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.

- Transparency International Sri Lanka No.366, Nawala Road Nawala, Rajagiriya
- 2. Ashala Nadishani Perera No.31, Shalawa Road Mirihana, Nugegoda

PETITIONERS

Supreme Court [Fundamental Rights]

Application No. /2023

Vs.

- Hon. Ranil Wickramasinghe
 Minister of Finance, Economic
 Stabilisation and National Policies
 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
- 3. Hon. Nimal Siripala de Silva Minister of Ports, Shipping and Aviation Ministry of Ports, Shipping and Aviation No.19, Chaithya Road Colombo 1
- 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
- 6. Hon. Susil Premajayanth
 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
- 9. Hon. (Dr.) Wijedasa Rajapakse Minister of Justice, Prison Affairs and Constitutional Reforms 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
- 11. Hon.(Dr.) Ramesh Pathirana
 Minister of Plantation Industries
 Ministry of Plantation Industries
 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

- 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
- 15. Hon. Kanchana Wijesekara Minister of Power and Energy Ministry of Power and Energy No.437, Galle Road Colombo 3
- 16. Hon. Nasser Ahmed
 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
- 19. Hon. Tiran Alles
 Minister of Public Security
 Ministry of Public Security
 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

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

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

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
 Chairman
 National Medicines Regulatory
 Authority

28. Dr. Vijith Gunasekara
Chief Executive Officer
National Medicines Regulatory
Authority

- 29. Dr. Pradeep Kumarasinghe de Silva Member
- 30. Dr. Kosala Karunaratne Member
- 31. Dr. Manoj Gamage Member
- 32. Dr. Supul Wijesinghe Member
- 33. Dr. Chathura Mohottigedara Member
- 34. Dr. Pradeep de Silva Member
- 35. Mr. Priya Serasinghe Member

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

- 36. Dr. Asela Gunawardena Director General of Health Services
- 37. Dr. A. T. Sudharshana
 Director
 Medical Supply Division
 (Department of Health Services)

Both of: No. 357 Beddegama Wimalawansha Mawatha Colombo 10

38. Kanishka Wijeratne
Director General
Commission to Investigate Allegations of
Bribery and Corruption

- 39. Hon. Justice Eva Wanasundera Chairperson
- 40. Hon. Justice Deepali Wijesundera Member
- 41. C. N. Wakishta 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
 Police Headquarters
 Colombo 12
- 45. Savorite Pharmaceuticals (Pvt) Limited 703, Atlantis Heights Sarabhai Compound, Vadiwadi Road Vadodara- 39007 Gujarat India
- 46. Kausikh Therapeutics (P) Limited No. 21, (and formerly No. 12)
 Durairaj Street
 Palavanthangal
 Chennai
 India
- 47. Honourable Attorney General Attorney General's Department Colombo 12

RESPONDENTS

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

The **Petition** of the **Petitioners** above-named, appearing by Thushari Jayawardena, its Attorney-at-Law, states as follows:

SCOPE OF THE APPLICATION

The instant application impugns the wrongful 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. The Petitioners *inter alia* allege the failure of one or more Respondents to uphold the fundamental rights of the Petitioners, 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, and to work towards the eradication of corruption from all spheres of life in Sri Lanka.
- 3. The 2nd Petitioner is the Executive Director 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, the names and particulars of the Directors of the 1st Petitioner, and its Articles of Association, compendiously marked <u>P1</u> are annexed hereto and pleaded as part and parcel hereof.

THE RESPONDENTS

1. 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, in terms of the Constitution.

Notwithstanding the fact that the 1st Respondent holds the office of the President of the Republic, 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.

- 2. The 2nd Respondent is the Prime Minister of Sri Lanka, and the Minister of Public Administration, Local Government and Home Affairs.
- 3. The 3rd to 21st Respondents form the membership of the Cabinet of Ministers of Sri Lanka.
- 4. 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.
- 5. 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.
- 6. 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.
- 7. The 27th and 28th Respondents are respectively the Chairman and Chief Executive Officer of the NMRA.

- 8. The 29th to 35th Respondents are the members of the NMRA.
- 9. The 36th Respondent is the Director General of Health Services of the Ministry of Health, and also an *ex officio* member of the NMRA.
- 10. The 37th Respondent is the Director the Medical Supplies Division of the Ministry of Health.
- 11. The 38th Respondent is the Director General of the Commission to Investigate Allegations of Bribery and Corruption.
- 12. The 39th Respondent is the Chairperson of the Commission to Investigate Allegations of Bribery and Corruption.
- 13. The 40th and 41st Respondents are members of the Commission to Investigate Allegations of Bribery and Corruption.
- 14. The 42nd Respondent is the Auditor General of Sri Lanka.
- 15. The 43rd Respondent is the Director General of Customs of Sri Lanka.
- 16. The 44th Respondent is the Inspector General of Police of Sri Lanka.
- 17. The 45th and 46th Respondents are two private entities which deal in pharmaceutical and/or medical supplies. The matters hereinafter urged in this application relate to attempts made by one or more Respondents to procure pharmaceutical and/or medical supplies from the said Respondents, in complete contravention of the law, as morefully enumerated hereinafter.
- 18. The 47th Respondent is the Attorney General of Sri Lanka, who is made party to the instant application in compliance with mandatory provisions of the law.
- 19. The impugned acts and/or omissions of the 1st to 37th Respondents and/or the 43rd Respondent and/or the 45th and 46th Respondents 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

