

IN THE SUPREME COURT OF
THE DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA

*In the matter of an application under and in
terms of Articles 17 and 126 of the Constitution
of the Democratic Socialist Republic of Sri Lanka.*

1. Transparency International Sri Lanka
No.366, Nawala Road
Nawala, Rajagiriya
2. Pulasthi R. K. Hewamanna
No.366, Nawala Road
Nawala, Rajagiriya

PETITIONERS

Supreme Court [Fundamental Rights]
Application No. 99 /2024

Vs.

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

Also:

Minister of Defence
Ministry of Defence
Defence Headquarters Complex
Sri Jayawardenapura, Kotte

2. 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
3. Minister of Ports, Shipping and Aviation
Ministry of Ports, Shipping and Aviation
No.19, Chaithya Road
Colombo 1
4. Minister of Wildlife & Forest Resources
Conservation
Ministry of Wildlife & Forest Resources
Conservation
No.1090
Sri Jayawardhanapura Road, Rajagiriya

5. Minister of Fisheries
Ministry of Fisheries
New Secretariat
Maligawatte Road
Colombo 10
6. Minister of Education
Ministry of Education
"Isurupaya"
Battaramulla
7. Minister of Transport and Highways
Ministry of Transport and Highways
9th Floor, "Maganeguma Mahamedura"
Denzil Kobbekaduwa Mawatha
Koswatte
Battaramulla
8. Minister of Agriculture
Ministry of Agriculture
No.80/5, "Govijana Mandiraya"
Rajamalwatte Road
Battaramulla
9. Minister of Justice, Prison Affairs and
Constitutional Reforms
Ministry of Justice
No.19, Sri Sangaraja Mawatha
Colombo 10
10. Minister of Tourism and Lands
Ministry of Tourism and Lands
No. 2, Asset Arcade Building
51/2/1, York Street, Colombo 1
11. Minister of Plantation Industries
Ministry of Plantation Industries
11th Floor, Stage II
"Sethsiripaya"
Battaramulla
12. Minister of Urban Development and
Housing
Ministry of Urban Development and
Housing
17th Floor "Suhurupaya"
Sri Subathipura Road
Battaramulla
13. Minister of Foreign Affairs
Ministry of Foreign Affairs
Republic Building
Sir Baron Jayathilake Mawatha
Colombo 1

14. Minister of Buddhasasana, Religious and Cultural Affairs
Ministry of Buddhasasana, Religious and Cultural Affairs
No.135, Srimath Anagarika Dharmapala Mawatha
Colombo 7
15. Minister of Power and Energy
Ministry of Power and Energy
No.437, Galle Road
Colombo 3
16. Minister of Environment
Ministry of Environment
No/416/C/1, "Sobadham Piyasa"
Robert Gunawardena Mawatha
Battaramulla
17. Minister of Irrigation
Ministry of Irrigation
No.500, 10th Floor
T. B. Jayah Mawatha
Colombo 10
18. Minister of Labour and Foreign Employment
Ministry of Labour and Foreign Employment
6th Floor, "Mehewara Piyasa"
Narahenpita
Colombo 5
19. Minister of Public Security
Ministry of Public Security
14th Floor, "Suhurupaya"
Battaramulla
20. 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
21. 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. Minister of Health
Ministry of Health
"Suwasiripaya"
No.385, Rev. Beddegama Wimalawansa
Thero Mawatha
Colombo 10
 23. Secretary to the Cabinet of Ministers
Office of the Cabinet of Ministers
Republic Building
Sir Baron Jayathilake Mawatha
Colombo 1
 24. Secretary to the Treasury
Ministry of Finance
The Secretariat
Colombo 1
 25. 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. Chairman
National Medicines Regulatory Authority
 28. Chief Executive Officer
National Medicines Regulatory Authority
 29. Member
 30. Member
 31. Member
 32. Member
 33. Member
 34. Member
 35. Member
- All of:
National Medicines Regulatory Authority
No.120, Norris Canal Road
Colombo 10

36. Director General of Health Services
37. Director
Medical Supply Division
(Department of Health Services)
- Both of:*
No. 357
Beddegama Wimalawansa Mawatha
Colombo 10
38. State Pharmaceutical Corporation of Sri Lanka
16th Floor
"Mehewara Piyasa"
Kirula Road, Colombo 5
39. Director General
Commission to Investigate Allegations of
Bribery and Corruption
40. Chairperson
41. Member
42. Member
- All of:*
Commission to Investigate Allegations of
Bribery and Corruption
No.36, Malalasekara Mawatha
Colombo 7
43. Auditor General
306, 72 Polduwa Road
Battaramulla
44. Director General of Customs
Sri Lanka Customs
No.40, Main Street
Colombo 12
45. Inspector General of Police
Police Headquarters
Colombo 12
46. Keheliya Rambukwella
'M', Sarana Road
Colombo 7
- Currently under remand custody at:*
Welikada Remand Prison
Dr. Danister de Silva Mawatha
Colombo 10

47. S. J. S. Chandraguptha
Former Secretary
Ministry of Health

Currently under remand custody at:
Welikada Remand Prison
Dr. Danister de Silva Mawatha
Colombo 10

48. Dr. Saman Rathnayake
Former Additional Secretary
Ministry of Health

Currently under remand custody at:
Welikada Remand Prison
Dr. Danister de Silva Mawatha
Colombo 10

49. Prof. S. D. Jayaratne
No.1073/F/1, Kumaragewatta Road
Thalawathugoda, Battaramulla

50. Dr. Vijith Gunasekara
No.79/1, Nagahawatta Road
Maharagama

51. Dr. Kapila Wickramanayake
Former Director
Medical Supplies Division
Ministry of Health

Currently under remand custody at:
Welikada Remand Prison
Dr. Danister de Silva Mawatha
Colombo 10

52. Shanthi Solomon
Former Assistant Director
Medical Supplies Division
Ministry of Health

Currently under remand custody at:
Welikada Remand Prison
Dr. Danister de Silva Mawatha
Colombo 10

53. Niran Dhananjaya
Former Accountant Supplies
Medical Supplies Division
Ministry of Health

Currently under remand custody at:
Welikada Remand Prison
Dr. Danister de Silva Mawatha
Colombo 10

54. Sujith Kumara
Former Pharmacist
Medical Supplies Division
Ministry of Health
- Currently under remand custody at:*
Welikada Remand Prison
Dr. Danister de Silva Mawatha
Colombo 10
55. Isolez Biotech Pharma AG (Pvt) Ltd.
No.251A, Sarana Mawatha
Baseline Road
Seeduwa
56. Sudath Janaka Fernando
Director
No.251A, Sarana Mawatha
Baseline Road
Seeduwa
- Currently under remand custody at:*
Welikada Remand Prison
Dr. Danister de Silva Mawatha
Colombo 10
57. Livealth BioPharma (Pvt) Ltd
Unit No.77
Ratnajyot Industrial Premises
Irla Gaothan
Vile Parle (West)
Mumbai
58. Yaden International (Pvt) Ltd
No.67, Norris Canal Road
Colombo 10
59. Nandani Medical Laboratories (Pvt) Ltd
No.221/5, Kanadia Main Road
Bicholi Hapsi Road, Indor
Madya Pradesh, 452001
60. Divine Laboratories (Pvt) Ltd
Mujmahuda, Vadodara, Gujrat
61. Gulfic Biosciences Limited
No.37, 1st Floor, Kamala Bhavan II
Swami Nityanand Road
Anderi (East), Mumbai
62. Novachem Lanka (Pvt) Ltd
No.78/2C, Shramadana Mawatha
Nugegoda

63. Slim Pharmaceuticals (Pvt) Ltd
No.98/10, Namal Mawatha
Kahantota Road, Malabe

64. Sri Lanka Medical Association
No.6, Wijerama Mawatha
Colombo 7

65. Commissioner General of Prisons
Department of Prisons
Prisons Headquarters
No.150, Baseline Road
Colombo 9

66. Honourable Attorney General
Attorney General's Department
Colombo 12

RESPONDENTS

On this 16th day of April 2024

TO HIS LORDSHIP THE CHIEF JUSTICE AND OTHER HONOURABLE JUDGES OF THE
SUPREME COURT OF THE DEMOCRATIC SOCIALIST REPUBLIC OF SRI LANKA

The PETITION of the Petitioners above-named, appearing by Ms. Thosainge Bindiya Krishani Perera Senarath, their Registered Attorney-at-Law states as follows:

SCOPE OF THE APPLICATION

The instant application impugns the wrongful procedure/processes followed by one or more Respondents to procure medical supplies from private entities, and the avoidance and/or failure and/or omission and/or disregard and/or neglect by one or more of the Respondents to comply with the law and/or guidelines and/or regulations and/or mandatory procedures applicable to the procurement and importation of medical supplies from pharmaceutical suppliers in the private sector, requiring review of the said acts and/or omissions of the Respondents by Your Lordships' Court.

