

Medicines Authority

Annual Report and Financial Statements

For the Year Ended 31 December 2024

Medicines Authority
For the Year Ended 31 December 2024
Contents

	<u>Page</u>
Report of the Chief Executive Officer	1
Statement of Financial Position	2 - 3
Statement of Comprehensive Income	4
Statement of Changes in Equity	5
Statement of Cash Flows	6
Notes to the Financial Statements	7 - 20
Independent Auditors' Report	

Medicines Authority

Report of the Chief Executive Officer

For the Year Ended 31 December 2024

The Chief Executive Officer ("CEO") presents his report and the audited financial statements of the Medicines Authority for the year ended 31 December 2024.

Functions of the Medicines Authority

The functions of the Medicines Authority (the "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 inspections of pharmaceutical manufacturing and distributing activities and monitoring the use of medical products in line with the 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 is responsible for the overall management and performance of the Authority.

This 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 are held and corporate issues are discussed at these meetings.

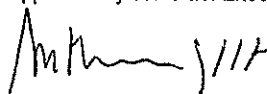
Results

The results for the year are as shown in the statement of comprehensive income on page 4. During 2024, the Authority reported a deficit of €940,396 (2023: €601,702).

Auditors

MRC Audit Ltd, Certified Public Accountants and Registered Auditors, have indicated their willingness to continue in office.

Approved by the Chief Executive Officer on 07 April 2025.



Anthony Serracino Inglott
Chief Executive Officer

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

Medicines Authority
Statement of Financial Position
31 December 2024

		<u>2024</u>	<u>2023</u>
	Note	€	€
ASSETS			
Non-current assets			
Intangible assets	5.	244,960	145,707
Property, plant and equipment	6.	124,339	106,167
Right-of-use asset	7.	76,323	228,968
Total non-current assets		<u>445,622</u>	<u>480,842</u>
Current assets			
Trade and other receivables	8.	1,701,167	1,258,117
Cash and cash equivalents	9.	8,499,772	9,555,103
Total current assets		<u>10,200,939</u>	<u>10,813,220</u>
TOTAL ASSETS		<u>10,646,561</u>	<u>11,294,062</u>

The notes on pages 7 to 20 form an integral part of these financial statements.

Medicines Authority
Statement of Financial Position
31 December 2024

	Note	2024 €	2023 €
EQUITY AND LIABILITIES			
Equity and reserves			
Accumulated reserves		6,729,197	7,669,593
Liabilities			
Non-current liabilities			
Lease liabilities	10.	-	40,211
Current liabilities			
Lease liabilities	10.	42,195	156,176
Trade and other payables	11.	3,875,169	3,428,082
Total current liabilities		3,917,364	3,584,258
TOTAL EQUITY AND LIABILITIES		10,646,561	11,294,062

The notes on pages 7 to 20 form an integral part of these financial statements.

These financial statements on pages 2 to 20 were approved, signed and authorised by the Chief Executive Officer on 07 April 2025:



Anthony Serracino Inglott

Chief Executive Officer

Medicines Authority
Statement of Comprehensive Income
For the Year Ended 31 December 2024

		2024	2023
	Note	€	€
Revenue	12.	6,990,677	6,133,931
Administrative expenses	13.	(8,064,290)	(6,713,130)
Operating deficit		(1,073,613)	(579,199)
Finance cost	15.	(8,558)	(13,777)
Other income/(costs)	16.	141,775	(8,726)
Deficit before tax		(940,396)	(601,702)
Taxation	17.	-	-
Deficit for the year		(940,396)	(601,702)

The notes on pages 7 to 20 form an integral part of these financial statements.

Medicines Authority
Statement of Changes in Equity
For the Year Ended 31 December 2024

	<u>Accumulated reserves</u> €
Balance at 1 January 2023	<u>8,271,295</u>
Changes in equity for 2023	
Deficit for the year	<u>(601,702)</u>
Balance at 31 December 2023	<u>7,669,593</u>
Changes in equity for 2024	
Deficit for the year	<u>(940,396)</u>
Balance at 31 December 2024	<u><u>6,729,197</u></u>

The notes on pages 7 to 20 form an integral part of these financial statements.

