

M.S.RAMALAH FOUNDATION
RAMALAH INSTITUTE OF LEGAL STUDIES

NO.23, GOKULA Extn, M.S. Ramaiah Road, Behind
M.S. Ramaiah Memorial Hall, Bangalore- 560054



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RILS
INTER-UNIVERSITY
MOOT COURT
COMPETITION

2026

11TH TO 13TH DECEMBER 2026

MOOT
PROPOSITION

MOOT PROPOSITION

1. The Republic of Navira is a sovereign, socialist, secular and democratic republic having a federal constitutional structure, with a strong Union and constitutionally recognised spheres of legislative and executive authority for the States. Navira attained independence from colonial rule in 1950 and adopted its Constitution in the same year. At the time of independence, Navira was predominantly an agrarian economy with limited industrial, educational and healthcare infrastructure. Over the following decades, the country underwent rapid economic transformation and witnessed substantial growth in industry, services, science and technology. Navira presently comprises 25 States and 7 Union Territories and, with a population of approximately 1.4 billion, is one of the world's largest countries by population and one of its largest economies. The Gross Domestic Product of the country reached approximately USD 3.92 trillion in 2025, up from USD 3.76 trillion in 2024 and USD 3.50 trillion in 2023. During this three-year period, the country maintained a strong real GDP growth rate averaging well above 7% annually, reflecting the rapid expansion of its economy.
2. Notwithstanding its economic growth, Navira continues to be regarded as a developing country, with considerable disparities in income, infrastructure, education and access to healthcare between different regions and sections of its population. The country continues to face significant challenges in ensuring equitable access to specialised and expensive medical treatment, particularly for persons belonging to economically vulnerable sections. The Constitution of Navira places matters relating to healthcare and medical regulation within the legislative spheres of both the Union and the States.
3. At the Union level, the Government of Navira had, for several years, been examining the difficulties faced by persons suffering from rare diseases, particularly the high cost of treatment and the limited availability of specialised medical facilities. On the recommendation of the Central Technical Committee for Rare Diseases, the Union Government introduced the National Rare Disease Policy ("National Policy") in 2021, with the objective of establishing a framework for the prevention, diagnosis and treatment of rare diseases and providing financial assistance to eligible patients.
4. The National Policy identified 63 diseases as rare diseases for the purposes of the Policy and categorised them into three groups based on the nature of the disease, the availability of treatment and the extent of medical intervention required. The third

- category broadly comprised diseases requiring long-term or lifelong treatment and medical management, particularly those involving exceptionally high treatment costs.
5. Under the National Policy, one-time financial assistance of up to ₹20 lakh was initially made available to eligible patients for the treatment of rare diseases falling under Groups I and II. In cases where the rare disease required lifelong treatment and recurring medical expenditure, particularly those falling under Group III, the National Policy contemplated crowdfunding as the principal mechanism for mobilising the resources required for such treatment. The relevant portions of the National Policy are produced as **Annexure A1**.
 6. Subsequently, by an Office Memorandum dated 30.08.2022, the Union Government revised the financial assistance available under the National Policy. The maximum one-time financial assistance available under the National Policy was increased from ₹20 lakh to ₹50 lakh per eligible patient. The revised limit was extended to patients suffering from diseases falling within all three categories identified under the National Policy. The Office Memorandum is produced as **Annexure A2**.
 7. The State of Malaya is among the more economically developed States of Navira. The State has historically maintained high levels of literacy and human development and has made substantial investments in public healthcare, education and social welfare. Successive Governments of Malaya have regarded public healthcare as an important component of the State's welfare policy and have consistently increased expenditure on healthcare and social protection.
 8. On 10.02.2021, the Government of Malaya constituted an Expert Committee to examine the manner in which the State could provide sustained financial assistance for the treatment of rare diseases. Following the recommendations of the Committee, on 15.08.2023, the State established a dedicated programme known as the "Malaya Rare Disease Assistance Programme" ("MRDAP") and created a Rare Disease Corpus for the purposes of the Programme. The Corpus was initially constituted through a budgetary contribution of ₹15 crore by the State Government, supplemented by a crowdfunding protocol introduced by the Government.
 9. Following the introduction of the MRDAP, children between the ages of 1 and 12 years suffering from specified rare diseases have been receiving treatment under the Programme without charge at designated Government hospitals across the State. The MRDAP was introduced in addition to the National Rare Disease Policy with the object of providing enhanced support to patients, particularly children, suffering from rare

diseases within the State. As of August 2026, 103 patients are receiving treatment under the Programme, and Drug "Spinoza", manufactured by Madlabs Pvt. Ltd. and priced at ₹5 lakh per vial, is being administered to eligible patients for whom the drug has been prescribed.

