MEDICINES AUTHORITY

Annual Report and Financial Statements
31 December 2023

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Report of the Chief Executive Officer

The Chief Executive Officer presents his report and the audited financial statements of the Medicines Authority for the year ended 31 December 2023.

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; medical devices activities; 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 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 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 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 8. During 2023, the Authority reported a deficit of €601,702 (2022: €108,790).

Report of the Chief Executive Officer - continued

Auditors

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

Approved by the Chief Executive Officer on 22 March 2024.

Anthony Serracino Inglott
Chief Executive Officer

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

Statement of financial position

	Notes	As at 31 December 2023 €	2022 €
ASSETS			
Non-current assets			
Intangible assets	5	**145,707**	5,255
Property, plant and equipment	6	**106,167**	121,993
Right-of-use asset	7	**228,968**	381,613
Total non-current assets		**480,842**	508,861
Current assets			
Trade and other receivables	8	**1,258,117**	1,068,479
Cash at bank and in hand	9	**9,555,103**	9,716,963
Total current assets		**10,813,220**	10,785,442
Total assets		**11,294,062**	11,294,303

The notes on pages 8 to 25 form an integral part of these financial statements.

Statement of financial position - continued

	Notes	As at 31 December 2023 €	2022 €
CAPITAL AND LIABILITIES			
CAPITAL AND RESERVES			
Reserves			
Accumulated reserves		**7,669,593**	8,271,295
LIABILITIES			
Non-current liabilities			
Lease liabilities	10	**40,211**	196,386
Current liabilities			
Lease liabilities	10	**156,176**	148,973
Trade and other payables	11	**3,428,082**	2,677,649
Total current liabilities		**3,584,258**	2,826,622
Total liabilities		**3,624,469**	3,023,008
Total capital and liabilities		**11,294,062**	11,294,303

The notes on pages 8 to 25 form an integral part of these financial statements.

The financial statements on pages 3 to 25 were approved, signed and authorised by the Chief Executive Officer on 22 March 2024:

Anthony Serracino Inglott

Chief Executive Officer

Statement of comprehensive income

	Notes	For the year ended 31 December 2023 €	2022 €
Revenue	12	**6,133,931**	5,979,988
Administrative expenses	13	**(6,713,130)**	(6,090,741)
Operating deficit		**(579,199)**	(110,753)
Finance cost	15	**(13,777)**	(12,279)
Other (costs)/income	16	**(8,726)**	14,242
Deficit before tax		**(601,702)**	(108,790)
Tax expense	17	**-**	-
Deficit for the year		**(601,702)**	(108,790)

The notes on pages 8 to 25 form an integral part of these financial statements.

Statement of changes in equity

	Accumulated reserves €
Balance at 1 January 2022	8,380,085
Changes in equity for 2022	
Deficit for the year	(108,790)
Balance at 31 December 2022	8,271,295
Changes in equity for 2023	
Deficit for the year	**(601,702)**
Balance at 31 December 2023	**7,669,593**

The notes on pages 8 to 25 form an integral part of these financial statements.

Statement of cash flows

	Notes	For the year ended 31 December 2023 €	2022 €
Cash flows from operating activities			
Cash generated from operations	18	**174,275**	347,236
Net cash generated from operating activities		**174,275**	347,236
Cash flows from investing activities			
Purchase of intangible assets	5	**(142,830)**	(2,000)
Purchase of property, plant and equipment	6	**(30,555)**	(48,483)
Net cash used in investing activities		**(173,385)**	(50,483)
Cash flows from financing activities			
Lease payments	10	**(162,750)**	(216,483)
Net cash used in financing activities		**(162,750)**	(216,483)
Net movement in cash and cash equivalents		**(161,860)**	80,270
Cash and cash equivalents at the beginning of the year		**9,716,963**	9,636,693
Cash and cash equivalents at the end of the year	9	**9,555,103**	9,716,963

The notes on pages 8 to 25 form an integral part of these financial statements.

Notes to the financial statements

1. Material accounting policies

The material 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 Repoi1ing 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 2023, the Authority registered a deficit before tax of €601,702 (2022: €108,790).

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.

Development costs directly attributable to the production of new or substantially improved products or processes controlled by the Authority are capitalised if the costs can be measured reliably, the products or processes are technically feasible, future economic benefits are probable, and the Authority intends to and has sufficient resources to complete development and to use the asset. All the remaining development costs are charged to Statement of Comprehensive Income.

