RIGHT TO HEALTH IN CASE OF ‘RARE DISEASES’: A CALL FOR CSR INITIATIVES

PALLAVI LAKHERA[1], HARSH BHARDWAJ[2], MR. SUNNY[3], RAJSHREE CHOURASIA[4] REKHA TEWATHIA[5], SUMANTA SARKAR[6]

Assistant Professor, School of Law and Public Policy, Avantika University, Ujjain (M.P.), India[1]
LL.M from Campus Law Center, Delhi University, India[2]
Advocate, Delhi High Court, India[3]
LL.B from Law Center I, Delhi University, India [4]
Assistant Manager, MHNN Consulting, Gurgaon (Delhi NCR), India[5]
LL.M from Faculty of Law, Banaras Hindu University,Varanasi (U.P.), India[6]
Email[1]- pallavi.lakhera@avantika.edu.in[1], Email[2]- bhardwajharsh119@gmail.com[2], Email[3]- advsunnykhatri@gmail.com, Email[4]- rajshreechourasia4@gmail.com[4], Email[5]- Tewathia4@gmail.com[5], Email[6]- sarkarsm@gmail.com
(Corresponding Author): Pallavi Lakhera
pallavilakhera26@gmail.com

***Abstract* – *Despite the government's steadily expanding support to healthcare, the issue of Rare Diseases remained mostly ignored for a long period. Subsidized pharmaceuticals for the treatment of patients suffering from rare diseases were likewise uncommon. These subsidies are critical for residents suffering from rare diseases, as the bulk of these patients come from economically disadvantaged backgrounds. Since a very long time a type of conflict was happening ahead of Indian courts finding government's notice and fiscal participation towards these 'Rare Diseases'. India has one of the lowest levels of public health financing on the globe, with the country's public health care system receiving only 1.26 percent of total GDP. The lacking support in political figures, for example a total absence of any form of law on rare diseases was voiced for first time in 2016 when the Delhi High Court mandated Health Ministry to develop a 'National Rare Disease Policy'. Furthermore, corporations should seize this chance to work with the government to improve the identification and treatment of rare diseases. This paper describes the topic of rare diseases and CSR activities that might be developed to guarantee that every Indian citizen has the right to health as mandated by Article 21 of Indian Constitution.*

Keywords: *Rare Diseases; Right to Health; Healthcare; CSR; Right to Life, Article 21, Corporate Social Responsibility*

INTRODUCTION

The health industry plays an important role in the economy of any country, developing and developed nations alike. However, several states have ignored or failed that this issue of developing genetic disorders and thus, extensive research is still required to cancel them. In certain countries such as the united states, nearly 17 percent of their GDP has been spent on medical care. These statistics appear to be compliant with all epic American market, allowing states with similarly sized markets to devote equal levels on medical improvement. Like a developing country, India had a budget of Rs.1900 Crores in 2019-20 for clinical research, which appears strikingly disproportionate to the health needs in excess of 135 crore population. India is among the states having the lowest public health funding on the planet, with public healthcare system in the country merely getting 1.26 percent of their complete GDP. In 2017 the Indian government implemented a plan directed towards fixing the dire need of research in genetic diseases and help with patients suffering from such rare diseases.

As the name suggests, very few people suffer from these diseases within a population. Whatever might be the causation of a disease, the mission of governments of various countries has been that no one is left behind when it comes to saving lives. The World Health Organization (WHO) Sustainable Development Goal 3 emphasizes on a vision of inclusive healthcare access. ‘Just because a disease affects a small number of people does not make it irrelevant or less important than diseases that affect millions'.

Despite the steady increasing government support to medical research, this industry i.e. Rare Disease Research, was neglected for a protracted period of time. Subsidized drugs for treatment of patients affected by rare diseases were uncommon. All these subsidies are necessary for citizens suffering from rare disorder, as majority of such patients are from economically backward strata. The concentration of wealth in the hands of a few in India, has led in several citizens falling beneath a bracket of financial deprivation. This pattern further extends itself in to the rarity of these diseases and the intermittent nature of these own impact. Just like genetic diseases, it's scientifically impossible to earth hereditary anomalies to a specific way of life, thereby affecting a larger diaspora of the population.

