
Revenue	12	**4,817,786**	4,201,470
Administrative expenses	13	**(4,461,991)**	(2,959,887)
Operating surplus before tax		**355,795**	1,241,583
Finance cost	15	**(18,521)**	-
Other income	16	**768,473**	-
Surplus before tax		**1,105,747**	1,241,583
Tax expense	17	**-**	-
Surplus for the year – total comprehensive income		**1,105,747**	1,241,583

The notes on pages 10 to 26 are an integral part of these financial statements.

Statement of changes in equity

	Accumulated reserves €	Total €
Balance at 1 January 2018	4,326,139	4,326,139
Surplus for the year – total comprehensive income	1,241,583	1,241,583
Balance at 31 December 2018	**5,567,722**	**5,567,722**
Balance at 1 January 2019	5,567,722	5,567,722
Surplus for the year – total comprehensive income	1,105,747	1,105,747
Balance at 31 December 2019	**6,673,469**	**6,673,469**

The notes on pages 10 to 26 are an integral part of these financial statements.

Statement of cash flows

	Notes	Year ended 31 December 2019 €	2018 €
Cash flows from operating activities			
Cash generated from operations	18	**1,741,633**	1,463,964
Interest paid	15	**18,521**	-
Net cash generated from operating activities		**1,760,154**	1,463,964
Cash flows from investing activities			
Purchase of intangible assets	5	**(497)**	-
Purchase of property, plant and equipment	6	**(44,904)**	(154,230)
Reclassification of property, plant and equipment	6	**17,510**	-
Net cash used in investing activities		**(27,891)**	(154,230)
Cash flows from financing activities			
Payments of lease liabilities	10	**(87,855)**	-
Net cash used in financing activities		**(87,855)**	-
Net movement in cash and cash equivalents		**1,644,408**	1,309,734
Cash and cash equivalents at beginning of year		**5,701,359**	4,391,625
Cash and cash equivalents at end of year	9	**7,345,767**	5,701,359

The notes on pages 10 to 26 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 2019, the Authority generated a surplus before tax of €1,105,747 (2018: €1,241,583).

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 Impairment of non-financial assets

Non-financial assets that are subject to amortisation and depreciation are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognised for the amount by which the asset's carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units). Non-financial assets that suffered impairment are reviewed for possible reversal of the impairment at the end of each reporting period.

1. Summary of significant accounting policies - continued

1.6 Financial assets

1.6.1 Classification

(a) IFRS 9 – effective as from 1 January 2018

All recognised financial assets that are within the scope of IFRS 9 are required to be measured subsequently at amortised cost or fair value on the basis of the entity's business model for managing the financial assets and the contractual cash flow characteristics of the financial assets.

The company classifies its financial assets in the following categories: at amortised cost, fair value through other comprehensive income or fair value through profit and loss.

- debt instruments held within a business model whose objective is to hold to collect contractual cashflows are measured at amortised cost;
- debt instruments that are held within a business model whose objective is both to collect the contractual cash flows and to sell the debt instruments, and that have contractual cash flows that are solely payments of principal and interest on the principal amount outstanding, are measured subsequently at fair value through other comprehensive income (FVTOCI);
- all other debt investments and equity investments are measured subsequently at fair value through profit or loss (FVTPL).

(b) IAS 39 – Effective prior to 1 January 2018 - continued

Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. They arise when the company provides money, goods or services directly to a debtor with no intention of trading the asset. They are included in current assets, except for maturities greater than twelve months after the end of the reporting period.

These are classified as non-current assets. The company's loans and receivables comprise trade and other receivables and cash and cash equivalents in the statement of financial position (Notes 1.7 and 1.9).

1.6.2 Recognition and measurement

The company recognises a financial asset in its statement of financial position when it becomes a party to the contractual provisions of the instrument. Regular way purchases and sales of financial assets are recognised on settlement date, which is the date on which an asset is delivered to or by the company. Any change in fair value for the asset to be received is recognised between the trade date and settlement date in respect of assets which are carried at fair value in accordance with the measurement rules applicable to the respective financial assets.

