IN THE SUPREME COURT OF THE

DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA

In the matter of an application in terms of Article 126 read with Article 17 of the Constitution of the Democratic Socialist Republic of Sri Lanka.

SC FR NO. 65/2023

1. Transparency International Sri Lanka
No.366,
Nawala Road
Nawala,
Rajagiriya.

2. Ashala Nadishani Perera
No.31,
Shalawa Road,
Mirihana,
Nugegoda.

PETITIONERS

Vs.

1. Hon. Ranil Wickramasinghe
Minister of Finance, Economic Stabilisation and National Policies,
Ministry of Finance,
The Secretariat,
Colombo 1.

1A. Minister of Finance, Planning and Economic

Development,
Ministry of Finance,
The Secretariat,
Colombo 1.

2. Hon. Dinesh Gunawardena,
Prime Minister
Minister of Public Administration, Home Affairs, Provincial Councils and Local Government Ministry of Public Administration, Home Affairs, Provincial Councils and Local Government,
Independence Square,
Colombo 1.

2A. Minister of Public Administration,
Provincial Councils and Local Government,
Ministry of Public Administration, Home Affairs, Provincial Councils and Local Government,
Independence Square,
Colombo 1.

3. Hon. Nimal Siripala de Silva,
Minister of Ports, Shipping and Aviation
Ministry of Ports, Shipping and Aviation
No.19,
Chaithya Road,
Colombo 1.

3A. Minister of Transport, Highways, Ports, and Civil Aviation,

Ministry of Transport, Highways, Ports, and Civil Aviation,
7th Floor,
Sethsiripaya,
Stage II,
Battaramulla.

4. Hon. Pavithra Devi Wanniarachchi,
Minister of Wildlife & Forest Resources Conservation Ministry of Wildlife & Forest Resources Conservation,
No.1090,
Sri Jayawardhanapura Road,
Rajagiriya.

5. Hon. Douglas Devananda,
Minister of Fisheries Ministry of Fisheries,
New Secretariat,
Maligawatte Road,
Colombo 10.

5A. Minister of Fisheries, Aquatic and Ocean Resources,
Ministry of Fisheries, Aquatic and Ocean Resources,
New Secretariat,
Maligawatte Road,
Colombo 10.

6. Hon. Susil Premajayantha,
Minister of Education,
Ministry of Education,

"Isurupaya",
Battaramulla.

6A. Minister of Education,
Ministry of Education,
"Isurupaya",
Battaramulla.

7. Hon. (Dr.) Bandula Gunawardena,
Minister of Transport and Highways,
Ministry of Transport and Highways,
9th Floor,
"Maganeguma Mahamedura",
Denzil Kobbekaduwa Mawatha,
Koswatte,
Battaramulla.

8. Hon. Mahinda Amaraweera,
Minister of Agriculture,
Ministry of Agriculture,
No. 80/5,
"Govijana Mandiraya",
Rajamalwatte Road,
Battaramulla.

8A. Minister of Agriculture, Livestock, Land and Irrigation,
Ministry of Agriculture, Livestock, Land and Irrigation,
No. 80/5,
"Govijana Mandiraya",
Rajamalwatte Road,

Battaramulla.

9. Hon. (Dr.) Wijedasa Rajapakse,
Minister of Justice, Prison Affairs and Constitutional Reforms,
Ministry of Justice,
No. 19,
Sri Sangaraja Mawatha,
Colombo 10.

9A. Minister of Justice, Prison Affairs and Constitutional Reforms,
Ministry of Justice,
No. 19,
Sri Sangaraja Mawatha,
Colombo 10.

9B. Minister of Justice and National Integration,
Ministry of Justice,
No. 19,
Sri Sangaraja Mawatha,
Colombo 10.

10. Hon. Harin Fernando,
Minister of Tourism and Lands,
Ministry of Tourism and Lands,
No. 2,
Asset Arcade Building,
51/2/1,
York Street,

Colombo 1.

10A. Minister of Tourism and Lands,

Ministry of Tourism and Lands,
No. 2,
Asset Arcade Building,
51/2/1,
York Street,
Colombo 1.

10B. Minister of Foreign Affairs, Foreign Employment and Tourism,

Ministry of Tourism and Lands,
No. 2,
Asset Arcade Building,
51/2/1,
York Street,
Colombo 1.

11. Hon. (Dr.) Ramesh Pathirana,
Minister of Plantation Industries,
Ministry of Plantation Industries,
11th Floor,
Stage II,
"Sethsiripaya",
Battaramulla.

11A. Minister of Plantation and Community Infrastructure,
Ministry of Plantation and Community Infrastructure,

11th Floor,
Stage II,
"Sethsiripaya",
Battaramulla.

12. Hon. Prasanna Ranathunga,
Minister of Urban Development and Housing,
Ministry of Urban Development and Housing,
17th Floor,
"Suhurupaya",
Sri Subathipura Road,
Battaramulla.

12A. Minister of Urban Development and Housing,

Ministry of Urban Development and Housing,
17th Floor,
"Suhurupaya",
Sri Subathipura Road,
Battaramulla.

13. Hon. Ali Sabry PC,
Minister of Foreign Affairs,
Ministry of Foreign Affairs Republic Building,
Sir Baron Jayathilake Mawatha,
Colombo 1.

14. Hon. Vidura Wickramanayake,
Minister of Buddhasasana, Religious and Cultural Affairs,

Ministry of Buddhasasana, Religious and Cultural Affairs,
No.135,
Srimath Anagarika Dharmapala Mawatha,
Colombo 7.

14A. Minister of Buddhasasana, Religious and Cultural Affairs,
Ministry of Buddhasasana, Religious and Cultural Affairs,
No.135,
Srimath Anagarika Dharmapala Mawatha,
Colombo 7.

15. Hon. Kanchana Wijesekara,
Minister of Power and Energy,
Ministry of Power and Energy,
No. 437,
Galle Road,
Colombo 3.

15A. Minister of Energy,
Ministry of Energy,
No. 437,
Galle Road,
Colombo 3.

16. Hon. Nasser Ahmed,
Minister of Environment.

16A. Minister of Environment,
Ministry of Environment,

No/416/C/1,
"Sobadham Piyasa",
Robert Gunawardena Mawatha,
Battaramulla.

17. Hon. Roshan Ranasinghe,
Minister of Irrigation,
Ministry of Irrigation,
No. 500,
10th Floor,
T. B. Jayah Mawatha,
Colombo 10.

18. Hon. Manusha Nanayakkara,
Minister of Labour and Foreign Employment,
Ministry of Labour and Foreign Employment,
6th Floor,
"Mehewara Piyasa",
Narahenpita,
Colombo 5.

18A. Minister of Labour and Foreign Employment,
Ministry of Labour and Foreign Employment,
6th Floor,
"Mehewara Piyasa",
Narahenpita,
Colombo 5.

18B. Minister of Labour,
Ministry of Labour,
6th Floor,
"Mehewara Piyasa",

Narahenpita,
Colombo 5.

19. Hon. Tiran Alles,
Minister of Public Security,
Ministry of Public Security,
14th Floor,
"Suhurupaya",
Battaramulla.

19A. Minister of Public Security and Parliamentary Affairs,
Ministry of Public Security and Parliamentary Affairs,
14th Floor,
"Suhurupaya",
Battaramulla.

20. Hon. Nalin Fernando,
Minister of Trade, Commerce and Food Security,
Ministry of Trade, Commerce and Food Security,
No.492,
L. H. Piyasena Building,
R. A. de Mel Mawatha,
Colombo 3.

20A. Minister of Trade, Commerce, Food Security and Cooperative Development,

Ministry of Trade, Commerce, Food Security and Cooperative Development,
No.492,
L. H. Piyasena Building,
R. A. de Mel Mawatha,
Colombo 3.

21. Hon. Jeevan Thondaman,
Minister of Water Supply and Estate Infrastructure Development,
Ministry of Water Supply and Estate Infrastructure Development,
No. 35,
"Lakdiya Medura",
New Parliament Road,
Pelawatte,
Battaramulla.