The Petitioners *inter alia* allege the failure of one or more Respondents to uphold the fundamental rights of the Petitioners, as well as of the General Public, as enshrined in Article 12(1) and 14A of the Constitution, as morefully enumerated hereinafter.

THE PETITIONERS

1. The 1st Petitioner is a body incorporated under and in terms of the Companies Act, No.7 of 2007, is a juristic person with the capacity to sue and be sued, and is represented by a membership of whom more than three-fourths are citizens of Sri Lanka.
2. The primary objects of the 1st Petitioner are, *inter alia* to encourage the growth of democratic concepts, practices and governance in Sri Lanka, to promote accountability, the eradication of corruption in public institutions, departments, and other areas of both government and private sector entities, to take steps to promote and bring about transparency and integrity in governance in all spheres of life in Sri Lanka.
3. The 2nd Petitioner is an Attorney-at-Law, and the Chairman of the 1st Petitioner.
4. In terms of Article 3 of the Constitution, sovereignty is vested in the People of the Republic of Sri Lanka, and sovereignty includes the powers of government, fundamental rights and franchise.
5. The Petitioners have filed the instant application in the PUBLIC INTEREST, and also in the interest of the 1st Petitioner's members, *inter alia* in terms of Article 28 of the Constitution, to uphold and defend the Constitution and the law, to further the national interest, to preserve and protect public property, to combat misuse and waste of public property, and to respect the rights and freedoms of others.
6. The Petitioners state they have a clear and direct interest to institute this application, being concerned in the well-being and health of the general public of Sri Lanka, and the potentially disastrous implications on the health of the general public arising from the acts and/or omissions of one or more Respondents, as morefully stated hereinafter.

Copies of the Certificate of Incorporation of the 1st Petitioner and its Articles of Association, compendiously marked P1 are annexed hereto and pleaded as part and parcel hereof.

THE RESPONDENTS

7. The 1st Respondent is the Minister of Finance, Economic Stabilization and National Policies, and the head of the Cabinet of Ministers. He is also the Minister of Defence, Minister of Women, Child Affairs and Social Empowerment, Minister of Technology and Minister of Investment Promotions, in terms of the Constitution.

Notwithstanding the fact that the incumbent 1st Respondent holds the office of the President of the Republic as well, it is specifically stated that he has not been made a party Respondent to this application in that capacity, but only in his capacity as a Member of the Cabinet of Ministers.

8. The 2nd Respondent is the Prime Minister of Sri Lanka, and the Minister of Public Administration, Home Affairs, Provincial Councils and Local Government.
9. The 3rd to 21st Respondents form the membership of the Cabinet of Ministers of Sri Lanka.
10. The 22nd Respondent is the Minister of Health, who is *inter alia* responsible for the formulation, implementation, monitoring and evaluation of policies, programmes and projects relating to the Departments, Corporations and Institutions relating to the subject of health, based on the national policies implemented by the government.
11. The 23rd, 24th and 25th Respondents are respectively the Secretary to the Cabinet of Ministers, Secretary to the Treasury and Secretary to the Ministry of Health [hereinafter 'MoH'].
12. The 26th Respondent is the National Medicines Regulatory Authority [hereinafter 'NMRA'] which is a body corporate that can sue and be sued in its name. The NMRA is vested with *inter alia* powers of authorising the registration and licensing of medicines, and regulating *inter alia* the registration and licensing of medicinal products, issuance of licenses for importation of medicines and granting approval for customs clearance of importation of medicines.
13. The 27th and 28th Respondents are respectively the Chairman and Chief Executive Officer (CEO) of the NMRA.
14. The 29th to 35th Respondents are the members of the NMRA.
15. The 36th Respondent is the Director General of Health Services of the Ministry of Health, and also an *ex officio* member of the NMRA.
16. The 37th Respondent is the Director the Medical Supplies Division [hereinafter 'MSD'] of the Ministry of Health.
17. The 38th Respondent is the State Pharmaceuticals Corporation of Sri Lanka (SPC), which is a corporation that has been established in terms of Section 2 of the Industrial Corporations Act No.49 of 1957, and can sue and be sued in its corporate name. The establishment of the SPC was published in Gazette No.14976/8 of 22/09/1971.
18. The 39th Respondent is the Director General of the Commission to Investigate Allegations of Bribery and Corruption.
19. The 40th Respondent is the Chairperson of the Commission to Investigate Allegations of Bribery and Corruption.
20. The 41st and 42nd Respondents are members of the Commission to Investigate Allegations of Bribery and Corruption.
21. The 39th to 42nd Respondents have been made party to this application for notice of the same. No relief has been sought against the said Respondents.

22. The 43rd Respondent is the Auditor General of Sri Lanka.
23. The 44th Respondent is the Director General of Customs of Sri Lanka.
24. The 45th Respondent is the Inspector General of Police of Sri Lanka.
25. The 46th Respondent is the former Minister of Health, a Member of Parliament, who is currently under remand custody for his involvement in *inter alia* failure to follow procurement procedures and/or comply with the law when procuring medical supplies, in particular human immunoglobulin medication, as morefully stated hereinafter.
26. The 47th Respondent is the former Secretary to the Ministry of Health, who reported directly to the former Minister of Health and is currently under arrest *vis-à-vis* the procurement of human immunoglobulin medication, as morefully stated hereinafter.
27. The 48th Respondent is the former Additional Secretary to the Ministry of Health, who reported directly to the former Minister of Health.
28. It is specifically stated that the 46th Respondent served as the Minister of Health during the procurement of the consignments impugned in this application, while the 47th and 48th Respondents served at the higher echelons of the MoH during all material times referred to in this application.
29. The 49th and 50th Respondents are respectively the former Chairman and CEO of the NMRA.
30. The 51st and 52nd Respondents are respectively the former Director and Assistant Director of the Medical Supplies Division [MSD] of the MoH who are currently under arrest *vis-à-vis* the procurement of human immunoglobulin medication, as morefully stated hereinafter.
31. The 49th and 50th Respondents served as Chairman and CEO, respectively, of the NMRA and while the 51st and 52nd Respondents served as Director and Assistant Director of the MSD of the MoH at all material times referred to in this application.
32. The 53rd and 54th Respondents are officers of the MSD and respectively served as Accountant- Supplies and Pharmacist. The 52nd to 54th Respondents are currently under arrest *vis-à-vis* the procurement of human immunoglobulin medication, as morefully stated hereinafter.
33. The Petitioners respectfully state that they are unaware of the personal addresses of the 47th, 48th, 51st, 52nd, 53rd and 54th Respondents and reserve the right to amend the caption to include their addresses, no sooner the same are ascertained. The Petitioners respectfully seek the permission of Your Lordships' Court to serve notice of this application on the said 47th, 48th, 51st, 52nd, 53rd and 54th Respondents through the Commissioner General of Prisons, in view of the said Respondents being in remand custody at the time of filing this application.

34. The 55th Respondent is a company incorporated in Sri Lanka, which has the capacity to sue and be sued. The 55th Respondent supplied the counterfeit human immunoglobulin medication, as morefully stated hereinafter.
35. The 56th Respondent is the proprietor and a Director of Isolez Biotech Pharma AG (Pvt) Ltd., and is currently under arrest *vis-à-vis* the procurement of human immunoglobulin medication, as morefully stated hereinafter.
36. The 57th Respondent is the alleged supplier of human immunoglobulin, a company registered in India, which denied involvement in the supply of the same to Sri Lanka. The 57th Respondent has been made party to this application for notice of the same. No relief has been sought against the said Respondent.
37. The 58th Respondent is a local importer of medical supplies which imported insulin soluble and insulin isophane, upon being granted a waiver of registration, on the basis of being a sole-bidder, as morefully stated hereinafter.
38. The 59th, 60th and 61st Respondents are companies incorporated in India, which have been issued waivers of registration for medical supplies manufactured by them which have caused adverse reactions in the citizens of Sri Lanka, as morefully stated hereinafter.
39. The 62nd and 63rd Respondents are companies registered in Sri Lanka and are local importers of medical supplies, which imported Propofol and Meropenem and Bupivacaine, respectively, as morefully stated hereinafter.
40. The 64th Respondent is the Sri Lanka Medical Association [SLMA] which has been incorporated under the Companies Act No.7 of 2007, and can sue and be sued in its corporate name.
- The 64th Respondent has been made a party to this application for notice of the same, and to assist Your Lordships' Court in the better adjudication of this matter, *inter alia* by providing material information, evidence and insights that may be at its disposal. No relief has been sought against the 64th Respondent.
41. The 65th Respondent is the Commissioner General of Prisons, who has been made party to the instant application only for the purpose of serving notices on the 47th, 48th, 51st, 52nd, 53rd and 54th Respondents, who are currently in remand custody. No relief has been sought against the 65th Respondent.
42. The 66th Respondent is the Honourable Attorney General who has been made party to the instant application in terms of the mandatory provisions of the law.
43. The impugned acts and/or omissions of the 1st to 38th Respondents, and/or the 46th to 54th Respondents and/or any one or more of them, constitute executive and/or administrative acts as contemplated by Article 17 and 126 of the Constitution of the Democratic Socialist Republic of Sri Lanka.