Financial assets are initially recognised at fair value plus transaction costs. Subsequently they are measured according to their classification as details in Note 1.6.1. Under IAS 39, loans and receivables were subsequently carried at amortised cost using the effective interest method. Amortised cost is the initial measurement amount adjusted for the amortisation of any difference between the initial and maturity amounts using the effective interest method.

1. Summary of significant accounting policies - continued

1.6 Financial assets - continued

1.6.2 Recognition and measurement - continued

Financial assets are derecognised when the rights to receive cash flows from the financial assets have expired or have been transferred and the company has transferred substantially all risks and rewards of ownership or has not retained control of the asset.

1.6.3 Impairment

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

Specifically, IFRS 9 requires the Company to recognise a loss allowance for expected credit losses on:

- Debt investments measured subsequently at amortised cost or at FVTOCI;
- Lease receivables;
- Trade receivables and contract assets; and
- Financial guarantee contracts to which the impairment requirements of IFRS 9 apply.

In particular, IFRS 9 requires the Company to measure the loss allowance for a financial instrument at an amount equal to the lifetime expected credit losses (ECL) if the credit risk on that financial instrument has increased significantly since initial recognition, or if the financial instrument is a purchased or originated credit-impaired financial asset. However, if the credit risk on a financial instrument has not increased significantly since initial recognition (except for a purchased or originated credit-impaired financial asset), the Company is required to measure the loss allowance for that financial instrument at an amount equal to 12-months ECL. IFRS 9 also requires a simplified approach for measuring the loss allowance at an amount equal to lifetime ECL for trade receivables, contract assets and lease receivables in certain circumstances.

1.7 Trade and other receivables

Trade and other receivables comprise amounts due from customers for merchandise sold or services performed in the ordinary course of business. If collection is expected in one year or less (or in the normal operating cycle of the business if longer), they are classified as current assets. If not, they are presented as non-current assets.

Trade and other receivables are recognised initially at fair value and subsequently measured at amortised cost using the effective interest method, less provision for impairment (Note 1.6.3). The carrying amount of the asset is reduced through the use of an allowance account, and the amount of the loss is recognised in profit or loss. When a receivable is uncollectible, it is written off against the allowance account for trade and other receivables. Subsequent recoveries of amounts previously written off are credited against profit or loss.

1. Summary of significant accounting policies - continued

1.8 Provisions

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

1.9 Cash and cash equivalents

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

1.10 Financial liabilities

The company recognises a financial liability in its statement of financial position when it becomes a party to the contractual provisions of the instrument. The company's financial liabilities are classified as financial liabilities which are not at fair value through profit or loss (classified as 'Other liabilities') under IAS 39. Financial liabilities not at fair value through profit or loss are recognised initially at fair value, being the fair value of consideration received, net of transaction costs that are directly attributable to the acquisition or the issue of the financial liability. These liabilities are subsequently measured at amortised cost.

The company derecognises a financial liability from its statement of financial position when the obligation specified in the contract or arrangement is discharged, is cancelled or expires.

1.11 Trade and other payables

Trade and other payables are obligations to pay for goods or services that have been acquired in the ordinary course of business from suppliers. Accounts payable are classified as current liabilities if payment is due within one year or less (or in the normal operating cycle of the business if longer). If not, they are presented as non-current liabilities.

Trade and other payables are recognised initially at fair value and subsequently measured at amortised cost using the effective interest method.

1.12 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.

1.13 Revenue recognition

In the prior year, the Authority has applied IFRS 15 Revenue from Contracts with Customers (as amended in April 2016) which was effective for an annual period that begins on or after 1 January 2018. IFRS 15 introduced a 5-step approach to revenue recognition.

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

1.13 Revenue recognition - continued

IFRS 15 uses the terms 'contract asset' and 'contract liability' to describe what might more commonly be known as 'accrued revenue' and 'deferred revenue', however the Standard does not prohibit an entity from using alternative descriptions in the statement of financial position.

