


**National Medicines  
Regulatory Authority**

**Financial Statement for the  
year ended  
31 December 2021**

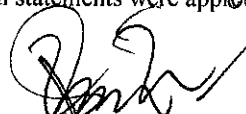
NATIONAL MEDICINES REGULATORY AUTHORITY  
STATEMENT OF FINANCIAL POSITION

As at 31 December,	Note	2021 Rs.	2020 Rs.
<b>Assets</b>			
<b>Non current assets</b>			
Property, plant and equipment	2	114,561,686	49,892,359
Capital Working Progress	2.1		5,600,619
<b>Total non current assets</b>		<b>114,561,686</b>	<b>55,492,978</b>
<b>Non Current Assets</b>			
Distress Lone Balance		5,125,570	
<b>Current assets</b>			
Inventory	3	1,947,084	1,655,865
Deposits and other receivable	4	16,561,415	22,544,810
Short term investments	5	2,141,652,055	3,149,130,138
Cash and cash equivalents	6	1,624,514,939	129,108,499
<b>Total current assets</b>		<b>3,784,675,492</b>	<b>3,302,439,312</b>
<b>Total assets</b>		<b>3,904,362,748</b>	<b>3,357,932,290</b>
<b>Equity and liabilities</b>			
<b>Equity</b>			
Accumulated Fund		2,994,730,451	2,404,402,488
Capital Gain		64,275,375	
<b>Total equity</b>		<b>3,059,005,826</b>	<b>2,404,402,488</b>
<b>Non Current liabilities</b>			
Provision for Gratuity		2,834,700	
Capital grant	7	5,920,019	157,364
Deferred tax	8	13,488,345	7,102,486
<b>Total non current liabilities</b>		<b>22,243,064</b>	<b>7,259,850</b>
<b>Current liabilities</b>			
Advance receipts	9	87,185,512	76,702,510
Provision for Income tax	19	151,836,233	575,361,535
VAT payable	10	52,463,719	68,856,674
Stamp duty payable	11	30,299,888	22,747,938
Provision for Treasury levy	12	400,000,000	146,929,966
Accrued expenses and other payables	13	101,328,507	55,671,329
<b>Total current liabilities</b>		<b>823,113,858</b>	<b>946,269,952</b>
<b>Total equity and liabilities</b>		<b>3,904,362,748</b>	<b>3,357,932,290</b>

The accounting policies and annexed notes to the financial statements are an integral part of these financial statements.


 **K. M. Y. K. Karunaratne**  
Accountant  
K.M.Y.K Karunaratne National Medicines Regulatory Authority  
Accountant No. 120, Norris Canal Road,

The financial statements were approved by the Board of Directors and signed on their behalf.

  
Dr. Rasitha Wijewantha  
Chairman

..... 2022

**Dr. Rasitha Wijewantha**  
MBBS, MD  
Chairman  
National Medicines Regulatory Authority  
Sri Lanka.

  
Dr. Saveen Semage  
Chief Executive Officer  
Dr. Saveen Semage  
MBBS, MSc, MD  
Chief Executive Officer  
National Medicines Regulatory Authority  
No. 120, Norris Canal Road  
Colombq 10.



**NATIONAL MEDICINES REGULATORY AUTHORITY**  
**STATEMENT OF COMPREHENSIVE INCOME**

*For the year ended 31 December,*

	Note	2021 Rs.	2020 Rs.
Revenue	14	1,252,757,342	1,059,441,826
Interest income		148,182,620	177,652,925
Other income	15	8,853,050	1,239,604
Administrative expenses	16	(119,812,930)	(93,984,429)
Salaries and wages	17	(152,382,467)	(146,730,584)
Other expenses	18	(12,182,753)	(58,605,113)
Amortization of capital grant			1,342,902
<b>Net income before taxation</b>		<b>1,125,414,862</b>	<b>940,357,130</b>
Income tax for the year	19	(158,222,092)	(266,752,264)
<b>Net income after taxation</b>		<b>967,192,769</b>	<b>673,604,866</b>
Provision for treasury levy		(400,000,000)	
<b>Net Income for 2021</b>		<b>567,192,769</b>	<b>673,604,866</b>

The accounting policies and annexed notes to the financial statements are an integral part of these financial statements.



**NATIONAL MEDICINES REGULATORY AUTHORITY  
STATEMENT OF CHANGES IN EQUITY**

<i>For the year ended,</i>	<b>Accumulated Fund Rs.</b>
<b>Balance as at 31 December 2018</b>	<b>1,047,449,960</b>
Prior year correction	(17,831,726)
<b>Restated balance as at 31 December 2018</b>	<b>1,029,618,234</b>
Profit for the year	795,694,791
Provision for treasury levy	(79,569,479)
<b>Balance as at 31 December 2019</b>	<b>1,745,743,546</b>
Prior year correction	52,414,563
<b>Restated balance as at 31 December 2020</b>	<b>1,798,158,109</b>
Profit for the year	673,604,866
Provision for treasury levy	(67,360,487)
<b>Balance as at 31 December 2020</b>	<b>2,404,402,488</b>
Prior year correction	23,135,193
<b>Restated balance as at 31 December 2021</b>	<b>2,427,537,681</b>
Profit for the year	567,192,769
Provision for treasury levy	-
<b>Balance as at 31 December 2021</b>	<b>2,994,730,451</b>

The accounting policies and annexed notes to the financial statements are an integral part of these financial statements.