- 20. 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.
- 21. 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.
- 22. Consequently, the Petitioners are still endeavouring to uncover additional material and/or clearer specifics to buttress the findings of the Petitioners, 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.
- 23. The Petitioners were made nascently and generally aware of the circumstances described hereinafter on or around 22/01/2023 [by a media article in the *Sunday Times Online* news-site dated 22/01/2023], and have instituted this application within the time period stipulated in the Constitution.
- 24. In any event, the Petitioners also very specifically state that there is a continuing and/or imminent violation of their fundamental rights.
- 25. The narrative described hereinafter is demonstrative of the glaring disregard by 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.
- 26. 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, purportedly under the Indian Credit Line (ICL) and other unspecified means of funding.
- 27. As described hereinafter, the Minister of Health (22nd Respondent) has purportedly sought the approval of the Cabinet of Ministers to utilize the 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.
- 28. The Minister of Health has on two occasions 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.
- 29. The names of the said Private Entities have been proposed to the Cabinet of Ministers by the 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.
- 30. The Petitioners are reliably informed that the Ministry of Health has 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 morefully described hereinafter.

Very significantly, *ex facie*, the mandatory conditions precedent that would justify such a waiver, are singularly absent in the instant case.

31. The Petitioners respectfully state that they are only in possession of documents sourced through the means available to them at the time of filing this application, and respectfully reserves the right to move the Court for directions on the Respondents to tender originals and/or certified copies thereof for the perusal of the Court.

MOVES BY THE MINISTRY OF HEALTH TO PROCURE MEDICAL SUPPLIES FROM UNREGISTERED PRIVATE SUPPLIERS THROUGH DIRECT CONTRACTING AND/OR UNSOLICITED BIDS

- 32. The Minister of Health submitted a Cabinet Memorandum on 25/10/2022, ostensibly pertaining to the uninterrupted supply of medical supplies in Sri Lanka.
 - A copy of the said Cabinet Memorandum No. 22/1693/610/024 submitted by the Minister of Health on 25/10/2022 marked <u>P2</u> is annexed hereto and pleaded as part and parcel hereof.
- 33. The Minister of Health makes reference to the NMRA, being the main regulatory body for procurement of medical supplies in Sri Lanka, and raises the issue of the process for procurement followed by the NMRA being protracted, causing delays in procurement thereof.
- 34. The said Cabinet Memorandum goes on to elaborate the purported dire shortages of medical supplies that is likely to arise, and refers to a private pharmaceutical entity, SPL, as having been identified as a supplier to provide an expeditious supply of medical supplies.
- 35. There is absolutely no indication of the basis for the selection of SPL, or of any competitive process of selection therefor.
- 36. Reference is also made to the extended periods of time consumed to arrange for payment for such medical supplies, in view of the prevailing economic crisis in Sri Lanka.
- 37. As a purported solution, the Minister of Health suggests that the ICL and other means of funding are utilized to import medical supplies from SPL, to provide for the requirement of medical supplies for three months.
- 38. In this context, the Minister requested the approval of the Cabinet of Ministers to two purported proposals submitted by the Ministry of Health [hereinafter 'MoH'], namely that, in cognisance of the prevailing emergency and need for medical supplies, to utilize the remaining funds available under the ICL and other means of funding, to import medical supplies approved by the State Pharmaceutical Corporation [hereinafter 'SPC'] through SPL and other selected suppliers, and to enter into an agreement for the supply of medical supplies with SPL and other selected suppliers by utilizing the ICL and other means of funding [Vide Item 4.1.1 and 4.1.2].
- 39. The Petitioners have reliably learned that the annexure to the said Cabinet Memorandum makes reference to several medical supplies which are not essential and/or life saving and/or not included in the list of medical supplies approved by the SPC as such.

40. At the time of filing this application, the Petitioners are not privy to a final Cabinet Decision which endorses and/or approves the said Cabinet Memorandum submitted by the Minister of Health. In view of the same, the Petitioners, by way of request dated 10/02/2023 tendered a Right to Information [RTI] request to the Ministry of Health.

A copy of the said RTI request dated 10/02/2023 made to the Cabinet of Ministers, and the MoH marked P3 and P4 are annexed hereto and pleaded as part and parcel hereof.

41. It is very pertinent that subsequently, in or around 05/12/2022, the MoH submitted a Note to the Cabinet reiterating the purported need to maintain an uninterrupted supply of medical supplies in Sri Lanka, citing a dire need caused by several medical supplies having reached zero stocks.

The Note to the Cabinet dated 05/12/2022 marked <u>P5</u> is annexed hereto and pleaded as part and parcel hereof.

- 42. In the said Note to the Cabinet, the MoH makes reference to yet another private supplier, KTL, as having agreed to provide sufficient stocks of medical supplies to Sri Lanka using the ICL and other means of funds.
- 43. By Items 3.1.1 and 3.1.2 of the said Note to the Cabinet, the MoH brought to the attention of the Cabinet the purported need to permit KTL to import medical supplies approved by SPC to Sri Lanka through the ICL and other means of funding, and to enter into agreements with KTL to agree on the modalities thereto.
- 44. It is vital to evaluate the Note to the Cabinet by the MoH on 05/12/2022, in a context that by a letter dated December 2022, the Additional Secretary to the MoH has informed the Secretary to the Ministry of Foreign Affairs of an impending visit by the Minister of Health to Chennai, India for inspection of the KTL factory from 21st to 24th December 2022.

A copy of the letter of the Additional Secretary to the MoH marked <u>P6</u> is annexed hereto and pleaded as part and parcel hereof.