22. Hon. (Dr.) Keheliya Rambukwella,
Former Minister of Health,
Currently under remand custody at: Welikada Remand Prison,
Dr. Danister de Silva Mawatha,
Colombo 10.

22A. Minister of Health,
Ministry of Health,
"Suwasiripaya",
No.385,
Rev. Beddegama Wimalawansa Thero Mawatha,
Colombo 10.

23. W. M. D. J. Fernando,
Secretary to the Cabinet of Ministers,
Office of the Cabinet of Ministers,
Republic Building,
Sir Baron Jayathilake Mawatha,
Colombo 1.

24. K. M. M. Siriwardena,
Secretary to the Treasury,
Ministry of Finance,
The Secretariat,
Colombo 1.

25. S. J. S. Chandraguptha,
Former Secretary,
Currently under remand custody at:
Welikada Remand Prison,
Dr. Danister de Silva Mawatha,
Colombo 10.

25A. Secretary Ministry of Health,
"Suwasiripaya",
No.385,
Rev. Beddegama Wimalawansa Thero Mawatha,
Colombo 10.

26. National Medicines Regulatory Authority,
No.120,
Norris Canal Road,
Colombo 10.

27. Prof. S. D. Jayaratne,
Former Chairman,
No.1073/F/1,
Kumaragewatta Road,
Thalawathugoda,
Battaramulla.

27A. Chairman,
National Medicines Regulatory Authority,
No. 120,
Norris Canal Road,
Colombo 10.

28. Dr. Vijith Gunasekara,
Former Chief Executive Officer,
Currently under remand custody at:
Welikada Remand Prison,
Dr. Danister de Silva Mawatha,
Colombo 10.

28A. Chief Executive Officer,
National Medicines Regulatory Authority,
No. 120,
Norris Canal Road,
Colombo 10.

29. Dr. Pradeep Kumarasinghe de Silva,
Member.

30. Dr. Kosala Karunaratne,
Member.

31. Dr. Manoj Gamage,
Member.

31A. Member

32. Dr. Supul Wijesinghe,
Member.

32A. Member

33. Dr. Chathura Mohottigedara,
Member.

33A. Member

34. Dr. Pradeep de Silva,
Member.

34A. Member

35. Mr. Priya Serasinghe,
Member.

35A. Member

All of:
National Medicines Regulatory Authority,
No. 120,
Norris Canal Road,
Colombo 10.

36. Dr. Asela Gunawardena,
Director General of Health Services,
(Department of Health Services),
No. 357,
Beddegama Wimalawansha Mawatha,
Colombo 10.

37. Dr. A. T. Sudharshana,
Director,
Currently under remand custody at:
Welikada Remand Prison,
Dr. Danister de Silva Mawatha,
Colombo 10.

37A. Director,
Medical Supply Division (Department of Health Services),
No. 357,
Beddegama Wimalawansha Mawatha,
Colombo 10.

38. Kanishka Wijeratne,
Director General.

38A. Director General,
Commission to Investigate Allegations of Bribery and Corruption.

39. Hon. Justice Eva Wanasundera,
Chairperson.

39A. Chairman

40. Hon. Justice Deepali Wijesundera,
Member.

40A. Member

41. C. N. Wakishta,
Member.

41A. Member

All of: Commission to Investigate Allegations of Bribery and Corruption,
No.36,
Malalasekara Mawatha,
Colombo 7.

42. W. P. C. Wickramaratne,
Auditor General 306,
72 Polduwa Road,
Battaramulla.

43. P. B. S. C. Nonis,
Director General of Customs,
Sri Lanka Customs,
No.40,
Main Street,
Colombo 12.

44. C. D. Wickramaratne,
Inspector General of Police.

44A. Inspector General of Police,
Police Headquarters,
Colombo 12.

45. Savorite Pharmaceuticals (Pvt) Limited,
No. 703,
Atlantis Heights Sarabhai Compound,
Vadiwadi Road,
Vadodara-39007,
Gujarat,
India.

46. Kausikh Therapeutics (Pvt) Limited,
No. 21,
(and formerly No.12),
Durairaj Street,
Palavanthangal,
Chennai,
India.

47. Honourable Attorney General,
Attorney General's Department,
Colombo 12.

RESPONDENTS

BEFORE : **P. PADMAN SURASENA, CJ**
KUMUDINI WICKREMASINGHE, J
JANAK DE SILVA, J

COUNSEL : Senany Dayaratne with Lasanthika Hettiarachchi, Sankhitha Gunaratne and Nishadi Wickremasinghe, Janani Abeywickrema and Maheshika Bandara for the Petitioners in **SC/FR/65/23.**

Nilshantha Sirimanne with Deshara Goonetilleke and Nelundi Herath for the Petitioners in **SC/FR/82/23.**

Dr. Romesh de Silva PC with Suren Fernando & Niran Anketel instructed by Mrs. C. Samarasinghe for the 45th Respondent in **SC/FR/65/23** & 33rd Respondent in **SC/FR/82/23.**

Anusha Sammandappeeruma instructed by Sharanya Jeyarajah for the 41st Respondent.

J.P. Gamage with Chamara Nirmal Fernando & Theekshan Ranaweera instructed by Udayashanthini Karmegam for the 31A-33A Respondents and 35A Respondent.

Uditha Egalahewa PC with Vishva Vimukthi instructed by Kanchana Senanayake for the 26th Respondent.

Faris Saly with Arshadha Subair, Shuhadha Hansala & Hansul Kanar instructed by Faris & Associates for the Respondent.

Widura Ranawaka with Menaka Warnapura & Bathiya Dassanayake instructed by Dananga Kiriella for the 34th Respondent in **SC/FR/82/23** and 46th Respondent in **SC/FR/65/23.**

Jagath Abenayaka instructed by Mahesh Dissanayake for the Respondent.

Nirmalan Wigneswaran DSG with Mihiri de Alwis SSC for the 1A, 2A, 3A, 5A, 6A, 8A, 9A, 9B, 10A, 10B, 11A, 12A, 14A, 15A, 16A, 18A, 19A, 20A, 22A, 25A, 36th, 37A, 42nd - 44th & 47th Respondents in **SC/FR/65/23** & 29th & 35th Respondents in **SC/FR/82/23.**

ARGUED ON : 24-09-2025

DECIDED ON : 27-03-2026

P. PADMAN SURASENA, CJ

At the commencement of the argument, the learned Counsel for all the parties agreed that Court can consolidate the hearing of the cases bearing Nos. SC/FR/65/2023 and SC/FR/82/2023. They also agreed that it would suffice for this Court to pronounce one Judgment in respect of both these cases, i.e., SC/FR/65/2023 and SC/FR/82/2023.

For convenience, unless otherwise mentioned, the references I will be making in this Judgment to identify the parties and the documents, would be references to the parties as appearing in the caption and the documents, filed in the case of SC/FR/65/2023.

Petitioners in these cases have complained against a procurement procedure, adopted for the importation of certain medical supplies from Savorite Pharmaceuticals (Pvt) Limited which stands as the 45th Respondent.[1] It is the position of the Petitioners that the former Minister of Health (the 22nd Respondent),[2] had sought and obtained the

[1] Savorite Pharmaceuticals (Pvt) Limited stands as the 33rd Respondent in SC/FR/82/2023

[2] Former Minister of Health stands as the 22nd Respondent in both SC/FR/65/2023 and SC/FR/82/2023.

approval of the Cabinet of Ministers to import the afore-said medical supplies contrary to law, utilizing the Indian Credit Line (ICL) facility.

The Petitioners have also alleged that the National Medicines Regulatory Authority (NMRA) (26th Respondent),[3] has granted a Waiver of Registration (hereinafter sometimes referred to as WOR) despite the failure of the 45th Respondent to submit all necessary documents to the NMRA required in terms of Section 109 of the National Medicines Regulatory Authority Act No. 05 of 2015 (NMRA Act). It is on the above basis that the Petitioners in their Petitions, have inter alia, prayed for the declarations that the Fundamental Rights guaranteed to them under Article 12(1) of the Constitution have been infringed by some of the Respondents. They have more fully set out the reliefs they have prayed, in the prayers of their respective Petitions.