**NATIONAL MEDICINES REGULATORY AUTHORITY  
STATEMENT OF CASH FLOW**

<i>As at 31 December,</i>	<b>2021 Rs.</b>	<b>2020 Rs.</b>
<b>Cash Flows from Operating Activities</b>		
Net income before taxation	1,125,414,862	940,357,130
<b>Adjustment for :</b>		
Depreciation	21,870,537	17,515,637
Interest income	(148,182,620)	(177,652,925)
Amortization of capital grant		(1,342,902)
Gratuity Expense	683,972	1,257,060
Adjustment on prior year	(51,820,238)	
<b>Operating Profit before Working Capital Changes</b>	<b>947,966,513</b>	<b>780,134,001</b>
<b>Changes in items of working capital</b>		
(Increase)/Decrease in Inventory	(291,219)	336,999
(Increase)/Decrease in Deposits and other receivable	(857,825)	(21,560,582)
(Increase)/Decrease in Advance receipts	10,483,002	(183,249,343)
(Increase)/Decrease in VAT payable	(14,608,754)	5,653,112
(Increase)/Decrease in Stamp duty payable	7,551,950	16,566,202
(Increase)/Decrease in Provision for treasury levy		
(Increase)/Decrease in Accrued expenses and other payables	45,241,658	5,801,201
(Increase)/Decrease in Short Term Investment Increase		-
<b>Cash generated from operations</b>	<b>995,485,324</b>	<b>603,681,589</b>
Treasury levy Paid	(146,929,966)	(80,917,066)
Tax Paid	(536,936,978)	(306,965,632)
<b>Net Cash from / (Used in) Operating Activities</b>	<b>311,618,380</b>	<b>215,798,891</b>
<b>Cash flows from investing activities</b>		
Acquisition of Property plant and equipment	22,396,988	(6,935,359)
WIP Changes	5,600,619	(128,543)
Investment in short term deposits	1,007,478,083	(669,499,875)
Interest income	148,182,620	177,652,925
<b>Net Cash from / (Used in) Investing Activities</b>	<b>1,183,658,310</b>	<b>(498,910,853)</b>
Net increase/ decrease in Cash & cash equivalents	1,495,276,690	(283,111,962)
Cash and cash equivalents at the beginning of the year	129,108,499	412,220,462
<b>Cash and cash equivalents at the ending of the year</b>	<b>1,624,385,189</b>	<b>129,108,499</b>

The accounting policies and annexed notes to the financial statements are an integral part of these financial statements.



**NATIONAL MEDICINES REGULATORY AUTHORITY**  
**NOTES TO THE FINANCIAL STATEMENTS**

*For the year ended 31 December 2021*

**1. Accounting policies**

**1.1 Reporting entity**

National Medicines Regulatory Authority (the "Authority") is incorporated under the National Medicines Regulatory Authority Act, No 5 of 2015 with effect from 01<sup>st</sup> July 2015. It is a Government Authority under the preview of Ministry of Health and Nutrition and Indigenous of Medicine and located at No: 120, Norris Canal Road, Colombo 10, Sri Lanka. Powers and all functions of National Medicines Quality Assurance Lab (NMQAL) is vested with the Authority.

**1.2 Principal activity and nature of the operation**

The objective of the Authority is ensuring the availability of efficacious, safe and good quality medicines, medical devices and borderline products to the general public at affordable prices. The Authority is registering and issuing licenses and involve in other regulatory activities in relation to the medicines, medical devices, borderline products, clinical trial and pharmacies.

**2. Basis of preparation**

**2.1 Statement of compliance**

The financial statements have been prepared in accordance with Sri Lanka Accounting Standards (SLFRS/LKAS) issued by the Institute of Chartered Accountants of Sri Lanka.

**2.2 Responsibility for financial statements**

The members of the authority are responsible for the preparation and fair presentation of the financial statements.

**2.3 Basis of measurement**

The financial statements have been prepared on the historical cost basis except for the assets and liabilities recognized at fair value as explained in the respective notes to the financial statements.

These financial statements have been prepared on the basis that the authority would continue as a going concern for the foreseeable future.

**2.4 Functional and presentation currency**

The financial statements are prepared in Sri Lankan Rupees, which is the Authority's functional currency.

**2.5 Use of estimates and judgments**

The preparation of financial statements in conformity with SLFRS for SMEs requires management to make judgements, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from those estimates.

Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimates are revised and in any future periods affected.

Information about critical judgments in applying accounting policies that have the most significant effect on the amounts recognised in the financial statements are included in the followings.

- Retirement benefit obligation
- Useful life time of the depreciable assets



**NATIONAL MEDICINES REGULATORY AUTHORITY  
NOTES TO THE FINANCIAL STATEMENTS**

*For the year ended 31 December 2021*

**2.6 Materiality and aggregation**

Each material class of similar items is presented separately in the financial statements. Items of dissimilar nature or function are presented separately unless they are immaterial.

**2.7 Comparative information**

The comparative information has been reclassifying where necessary to confirm to the current year's presentation.

**3. Summary of significant accounting policies**

The accounting policies set out below are consistently followed during the year.

**3.1 Plant and equipment**

**3.1.1 Recognition and measurement**

Items of plant and equipment are measured at cost less accumulated depreciation and accumulated impairment losses.