FACTUAL BACKGROUND TO THE INSTANT APPLICATION

44. The Petitioners have invoked the jurisdiction of Your Lordships' Court in view of the overwhelming PUBLIC INTEREST relating to the matters urged in this application.

45. At the outset, it is stated that, notwithstanding the intensely public nature of the matters placed in issue in this application, and their vital importance to the general public, as well as the paramountcy of transparency and openness in good governance, there is a paucity of officially available data and information thereof.

Consequently, the Petitioners have had to obtain the said data and information with extreme difficulty, in the face of a palpable culture of secrecy surrounding the same, and with the assistance of *bona fide* and civic-minded concerned citizens.

46. Consequently, the Petitioners are still endeavouring to uncover additional material and/or clearer specifics to buttress the findings of the Petitioners, which are urged in this application, and respectfully reserve the right to tender any further information and/or material to Your Lordships' Court, as and when the same are discovered by the Petitioners.

47. The Petitioners were made nascently and generally aware of the failure and/or utter disregard for the law and/or regulations and/or procedures applicable to procurement of medical supplies by one or more Respondents in on or around 22/01/2023, subsequent to which, the 1st Petitioner invoked the jurisdiction of Your Lordships' Court by way of an application bearing number SCFR/65/2023 on 15/02/2023, as more fully stated hereinafter.

48. The matters pleaded hereinafter are demonstrative of the abject disregard of one or more Respondents to comply with the law, regulations, guidelines and/or procedures for the procurement and importation of medical supplies from private pharmaceutical suppliers for the use of the general public in Sri Lanka.

49. It is stated that these Petitioners are becoming incrementally aware of the nature, magnitude and impact of the impugned acts and/or omissions of the Respondents, and that the said process is continuing, with startling new disclosures reaching the public domain periodically, *inter alia* during the course of related judicial proceedings.

It is further stated that the impugned acts and/or omissions of the Respondents form a connected sequence of events, which the Petitioners are continuing to become aware of.

In these circumstances, it is very specifically stated that there is a continuing violation of the fundamental rights of the Petitioners, and the general public.

50. The narrative described hereinafter evinces a trend in the healthcare sector to circumvent checks and balances that are placed by the law, regulations, guidelines and/or procedures for the procurement and importation of medical supplies, and in particular for the avoidance of serious detriment being caused to the healthcare of the general public.

51. The Petitioners are reliably informed that one or more Respondents have sought to circumvent the law, regulations, guidelines and/or procedures for the procurement and importation of medical supplies on an unsolicited basis [Direct Contracting], from manufacturers who have not been registered with the NMRA, entailing disastrous consequences for patients relying on medical supplies imported thus.
52. As described hereinafter, the former Minister of Health has misled and purportedly sought the approval of the Cabinet of Ministers to utilize the Indian Credit Line (ICL) and other unspecified means of funding to ostensibly maintain an uninterrupted supply of medicine, with the purported view to prevent acute shortages in medical supplies in government health institutions in Sri Lanka.
53. In doing so, the former Minister of Health, along with one or more Respondents to this application, have caused severe detriment to the general public, who have suffered complications, and in some instances succumbed to such complications, requiring immediate review of the waivers of registration issued by the NMRA, as morefully stated hereinafter.
54. The Petitioners have carefully followed the developments pertaining to the use of waivers of registration issued by the NMRA, to procure substandard and/or counterfeit medication over the course of several months, and have invoked the jurisdiction of Your Lordships' Court seeking the intervention of Your Lordships' Court to prevent the infringement and/or imminent infringement and/or continuing infringement of the fundamental rights of the Petitioners as well as the greater citizenry of Sri Lanka.

HISTORICAL ANTECEDENTS TO THIS APPLICATION

55. In September 2022, the former Minister of Health submitted a Cabinet Memorandum, on the purported basis of maintaining an uninterrupted supply of medicine in the country.
56. The said Cabinet Memorandum marks the commencement of a series of events which spiralled to culminate in seriously compromising the health and safety of the general public of Sri Lanka.
57. In view of the glaring malpractices and/or utter disregard for compliance with provisions of law pertaining to transparent procurement of medical supplies, the 1st Petitioner (and its Executive Director) invoked the jurisdiction of Your Lordships' Court by way of application bearing No. SCFR/65/2023, dated 15/02/2023.

The Petitioners respectfully reserve the right to tender the certified copy of the entire record pertaining to SCFR/65/2023, if Your Lordships' Court deems it necessary.

A copy of the Petition filed in SCFR/65/2023 marked P2 is annexed hereto and pleaded as part and parcel hereof.

58. The Petitioners in SCFR/65/2023 sought the intervention of Your Lordships' Court in respect of the importation of 38 pharmaceuticals, which were purportedly required on an urgent basis, the procurement of which demonstrated patent deviation from the applicable law, regulations and guidelines, raising serious doubts as to the transparency of the said procurement, and the impact on the health of the general public.
59. The former Minister of Health proposed the names of Savorite Pharmaceuticals (Pvt) Limited [hereinafter sometimes 'SPL'] and Kausikh Therapeutics (P) LTD [hereinafter sometimes 'KTL'] as identified suppliers [hereinafter collectively referred to as 'Private Entities'] from whom the procurement and importation of medical supplies would be made to Sri Lanka, in respect of certain medicines.
60. The names of the said Private Entities were proposed to the Cabinet of Ministers by the former Minister of Health for the relevant procurements, despite the said Private Entities not having the requisite registrations by the NMRA, and in the complete absence of a competitive procurement process.
61. The Petitioners were reliably informed that the former Minister of Health sought a Waiver of Registration [hereinafter sometimes 'WoR'] from the NMRA, presumably under and in terms of Section 109 of the National Medicines Regulatory Authority Act, No. 5 of 2015, to import medicinal supplies from one or both the said Private Entities, a procedure which is reserved to be invoked under specific and exceptional circumstances at the discretion of the NMRA, as more fully described hereinafter.

Very significantly, *ex facie*, the mandatory conditions precedent that would justify such a waiver, were singularly absent in the procurement of medicine from the aforesaid suppliers.

62. Upon being apprised of the glaring and utter disregard for the law, regulations, guidelines and/or procedures for the procurement and importation of medical supplies, and/or in the issuance of WoR, Your Lordships' Court, by way of Order dated 06/04/2023 held *inter alia* that:

Notwithstanding the urgency in procuring 38 pharmaceuticals referred to by the former Minister of Health, the decision to procure the same is affected by:

- a. serious doubts regarding the quality, safety and efficacy of the pharmaceuticals;
- b. non-satisfaction that the most favourable terms and conditions have been received pertaining to the impugned procurement;
- c. serious doubts regarding the lawfulness of the impugned procurement.

Your Lordships' Court was pleased to grant leave to proceed under Article 12(1) of the Constitution and suspended further importations of pharmaceuticals arising out of the impugned procurement pending a further order from Your Lordships' Court.

It was directed that material must be placed before Your Lordships' Court to satisfy Court as to the necessary quality requirements being satisfied and that the procurement is lawful.

The release of the consignments that had already reached Sri Lanka were ordered to be contingent on the conducting of necessary tests and upon the NMRA expressing its satisfaction that the imported pharmaceuticals met the required standards of safety, efficacy and quality.

A copy of the Order of Your Lordships' Court dated 06/04/2023 in SCFR/65/2023 marked P3 is annexed hereto and pleaded as part and parcel hereof.

63. It is very pertinent that the Respondents to the said application are yet to file their formal statement of objections contradicting the contentions raised by the Petitioners thereto. It is also material that the NMRA is yet to express its satisfaction regarding the safety, efficacy and quality of the consignment of pharmaceuticals impugned in that application.

64. The said application was fixed for argument on 22/03/2024.

65. Several newspaper articles also covered the developments on the importation of pharmaceuticals from the said Private Entities, prior to support of SCFR/65/2023 before Your Lordships' Court, while several newspaper articles covered *inter alia* the issuance of the aforesaid Order of Your Lordships' Court.

Copies of relevant newspaper articles compendiously marked P4 are annexed hereto and pleaded as part and parcel hereof.