Upon the Petitioners supporting this case, the Court, by its Order dated 06th April 2023, while granting Leave to Proceed in respect of the alleged infringements of the Petitioners' Fundamental Rights guaranteed under Article 12(1) of the Constitution, has made the following Order:

> *"Heard the learned Counsel for the Petitioners and the learned Deputy Solicitor General for all the Respondents excluding the 45th & 46th Respondents. Upon a consideration of the material placed before this Court and submissions made by the learned Counsel, it is the view of this Court that there is prima-facie evidence to conclude that notwithstanding the urgency in procuring the 38 pharmaceuticals referred to in this application, the impugned procurement decision is prima-facie affected by,*
>
> *(a) Serious doubts arising regarding the quality, safety and efficacy of the pharmaceuticals that have been ordered; and*

[3] The NMRA stands as the 26th Respondent in both SC/FR/65/2023 and SC/FR/82/2023.

(b) Non satisfaction that most favourable terms and conditions have been received pertaining to the impugned procurement. Further serious doubts have arisen regarding the lawfulness of the impugned procurement transaction.

In the circumstances, in the interests of justice this Court makes the following Orders,

(1) Grant Leave to Proceed under Article 12(1) of the constitution.

(2) Suspend further importations of pharmaceuticals pertaining and or arising out of the impugned procurement decision pending a further Order being obtained from this Court following material being placed before this Court that necessary quality requirements have been satisfied and the procurement is lawful.

(3) Release for use the two consignments that have already reached Sri Lanka only after the conduct of necessary tests and NMRA expresses satisfaction regarding the safety, efficacy and quality of the imported pharmaceuticals.

…"

Time Bar

The learned President's Counsel for the 45th Respondent at the outset, raised a preliminary objection against the maintainability of these cases by the Petitioners before this Court on the basis that the Petitioners have failed to file these cases within the specified time limit (one month) set out in Article 126(2) of the Constitution.

According to the Petitioners, it is primarily the 22nd Respondent (the former Minister of Health) who is alleged to have manipulated the whole proceedings which had ultimately led to an illegal importation of the relevant drugs to Sri Lanka, violating the

relevant laws. This process appears to have started with the Cabinet Memorandum dated 25-10-2022 (**P-2**). However, the Petitioner in SC/FR/65/2023 has filed this case on 16-02-2023 and the Petitioner in SC/FR/82/2023 has filed his case on 02-03-2023. Thus, the first issue that this Court has to resolve is whether the Petitioners' Applications are out of time.

It is now settled law that any Petitioner must file the Petition in a Fundamental Rights Application within one month of the alleged violation as set out in Article 126(2) of the Constitution. However, this Court has consistently held that a person who is unaware of the fact that his fundamental rights were being violated, is entitled to file a Petition in terms of Article 126(2) within one month from the time he had become aware of the alleged infringements of his fundamental rights.

In the case of *Demuni Sriyani de Zoysa and others Vs Chairman, Public Service Commission and others*,[4] Prasanna Jayawardena PC J held as follows:

> *"When applying the aforesaid principles, one has to sequentially ask the following questions:*
>
> *(i) (a) When did the alleged infringement occur?; or, if Petitioners claim they became aware of the alleged infringement only sometime after it occurred, when did they become aware of it or when should they have become aware if it?*
>
> *(b) If the alleged infringement is in the nature of a continuing one which the Petitioners were aware of, till when did it continue?;*
>
> *(ii) If the application has been filed more than one month after the latest date determined when considering (a) and (b) above, have the Petitioners established that, they were unable to invoke the jurisdiction of this Court due to circumstances, which were beyond their control and that, there has been no lapse, fault or delay on their part?*

[4] SC FR 206 /2008 decided on 09-12-2016.

(iii) If so, have the Petitioners filed this application within one month of any such disability ending?

As has been held in that judgment, 'the date determined in answer to the first subset of questions will determine the date on which the one month period stipulated in Article 126 (2) commences to run."

It is the Position of the Petitioners in SC/FR/65/2023 that they became aware of this incident through a news item published on the newspaper 'Sunday Times' on 22-01-2023 while the Petitioners in SC/FR/82/2023 state that they became aware of this incident through a news item published online by the Ceylon Today newspaper on 23-02-2023. The Petitioners have pleaded this position in their respective Petitions and affidavits. The 45th Respondent has not countered this position and appears to have been content by only saying that the Cabinet Memorandum **P-2** is dated 25-10-2022.

Having considered the material adduced in this case, the submissions made by Counsel and the circumstances in which the alleged incidents relating to the relevant procurement has occurred (I would advert to these in the course of this Judgment), I hold that there is no merit in the preliminary objection raised, on behalf of the 45th Respondent.

Merits

The Cabinet Memorandum dated 26-09-2022 (**25R-14**) has been submitted by the 25th Respondent (the then Secretary to the Ministry of Health (Seemahewage Janaka Sri Chandraguptha) with his affidavit dated 22-03-2023; the said affidavit was filed as Limited Objections before this Court granted Leave to Proceed by its Order dated 06-04-2023. The 25th Respondent, in the said affidavit (the affidavit dated 22-03-2023), has confirmed that the 22nd Respondent (former Minister of Health) had sought approval to import certain pharmaceuticals on the basis that they are urgently required, from the agents of private sector using the funds through the ICL, adhering

to the existing pricing mechanism at the time decided by the Pricing Committee of the Ministry of Health.

The Petitioner has produced the Cabinet Memorandum dated 25-10-2022 marked **P-2**. The present Secretary to the Minister of Health (Palitha Mahipala Gunaratne, 25A Respondent) who subsequently succeeded the former Secretary to the Ministry of Health (Seemahewage Janaka Sri Chandraguptha who filed the affidavit dated 22-03-2023), has also filed the same Cabinet Memorandum dated 25-10-2022, marked **25R-3**. This is with his affidavit dated 15-09-2024, filed along with his Statement of Objections after this Court granted Leave to Proceed to this Petition.

It is to be noted that the former Minister of Health, by the Cabinet Memorandum dated 25-10-2022, had sought permission of the Cabinet of Ministers to import stocks of the said medical supplies which he had stated to be a stock sufficient to meet the demand for the next three months. The former Minister of Health, in the said Cabinet Memorandum has stated that it had become necessary to maintain an uninterrupted supply of stocks of medical supplies in view of the crisis relating to the non-availability of foreign exchange in the country. According to this Cabinet Memorandum, the available stocks of the said medical supplies had been at zero level.

The then Minister of Finance, as per the request of the Cabinet of Ministers, had forwarded his observations. The Petitioner has produced a copy of this observation dated 02-11-2022, marked **P-9**. It is worthwhile to reproduce some part of this observation made by the then Minister of Finance particularly because it has positively stated that this is an unsolicited procurement. It is as follows:

> *"It is observed that, according to the cabinet memorandum some vital and essential drugs are out of stock in the medical supply division and some drugs will be out of stock within three weeks. Therefore, considering the national requirement for drugs, I have no objections to proposals No. 4.1.1. and 4.1.2., subject to the followings;*

(a)The proposed supplier mentioned in the Cabinet memorandum is selected on an unsolicited basis. Therefore, the prices and quality of medical supplies should be reviewed and negotiated by the Cabinet Appointed Negotiation Committee (CANC) or Health Sector Emergency Procurement Committee (HSEPC) which is already appointed to the Ministry of Health to obtain realistic and reasonable prices on par with the market rates and also the quality of the drugs.

(b)the Ministry of Health should follow the procedures which are applicable for private sector pharmaceutical suppliers to import drugs on behalf of the State Pharmaceutical Corporation under the Indian Credit line scheme for the proposed supplier.

(c)the minister of health and the proposed supplier enter into an agreement regarding prices and quality of drugs before the importation.