All items of property plant and equipment are recognized initially at cost. The cost of plant and equipment includes expenditure that is directly attributable to the acquisition of the asset. The cost of self-constructed assets includes the cost of materials and direct labor, any other costs directly attributable to bringing the asset to a working condition for its intended use. Purchased software that is integral to the functionality of the related equipment is capitalized as a part of that equipment.

When parts of an item of plant and equipment have different useful lives, they are accounted for as separate items (major components) of plant and equipment.

**3.1.2 Subsequent costs**

The cost of replacing a part of an item of plant & equipment is recognized in carrying amount of the item if it is probable that the future economic benefits embodied within the part will flow to the Authority and its cost can be measured reliably. The carrying amounts of the parts that are replaced are derecognized from the cost of the assets.

The cost of the day-to-day servicing of plant & equipment are recognized in the statement of comprehensive income as incurred.

**3.1.3 Depreciation**

Depreciation is recognized in the statement of comprehensive income on a straight-line basis over the estimated useful lives of items of each part of an item of plant and equipment.

The estimated useful lives for the current and comparative periods are as follows.

Furniture & Fittings	05 years
Office Equipment	05 years
Computer Equipment	04 years
Filing Store	05 years
Lab Equipment	05 years
Computer Software	04 years

Depreciation 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 and the date that the asset is derecognized.

Depreciation methods, useful lives and residual values are reassessed at the reporting date.



**NATIONAL MEDICINES REGULATORY AUTHORITY**  
**NOTES TO THE FINANCIAL STATEMENTS**

*For the year ended 31 December 2021*

**3.1.4 De-recognition**

The carrying amount of an item of property, plant and equipment is de-recognized upon disposal or when no future economic benefits are expected from its use or disposal. The gain or loss arising from the derecognition of an item of property, plant and equipment is included in profit or loss when item is derecognition.

**3.2 Financial Instruments**

**3.2.1 Initial recognition and subsequent measurement**

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or equity instrument of another entity.

Financial assets are classified, at initial recognition, as subsequently measured at amortized cost, fair value through other comprehensive income (OCI) and fair value through profit or loss.

**3.2.2 Subsequent measurement**

For purposes of subsequent measurement, financial assets are classified in four categories

- i. Financial assets at amortized cost (debt instruments)
- ii. Financial assets at fair value through OCI with recycling of cumulative gains and losses (debt instrument)
- iii. Financial assets designated at fair value through OCI with recycling of cumulative gains and losses upon derecognition (equity instruments)
- iv. Financial assets at fair value through profit or loss

**3.2.3 Financial assets at amortized cost (debt instrument)**

This category is the most relevant to the authority. The group measures financial assets at amortized cost if both of the following condition are met,

The financial assets are held within a business model with the objective to hold financial assets in order to collect contractual cash flows and

The contractual terms of the financial asset give rise on specified dates to cash flows that are solely payment of principle and interest on the principal amount outstanding.

Financial assets at amortized cost are subsequently measured using the effective interest (EIR) method and are subject to impairment. Gains and losses are recognized in profit or loss when the assets are derecognized, modified or impaired.

**3.2.4 Derecognition of financial assets**

A financial asset is primarily derecognized when the rights to receive cash flows from the assets have expired.

**3.3 Trade & other receivables**

Trade and other receivables are stated at their estimated realizable amounts.

**3.4 Cash & cash equivalents**

Cash and cash equivalents comprise cash balances and call deposits. Bank overdrafts that are repayable on demand and form an integral part of the Authority's cash management are included as a component of cash and cash equivalents for the purpose of the statement of cash flows.

Cash flow statement is prepared under the indirect method as per Section 07, Statement of Cash Flows if any.





**NATIONAL MEDICINES REGULATORY AUTHORITY  
NOTES TO THE FINANCIAL STATEMENTS**

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*For the year ended 31 December 2021*

**3.5 Inventories**

Inventories are recognized at cost and net realizable value, whichever is lower after making due allowance for obsolete and slow-moving items which are valued at 'First in first out' basis.

**3.6 Liabilities and provisions**

Liabilities classified as current liabilities on the statement of financial position are those which fall due for payment on demand or within one year from the reporting date. Non-current liabilities are those balances that fall due for payment later than one year from the reporting date.

All known liabilities have been accounted and considered for preparation of financial statements.

**3.6.1 Provisions**

A provision is recognized if, as a result of a past event, the Authority has a present legal or constructive obligation that can be estimated reliably, and it is probable that an outflow of economic benefits will be required to settle the obligation

**3.7 Employee benefits**

**3.7.1 Defined contribution plan**

A defined contribution plan is a post-employment benefit plan under which an entity pays fixed contributions into a separate entity and will have no legal or constructive obligation to pay further amounts. Obligations for contributions to defined contribution pension plans are recognized as an employee benefit expense in statement of comprehensive income when they are due. Prepaid contributions are recognized as an asset to the extent that a cash refund or a reduction in future payments is available.

The Authority contributes 12% and 3% of gross emoluments of employees as provident fund (EPF), and trust fund (ETF) contribution respectively.

**3.7.2 Defined benefit plan**

A defined benefit plan is a post-employment benefit plan other than a defined contribution plan. The liability recognized in the statement of financial position in respect of defined benefits plan is the present value of the defined benefit obligation at the reporting date. The defined benefit obligation is calculated annually using the projected unit credit method by qualified actuary as recommended by LKAS 19. The present value of the defined benefit obligation is determined by discounting the estimated future cashflows using interest rate that are denominated in the currency in which the benefits will be paid and that have terms of maturity approximating to the terms of the liability.