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.

Notes to the financial statements - continued

1. Material 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.

Notes to the financial statements - continued

1. Material accounting policies - continued

1.6 Financial assets

1.6.1 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).

1.6.2 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 detailed in Note 1.6.1. 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.

Notes to the financial statements - continued

1. Material accounting policies - continued

1.6 Financial assets - continued

1.6.3 Impairment

In relation to the impairment of financial assets, IFRS 9 requires an expected credit loss model. 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 allowanse 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-ımpaired financial asseL 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.

1.7 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.

Notes to the financial statements - continued

1. Material 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 requiredto 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 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.

1.11 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.

Notes to the financial statements - continued

1. Material accounting policies - continued

1.13 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
- Inspectorate and Enforcement Activities
- Post-Licensing Activities
- EMA Linguistic Checks
- Inspectorate 3rd Country Inspections
- Medical Devices Activities

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.

Notes to the financial statements - continued

2. Financial risk management

At 31 December 2023 and 2022 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.

Notes to the financial statements - continued

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 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 and disclosures

4.1 Initial Application of an International Financial Reporting Standard

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 2023.

- Amendments to IAS 1 Presentation of Financial Statements and IFRS Practice Statement 2: Disclosure of Accounting policies (issued on 12 February 2021) (effective on 1 January 2023)

Although the amendments did not result in any changes to the accounting policies themselves, they impacted the accounting policy information disclosed in the financial statements.

The amendments require the disclosure of 'material' rather than 'significant' accounting policies. The amendments also provide guidance on the application of materiality to disclosure of accounting policies, assisting entities to provide useful, entity specific accounting policy information that users need to understand other information in the financial statements.

Management reviewed the accounting policies and made updates to the information disclosed in the Material accounting policies (2022 – Significant accounting policies) in certain instances in line with these amendments.

Notes to the financial statements - continued

4. Changes in accounting policies - continued

- Amendments to IAS 8 Accounting policies, Changes in Accounting Estimates and Errors: Definition of Accounting Estimates (issued on 12 February 2021) (effective on 1 January 2023)

The amendments to IAS 8 focus entirely on accounting estimates with the definition of a change in accounting estimates being replaced with a definition of accounting estimates. Accounting estimates are now defined as "monetary amounts in financial statements that are subject to measurement uncertainty".

Accounting estimates arise when accounting policies require items in financial statements to be measured in a way that involves measurement uncertainty. The amendments clarify that a change in accounting estimate that results from new information or new developments is not the correction of an error and that the effects of a change in an input or a measurement method used to derive an accounting estimate are changes in accounting estimates if they do not result from the correction of prior period errors.

The effect of the change relating to the current period is recognised as income or expense in the current period. The effect, if any, on future periods is recognised as income or expense in those future periods.

The application of these amendments did not have a material effect on the Authority's financial statements.

- Amendments to IAS 12 Income Taxes: Deferred Tax related to Assets and Liabilities arising from a Single Transaction (issued on 7 May 2021) (effective on 1 January 2023)

The amendments narrow the scope of the recognition exemption in paragraph 15 of IAS 24 (recognition exemption) so that it no longer applies to transactions that, on initial recognition, give rise to equal taxable and deductible temporary differences.

- Amendments to IAS 12, Income taxes: International Tax Reform – Pillar Two Model Rules (issued 23 May 2023) (effective on 1 January 2023)

The amendment introduces a temporary, mandatory exemption from accounting for deferred taxes resulting from the introduction of the global minimum taxation and targeted disclosures in the notes for effected entities.

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

Notes to the financial statements - continued

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 IAS 1, Presentation of Financial Statements: Classification of Liabilities as Current or Non-current (issued on 23 January 2020), Classification of Liabilities as Current or Non-current - Deferral of Effective Date (issued on 15 July 2020) and Non-Current Liabilities with Covenants (issued on 31 October 2020) (effective on 1 January 2024)

The amendments requires that a right to defer settlement for at least 12 months must exist at the reporting date and have substance. This right may be subject to compliance with conditions specified in a loan arrangement and only those existing at the reporting date are to be considered. However, information about conditions or covenants that apply in future periods are to be disclosed. Also, liabilities relating to convertible debt may become current. The amendments apply retrospectively.