(d)if there are any private sector supplier who comes under unsolicited basis to provide medical supplies under the Indian Credit Line, the Ministry of Health should follow the process of (a), (b), (c) above for them. Further, if funds utilized other than the Indian Credit Line, the appropriate procurement guidelines should be followed by the Ministry of Health..."

The 25A Respondent (the present Secretary to the Ministry of Health) has produced the letter dated 25-10-2022 (marked **25R-4**), issued by the former Secretary to the Ministry of Health, addressed to the Deputy Director General Medical Supplies Division informing him that the Cabinet of Ministers had approved the procurement of the aforesaid medical supplies directly from the 45th Respondent (Savorite Pharmaceuticals (Pvt) Limited) through the Indian Credit Line. It is through the above process that the 45th Respondent had imported the stock of medical supplies which the Petitioners have impugned in these cases.

Let me first probe whether in fact the available stocks of the said medical supplies had been at zero level as claimed by the former Minister of Health. The 37th Respondent (Arambegedera Thusitha Sudarshana) is the then Director of the Medical Supplies Division of the Ministry of Health. The Medical Supplies Division is responsible for maintaining the stocks necessary for the medical supplies in the country. That being so, under general circumstances, there cannot be a situation where the 37th Respondent has waited without doing anything until any stock of any essential medical supply comes to zero level.

Had any stock of any medical supply needed to be replenished, the 37th Respondent should have taken an initiative to do so. However, the 37th Respondent has not initiated any such move with regard to any of the items of medical supplies which the former Minister of health had wanted to procure through **P-2**. It is only the former Minister of Health who has asserted that the relevant medical supplies had come to zero level. The 37th Respondent has filed the affidavit dated 11-11-2024. In the said affidavit, he has categorically stated that it was the Secretary of the Ministry of Health who, by letter dated 28-10-2022 (**37R-1**), had instructed the Medical Supplies Division to take necessary steps without delay to purchase medical supplies from the 45th Respondent on the basis that the Cabinet of Ministers had so decided. The 37th Respondent has also stated that the 45th Respondent was not among the registered suppliers and therefore he had decided to refer the said fact to the NMRA, asking for a Waiver of Registration by **P-10**. He admits signing the letter **P-10**.

The person who succeeded the 25th Respondent (Seemahewage Janaka Sri Chandraguptha) is Palitha Gunarathna Mahipala (25A Respondent). He has filed his affidavit dated 15-09-2024. In his affidavit, he has admitted that the 45th Respondent (Savorite Pharmaceuticals (Pvt) Limited) was not a registered manufacturer.[5]

The 25A Respondent (succeeding Secretary, Ministry of Health) in his affidavit dated 15-09-2024 has categorically stated that there is no shortage of the drugs in question

[5] Paragraph 30 of the affidavit dated 15-09-2024

at present and the stock positions of the relevant drugs are at a satisfactory level. He has annexed to his affidavit a certified copy of the stock position of the drugs in question as at 17-04-2024 marked **25R-15**.

The Cabinet Memorandum submitted by the former Minister of Health is dated 25-10-2022 (**P-2**). The NMRA had granted the Waiver of Registration dated 14-12-2022. The Petitioners in SC/FR/65/2023 have filed this case on 16-02-2023 and the Petitioners in SC/FR/82/2023 have filed their case on 02-03-2023. This Court made the Interim Order on 06-04-2023. Except the 25th Respondent (the former Secretary Ministry of Health), no other Respondent has ever taken a position that these medical supplies were indeed at zero level at the relevant time and therefore they had to immediately replenish them through other means even after this Court made the Interim Order. To the contrary, the only position made available before Court is the fact that the stock positions of the relevant drugs are at a satisfactory level. Obviously, the succeeding Secretary, Ministry of Health has stated this position as an assistance to this Court knowing that the Court has to decide on this issue. He has never taken a position in his affidavit that these medical supplies were indeed at zero level at the relevant time and therefore they had to immediately be replenished as claimed by the former Minister of Health.

Moreover, the 25A Respondent (succeeding Secretary, Ministry of Health) in his affidavit dated 15-09-2024 has categorically stated that the Ministry of Health in this instance had proceeded with suppliers who submitted unsolicited bids.

The 37th Respondent by the letter dated 30-11-2022 (**P-10**) addressed to the Chairman NMRA, has sought the issuance of a WOR in favour of the 45th Respondent (Savorite Pharmaceuticals (Pvt) Limited) to import and supply the relevant items of medical supply as per the aforesaid cabinet decision. It is worthwhile reproducing the body of that letter (dated 30-11-2022) which appears below (verbatim):

"Maintenance of uninterrupted supply of medical supplies to Sri Lanka (import and supply of vital and essential pharmaceuticals through Savorite Pharmaceuticals Pvt Ltd - India)

MSD was place the orders to Savorite Pharmaceuticals Pvt Limited for 38 nos of essential pharmaceutical items to maintain the uninterrupted supply of pharmaceuticals to Sri Lanka according to the cabinet memorandum no. 22/1693/610/024 and dated 25-10-2022.

M/s Savorite Pharmaceuticals Pvt Ltd is not registered at the NMRA and Since this item is urgently needed at health institutions, please be kind enough to issue WOR for Savorite Pharmaceuticals Pvt Limited to import & supply these items at your earliest.

Item list and Performa invoices attached herewith for your reference."

Having regard to the several averments in the affidavit of the 37th Respondent, one cannot gather any specific information that the Medical Supplies Division was facing a problem to supply the relevant pharmaceutical items and therefore was instrumental in initiating the impugned process. The averments contained in the 37th Respondent's affidavit indicate otherwise. This could be gathered from statements such as, *"I had neither resources nor the authority to act in contravention to a Cabinet Memorandum or directions of the secretary to the Ministry of Health"*.[6] In the above circumstances, I hold that the 37th Respondent has failed to prove that there was indeed a necessity to procure these items on an urgent basis, bypassing all relevant procedures in that regard.

Let me now briefly examine how this procurement has been done. It is pertinent at this juncture to refer to several relevant sections in the National Medicines Regulatory Authority Act (NMRA Act No. 05 of 2015).

[6] Paragraph 20(f) of his affidavit dated 11-11-2024.

Section 3

The objects of the Authority shall be to –

(a) ensure the availability of efficacious, safe and good quality medicines, efficacious, safe and good quality medical devices and efficacious, safe and good quality borderline products to the general public at affordable prices;

(b) function as the central regulator for all matters connected with the registration, licensing, cancellation of registration or licensing, pricing, manufacture, importation, storage, transport, distribution, sale, advertising and disposal of medicines, medical devices and borderline products;

(c) ensure that all activities related to registration, licensing and importation of medicines, medical devices, borderline products and investigational medicinal products are carried out in a transparent, sustainable and equitable manner;

(d) encourage the manufacturing of good quality medicines in Sri Lanka with a view to assuring the availability of essential medicines at affordable prices;

(e) promote the safe and rational use of medicines, medical devices and borderline products by health care professionals and consumers;

(f) recommend appropriate amendments to relevant laws pertaining to medicines, medical devices and borderline products;

(g) educate the general public, health care professionals and all stakeholders on medicines, medical devices and borderline products;

(h) regulate the promotion and marketing of medicines, medical devices and borderline products;

(i) regulate the availability of the medicines, medical devices and borderline products;

(j) conduct post marketing surveillance on quality, safety and adverse reaction of the medicines, medical devices and borderline products; and

(k) regulate all matters pertaining to the conduct of clinical trials in Sri Lanka.