Provision will be made in the financial statements for retiring gratuities after the completion of five years continued service of employees with conformity of Gratuity Act No.12 of 1983.

**3.8 Trade and other payables**

Trade and other payables are stated at their cost.



**NATIONAL MEDICINES REGULATORY AUTHORITY  
NOTES TO THE FINANCIAL STATEMENTS**

*For the year ended 31 December 2021*

**3.9 Revenue**

**3.9.1 Services**

Revenue from services rendered is recognized in the income statement on completion of the transaction cycle and the passing of risks and rewards, at the reporting date.

**3.9.2 Interest income**

Interest income is recognized as it accrues in the income statement. Interest income of long-term financial instrument are recorded using the effective interest rate (EIR).

**3.10 Government Grants**

Government Grants are assistance by government in the form of transfers of resources to an entity.

Government grant related to assets, non-monetary grants at fair value, shall be presented in the statement of financial position either by setting up the grant as deferred income or by deducting the grant in arriving at the carrying amount of the asset.

**3.11 Expenses**

All expenditure incurred in the running of the business has been charged to statement of comprehensive income in arriving at the profit for the year.

**3.12 Foreign currency transaction**

Transaction in foreign currencies are initially recorded by the authority the spot rate of at their respective functional currency at the date the transaction first qualifies for recognition.

Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency spot rates of exchange at the reporting date.

**3.13 Tax expenses**

Income tax expense comprises current and deferred tax. Income tax expense is recognized in the statement of comprehensive income except to the extent that it relates to items recognized directly in equity, in which case it is recognized in equity.

**3.13.1 Current tax**

Current tax is the expected tax payable on the taxable income for the period, using tax rates enacted or substantively enacted at the reporting date, and any adjustment to tax payable in respect of previous periods.

The Authority liability to taxation has been computed according to the provision of the Inland Revenue Act No. 10 of 2006 and amendments thereon.

**3.13.2 Deferred taxation**

Deferred tax is recognized using the liability method, providing for temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes.



**NATIONAL MEDICINES REGULATORY AUTHORITY**  
**NOTES TO THE FINANCIAL STATEMENTS**

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*For the year ended 31 December 2021*

Deferred tax is not recognized for the following temporary differences: the initial recognition of assets or liabilities in a transaction that is not a business combination and that affects neither accounting nor taxable profit nor loss.

A deferred tax asset is recognized to the extent that it is probable that future taxable profits will be available against which the temporary difference can be utilized. Deferred tax assets are reviewed at each reporting date and are reduced to the extent that it is no longer probable that the related tax benefit will be realized.

**3.14 Statement of cash flows**

The statement of cash flows has been prepared using the “indirect method” in accordance with LKAS 7 “Statement of cash flows”.

Interest paid is classified as operating cash flows, interest received are classified as investing cash flows, while treasury levy paid are classified as financing cash flows for the purpose of presenting the cash flow statement.

**3.15 Commitment and contingencies**

Contingencies are possible assets or obligations that arise from a past event and would be confirmed only on the occurrence or non-occurrence of uncertain future events, which are beyond the Authority’s control.

**3.16 Related party transaction**

Contingencies are possible assets or obligation that arise from past event and would be confirmed only on the occurrence or non-occurrence of uncertain future events, which not wholly within control of the Group.

**3.17 Events after the reporting date**

All material events after the reporting date have been considered and where appropriate adjustments or disclosures have been made in notes to the financial statements.



NATIONAL MEDICINES REGULATORY AUTHORITY  
NOTES TO THE FINANCIAL STATEMENTS

As at 31/12/2021

2 Property, plant and equipment

Cost	Filing store		Lab equipment		Furniture and fittings		Office equipment		Computer equipment		Computer Software		Total	
	Rs.	Rs.	Rs.	Rs.	Rs.	Rs.	Rs.	Rs.	Rs.	Rs.	Rs.	Rs.	Rs.	Rs.
Restated Balance as at 01 January 2019	15,257,976	9,451,740	2,084,965	5,319,876	7,915,653	224,400	40,583,935							
Correction - Working Progress	-	-	-	-	-	-	(329,325)							
Additions during the year	-	31,436,266	714,659	852,070	170,500	-	33,173,495							
Balance as at 31 December 2019	15,257,976	40,888,006	2,799,624	6,171,946	8,086,153	224,400	73,428,105							
Restated Balance as at 01 January 2020	15,257,976	40,888,006	2,799,624	6,171,946	8,086,153	224,400	73,428,105							
Correction - Working Progress	-	-	-	-	-	-	-							
Additions during the year	-	9,789,666	1,602,640	1,988,433	3,853,610	549,000	17,783,349							
Balance as at 31 December 2020	15,257,976	50,677,672	4,402,264	8,160,379	11,939,763	773,400	91,211,454							
Restated Balance as at 01 January 2021	15,257,976	50,677,672	4,402,264	8,160,379	11,939,763	773,400	91,211,454							
Correction - Working Progress	-	64,275,375	-	-	(123,120)	-	64,152,255							
Additions during the year	-	6,881,019,25	9,088,839	9,088,839	149,250	6,277,880	22,396,988							
Balance as at 31 December 2021	15,257,976	114,953,047	11,283,283	17,249,218	11,965,893	7,051,280	177,760,697							
<b>Accumulated depreciation</b>														
Balance as at 31 December 2020	9,765,104	17,806,655	2,054,421	4,252,765	7,188,694	251,456	41,319,095							
Restated Balance as at 01 January 2021	9,765,104	17,806,655	2,054,421	4,252,765	7,188,694	251,456	41,319,095							
Prior Year Correction	-	-	-	16,211	(6,831)	-	9,380							
Charge for the year	3,051,595	11,473,871	2,023,543	2,559,425	2,058,353	703,749	21,870,537							
Balance as at 31 December 2021	12,816,699	29,280,526	4,077,964	6,828,400	9,240,216	955,205	63,199,011							
<b>Carrying value</b>														
As at 31 December 2021	2,441,277	85,672,521	7,205,319	10,420,818	2,725,677	6,096,075	114,561,686							