The application of IFRS 15 had not had a significant impact on the financial position and/or financial performance of the Authority.

Revenue is measured based on the consideration specified in a contract with a customer and excludes amounts collected on behalf of third parties and discounts. The Authority recognises revenue when it transfers control over a product to a customer.

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

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

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

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

(b) Government subvention

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

1.14 Leases

The Authority recognises a right-of-use asset and a lease liability at the lease commencement date. The right-of-use asset is initially measured at cost, and subsequently at cost less any accumulated depreciation and impairment losses, and adjusted for certain remeasurements of the lease liability. When a right-of-use asset meets the definition of investment property, it is presented in investment property. The right-of-use asset is initially measured at cost, and subsequently measured at fair value, in accordance with the Authority's accounting policies.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the Authority's incremental borrowing rate. Generally, the Authority uses its incremental borrowing rate as the discount rate.

The lease liability is subsequently increased by the interest cost on the lease liability and decreased by lease payment made. It is remeasured when there is a change in future lease payments arising from a change in an index or rate, a change in the estimate of the amount expected to be payable under a residual value guarantee, or as appropriate, changes in the assessment of whether a purchase or extension option is reasonably certain to be exercised or a termination option is reasonably certain not to be exercised.

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

1.14 Leases - continued

IAS 17 – Periods prior 1 January 2019

(a) Finance 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.

(b) 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 2019 and 2018 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.

(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.

2. Financial risk management - continued

2.1 Financial risk factors - continued

(b) Credit risk - continued

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 9 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. Changes in accounting policies

4.1 New and amended IFRS Standards that are effective for the current year

In the current year, the Authority has applied new and amended IFRS Standards issued by the International Accounting Standards Board (IASB) and adopted by the EU that are mandatorily effective in EU for an accounting period that begins on or after 1 January 2019.

- IFRS 16 – Leases (effective for financial years beginning on or after 1 January 2019)
- Amendment to IFRS 9: Prepayment features with negative compensation (effective for financial years beginning on or after 1 January 2019)
- IFRIC 23—Uncertainty over income tax treatment (effective for financial years beginning on or after 1 January 2019)
- Amendments to IAS 28: Long-term interests in associates and joint ventures (effective for financial years beginning on or after 1 January 2019)
- Annual improvements to IFRS standards 2015 – 2017 Cycle (effective for financial years beginning on or after 1 January 2019)
- Amendments to IAS 19: Plan Amendment, Curtailment or Settlement (effective for financial years beginning on or after 1 January 2019)

The adoption of new and amended standards did not have a material impact on the Authority's financial statements, except of the adoption of the IFRS 16 – Leases as disclosed below.

The Authority has initially adopted IFRS 16 Leases from 1 January 2019.

IFRS 16 introduced a single, on-balance sheet accounting model for lessees. As a result, the Authority, as a lessee, has recognised right-of-use assets representing its rights to use the underlying assets and lease liabilities representing its obligation to make lease payments. Lessor accounting remains similar to previous accounting policies. The Authority has applied IFRS 16 using the modified retrospective approach, under which the cumulative effect of initial application is recognised in retained earnings at 1 January 2019. Accordingly, the comparative information presented for 2018 has not been restated – i.e. it is presented, as previously reported, under IAS 17 and related interpretations.

The details of the changes in accounting policies are disclosed below.

(a) Definition of a lease

Previously, the Authority determined at contract inception whether an arrangement was or contained a lease under IFRIC 4 Determining Whether an Arrangement contains a Lease. The Authority now assesses whether a contract is or contains a lease based on the new definition of a lease. Under IFRS 16, a contract is, or contains, a lease if the contract conveys a right to control the use of an identified asset for a period of time in exchange for consideration. On transition to IFRS 16, the Authority elected to apply the practical expedient to grandfather the assessment of which transactions are leases. It applied IFRS 16 only to contracts that were previously identified as leases. Contracts that were not identified as leases under IAS 17 and IFRIC 4 were not reassessed. Therefore, the definition of a lease under IFRS 16 has been applied only to contracts entered into or changed on or after 1 January 2019.

