



Rare Disease Policy: Provisions to Enable Institutional Donations

**Recommendations of Roundtable Discussion held on
March 25, 2022, 1200-1.30 PM IST**

Rare Disease Policy: Provisions to Enable Institutional Donations

As the incidence rate of rare diseases is small, it has often failed to catch the necessary attention. India, however, has a dedicated National Policy for Rare Diseases, allocated funding to strengthen Centres of Excellences (CoEs), financial support to those patients that require one time support and a digital portal to enable¹ sustainable flow of funds for those under Group 3 of rare diseases that require high-cost treatment support.

Estimates in India suggest that there might be 72 to 96 million patients with a rare disease². To address this large patient cohort, the National Policy for Rare Diseases was envisaged to enable early detection and prevention of such births, enhanced standard of care, financial support, and provisions for fund generation to ensure sustainable flow of funds.

The policy provides financial support to those patients belonging to Group I and Group II, with provisions for sustainable flow of funds in place for Group III through the digital portal, a crowd funding platform, to fulfil the needs of costly therapies and life-long support. The platform currently has 275 registered patients with over INR 120,000 in donations received³ thus far. Under the policy, eight Centres of Excellences (CoEs) have been notified with fund allocation for infrastructure development, and patient care services for screening, diagnosis and prevention of rare diseases. The portal is linked to these eight CoEs for uploading data of eligible patients and generate funds through crowdsourcing for treatment of the patients

Even with all the existing provisions, there are gaps preventing the flow of funds towards rare disease patients. US India Strategic Partnership Forum (USISPF) organized a roundtable to help build awareness towards funding rare disease patients, to discuss the enablers/barriers faced by institutional donors/ corporates in allocating CSR funds to rare disease and support the Government of India's efforts to achieve another milestone in its commitment towards rare disease patients.

With the participation of key stakeholders such as CoEs, Patient Support Groups, Donors, CSR experts, and Ministry of Health and Family Welfare, this discussion focused around the following questions:

- What are the challenges associated with receiving CSR funds to aid the treatment of rare disease patients?
- How can we address the apprehensions/challenges faced by corporates towards donating to rare disease patients?
- What are the challenges faced as Centres of Excellences for raising the funds for the enrolled patients?
- What are the hinderances that are blocking the potential support from PSUs to CoE for RD treatment despite of the stated provision of crowdfunding in the National Policy for Rare Disease? How do we ensure the sustainable flow of funds towards patients?