'Rare' or 'Orphan' ailments have received scant consideration to the public domain ; even more so in the current scenario owing to the pandemic. Treatment for these ailments, exactly in which obtainable, are usually pricey and recurring, making it unaffordable for most. Budget for these infections is provided from the government through Rashtriya Arogya Nidhi (RAN). In the monsoon session of Parliament, a question on finance allocation and utilisation of the capital under RAN had been raised. Budgets assigned for the component(RAN) for 2018-19 and also 2019-20 were 7.5 crore and 25 crore Rupees respectively. However, zero resources were released in 2018-19 while Rupees 1.5 crore was released in 2019-20.

A major repeated issue is that, various nations have a tendency to forget is the issue of Rare illnesses. During the last century, even several countries like USA, Japan and Russia have diverted their resources and laws towards battling rare-diseases. India has just recently begun spending heed for this problem. The missing support in political figures, for example a complete lacuna of any sort of law on rare diseases was expressed for first time in 2016 when the Delhi High Court dictated Health Ministry to launch a 'National Rare Disease Policy'.

A second more puzzling concern is that utilisation is quite low too, despite high demand for funds. According to some numbers, around 200 children in India suffer from a set of rare diseases classified as Lysosomal Disorders (LSD), and have applied to the Health Ministry for assistance. Industry sources estimate that the average cost of treatment for a child weighing approximately 10 kg could vary from ₹18-45 lakh. Several rare diseases, including LSDs, are generally chronic in nature with high and recurring treatment costs.

However, RAN only provides for a one-time grant of ₹15 lakh as treatment support at government hospitals for specified rare diseases. In the above example, the support given by RAN is insufficient to pay the cost of the least possible estimate of one-time remedy itself, let alone recurring expenses. Is the minimal allocation of funds that does not even meet minimal therapy costs a deterrent to utilisation?

Another reason for such low utilisation might be lack of knowledge of rare diseases and access to such funds.

It is clear that the people suffering from rare disorders are not getting adequate support. Consequently, the battle has already been started before the Indian Courts to recoznise the issue of the 'Rare Diseases' and this battle started with a 2013 case of Mohd Ahmed(Minor) vs. Union of India.

1. GLOBAL POLICIES AND PERSPECTIVE RELATING TO 'ORPHAN DRUGS'

The Cuban Constitution adopted in 1976, obligated the State to assure that there shall be 'no sick person who does not receive medical attention.'

The courts in Argentina have ordered the State to ensure an continuous supply of antiretroviral drugs to persons with HIV/AIDS, to ensure the manufacturing of a vaccine against an endemic disease, and to guarantee the continued delivery free of charge of a drug against bone disease.

In the United States, Orphan Drug Act, 1983 defines the expression 'rare disease or condition' to imply any disease or condition which occurs so infrequently that there's not any realistic expectation that the price of creating and making accessible a drug for such disease or condition will be recovered by earnings of this kind of medication. The Orphan Drug Act, 1983 not merely extends tax charge in addition to patent duration of these medications but the authorities gives grants and enters into contracts with entities to help in defraying the expenses of expenditures incurred in relation to the advancement of drugs.

The European Union Regulation 1999 provides incentive of market exclusivity to the patrons of orphan drugs. Further, through the EUROPLAN, the European Union has assigned that each member country should develop a National Strategy Plan for rare diseases embracing a seven step involvement, viz. policy making, definition and classification of rare diseases, research on rare disease, creation of centres of expertise for rare diseases, gathering proficiency at EU level, empowering patient organizations and sustainability of the strategies.

The Courts in the United Kingdom had also had the prospect to scrutinize this issue. In the case of R.V. Cambridge Health Authority Ex pare B (A Minor) [1995] EWCA Civ 49, where the treatment for a child distressed from non-Hodgkins Lymphoma had failed and treatment that was considered experimental was sought under the National Health Service of the UK, the Court denied to interfere while admitting the strain on resources and that the question of allocation of resources was a policy decision observed that, “Difficult and agonising judgments have to be made as to how a limited budget is best allocated to the maximum advantage of the maximum number of patients. That is not a judgment which the Court can make". The Court concluded that, "I have no doubt that in a perfect world any treatment which a patient, or a patient's family, sought would be provided if Doctors were willing to give it, no matter how much it cost, particularly when a life was potentially at stake. It would however, in my view, be shutting one's eyes to the real world if the Court were to proceed on the basis that we do live in such a world. It is common knowledge that health authorities of all kinds are constantly pressed to make ends meet.”