Currently the Authority is using infrastructure facilities such as building, vehicles and other assets, which are belong to Ministry of Health Nutrition and Indigenous Medicines and the Authority is in the process of acquiring those assets for it self.



**NATIONAL MEDICINES REGULATORY AUTHORITY**  
**NOTES TO THE FINANCIAL STATEMENTS**

*For the year ended 31 December,*

	2021 Rs.	2020 Rs.
<b>2.1 Capital Working Progress</b>		
On going Public Finger Print Scanners		-
On going cost Public Addressing System		543,591
On going cost CCTV Systems		4,658,794
On going cost Narahenpita building		215,484
On going cost Security Access		182,750
	-	<b>5,600,619</b>
<b>3 Inventory</b>		
Opening Inventory	1,655,865	1,992,864
Purchased for year	3,960,087	1,773,231
	5,615,952	3,766,095
Consumption	(3,668,868)	2,110,230
Closing Inventory	1,947,084	<b>1,655,865</b>
<b>4 Deposits and other Receivable</b>		
Deposit for Fuel	50,000	50,000
Other Receivables		5,550
Prepayments	1,019,375	62,000
Festival Advance	(1,500)	126,000
Advance Receivables		5,000
Building Rent	13,500,000	13,500,000
Distress Loan Receivable	1,926,540	8,796,260
Deposit for Drinking water	67,000	
<b>Total deposits and prepayments</b>	<b>16,561,415</b>	<b>22,544,810</b>
<b>5 Short term investments</b>		
Opening Balance	3,149,130,138	2,479,226,476
Invest for the Year	299,999,999	492,250,737
Interest for the year	148,182,620	177,652,925
Maturity Investment	(1,455,660,702)	
	<b>2,141,652,055</b>	<b>3,149,130,138</b>
<b>6 Cash and cash equivalents</b>		
BOC Current and Savings Account(ZIBA)	1,624,514,939	129,108,496
Petty Cash		3
<b>Total cash and cash equivalents</b>	<b>1,624,514,939</b>	<b>129,108,499</b>
<b>7 Capital grant</b>		
Capital grant	5,920,019	1,500,266
Amortization of capital grant		(1,342,902)
<b>Total Capital grant</b>	<b>5,920,019</b>	<b>157,364</b>
<b>8 Deferred tax liability</b>		
Accounting written down value of Property plant and equipn	114,561,684	49,892,359
Tax base of Property plant and equipment	(66,389,022)	24,526,336
Taxable Temporary deference	48,172,661	25,366,023
Tax @ 28%	13,488,345	7,102,486
Deferred Liability at the end of the year	13,488,345	<b>7,102,486</b>
Deferred Liability as at beginning of the year	(7,102,486)	2,971,330
Charge as deferred tax during the year	6,385,859	<b>4,131,156</b>



NATIONAL MEDICINES REGULATORY AUTHORITY  
NOTES TO THE FINANCIAL STATEMENTS

	2021 Rs.	2020 Rs.
<b>9 Advance receipts</b>		
Fees received in advance	72,972,666	72,972,666
Deposit to be Classified	11,894,247 ✓	2,628,262
Over Payment	2,318,598 ✓	1,101,582
<b>Total advance receipts</b>	<b>87,185,512</b>	<b>76,702,510</b>
	<b>2021 Rs.</b>	<b>2020 Rs.</b>
<b>10 VAT payable</b>		
Opening Balance	68,856,674	63,915,809
VAT for the year	100,323,931	-
Input VAT for the year	(3,089,222)	72,768,399
Input VAT		(3,199,478)
Other Adjustment	303,335	29,051,265
Paid for the year	(113,931,000)	(92,967,074)
Prior Year Correction		(712,247)
VAT Payable	<b>52,463,719</b>	<b>68,856,674</b>
<b>11 Stamp duty payable</b>		
Opening Balance	22,747,938	6,181,736
Stamp Duty for the year	45,019,763	22,747,938
Paid for the year	(37,467,813)	(6,978,956)
Prior Year Corrections		797,220
Stamp duty payable	<b>30,299,888</b>	<b>22,747,938</b>
<b>12 Provision for Treasury levy</b>		
Net income after taxation	967,735,433	673,604,866
Provision 2% for year	400,000,000	67,360,487
Opening Balance	146,929,966	79,569,479
Paid for the year	(146,929,966)	-
	<b>400,000,000</b>	<b>146,929,966</b>
<b>13 Accrued expenses and other payables</b>		
Accounts Payables	9,636,600	9,198,979
Accrued expenses	4,180,765	129,950
Other Payables	1,794,043	-
Retention Deposit	108,646	14,977
EPF Payable		13,607
ETF Payable		2,041
Payee Payable		-
Pension Payable		104,087
Secondment Allowances Payable	21,235	79,794
		2,150,728
Audit Fees Payable	2,400,000	2,223,000
Committees & Evaluation Payable	117,475	179,475
Contribution for MOH Staff Salary	83,069,743	41,500,000
Salary Payable		62,543
W & OP Payable		12,148
<b>Total Accrued expenses</b>	<b>101,328,507</b>	<b>55,671,329</b>