According to Section 14 of the NMRA Act the powers and functions of the Authority includes :-

- decide on classifying a product as a medicine, medical device, borderline product or any other product;
- authorize registration and licensing of medicines, medical devices, borderline products and investigational medicinal products or cancel or suspend any such registration or licence in terms of this Act;
- regulate the registration, licensing, manufacture, importation, storage, re-packing, transportation, distribution, sale, advertising, promotion, recall and disposal of medicines, medical devices, borderline products or investigational medicinal products;
- authorize registration and regulation of Pharmacies and medicines stores;
- issue licences for manufacture, import, storage, distribution, transport and sale of medicines, medical devices, borderline products or investigational medicinal products and to cancel such licences in terms of this Act;

- appoint sub-committees as may be necessary for the effective discharge of the functions of the Authority;

- grant approval for the custom clearance of consignments of medicines, medical devices, borderline products, raw materials, packing materials, machinery or laboratory material needed for local manufacture of medicines, medical devices, borderline products or investigational medicinal products subject to the provisions of this Act and any other written law;

- monitor the registration and licensing process and the usage of medicines, medical devices, borderline products or investigational medicinal products which are registered and licensed under this Act for adverse reactions through use thereof, and to take immediate and necessary action in such an instance;

The above provisions of law make it clear that the NMRA has its own statutory functions i.e., to ensure the availability of efficacious, safe and good quality medical supplies in the country. The NMRA is therefore required to exercise its powers independently. Thus, the NMRA is responsible for whatever the actions it has taken. It cannot pass the responsibility of its actions to any other.

The provisions of law in the NMRA Act show clearly that it is mandatory to register any drug/medical supply before such drug could be imported to the country. The only exception found in the law is found in its Section 109. Under this Section the NMRA can grant permission under certain circumstances to import and supply a specified pharmaceutical item in a specified quantity. This exception is commonly referred to as obtaining 'a Waiver of Registration' (WOR).
The Section 109 is reproduced below:

Section 109

(1)The Authority may grant permission in special circumstances such as to save a life, to control an outbreak of an infection or an epidemic or any other

national emergency or for national security to import and supply a particular medicine, medical device or borderline product in specified quantities.

(2)Such permission may be granted:—

(a)on a request made by the Ministry of Health; or

(b)on a request made by an individual or an organization recommended by the Ministry of Health.

(3)The importer shall be responsible for the accountability and management of the medicine, medical device or borderline product imported under this section.

(4)The importer shall submit routine reports in the prescribed manner to the Authority, on the medicine, medical device or borderline product imported under this section.

The procedures set out in the Procurement Guidelines 2006 for Goods and Works issued by the National Procurement Agency (**P-22(a)**) should be adhered to by the procurement entity in carrying out any procurement action financed in whole or in part by the Government of Sri Lanka or a foreign funding agency. Clause 3.5 of the said Procurement Guidelines is reproduced below.

3.5 Direct Contracting

3.5.1

(a) Direct contracting is a means of Procurement of Goods or Services or Works from a single supplier source.

(b) It entails no competition and shall be used only under exceptional circumstances.

(c) This method is appropriate under the following circumstances:

(i) When the prices or rates are fixed pursuant to legislation by regulatory bodies;

(ii) Standardization of equipment, for compatibility with existing equipment, may justify additional purchases of the same type of Goods;

in such purchases-

- *the number of such items in the new Procurement shall generally be less than 50% of the existing number,*
- *the price shall be reasonable, and*
- *the advantages of another make or source of equipment shall have been considered;*

(iii) the required equipment is proprietary and obtainable only from one source such as proprietary software, text books, spare parts, defence items; and

(iv) the process design requires the purchase of critical items from a particular supplier as a condition of a performance guarantee.

(d) When direct contracting is used under any of the reasons above, the value of the Procurement shall be subjected to the upper limits given under Guideline 2.14. No government agency will qualify for automatic direct contract award unless the above requirements are satisfied.

Having regard to the way and the circumstances under which the impugned procurement has been made at the instance of the former Minister of Health, I can observe that the procurement entity in this instance has failed to follow or give any consideration to the above guidelines.

Furthermore, Clause 3.8.1 of the Procurement Guidelines 2006 [**P-22(a)**] states as follows:

3.8 Emergency Procurement

3.8.1

(a) A PE may utilize this method of Procurement –

(i) in exceptional circumstances, such as manmade or natural disasters;

(ii) to meet unforeseen social obligations and such other similar situations which shall be determined and declared by the GoSL as being an emergency situation which warrants Procurements under the provisions contained herein;

(b) to initiate Procurements exceeding the financial thresholds stipulated under Guideline 2.14, a formal approval shall be obtained from the relevant authorities at the first available opportunity.

However, although the Procurement Guidelines 2006 has made the above provision available for emergency purchasing the procurement entity in this instance had failed to give due consideration to the above guideline. Moreover, the phrase 'emergency procurements' has been defined in clause 6.6 of the Guidelines for Procurement of Pharmaceuticals & Medical Devices 2006 [**P-22(b)**].

6. METHODS OF PROCUREMENT

6.6. Emergency Procurements

6.6.1. *For the purposes herein, Emergency shall be deemed to be a situation which has arisen due to either of the following causes:*

(a) man made or natural disasters which is declared as an Emergency by the Government of Sri Lanka, or

(b) the sudden outbreak of disease as declared by the Government/MoH.

6.6.2.

(a) The PE shall in such exceptional circumstances be authorized to procure the required quantities of Pharmaceuticals and Medical Devices, without resorting to any of the procurement methods stipulated in Guideline 6 from

- *State Organizations or UN Agencies where appropriate,*
- *established list of suppliers/manufacturers pre-qualified as per the criteria*

- *stipulated in these Guidelines,*
- *suppliers/manufacturers registered by the MSD/SPC where appropriate.*

(b) If the product to be procured is not available from the above sources the PE shall procure such items from:

- *local authorized agents for such particular product;*
- *any worldwide manufacturer/s, suppliers, distributors*

6.6.3.

(a) Except in the case of Single Source or Limited Source products, PE shall ensure that the suppliers/manufacturers have not over priced the products to be sourced. For this purpose the PE shall have reference to historical prices.
For Pharmaceutical products the PE may also refer to the Annual International Drug Price Indicator Guide published by the Management Sciences for Health.
Website:www.msh.org/
Address Development Offices, MSH, 165 Allandale Road, Boston, MA
Telephone: (617) 524 7799
Fax: (617) 524 (783
Email: developments@msh.org

(b) PE may also consult with neighbouring countries to check on prices offered to them by such suppliers and manufacturer.

6.6.4. *The limits of authority for such procurements are as follows:*

(a) Secretary MOH, upto a maximum limit of SLR Ten million or the equivalent thereof in any other foreign currency, per event.

(b) Director-MSD upto a maximum limit of SLR Two Million or the equivalent thereof in any other foreign currency, per event.

(c) Managing Director SPC upto a maximum limit of SLR Two Million or the equivalent thereof in any other foreign currency, per event.

Further, the Guidelines for Procurement of Pharmaceuticals and Medical Devices 2006 [**P-22(b)**] also sheds light on urgent procurements. It is as follows:

6.7. *Urgent Procurements*

6.7.1. *Pharmaceuticals and Medical Devices may be procured from the domestic and/or international market in very limited quantities as an urgent procurement and until the resumption of normal supply, in a situation which has arisen due to one or more of the following causes*

(a) withdrawal of a product/s due to quality failure, or

(b) shortage of a product/s due to suppliers default; or

(c) shortage of a product/s due to an event/circumstance of Force Majeure as defined herein; or

(d) on a written request made by a Consultant in order to treat a grave/life threatening situating of a patient, on a case by case basis.

6.7.2.

(a) Limits of Authority for such urgent procurements are as follows:

(i) Secretary MOH-Up to a maximum of SLR 1,000,000.00 (one million) or the equivalent thereof in any foreign currency, per event;

(ii) Director-General Health Services Upto a maximum of SLR 500,000.00 (five hundred thousand) or the equivalent thereof in any foreign currency, per event;

(iii) Director MSD Up to a maximum of SLR 250,000.00 (two hundred and fifty thousand) or the equivalent thereof in any foreign currency, per event.

(iv) Managing Director-SPC Up to a maximum limit of SLR 250,000.00 or the equivalent thereof in any foreign currency, per event.

(b) In the aforesaid circumstances every effort shall be made to procure such products initially from the list of pre-qualified suppliers/manufacturers.

6.7.3.

