MEDICINES AUTHORITY

Annual Report and Financial Statements
31 December 2020

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 2020.

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 2020, the Authority generated a surplus of €1,092,519 (2019: €1,105,747).

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 2021.

Anthony Serracino Inglott
Chairperson/Chief Executive Officer

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

Independent auditors' report
To the Ministry for Tourism and Consumer Protection

Report on the audit of the financial statements

Our Opinion

- Medicines Authority's financial statements give a true and fair view of the Authority's financial position as at 31 December 2020, 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 Medicines Act, 2003 (Cap 458).

What we have audited

Medicine Authority's financial statements, set out on pages 7 to 26 comprise:

- the statement of financial position as at 31 December 2020;
- 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; and
- the notes to the financial statements, which include a summary of significant accounting policies.

Emphasis of Matter

We draw attention to Note 1.2, in relation to the impact of COVID-19 Pandemic on the Authority, which addresses developments in connection with COVID-19, and the potential impact on financial and operational performance. This matter is considered to be of fundamental importance to the users of the study of the financial statements because of the potentially unfavourable nature of these developments, and the impact it could have on the basis of preparation of these financial statements. Our opinion is not modified in respect of this matter.

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 (Cap. 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 Report of the Chairperson/ Chief Executive Officer ("CEO") 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.

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 ("CEO") for the financial statements

The Chairperson/ Chief Executive Officer ("CEO") is responsible for the preparation of financial statements that give a true and fair view in accordance with IFRS as adopted by the EU, and for such internal control as the Chairperson/ Chief Executive Officer ("CEO") 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 ("CEO") 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 ("CEO") 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.

Independent auditors' report

To the Ministry for Tourism and Consumer Protection

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 ("CEO").
- Conclude on the appropriateness of the Chairperson/ Chief Executive Officer ("CEO")'s use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Authority's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditors' report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditors' report. However, future events or conditions may cause the Authority to cease to continue as a going concern.
- Evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

We communicate with the Chairperson/ Chief Executive Officer ("CEO") 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 any 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, (Cap.386) 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 the Chairperson/ Chief Executive Officer ("CEO")'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
GCS Assurance Malta Limited
Certified Public Accountants

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

8 February 2021

Statement of financial position

	Notes	As at 31 December 2020 €	2019 €
ASSETS			
Non-current assets			
Intangible asset	5	**3,826**	1,390
Property, plant and equipment	6	**150,533**	135,920
Right-of-use assets	7	**240,098**	400,164
Total non-current assets		**394,457**	537,474
Current assets			
Trade and other receivables	8	**1,849,493**	1,572,972
Cash and cash equivalents	9	**7,973,094**	7,345,737
Total current assets		**9,822,587**	8,918,709
Total assets		**10,217,044**	9,456,183
CAPITAL AND LIABILITIES			
Capital and reserves			
Accumulated reserves		**7,765,988**	6,673,469
Total capital and reserves		**7,765,988**	6,673,469
Liabilities			
Non-current liabilities			
Lease liabilities	10	**91,757**	263,585
Current liabilities			
Lease liabilities	10	**165,791**	147,248
Trade and other payables	11	**2,193,512**	2,371,881
Total current liabilities		**2,359,299**	2,519,129
Total liabilities		**2,451,056**	2,782,714
Total capital and liabilities		**10,217,044**	9,456,183

The notes on pages 11 to 26 are an integral part of these financial statements.

The financial statements on pages 7 to 26 were approved by the Chairperson/Chief Executive Officer on 8 February 2021:

Anthony Serracino Inglott
Chairperson/Chief Executive Officer

Statement of comprehensive income

	Notes	Year ended 31 December 2020 €	2019 €
Revenue	12	**5,396,957**	4,817,786
Administrative expenses	13	**(4,671,900)**	(4,461,991)
Operating surplus before tax		**725,057**	355,795
Finance cost	15	**(28,344)**	(18,521)
Other income	16	**395,806**	768,473
Surplus before tax		**1,092,519**	1,105,747
Tax expense	17	**-**	-
Surplus for the year – total comprehensive income		**1,092,519**	1,105,747

The notes on pages 11 to 26 are an integral part of these financial statements.

Statement of changes in equity

	Accumulated reserves €	Total €
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**
Balance at 1 January 2020	6,673,469	6,673,469
Surplus for the year – total comprehensive income	1,092,519	1,092,519
Balance at 31 December 2020	**7,765,988**	**7,765,988**

The notes on pages 11 to 26 are an integral part of these financial statements.