At inception or on reassessment of a contract that contains a lease component, the Authority allocates the consideration in the contract to each lease and non-lease component on the basis of their relative stand-alone prices. However, for leases of properties in which it is a lessee, the Authority has elected not to separate non-lease components and will instead account for the lease and non-lease components as a single lease component.

4. Changes in accounting policies - continued

4.1 New and amended IFRS Standards that are effective for the current year - continued

(b) As a lessee

The Authority does not lease many assets, only the offices that uses and parking spaces.

As a lessee, the Authority previously classified leases as operating or finance leases based on its assessment of whether the lease transferred substantially all of the risks and rewards of ownership. Under IFRS 16, the Authority recognises right-of-use assets and lease liabilities for most leases – i.e. these leases are on-balance sheet. However, the Authority has elected not to recognise right-of-use assets and lease liabilities for some leases of low-value assets (e.g. parking spaces). The Authority recognises the lease payments associated with these leases as an expense on a straight-line basis over the lease term. The Authority presents right-of-use assets that do not meet the definition of investment property in 'Right-of-use asset'. Right-of-use assets that meet the definition of investment property are presented within investment property.

(i) Transition

Previously, the Authority classified property leases as operating leases under IAS 17. These include offices and parking spaces. The leases typically run for a period of 3 years. Some leases include an option to renew the lease for an additional five years after the end of the non-cancellable period. Some leases provide for additional rent payments that are based on changes in local price indices.

At transition, for leases classified as operating leases under IAS 17, lease liabilities were measured at the present value of the remaining lease payments, discounted at the Authority's incremental borrowing rate as at 1 January 2019. Right-of-use assets are measured at either:

- their carrying amount as if IFRS 16 had been applied since the commencement date, discounted using the lessee's incremental borrowing rate at the date of initial application - the Authority applied this approach to all other leases; or
- an amount equal to the lease liability, adjusted by the amount of any prepaid or accrued lease payments – the Authority did not apply this approach.

The Authority used the following practical expedients when applying IFRS 16 to leases previously classified as operating leases under IAS 17.

- Applied the exemption not to recognise right-of-use assets and liabilities for leases with less than 12 months of lease term;
- Excluded initial direct costs from measuring the right-of-use asset at the date of initial application; and
- Used hindsight when determining the lease term if the contract contains options to extend or terminate the lease.

(c) Impacts on financial statements

(i) Impact on transition

On transition to IFRS 16, the Authority recognised additional right-of-use assets, recognising the difference in retained earnings. The impact on transition was minimum since previous operating leases were expired within the first quarter of the current period.

4. Changes in accounting policies - continued

4.1 New and amended IFRS Standards that are effective for the current year - continued

(c) Impacts on financial statements - continued

(ii) Impact for the period

As a result of applying IFRS 16, the Authority recognised €400,164 of right-of-use assets and €410,833 of lease liabilities as at 31 December 2019. Also, in relation to those leases under IFRS 16, the Authority has recognised depreciation and interest costs, instead of operating lease expense. During the year ended 31 December 2019, the Authority recognised €80,033 of depreciation charges and €18,521 of interest costs from these leases.

When measuring lease liabilities for leases, the Authority discounted lease payments using its interest rate implicit in the lease at date of recognition, which is 8%.

The Authority opt to recognise a lease expense on a straight-line basis as permitted by IFRS 16 for short-term leases (lease term of 12 months or less) and leases of low-value assets (such as parking spaces). These arrangements did not have a significant impact on the financial position and/or financial performance of the company.

4.2 Standards, amendments and interpretations to existing standards that are not yet effective and have not been adopted early by the Authority

At the date of the authorisation of these financial statements, certain new standards, amendments and interpretations to existing standards have been published by the IASB but are not yet effective and have not been adopted early by the Authority.