- 45. It is categorically stated that the conduct of the Minister of Health reeks of bias, procedural irregularity, preference and/or partiality towards a single supplier, absence of integrity and total disregard for the need to provide fair, equal and maximum opportunity for eligible interested parties to participate in procurement, while ensuring transparency, and consistency in evaluation and selection procedure.
- 46. The conduct of the Minister of Health *ex facie* demonstrates that the decision to obtain medical supplies from KTL was made, and that the *ex post facto* formalities sought to be followed, are farcical attempts to bring some semblance of legitimacy to an utterly irregular and/or wrongful and/or unlawful process.
- 47. The Petitioners are reliably informed that the said KTL is a supplier which had been previously blacklisted by the SPC as recently as 2017, and respectfully reserve the right to move the Court for directions on the Respondents to tender documentary evidence in support of the same to Your Lordships' Court.
- 48. The decisions and/or recommendations sought to be approved by the Cabinet of Ministers, which have been submitted by the Minister of Health does not stand the test of objective scrutiny, in view of the complete neglect and/or failure and/or omission to follow the law, regulations, guidelines and/or procedures, as morefully stated hereinafter.

THE ROLE OF THE CABINET OF MINISTERS IN PROCURING MEDICAL SUPPLIES THROUGH UNREGISTERED PRIVATE SUPPLIERS

- 49. By his letter dated 26/10/2023, the Secretary to the Cabinet of Ministers informed the Secretary-MoH that the Cabinet of Ministers, upon discussion of the said Cabinet Memorandum dated 25/10/2022, had decided on principle, to approve Items 4.1.1 and 4.1.2 therein, and to submit the said Memorandum to the Minister of Finance, Economic Stabilization and National Policies for his observations, with a view to placing the same before the Cabinet Sub-committee on Management of State Expenditure for its consideration.
 - A copy of letter dated 26/10/2023 authored by the Secretary to the Cabinet of Ministers marked **P7** is annexed hereto and pleaded as part and parcel hereof.
- 50. On 25/10/2022, provisional approval was given to the said Cabinet Memorandum dated 25/10/2023, i.e., Items 4.1.1 and 4.1.2, in principle, subject to the observations of the Minister of Finance, Economic Stabilization and National Policies, and consideration by the Cabinet Sub-committee on Management of State Expenditure.
 - A copy of letter dated 01/11/2022 of the Secretary to the Cabinet of Ministers marked <u>P8</u> is annexed hereto and pleaded as part and parcel hereof.
- 51. The Minister of Finance, on 05/11/2022, tendered his observations pertaining to the said Cabinet Memorandum dated 25/10/2022. The Minister of Finance conveys that he has no objections to the proposals at Items 4.1.1 and 4.1.2, subject to several conditions.
 - A copy of the observations of the Minister of Finance dated 05/11/2022 marked <u>P9</u> is annexed hereto and pleaded as part and parcel hereof.
- 52. It is very pertinent that the Minister of Finance has observed that the proposed supplier has been selected on an unsolicited basis, and therefore should be in compliance with procedures applicable for private sector pharmaceutical suppliers who import drugs on behalf of the SPC under the ICL, and if funds beyond the ICL are used, that the appropriate Procurement Guidelines should be followed.
- 53. It is also relevant that further observations are made about the Ministry of Health not following procurement planning by keeping sufficient lead time and buffer stocks to avoid shortages, and to develop proper monitoring and coordinating mechanisms within the institutions under the purview of the Ministry of Health to avoid delays in the procurement process.
- 54. The ineptitude of the MoH which led to the shortages in medical supplies is implied in the observations of the Minister of Finance, giving rise to serious concerns on whether the purported shortages of medical supplies were a creation of prolonged mismanagement and/or incompetence to plan and monitor the levels of stocks of medicine within the MoH.

- 55. The said Provisional decision is not reflective of the ground realities existing in Sri Lanka, particularly in view of several medical supplies referred to, being neither essential nor 'lifesaving' medicines, as claimed by the Minister of Health.
- 56. It is very pertinent that in its Note to the Cabinet, dated 05/12/2022, the Ministry of Health makes reference to a Cabinet decision dated 14/11/2022, which the Petitioners are not privy to, and have not been able to obtain through official channels.

THE ROLE OF THE NMRA IN PROVIDING A WAIVER OF REGISTRATION TO PROCURE MEDICAL SUPPLIES FROM UNREGISTERED SUPPLIERS

- 57. On 30/11/2022, the Director, Medical Supplies Division of the Department of Health Services, within the purview of the Ministry of Health, requested the Chairman of the NMRA to issue a WoR to SPL, to enable importation of 38 items of purportedly essential pharmaceuticals from SPL.
 - A copy of letter dated 30/11/2022 of the Director, MSD marked <u>P10</u> is annexed hereto and pleaded as part and parcel hereof.
- 58. The Petitioners are now in possession of a list containing reference to 38 pharmaceuticals for which WoR has been sought to import the said medical supplies from SPL through the ICL, transmitted by the MoH to the Medicines Evaluation Committee [MEC] of the NMRA.
 - It is very pertinent that the said list makes reference to WoR being approved by the CEO of the NMRA, raising a concern as to whether the CEO had approved the WoR prior to the Board of the NMRA making a decision thereon.
 - A copy of a list containing medical supplies for which WoR has been sought marked P11 are annexed hereto and pleaded as part and parcel hereof.
- 59. Subsequently, on or about 13/12/2022, the Secretary, MoH has informed the Chief Executive Officer (CEO) of the NMRA of an approval of the Cabinet of Ministers to obtain a supply of medical supplies from SPL for a period of three months, and that the MSD would import the same directly. The Secretary-MoH sought a WoR for a list of medical supplies attached to the said letter.
 - A copy of letter dated 13/12/2022 from the Secretary, MoH marked <u>P12</u> is annexed hereto and pleaded as part and parcel hereof.
- 60. It is very pertinent that the 38 pharmaceutical products listed in the annex to the aforesaid letter of the Secretary-MoH, are identical to the list of products for which WoR had been sought, and the CEO of the NMRA had seemingly approved [Vide P11], buttressing the authenticity of the said document, which indicates that the CEO of the NMRA had already provided approval for WoR for the 38 pharmaceutical products referred therein in complete breach of the law, as morefully averred hereinafter.
- 61. On 29/12/2022, at the Board meeting of the NMRA, the said Board has agreed to provide No Objection Letters and Waiver of Registration letters, in response to the request of the Cabinet of Ministers to grant WoR. The NMRA has further decided to add that it would not take responsibility for the "safety, efficacy and quality of the

products", amply demonstrating the magnitude of the danger of procuring medical supplies from unregistered private suppliers.