- Amendments to IFRS 16, Leases: Lease liability in a sale and leaseback (issued on 22 September 2022) (effective on 1 January 2024)

The narrow scope amendment impact how a seller-lessee accounts for variable payments that arise in a sale-and-leaseback transaction. The amendments introduce a new accounting model for variable payments and requires seller-lessees to reassess and potentially restate retrospectively as from date of application of IFRS 16.

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. Management does not anticipate any material impact on adoption of the above.

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

- Amendments to IAS 7, Statement of Cash Flows and IFRS 7 Financial Instruments: Disclosures: Supplier Finance Arrangements (issued on 25 May 2023)
- Amendments to IAS 21, The Effects of Changes in Foreign Exchange Rates: Lack of Exchangeability (issued 15 August 2023)

Management is assessing the impact that the adoption of these Financial Reporting Standards will have in the financial statement of the Authority in the period of initial application.

Notes to the financial statements - continued

5. Intangible Asset

	Website	Development costs	Total
	€	€	€
At 1 January 2022			
Cost	51,083	-	51,083
Accumulated amortisation	(45,325)	-	(45,325)
Net book amount	5,758	-	5,758
Year ended 31 December 2022			
Opening net book amount	5,758	-	5,758
Additions	2,000	-	2,000
Amortisation charge	(2,503)	-	(2,503)
Closing net book amount	5,255	-	5,255
At 31 December 2022			
Cost	53,083	-	53,083
Accumulated amortisation	(47,828)	-	(47,828)
Net book amount	5,255	-	5,255
Year ended 31 December 2023			
Opening net book amount	**5,255**	**-**	**5,255**
Additions	**-**	**142,830**	**142,830**
Amortisation charge	**(2,378)**	**-**	**(2,378)**
Closing net book amount	**2,877**	**142,830**	**145,707**
At 31 December 2023			
Cost	**53,083**	**142,830**	**195,913**
Accumulated amortisation	**(50,206)**	**-**	**(50,206)**
Net book amount	**2,877**	**142,830**	**145,707**

Development costs are outsourced to a third-party development company.

Notes to the financial statements - continued

6. Property, plant and equipment

	Furniture & fittings	Office & computer equipment	Motor vehicles	Leasehold improvements	Total
	€	€	€	€	€
At 1 January 2022					
Cost	122,241	276,106	51,460	106,559	556,366
Accumulated depreciation	(79,461)	(218,858)	(26,456)	(105,602)	(430,377)
Net book amount	42,780	57,248	25,004	957	125,989
Year ended 31 December 2022					
Opening net book amount	42,780	57,248	25,004	957	125,989
Additions	2,711	45,772	-	-	48,483
Depreciation charge	(8,877)	(36,945)	(6,252)	(405)	(52,479)
Closing net book amount	36,614	66,075	18,752	552	121,993
At 31 December 2022					
Cost	124,952	321,878	51,460	106,559	604,849
Accumulated depreciation	(88,338)	(255,803)	(32,708)	(106,007)	(482,856)
Net book amount	36,614	66,075	18,752	552	121,993
Year ended 31 December 2023					
Opening net book amount	**36,614**	**66,075**	**18,752**	**552**	**121,993**
Additions	**6,498**	**24,057**	**-**	**-**	**30,555**
Depreciation charge	**(9,197)**	**(30,382)**	**(6,250)**	**(552)**	**(46,381)**
Closing net book amount	**33,915**	**59,750**	**12,502**	**-**	**106,167**
At 31 December 2023					
Cost	**131,450**	**345,935**	**51,460**	**106,559**	**635,404**
Accumulated depreciation	**(97,535)**	**(286,185)**	**(38,958)**	**(106,559)**	**(529,237)**
Net book amount	**33,915**	**59,750**	**12,502**	**-**	**106,167**

Notes to the financial statements - continued

7. Right of use asset

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

	Office building €
At 1 January 2022	
Cost	480,197
Accumulated depreciation	(400,164)
Net book amount	80,033
Year ended 31 December 2022	
Opening net book amount	80,033
Disposal of ROU on expiry of lease	(480,197)
Recognition of ROU	457,936
Depreciation charge for the year	(156,356)
Derecognition of depreciation on expiry of lease	480,197
Closing net book amount	381,613
At 31 December 2022	
Cost	457,936
Accumulated depreciation	(76,323)
Net book amount	381,613
Year ended 31 December 2023	
Opening net book amount	**381,613**
Depreciation charge for the year	**(152,645)**
Closing net book amount	**228,968**
At 31 December 2023	
Cost	**457,936**
Accumulated depreciation	**(228,968)**
Net book amount	**228,968**

Notes to the financial statements - continued

8. Trade and other receivables

	2023 €	2022 €
Trade receivables	**941,378**	664,338
Prepayments	**159,376**	301,945
Accrued income	**157,363**	102,196
	1,258,117	1,068,479

Trade receivables are stated net of provision for bad debts amounting to €98,891 (2022: €174,320).