10. The State of Aruna is comparatively less economically developed than Malaya. A substantial portion of its population resides in rural and geographically difficult areas, and specialised medical facilities are concentrated largely in a limited number of urban centres. Although the State has made considerable progress in expanding its public healthcare infrastructure since independence, its fiscal capacity remains comparatively limited. The State has not established a dedicated programme or corpus for the treatment of rare diseases comparable to the Malaya Rare Disease Assistance Programme. Consequently, patients suffering from rare diseases within the State are dependent primarily upon the financial assistance available under the National Rare Disease Policy, 2021.
11. In March 2024, Aadhya, a two-year-old girl residing with her parents in the State of Aruna, was brought to a Government District Hospital with complaints of progressive weakness of the limbs, difficulty in sitting without support and frequent respiratory infections. Upon clinical examination, the child was diagnosed with Spinal Muscular Atrophy Type II ("SMA-II"), a rare genetic disorder characterised by progressive weakening of the muscles, which may substantially impair motor and respiratory functions and, if left untreated, may ultimately be fatal.
12. The treating doctors recommended treatment with Drug "Spinoza" and Aadhya was medically advised to undergo treatment requiring 10 vials every three months. The cost of treatment was therefore approximately ₹50 lakh every three months and ₹2 crore annually. Mr. Arun Kumar had applied for financial assistance under the National Policy, 2021 and an amount of ₹50 lakh was sanctioned under the Policy, which was sufficient only for the first three months of treatment.
13. Aggrieved by the inability of the State and the Union Government to provide continued treatment beyond the assistance of ₹50 lakh, Mr. Arun Kumar had preferred a Writ Petition as W.P.(C) No. 67 of 2026 before the Hon'ble High Court of Aruna, inter alia, seeking the issuance of a Writ of Mandamus directing the Union Government and the Government of Aruna to provide the requisite treatment to Aadhya free of cost for as long as medically required. The Petitioner had also challenged the upper limit of ₹50 lakh prescribed under the National Rare Disease Policy, contending that the ceiling was

arbitrary and incapable of securing meaningful access to treatment for children suffering from rare diseases requiring lifelong or recurring treatment.

14. The Union Government and the Government of Aruna filed their respective Counter Affidavits, contending that the financial assistance under the National Policy was a policy measure subject to the availability of public resources and that no individual could claim an enforceable right to treatment beyond the maximum assistance prescribed under the Policy. It was further contended that the decision to prescribe a financial ceiling involved complex questions of public health priorities, resource allocation and economic policy, in which judicial interference ought to be limited.
15. The High Court of Aruna, after considering the submissions of the parties, dismissed the Writ Petition by Judgment dated 17-08-2026. The Court held that *“the financial assistance under the National Rare Disease Policy was a matter of governmental policy and that the prescription of an upper limit could not be interfered with merely on the ground that the cost of treatment exceeded the assistance available under the Policy.”* The High Court further held that *“the determination of the amount of financial assistance to be provided under the Policy was a matter for the Government, having regard to the resources available to it and the competing demands upon public funds.”*
16. Aggrieved by the dismissal of the Writ Petition, the Petitioner has preferred a Special Leave Petition before the Supreme Court of Navira as SLP (Civil) No. 5885 of 2026, contending that the High Court failed to properly appreciate the constitutional obligations of the Union and the State towards ensuring access to essential medical treatment and erred in upholding the financial ceiling prescribed under the National Rare Disease Policy. The Union Government and the Government of Aruna have filed their respective Counter Affidavits, reiterating the stand adopted before the High Court. The matter now stands posted for final hearing.
17. In October 2025, HOLAR Pvt. Ltd., a pharmaceutical company incorporated in Navira, introduced a generic version of Drug "Spinoza", hereinafter referred to as "Spinoza-G". HOLAR claimed that Spinoza-G was therapeutically equivalent to Spinoza and had developed its own formulation and manufacturing process for Spinoza-G. The Central Drugs Standards Control Authority ("CDSC"), the regulatory authority responsible for the approval and regulation of pharmaceutical products in Navira, granted approval for the manufacture and marketing of Spinoza-G. While a vial of Spinoza manufactured by Madlabs Pvt. Ltd. costs ₹5 lakh, a vial of Spinoza-G was priced at approximately ₹15,000. The substantial difference in price attracted the attention of the Government

of Malaya, particularly in view of the increasing number of children requiring treatment.