Several other countries such as Japan, Australia and Israel have developed policies to combat the complications of rare diseases and orphan drugs.

The Government of India doesn't have any policy measure set up to deal with uncommon diseases, especially those of a chronic nature. Each of the Central and State approaches in the highest supply for a one- time award for life threatening procedures and don't consider continuous financial aid for a chronic illness, which entails lifelong investment. There are no incentives in place for Indian producers to come up with local options to orphan drugs.

The human right to health is also recognized in numerous international instruments. Article 25.1 of the Universal Declaration of Human Rights affirms: "Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services".

“The International Covenant on Economic, Social and Cultural Rights provides the most comprehensive article on the right to health in international human rights law. In accordance with article 12.1 of the Covenant, States parties recognize "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health", while article 12.2 enumerates, by way of illustration, a number of steps to be taken by the States parties to achieve the full realization of this right.

The General Comment No. 14 and the General Comment No. 3, issued by the United Nations Committee on Economic, Social and Cultural Rights in 2000 states were also discussed in the case which talks about the essential elements and the obligations, the precise application of which is required to implement and the realization of the right to health in all its forms.

The General Comment 14 issued by the UN Committee on Economic, Social and Cultural Rights in 2000. The applicable portion reads as under:-

“The notion of the ‘highest attainable standard of health’ in Article 12(1) of ICESCR takes into account both the individual's biological and socio-economic preconditions and a State's available resources. There is a number of aspects which cannot be addressed solely within the relationship between States and individuals; in particular, good health cannot be ensured by a State, nor can States provide protection against every possible cause of human ill health. Thus genetic factors, individual susceptibility to ill health and the adoption of unhealthy or risky lifestyles may play an important role with respect to an individual's health. Consequently, the right to health must be understood as a right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health."

Several regional human rights instruments also recognize the right to health, such as the European Social Charter of 1961 as revised (art. 11), the African Charter on Human and Peoples' Rights of 1981 (art. 16) and the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights of 1988 (art. 10). Similarly, the right to health has been proclaimed by the Commission on Human Rights, as well as in the Vienna Declaration and Programme of Action of 1993 and other international instruments.

2. 'RIGHT TO HEALTH', 'ARTICLE 21' AND THE 'RARE DISEASES' IN INDIA

The question is, whether the Indian Government owes a constitutional duty to provide free medical treatment to the petitioner suffering from a rare and a chronic disease?

Whilst the jurisprudence of different countries discussed above on the subject of healthcare access contains valuable insights, it is important to bear in mind that our Constitution is structured differently from the aforesaid Constitutions.

In fact, though the issue raised in the present proceedings is common to all developing countries, yet India is fortunate to have a developed, liberal and progressive Constitution. As held by Justice Chaskalson P. of South African Constitutional Court in T. Soobramoney vs. Minister of Health (Kwazulu-Natal) the Indian Supreme Court has developed a jurisprudence around the right to life so as to impose positive obligations on the government in respect of the basic needs of its inhabitants.

The Indian Supreme Court in a catena of cases has held that right to health and medical care is a fundamental right under Article 21 read with Articles 39(e), 41 and 43. It has further held that self-preservation of one's life is the necessary concomitant of the right to life enshrined in Article 21, fundamental in nature, sacred, precious and inviolable.

In fact, in State of Maharashtra Vs. Chandrabhan , the Supreme Court held that "right to life, enshrined in Article 21 means something more than survival or animal existence. It includes all those aspects of life which go to make a man's life meaningful, complete and worth living. That which alone can make it possible to live must be declared to be an integral component of the right to life."

This Court was of the view that Article 21 has to be interpreted in conformity with International Covenant on Civil and Political Rights, 1966 as India is a signatory to the same."