**NATIONAL MEDICINES REGULATORY AUTHORITY**  
**NOTES TO THE FINANCIAL STATEMENTS**

	2021	2020
	Rs.	Rs.
<b>14 Revenue</b>		
Drug Sample License Income	7,835,689	889,460
Device Sample License Income	9,702,717	7,956,394
Cosmetic Sample License Income	468,800	278,800
Borderline Sample License Income	598,164	747,821
Drug Import License Income	128,877,215	65,457,634
Device Import License Income	95,323,161	44,851,068
Cosmetic Import License Income	8,012,734	4,344,000
Borderline Import License Income	1,388,942	767,295
Drug Manufacturing License Income A	10,894,168	4,937,907
Drug Manufacturing License Income B	161,990	
Device Manufacturing License Income A	1,147,073	382,264
Device Manufacturing License Income B	415,305	
Cosmetic Manufacturing License Income	401,000	334,000
Drug Registration Income FR Local A	686,488	82,769,330
Drug Registration Income FR Local B	20,289	
Drug Registration Income FR Foreign	10,511,017	
Drug Registration Income PR Local A	4,885,524	
Drug Registration Income PR Local B	61,069	
Drug Registration Income PR Foreign	103,457,358	
Device Registration Income FR Local A	823,018	48,962,225
Device Registration Income FR Local B	81,072	
Device Registration Income FR Foreign	15,491,862	
Device Registration Income PR Local A	687,715	
Device Registration Income PR Local B	593,769	
Device Registration Income PR Foreign	102,588,782	
Cosmetic Registration Income FR Foreign	3,120,500	6,147,500
Cosmetic Registration Income FR Local	48,000	
Cosmetic Registration Income PR Foreign	7,217,344	
Cosmetic Registration Income PR Local	547,500	
Cosmetic Registration Income Renewal	57,500	
Borderline Registration Income PR Foreign	1,470,583	1,231,297
Borderline Registration Income PR Local	19,987	
Laboratory Test	10,483,170	8,519,342
Drug Processing Fees Local A	9,346,269	83,960,364
Drug Processing Fees Local B		
Drug Processing MP Foreign	10,464,835	
Drug Processing Combined	913,496	
Drug Processing New Dosage	304,019	
Drug Processing Foreign	28,718,995	
Drug Processing Fees Renewal Local A	1,930,959	
Drug Processing Fees Renewal Foreign	29,505,191	
Drug Processing Fees Therapeutic	16,224,433	
Drug Processing Fees NCE	6,944,235	
Drug Processing Fees NCE int	3,343,032	
Device Processing Fees Local A	3,326,424	122,948,986.14
Device Processing Fees Local B	2,015,922	
Device Processing Fees MP Foreign	21,941,608	
Device Processing Fees Foreign	34,849,066	
Device Processing Fees Renewal Local A	98,310	
Device Processing Fees Renewal Local B	9,459	



**NATIONAL MEDICINES REGULATORY AUTHORITY**  
**NOTES TO THE FINANCIAL STATEMENTS**

<b>14 Revenue Cont.....</b>		
Device Processing Fees Renewal Foreign	17,379,972	
Cosmetic Processing Fees	1,356,000	976,500
Borderline Processing Fees Foreign	10,718,145	3,247,209
Borderline Processing Fees Local	447,808	
Borderline Processing Fees Ini for	16,973,578	
Clinical Trial Processing Fees	1,361,039	93,958
Drug Advertising Fees	805,313	372,257
Retail Pharmacy License Income	43,174,597	1,873,949
Wholesale Pharmacy License Income	36,125,829	375,784
Transport Pharmacy License Income	18,041,828	17,806,634
Drug WOR	3,167,994	28,463,728
Device WOR	21,055,896	15,614,479
Borderline WOR		93,399
GMP Device Local Repac	40,427	-
Device GMP - Local A	442,903	588,194
Device GMP - Local B	944,952	
Drug GMP - Local A	560,702	23,966,690
Drug GMP - Local B	179,238	
Drug WHO Inspection	486,887	245,365
Device WHO Inspection	383,507	74,798
Drug COPP Certificate	49,902	261,557
Additional Drug Foreign	85,536,487	126,286,003
Additional Drug Local A	5,588,762	90,134,252
Additional Drug Local B	1,477,119	
Additional Drug Variation	14,504,402	
Additional Drug MP	2,285,117	
Additional Device Foreign	89,334,411	
Additional Device Local A	1,774,416	
Additional Device Local B	472,763	
Additional Device Variation	2,894,477	
Additional Borderline Foreign	5,644,946	3,118,960
Additional Borderline Local	80,574	
Agency Transfer	35,581,888	31,933,754
Device Free sale Certificates Clarification	152,249	46,288
Device Clarification	1,476,411	719,174
Drug Clarification	963,678	48,699
Device Amendment	1,118,013	1,007,820
Drug Amendment	1,333,413	3,911,282
Cosmetic Amendment	65,000	98,000
Borderline Amendment	79,495	
Drug Formulation Approval	2,644,301	850,679
Borderline Formulation Approval		112,914
Borderline Advertisement	399,740	
Device Advertisement	2,032,505	
Device Duplicate Certificate	99,361	
Drug Free Sale		36,697
Cosmetic Renewal		150,000
Automation Income	125,505,536	71,277,943
2018 · Advance Receipts Income	-	20,307,230
2019 · Advance Receipts Income	-	129,861,944
<b>Total Income</b>	<b>1,252,757,342</b>	<b>1,059,441,826</b>