66. Upon the 1st Petitioner filing an application under the Right to Information Act, on 10/02/2023, the 1st Petitioner has received information which verifies that:

- a. A Cabinet Memorandum was submitted for the maintenance of uninterrupted medical supplies;
- b. The same received approval from the Cabinet;
- c. The above-named Private Entities were selected as suppliers, despite procurement not being done through KTL;
- d. The former Minister of Health himself visited a prospective supplier i.e., KTL's factory.

A copy of the application filed under the Right to Information Act, dated 10/02/2023 along with the response thereto, dated 05/07/2023 and annexures to the same, compendiously marked P5 are annexed hereto and pleaded as part and parcel hereof.

MATTERS IMPUGNED IN THE INSTANT APPLICATION

67. The aforesaid circumstances form the background to the matters urged in this application. The Petitioners respectfully reiterate that the matters urged in this application are in consequence of the efforts made by the Petitioners, over a period of time, to discover more information relating to the issue of medical procurement by the public sector.
68. The Petitioners are now aware of several pharmaceuticals, for which WoRs have been sought, being released to the market for consumption of the general public, entailing serious and irremediable adverse effects on the general public which uses the said pharmaceuticals.
69. The matters morefully stated hereinafter are buttressed by the coverage of the same by civic-minded individuals who have meticulously followed the developments regarding the crisis faced by the medical sector and revealed their findings through digital media and newspapers.
70. The Petitioners have reliably learnt of the following matters through the efforts of such civic-minded individuals whose careful analysis of the crisis in the health sector has provided the impetus to the Petitioners to seek the intervention of Your Lordships' Court in the matters urged in this application.
71. Misuse of the WoRs issued by the NMRA has been covered in several investigative articles published in newspapers, which have not been contradicted, revealing the resistance of medical professionals to the procurement of stocks of medical supplies from unregistered pharmaceutical suppliers.

It has been revealed that bypassing the usual procurement processes has caused the country to incur substantial losses, in particular by importation of medical supplies from entities which quote higher prices than competitors.

The absence of compliance with the procurement procedures have enabled the importation of such medical suppliers *sans* any transparency, permitting interested parties to benefit from the same, at the expense of the public purse and serious detriment to public health.

*Copies of newspaper articles evincing the same, compendiously marked **P6** are annexed hereto and pleaded as part and parcel hereof.*

72. The misuse of WoRs to arbitrarily award tenders for the procurement of medical supplies from unregistered entities has caused a significant strain on the public purse, particularly by procurement being conducted with utter disregard for procurement through the lowest responsive bidder, as required by law.

This is morefully borne out by the example of importing insulin from a local supplier, Yaden International (Pvt) Ltd [Yaden], which was granted a WoR and from whom insulin

was procured. News reports claim that the cost of procuring insulin from this entity was far higher than the cost incurred if insulin was to be procured from a competitor. It is shocking that in such a context, Yaden was awarded the tender for 30,000 vials of insulin soluble and 12,500 vials of insulin isophane at \$4 per vial, when competitors offered a vial at a cost of \$1.55.

Notwithstanding the gross disparity in the cost of a vial of insulin offered by Yaden against its competitors, the Health Sector Emergency Procurement Committee (HSEPC) saw it fit to award the tender to Yaden.

The Petitioners are now in possession of the application for WoR tendered by Yaden and the request made to the NMRA by the State Pharmaceuticals Corporation (SPC) to consider the said request, which was presumably granted by the NMRA.

A copy of the newspaper article which refers to importation of insulin from Yaden, the application by Yaden for a WoR and the request made to the NMRA by the SPC, compendiously marked P7 is annexed hereto and pleaded as part and parcel hereof.

73. A series of newspaper articles, which have not been contradicted, have covered the defects of the medical supplies imported through the use of WoRs, resulting in complications in the health of the public, including deaths.

It has been reported that several batches of medication that were released into the market were recalled by the NMRA in view of adverse reactions suffered by patients using the same. An anaesthetic, branded Zupivac-H, procured from India under a WoR, was reported to have caused the deaths of two individuals.

Deaths of individuals were also caused by insertion of a cannula, as well as an antibiotic injection, namely Ceftiaxone, a common antibiotic used in the country.

Infections were reported among individuals who underwent eye surgeries, due to an eye-drop, namely Prednisolone Acetate Ophthalmic Suspension, sourced from India, which contained a bacteria which caused infections among users, leading to blindness.

The meningococcal vaccine administered to prevent Meningitis was also reported to have been administered through unregulated means, with doctors going so far as to state that the vaccine was imported in regular passenger baggage, without the guarantee of cold chain management.

It is shocking that numerous cases of quality failure have been reported from all parts of the island, evincing that the health sector of the country has been significantly compromised by the WoRs issued by the NMRA.

In fact, the Auditor General has decided to launch a special investigation into the importation of medical supplies, owing to the substandard medical supplies circulating in the market.

Copies of the relevant newspaper articles, compendiously marked P8 are annexed hereto and pleaded as part and parcel hereof.

74. The Petitioners have learnt that an anaesthetic named Propofol, imported under the brand name Anesthefol caused adverse reactions in patients, which in one case resulted in cardiac arrest. The Petitioners are now in possession of a report on adverse reactions to medicines, dated 06/07/2023 which refers to such an adverse reaction upon the use of Propofol. Propofol has reportedly been imported by the local company Novachem Lanka (Pvt) Ltd., from an Indian manufacturer named Nandani Medical Laboratories (Pvt) Ltd., on a WoR issued by the NMRA.

A copy of the report on adverse reaction to medicines, dated 06/07/2023 marked P9 is annexed hereto and pleaded as part and parcel hereof.

75. Additionally, yet another anaesthetic injection, Bupivacaine, imported under the brand name Zupivac-H, has also caused adverse reactions in patients resulting in at least two deaths. It is learnt that the consignment of Bupivacaine was sourced from the Indian manufacturer Divine Laboratories (Pvt) Ltd. which was imported to Sri Lanka by the local company Slim Pharmaceuticals (Pvt) Ltd., on a WoR issued by the NMRA.

76. It is very significant that the NMRA itself has admitted to quality failures of several pharmaceuticals imported under WoRs.

Copies of newspaper articles evincing the same, compendiously marked P10 are annexed hereto and pleaded as part and parcel hereof.

77. The use of WoRs has been justified on the purported basis of emergency medical supplies being required in view of depletion of stocks. However, this is a pretext for circumventing the procedural safeguards imposed by law, regulations and rules to ensure transparent procurement of medical supplies.

78. Revealing the seriousness of the situation, H.E. the President himself called for transparent distribution of medical supplies and the need to provide for real-time updates of medical stocks to prevent depletion of stocks to require emergency supply of such stocks by the use of WoRs.

A copy of a newspaper article demonstrating the same, marked P11 is annexed hereto and pleaded as part and parcel hereof.

PROCUREMENT OF HUMAN IMMUNOGLOBULIN

79. In this context, the Petitioners have reliably learnt that a medical supply, namely human immunoglobulin (Human-IG), which is manufactured by using immunoglobulin from the plasma of blood donors, and administered through an injection to the end-user, has been seriously compromised.

80. Human-IG is administered to patients whose immunity is already compromised. The medication is administered to enable such patients to improve their weakened immune system through the infusion of antibodies into their system through the use of Human-IG. The medication is also used to increase the blood count, i.e., platelets in the human system.
81. Thus, it is evident that it is for patients whose health is extremely fragile, and require life-saving medication, that the Human-IG vaccine is administered.
82. It is in respect of the medication supplied to such patients that WoRs have been issued by the NMRA, resulting in adverse effects being caused to patients who are administered the same.
83. Several news reports regarding the procurement of Human-IG, which have not been contradicted, reveal that:
- a. 22,500 vials of Human-IG were withdrawn due to adverse reactions, including anaphylaxis;
 - b. The purported manufacturer of the Human-IG, Livealth Biopharma (Pvt) Ltd., denied manufacturing the same;
 - c. The local company Isolez Biotech Pharma AG (Pvt) Ltd., sold the said Human-IG to the MSD of the MoH;
 - d. A tender for 22,500 vials of Human-IG was awarded to Isolez for a contract value of Rs.960 Million;
 - e. Isolez was also awarded a tender for Rituximab 500mg injections at a unit cost of Rs.50,000 each, despite Isolez being the second lowest responsive bidder;
 - f. Rs. 144.4 Million has been paid by the MSD of the MoH, as part of the payment for the consignment of Human-IG imported;
 - g. Two more pharmaceuticals had been ordered from Isolez, one being Rituximab, which is now being withheld from use;
 - h. The former Minister of Health purported to lodge a complaint regarding the procurement to the Criminal Investigation Division (CID);
 - i. The CEO of the NMRA denied signing the WoR for the stock of Human-IG, claiming that his signature was forged;
 - j. Isolez is not among the list of companies that imported blood plasma to Sri Lanka, which is a raw material used in manufacturing Human-IG;

k. The Medical Research Institute (MRI) revealed that the vials of Human-IG contained immunoglobulin 'below detectable levels';

l. Four officials from the MoH were arrested, along with the Director of Isolez;

Copies of the relevant newspaper articles, compendiously marked P12 are annexed hereto and pleaded as part and parcel hereof.