A copy of the Minutes of the Board Meeting of the NMRA held on 29/12/2022 marked <u>P13</u> is annexed hereto and pleaded as part and parcel hereof.

62. The Petitioners, by way of RTI request dated 10/02/2023, sent a request for information to the NMRA, making particular reference to whether WoR has been provided to procure medical supplies from SPL and/or KTL.

A copy of the said RTI request dated 10/02/2023 sent to the NMRA marked <u>P14</u> is annexed hereto and pleaded as part and parcel hereof.

REACTION TO THE ACTS OF THE MOH

- 63. It is imperative to note that members of the public, including medical professionals and journalists, have now come to unearth information regarding the acts of the Minister of Health and MoH to procure medical supplies from unregistered private suppliers, whilst totally circumventing procedural and legal imperatives.
- 64. The Petitioners are now in possession of a letter by a nominated member of the NMRA, Dr. Pradeep Kumarasinghe de Silva, dated 16/01/2023, wherein he wrote to the Chairman of the NMRA, raising several concerns and/or issues regarding the decision of the Board of the NMRA on 29/12/2022 to provide No Objection Letters and Waiver of Registration letters to procure supplies from SPL.

The said letter highlights the issue of whether or not the list of 38 purported life-saving drugs would serve the purpose of being "life-saving", and whether the shortage would continue to exist even after receiving the medical supplies obtained from SPL for whom WoR was sought. Dr. Kumarasinghe de Silva further highlights whether further consignments of medical supplies ought to be purchased after purchasing supplies from SPL.

A copy of letter dated 16/01/2023 authored by Dr. Kumarasinghe de Silva marked <u>P15</u> is annexed hereto and pleaded as part and parcel hereof.

65. The Petitioners are also now in possession of several letters authored by the Sri Lanka Medical Association [SLMA], the Sri Lanka College of Paediatricians, the College of Surgeons of Sri Lanka, the Sri Lanka Chamber of the Pharmaceutical Industry addressing several matters canvassed by the Petitioners in this application.

Copies of the said letters are marked as follows and are pleaded as part and parcel hereof.

Letter dated 16/01/2023, 23/01/2023 and 01/02/2023 of the SLMA respectively marked P16(a), P16(b) and P16(c).

Letter dated 19/01/2023 of the Sri Lanka College of Paediatricians marked P17.

Letter dated 19/01/2023 of the College of Surgeons of Sri Lanka marked P18.

Letter dated 31/01/2023 of the Sri Lanka Chamber of Pharmaceutical Industry marked <u>P19</u>.

- 66. The SLMA has raised the issue pertaining to procurement of medical supplies with His Excellency the President [*Vide* P16(a)] and highlighted concerns on the safety, efficacy and quality of medicines supplied through unregistered entities and the failure to adhere to procedural prerequisites when selecting suppliers. It is very pertinent that the SLMA has made specific reference to KTL having been blacklisted in 2017 by the SPC.
- 67. Additionally, the fact that several non-essential medicines having been included in the list of medicines to be imported, and that reasonable levels of stocks of some medicines being available, thus not requiring urgent importation, has also been raised. The SLMA has recommended complying with usual procedures adopted when procuring medicine from private entities, thus avoiding procurement through unregistered private entities.
- 68. It is pertinent to note that appointed members of the NMRA who represent the Councils of the Ceylon College of Physicians, College of Surgeons in Sri Lanka, Sri Lanka College of Obstetricians and Gynaecologists and the Sri Lanka College of Paediatricians collectively raised their concerns by letter dated 27/01/2023 and a media release on 31/01/2023. Additionally, the President of the Ceylon College of Physicians raised concerns and reservations regarding the WoR for supply of essential medical supplies from SPL.

Copies of letter dated 27/01/2023, the media release dated 31/01/2023 and the letter authored by the President of the Ceylon College of Physicians respectively marked <u>P20(a), P20(b)</u> and <u>P20(c)</u> are annexed hereto and pleaded as part and parcel hereof.

- 69. The College of Paediatricians have raised similar concerns as the SLMA, and have referred to several medicines listed by the MoH as being life-saving drugs not being so, and of the need to adhere to regular procurement procedures when procuring supplies from private entities [*Vide* P17]. It is vital to note that the College of Paediatricians have referred to the possibility of conducting a formal registration process expeditiously, demonstrating that the decision of the MoH to seek WoR to be futile and unnecessary.
- 70. The President of the College of Surgeons raised similar concerns in his letter [Vide P18] and highlighted the need of the NMRA to ensure that WoR is not issued for the purchase of non-essential medicine and medical supplies of which reasonable stocks are available.
- 71. It is very pertinent that the Sri Lanka Chamber of the Pharmaceutical Industry [SLCPI] has referred to the possibility of procuring medical supplies through its members who are registered with the NMRA, rendering the need to procure the same from unregistered suppliers to be unnecessary [Vide P 19].