Medicines Authority**Statement of Cash Flows****For the Year Ended 31 December 2024**

		<u>2024</u>	<u>2023</u>
	Note	€	€
Cash flows from operating activities:			
Net cash (used in)/generated from operations	18.	<u>(718,050)</u>	<u>174,275</u>
Cash flows from investing activities:			
Payments to acquire intangible assets	5.	(101,061)	(142,830)
Payments to acquire property, plant and equipment	6.	(73,658)	(30,555)
Proceeds from disposal of property, plant and equipment	6.	188	-
Net cash flows used in investing activities		<u>(174,531)</u>	<u>(173,385)</u>
Cash flows from financing activities:			
Lease payments	10.	<u>(162,750)</u>	<u>(162,750)</u>
Net cash flows used in financing activities		<u>(162,750)</u>	<u>(162,750)</u>
Net movement in cash and cash equivalents		<u>(1,055,331)</u>	<u>(161,860)</u>
Cash and cash equivalents at beginning of year		9,555,103	9,716,963
Cash and cash equivalents at end of year	9.	<u><u>8,499,772</u></u>	<u><u>9,555,103</u></u>

The notes on pages 7 to 20 form an integral part of these financial statements.

Medicines Authority

Notes to the Financial Statements

For the Year Ended 31 December 2024

1. Material Accounting Policies

The material accounting policies applied in the preparation of these 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 and presented in accordance with the requirements of the 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 2024, the Authority registered a deficit before tax of €940,396 (2023: €601,702)

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 translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognised in surplus or deficit.

1.3. Intangible assets

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 or loss.

Medicines Authority

Notes to the Financial Statements (continued)

For the Year Ended 31 December 2024

1. Material Accounting Policies (continued)

1.4. Property, plant and equipment

The Medicines Authority's (the "Authority") property, plant and equipment is 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 life, using the straight-line method, on the following bases:

Furniture and fixtures	10 years
Motor vehicles	5 years
Office and computer equipment	4 years
Leasehold improvements	3 years

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 value in use and its fair value less cost to sell. For the purpose 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.

1.6. 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).

Medicines Authority

Notes to the Financial Statements (continued)

For the Year Ended 31 December 2024

1. Material Accounting Policies (continued)

1.6. Financial assets (continued)

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.

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 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.

1.7. 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.

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.

Medicines Authority

Notes to the Financial Statements (continued)

For the Year Ended 31 December 2024

1. Material Accounting Policies (continued)

1.8. Provisions

Provisions are recognised when the Authority has a 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 of the amount of the obligation can be made. Provisions are measured at the Chief Executive Officer's best estimate of the expenditure required to settle the present obligation at the financial position date. If the effect of the time value of money is material, provisions are determined by discounting the expected future cash flows at a pre-tax rate that reflects current market assessments of the time value of money and, where appropriate, the risks specific to the liability. Provisions are not recognised for future operating losses.

1.9. 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, cancelled or expires.

1.11. Trade and other payables

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

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

1.12. Offsetting financial instruments

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

1.13. Revenue recognition

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

Medicines Authority

Notes to the Financial Statements (continued)

For the Year Ended 31 December 2024

1. Material Accounting Policies (continued)

1.13. Revenue recognition (continued)

- EMA Linguistic Check
- Inspectorate 3rd Country Inspections
- Medical Devices Activities

1.14. Leases

The Authority recognizes 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 payments 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 2024 and 2023 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

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.

Interest Rate Risk

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

Medicines Authority

Notes to the Financial Statements (continued)

For the Year Ended 31 December 2024

1. Material Accounting Policies (continued)

2. Financial Risk Management (continued)

b. Credit Risk

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

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

c. Liquidity Risk

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

2.2. Capital risk management

The Authority's objective when managing capital is 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 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 the EU for an accounting period on or after 1 January 2024.