18. The Government of Malaya referred the matter to the Technical Committee constituted under the MRDAP to examine whether Spinoza-G could be procured and administered to patients receiving treatment under the Programme. The Committee observed that the substantially lower cost of Spinoza-G would enable the State to utilise the funds available under the MRDAP for treating a significantly larger number of children suffering from rare diseases and thus recommended the State to replace Spinoza with Spinoza-G for patients receiving treatment under the Programme.
19. The parents of all the children presently receiving Spinoza submitted representations before the Government of Malaya, contending that the approval granted by the CDSC did not establish that Spinoza-G was therapeutically equivalent to Spinoza for children who were already receiving and responding to Spinoza. They further contended that no adequate bio-efficacy and therapeutic efficacy studies had been conducted to assess the consequences of switching children from Spinoza to Spinoza-G and that the possible clinical impact of such a switch had not been adequately examined. The parents requested that children who were already receiving Spinoza under the MRDAP should be permitted to continue with the existing treatment pending comprehensive studies on the bio-equivalence and therapeutic efficacy of Spinoza-G, particularly in view of the fact that the generic drug had only recently been introduced into the market and that limited research material was available regarding its use in children and other patients already undergoing treatment with Spinoza.
20. On 15.07.2026, the Government of Malaya issued a Government Order deciding to procure Spinoza-G for the purposes of the Malaya Rare Disease Assistance Programme and to administer the same to patients receiving treatment under the Programme. It was stated that the procurement of Spinoza-G, being substantially less expensive than Spinoza, would enable the State to utilise the funds available under the MRDAP to provide treatment to a larger number of eligible patients. A copy of the Government Order is produced as **Annexure-A3**.
21. Aggrieved by the Government Order dated 15.07.2026, the parents of the affected children formed an unregistered association under the name "Parents United" and approached the High Court of Malaya by filing a Writ Petition as W.P.(C) No. 1212 of 2026. The Petitioners challenged the decision to substitute Spinoza-G for Spinoza in respect of children who were already receiving treatment under the MRDAP. They

contended that the decision was taken without examining the safety and therapeutic consequences of switching them from Spinoza to Spinoza-G. It was further contended that the mere approval of Spinoza-G by the CDSC could not, by itself, justify its compulsory substitution for a drug with which the children were already receiving treatment.

22. The Government of Malaya filed a Counter Affidavit defending the Government Order. It contended that Spinoza-G had been duly approved by the CDSC for the treatment of the relevant disease and that the State was entitled to determine the medicine to be procured under a publicly funded healthcare programme. It was further contended that the substantially lower cost of Spinoza-G would enable the State to extend the benefits of the MRDAP to a larger number of children and that requiring the State to continue procuring the more expensive Spinoza for existing patients would substantially restrict the number of beneficiaries under the Programme.
23. The High Court of Malaya, after considering the submissions of the parties, was pleased to allow the Writ Petition by Judgment dated 17-07-2026. The Hon'ble High Court held that *"the decision to procure and administer Spinoza-G was based substantially upon the recommendations of the Technical Committee and was taken without conducting adequate bio-equivalence or therapeutic efficacy studies to examine the consequences of switching children who were already undergoing treatment with Spinoza. The compulsory substitution of the existing treatment solely on considerations of cost, without an adequate assessment of the individual medical circumstances of the affected children and the possible clinical consequences of such substitution, was arbitrary and violative of Articles 14 and 21 of the Constitution of Navira."*
24. Aggrieved by the Judgment allowing the Writ Petition, the State of Malaya has preferred a Special Leave Petition before the Supreme Court of Navira as SLP (Civil) No. 55 of 2026, contending that the High Court was not justified in interfering with a technical decision taken on the basis of expert opinion and that it erred in substituting its own view for that of the competent expert bodies in matters requiring specialised medical and technical assessment. The Respondents in the Special Leave Petition have filed their Counter Affidavits, reiterating the stand taken before the High Court.
25. The Special Leave Petition arising from the Judgment of the High Court of Aruna, being SLP (Civil) No. 5885 of 2026, and the Special Leave Petition arising from the Judgment of the High Court of Malaya, being SLP (Civil) No. 55 of 2026, were subsequently tagged together by the Supreme Court of Navira. The matters were thereafter listed for