- 72. The fact that the failure to settle dues to the members of the SLCPI by the SPC, leading to non-participation of its registered members in the tender process has been raised in the said letter, highlighting the ineptitude and utter mismanagement of processes within the MoH, signifying the creation of a dearth in the supply of medical supplies.
- 73. It is material that the SLCPI has made reference to the absence of any notification in the tender invitation for bids of non-registered pharmaceutical entities' bids being entertained, which would have led to members of the SLCPI supplying such medical supplies. Thus evincing the availability of viable alternative suppliers.
- 74. The Councils of the Ceylon College of Physicians, College of Surgeons in Sri Lanka, Sri Lanka College of Obstetricians and Gyneacologists and the Sri Lanka College of Paediatricians have collectively made reference to several medicines listed as being "life-saving" not being so. The said Colleges have gone so far as to question the *bona fides* of the MoH for having falsely declaring non-life saving medicine as life-saving medicine, and have collectively referred to the possibility of carrying out the registration process of suppliers of pharmaceuticals.
- 75. Several newspaper articles covering the events canvassed in this application, bearing the following titles, "Medical bodies say Health Ministry's new Indian purchases could endanger lives", "Life-or-death battle over drugs: Medical bodies go to President" and "Medical professional oppose cabinet proposal to waive NMRA registration to import medicine" have been published in print media.
 - Copies of newspaper articles dated 22/01/2023, 29/01/2023 and 03/02/2023 respectively marked <u>P21(a)</u>, <u>P21(b)</u> and <u>P21(c)</u> are annexed hereto and pleaded as part and parcel hereof.
- 76. The aforesaid amply demonstrates that the Petitioners' concerns as to the *bona fides* of the MoH, and the purported need to circumvent the law and regular procurement processes to allow unregistered private entities to supply pharmaceuticals to Sri Lanka, to be well-founded.
- 77. The concerns of the Petitioners as to the quality, efficacy and safety of medical supplies sourced through unregistered private entities, the overwhelming need to surpass the usual registration processes to determine whether the unregistered entities could be granted registration by the NMRA, and the need to classify non-life saving medicine as life-saving are shared by medical professionals, causing the processes adopted and *bona fides* of the MoH to be tainted with impropriety.

THE WAIVER OF REGISTRATION BY THE NMRA

78. In this context, it is necessary to examine the role of the NMRA and the provision of WoR by the NMRA.

- 79. The NMRA, is *inter alia* vested with the powers of registering medical suppliers/supplies which supply pharmaceutical products to the SPC.
- 80. 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.
- 81. 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.
- 82. 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.
- 83. The circumstances surrounding this application demonstrate that the MSD of the MoH, under the auspices of the Minister of Health, has sought that the NMRA provide WoR in respect of unregistered private suppliers/supplies [*Vide* P10 and P12].
- 84. It is evident from the fact stated hereinbefore, that no attempt has been made to obtain registration of the said suppliers/supplies i.e., SPL and KTL through the usual process applied by the NMRA.
- 85. Instead, the Minister of Health has 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.
- 86. Thus, it is amply evident that the 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.
- 87. It is specifically stated that this position is exacerbated by several purported "life-saving" medication not being so, stocks of several medication that have been requisitioned being available in Sri Lanka, and 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.
- 88. Additionally, as reliably learned by the Petitioners, and alluded to by the SLMA, one private entity, KTL, has been blacklisted by the SPC in 2017, raising a serious concern as to the *bona fides* of one or more Respondents to pursue procurement from such an entity in the midst of the crisis situation prevailing in Sri Lanka.
- 89. The insistence on the two private entities referred to by the Minister of Health raises questions as to why two Private Entities are singled out in a context where the SLPCI has stated that its members who are unregistered pharmaceutical suppliers are potentially capable of making a bid in response to an invitation to bid by unregistered medical suppliers.
- 90. The entire process is further tainted by KTL, an unregistered supplier referred to by the MoH, having caused the Minister of Health to undertake an inspection of its factory in

Chennai, raising serious doubts as to whether the suggestion by the Minister of the said entity was unsolicited.

NON~COMPLIANCE WITH PROCUREMENT GUIDELINES

91. 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 <u>P22(a)</u>, <u>P22(b)</u> and <u>P22(c)</u> are annexed hereto and pleaded as part and parcel hereof.

- 92. 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.
- 93. 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.
- 94. 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.
- 95. It is very specifically stated that the procurement processes must necessarily be adhered to, in the context of the ICL and other means of funding being utilized to source the purportedly required medical supplies, being public funds.
- 96. In fact, one or more Respondents have sought to entirely neglect and/or totally disregard the procurement procedure laid down by the law, regulations and guidelines, demonstrating the same being observed in the breach.
- 97. 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.
- 98. 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

- 99. It is specifically stated that deviation from the usual procedures for procurement is only justified in limited circumstances.
- 100. 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.
- 101. 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.
- 102. 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.
- 103. 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.
- 104. 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 though a process which is totally unjustified and unnecessary.
- 105. 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.
- 106. Therefore, the Minister of Health has evidently sought to rely on an abridged process to ensure procurement through preferred entities while surpassing all applicable legal, moral and medical justifications for procuring supplies from SPL and KTL.

ABUSE OF PROCESS BY THE MINISTER OF HEALTH FUELLED BY EXTRANEOUS CONSIDERATIONS

107. The Petitioners are now in possession of a copy of a letter dated 17/12/2022, to the Minister of Health from KTL, inviting the said Minister for an inspection of the factory of KTL.

A copy of letter dated 17/12/2022 marked <u>P23</u> is annexed hereto and pleaded as part and parcel hereof.