Medicines Authority

Notes to the Financial Statements (continued)

For the Year Ended 31 December 2024

4. Changes in accounting policies and disclosures (continued)

4.1. Initial Application of an International Financial Reporting Standard (continued)

- 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 require that a right to defer settlement for at least 12 months after the reporting period must have substance and must exist at the end of the reporting period. 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.

- Amendments to IAS 7, Statement of Cash Flows and IFRS 7 Financial Instruments: Disclosures: Supplier Finance Arrangements (issued on 25 May 2023) (effective on 1 January 2024)

The amendments require entities to provide certain specific disclosures (qualitative and quantitative) related to supplier finance arrangements. The amendments also provide guidance on characteristics of supplier finance arrangements.

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

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

- Amendments to IAS 21, The Effects of Changes in Foreign Exchange Rates: Lack of Exchangeability (issued 15 August 2023) (effective 1 January 2025)
- Amendments to the Classification and Measurement of Financial Instruments (Amendments to IFRS 9 and 7) (issued 30 May 2024) (effective 1 January 2026)

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

- IFRS 18 'Presentation and Disclosure in Financial Statements' (issued 9 April 2024) (effective 1 January 2027)
- IFRS 19 'Subsidiaries without Public Accountability: Disclosures' Statements' (issued 9 May 2024) (effective 1 January 2027)

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.

Medicines Authority

Notes to the Financial Statements (continued)

For the Year Ended 31 December 2024

5. Intangible assets

	Development costs €	Website €	Total €
At 01 January 2023			
Cost			
Opening balance	-	53,083	53,083
Additions	142,830	-	142,830
Balance at 31 December 2023	142,830	53,083	195,913
Amortisation			
Opening balance	-	(47,828)	(47,828)
Amortisation	-	(2,378)	(2,378)
Balance at 31 December 2023	-	(50,206)	(50,206)
At 01 January 2023	-	5,255	5,255
At 31 December 2023	142,830	2,877	145,707
	Development costs €	Website €	Total €
At 01 January 2024			
Cost			
Opening balance	142,830	53,083	195,913
Additions	101,061	-	101,061
Balance at 31 December 2024	243,891	53,083	296,974
Amortisation			
Opening balance	-	(50,206)	(50,206)
Amortisation	-	(1,808)	(1,808)
Balance at 31 December 2024	-	(52,014)	(52,014)
At 01 January 2024	142,830	2,877	145,707
At 31 December 2024	243,891	1,069	244,960

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

Medicines Authority

Notes to the Financial Statements (continued)

For the Year Ended 31 December 2024

6. Property, plant and equipment

	Furniture & fixtures	Motor vehicles	Office & computer equipment	Leasehold improvements	Total
	€	€	€	€	€
At 01 January 2023					
Cost					
Opening balance	124,952	51,460	321,878	106,559	604,849
Additions	6,498	-	24,057	-	30,555
Balance at 31 December 2023	131,450	51,460	345,935	106,559	635,404
Depreciation and impairment losses					
Opening balance	(88,338)	(32,708)	(255,803)	(106,007)	(482,856)
Depreciation	(9,197)	(6,250)	(30,382)	(552)	(46,381)
Balance at 31 December 2023	(97,535)	(38,958)	(286,185)	(106,559)	(529,237)
Net book amount					
At 01 January 2023	36,614	18,752	66,075	552	121,993
At 31 December 2023	33,915	12,502	59,750	-	106,167
	Furniture & fixtures	Motor vehicles	Office & computer equipment	Leasehold improvements	Total
	€	€	€	€	€
At 01 January 2024					
Cost					
Opening balance	131,450	51,460	345,935	106,559	635,404
Additions	22,365	-	51,293	-	73,658
Disposals	-	-	(692)	-	(692)
Balance at 31 December 2024	153,815	51,460	396,536	106,559	708,370
Depreciation and impairment losses					
Opening balance	(97,535)	(38,958)	(286,185)	(106,559)	(529,237)
Disposals	-	-	504	-	504
Depreciation	(10,495)	(6,252)	(38,551)	-	(55,298)
Balance at 31 December 2024	(108,030)	(45,210)	(324,232)	(106,559)	(584,031)
Net book amount					
At 01 January 2024	33,915	12,502	59,750	-	106,167
At 31 December 2024	45,785	6,250	72,304	-	124,339