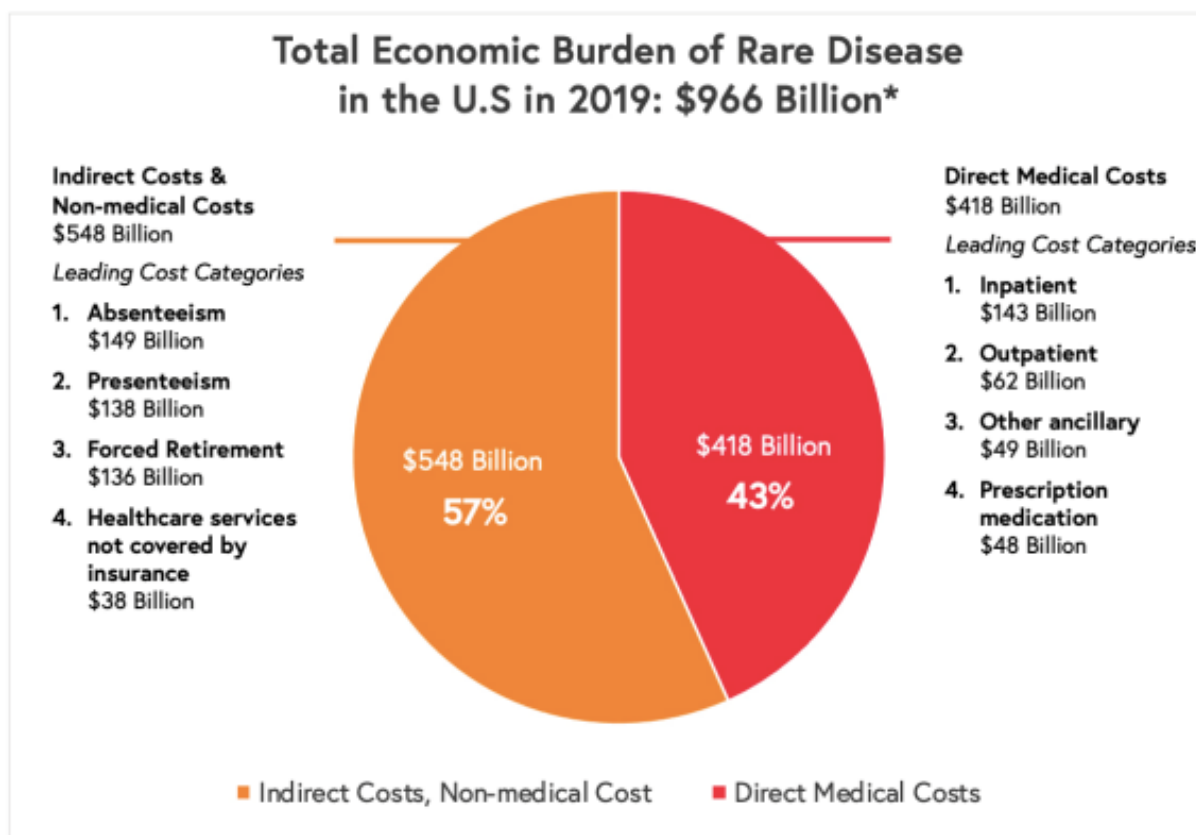
¹ <https://rarediseases.nhp.gov.in/>

² <https://main.mohfw.gov.in/sites/default/files/Rare%20Diseases%20Policy%20FINAL.pdf>

Challenges Associated with CSR Funding

Corporates, foundations, and Public Sector Units (PSUs) lack the necessary awareness on rare diseases, its associated policies, the digital portal created by the government to mobilize funding, and the need to provide funding. Even if awareness of the existing policy and its provisions exists, there is a disconnect in understanding the extent of the total economic burden of rare diseases.

Data around the total economic burden of rare disease in India is limited, international evidence from the US in 2019 suggests the total economic burden of rare disease is USD 966 billion⁴, with indirect costs and non-medical costs amounting to USD 548 billion. The cost of rare disease prescription medication overall is USD 48 million.



Source: Lewin analyses of RD prevalence calculated from the 2018 dNHI claims, 2019 Medicare SAF 5% sample claims, and 2016 Medicaid claims combined with the Census population projection for 2019; direct medical cost estimates obtained using 2018 dNHI claims, 2019 Medicare SAF 5% sample claims, and 2016 Medicaid claims; indirect and non-medical costs estimated using Lewin's analyses of the RD Impact Survey data.

The indirect-costs and non-medical costs inclusive of costs associated with absenteeism, forced retirement and healthcare services not covered by insurance highlights the need to raise awareness at the corporate/PSU board level to mobilize funds towards rare diseases.

⁴ https://everylifefoundation.org/wp-content/uploads/2021/02/The_National_Economic_Burden_of_Rare_Disease_Study_Summary_Report_February_2021.pdf

Additionally, there is a lack of awareness and apprehensions among donors of the existing CSR policy that allows for the treatment of patients with rare diseases. Schedule VII of the CSR act states that “Activities which may be included by companies in their Corporate Social Responsibility Policies Activities relating to: eradicating hunger, poverty and malnutrition, promoting health care including preventive health care and sanitation including contribution to the Swach Bharat Kosh set-up by the Central Government for the promotion of sanitation] and making available safe drinking water⁵.” Due to the specific mention of “promoting healthcare including preventive health care,” donors may not have known that funding towards treatment of diseases including rare diseases was allowed, therefore, measures need to be taken to help rectify this apprehension that may exist.

Although the digital portal is linked to the CoEs who treat patients, there is a perception in the mindset of donors owing to the credibility (or lack of) to treat patients by providing funding through a portal. It is necessary that the Government highlights explicitly that this portal is linked to the notified CoEs to help boost confidence and to rid of any apprehensions among donors.

When addressing aspects of funding using CSR, it is important to note; CSR funders primarily look for number of lives benefited by a given intervention. Rare diseases do not fall under this category as they may have less numbers being benefited, leading to less visibility or lack of immediate impact. This also effects the monitoring criteria when drafting a proposal.

While defining a project, it is necessary that progress indicators be elucidated. Unlike other healthcare projects, creating metrics for evaluation progress of CSR interventions in rare diseases is extremely difficult. Therefore, is it possible for the government or an independent body to create metrics to evaluate and monitor the progress of rare disease patients that is accepted under the regulatory requirements of CSR Act. If such a metric is created and clarity is provided on regulatory fulfillments, it will enable customization of proposals to suit CSR funding needs and requirements.

Enabling the Funding of Rare Diseases

If the above-mentioned apprehensions/lack of awareness currently exist among corporates, CSR Policy - it can be rectified by including rare diseases as part Schedule VII of CSR, as part of healthcare and prevention. By notifying it under Schedule VII, it improves the ease of receiving funds from PSUs as direct provision of funds from PSUs can be received.