The Indian Supreme Court in the case of Pt. Parmanand Katara Vs. Union of India and Others , recognized the obligation of the Government to preserve life. In the said case a victim of a scooter accident was denied treatment as the hospital did not have the requisite arrangements for medico-legal cases. Failure to receive timely treatment eventually led to the victim's death. While interpreting the ambit of the right to life under Article 21 of the Constitution, the Supreme Court held "Article 21 of the Constitution casts the obligation on the State to preserve life. ......The obligation being total, absolute and paramount, laws of procedure whether in statutes or otherwise which would interfere with the discharge of this obligation cannot be sustained and must, therefore, give way."

In the case of Paschim Bangal Khet Mazdoor Samity and Others , a member of the petitioner Mazdoor Samity suffered a brain injury after falling from a train and was denied treatment at several hospitals due to lack of expertise and lack of beds and was forced to seek treatment at a private hospital. The petition was filed for compensation of the expenses incurred. The Supreme Court observed that the obligation to provide medical care was an obligation of the welfare state and held "The Constitution envisages the establishment of a welfare State at the federal level as well as at the State level. In a welfare State the primary duty of the Government is to secure the welfare of the people. The government hospitals run by the State and the medical officers employed therein are duty-bound to extend medical assistance for preserving human life. Failure on the part of a government hospital to provide timely medical treatment to a person in need of such treatment results in violation of his right to life guaranteed under Article 21. ....It is no doubt true that financial resources are needed for providing these facilities. But at the same time it cannot be ignored that it is the constitutional obligation of the State to provide adequate medical services to the people. Whatever is necessary for this purpose has to be done......In the matter of allocation of funds for medical services the said constitutional obligation of the State, has to be kept in view. It is necessary that a time-bound plan for providing these services should be chalked out keeping in view the recommendations of the Committee as well as the requirements for ensuring availability of proper medical services in this regard as indicated by us and steps should be taken to implement the same." (emphasis supplied).

Consequently, right to health and health care access are a part of Articles 21, 38 and 46 of the Constitution. Accordingly, every person has a fundamental right to quality health care which is also affordable, accessible and compassionate.

In the subsequent Constitution Bench judgment in the case of Confederation of Ex-servicemen Associations and Ors. the Supreme Court reiterated that right to medical aid is a fundamental right of all citizens guaranteed by Article 21. The Constitution Bench only held that the contributory scheme framed by the Government qua ex-service men, under which they had to pay one time contribution, was constitutionally valid. In the opinion of this Court, if a class or category of its citizens can afford to pay or partially pay for their medical treatment because of their economic background, Government can certainly frame a contributory scheme for medical treatment."

However, it seems like, the Supreme Court in subsequent judgments in State of Punjab & Ors. vs. Ram Lubhaya Bagga , and Confederation of Ex-servicemen Associations and Ors. vs. Union of India & Ors., has diluted the right to health.

In State of Punjab & Ors. vs. Ram Lubhaya Bagga , the court has stated that "When we speak about a right, it correlates to a duty upon another, individual, employer, government or authority. In other words, the right of one is an obligation of another. Hence the right of a citizen to live under Article 21 casts obligation on the State. This obligation is further reinforced under Article 47, it is for the State to secure health to its citizen as its primary duty.

However, "No State of any country can have unlimited resources to spend on any of its projects. That is why it only approves its projects to the extent it is feasible. The same holds good for providing medical facilities to its citizens including its employees. Provision of facilities cannot be unlimited. It has to be to the extent finances permit."

Confederation of Ex-servicemen Associations and Ors. vs. Union of India & Ors. , the court stated that " In our considered opinion, though the right to medical aid is a fundamental right of all citizens including ex-servicemen guaranteed by Article 21 of the Constitution, framing of scheme for ex-servicemen and asking them to pay ―one-time contribution‖ neither violates Part III nor is it inconsistent with Part IV of the Constitution. Ex-servicemen who are getting pension have been asked to become members of ECHS by making ―one-time contribution‖ of reasonable amount (ranging from Rs 1800 to Rs 18,000). To us, this cannot be held illegal, unlawful, arbitrary or otherwise unreasonable."