- Amendments to IAS 1 and IAS 8: Definition of Material (effective for financial years beginning on or after 1 January 2020)
- Amendments to IFRS 9, IAS 39 and IFRS 7: Interest Rate Benchmark Reform (effective for financial years beginning on or after 1 January 2020)
- Amendments to References to the Conceptual Framework in IFRS Standards (effective for financial years beginning on or after 1 January 2020)

Management anticipates that all the relevant pronouncements will be adopted in the Authority's accounting policies for the first period beginning after the effective date of the pronouncement.

Certain new standards and interpretations have been issued but are not expected to have a material impact on the Authority's financial statements.

4.3 Standards, amendments and interpretations to published standards that are not yet endorsed by the EU

- IFRS 17—Insurance contracts (effective for financial years beginning on or after 1 January 2021)
- Amendment to IFRS 3 Business Combinations (effective for financial years beginning on or after 1 January 2020)
- Amendments to IAS 1 Presentation of Financial Statements: Classification of Liabilities as Current or Non-Current

5. Intangible asset

	Website €	Total €
At 1 January 2018		
Cost	43,074	43,074
Accumulated amortisation	(38,142)	(38,142)
Net book amount	4,932	4,932
Year ended 31 December 2018		
Opening net book amount	4,932	4,932
Amortisation charge	(2,519)	(2,519)
Closing net book amount	2,413	2,413
At 1 January 2019		
Cost	43,074	43,074
Accumulated amortisation	(40,661)	(40,661)
Net book amount	2,413	2,413
Year ended 31 December 2019		
Opening net book amount	2,413	2,413
Additions	497	497
Amortisation charge	(1,520)	(1,520)
Closing net book amount	**1,390**	**1,390**
At 31 December 2019		
Cost	43,571	43,571
Accumulated amortisation	(42,181)	(42,181)
Net book amount	**1,390**	**1,390**

6. Property, plant and equipment

	Furniture & fittings €	Office and computer equipment €	Motor vehicle €	Leasehold Improvements €	Total €
At 1 January 2018					
Cost	72,692	114,412	35,806	61,723	284,633
Accumulated depreciation	(29,707)	(66,518)	(17,375)	(38,511)	(152,111)
Net book amount	42,985	47,894	18,431	23,212	132,522
Year ended 31 December 2018					
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)
Closing net book amount	62,744	71,085	11,270	32,205	177,304
At 1 January 2019					
Cost	106,785	174,095	35,806	122,177	438,863
Accumulated depreciation	(44,041)	(103,010)	(24,536)	(89,972)	(261,559)
Net book amount	62,744	71,085	11,270	32,205	177,304
Year ended 31 December 2019					
Opening net book amount	62,744	71,085	11,270	32,205	177,304
Additions	6,525	38,010	-	369	44,904
Reclassification	-	-	-	(17,510)	(17,510)
Depreciation released on reclassification	-	-	-	1,754	1,754
Depreciation charge	(19,077)	(36,244)	(7,161)	(8,050)	(70,532)
Closing net book amount	**50,192**	**72,851**	**4,109**	**8,768**	**135,920**
At 31 December 2019					
Cost	113,310	212,105	35,806	105,036	466,257
Accumulated depreciation	(63,118)	(139,254)	(31,697)	(96,268)	(330,337)
Net book amount	**50,192**	**72,851**	**4,109**	**8,768**	**135,920**

During the year, the Authority received a credit note related to capitalised Leasehold Improvements amounting to €17,510 and the amount was reclassified as stated above.

7. Right of use of asset

The Authority's offices are leased out under an operating lease with the following amounts:

	Office buildings €	Total €
Year ended 31 December 2019		
Opening net book amount	-	-
Additions	480,197	480,197
Depreciation charge	(80,033)	(80,033)
Closing net book amount	**400,164**	**400,164**
At 31 December 2019		
Cost	480,197	480,197
Accumulated depreciation	(80,033)	(80,033)
Net book amount	**400,164**	**400,164**

8. Trade and other receivables

	2019 €	2018 €
Current		
Trade receivables	**1,175,986**	1,267,265
Prepayments	**304,406**	250,733
Accrued income	**92,580**	44,050
	1,572,972	1,562,048

Trade receivables are unsecured, interest free and repayable on demand.

