

Medicines Authority

Annual Report and Financial Statements

For the Year Ended 31 December 2025

Medicines Authority

For the Year Ended 31 December 2025

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Medicines Authority

Report of the Chief Executive Officer

For the Year Ended 31 December 2025

The Chief Executive Officer ("CEO") presents his report and the audited financial statements of the Medicines Authority for the year ended 31 December 2025.

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, Senior Heads 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 2025, the Authority reported a deficit of €1,589,383 (2024: €940,396).

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 22 April 2026.



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 2025

	Note	<u>2025</u>	<u>2024</u>
		€	€
ASSETS			
Non-current assets			
Intangible assets	5.	283,708	244,960
Property, plant and equipment	6.	96,443	124,339
Right-of-use asset	7.	752,255	76,323
Total non-current assets		<u>1,132,406</u>	<u>445,622</u>
Current assets			
Trade and other receivables	8.	1,597,977	1,701,167
Cash and cash equivalents	9.	7,162,788	8,499,772
Total current assets		<u>8,760,765</u>	<u>10,200,939</u>
TOTAL ASSETS		<u>9,893,171</u>	<u>10,646,561</u>

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

Medicines Authority

Statement of Financial Position

31 December 2025

	Note	2025 €	2024 €
EQUITY AND LIABILITIES			
Equity and reserves			
Accumulated reserves		5,139,814	6,729,197
Liabilities			
Non-current liabilities			
Lease liabilities	10.	605,463	-
Current liabilities			
Lease liabilities	10.	155,390	42,195
Trade and other payables	11.	3,992,504	3,875,169
Total current liabilities		4,147,894	3,917,364
TOTAL EQUITY AND LIABILITIES		9,893,171	10,646,561

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 22 April 2026:



Anthony Serracino Inglott

Chief Executive Officer

Medicines Authority
Statement of Comprehensive Income
For the Year Ended 31 December 2025

	Note	2025 €	2024 €
Revenue	12.	7,678,754	6,990,677
Administrative expenses	13.	(9,542,416)	(8,064,290)
Operating deficit		(1,863,662)	(1,073,613)
Finance cost	15.	(58,588)	(8,558)
Other income	16.	332,867	141,775
Deficit before tax		(1,589,383)	(940,396)
Taxation	17.	-	-
Deficit for the year		(1,589,383)	(940,396)

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 2025

	<u>Accumulated reserves</u> €
Balance at 01 January 2024	7,669,593
Changes in equity for 2024	
Deficit for the year	<u>(940,396)</u>
Balance at 31 December 2024	<u>6,729,197</u>
Changes in equity for 2025	
Deficit for the year	<u>(1,589,383)</u>
Balance at 31 December 2025	<u>5,139,814</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 2025

		<u>2025</u>	<u>2024</u>
	Note	€	€
Cash flows from operating activities:			
Net cash used in operations	18.	<u>(1,095,965)</u>	<u>(718,050)</u>
Cash flows from investing activities:			
Payments to acquire intangible assets	5.	(39,453)	(101,061)
Payments to acquire property, plant and equipment	6.	(26,377)	(73,658)
Proceeds from disposal of property, plant and equipment	6.	581	188
Net cash flows used in investing activities		<u>(65,249)</u>	<u>(174,531)</u>
Cash flows from financing activities:			
Lease payments	10.	(175,770)	(162,750)
Net cash flows used in financing activities		<u>(175,770)</u>	<u>(162,750)</u>
Net movement in cash and cash equivalents			
Cash and cash equivalents at beginning of year		(1,336,984)	(1,055,331)
Cash and cash equivalents at end of year	9.	<u>8,499,772</u>	<u>9,555,103</u>
		<u>7,162,788</u>	<u>8,499,772</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 2025

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 2025 the Authority registered a deficit before tax of €1,589,383 (2024: €940,396).

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 2025

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 preproperty, 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 2025

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 2025

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 2025

1. Material Accounting Policies (continued)

1.13. Revenue recognition (continued)

- EMA Linguistic Check
- Inspectorate 3rd Country Inspections
- Medical Devices Activities
- Medicines Intelligence and Access Unit 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 2025 and 2024 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 value 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 2025

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.