**NATIONAL MEDICINES REGULATORY AUTHORITY**  
**NOTES TO THE FINANCIAL STATEMENTS**

	2021	2020
	Rs.	Rs.
<b>15 Other Income</b>		
Tender Application Fees	12,000	15,000
Other Income	39,901	-
Supplier Registration	285,000	444,000
Exam Fees Income		594,000
Distress Loan Interest	311,289	186,604
Savings A/C Interest	8,204,860	-
	<b>8,853,050</b>	<b>1,239,604</b>
<b>16 Administrative expenses</b>		
Depreciation	21,870,537	17,515,637
Water	483,928	252,597
Electricity	6,691,499	6,913,019
Telephone	1,944,800	1,339,143
Postage	138,763	181,705
Stationery	3,668,868	2,110,230
Travelling - Local	15,662,199	5,967,566
Travelling - Foreign		32,823
Training and development expenses	1,259,700	1,054,847
Fuel expense	1,452,280	2,449,145
Security charges	6,362,757	3,998,503
Document handling charges	1,559,470	1,474,015
Publication, Translation and advertisement charges	3,765,858	5,485,127
Cleaning service	3,603,950	3,883,700
Vehicle maintenance	5,630,350	3,251,319
Maintenance of Laboratory equipment	9,257,490	6,453,384
Maintenance of fire extinguisher	113,800	12,500
Maintenance of Air-conditioning	108,100	566,235
Maintenance of building	7,782,372	1,599,802
Maintenance of computer items and other	2,463,240	6,880,627
Maintenance of website	45,920	458,200
Maintenance of Office Equipments	541,947	619,709
Maintenance of Software & Packages	3,931,022	232,563
Expenses for Good Manufacturing Practice visits		7,178,988
WHO meeting expenses		-
Reservation of Conference Hall	429,910	1,134,920
Rates and taxes	495,670	475,999
Audit fee	1,200,000	1,200,000
Forensic Audit Fee		3,200,000
Sample Testing Expenses	16,072	23,204
Books, Journals & Information	929,200	3,308,791
Consultation Fee		23,301
Sanitary Items Expense		29,115
Building Rent	16,200,000	2,700,000
Consumable Expenses	227,338	531,190
Covid 19 Expenses	1,390,212	819,485
Interview Fees	24,210	26,400
Vehicle Insurance	545,495	573,784
Vehicles Parking Fee	15,975	26,855
	<b>119,812,930</b>	<b>93,984,429</b>
<b>Total</b>	<b>119,812,930</b>	<b>93,984,429</b>



**NATIONAL MEDICINES REGULATORY AUTHORITY**  
**NOTES TO THE FINANCIAL STATEMENTS**

	2021 Rs.	2020 Rs.
<b>17 Salaries and wages</b>		
Salaries and wages	35,621,594	32,089,561
Other allowances	49,042,457	14,360,516
MOH Staff Salary	51,727,213	82,675,993
Overtime & 1/20 payment	8,236,021	7,319,886
Secondment allowance	187,721	1,326,781
Contribution for Pension	73,553	1,217,983
Contribution for Employee Provident Fund	3,896,579	3,556,390
Contribution for Employee Trust Fund	974,145	889,097
Contribution for W & OP		-
National Insurance Trust Fund E		-
Gratuity Expense	683,972	1,257,060
Staff Bonus	1,939,213	2,037,317
<b>Total</b>	<b>152,382,467</b>	<b>146,730,584</b>
<b>18 Other expenses</b>		
Refreshment and other expenses	2,331,483	1,175,826
Bank Charges		500
Staff Tea	2,237,601	1,662,271
Legal Expenses	1,061,500	1,733,570
Payment for Committees	4,703,734	1,820,033
Miscellaneous Expenses	99,748	104,726
Expert for Reviewing of Dossiers		1,534,966
Surcharges	13,216	-
Donation for COVID 19 Fund		50,000,000
Valuation Fee		488,220
Clinical Control A/C		85,000
Corporate Plan Expenses	1,519,987	
Expences for Basic requarment on poposed Narahenpita Bu	215,484	
<b>Total</b>	<b>12,182,753</b>	<b>58,605,113</b>