Alternatively, apprehension can also be addressed through a joint letter with a directive or request written to Chief Managing Directors of PSUs from Ministry of Health and Family Welfare, Ministry of Corporate Affairs and Department of Public Enterprises. This letter should provide a background of rare diseases, the CoEs that are currently recognized, the policy, the portal and the funding requirement. This will help streamline the process of funding.

The National Policy for Rare Disease 2021 specifies funding support from PSUs & Corporates under the CSR provision basis Schedule VII of Companies Act 2013. It is important and interesting to note a couple of developments in this context:

⁵ <https://www.mca.gov.in/content/mca/global/en/acts-rules/ebooks/acts.html?act=NTk2MQ==>

- a. In 2014, the Ministry of Corporate Affairs (MoCA) had filed a letter on 24th March 2014 before the Delhi High Court submitting that Schedule VII of the Companies Act will encompass the entire health care area including the treatment of rare diseases⁶. This was highlighted in the case Mohd. Ahmed (Minor) vs Union of India & Ors. On 17 April 2014⁷.
- b. In 2021, in the affidavit submitted by Union of India, MoHFW to the Supreme Court, it is clearly mentioned that the MoCA in their letter dated 28/08/2021 had mentioned that companies can undertake activities related to treatment of patients suffering from rare diseases as per schedule VII of Companies act⁸.

Therefore, the provisions under Schedule VII are already in place. It is now a matter of sensitizing the industry and mobilizing funds through the existing platforms. To help mobilize funds, the MoHFW needs to work alongside industry associations to leverage their members and their CSR leaders to help spread awareness about rare diseases, the associated policies and the existing provisions to enable large scale funding. Stakeholders across industries need to be brought together through a directive by the Government of India to enable large scale sensitization.

Challenges and Solutions in Sourcing Funds

As the process is new to the eight notified Centres of Excellences (CoEs), the Standard Operating Procedures (SoPs) for CSR funding for both donors and recipients are still being defined. Each CoE may have their own CSR cell along with their own CSR rules. These rules vary between the eight CoEs. As most funding via CSR is devolved through project modes, drafting relevant proposals becomes an important criterion. Donors also have their own formats through which proposals are written, and CoEs may not have expertise and bandwidth to write proposals that are aligned to the needs of corporates and PSUs, as their expertise lie in the clinical treatment of patients.

This can be solved by having intermediaries such as NGOs who have the relevant expertise and technical know-how to act as a link between CoEs and PSUs/Corporates. The NGO becomes the implementing agency while the projects will be implemented through the CoEs. Another solution is to create ready-made templates of proposals. Each CoE can then customize it depending on the need.

The Ministry of Health and Family Welfare (MoHFW) has prior experience with deploying technical resource units in their various departments to enhance outreach and bring techno-managerial skills to build efficiency. These technical units can be created and utilized to address challenges that are associated with rare diseases on the same lines as those under the National Aids Control Organization (NACO) that have been created for multiple areas of work such as research and evaluation, pediatric HIV care, lab services, anti-retroviral therapy, HIV surveillance and estimation, and so forth⁹. TRUs can be established for various activities of rare diseases such as raising awareness, writing proposals, mobilizing funds, and addressing concerns of different diseases that fall under rare diseases to help families.

⁶ Annexure I

⁷ <https://indiankanoon.org/doc/77985236/>

⁸ Annexure I

⁹ <http://naco.gov.in/technical-resource-group>

Currently, the digital portal is aligned towards receiving funds from individual donors rather than institutional donors. As a general practice, donors receive long term project proposals seeking CSR funding. Donations as a corpus through the portal supporting individual cases are not common practice in CSR or PSUs. Therefore, changes need to be made in portal help facilitate institutional donations through the existing portal. Such requirements could be collected from PSUs and CSR to build the workflows and features in digital platform.

The digital portal can also be used as an enabler for this dialogue. The portal can be used for uploading proposals and receiving responses for the same. CSR/PSUs that are willing to provide funds can put their expression of interest on the portals, which list out the criteria's that need to be met, and templates filled in accordingly. This will help in understanding the various mechanisms, formats and administrative issues for institutional donors to donate.

Additionally, for rare diseases, it is necessary to create a mechanism that allows funding to be directly sourced to the CoEs, rather than routing it through the portal. This is a feature that needs to be contemplated by MoHFW to understand the benefits and drawbacks associated with directly routing funds

Addressing the Concern of Sustainability

To help address the concern of generating a sustainable flow of funds it is necessary that while designing a Memorandum of Undertaking between institutional donors and receiving agencies, the agreement should be structured by incorporating a sustainable model where patients are treated to a point until medically feasible. This can be achieved by creating a mechanism through which pooling of funds from different PSUs is an option for bigger projects. Additionally, creating a fund that is notified under schedule VII provides the most viable option as it allows stakeholders to continue donating funds.