Medicines Authority

Notes to the Financial Statements (continued)

For the Year Ended 31 December 2025

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 2025.

- Amendments to IAS 21, The Effects of Changes in Foreign Exchange Rates: Lack of Exchangeability (issued 15 August 2023) (effective 1 January 2025)

The amendments provide guidance on how to determine the exchange rate when a currency is not exchangeable. They introduce a framework for assessing exchangeability and require additional disclosures when exchangeability is lacking, including the nature and financial impact of the situation.

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 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' (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 2025

5. Intangible assets

	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
At 01 January 2025			
Cost			
Opening balance	243,891	53,083	296,974
Additions	39,453	-	39,453
Balance at 31 December 2025	283,344	53,083	336,427
Amortisation			
Opening balance	-	(52,014)	(52,014)
Amortisation	-	(705)	(705)
Balance at 31 December 2025	-	(52,719)	(52,719)
Other changes, movements			
At 01 January 2025	243,891	1,069	244,960
At 31 December 2025	283,344	364	283,708

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

Medicines Authority

Notes to the Financial Statements (continued)

For the Year Ended 31 December 2025

6. Property, plant and equipment

	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

	Furniture & fixtures	Motor vehicles	Office & computer equipment	Leasehold improvements	Total
	€	€	€	€	€
At 01 January 2025					
Cost					
Opening balance	153,815	51,460	396,536	106,559	708,370
Additions	5,498	-	20,879	-	26,377
Disposals	(1,481)	-	-	-	(1,481)
Balance at 31 December 2025	157,832	51,460	417,415	106,559	733,266
Depreciation and impairment losses					
Opening balance	(108,030)	(45,210)	(324,232)	(106,559)	(584,031)
Depreciation	(11,538)	(6,250)	(35,904)	-	(53,692)
Disposals	900	-	-	-	900
Balance at 31 December 2025	(118,668)	(51,460)	(360,136)	(106,559)	(636,823)
Net book amount					
At 01 January 2025	45,785	6,250	72,304	-	124,339
At 31 December 2025	39,164	-	57,279	-	96,443

Medicines Authority

Notes to the Financial Statements (continued)

For the Year Ended 31 December 2025

7. Right of use asset

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

	<u>Office building</u>
	<u>€</u>
At 01 January 2024	
Cost	
Opening balance	457,936
Balance at 31 December 2024	<u>457,936</u>
Depreciation	
Opening balance	(228,968)
Charge for the year	(152,645)
Balance at 31 December 2024	<u>(381,613)</u>
Net book amount	
At 01 January 2024	<u>228,968</u>
At 31 December 2024	<u>76,323</u>
At 01 January 2025	<u>Office building</u>
	<u>€</u>
Cost	
Opening balance	457,936
Additions	835,839
Derecognition	(457,936)
Balance at 31 December 2025	<u>835,839</u>
Depreciation	
Opening balance	(381,613)
Charge for the year	(159,907)
Derecognition	457,936
Balance at 31 December 2025	<u>(83,584)</u>
Net book amount	
At 01 January 2025	<u>76,323</u>
At 31 December 2025	<u>752,255</u>

Medicines Authority

Notes to the Financial Statements (continued)

For the Year Ended 31 December 2025

8. Trade and other receivables

	2025	2024
	€	€
Trade receivables	614,987	800,589
Prepayments	582,585	759,136
Accrued Income	400,405	141,442
Total	1,597,977	1,701,167

Trade receivables are stated net of provision for bad debts amounting to €232,591(2024: €91,892).

9. Cash and cash equivalents

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

	2025	2024
	€	€
Cash at bank and in hand	7,162,788	8,499,772

10. Lease liabilities

The present value of finance lease liabilities is as follows:

	2025	2024
	€	€
Non-current lease liabilities	605,463	-
Current lease liabilities	155,390	42,195
Total	760,853	42,195

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% (2024: 4.75%). The undiscounted lease commitments are disclosed in note 19. The undiscounted lease payments made during 2025 amounted to €175,770 (2024: €162,750).