**NATIONAL MEDICINES REGULATORY AUTHORITY**  
**NOTES TO THE FINANCIAL STATEMENTS**

	2021 Rs.	2020 Rs.
<b>19 Income tax for the year</b>		
19.2 Income tax expense for the year	151,836,233	262,621,108
Deferred tax expense for the year	6,385,859	4,131,156
<b>Tax expense for the year</b>	<b>158,222,092</b>	<b>266,752,264</b>
<b>19.2 Net income before taxation</b>	<b>1,125,414,862</b>	<b>940,357,130</b>
Add : Disallowable expense	24,202,020	24,202,020
Less : Allowable expense	(65,072,359)	(65,072,359)
Less : Income not subject to income tax		-
Adjusted profit for the year	1,084,544,523	899,486,791
Other profit and income liable to tax		-
Total statutory income/ Taxable income	1,084,544,523	899,486,791
Income tax for the year	151,836,233	251,856,301
Tax Credits:		-
Notional Tax		-
Prior Year Correction	(38,424,557)	240,506
Income tax expense for the year	151,836,233	262,621,108
Opening Balance	575,361,535	312,499,921
Paid for the year	(536,936,978)	
<b>Total tax payable as at the year end</b>	<b>151,836,233</b>	<b>575,361,535</b>
<b>20 Prior year adjustment</b>	<b>23,135,193</b>	<b>52,414,563</b>
Prior year adjustment was made to rectify the following matters;		
Advance		-
Other		-
2018 Notional Tax Correction		(5,666,983)
Distress loan		15,900
Income Tax	38,424,557	5,426,477
Festival Advance		(13,500)
Advance		966
Salary Reimbursement		440,455
EPF		521,790
ETF		240,832
PAYEE		170,312
NITF		(375)
W & OP		(6,960)
Pension Payable		13,998,017
Secondment Payable		11,162,236
Accrued	(7,274,029)	2,994,615
Fixed Assets	(123,120)	10,847,990
Depreciation		(602,212)
Retention		(242,906)
Advance Receipts		11,980,542
VAT	(1,305,021)	712,247
Short Terms Investment		403,787
WHT		31,333
Cash Book	(951,159)	
Audit Fee	108,000	
Capital Grant	(5,762,655)	
Acc .Dip.	(9,380)	
Prepayment	(0)	
Accounts Payable	28,000	
	<b>23,135,193</b>	<b>52,414,563</b>



**NATIONAL MEDICINES REGULATORY AUTHORITY**  
**NOTES TO THE FINANCIAL STATEMENTS**

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21 Revenue and Expenditure for the year 2021 have been analyzed and presented in detail as compared to the year 2020

**22 Events after the reporting date**

The NMRA identified the unavailability of supporting documents for the applications on the e-NMRA System on July 9th, 2021.

For the incident, NMRA made a complaint to the Criminal Investigation Department (CID) on 22nd July 2021 and the investigation was started by the CID.

The e-nmra System data recovery operation was started by Epic Lanka Technologies to recover the lost data and is currently continuing with the supervision of a technical expert committee, which was appointed by the Secretary to the State Ministry of Production, Supply, and Regulation of Pharmaceuticals.

**23 Contingent Liabilities**

There is no any commitment and contingencies as at the reporting date.

**24 Litigation and claims**

In 2021 26 cases have been filed by FDII for the violations identified. No of cases pending 05. Total collection of fiacs - Rs.646,500.00. Detail of prosecutions conducted by provincial FD II - 2021. No of Cases 16 .No of cases pending 02. Total collection of fiacs Rs 473,000.00

B.J International (Pvt) Ltd filed a case against the NMRA at Commercial High-Court of Colombo, bearing Case no. HC.CIVIL 425/2017/MR, Challenging non-issuance of renewing certificates of registration and asking total sum of rupees Rs.497,700,000/=. The order was given on 11.11.2021. Now, B.J International (Pvt) Ltd appealed to section 755 (1) of the civil procedure code. Further, up to the year 2019, 13 cases were pending before the court filed by NMRA, and 11 cases were pending before the court filed against NMRA. Up to 2020, 11 cases were pending before the court filed by NMRA, and 9 cases were pending before the court filed against NMRA. The above all cases are handled by Legal Division. No of 20 cases were pending up to 31<sup>st</sup> of December 2020.

**25 Board of Members responsibility**

Board of members are responsible for the preparation and presentation of these financial statements in accordance with Sri Lanka Accounting Standards.

**26 Approval of financial statements**

These Financial statements were approved by the Board of members and authorized for issue on ..... 2022.

**27 Nature of the Prior year adjustment**

Nature of the Prior year adjustment is correction of the opening balances.



**Income Tax computation**  
**Year of Assesment 2021**

Net income before taxation	1,125,414,862
Add : Disallowable expense	
Depreciation	21,870,537
Refreshment expenses	2,331,483
	<u>1,149,616,881</u>
Less : Allowable expenses	
Capital allowance	(65,072,359)
Less : income not subject to income tax	-
Amortization of capital grant	
Adjusted net profit for the year	<u>1,084,544,522</u>
<b>Taxable profit trade and</b>	<b><u>1,084,544,522</u></b>
Tax Loss:	-
Total statutory income	1,084,544,522
Tax expense for the period, @ 14%	151,836,233
Tax expense for the period	151,836,233
Tax Credit	
<b>Income Tax payable</b>	<b>151,836,233</b>
Deffreed tax computation	
Accounting written down value of PPP	114,561,686
Tax base of PPP	(66,389,022)
Taxable Temporary deference	48,172,664
Tax @ 28% rate	13,488,346
Deferred Liability as at beginning of the year	7,102,486
Charge as deferred tax during the year	6,385,860