84. On or around 06/08/2023 a No-Confidence motion was placed on the order book of Parliament against the former Minister of Health with the signatures of 45 Members of Parliament, in view of tender procedures being deviated from, resulting in sub-standard medication entering the country.

A copy of newspaper article dated 06/08/2023 marked P13 is annexed hereto and pleaded as part and parcel hereof.

85. In the context of the aforesaid, the Petitioners are now aware of the following facts which are pleaded hereinafter, which demonstrate that WoRs have been misused by one or more Respondents to procure sub-standard Human-IG supplies from a private entity known as Isolez.

86. In the course of ascertaining information regarding the matters urged in this application, the Petitioners have also discovered that Isolez supplied an injection named Rituximab to the MoH by using WoRs. This injection was subsequently recalled from public consumption.

87. In or around September 2022, the MoH called for Expressions of Interest (EoI) for the supply of vital and essential pharmaceuticals to Sri Lanka.

The following documents are annexed hereto and pleaded as part and parcel hereof, *vis-à-vis* the EoI called for:

P14(a) Invitation for Expressions of Interest to import and supply vital and essential pharmaceuticals to Sri Lanka dated September 2022;

P14(b) Appointment of an EoI evaluation committee by letters dated 30/09/2022 and 26/10/2022 by the Ministry of Health;

P14(c) Decisions of the HSEPC on 13/10/2022 and 18/10/2022;

P14(d) Acceptance of the EoI submitted by Isolez by letter dated 10/11/2022;

88. Thus, it is evident that Isolez had been accepted as a potential supplier of medical supplies upon it having tendered an EoI to the MoH.

89. The Petitioners are now in possession of a quotation issued in or around October 2023, from Isolez for 7,500 packs of Human-IG. Additionally, Isolez had also tendered a quotation for the Rituximab Injection on 03/10/2023.

Copies of the quotations submitted by Isolez on 03/10/2023, compendiously marked P15 is annexed hereto and pleaded as part and parcel hereof.

90. On or around February 2023 the NMRA has issued WoRs permitting the importation of Human-IG and the Rituximab Injection.

Copies of the approval granted by the NMRA in February 2023 compendiously marked P16 are annexed hereto and pleaded as part and parcel hereof.

91. The Petitioners have reliably learnt that on or around 11/05/2023, an invoice has been generated by Isolez for 550 vials of the Rituximab injection.

A copy of the invoice dated 11/05/2023 marked P17 is annexed hereto and pleaded as part and parcel hereof.

92. The sub-standard quality of the Human-IG released to the market is evident from the report submitted upon an adverse reaction being recorded. Pursuant to the efforts of the Petitioners, they are now in possession of such a report issued upon an adverse reaction in a patient upon being administered Human-IG.

A copy of the said report of the adverse reaction dated 20/08/2023 and the drug sample testing complaint, dated 21/08/2023, compendiously marked P18 is annexed hereto and pleaded as part and parcel hereof.

93. On 08/08/2023, the NMRA was compelled to admit to the deficient quality of several medical supplies in the market and issued a media release in respect thereof.

A copy of the statement made by the NMRA to the media on 08/08/2023, marked P19 is annexed hereto and pleaded as part and parcel hereof.

94. On 03/10/2023, the NMRA once again issued a statement to the media referring to recalling of Human-IG released to the market as it failed to meet the requisite standard of quality.

A copy of the media release by the NMRA dated 03/10/2023 marked P20 is annexed hereto and pleaded as part and parcel hereof.

95. Upon the said statement being released to the media, the Indian Company, which allegedly supplied the consignment of Human-IG disputed supplying the same by its letter dated 07/10/2023.

A copy of letter dated 07/10/2023 issued by Livealth BioPharma (Pvt) Ltd marked P21 is annexed hereto and pleaded as part and parcel hereof.

96. The Petitioners are now in possession of letter dated 09/10/2023 authored by the Proprietor of Isolez, seeking withdrawal of the complaint made to the CID by the former Minister of Health against Isolez.

A copy of letter dated 09/10/2023 marked P22 is annexed hereto and pleaded as part and parcel hereof.

97. In view of the serious ramifications caused to the healthcare sector in view of issuing WoRs, the NMRA, by letter dated 10/10/2023 informed the MSD that as a belated safeguard, pre-shipment samples of batches of medicine for which WoR requests are sought must be granted prior to issuance of future WoRs.

A copy of letter dated 10/10/2023 marked P23 is annexed hereto and pleaded as part and parcel hereof.

98. On or around 12/10/2023, the NMRA sought the assistance of the World Health Organisation to test samples of Human-IG imported to Sri Lanka.

A copy of letter dated 12/10/2023 of the NMRA marked P24 is annexed hereto and pleaded as part and parcel hereof.

99. The Petitioners have discovered that several laboratory reports on the sample tests conducted on Human-IG samples revealed that the product supplied by Isolez failed to meet the expected standard of quality.

Copies of the reports on the tests conducted Human-IG by the MRI and NMRA compendiously marked P25 are annexed hereto and pleaded as part and parcel hereof.

100. On 24/10/2023, an application had been made by the NMRA to the Magistrate of Negombo, seeking a search warrant of the factory purportedly belonging to Isolez in case bearing number AR/9996/23 in the Magistrate's Court, Negombo.

The Petitioners respectfully seek the permission of Your Lordships' Court to tender a certified copy of the complete case record in case number AR/9996/23 in the Magistrate's Court, Negombo, if Your Lordships' Court deems the same to be necessary.

A copy of the application for a search warrant dated 24/10/2023 marked P26 is annexed hereto and pleaded as part and parcel hereof.

101. The report of the search conducted on the said factory revealed that no evidence was found of raw materials used in the manufacture of Human-IG, finished products of Human-IG, packing materials used for the same and/or any documents pertaining to the manufacture of Human-IG.

A copy of the report marked P27 is annexed hereto and pleaded as part and parcel hereof.

102. On 24/11/2023, the NMRA formally informed the learned Judge of the Magistrate's Court, Maligakanda, that the level of Human-IG in the samples tested were of a negligible value and that the test barely revealed a content of immunoglobulin in the sample.

A copy of the report of the NMRA dated 24/11/2023 marked P28 is annexed hereto and pleaded as part and parcel hereof.

103. It is specifically stated that the aforesaid narrative is demonstrative of the serious ramifications that entail on the health sector as well as the general public in the absence of registration credentials of the private suppliers, bringing to serious doubt the quality, safety and efficacy of the medical supplies to be procured through such entities.

104. The Petitioners state that the consequences arising from the grant of WoRs, and that the example of Isolez and the procurement of Human-IG as well as Rituximab injections through Isolez, form one of many instances which evince the complete breakdown in the health care system caused by the incidence of issuing WoRs.

105. The Petitioners are reliably informed that several medical supplies which were imported through suppliers for whom WoRs were given have reportedly failed to meet the requisite quality. The MSD itself has reported on the failure of samples of medicine which were tested having not met the required quality, requiring the withdrawal of the same from consumption by the public.

Copies of reports of tests conducted on several medical supplies, compendiously marked P29 are annexed hereto and pleaded as part and parcel hereof.

106. As such, the grant of WoRs, issued in complete disregard of the law, procedures and regulations in place for procuring medical supplies raises serious concerns in view of the use of the same in importation of medical supplies being gravely prejudicial to the health care sector as well as the general public.

107. Having followed the developments regarding sub-standard medical supplies being imported through the use of WoRs, the 1st Petitioner filed a complaint to the Human Rights Commission (HRC) on 08/11/2023, complaining of *inter alia* the use of WoRs for importing counterfeit Human-IG to be consumed by the public.

A copy of the complaint made to the HRC on 08/11/2023 marked P30 is annexed hereto and pleaded as part and parcel hereof.

108. In its complaint to the HRC, the 1st Petitioner also referred to the importation of a consignment of Meropenem injections which are used for infections caused by bacteria and meningitis. The 1st Petitioner referred to the fabrication of a situation of 'emergency' as a guise for importing sub-standard medication at a higher cost to the public, and referred to the importation of Meropenem through the use of WoRs, as an instance of the same. The Petitioners have learnt that Meropenem was sourced from an Indian Manufacturer named Gulfic Biosciences Limited and imported by the local company Slim Pharmaceuticals Ltd., at a higher cost than that offered by competitors.

109. The Petitioners are now in possession of a purchase order issued by the SPC and a request to the HSEPC from SPC to enhance the order for Meropenem by 100%.