(a) Except in the case of Single Source or Limited Source products, PE shall also ensure that the suppliers/manufacturers have not over priced the Pharmaceuticals to be sourced by reference to historical prices.

(b) For Pharmaceutical products the PE may also refer to the Annual International Drug Price Indicator Guide published by the Management Sciences for Health.

6.7.4. *In circumstances where an Urgency has arisen due to withdrawal of products as a result of quality failure then the PE shall ensure that such suppliers/manufacturers are disqualified from*

participating in any future bidding process for that particular product at least for a minimum period of three (03) years.

6.7.5.

(a) In circumstances where an Urgency has arisen due to (a) In circumstances where an Urgency suppliers/manufacturers default in complying with contractual obligations, the PE shall issue a "show-cause notice" to such suppliers/manufacturers

(b) If the PE is not satisfied with the explanation offered by such suppliers/manufacturers, PE shall ensure that such suppliers/manufacturers are disqualified from participating in future bidding process for that particular product at least for a minimum of three (03) years.

6.7.6. *The names of suppliers/manufacturers who are disqualified under these provisions shall be forwarded to the CDDA for necessary action and to the NPA in accordance with PG 8.11.*

6.7.7. *Any additional costs that are or may be incurred by the PE due to such default on the part of manufacturer/supplier should be borne by such manufacturer/supplier and a provision to this effect should be included in the Bidding documents*

The above provisions show clearly that the relevant Respondents have knowingly violated all norms relating procurement when the 45th Respondent was asked to supply the relevant items. None of the Respondents has even attempted to show as to how and on what basis the former Minister of Health had selected the 45th Respondent as the supplier. The 45th Respondent is not a registered supplier. The drugs he was asked to supply are not registered in terms of the NMRA Act. The NMRA has stated that it

has had internal procedure for granting a Waiver of Registration which outlined the guideline for the Waiver of Registration of pharmaceutical products to be imported to Sri Lanka. The NMRA, the 26th Respondent, has produced this guideline as **26R-1**. This is dated 15-10-2019. The procedure set out in this document (**26R-1**) is as follows:

It is necessary that the Applicant must submit the following documents to obtain permission under S. 109 of the NMRA Act.

i. Request letter from the applicant
ii. Recommendation of Technical Evaluation Committee (TEC) when the request is made by the Ministry of Health or the request is made on behalf of the Ministry of Health.
iii. Recommendation of the end-user
iv. Indent/ commercial invoice
v. Certificate of Analysis (COA) of the relevant product
vi. Certificate of Pharmaceutical Product (COPP)
vii. Real time stability report
viii. Quotation Document
ix. Approval of relevant Procurement Committee
x. Purchase order
xi. Custom detain document
xii. Label of the product
xiii. Product Information Leaflet (PIL)

The NMRA has not established before Court that the available material had satisfied it to enable it to allow these pharmaceutical items to be imported to country for the use of general public without registration.

There is a general rule in the construction of statutes that what a court or a person is prohibited from doing directly, cannot be done indirectly or in a circuitous manner.[7]

[7] *Bandaranayake Vs. Weeraratne & others* [1981] 1 SLR 10 at 16.

Ministers and the public officers have been conferred with powers by various statutes to exercise them fairly according to law for the benefit of the people. They hold and exercise these powers in trust for the general public in this country. In this instance, the actions of the former Minister of Health, NMRA, the Director Medical Supplies Division and the then Secretary Ministry of Health are not mere lapses. They knew very well that there was no shortage of the relevant medicines in the stocks. They also knew that the 45th Respondent was not a registered supplier. They also knew that they were acting contrary to the procurement guidelines and all provisions of law relating to the procurements. Yet, they proceeded to facilitate this illegal importation of questionable drugs by the 45th Respondent.

This Court by its Interim Order dated 06-04-2023 (reproduced above)[8], had suspended further importations of pharmaceuticals under the impugned procurement process. Court further ordered that the two consignments of pharmaceuticals which had already reached Sri Lanka under the impugned procurement process to be released only upon the 26th Respondent (NMRA) expressing satisfaction regarding the 'safety, efficacy and quality' of the imported pharmaceuticals.

The 45th Respondent, by the Motion dated 28-04-2025, had prayed that this Court should direct the 43rd Respondent (Sri Lanka Customs) to release the consignment of pharmaceuticals, which had already reached Sri Lanka under the impugned procurement process, to the 37th Respondent (Medical Supplies Division, Ministry of Health) and further prayed that it should also direct the 37th Respondent and/or the 26th Respondent (NMRA) to conduct further testing of the aforesaid pharmaceuticals and submit a report to this Court.

The present Chairman of the 26th Respondent (NMRA) by his affidavit dated 19-05-2025 has filed objections to the Motion of the 45th Respondent dated 28-04-2025.

[8] See pages 33-34

The 45th Respondent filed the above Motion in expectation that the aforesaid consignment can be subsequently released for the use by the public, if the report thus obtained satisfied the NMRA with regard to the 'safety, efficacy and quality' of the imported pharmaceuticals. This was to enable the 45th Respondent to recover the costs incurred in importing the consignments.

Following the issuance of the above-mentioned Interim Order by this Court on 06-04-2023, the 25th Respondent (then Secretary to the Ministry of Health, Seemahewage Janaka Sri Chandraguptha), by letter dated 25-04-2023 (**26R-12**), instructed the 45th Respondent to carry out the necessary testing of the retained samples for all 38 pharmaceutical products at any WHO Prequalified Medicines Quality Control Laboratory recommended by the 26th Respondent (NMRA). Accordingly, the 45th Respondent took steps to test the samples and submitted the relevant test reports.[9] These test reports were scrutinized by a five-member expert committee, appointed by the 26th Respondent consequent to a decision by its Board on 19-05-2023 (**26R-13(A)**).

The five-member expert committee, after evaluating the test reports, submitted the "Technical Review report on the certificate of analysis data submitted by Savorite Pharmaceuticals (Pvt) Ltd", dated 11-08-2023 (**26R-14**) (hereinafter referred to as the 'first Technical Review report'). The first Technical Review report concluded that testing done by the 45th Respondent were incomplete. The following is revealed through the said report:

- Only 19 of 201 submitted reports were issued by WHO-prequalified laboratories while others were issued by Indian accredited laboratories.[10] (It must be noted that of the 8 laboratories where tests were performed, only one was WHO prequalified, one laboratory did not have accreditation or WHO prequalification status.)[11]

[9] Paragraph 10 of the Objections of the 26th Respondent dated 19-05-2025
[10] Point No. 1 under Sub-topic No. 4 (i.e. Conclusions) in the Technical Review Report dated 11-08-2023 (**26R-14**)
[11] Point No. 3 under Sub-topic No. 2 (i.e. Observations on laboratories where tests had been performed) in the Technical Review Report dated 11-08-2023 (**26R-14**)

- Complete test reports were available for only 23 products out of 32 products.[12]

- Only 23 products complied with pharmacopeia standards.[13]

The five-member expert committee proceeded to make certain recommendations which are as follows:

- Recommended that testing be done in relation to the remaining 9 products for which reports were not complete.[14]

- Since, the pharmaceutical products were procured under a WOR, the relevant documents required under the WOR guidelines of the NMRA (**26R-1**) must be called for.[15]

- Additionally, the NMRA should conduct tests through the accredited laboratories/ WHO prequalified laboratories in respect of the consignments that have arrived in Sri Lanka, independent of the 45th Respondent.[16]

Thus, the five-member expert committee was unable to take a decision on the quality of the pharmaceuticals (required for the implementation of the Interim Orders of this Court) due to the failure of the 45th Respondent to produce the necessary reports.