final hearing on 15.08.2026 before a Bench comprising the Chief Justice of Navira and two other Judges. At the commencement of the hearing, the Chief Justice disclosed that his son was employed as a Senior Marketing Officer with HOLAR Pvt. Ltd., the manufacturer of Spinoza-G. In view of the said relationship, the Chief Justice recused himself from hearing the matters. The Chief Justice thereafter constituted a fresh Bench comprising three other Judges of the Supreme Court and directed that the matters be listed before the newly constituted Bench on 16.08.2026.

26. Aggrieved by the constitution of a fresh Bench by the Hon'ble Chief Justice, the Respondents in SLP (Civil) No. 55 of 2026 filed an Interlocutory Application before the Supreme Court, contending that once the Chief Justice had recused himself from the matters, he ought not to have proceeded to constitute the Bench which was to hear them. The Respondents sought appropriate directions for the constitution of the Bench by an authority other than the Hon'ble Chief Justice, who had recused himself from hearing the matters.
27. The Union Government and the Government of Malaya filed their respective Counter Affidavits to the Interlocutory Application, contending that the Chief Justice, notwithstanding his recusal from hearing the matters, was competent to constitute the Bench in his administrative capacity as Chief Justice. It was further contended that the recusal was limited to the judicial hearing of the matters and did not affect his administrative authority to constitute Benches in accordance with the applicable practice of the Supreme Court.
28. The matters are presently before the Supreme Court of Navira for final hearing. The Court has agreed to determine, as a preliminary issue, the validity of the constitution of the Bench following the recusal of the Chief Justice. The remaining issues concerning the challenge to the National Rare Disease Policy and the Government Order dated 15.07.2026 relating to the procurement and administration of Spinoza-G shall be considered thereafter.

Note: For the purposes of the present Moot Proposition, the Constitution and laws of the Republic of Navira shall be construed as being *pari materia* with the Constitution and laws of India, unless otherwise expressly stated herein.

Annexure-A1

NATIONAL POLICY ON RARE DISEASES, 2021

1. Background

Rare diseases constitute a complex and heterogeneous group of conditions, many of which are chronic, debilitating and potentially life-threatening. The absence of adequate epidemiological data, limited clinical expertise, difficulties in diagnosis and the high cost of available therapies pose significant challenges to the formulation and implementation of a comprehensive policy framework.

2. Challenges relating to Rare Diseases

The diagnosis and treatment of rare diseases present several challenges. Owing to limited awareness, inadequate diagnostic facilities and the small number of affected persons, many rare diseases remain undiagnosed or are diagnosed only after considerable delay. Further, effective treatment is unavailable for several such conditions. Even where definitive therapies are available, they are often prohibitively expensive and may require lifelong administration. The high cost of treatment, coupled with the limited number of patients affected by each individual condition, creates substantial challenges in ensuring equitable and sustainable access to treatment.

3. Balancing Competing Public Health Priorities

The formulation of policy relating to rare diseases must take into account the constraints on available public resources and the competing healthcare needs of the population. While the needs of persons suffering from rare diseases require recognition and support, public health resources must be allocated in a manner that seeks to achieve the greatest possible overall health benefit while also ensuring equitable access to healthcare.

Accordingly, decisions relating to the funding and prioritisation of high-cost treatments must balance the interests of individual patients against the broader healthcare requirements of the population and the need to ensure the judicious utilisation of limited public resources.

4. Classification of Rare Diseases

For the purposes of this Policy, rare diseases shall be broadly classified into the following groups:

Group I: Disorders amenable to one-time curative treatment, including conditions for which treatment through procedures such as transplantation or other definitive interventions may provide a long-term cure.

Group II: Disorders requiring long-term or lifelong treatment, where the cost of therapy is relatively lower and the benefits of treatment are supported by established clinical evidence. Such conditions may require special dietary interventions, nutritional formulations, hormonal therapy or other specific medicines, together with periodic medical monitoring.