- 108. It is evident that the Minister of Health accepted the said invitation, as evinced by the communication of the Additional Secretary of the MoH to the Secretary, Ministry of Foreign Affairs to provide the necessary protocol assistance to the Minister during his visit to India [Vide P6]. It is imperative to note that the said letter from the MoH bears a caption which makes specific reference to the "Inspection of Kausikh Therapeutics (P) Ltd Factory".
- 109. It is thus *ex facie* evident that the Minister of Health undertook a private tour, with the CEO of the NMRA, of the factory of a supplier from whom the Minister has sought to procure medical supplies to Sri Lanka whilst circumventing the procurement processes.
- 110. The confirmation of the stay of the Minister of Health at the ITC Grand Chola Hotel from 21/12/2022 to 24/12/2022, which the Petitioners are now in possession of, further buttresses the fact that the Minister accepted the said invitation, and that he was directly in communication with a supplier suggested by himself, while circumventing the procurement process.

The confirmation of the stay of the Minister of Health at the ITC Grand Chola Hotel marked <u>P24</u> is annexed hereto and pleaded as part and parcel hereof.

- 111. The conduct of the Minister of Health reeks of irregularity, impropriety, conduct motivated by ulterior motives and extraneous considerations, in complete breach of procedural safeguards to ensure fairness, transparency, equality, and consistency in procurement.
- 112. It is manifest that the Minister of Health has taken a keen personal interest in KTL, and has proceeded to act with unrestrained bias in proposing the name of KTL, a hitherto blacklisted, unregistered supplier to procure medical supplies to Sri Lanka, notwithstanding the serious ramifications on the health, safety and well-being of the general public which consumes such supplies.
- 113. The impropriety of the conduct of the Minister of Health and his ulterior motives founded on extraneous considerations, is further demonstrated by the MoH having suggested the WoR to procure medical supplies from unregistered suppliers/supplies, in a context where several of the 38 medical supplies purported to be essential life-saving medication, are not essential.

- 114. The purported severe imminent shortage of medical supplies that the Minister of Health alludes to as the justification for procuring medical supplies from SPL and KTL, must be evaluated in a context where several such medications, purportedly listed as essential, are not essential.
- 115. This state of affairs raises grave doubts about the *bona fides* of the Minister of Health to procure purportedly "essential" medical supplies, when in fact, several such medical supplies are not essential.
- 116. The Revision of Pharmaceutical Formulary for Government Healthcare Institutions 2020/2021 of the MSD of the MOH which classifies medical supplies as being essential or non-essential, clearly demonstrates that several of the 38 medical supplies listed as being essential, are not so.

Copies of excerpts of the relevant pages of The Revision of Pharmaceutical Formulary for Government Healthcare Institutions 2020/2021, accessible on the website of the MSD at https://www.msd.gov.lk/ marked P25 are annexed hereto and pleaded as part and parcel hereof.

- 117. The aforesaid circumstances reveal that the 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.
- 118. However, the aforesaid brings to question the narrative of the Minister of Health, which has seemingly been endorsed and adopted by the MoH.
- 119. In view of the blatant abuse of process by *inter alia* the said Minister of Health for procuring medical supplies, the Petitioners tendered a complaint to the Commission to Investigate Allegations of Bribery and Corruption [CIABOC] on 14/02/2023.

A copy of the complaint of the Petitioners to the CIABOC dated 14/02/2023 marked <u>P26</u> is annexed hereto and pleaded as part and parcel hereof.

- 120. 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.
- 121. This is further exacerbated by the prevailing economic crisis causing severe strain on the foreign exchange, the availability of which is drastically low.
- 122. The aforesaid narrative is replete with justifications for the need to investigate into the abuse of due process by the Minister of Health, 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

- 123. 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.
- 124. 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.
- 125. The absence of adequate official information pertaining to Cabinet Decisions and/or provisional decisions on public fora and/or through the usual channels on which such information is made available to the public, is demonstrative of the attempts by one or more Respondents to conduct the impugned procurement process 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.
- 126. 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.
- 127. 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.
- 128. The utilisation of resources for procurement, whether through the ICL or by other means of funding, must necessarily be used in trust for the public, to ensure maximum benefits to the public.
- 129. The exercise of powers in this manner would require the use of the ICL or any other means of funding being utilized to procure the highest quality of medical supplies at the lowest cost, to ensure optimum benefit to the general public, particularly in view of the prevailing crisis relating to the dearth of foreign exchange in the country to finance imports.
- 130. 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.
- 131. 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.
- 132. 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.
- 133. 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.
- 134. 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.
- 135. 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 unconstitutional.
- 136. 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.
- 137. 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.
- 138. The Petitioners have not previously invoked the Jurisdiction of Your Lordships' Court in respect of this matter.

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

WHEREFORE, the Petitioner prays 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 pertaining to the moves to procure medical supplies from Savorite Pharmaceuticals (Pvt) Limited, as pleaded;
- c. call for the entire file and/or records held by any one or more Respondents pertaining to the moves to procure medical supplies from Kausikh Therapeutics (P) Limited, as pleaded;

d. in particular,

- I. direct the 1st to 22nd and/or 23rd Respondents to produce:
 - 1) certified copies of any and all Cabinet decisions, including Cabinet Sub-Committee decisions, pertaining to the 22nd Respondent's said Cabinet Memorandum dated 25/10/2022 regarding the procurement of medical supplies from Savorite Pharmaceuticals (Pvt) Limited, as pleaded;
 - 2) certified copies of any and all Cabinet decisions, including Cabinet Sub-Committee decisions, pertaining to the 22nd Respondent's said Cabinet Memorandum dated 05/12/2022 regarding the procurement of medical supplies from Kausikh Therapeutics (P) Limited, as pleaded;
 - 3) certified copies of any other Cabinet decisions, including Cabinet Sub-Committee decisions, pertaining to any Cabinet Memoranda presented by the 22nd Respondent regarding the procurement of medical supplies from Savorite Pharmaceuticals (Pvt) Limited and/or Kausikh Therapeutics (P) Limited;
- II. direct the 22nd, 25th, 36th and 37th Respondents to produce:

- 1) the unsolicited bid of Savorite Pharmaceuticals (Pvt) Limited regarding the supply of medical supplies, as pleaded;
- 2) any and all communications between the Ministry of Health and Savorite Pharmaceuticals (Pvt) Limited regarding the supply of medical supplies, as pleaded;
- 3) the unsolicited bid of Kausikh Therapeutics (P) Limited regarding the supply of medical supplies, as pleaded;
- 4) any and all communications between the Ministry of Health and Kausikh Therapeutics (P) Limited regarding the supply of medical supplies, as pleaded;
- 5) certified copies of any reports obtained on the suitability of Savorite Pharmaceuticals (Pvt) Limited to supply medical supplies, without a competitive procurement process, as pleaded;
- 6) certified copies of any reports obtained on the suitability of Kausikh Therapeutics (P) Limited to supply medical supplies, without a competitive procurement process, as pleaded;
- 7) certified copies of the selection criteria adopted to select Savorite Pharmaceuticals (Pvt) Limited and/or Kausikh Therapeutics (P) Limited for the supply of medical supplies, without a competitive procurement process, as pleaded;
- 8) certified copies of any Technical Evaluation regarding the suitability of Savorite Pharmaceuticals (Pvt) Limited and/or Kausikh Therapeutics (P) Limited to supply medical supplies, without a competitive procurement process, as pleaded;
- 9) a certified copy of the invitation/request for an inspection of Kausikh Therapeutics (P) Limited's facility by the 22nd Respondent, as pleaded;
- 10)a detailed account of the expenditure involved in the inspection of Kausikh Therapeutics (P) Limited's facility by the 22nd Respondent, as pleaded, including the total cost involved, the source of the funding, and the manner of the disbursement of the said funds;
- 11) the post-inspection technical report of the 22nd Respondent on the suitability of Kausikh Therapeutics (P) Limited to supply medical supplies;
- III. direct the 26th to 35th and 36th Respondents to produce:

- 1) certified copies of any and all requests for the Waiver of Registration received from the Ministry of Health regarding medical supplies from Savorite Pharmaceuticals (Pvt) Limited, as pleaded;
- 2) certified copies of any and all requests for the Waiver of Registration received from the Ministry of Health regarding medical supplies from Kausikh Therapeutics (P) Limited, if any;
- 3) certified copies of all decisions taken by the 26th and/or 27th to 35th and 36th Respondents regarding any requests made by the Ministry of Health regarding Waiver of Registration for medical supplies from Savorite Pharmaceuticals (Pvt) Limited, as pleaded;
- 4) certified copies of all decisions taken by the 26th and/or 27th to 35th and 36th Respondents regarding any requests made by the Ministry of Health regarding Waiver of Registration for medical supplies from Kausikh Therapeutics (P) Limited, if any;
- 5) certified copies of any and all reports/evaluations on the suitability of Waiving Registration for medical supplies from Savorite Pharmaceuticals (Pvt) Limited;
- 6) certified copies of any and all reports/evaluations on the suitability of Waiving Registration for medical supplies from Kausikh Therapeutics (P) Limited, if any;
- 7) a certified copy of the invitation/request for an inspection of Kausikh Therapeutics (P) Limited's facility by the 28th Respondent, as pleaded;
- 8) a detailed account of the expenditure involved in the inspection of Kausikh Therapeutics (P) Limited's facility by the 28th Respondent, as pleaded, including the total cost involved, the source of the funding, and the manner of the disbursement of the said funds;
- 9) the post-inspection technical report of the 28th Respondent on the suitability of Kausikh Therapeutics (P) Limited to supply medical supplies;
- 10) a certified copy of the 26th and/or 27th to 35th and 36th Respondents' approval for an inspection of Kausikh Therapeutics (P) Limited's facility by the 28th Respondent;
- 11) a certified copy of the document marked <u>P11</u>;
- 12) certified copies of any and all Waivers of Registration made by the 26th and/or 27th to 35th and 36th Respondents regarding medical supplies from Savorite Pharmaceuticals (Pvt) Limited, if any;

- 13) certified copies of any and all Waivers of Registration made by the 26th and/or 27th to 35th and 36th Respondents regarding medical supplies from Kausikh Therapeutics (P) Limited, if any;
- e. 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 37th and/or 43rd and/or 45th and 46th Respondents and/or any one or more of them, and/or their servants and/or agents;
- f. declare that there is an 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 37th and/or 45th and 46th Respondents, and/or any one or more of them, and/or their servants and/or agents;
- g. declare that the purported decision and/or determination of the 1st to 22nd and/or the 25th, 36th and 37th Respondents, and/or any one or more of them, and/or their servants and/or agents, to procure medical/medicinal/pharmaceutical supplies from the 45th Respondent 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;
- h. declare that the purported decision and/or determination of the 1st to 22nd and/or the 25th, 36th and 37th Respondents, and/or any one or more of them, and/or their servants and/or agents, to procure medical/medicinal/pharmaceutical supplies from the 46th Respondent through Direct Contracting and/or on an Unsolicited Bid, without a competitive procurement process, as pleaded, 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 Respondents, and/or any one or more of them, and/or their servants and/or agents, to grant a Waiver of Registration for the said 38 medical/medicinal/pharmaceutical supplies from the 45th Respondent, as

pleaded, is wrongful, arbitrary and capricious, illegal, unlawful, null and void, and of no force or avail in law;