A copy of the purchase order and the request to enhance the order for Meropenem by 100%, compendiously marked P31 are annexed hereto and pleaded as part and parcel hereof.

110. In response to a request for information made by the 1st Petitioner to the NMRA on 06/06/2023, regarding *inter alia* the existence of a special pathway for issuance of WoRs, the 1st Petitioner was in receipt of a response dated 22/11/2023 from the NMRA, which buttress other findings of the Petitioners regarding the use of a 'special pathway' under the guise of an 'emergency' for issuing WoRs to unregistered medical suppliers.

A copy of the request for information dated 06/06/2023 along with the response dated 22/11/2023 and annexures thereto, compendiously marked P32 are annexed hereto and pleaded as part and parcel hereof.

111. Subsequently, the 1st Petitioner made yet another request for information to the NMRA on 19/01/2024, regarding the cancellation of the special pathway for issuing WoRs and the reasons for the cancellation.

In response, the NMRA informed the 1st Petitioner of the acceptance by the NMRA of the failure of granting WoRs in the procurement of medical supplies by its decision to cancel the internal fast-track pathway for issuance of WoRs.

A copy of the request for information dated 19/02/2024 and the response thereto, dated 20/02/2024, compendiously marked P33 are annexed hereto and pleaded as part and parcel hereof.

112. The Petitioners are now aware that the Auditor General's Department launched a special audit into the procedures taken to avoid the shortage of pharmaceuticals in government hospitals. A report in respect of the same has been published in May 2022. The said report covers a range of factors including gross mismanagement, utter negligence, complete disregard for stock maintenance and the overall failure of the MoH, MSD and SPC to prevent the shortages, evincing that the purported 'emergency' was indeed a saga of gross mismanagement.

A copy of the said report of the Auditor General's Department marked P34 is annexed hereto and pleaded as part and parcel hereof.

113. Thus, it is evident that the alleged 'emergency' which prevailed in the healthcare sector was largely owing to mismanagement, giving rise to concerns as to whether such gross mismanagement is indicative of the machinations of individuals holding office in *inter alia* the MoH, who orchestrated the said emergency for ulterior motives.

114. The Petitioners are now aware that an audit query has been raised by the National Audit Office on the importation of Human-IG and Rituximab injections, without

compliance with procurement guidelines, through a purported emergency procurement, entailing the importation of sub-standard supplies.

The observations of the National Audit Office demonstrates that the importation of Human-IG and Rituximab injections from Isolez resulted in the dispensation of substandard and/or counterfeit medical supplies to the market for consumption by the general public.

Additionally, the Petitioners have learnt of an audit query being investigated by the National Audit Office into the failures of the internal controls of the NMRA. A report containing observations of the National Audit Office has been released on 12/12/2023 in this regard, which demonstrates the operational failures within the NMRA that led to and/or exacerbated the deficiency in stocks of medical supplies and/or led to mismanagement of the same.

Copies of the said reports of the National Audit Office, dated 12/12/2023 and 29/12/2023, marked P35(a) and P35(b) are annexed hereto and pleaded as part and parcel hereof.

115. The Petitioners therefore seek the intervention of Your Lordships' Court to review the issuance of WoRs and/or direct one or more Respondents to comply with the law, procedures and regulations which check the abuse of process and prevent prejudice being caused to the well-being of the citizenry.

CRIMINAL INVESTIGATIONS REGARDING THE PROCUREMENT OF HUMAN-IG

116. In the context of the aforesaid narrative, criminal investigations were commenced into the procurement of Human-IG from Isolez.

117. The Honourable Attorney General sought an order from the Magistrate of Maligakanda to order the CID to investigate the remittance of Rs.144.4 million paid to Isolez for counterfeit Human-IG.

A copy of a newspaper article dated 31/12/2023 marked P36 is annexed hereto and pleaded as part and parcel hereof.

118. Accordingly, to the best of the knowledge of the Petitioners, criminal action has been instituted against the 46th to 48th, 51st to 54th and 56th Respondents by the Magistrate of Maligakanda, in action bearing number B42158/23, for the importation of sub-standard Human-IG to be distributed to State hospitals, incurring a cost of Rs.130 million.

The Petitioners respectfully reserve the right to tender the complete case record in B42158/23, no sooner the same is obtained.

A copy of the case record in B42158/23, as at 08/12/2023, marked P37 is annexed hereto and pleaded as part and parcel hereof.

119. Subsequently, on or about 02/02/2024, the former Minister of Health was arrested for his complicity in the procurement of importing sub-standard Human-IG, and is in remand custody at the time of filing this application.

A copy of an article published on the Ada Derana website on 02/02/2024 marked P38 is annexed hereto and pleaded as part and parcel hereof.

120. The Petitioners state that further investigations are currently ongoing regarding the procurement of Human-IG and that the case before the Magistrate's Court, Maligakanda is pending, evincing a continuing violation of the fundamental rights of the Petitioners as well as the public of Sri Lanka.

THE WAIVER OF REGISTRATION BY THE NMRA

121. It is necessary to examine the role of the NMRA and the provision of WoR by the NMRA.

122. The NMRA, is *inter alia* vested with the powers of registering medical suppliers/supplies which supply pharmaceutical products to the SPC.

123. In the existence of 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, the NMRA has the discretion to grant a WoR.

124. In terms of the law, such powers of granting a WoR are at the discretion of the NMRA, and cannot be the subject of a direction given by the MoH to the NMRA.

125. Thus, the NMRA has complete control over the provision of WoR, and is not mandated by law to give effect to a direction by the Minister of Health.

126. The aforesaid narrative demonstrates that the MSD of the MoH, under the auspices of the Minister of Health, sought that the NMRA provide WoR in respect of unregistered private suppliers/supplies, namely Isolez.

127. The Petitioners are now in possession of several documents which demonstrate that since around September 2022, WoRs have been sought to procure medical supplies, at times, under the guise of the same being an emergency procurement to minimise delays under a 'Special Pathway'.

The following documents are annexed hereto and pleaded as part and parcel hereof, demonstrating the use of WoRs and/or the 'Special Pathway' to procure medical supplies.

P39(a) - Letter dated 02/09/2022 of the CEO of the NMRA seeking permission from the Secretary of the Ministry of Health to use WoRs to minimise delays

P39(b) A list of medical supplies for which WoRs were issued in 2022;

P39(c) Minute dated 06/09/2022 by the former Secretary, Ministry of Health regarding fast-track approval and issuance of WoRs;

P39(d) Letter dated 22/09/2022 issued by the Additional Secretary, Ministry of Health for emergency procurement of medical supplies through private suppliers, using the ICL;

P39(e) Letters dated 01/11/2022 and 17/11/2022 issued by the Medical Supplies Division regarding 'Special Procurement Action' to be taken;

P39(f) Minutes of the Board Meeting of the NMRA held on 29/12/2022;

P39(g) Letter dated 02/02/2023 issued by the NMRA granting permission to import medical supplies under a WoR

P39(h) Applications for WoRs submitted by Yaden International (Pvt) Ltd for Insulin Soluble (Human) 1000IU.

128. The former Minister of Health sought to circumvent registration of the said private entities entirely, and sought a WoR to exempt the identified suppliers/supplies from the requirement of registration, a prerequisite for procuring medical supplies to Sri Lanka.
129. It is amply evident that in the case of Isolez being granted WoRs, one or more Respondents have sought to sidestep the regular processes to be followed when procuring medical supplies from private entities, raising a serious doubt as to the *bona fides* of the said procurement.
130. The manifest product failures of medical supplies imported through Isolez wholly evinces that the use of WoRs has crippled the healthcare sector and seriously compromised the health of the public.
131. Admission by the NMRA of several medical supplies failing to meet the required standard buttresses the contentions of the Petitioners that the use of WoRs has significantly prejudiced the healthcare sector and public health.

NON-COMPLIANCE WITH PROCUREMENT GUIDELINES

132. The Procurement Guidelines (Goods and Works), 2006 read with the Guidelines for Procurement of Pharmaceuticals & Medical Devices, 2006 and the Guidelines for Procurement of Pharmaceuticals & Medical Devices, 2022 provide for the applicable processes for procurement of medical supplies from private entities.

Copies of the Procurement Guidelines (Goods and Works), 2006, the Guidelines for Procurement of Pharmaceuticals & Medical Devices, 2006 and the Guidelines for Procurement of Pharmaceuticals & Medical Devices, 2022 respectively marked P40(a), P40(b) and P40(c) are annexed hereto and pleaded as part and parcel hereof.