11. Trade and other payables

	2025	2024
	€	€
Trade payables	587,575	285,471
Accruals	1,086,285	1,040,123
Deferred income	2,318,644	2,549,575
Total	3,992,504	3,875,169

12. Revenue

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

Medicines Authority

Notes to the Financial Statements (continued)

For the Year Ended 31 December 2025

13. Expenses by nature

13.1. Administrative expenses

	2025	2024
	€	€
Employee benefit expenses (Note 14)	8,040,148	6,555,607
Amortisation of intangible assets (Note 5)	705	1,808
Depreciation of property, plant & equipment (Note 6)	53,692	55,298
Depreciation of right-of-use asset (Note 7)	159,907	152,645
Lease expenses	38,203	49,595
Professional fees	168,730	194,516
Staff training	314,100	436,302
Travel and accommodation	172,915	110,071
Computer expenses	292,393	348,026
Bad debts written off	383	12,460
Provision for bad debts	140,698	(6,999)
Other expenses	160,542	154,961
Total administrative expenses	9,542,416	8,064,290

13.2. Audit fees

Fees charged by the auditors for services rendered during the financial years ended 31 December 2025 and 2024 relate to the following:

	2025	2024
	€	€
Annual statutory audit	4,450	4,450

14. Employees

14.1. Employee benefit expenses

	2025	2024
	€	€
Management	2,858,909	1,679,702
Wages and salaries	4,824,699	4,546,399
Social security costs	356,540	329,506
Total	8,040,148	6,555,607

14.2. Average number of employees

The average weekly number of persons employed by the Medicines Authority during the financial reporting year was 136 (2024: 131).

Medicines Authority

Notes to the Financial Statements (continued)

For the Year Ended 31 December 2025

14. Employees (continued)

14.2. Average number of employees (continued)

	2025	2024
	€	€
Management	30	30
Technical staff	85	78
Administration	21	23
Total	136	131

15. Finance cost

	2025	2024
	€	€
Lease interest expense	58,588	8,558

16. Other income

	2025	2024
	€	€
Other income	332,867	141,775

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 operations

Reconciliation of deficit before tax to cash used in operations:

	2025	2024
	€	€
Deficit before tax	(1,589,383)	(940,396)
Adjustments for:		
Amortisation of intangible assets (Note 5)	705	1,808
Depreciation of property, plant and equipment (Note 6)	53,692	55,298
Depreciation of right-of-use asset (Note 7)	159,907	152,645
Bad debts written off	383	12,460
Provision for bad debts	140,698	(6,999)
Interest expense (Note 15)	58,588	8,558
Changes in working capital		
Trade and other receivables	(37,890)	(448,511)
Trade and other payables	117,335	447,087
Cash used in operations	(1,095,965)	(718,050)

Medicines Authority

Notes to the Financial Statements (continued)

For the Year Ended 31 December 2025

19. Commitments

	<u>2025</u>	<u>2024</u>
	€	€
Non-cancellable lease commitments qualifying as ROU		
Less than one year	188,790	40,688
Between 1 and 5 years	660,765	-
Total lease commitments	<u>849,555</u>	<u>40,688</u>
Other commitments		
Capital commitments committed and contracted for	<u>214,014</u>	<u>253,467</u>

20. Related party transactions

During the year ended 31 December 2025 and 2024, 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 2025, 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 2025 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 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.

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.



Independent Auditors' Report (continued)

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.

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.

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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 Mercieca FCCA, MIA, CPA(PC), Cert. Tax, Cert. CII, Marjean Mercieca B.Sc. (Hons) (Pharm.Sc.), M.Pharm.



Independent Auditors' Report (continued)

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.

A handwritten signature in blue ink, appearing to read 'Darren Mercieca', is written over a light blue horizontal line.

Darren Mercieca
for and on behalf of
MRC Audit Ltd
Registered Auditors

22 April 2026

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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 Mercieca** FCCA, MIA, CPA(PC), Cert. Tax, Cert. CII, **Marjean Mercieca** B.Sc. (Hons) (Pharm.Sc.), M.Pharm.