- j. declare that any purported decision and/or determination of the 1st to 22nd and/or the 25th, 36th and 37th Respondents, and/or any one or more of them, and/or their servants and/or agents, and/or their successors, to place any orders for the procurement of medical/medicinal/pharmaceutical supplies from the 45th and/or 46th Respondent through Direct Contracting and/or on an Unsolicited Bid, without a competitive procurement process, as pleaded, is wrongful, arbitrary and capricious, illegal, unlawful, null and void, and of no force or avail in law;
- k. declare that any decision and/or determination made by the 26th and/or 27th to 35th and/or 36th 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 38 medical/medicinal/pharmaceutical supplies from the 45th Respondent, as pleaded, is wrongful, arbitrary and capricious, illegal, unlawful, null and void, and of no force or avail in law;
- 1. declare that the importation into Sri Lanka of the said 38 medical/medicinal/pharmaceutical supplies from the 45th Respondent, as pleaded, is wrongful, arbitrary and capricious, illegal, unlawful, null and void, and of no force or avail in law;
- m. declare and direct the 43rd 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 the said 38 medical/medicinal/pharmaceutical supplies from the 45th Respondent;
- n. declare that the 1st to 22nd and/or the 25th, 36th and 37th 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 45th Respondent for the said 38 medical/medicinal/pharmaceutical supplies from the 45th Respondent, as pleaded;
- o. declare that any decision and/or determination made by the 26th and/or 27th to 35th and/or 36th 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 45th Respondent, 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;

- p. declare that any decision and/or determination made by the 26th and/or 27th to 35th and/or 36th 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 supplies from the 46th Respondent, 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;
- q. direct the 44th Respondent and/or his servants and/or agents and/or successors to take steps in terms of the law against the 27th to 36th Respondents, or any one or more of them, in accordance with the National Medicines Regulatory Authority Act, No. 5 of 2015 for the commission of any one or more of the offences provided in the said Act;
- r. direct the 38th to 41st Respondents to take steps in terms of the law, and in particular the Bribery Act, No.11 of 1954, as amended, as well as the Commission to Investigate Allegations of Bribery and Corruption Act, No.19 of 1994, as amended, against any one or more of the 1st to 22nd, 23rd, 24th, 25th, and/or 26th to 36th and/or 37th and/or the 45th and 46th Respondents and/or their servants and/or agents, in respect of the said decision and/or determination to procure medical and/or pharmaceutical supplies from the 45th and/or 46th Respondents, as pleaded;
- s. direct the 42nd Respondent to conduct an inquiry/investigation into the said decision and/or determination to procure medical and/or pharmaceutical supplies from the 45th and/or 46th Respondents, 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 such other guidelines in this regard, as deemed appropriate by Your Lordships' Court;

- u. 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, 36th and 37th Respondents, and/or any one or more of them, and/or their servants and/or agents, to procure medical/medicinal/pharmaceutical supplies from the 45th Respondent through Direct Contracting and/or on an Unsolicited Bid, as pleaded, until the final determination of this application, subject to such terms, if any, as to Your Lordships' Court sees fit;
- v. and in particular, 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, 36th and 37th Respondents, and/or any one or more of them, and/or their servants and/or agents, to procure the said 38 medical/medicinal/pharmaceutical supplies from the 45th Respondent through Direct Contracting and/or on an Unsolicited Bid, 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 any purported decision and/or determination, if any, of the 1st to 22nd and/or the 25th, 36th and 37th Respondents, and/or any one or more of them, and/or their servants and/or agents, and/or their successors, to place any orders for the procurement of medical/medicinal/pharmaceutical supplies from the 45th and/or 46th Respondent through Direct Contracting and/or on an Unsolicited Bid, without a competitive procurement process, as pleaded, 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** staying and/or suspending the purported decision and/or determination, if any, made by the 26th and/or 27th to 35th Respondents, and/or any one or more of them, and/or their servants and/or agents, to grant a Waiver of Registration for the said 38 medical/medicinal supplies from the 45th Respondent, 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 importation into Sri Lanka of the said 38 medical/medicinal supplies from the 45th Respondent, as pleaded, until the final determination of this application, subject to such terms, if any, as to Your Lordships' Court sees fit;

- z. grant and issue an **Interim Order** preventing the 43rd Respondent and/or his servants and/or agents and/or successors from permitting the importation and/or providing customs clearance and/or approving for clearance of the said 38 medical/medicinal supplies from the 45th Respondent;
- aa. grant and issue an **Interim Order** preventing the 1st to 22nd, and/or the 24th Respondent, and/or the 25th, 36th and 37th Respondents, and/or any one or more of them, and/or their servants and/or agents and/or his servants and/or agents and/or successors from making any payments to the 45th Respondent in respect the purported procurement/importation into Sri Lanka of any medical/medicinal supplies from the 45th Respondent, and in particular the said 38 medical/medicinal supplies, as pleaded, until the final determination of this application, subject to such terms, if any, as to Your Lordships' Court sees fit;
- bb. grant and issue an **Interim Order** preventing the 1st to 22nd, and/or the 24th Respondent, and/or the 25th, 36th and 37th Respondents, and/or any one or more of them, and/or their servants and/or agents and/or his servants and/or agents and/or successors from making any payments to the 46th Respondent in respect the purported procurement/importation into Sri Lanka of any medical/medicinal supplies from the 46th Respondent, until the final determination of this application, subject to such terms, if any, as to Your Lordships' Court sees fit;
 - cc. 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;

dd. grant costs; and,

ee. grant such further and other relief as to Your Lordships' Court shall seem meet.

ATTORNEY-AT-LAW FOR THE PETITIONERS