The 45th Respondent had subsequently tendered another set of test reports,[17] upon which the above five-member expert committee submitted the "Technical Review report on the certificate of analysis data submitted by Savorite Pharmaceuticals (Pvt)

[12] Point No. 2 under Sub-topic No. 4 (i.e. Conclusions) in the Technical Review Report dated 11-08-2023 (**26R-14**)
[13] Point No. 3 under Sub-topic No. 4 (i.e. Conclusions) in the Technical Review Report dated 11-08-2023 (**26R-14**)
[14] Point No. 1a under Sub-topic No. 5 (i.e. Recommendations) in the Technical Review Report dated 11-08-2023 (**26R-14**)
[15] Point No. 1b, 1c and 1d under Sub-topic No. 5 (i.e. Recommendations) in the Technical Review Report dated 11-08-2023 (**26R-14**)
[16] Point No. 2 under Sub-topic No. 5 (i.e. Recommendations) in the Technical Review Report dated 11-08-2023 (**26R-14**)
[17] Paragraph 5 of the Motion of the 45th Respondent dated 28-04-2025.

Ltd", dated 14-10-2023 (**26R-17**) (hereinafter referred to as the 'second Technical Review report). Upon perusal of this second Technical Review report, it reveals that *"Only 25 products had test reports done by a WHO prequalified laboratory or a laboratory with valid ISO 17025 Accreditation..."*. [18] The committee notes that once again, out of the 9 laboratories where tests were performed only one was WHO prequalified and another one of the laboratories does not have valid accreditation,[19] similar to the previous reports tendered by the 45th Respondent. The committee also reiterated the necessity to evaluate the documents required under the WOR guidelines of NMRA to determine the quality of the products, since these pharmaceutical consignments were approved under a WOR.[20] Further, the committee once again recommends that the NMRA, independent of the 45th Respondent, should conduct quality checks of the consignments that have arrived in Sri Lanka using randomly selected samples.[21]

These recommendations indicate that the NMRA was not satisfied as to the quality of the samples, particularly as the required reports were not submitted by the 45th Respondent as per the requirements of the NMRA, on both occasions.

Thus, as admitted by the 45th Respondent,[22] the 26th Respondent by its letter dated 24-01-2024 (**26R-19**) and email dated 12-02-2024 (**26R-20**), had directed further reports to be submitted by the 45th Respondent. The 45th Respondent has not tendered any further reports in accordance with the said direction.[23] The 45th Respondent alleges that in response to the above correspondence (**26R-19**/**26R-20**), it had apparently queried from the NMRA as to why further tests where necessary, but since it didn't receive a clarification as to this, the 45th Respondent did

[18] Point No. 4 under Sub-topic No. 4 (i.e. Conclusions) in the Technical Review Report dated 14-10-2023 (**26R-17**)
[19] Point No. 3 under Sub-topic No. 2 (i.e. Observations on laboratories where tests had been performed) in the Technical Review Report dated 14-10-2023 (**26R-17**)
[20] Point No. 1 under Sub-topic No. 5 (i.e. Recommendations) in the Technical Review Report dated 14-10-2023 (**26R-17**)
[21] Point No. 2 under Sub-topic No. 5 (i.e. Recommendations) in the Technical Review Report dated 14-10-2023 (**26R-17**)
[22] Paragraph 14 of the Motion of the 45th Respondent dated 28-04-2025
[23] ibid

not submit any further reports.[24] However, the 45th Respondent has not tendered any documentation in proof of making such query. The 26th Respondent too denies any query being put to it by the 45th Respondent,[25] and further avers that the 45th Respondent deliberately avoided testing its medicine at WHO-prequalified laboratories, despite assurance by the 45th Respondent that the tests were conducted by WHO-prequalified laboratories.[26] It was this conscious bypassing of the said requirement by the 45th Respondent, that necessitated further testing.[27]

In a further attempt to justify its failure to tender further reports, the 45th Respondent argues that it had conducted its previous tests by utilizing all the retained samples intended to be used for testing and had no access to the consignments which were in the custody of the 43rd Respondent (Sri Lanka Customs) in order to conduct further tests.[28] In response, the 26th Respondent states that there was no necessity to test the consignment in order to issue the reports requested by the expert committee as the required reports are standard documentation that should be maintained by the manufacturer to demonstrate the quality of the pharmaceuticals and thereby must be readily available in the custody of the 45th Respondent at any given time.[29]

As per the 26th Respondent, it was due to the above failures of the 45th Respondent to tender the necessary documentation, that the 26th Respondent was not in a position to express any view regarding the safety, efficacy and quality of the pharmaceutical consignments that have arrived in Sri Lanka which are the subject matter of the Interim Order of this Court.

It was in that backdrop that this Court heard the submissions of the learned Counsel for the 45th Respondent in support of the Motion of the 45th Respondent dated 28-04-2025.

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[24] Paragraphs 15 and 16 of the Motion of the 45th Respondent dated 28-04-2025
[25] Paragraph 29 of the Objections of the 26th Respondent dated 19-05-2025
[26] Paragraph 29(c) and (h) of the Objections of the 26th Respondent dated 19-05-2025. Assurance given by email correspondence dated 08-05-2023 (**26R-12**)
[27] Paragraph 29(g) of the Objections of the 26th Respondent dated 19-05-2025
[28] Paragraph 17 of the Motion of the 45th Respondent dated 28-04-2025
[29] Paragraph 20 of the Objections of the 26th Respondent dated 19-05-2025

The Order dated 06-08-2025 on the said Motion reads as follows:

In the motion dated 28/04/2025, the 45th Respondent seeks an order from this Court to get the consignments of Medicine pertaining to this case which have already arrived in the Country, released.

The Interim Order made by this Court on 06/04/2023 relevant to the release of the two consignments that had already reached the Country is as follows;

> *"Release for use, the two consignments that have already reached Sri Lanka only after the conduct of necessary tests and NMRA expresses satisfaction regarding the safety, efficacy and quality of the imported pharmaceuticals."*

Under the NMRA Act, it is necessary for a Medicine to be registered before importation. However, waiver of such registration can be allowed under certain circumstances i.e.; if the NMRA is satisfied, under certain circumstances, such permission could be granted for the importation of such product.

The effect of the Order made by this Court is also giving authority/discretion for the NMRA to release the goods after satisfying itself regarding the safety, efficacy and quality of the relevant imported pharmaceuticals. It is for that purpose that the NMRA has called for number of documents from the 45th Respondent. 45th Respondent has so far not tendered all the documents so requested.

In these circumstances, and also in view of the fact that the expertise to make this decision lies with the NMRA (rather than this Court), Court is not inclined to make an Order as requested by the Motion dated 28/04/2025.

Taking into considerations the submissions of Counsel, this Court was of the opinion that the 26th Respondent NMRA was the authority with the expertise to determine whether the pharmaceutical consignments *inter alia* were of sufficient quality. Thus, it had the discretion to release the goods after satisfying itself as to *"the safety, efficacy and quality of the relevant imported pharmaceuticals"* and satisfying itself as to the fulfillment of any other requirements under the WOR guidelines. Thus, this Court was not inclined to grant the requests of the 45th Respondent.

Another incident revealed in the course of the above submission was that, subsequent to the first Technical Review Report (**26R-14**), the Board of the 26th Respondent at its meeting held on 18-08-2023, decided to conduct testing independently at its own laboratories (NMQAL), as per its minutes (**26R-15**), in order to expeditiously facilitate the Interim Orders of this Court. However, it should be noted that despite such decision taken, the 27th Respondent (the then Chairman of the National Medicines Regulatory Authority, Prof. S.D. Jayaratne), proceeded to send a letter to the Attorney General (**26R-16**) to release the consignments of the 23 medical products, the reports of which comply with the requirements of the NMRA and release the other consignments of the other 9 medical products upon the reports for those medical products comply with the NMRA requirements. The 26th Respondent alleges that this action of the 27th Respondent was misleading and illegal.[30] This allegation seems to have merit, since no such recommendation was made by the five-member expert committee by its Technical Review Report (**26R-14**). In fact, to the contrary, the expert committee *inter alia*, recommended further testing to be done and such testing to be done independent of the 45th Respondent using samples from the consignments, which would not be possible if the consignments were released as per the letter. This raises serious concerns as to the motives of/ reasons for the 27th Respondent to have taken it upon himself to send the said letter (**26R-16**). However, the Hon. Attorney General had not responded to the said letter as per the 26th Respondent.[31]

[30] Paragraph 18 of the Objections of the 26th Respondent dated 19-05-2025
[31] Paragraph 22 of the Objections of the 26th Respondent dated 19-05-2025

In these circumstances I hold that the Petitioners are entitled to succeed as those Respondents have infringed their fundamental right guaranteed by Article 12(1) of the Constitution for the equal protection of the law.