In this regard, she also mentioned to the General Comment 14 issued by the UN Committee on Economic, Social and Cultural Rights in 2000. The applicable portion of the aforementioned Comment relied upon by her reads as under:-

"The notion of the 'highest attainable standard of health' in Article 12(1) of ICESCR takes into account both the individual's biological and socio-economic preconditions and a State's available resources. There is a number of aspects which cannot be addressed solely within the relationship between States and individuals; in particular, good health cannot be ensured by a State, nor can States provide protection against every possible cause of human ill health. Thus genetic factors, individual susceptibility to ill health and the adoption of unhealthy or risky lifestyles may play an important role with respect to an individual's health. Consequently, the right to health must be understood as a right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health."

Thus, there is the obligation and the duty of the state in this regard but also limitations which a state might face while trying to achieve this ideal. All the patients have to be treated equally.

Therefore, the State can't focus all of its resources on a single individual, while denying fundamental amenities to other people.

In India, health is a state subject, and the state government is accountable for the successful implementation of healthcare programmes. However, the central government is also an equal partner in healthcare governance according to Indian Constitution Article 14 (Right to Equality) and Article 21 (Right to Life). After all, health is not a luxury for the sole possession of privileged few. Just because someone is poor, the centre/state cannot allow him to die (Md Ahmed vs Union of India, 2014). It is the constitutional obligation of the government, whether centre or state, to provide access to treatment if the patient is suffering from a Rare Diseases or a chronic disease or in case of a pandemic, maintaining the overall well-being of its citizens.

Given the small number of people suffering from these diseases, individually, each disease may not be contributing much; however, the burden on the affected family is quite substantial. While speaking to a few families with patients suffering from Rare Diseases, we noticed that it takes a long time to arrive at the correct diagnosis. The costs incurred by the family keep adding up in the interim. Furthermore, the cost to the governments is also not trivial, especially when we consider the patient lawsuits and the cost of defending them;for example, in a recent court case, the Delhi High Court ordered All India Medical Sciences to treat a young patient with Gaucher'sdisease (PTI, 2020). Similarly, in April 2021, the Karnataka High Court ordered the state government to release ₹59.5 million for the next 4 months for the treatment of 45 existing patients from its unutilized corpus fund (The Hindu, 2021). In January 2020, The Madras High Court called upon the State Government of Tamil Nadu to allocate ₹50 million per annum and directed the central health ministry to allocate ₹44 million as an annual budget for the treatment of 11 patients (Imranullah, 2020).

On 23 September 2019, there was a political declaration by the UN on the inclusion of Rare Diseases within Universal Health Coverage. As India is one of the member states, it is important for The Ministry of Health and Family Welfare (MOHFW), Government of India to develop actionable items for alleviating the grievances of Rare Diseases patients. Recently, MOHFW came up with the draft National Policy for Rare Diseases 2020 (GOI, 2021). Some of the key recommendations include

- Identifying high-risk families and couples of reproductive age and screening them for any genetic abnormalities and potential preventive mechanisms;
- popularizing screening for newborns and improving diagnostic equipment; and
- providing better supporting infrastructure to the suffering population.

Currently, the acute treatment interventions, as mentioned in Group 1 of the Policy, can be covered under Ayushman Bharat Pradhan Mantri Jan Arogya Yojana or Rashtriya Arogya Nidhi (RAN) commitment. Ideally, while the policy mentions the government's commitment to Rare Diseases, in totality, there is a definite need to allocate funds for RARE DISEASES treatments (wherever available). The policy is clearly silent about the sustainable funding mechanism to provide treatment for Rare Diseases that need chronic treatment support

3. THE ISSUE OF 'FUND AVAILABILITY'

Undoubtedly, availability of finance with the Government is a relevant factor.

No one can direct that entire budget of a country should be spent on health and medical aid. After all competing claims like education and defence cannot be ignored.

Consequently, courts cannot direct that all inhabitants of this country be given free medical treatment at state expense. Even if such a direction were issued it would not be implementable as there would be neither infrastructure nor finance available for compliance of the said direction.

However core obligations like access to essential medicines are non-derogable. Core obligations under the right to health are non-derogable. This minimum core is not easy to define, but includes at least the minimum decencies of life consistent with human dignity. No one should be condemned to a life below the basic level of dignified human existence."