133. The objectives of the procurement process is to ensure providing fair, equal, and maximum opportunity for eligible interested parties to participate in procurement while ensuring transparency and consistency in the evaluation and selection procedure.
134. Such objectives are formulated and form part of the law relating to procurement to enable a level playing field between competitive bidders, who are presented with an equal opportunity to be awarded a tender.
135. The factual circumstances described hereinbefore is the antithesis of a fair, equal, transparent, and consistent procedure for awarding a tender to the lowest responsive bidder.
136. It is specifically stated that this is in stark contrast to the principles endorsed by Your Lordships' Court in instances where procurement processes have been challenged for their lack of adherence to the law, entailing a violation of equal protection of the law to those affected by such procurement processes.
137. In instances where the procurement processes have been observed in the breach, Your Lordships' Court has had no hesitation in declaring the acts of relevant public authorities to be violative of fundamental rights and struck down such processes for non-compliance with the law.

PROCUREMENT DURING AN EMERGENCY

138. It is specifically stated that deviation from the usual procedures for procurement is only justified in limited circumstances.
139. The existence of an emergency, requiring emergency procurement may permit such deviation. However, even in such instances, the law requires that the procuring entity complies with the specific law which provides for procurement during such emergency situations.
140. The Petitioners state that the circumstances relevant to this application do not disclose an emergency, rather, it is plausible that the alleged shortages in medical supplies were caused by mismanagement by the MoH leading to the absence of buffer stocks and orders not being made with sufficient lead time.
141. Emergency procurement is justified by the Procurement Guidelines [Goods & Works], 2006, in exceptional circumstances such as man-made or natural disasters or unforeseen social obligations and other similar situations which are determines and declared by the Government as being an emergency situation warranting emergency procurement.

142. Similarly, the Guidelines for Procurement of Pharmaceuticals & Medical Devices, 2006 provides for emergency procurement in situations where an emergency is declared due to man-made or natural disasters which is declared as an emergency by the Government or the sudden outbreak of disease declared by the Government or MoH.

143. The absence of such a state of emergency in the present circumstances is amply evident, raising serious doubts as to the *bona fides* of the MoH and one or more Respondents to call for procurement of medical supplies through a process which is totally unjustified and unnecessary.

144. Even if the MoH were to resort to emergency procurement, the ground realities evince the total absence of the same, giving rise to serious concerns for the reason for the MoH and the Minister of Health to seek to short circuit the existing procedures and processes for procurement of medical supplies.

ABUSE OF PROCESS BY THE FORMER MINISTER OF HEALTH

145. The aforesaid circumstances reveal that the former Minister of Health has fabricated a narrative of the existence of the need to supply essential medical supplies to maintain an uninterrupted supply of medical supplies to ensure the provision of life-saving medication to the general public, which would justify circumventing the requirement of registration of such suppliers with the NMRA.

146. It is manifest that the financial implications to the public purse, which are currently unascertainable and shrouded in secrecy, are disastrously high in a context where non-essential supplies are imported regardless of their classification.

147. The example of Human-IG is demonstrative of the manipulation of the system, by the use of WoRs, to enable unspecified persons to profit from the same, whilst compromising on public health and crippling the healthcare sector.

148. The aforesaid narrative is replete with justifications for the need to investigate into the abuse of due process by one or more Respondents, and considerations of whether the same were fuelled by ulterior motives and extraneous considerations which caused a benefit to the Minister of Health and/or the MoH and/or any one or more Respondents to this application.

VIOLATION OF THE PETITIONERS' FUNDAMENTAL RIGHTS

149. The totality of the aforesaid is amply demonstrative of the violation of the fundamental rights and/or continuing violation and/or imminent violation of the fundamental rights of the Petitioners to equality before the law and equal protection of the law.

150. The aforesaid narrative is amply demonstrative of the entirety of the general public of Sri Lanka being subjected to violation of their fundamental rights and/or continuing violation and/or imminent violation of their fundamental rights guaranteed under Article 12(1) of the Constitution by the acts of one or more Respondents.
151. The absence of adequate official information pertaining to *inter alia* WoRs, transparency in granting WoRs to identified parties, the procedure followed in granting such WoRs, are all matters which are shrouded in secrecy and unavailable on the usual channels on which such information is made available to the public.
152. This is demonstrative of the attempts by one or more Respondents to conduct the impugned procurement process of issuing WoRs to the exclusion of public scrutiny and is violative of the fundamental right of the Petitioners to information as guaranteed under Article 14A of the Constitution.
153. Such information must necessarily be available on public channels, instead of being shrouded in secrecy, requiring the general public to have to unearth such information with great difficulty, as encountered by the Petitioners to this application, whose investigation into the matters urged herein has been ongoing for several months.
154. The aforesaid narrative is demonstrative of one or more Respondents, who are repositories of the power held in trust for the public, failing to exercise such powers for the well-being of the general public.
155. It is evident that the acts of one or more Respondents have been in total disregard of the public trust entrusted to them towards providing the public with the ultimate benefits arising therefrom.
156. The total disregard and/or neglect by one or more Respondents to ensure that public health is safeguarded and consistently maintained is demonstrative of the abuse of power vested in the Respondents.
157. One or more Respondents acting with total disregard and/or neglect to comply with the prerequisite procurement procedures when sourcing pharmaceutical supplies amply demonstrates the total disregard for the law and the total disregard to ensure equal protection of the law to the general public, entailing the violation of the fundamental rights of the Petitioners and the greater public.
158. The acts of one or more Respondents reek of partiality to preferred suppliers to the detriment of the health, safety and well-being of the general public in Sri Lanka, and is indicative of the furtherance of ulterior motives of the Respondents involved.
159. One or more Respondents have acted in utter contempt for the fundamental duties vested in them to safeguard the health, safety and well-being of the general public in Sri Lanka, which is further exacerbated by the prevailing economic crisis in Sri Lanka.
160. Failure to take cognizance of the totality of the aforesaid constitutes treatment of the Petitioners which are violative of their fundamental rights and/or constitute a continuing

violation and/or imminent violation of the fundamental rights of the Petitioners and is hence illegal, unlawful, null and void, and of no force or avail in law, as will be morefully demonstrated during the course of the hearing of this application inasmuch as, *inter alia*

- a. it totally nullifies and negates the legitimate expectations of the Petitioners of being entitled to equality before the law, as enshrined in Article 12(1) of the Constitution;
- b. it is contrary to the spirit and the letter of existing laws, regulations, guidelines and circulars on procurement of medical supplies from private entities;
- c. the conduct of one or more Respondents is demonstrative of utter disregard for the health, safety and well-being of the general public;
- d. is a total abuse of the public trust vested in one or more Respondents;
- e. is a total abuse of public funds which must necessarily be subjected to optimum use;
- f. is contrary to the Directive Principles of State Policy; and,
- g. is unconstitutional.

161. The Petitioners specifically state that the 46th to 54th Respondents held office in the MoH and/or NMRA at all times material to this application, as pleaded hereinbefore and are liable for administrative and executive acts that have been complained of in this application.

162. The Petitioners state that grave and irreparable loss, harm, damage and prejudice would be caused to them and the instant application would be rendered nugatory and futile, unless Your Lordships' Court be pleased to grant and issue the interim relief prayed for through the application.

163. The Petitioners respectfully reserve the right to amend this Petition and/or add further parties and/or adduce further material in the event it becomes necessary and/or expedient to do so, depending on the disclosures emanating from the pleadings and/or submissions made on behalf of the Respondents.

164. The Petitioners have not previously invoked the Jurisdiction of Your Lordships' Court in respect of this matter, except as averred hereinbefore *vis-à-vis* application number SCFR/65/2023.

165. An Affidavit of the 2nd Petitioner is annexed hereto in support of this Petition.

WHEREFORE, the Petitioners pray that Your Lordships' Court be pleased to:

- a. grant the Petitioners leave to proceed to Your Lordships' Court in the first instance;
- b. call for the entire file and/or records held by any one or more Respondents, in particular:
 - i. the notes of the investigation into the procurement of Human-IG and/or any other medical/medicinal/pharmaceutical supplies from the 54th Respondent in the possession of the CID;
 - ii. documentation pertaining to the grant of WoRs by the NMRA since 2022, identifying the suppliers to whom WoRs were issued;
 - iii. records of medical supplies imported by the MSD from the suppliers/importers to whom WoRs were issued since 2022 by the NMRA;
 - iv. records of payments made to the 55th and/or 57th to 63rd Respondents and/or any other supplier/importer of medical/medicinal/pharmaceutical supplies who have been issued Waivers of Registration since 2022;
- c. declare that there is an infringement and/or a continuing infringement and/or imminent infringement of the fundamental rights of the Petitioners to equality before the law and equal protection of the law, as guaranteed under and in terms of Article 12(1) of the Constitution by the actions/inactions of the 1st to 38th Respondents and/or their servants and/or agents and/or successors and/or the 46th to 54th Respondents and/or any one more of them.
- d. declare that there is an infringement and/or a continuing infringement and/or imminent infringement of the fundamental rights of the Petitioners to the fundamental right to information, as guaranteed under and in terms of Article 14A of the Constitution by the actions/inactions of the 1st to 38th Respondents and/or their servants and/or agents and/or successors and/or the 46th to 54th Respondents;
- e. declare that the purported decision and/or determination of the 1st to 22nd and/or the 25th to 38th Respondents, and/or any one or more of them, and/or their servants and/or agents, to procure medical/medicinal/pharmaceutical supplies from the 55th and/or 57th to 63rd Respondents through Direct Contracting and/or on an Unsolicited Bid, without a competitive procurement process, as pleaded, is wrongful, illegal, unlawful, null and void, and of no force or avail in law;
- f. declare that the purported decision and/or determination of the 1st to 22nd and/or the 25th to 38th Respondents, and/or any one or more of them, and/or their servants and/or agents, to procure medical/medicinal/pharmaceutical supplies and/or through any other importer through Direct Contracting and/or on an Unsolicited Bid,