I grant the following relief:

1. A declaration that the former Minister of Health (Keheliya Rambukwella, 22nd Respondent) has infringed the fundamental right of the Petitioners to equal protection of law, as guaranteed in terms of Article 12(1) of the Constitution;

2. A declaration that the former Secretary to the Ministry of Health (S. J. S. Chandraguptha, the 25th Respondent) has infringed the fundamental right of the Petitioners to equal protection of law, as guaranteed in terms of Article 12(1) of the Constitution;

3. A declaration that the former Chairman of the National Medicines Regulatory Authority (Prof. Shanthilal Dewapriya Jayaratne, 27th Respondent) has infringed the fundamental right of the Petitioners to equal protection of law, as guaranteed in terms of Article 12(1) of the Constitution;

4. A declaration that the former Chief Executive Officer of the National Medicines Regulatory Authority (Dr. Vijith Gunasekara, 28th Respondent) has infringed the fundamental right of the Petitioners to equal protection of law, as guaranteed in terms of Article 12(1) of the Constitution;

5. A declaration that the former Director of Medical supplies Division (Arambegedera Thusitha Sudarshana, 37th Respondent) has infringed the fundamental right of the Petitioners to equal protection of law, as guaranteed in terms of Article 12(1) of the Constitution;

6. A declaration that the decision and/or determination to procure the relevant medical supplies from the 45th Respondent through Direct Contracting and/or

on an unsolicited bid, without a competitive procurement process, is wrongful, unlawful and hence null and void, and of no force or avail in law;

7. A declaration that the decision and/or determination, to grant a Waiver of Registration for the said 38 items of medical supplies from the 45th Respondent, is wrongful, arbitrary and capricious, illegal, unlawful, and hence null and void, and of no force or avail in law;

8. A declaration that the decision and/or determination, to place the relevant orders for the procurement of the relevant medical supplies from the 45th Respondent through Direct Contracting and/or on an unsolicited bid, without a competitive procurement process, is wrongful, arbitrary and hence no force or avail in law;

9. A declaration that the importation into Sri Lanka, the said 38 medical supplies from the 45th Respondent, is wrongful, arbitrary and capricious, illegal, unlawful, and hence null and void, and of no force or avail in law;

10. A declaration that no Respondent is entitled to make any payment to the 45th Respondent for the said 38 medical supplies from the 45th Respondent.

I have taken into consideration, the arbitrary nature in which the afore-said Respondents have acted in this instance to deprive the State and the general public of the funds available for the well-being of the citizens of this country. The Respondents have done this when they are expected to discharge the powers conferred on them by the statutes only for the betterment of people. If these Respondents do not understand the importance of their duties and obligations to the ordinary citizenry of this country, this Court has an obligation to remind them of the same.

In the seminal decision of *Sugathapala Mendis and Another v Chandrika Kumaratunga and others (The Water's Edge case)*,[32] which similar to the instant matter was filed in the interest of the Public, this Court was tasked with determining whether the actions of the Respondents, who were members of the executive and officials of state entities, were in violation of the guidelines laid down to regulate the impugned acts, including the alienation of state property and thus arbitrary and violative of Article 12 of the Constitution. This Court was of the opinion that 'The irregularities of the [impugned] actions cannot be dismissed...' and that 'Such actions can be seen to be, at best, revealing an incompetence and an unacceptable abdication of responsibility of the most powerful state official of Sri Lanka, and at worst, a pattern of behaviour evidencing an agenda at odds with ensuring optimal use of public lands...'.[33] These findings finally culminated in the conclusion that the impugned project which '*was allowed to proceed to finish on land taken from the citizenry is testament to the breakdown of the procedural process that was meant to protect the Public Trust and the repugnant actions of several principals actors in this case, causing government losses running into hundreds of millions of Rupees.'* [34] In this backdrop Justice Tilakawardane proceeded to order the 1st Respondent of that case (head of the executive) to pay compensation in the form of a 'token payment of the real loss to the state of several hundreds of millions' adding that such an order for compensation would *'serve to "remind" present and future state actors and agencies (i) of their paramount duty to further the Public Trust and (ii) that their actions are subject to the Rule of Law'.*[35]

In the recent decision of *Center for Environmental Justice (Guarantee) Limited and Others v Marine Environment Protection Authority and Others (MV X-Press Pearl Marine Environmental Pollution Case)*,[36] a divisional bench of this Court was inclined to *inter alia* order the entity responsible for the extensive pollution, to make an 'initial payment of USD 1 billion'.[37] This was notwithstanding the several previous payments

[32] [2008] 2 SLR 339
[33] ibid at page 379-380
[34] ibid at page 387
[35] ibid at page 390
[36] SC Minutes 24-07-2025
[37] Vide page 354 at Paragraph 891(i)

of compensation made by the said entity.[38] Such substantial payments of compensation were ordered considering the environmental impact which the relevant incident had.

The landmark decision in *Ravindra Gunawardena Kariyawasam v Central Environment Authority and Others (Chunnakam case)*, [39] too dealt with a matter of public interest, wherein the townspeople who were aggrieved by the actions/inactions of the Respondents in constructing a thermal power station in Chunnakam, were awarded compensation amounting to 20 million rupees 'to offset at least a part of the substantial loss, harm and damaged caused to the residents of the Chunnakam area...'.[40]

Similar to the Waters' Edge case above,[41] the nature of the irregularities in the instant matter, at best, reveal a failure primarily on the part of the 22nd, 25th, 27th, 28th and 37th Respondents as state and executive authorities, to abide by the stipulated guidelines for procurements and at worst, a concerted effort to defraud the state and the public of the resources allocated for their benefit.

Echoing the sentiments of Her Ladyship Justice Shiranee Tilakawardane (above), to serve as a reminder to state actors both present and future of their paramount duty to serve the interest of the public, I direct the following Respondents to pay the following sums of money as costs to the state:

(I) The former Minister of Health Keheliya Rambukwella (22nd Respondent) to pay Rupees Seventy-Five Million (Rs. 75,000,000/=) to the state;

(II) The former Secretary to the Ministry of Health S. J. S. Chandraguptha) (25th Respondent) to pay Rupees Fifty Million (Rs. 50,000,000/=) to the state;

[38] Vide page 190 at Paragraph 484
[39] SC/FR/141/215, SC Minutes 04-04-2019
[40] ibid at page 64
[41] At page 71

(III) The former Chairman of the National Medicines Regulatory Authority (Prof. S. D. Jayaratne) (27th Respondent) to pay Rupees Fifty Million (Rs. 50,000,000/=) to the state;

(IV) The former Chief Executive Officer of the National Medicines Regulatory Authority (Dr. Vijith Gunasekara) (28th Respondent) to pay Rupees Fifty Million (Rs. 50,000,000/=) to the state;

(V) The former Director of Medical supplies Division (Dr. Arambegedera Thusitha Sudharshana) (37th Respondent) to pay Rupees Fifty Million (Rs. 50,000,000/=) to the state;

I direct the 38A Respondent and the Commission to Investigate Allegations of Bribery and Corruption (CIABOC) to consider taking steps in terms of law, against any one or more of the Respondents, in respect of any violation of law coming within the purview of CIABOC with regard to the decision and/or determination to procure medical and/or pharmaceutical supplies from the 45th Respondents, or any other matter connected or incidental thereto.

CHIEF JUSTICE

KUMUDINI WICKREMASINGHE, J

I agree.

JUDGE OF THE SUPREME COURT

JANAK DE SILVA, J

I agree.

JUDGE OF THE SUPREME COURT