At the same time, no Government can say that it will not treat patients with chronic and rare diseases due to financial constraint. It would be as absurd as saying that the Government will provide free treatment to poor patients only for stomach upset and not for cancer/HIV/or those who suffer head injuries in an accident!

Disease is a natural catastrophe that fells its victims unpredictably. The right to adequate health care flows from the sanctity of human life and the dignity that belongs to all persons. Health is a fundamental human right, which has as its prerequisites social justice and equality. It should be accessible to all.

Healthcare access is the ability to obtain healthcare services such as prevention, diagnosis, treatment and management of diseases, illness, disorders, and other health-impacting conditions. For healthcare to be accessible it must be affordable and convenient.

4. NEED TO PROMOTE THE 'CORPORATE SOCIAL RESPONSIBILITY' IN CASES OF RARE DISEASES

Section 135 of the Companies Act, 2013 stipulates that a company having a net worth of more than Rs. 500 crores or turnover in excess Rs. 1,000 crores or a net profit of Rs. 5 crores during a financial year must spend at least 2% of its average net profits during the last three financial years on CSR activities covered in Schedule VII of the Companies Act, 2013.

Prior to the enactment of this new Companies Act of 2013, there existed only a set of Voluntary Guidelines issued by the Ministry of Corporate Affairs in 2009 and Schedule VII of the Companies Act, 2013 permitted companies to carry out CSR activities under ten heads which included "reducing child mortality"(at Sr. no. 4 of the un- notified Schedule VII) and "combating HIV, AIDS, malaria and other diseases" (at Sr. no. 5 of the un-notified Schedule VII).

However, when Schedule VII was notified on 27th February, 2014 these two entries were inexplicably dropped from the list of permitted CSR activities. The only area under the then notified Schedule VII was "preventive healthcare". Since the notified Schedule VII would have closed the CSR funding route as an option to sponsor treatments for rare diseases, this Court vide its order dated 28th February, 2014 directed the Ministry of Corporate Affairs to re-examine the matter."

The Ministry of Corporate Affairs filed a letter dated 24th March, 2014 before this Court stating "Ministry of Corporate Affairs has decided to amend the Schedule VII of the Companies Act, 2013 as 'promoting health care including preventive health care'. This would encompass the entire health care area, including the treatment of diseases etc. "

On 28th March, 2014, the Ministry of Corporate Affairs filed an affidavit elucidating the scope of the term "normal course of business" used in Rules 4 and 6 of the Companies (Corporate Social Responsibility Policy) Rules, 2014, by giving the following example:-

"....a pharmaceutical company donating medicines/drugs within section 135 read with Schedule VII to the Act is a CSR Activity, as the same is not an activity undertaken in pursuance of its normal course of business which is relatable to health care or any other entry in Schedule VII.

CONCLUSION AND RECOMMENDATIONS

It is not realistic to expect free markets to solve the problems associated with Rare Diseases. Moreover, since these diseases will never be a priority from a public health perspective, it is difficult to expect various governmental departments to allocate any part of their healthcare budgets towards provisioning for Rare Diseases. In other words, since these departments are hard-pressed for funds to combat other health exigencies, the allocation for Rare Diseases would never be a priority. Therefore, the only feasible solution is for the governments to allocate a fixed portion of the healthcare budget to treat Rare Diseases. It can be argued that for a country like India, which suffers significantly from a paucity of funds for healthcare, can the states afford to earmark some funds exclusively for Rare Diseases? Since free markets will not be able to solve these problems, a small fraction of healthcare budgets needs to be allocated, especially because healthcare is a universal right.

While such allocation solves a part of the problem, it does not solve the entire problem of affordability. The pharmaceutical companies that manufacture these drugs should be willing to subsidize the patient significantly so that the shortfall, if any, in governmental allocation can be filled;that is, it has to be a joint effort on the part of pharmaceutical companies and the government to tackle the issue of Rare Diseases, and a fixed allocation by the government allows all the concerned parties to estimate the commitment required. In this argument of the government versus pharmaceutical companies, another factor comes into the picture. Since several Rare Diseases have no cure currently available, the actual number of patients who would require government funding could be quite small. While more accurate estimation is required, our understanding is that even a very small allocation could be significant in alleviating the problem. Such an approach is not without precedence in India;for example, the Government of Kerala has set up such fund exclusively for the treatment of Rare Diseases.