CSR projects accepted by a PSU have a maximum funding cycle of three years and need to be renewed for continuity, therefore; in order to reduce dependence on a single entity, pooling of funds from various sources can help ensure sustained treatment for a longer period of time. This will be most beneficial to Group III patients.

There are multiple areas of concerns that stakeholders need to be sensitized about along with relevant information that address most of the queries and challenges associated with rare diseases, the policy and provisions for funding. Therefore, it is necessary that a Frequently Asked Questions (FAQ) page be uploaded on the website and revised periodically. This will help make the process more efficient.

There are three key recommendations to help summarize the report. These are:

- Notification to all CSR organisations to allocate funding towards rare diseases.
- Strengthen the crowd funding platform by providing provisions for proposal submission and access of information about CSR funding allocated by CSR organisations.
- Set up a National Support Unit to facilitate collaboration and fund mobilisation.

As rare diseases are constantly evolving, concerted efforts are required from all stakeholders from the government, academia, industry, civil society, and patient groups to work collaboratively towards creating a mechanism that will allow for the sustainable flow of funds to all rare disease patients in India.

Annexure I

iv. Voluntary crowd-funding for treatment

difficult for the Government to **fully finance treatment** of high cost rare diseases.

The gap can however be filled by creating a digital platform for bringing together

Mohd. Ahmed (Minor) vs Union Of India & Ors. on 17 April, 2014
Delhi High Court
Mohd. Ahmed (Minor) vs Union Of India & Ors. on 17 April, 2014
Author: Manmohan


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* IN THE HIGH COURT OF DELHI AT NEW DELHI
* W.P. (C) 7279/2013
MOHD. AHMED (MINOR)
Through
versus
UNION OF INDIA & ORS.

..... Petitioner
Mr. Ashok Aggarwal, Advocate with
Ms. Kusum Sharma, Advocate.
..... Respondents


76. The Ministry of Corporate Affairs filed a letter dated 24 th March, 2014 before this Court stating "Ministry of Corporate Affairs has decided to amend the Schedule VII of the Companies Act, 2013 to bring in clarity regarding the ambit of 'promoting preventive health care' as included in the said Schedule. It has been decided to amend the said item in Schedule VII as follows: **promoting health care including preventive health care**. This would encompass the entire health care area, including **the treatment of diseases etc.**"

- Ministry of Corporate affairs submission to Delhi High Court clearly establishes support for treatment of diseases as legitimate CSR contribution by Public Sector Undertakings and Corporates.

<p>2. Organization of conference to motivate companies for CSR funding</p>	<p>Ministry of Corporate Affairs/ MoHFW</p>	<p>Conference was organised on 17.06.2021 and the participants were sensitized about the Policy and were motivated to donate generously under CSR(Rules). The Ministry of Corporate Affairs vide letter dated 27.08.2021 had inter alia stated that Schedule VII includes promoting healthcare including preventive healthcare and under this head, the companies can undertake activities related to treatment of patients suffering from rare diseases subject to compliance of the provisions of CSR rules and guidelines issued thereunder from time to time. They informed that a total amount of Rs. 16,702 crores has been spent by the companies under the head healthcare, which is approximately 18% of the total CSR expenditure incurred. The Ministry of Corporate Affairs also informed that Section 181 of the Act enables a company to contribute to bonafide and charitable funds, subject to</p>
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Seal of the Oath Commission, Delhi High Court
No. 12-04-2823



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Acknowledgments

List of Speakers at the USISPF Virtual Roundtable “Rare Disease Policy: Provisions to Enable Institutional Donations”

- **Ms. Roli Singh**, Additional Secretary, Ministry of Health and Family Welfare, Government of India
- **Dr. L. Swasticharan**, Additional Deputy Director-General, Ministry of Health and Family Welfare, Government of India
- **Professor Madhulika Kabra**, Professor, Division of Genetics, Department of Pediatrics, All India Institute of Medical Sciences, New Delhi, India
- **Mr. Ajeet Kumar Sharma**, Additional General Manager, Bharat Heavy Electricals Limited
- **Dr. Ratna Devi**, CEO, and Co-Founder of DakshamA Health & Board Chair, International Alliance for Patient’s Organization
- **Dr. Pramod Kumar Sinha**, Senior Advisor, Development Sectors
- **Mr. Nixon Joseph**, CEO, Children’s LoveCastles Trust India
- **Dr. Rajen Ghadiok**, Senior Advisor, Dua Consulting
- **Dr. Chitra Gupta**, Senior Director Healthcare, US India Strategic Partnership Forum

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