9. Cash and cash equivalents

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

	2023 €	2022 €
Cash at bank and in hand	**9,555,103**	9,716,963

10. Lease liabilities

	2023 €	2022 €
Non-current lease liabilities	**40,211**	196,386
Current lease liabilities	**156,176**	148,973
Total lease liabilities	**196,387**	345,359

The finance cost arising on the lease liability is disclosed in note 15. Lease payments were discounted to present value by applying the incremental borrowing rate of 4.75% (2022: 4.75%). The undiscounted lease commitments are disclosed in note 19. Total undiscounted lease payments made during 2023 amounted to €162,750 (2022: €216,483).

11. Trade and other payables

	2023 €	2022 €
Trade payables	**374,436**	414,784
Accruals	**1,173,814**	749,014
Deferred income	**1,879,832**	1,513,851
	3,428,082	2,677,649

Notes to the financial statements - continued

12. Revenue

Revenue represents licensing, post-licensing. inspectorate, advanced scientific initiatives and enforcement fees, third country inspections and medical devices activities.

13. Expenses by nature

13.1: Administrative expenses

	2023	2022 as restated
	€	€
Employee benefit expenses (Note 14)	**5,551,541**	4,908,765
Amortisation of intangible assets (Note 5)	**2,378**	2,503
Depreciation of property, plant and equipment (Note 6)	**46,381**	52,479
Depreciation of right-of-use asset (Note 7)	**152,645**	156,356
Lease expenses	**49,595**	31,201
Professional fees	**178,479**	214,395
Staff training	**316,336**	350,500
Travel and accommodation	**120,949**	66,731
Computer expenses	**207,846**	135,762
Bad debts written-off	**15,803**	7,706
Provision for bad debts	**(75,429)**	95
Other expenses	**146,606**	164,248
Total administrative expenses	**6,713,130**	6,090,741

13.2: Audit fees

Fees charged by the auditors for services rendered during the financial years ended 31 December 2023 and 2022 relate to the following:

	2023	2022
	€	€
Annual statutory audit	**5,000**	5,000

14. Employees

14.1: Employee benefit expenses

	2023	2022 as restated
	€	€
Management	**1,755,134**	1,529,402
Wages and salaries	**3,501,633**	3,104,607
Social security costs	**294,774**	274,756
	5,551,541	4,908,765

Notes to the financial statements - continued

14. Employees - continued

14.2: Average number of employees

The average weekly number of persons employed by the Medicines Authority during the financial reporting year was 126 (2022: 117):

	2023	2022
Management	29	29
Technical staff	78	67
Administration	19	21
	126	117

15. Finance cost

	2023 €	2022 €
Lease interest expense	13,777	12,279

16. Other (costs)/income

	2023 €	2022 €
Other income	25,780	14,242
Unutilised project funds refunded	(34,506)	-
	(8,726)	14,242

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).

Notes to the financial statements - continued

18. Cash generated from operations

Reconciliation of deficit before tax to cash generated from operations:

	2023 €	2022 €
Deficit before tax	**(601,702)**	(108,790)
Adjustments for:		
Amortisation of intangible assets (Note 5)	**2,378**	2,503
Depreciation of property, plant and equipment (Note 6)	**46,381**	52,479
Depreciation of right-of-use asset (Note 7)	**152,645**	156,356
Bad debts written off	**15,803**	7,706
Provision for bad debts	**(75,429)**	95
Interest expense (Note 15)	**13,777**	12,279
Changes in working capital		
Trade and other receivables	**(130,012)**	157,014
Trade and other payables	**750,434**	67,594
Cash generated from operations	**174,275**	347,236

19. Commitments

	2023 €	2022 €
Non-cancellable lease commitments qualifying as ROU		
Less than one year	**162,750**	162,750
Between 1 and 5 years	**40,688**	203,438
	203,438	366,188
Other lease commitments		
Less than one year	**49,277**	49,277
Between 1 and 5 years	**93,775**	61,596
	143,052	110,873
Total lease commitments	**346,490**	477,061
Other commitments:		
Capital commitments committed and contracted for	**497,358**	640,188

20. Related party transactions

During the year ended 31 December 2023 and 2022, there were no transactions with key management personnel except for emolument payments as disclosed in Note 14.