Real, true CSR in the innovative pharmaceutical industry requires either abandoning or at least reducing monopolistic privileges and offering medicines for rare diseases at lower prices. Pharmaceutical corporations should take into consideration the differences in GDP per capita between developed and developing countries.

Traditional CSR practices in the pharmaceutical industry (corporate philanthropy, community and neighborhood programmes, volunteerism etc.) do not seem to be sufficient “compensation” for the high prices of the medicines. Stronger co-operation between different groups of stakeholders in different countries would be necessary in order to use financial resources in a more efficient way; societies and individuals would be able to offer to support patients with rare diseases and their families.

A key issue of CSR in the innovative pharmaceutical industry seems to be the pricing of drugs, especially orphan and ultra-orphan drugs. Corporations use their monopolistic position to set extremely high prices. However, without the market/marketing exclusivity offered to pharmaceutical firms by the law, orphan drugs would not be probably developed, produced and commercialized.

An integrated approach from both centre as well as the state to address the overall benefit of the patient and attempt for steady financial support from various sources like centre aid, crowdfunding, fundraising through CSR, etc can be adopted. Furthermore, Creation of a digital platform to bring together the centre of excellence, and possible donors. to address the transparency of funding received through any source the Center of excellences should have linkage to ICMR registries.

REFERENCES

[1] *(1989) 4 SCC 286*

[2] *(1998) 4 SCC 117*

[3] *AIR 1983 SC 803*

[4] *AIR 2006 SC 2945*

[5] *Case CCT 32/97*

[6] *Federal Administrative Court, Chamber IV, Viceconte, Mariela v. Estado nacional - Ministerio de Salud y Accion Social slamparo ley 16.986, 2 June 1998*

[7] *Government of India (GOI). (2021). National policy for rare diseases. Ministry of Health and Family Welfare. https://main.mohfw.gov.in/sites/default/files/Final%20NPRD%2C%202021.pdf*

[8] *Imranullah M.S. (2020, February 11) Draft national policy on rare diseases published, Centre tells Madras HC. https://www.thehindu.com/news/cities/chennai/draft-national-policy-on-rare-diseases-published-centre-tells-madras-hc/article30788174.ece*

[9] *Mohd Ahmed(Minor) vs. Union of India, W.P. (C) 7279/2013; MANU/DE/0915/2014.*

[10] *Mohd Ahmed(Minor) vs. Union of India, W.P. (C) 7279/2013; MANU/DE/0915/2014.*

[11] *Para 26 and 29, (1998) 4 SCC 117*

[12] *Para 66, AIR 2006 SC 2945*

[13] *Press Trust of India (PTI). (2020, March 25). High court asks AIIMS to treat 18-month-old for rare disease ‘gaucher’.https://www.ndtv.com/india-news/high-court-asks-aiims-to-treat-18-month-old-for-rare-disease-gaucher-2200700*

[14] *Supreme Court of Justice, Asociacion Benghalensis y otros vs. Ministerio de Salud y Accion Social, case 323:1339, 1 June 2000*

[15] *Supreme Court of Justice, Campodonico de Beviacqua, Ana Carina v. Ministerio de Salud y Accion Social - Secretaria de Programas de Salud y Banco de Drogas Neoplasicas, 24 October 2000*

[16] *The Hindu. (2021 April 24). HC directs centre and state to release ₹5 crore for treating children with lysosomal storage disorder. The Hindu. https://www.thehindu.com/news/cities/bangalore/hc-directs-centre-and-state-to-release-5-crore-for-treating-children-with-lysosomal-storage-disorder/article34395043.ece*

[17] *United Nations. Economic and Social Council. The Right to the highest attainable standard of health : 08/11/2000. E/C 12/2000/4*

[18] *World Health Organisation (WHO). (2018, February 27). Statement for rare disease day. https://www.who.int/news/item/27-02-2018-statement-for-rare-disease-day*