Medicines Authority**Notes to the Financial Statements (continued)****For the Year Ended 31 December 2024****7. Right of use asset**

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

	<u>Office building</u> €
At 1 January 2023	
Cost	
Opening balance	457,936
Balance at 31 December 2023	457,936
Depreciation	
Opening balance	(76,323)
Charge for the year	(152,645)
Balance at 31 December 2023	(228,968)
Net book amount	
At 1 January 2023	381,613
At 31 December 2023	228,968
At 1 January 2024	
Cost	
Opening balance	457,936
Balance at 31 December 2024	457,936
Depreciation	
Opening balance	(228,968)
Charge for the year	(152,645)
Balance at 31 December 2024	(381,613)
Net book amount	
At 01 January 2024	228,968
At 31 December 2024	76,323

Medicines Authority**Notes to the Financial Statements (continued)****For the Year Ended 31 December 2024****8. Trade and other receivables**

	2024	2023
	€	€
Trade receivables	800,589	941,378
Prepayments	759,136	159,376
Accrued Income	141,442	157,363
Total	1,701,167	1,258,117

Trade receivables are stated net of provision for bad debts amounting to €91,892 (2023: €98,891).

9. Cash and cash equivalents

Cash and cash equivalents for the purpose of the cash flow statement are as follows:

	2024	2023
	€	€
Cash at bank and in hand	8,499,772	9,555,103

10. Lease liabilities

The present value of finance lease liabilities is as follows:

	2024	2023
	€	€
Non-current lease liabilities	-	40,211
Current lease liabilities	42,195	156,176
Total	42,195	196,387

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% (2023: 4.75%). The undiscounted lease commitments are disclosed in note 19. The undiscounted lease payments made during 2024 amounted to €162,750 (2023: €162,750).

11. Trade and other payables

	2024	2023
	€	€
Trade payables	285,471	374,436
Accruals	1,040,123	1,173,814
Deferred income	2,549,575	1,879,832
Total	3,875,169	3,428,082

12. Revenue

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

Medicines Authority**Notes to the Financial Statements (continued)****For the Year Ended 31 December 2024****13. Expenses by nature****13.1. Administrative expenses**

	2024	2023
	€	€
Employee benefit expenses (Note 14)	6,555,607	5,551,541
Amortisation of intangible assets (Note 5)	1,808	2,378
Depreciation of property, plant & equipment (Note 6)	55,298	46,381
Depreciation of right-of-use asset (Note 7)	152,645	152,645
Lease expenses	49,595	49,595
Professional fees	194,516	178,479
Staff training	436,302	316,336
Travel and accommodation	110,071	120,949
Computer expenses	348,026	207,846
Bad debts written off	12,460	15,803
Provision for bad debts	(6,999)	(75,429)
Other expenses	154,961	146,606
Total administrative expenses	8,064,290	6,713,130

13.2. Audit fees

Fees charged by the auditors for services rendered during the financial years ended 31 December 2024 and 2023 relate to the following:

	2024	2023
	€	€
Annual statutory audit	4,450	5,000

14. Employees**14.1. Employee benefit expenses**

	2024	2023
	€	€
Management	1,679,702	1,755,134
Wages and salaries	4,546,399	3,501,633
Social security costs	329,506	294,774
Total	6,555,607	5,551,541

14.2. Average number of employees

The average weekly number of persons employed by the Medicines Authority during the financial reporting year was 131 (2023: 126).