Notes to the financial statements - continued

21. Comparative figures

Comparative figures were reclassified to comply with current year presentations. The Chief Executive Officer believes that the current presentation provides a better representation of the results at year end. Changes are summarised below:

	2022 As previously reported €	Adjustment €	2022 As restated €
Administrative expenses			
Professional fees	182,327	32,068	214,395
Staff costs	4,940,791	(32,026)	4,908,765
Other expenses	164,290	(42)	164,248

22. Statutory information

Medicines Authority is a State-owned Authority. The Authority's ultimate controlling party is the Ministry for Health and Active Ageing on behalf of the Government of Malta who's registered office is Palazzo Castellania, Merchant Street, Valletta, Malta.

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Independent auditor's report

To the Ministry for Health and Active Ageing

Report on the Audit of the Financial Statements

Opinion

We have audited the financial statements of the Medicines Authority (the Authority), set out on pages 3 to 25, which comprise the statement of financial position as at 31 December 2023 and the statement of comprehensive income, statement of changes in equity and statement of cash flows for the year then ended, and notes to the financial statements, including material accounting policy information.

In our opinion, the accompanying financial statements:

a. present fairly, in all material respects, the financial position of the Authority as at 31 December 2023, and of its financial performance and its cash flows for the year then ended in accordance with International Financial Reporting Standards as adopted by the EU (EU IFRSs)
b. have been prepared in accordance with the Medicines Act 2003 (Cap. 458) except that the requirement to present audited financial statements within six weeks from year end as required by Article 10(2) of the Medicines Act was not met.

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 Auditor's Responsibilities for the Audit of the Financial Statements section of our report. 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 that are relevant to our audit of the financial statements in accordance with the Accountancy Profession (Code of Ethics for Warrant Holders) Directive issued in terms of the Accountancy Profession Act (Cap. 281) in Malta, and we have fulfilled our other ethical responsibilities in accordance with these requirements and the IESBA Code. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Other Information

The Chief Executive Officer is responsible for the other information. The other information comprises the Report of the Chief Executive Officer. Our opinion on the financial statements does not cover this information. In connection with our audit of the financial statements, our responsibility is to read the other information 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. Based on the work we have performed, in our opinion the information given in the Report of the Chief Executive Officer for the financial year for which the financial statements are prepared is consistent with the financial statements.

In addition, in light of the knowledge and understanding of the Authority and its environment obtained in the course of the audit, we are required to report if we have identified material misstatements in the Report of the Chief Executive Officer. We have nothing to report in this regard.

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Independent auditor's report

To the Ministry for Health and Active Ageing (continued)

Responsibilities of the Chief Executive Officer

The Chief Executive Officer is responsible for the preparation of the financial statements that give a true and fair view in accordance with EU IFRS's, and for such internal control as the Chief Executive Officer determines to be 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 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 Chief Executive Officer either intends to liquidate the Authority or to cease operations, or has no realistic alternative but to do so.

Auditor's 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 auditor's 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 judgement 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 Chief Executive Officer.
- Conclude on the appropriateness of the 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 Authrity's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's 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 auditor's report. However, future events or conditions may cause the Authority to cease to continue as a going concern.

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Independent auditor's report

To the Ministry for Active Ageing (continued)

Auditor's Responsibilities for the Audit of the Financial Statements (continued)

- 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 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.

Use of audit report

This report is made solely to the Ministry for Health and Active Ageing as a body in accordance with the requirements of the Medicines Act 2003 (Cap. 458) of the laws of Malta. Our audit work has been undertaken so that we might state to the Ministry those matters that we are required to state to them in an auditor's report and for no other purpose. To the full extent permitted by law we do not assume responsibility to anyone other than the Ministry as a body for our audit work, for this report or for the opinions we have formed.

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

Mazars Malta
Certified Public Accountants
Birkirkara,
Malta

22 March 2024