- without a competitive procurement process, as pleaded, is wrongful, illegal, unlawful, null and void, and of no force or avail in law;
- g. declare that any decision and/or determination made by the 26th and/or 27th to 35th and/or 36th to 38th Respondents, and/or any one or more of them, and/or their servants and/or agents, to grant a Waiver of Registration to the 55th and/or 57th to 63rd Respondents, and/or any other importer, for importation of medical/medicinal/pharmaceutical supplies as pleaded, is wrongful, arbitrary and capricious, illegal, unlawful, null and void, and of no force or avail in law;
 - h. declare that any decision and/or determination made by the 26th and/or 27th to 35th and/or 36th to 38th Respondents, and/or any one or more of them, and/or their servants and/or agents, to grant Waivers of Registration to the 55th and/or 57th to 63rd Respondents, is wrongful, arbitrary and capricious, illegal, unlawful, null and void, and of no force or avail in law;
 - i. declare that any decision and/or determination made by the 26th and/or 27th to 35th and/or 36th to 38th Respondents, and/or any one or more of them, and/or their servants and/or agents, to grant Customs/Importation Clearance/Approval for the said importation of medical/medicinal/pharmaceutical supplies from the 55th and/or 57th to 63rd Respondents as pleaded, is wrongful, arbitrary and capricious, illegal, unlawful, null and void, and of no force or avail in law;
 - j. declare that the importation into Sri Lanka of the said medical/medicinal/pharmaceutical supplies from the 55th and/or 57th to 63rd Respondents, as pleaded, is wrongful, arbitrary and capricious, illegal, unlawful, null and void, and of no force or avail in law;
 - k. declare and direct the 44th Respondent and/or his servants and/or agents and/or successors to prevent the importation and/or provide customs clearance and/or approval for clearance of medical/medicinal/pharmaceutical supplies from the 55th and/or 57th to 63rd Respondents;
 - l. declare that the 1st to 22nd and/or the 25th, 36th to 38th Respondents, and/or any one or more of them, and/or their servants and/or agents, and/or their successors, are not entitled to make any payments to the 55th and/or 57th to 63rd Respondents for the procurement of medical/medicinal/pharmaceutical supplies, as pleaded;
 - m. declare that any decision and/or determination made by the 26th and/or 27th to 38th Respondents, and/or any one or more of them, and/or their servants and/or agents, to grant a Waiver of Registration for any medical/medicinal/pharmaceutical supplies from the 55th and/or 57th to 63rd Respondents, other than strictly in terms of the provisions of Section 109 of the National Medicines Regulatory Authority Act, No.5 of 2015, is wrongful, arbitrary and capricious, illegal, unlawful, null and void, and of no force or avail in law;
 - n. declare that any decision and/or determination made by the 26th and/or 27th to 38th Respondents, and/or any one or more of them, and/or their servants and/or agents,

- to grant a Waiver of Registration for any medical/medicinal/pharmaceutical supplier/importer, other than strictly in terms of the provisions of Section 109 of the National Medicines Regulatory Authority Act, No.5 of 2015, is wrongful, arbitrary and capricious, illegal, unlawful, null and void, and of no force or avail in law;
- o. direct the 43rd Respondent to conduct a special inquiry/investigation into the said decision and/or determination to procure medical and/or pharmaceutical supplies from the 55th and/or 57th to 63rd Respondents and/or any other medical supplier/importer to whom WoRs had been issued, as pleaded;
 - p. direct the 43rd Respondent to compute the cost incurred by the State by procuring medical supplies through the 55th and/or 57th to 63rd Respondents and/or any other medical supplier/importer to whom WoRs had been issued, as pleaded;
 - q. direct the 66th Respondent to take immediate steps to cause/initiate and/or commence prosecution of persons identified through investigations of the 45th Respondent and/or his servants and/or agents, to have obtained financial and/or any other benefits through the procurement of medical supplies through the use of WoRs, as pleaded;
 - r. direct the 66th Respondent and/or any one or more Respondents to take immediate steps to initiate and/or commence action to recover the costs incurred to the State and/or the general public of Sri Lanka by procuring medical supplies through the 55th and/or 57th to 63rd Respondents and/or any other medical supplier/importer to whom WoRs had been issued, as pleaded, and/or from any one or more of the 46th, 47th, 48th, 51st, 52nd, 53rd, 54th and 56th Respondents, and/or from any persons identified through the investigations of the 45th Respondent and/or his servants or agents, as pleaded;
 - s. direct the 66th Respondent and/or any one or more Respondents to take immediate steps to initiate and/or commence action to seek compensation from the 55th and/or 57th to 63rd Respondents and/or any other medical supplier/importer to whom WoRs had been issued, as pleaded, and/or from any one or more of the 46th, 47th, 48th, 51st, 52nd, 53rd, 54th and 56th Respondents, and/or from any persons identified through the investigations of the 45th Respondent and/or his servants or agents, as pleaded;
 - t. declare and direct that the procurement of medical and/or pharmaceutical supplies by the Ministry of Health be done strictly in terms of the Procurement Guidelines (Good & Works) 2006, and/or the Guidelines for Procurement of Pharmaceutical and Medical Devices 2006, and/or any other lawfully applicable Procurement Guidelines, **and issue guidelines in this regard**, as deemed appropriate by Your Lordships' Court;
 - u. direct the 25th and/or 26th to 38th Respondents, and/or any one or more of them, and/or their servants and/or agents to review the Waivers of Registration issued to any medical/medicinal/pharmaceutical supplier since 2022 by the 25th and/or 26th to 38th Respondents and/or any one or more of them;


- v. grant and issue an **Interim Order** staying and/or suspending the purported decision and/or determination of the 1st to 22nd and/or the 25th to 38th Respondents, and/or any one or more of them, and/or their servants and/or agents, to procure medical/medicinal/pharmaceutical supplies from the 55th and/or 57th to 63rd Respondents, as pleaded, until the final determination of this application, subject to such terms, if any, as to Your Lordships' Court sees fit;
- w. grant and issue an **Interim Order** staying and/or suspending the purported decision and/or determination, if any, made by the 26th and/or 27th to 38th Respondents, and/or any one or more of them, and/or their servants and/or agents, to grant a Waiver of Registration, as pleaded, to the 55th and/or 57th to 63rd Respondents, until the final determination of this application, subject to such terms, if any, as to Your Lordships' Court sees fit;
- x. grant and issue an **Interim Order** preventing the importation into Sri Lanka any medical/medicinal supplies from the 55th and/or 57th to 63rd Respondents, as pleaded, until the final determination of this application, subject to such terms, if any, as to Your Lordships' Court sees fit;
- y. grant and issue an **Interim Order** preventing the 1st to 22nd, and/or the 24th Respondent, and/or the 25th, 36th to 38th Respondents, and/or any one or more of them, and/or their servants and/or agents and/or successors from making any payments to the 55th and/or 57th to 63rd Respondents and/or any agent of the said Respondents in respect the purported procurement/importation into Sri Lanka of any medical/medicinal supplies, until the final determination of this application, subject to such terms, if any, as to Your Lordships' Court sees fit;
- z. make such further and other just and equitable orders as to Your Lordships' Court shall seem fit, in the circumstances of this application, under and in terms of Article 126(4) of the Constitution of the Republic;
- aa. grant compensation, in such sum, and to such persons, as deemed appropriate to Your Lordships' Court;
- bb. grant costs; and,
- cc. grant such further and other relief as to Your Lordships' Court shall seem meet.



ATTORNEY-AT-LAW FOR THE
PETITIONERS

Thosainge Bindiya Krishani Perera Senarath
L.L.B. (London)
Attorney-at-Law and (A. 20489)
Notary Public
Commissioner for Oaths
Senarath Niwasa, Kaduwela.
Sri Lanka.
Tele : 077 6 281 377

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TRUE COPY


T. B. K. P. Senarath
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ATTORNEY-AT-LAW