Trade receivables are stated net of provisions for bad debts amounting to €218,630 (2018: €255,264).

9. Cash and cash equivalents

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

	2019 €	2018 €
Cash at bank and in hand	**7,345,737**	5,701,359

10. Lease liabilities

	2019 €	2018 €
Non-current		
Lease liabilities	**263,585**	-
Current		
Lease liabilities	**147,248**	-

For interest expense in relation to lease liabilities, refer to finance costs Note 15.

The Authority discounted lease payments using the interest rate implicit in the lease, which is 8%, as disclosed in Note 4.

11. Trade and other payables

	2019 €	2018 €
Current		
Trade payables	**460,011**	505,093
Accruals	**441,500**	302,264
Deferred income	**1,470,370**	1,068,045
	2,371,881	1,875,402

Trade payables are unsecured, interest free and repayable on demand.

12. Revenue

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

13. Expenses by nature

	2019 €	2018 €
Employee benefit expense (Note 14)	**3,427,111**	2,142,563
Amortisation of intangible asset (Note 5)	**1,520**	2,519
Depreciation of property, plant and equipment (Note 6)	**70,532**	109,448
Depreciation of right-of-use-of asset (Note 7)	**80,033**	-
Lease expense	**28,243**	-
Professional fees	**189,240**	108,659
Staff training	**336,508**	217,656
Travel and accommodation	**118,608**	106,312
Computer expenses	**90,277**	84,860
Other expenses	**119,919**	187,870
Total administrative expenses	**4,461,991**	2,959,887

13. **Expenses by nature** - continued

Auditors' fees

Fees charged by the auditors for services rendered during the financial years ended 31 December 2019 and 2018 relate to the following:

	2019	2018
	€	€
Annual statutory audit	**2,360**	2,360

14. Employee benefit expense

	2019	2018
	€	€
Management	**710,784**	537,734
Wages and salaries	**2,533,499**	1,337,699
Social security costs	**182,828**	267,130
	3,427,111	2,142,563

The average weekly number of persons employed by the Medicines Authority during the financial reporting year was 93 (2018: 63):

	2019	2018
Management	**16**	11
Technical staff	**57**	39
Administration	**20**	13
	93	63

15. Finance cost

	2019	2018
	€	€
Lease interest expense	**18,521**	-

16. Other income

	2019	2018
	€	€
Reimbursement of payroll expenses	**707,304**	-
Other income	**61,169**	-
	768,473	-

17. Tax expense

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

18. Cash generated from operations

Reconciliation of surplus before tax to cash generated from operations:

	2019	2018
	€	€
Surplus before tax	**1,105,747**	1,241,583
Adjustments for:		
Amortisation of intangible asset (Note 5)	**1,520**	2,519
Depreciation of property, plant and equipment (Note 6)	**70,532**	109,448
Depreciation of right-of-use-of-asset (Note 7)	**80,033**	-
Depreciation released on reclassification of property, plant and equipment (Note 6)	**(1,754)**	-
Provision for bad debts	**(36,634)**	(24,060)
Changes in working capital:		
Trade and other receivables	**25,710**	13,424
Trade and other payables	**496,479**	121,050
Cash generated from operations	**1,741,633**	1,463,964

19. Commitments

	2019	2018
	€	€
Non-cancellable operating commitments:		
Less than one year	**168,088**	17,700
2-5 years	**268,295**	-
More than five years	**-**	-
	436,383	17,700

20. Related party transactions

During the year ended 31 December 2019 and 2018, there were no transactions with key management personnel except for emolument payments as disclosed in Note 14.

21. Statutory information

Medicines Authority is a State-owned Authority. The Authority's ultimate controlling party is the Ministry for Tourism and Consumer Protection on behalf of Government of Malta, the registered office is 233, Republic Street, Valletta, Malta.