Group III: Disorders for which definitive or disease-specific treatment is available, but which present significant challenges owing to the exceptionally high cost of therapy, the need for lifelong treatment, and the necessity of careful patient selection to ensure meaningful clinical benefit. In certain conditions, sufficient evidence may exist regarding long-term treatment outcomes, whereas, in others, the available evidence may be limited or based on relatively short-term studies.

5. Treatment of Group I and II Disorders

The Government shall provide one-time financial assistance of up to ₹20 lakh per patient for the treatment of rare diseases falling under Groups I and II, subject to such eligibility criteria and conditions as may be prescribed.

6. Treatment of Group III Disorders

Treatment of diseases falling within Group III shall be considered having regard to the clinical condition of the patient, the likely therapeutic benefit, the available scientific evidence, and the financial implications of long-term treatment.

Given the exceptionally high cost associated with such therapies and the competing demands on limited public health resources, it may not always be feasible for the Government to provide complete financial assistance for all patients requiring treatment under this category. The

Government may therefore facilitate alternative mechanisms for raising and mobilising financial resources, including contributions from individuals, charitable institutions and corporate entities.

Hospitals and specialised treatment centres may provide appropriate information regarding eligible patients, the nature of their condition and the estimated cost of treatment through such mechanisms, subject to applicable safeguards. Funds received for a particular patient shall ordinarily be utilised towards that patient's treatment.

Annexure-A2

Dated: 30-08-2022

OFFICE MEMORANDUM

The undersigned is directed to state that the provision contained in Paragraph 5 of the National Policy on Rare Diseases, 2021 shall stand substituted by the following:

“The Government shall provide one-time financial assistance of up to ₹50 lakh per patient for the treatment of rare diseases falling under all three categories of Rare Diseases, subject to such eligibility criteria and conditions as may be prescribed.”

All other provisions of the Policy shall remain unchanged.

The above amendment shall come into effect from the date of issue of this Office Memorandum.

**Under Secretary to the
Government of Navira**

Annexure-A3

GOVERNMENT OF MALAYA

Dated 15-07-2026

Health and Family Welfare Department – Treatment of patients suffering from Spinal Muscular Atrophy under the Malaya Rare Disease Assistance Programme – Procurement of the CDSC-approved generic formulation of Drug “Spinoza” manufactured by HOLAR Pvt. Ltd. – Sanction accorded – Orders issued.

HEALTH AND FAMILY WELFARE (FW) DEPARTMENT

Read:

1. Recommendations of the Technical Committee constituted under the MRDAP

ORDER

The State Mission Director, National Health Mission (NHM), Malaya, reported that the management of Spinal Muscular Atrophy (SMA) under the Malaya Rare Disease Assistance Programme aims to provide uninterrupted access to Drug “Spinoza”, which is prescribed for affected children. The existing stock of the drug was reported to be insufficient to sustain treatment in the coming months.

At present, HOLAR Pvt. Ltd. has been granted approval by the Central Drugs Standards Control Authority (CDSC) to manufacture and market a generic formulation of Drug “Spinoza”, namely “Spinoza-G”. The cost of Spinoza-G is substantially lower than that of Spinoza. Accordingly, the State Mission Director proposed that the CDSC-approved generic formulation be procured under the Malaya Rare Disease Assistance Programme to enable treatment to be provided to a larger number of eligible beneficiaries.

The matter was discussed in detail by the Technical Committee. The Technical Committee considered the proposal and noted that Spinoza-G, manufactured by HOLAR Pvt. Ltd., had been approved by the Central Drugs Standards Control Authority for manufacture and marketing in Navira. The Committee further noted the substantial difference in cost between

Spinoza and Spinoza-G and recommended the procurement of Spinoza-G for use under the Malaya Rare Disease Assistance Programme.

Government have examined the matter and, based on the proposal of the State Mission Director, National Health Mission and the recommendations of the Technical Committee, sanction is accorded for the procurement of the CDSC-approved generic formulation “Spinoza-G”, manufactured by HOLAR Pvt. Ltd., for beneficiaries under the Malaya Rare Disease Assistance Programme.

(By order of the Governor)

ADDITIONAL SECRETARY