

# COVID-19 VACCINES IN INDIA: JUDICIAL BLIND SPOTS IN UPHOLDING THE RIGHT TO HEALTH

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*The COVID-19 pandemic brought to the forefront the intrinsic link between health and human rights and exposed the conflict between public health measures and individual rights and liberties. These conflicts are apparent in the context of COVID-19 vaccines as well. Vaccines were fast-tracked, given emergency approval and produced and distributed by a few manufacturers with the help of the government and multiple agencies, to control the COVID-19 pandemic. However, the lack of transparency in regulation, the formulation of arbitrary policies, unfair pricing, unequal procurement, restricted and discriminatory distribution, lack of informed consent and lack of accountability for adverse events following immunization (AEFI) also created conflicts and controversies, exacerbated inequities and violated the right to life and health. As people turned to the courts, the judiciary received appreciation for reiterating the recognition of the constitutional right to health and nudging the government's vaccine policy in the right direction. However, a closer look at various aspects and questions before the courts reveals certain blind spots on the part of the judiciary in fully upholding the right to health. The article relies on key elements of the right to health, in particular the availability,*

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*accessibility, acceptability and quality (AAAQ) framework to analyse court orders, the government's stand and their impact on individual and public health. This analysis is contextualized with the help of media reports, investigative journalism and interventions by civil society organisations. In presenting the right to health as an important and useful foundation for the government and the judiciary to reflect on and review the decisions and actions of the past three years, this paper seeks to lend support to efforts to ensure that the injustices and inequities of these pandemic years are not repeated.*

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## I. INTRODUCTION

The right to health requires that the State formulate public health policies to prevent the spread of disease and control pandemics, while maintaining and respecting human rights. Historically, measures to control the spread of infectious diseases were based on limiting the rights of a few people through mandatory testing, quarantine, isolation, treatment, care and support.<sup>1</sup> Mandatory and coercive approaches conflict with human rights and had largely become irrelevant before the COVID-19 pandemic.<sup>2</sup> Limitations on rights are permissible, but they need to be the least restrictive, least intrusive, non-arbitrary and evidence-based.<sup>3</sup> Contemporary thinking and modern public health practices have instead emphasized on respecting the rights of the people, providing them with full information and the tools and technologies to protect themselves and others.<sup>4</sup> This has been the hallmark of public health programs in recent

<sup>1</sup> Jonathan M. Mann, Lawrence Gostin, Sofia Gruskin, Troyen Brennan, Zita Lazzarini, Harvey V. Fineberg, 'Health and Human Rights' (1994) 1 Health and Human Rights Journal 6.

<sup>2</sup> *ibid.*

<sup>3</sup> 'The Siracusa Principles on the Limitation and Derogation Provisions in the International Covenant on Civil and Political Rights', (E/CN.4/1985/4, UN Commission on Human Rights 1984) <<https://www.refworld.org/docid/4672bc122.html>> accessed 12 April 2023.

<sup>4</sup> *ibid.*

years for diseases like HIV and tuberculosis.<sup>5</sup> However, the COVID-19 pandemic witnessed these well-established rights-based public health approaches give way to fear and panic, which allowed governments to use force, coercion, arbitrary and discriminatory methods to control the spread of the coronavirus. The global health challenge of the COVID-19 pandemic has brought the intrinsic link between health and human rights to the forefront, and has exposed the conflict between public health measures and civil liberties.

These conflicts are apparent in the context of COVID-19 vaccines as well. In India, as elsewhere, the disastrous social and economic consequences of lockdowns fueled the urgency to find a vaccine, cure, or treatment against SARS-CoV-2. In early 2021, two vaccines against SARS-Cov-2 were given emergency use approval in India and were rolled out in stages across the adult and pediatric populations. Since then, several other vaccines have also received approval and over three years since the pandemic hit India, vaccine coverage is widespread.<sup>6</sup> However government messaging, which has promoted a narrative of triumphalism, masks the many legal and ethical concerns that have arisen in the development, approval and rollout of these vaccines.