Statement of cash flows

	Notes	2020 €	2019 €
		Year ended 31 December	
Cash flows from operating activities			
Cash generated from operations	18	**866,198**	1,741,633
Interest paid	15	**(28,344)**	18,521
Net cash generated from operating activities		**857,854**	1,760,154
Cash flows from investing activities			
Purchase of intangible assets	5	**(3,578)**	(497)
Purchase of property, plant and equipment	6	**(65,130)**	(44,904)
Proceeds from disposal of property, plant and equipment		**10,000**	-
Reclassification of property, plant and equipment	6	**-**	17,510
Net cash used in investing activities		**(58,708)**	(27,891)
Cash flows from financing activities			
Payments of lease liabilities	10	**(151,819)**	(87,855)
Net cash used in financing activities		**(151,819)**	(87,855)
Net movement in cash and cash equivalents		**627,327**	1,644,408
Cash and cash equivalents at beginning of year		**7,345,767**	5,701,359
Cash and cash equivalents at end of year	9	**7,973,094**	7,345,767

The notes on pages 11 to 26 are an integral 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 2020, the Authority generated a surplus before tax of €1,092,519 (2019: €1,105,747).

1.2 Impact of COVID-19 Pandemic on the Authority

The outbreak of the COVID-19 pandemic and the subsequent measures adopted by the governments in several countries to mitigate the pandemic's spread has not impacted significantly the authority's activities.

1.3 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.

1.4 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

1.5 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.

1.6 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

1.7 Financial assets

1.7.1 Classification

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 Authority 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).

1.7.2 Recognition and measurement

The Authority 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 Authority. 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 1.7.1. 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.

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

1. Summary of significant accounting policies - continued

1.7 Financial assets - continued

1.7.3 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 Authority 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 Authority 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 Authority 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 Authority 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.

1.8 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 1.7.3). 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

1.9 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.

1.10 Cash and cash equivalents

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

1.11 Financial liabilities

The Authority recognises a financial liability in its statement of financial position when it becomes a party to the contractual provisions of the instrument. The Authority's financial liabilities are classified as financial liabilities which are not at fair value through profit or loss (classified as 'Other liabilities') under IFRS 9. 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 Authority 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.

1.12 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.

1.13 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. Summary of significant accounting policies - continued

1.14 Revenue recognition

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.

1.15 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.

2. Financial risk management

At 31 December 2020 and 2019 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.

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. **Financial risk management** - continued

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 2020.

- Amendments to IFRS 16 Leases Covid 19 – Related Rent Concessions (effective for financial years beginning on or after 1 January 2020)
- 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)
- Amendments to IFRS 3 Business Combinations (effective for financial years beginning on or after 1 January 2020)

The adoption of new and amended standards did not have a material impact on the Authority's financial statements.

4. Changes in accounting policies - continued

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 IFRS 4 Insurance Contracts – deferral of IFRS 9 (effective for financial years beginning on or after 1 January 2021)
- Amendments to IFRS 9, IAS 39 and IFRS 7, IFRS 4 and IFRS 16 Interest Rate Benchmark Reform – Phase 2 (effective for financial years beginning on or after 1 January 2021)

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 2023)
- Amendment to IFRS 3 Business Combinations, IAS 16 Property, Plant and Equipment, IAS 37 Provisions, Contingent Liabilities and Contingent Assets, Annual Improvements 2018 - 2020 (effective for financial years beginning on or after 1 January 2022)
- Amendments to IAS 1 Presentation of Financial Statements: Classification of Liabilities as Current or Non-Current and Classification of Liabilities as Current or Non-Current – Deferral of Effective Date (effective for financial years beginning on or after 1 January 2023)

5. Intangible asset

	Website	Total
	€	€
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 1 January 2020		
Cost	43,571	43,571
Accumulated amortisation	(42,181)	(42,181)
Net book amount	1,390	1,390
Year ended 31 December 2020		
Opening net book amount	1,390	1,390
Additions	3,578	3,578
Amortisation charge	(1,142)	(1,142)
Closing net book amount	**3,826**	**3,826**
At 31 December 2020		
Cost	47,149	47,149
Accumulated amortisation	(43,323)	(43,323)
Net book amount	**3,826**	**3,826**