Medicines Authority

Notes to the Financial Statements (continued)

For the Year Ended 31 December 2024

14. Employees (continued)

14.2. Average number of employees (continued)

	2024	2023
	€	€
Management	30	29
Technical staff	78	78
Administration	23	19
Total	131	126

15. Finance cost

	2024	2023
	€	€
Lease interest expense	8,558	13,777

16. Other income/(costs)

	2024	2023
	€	€
Other income	141,775	25,780
Unutilised project funds refunded	-	(34,506)
	141,775	(8,726)

17. Taxation

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

18. Cash (used in)/generated from operations

Reconciliation of deficit before tax to cash (used in)/generated from operations:

	2024	2023
	€	€
Deficit before tax	(940,396)	(601,702)
Adjustments for:		
Amortisation of intangible assets	1,808	2,378
Depreciation of property, plant and equipment (Note 6)	55,298	46,381
Depreciation of right-of-use asset (Note 7)	152,645	152,645
Bad debts written off	12,460	15,803
Provision for bad debts	(6,999)	(75,429)
Interest expense (Note 15)	8,558	13,777
Changes in working capital		
Trade and other receivables	(448,511)	(130,012)
Trade and other payables	447,087	750,434
Cash (used in)/generated from operations	(718,050)	174,275

Medicines Authority**Notes to the Financial Statements (continued)****For the Year Ended 31 December 2024****19. Commitments**

	2024	2023
	€	€
Non-cancellable lease commitments qualifying as ROU		
Less than one year	40,688	162,750
Between 1 and 5 years	-	40,688
	<u>40,688</u>	<u>203,438</u>
Other lease commitments		
Less than one year	-	49,277
Between 1 and 5 years	-	93,775
	<u>-</u>	<u>143,052</u>
Total lease commitments	<u>40,688</u>	<u>346,490</u>
Other commitments		
Capital commitments committed and contracted for	<u>253,467</u>	<u>497,358</u>

20. Related party transactions

During the year ended 31 December 2024 and 2023, 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 Health and Active Ageing on behalf of the Government of Malta who's registered office is Palazzo Castellania, Merchant Street, Valletta, Malta.



Independent Auditors' Report

To the Ministry for Health and Active Ageing

Report on the Audit of the Financial Statements

Opinion

We have audited the accompanying financial statements of Medicines Authority (the Authority) set out on pages 2 - 20 which comprise the statement of financial position as at 31 December 2024, 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 a summary of material accounting policies.

In our opinion, the accompanying financial statements:

- a. give a true and fair view of the financial position of the Authority as at 31 December 2024, and of its financial performance for the year then ended in accordance with International Financial Reporting Standards as adopted by the European Union.
- b. have been properly prepared in accordance with the Medicines Act, 2003 (Cap. 458) and have been presented within fourteen weeks from the year end as required by the revised Article 10(2) of the Medicines Act.

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 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 Matter

The financial statements of the Authority for the year ended 31 December 2023, were audited by another auditor who expressed an unmodified opinion on those statements on 22 March 2024.

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 and we do not express any form of assurance conclusion thereon. 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.

"Mercleca", Suite 2, Triq It-Tabib Anton Tabone, Victoria, Gozo – Malta

T +356 2155 3892 M +356 7989 0810 E darren@mercieca.com.mt

MRC Audit Ltd is a registered company in Malta with reg. no. C88738, is a registered Accountancy & Audit Firm with the Accountancy Board with reg. no. AB/2/18/15 and authorised to act as a Company Service Provider by the Malta Financial Services Authority.

Directors: **Darren Mercleca** FCCA, MIA, CPA(PC), Cert. Tax, Cert. CII, **Marjean Mercleca** B.Sc. (Hons) (Pharm.Sc.), M.Pharm.



Independent Auditors' Report (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 IFRSs as adopted for the EU, and for such internal control as the Chief Executive Officer determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the 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 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 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 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 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 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.

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Independent Auditors' Report (continued)

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 and for the opinions we have formed.

Darren Mercieca

for and on behalf of

MRC Audit Ltd

Registered Auditors

07 April 2025

"Mercieca", Suite 2, Triq It-Tabib Anton Tabone, Victoria, Gozo – Malta

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