6. Property, plant and equipment

	Furniture & fittings €	Office and computer equipment €	Motor vehicle €	Leasehold Improvements €	Total €
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 1 January 2020					
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
Year ended 31 December 2020					
Opening net book amount	50,192	72,851	4,109	8,768	135,920
Additions	7,087	25,266	31,254	1,523	65,130
Disposals	-	-	(15,600)	-	(15,600)
Depreciation released on disposal	-	-	15,600	-	15,600
Depreciation charge	(7,737)	(34,517)	(3,901)	(4,362)	(50,517)
Closing net book amount	**49,542**	**63,600**	**31,462**	**5,929**	**150,533**
At 31 December 2020					
Cost	120,397	237,371	51,460	106,559	515,787
Accumulated depreciation	(70,855)	(173,771)	19,998	100,630	365,254
Net book amount	**49,542**	**63,600**	**31,462**	**5,929**	**150,533**

During 2019, the Authority had 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
Year ended 31 December 2020		
Opening net book amount	400,164	400,164
Depreciation charge	(160,066)	(160,066)
Closing net book amount	**240,098**	**240,098**
At 31 December 2020		
Cost	480,197	480,197
Accumulated depreciation	(240,099)	(240,099)
Net book amount	**240,098**	**240,098**

8. Trade and other receivables

	2020 €	2019 €
Current		
Trade receivables	**1,069,841**	1,175,986
Prepayments	**338,285**	304,406
Accrued income	**441,367**	92,580
	1,849,493	1,572,972

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

Trade receivables are stated net of provisions for bad debts amounting to €178,337 (2019: €218,630).

9. Cash and cash equivalents

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

	2020	2019
	€	€
Cash at bank and in hand	**7,973,094**	7,345,737

10. Lease liabilities

	2020	2019
	€	€
Non-current		
Lease liabilities	**91,757**	263,585
Current		
Lease liabilities	**165,791**	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%.

11. Trade and other payables

	2020	2019
	€	€
Current		
Trade payables	**347,032**	460,011
Accruals	**500,515**	441,500
Deferred income	**1,345,965**	1,470,370
	2,193,512	2,371,881

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

	2020 €	2019 €
Employee benefit expense (Note 14)	**3,731,122**	3,427,111
Amortisation of intangible asset (Note 5)	**1,142**	1,520
Depreciation of property, plant and equipment (Note 6)	**50,517**	70,532
Depreciation of right-of-use-of asset (Note 7)	**160,066**	80,033
Lease expense	**25,357**	28,243
Professional fees	**209,267**	189,240
Staff training	**198,058**	336,508
Travel and accommodation	**28,186**	118,608
Computer expenses	**122,802**	90,277
Bad debts written-off	**13,805**	-
Other expenses	**131,578**	119,919
Total administrative expenses	**4,671,900**	4,461,991

Auditors' fees

Fees charged by the auditors for services rendered during the financial years ended 31 December 2020 and 2019 relate to the following:

	2020 €	2019 €
Annual statutory audit	**2,360**	2,360

14. Employee benefit expense

	2020 €	2019 €
Management	**824,152**	710,784
Wages and salaries	**2,690,592**	2,533,499
Social security costs	**216,378**	182,828
	3,731,122	3,427,111

The average weekly number of persons employed by the Medicines Authority during the financial reporting year was 97 (2019: 93):

	2020	2019
Management	**16**	16
Technical staff	**58**	57
Administration	**23**	20
	97	93

15. Finance cost

	2020 €	2019 €
Lease interest expense	**28,344**	18,521

16. Other income

	2020 €	2019 €
Reimbursement of payroll expenses	**373,456**	707,304
Other income	**22,350**	61,169
	395,806	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:

	2020 €	2019 €
Surplus before tax	**1,092,519**	1,105,747
Adjustments for:		
Gain on disposal of property, plant and equipment	**(10,000)**	-
Amortisation of intangible asset (Note 5)	**1,142**	1,520
Depreciation of property, plant and equipment (Note 6)	**50,517**	70,532
Depreciation of right-of-use-of-asset (Note 7)	**160,066**	80,033
Depreciation released on reclassification of property, plant and equipment (Note 6)	**-**	(1,754)
Bad debts written-off	**13,805**	-
Provision for bad debts	**(40,293)**	(36,634)
Changes in working capital:		
Trade and other receivables	**(223,187)**	25,710
Trade and other payables	**(178,371)**	496,479
Cash generated from operations	**866,198**	1,741,633

19. Commitments

	2020	2019
	€	€
Non-cancellable operating commitments:		
Less than one year	**329,411**	168,088
2-5 years	**164,747**	268,295
	494,158	436,383

20. Related party transactions

During the year ended 31 December 2020 and 2019, 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.