At its core, vaccination represents an individual intervention, wherein understanding risks and benefits, and providing informed consent are important. However these individual interventions are in reality public health measures, which not only benefit individuals but also the society, as they are meant to prevent and treat diseases at a community level. Individual autonomy is juxtaposed against societal interests raising many legal and ethical issues in vaccines and vaccinations. These legal and ethical issues lie at the intersection of science, law, ethics and public health and have been the subject of crucial cases before the Supreme Court (SC) and the High Courts (HC). The SC, in particular, has passed two important judgments relating to COVID-19 vaccines. In a suo moto writ petition, *Distribution of Essential Supplies and Services During Pandemic, In re*<sup>7</sup> the SC in a series of orders examined vaccine availability and access from the perspective of the rights to health, life and equality. In

<sup>5</sup> See for eg., OHCHR and UNAIDS, 'Handbook on HIV and Human Rights for National Human Rights Institutions' (2007) <<https://www.ohchr.org/sites/default/files/Documents/Publications/HandbookHIVNHRIs.pdf>> accessed 3 July 2023; World Health Organization, 'Ethics guidance for the implementation of the End TB Strategy' (2017) <<https://apps.who.int/iris/bitstream/handle/10665/254820/9789241512114-eng.pdf?sequence=1&isAllowed=y>> accessed 3 July 2023; Licence: CC BY-NC-SA 3.0 IGO.

<sup>6</sup> Number of vaccinations: Total vaccinations: 2,20,06,25,208; Dose 1: 1,02,71,66,278; Dose 2: 95,11,41,127; Precaution Dose: 22,23,17,803<sup>3</sup> (*Co-Win: Winning Over COVID-19*) <<https://web.archive.org/web/20221225221137/https://dashboard.cowin.gov.in/>> accessed 2 May 2023.

<sup>7</sup> *Distribution of Essential Supplies and Services During Pandemic, In re*, <[https://main.sci.gov.in/supremecourt/2021/11001/11001\\_2021\\_35\\_301\\_27825\\_Judgement\\_30-Apr-2021.pdf](https://main.sci.gov.in/supremecourt/2021/11001/11001_2021_35_301_27825_Judgement_30-Apr-2021.pdf)> accessed 2 May 2023 and, *Distribution of Essential Supplies and Services During Pandemic, In re*, (2021) 7 SCC 772 [https://main.sci.gov.in/supremecourt/2021/11001/11001\\_2021\\_35\\_301\\_28040\\_Judgement\\_31-May-2021.pdf](https://main.sci.gov.in/supremecourt/2021/11001/11001_2021_35_301_28040_Judgement_31-May-2021.pdf) accessed 2 May 2023.

*Jacob Puliyel v Union of India*,<sup>8</sup> it examined issues related to the right to privacy and bodily integrity in the context of public health as well as concerns with transparency in vaccine approvals and the reporting of adverse events. In both cases the SC held that while it would normally defer to the executive in matters of policy making, it had the jurisdiction to review those policies in case of violations of fundamental rights. In the ongoing case of *Rachna Gangu v Union of India*,<sup>9</sup> the SC may also examine in greater detail the issue of informed consent and of government responsibility for compensating those who suffer from adverse effects of vaccination.

The SC in effect has been examining various aspects of the right to health while reviewing India's COVID-19 vaccine policy and has been appreciated for reiterating the recognition of the constitutional right to health and nudging government policy in the right direction. However, a closer look at various aspects and questions before the SC as well as before some of the HCs, reveals certain blind spots on the part of the judiciary in fully upholding this right. In highlighting these blind spots, this article seeks to raise pertinent questions on the use of government resources and funds, issues related to clinical trials which provide data on vaccine safety, efficacy and side effects, the affordability, availability, and accessibility of the vaccines and the relationship and roles of key stakeholders, including academic researchers, experts, scientists, government, pharmaceutical companies and civil society groups.

The article relies on key elements of the right to health, in particular the availability, accessibility, acceptability and quality (AAAQ) framework, to highlight key legal and policy questions that have arisen in the context of COVID-19 vaccines in India and how the courts, particularly the SC, have approached these issues. The analysis of the approaches taken by the government and the courts and their impact is contextualized with the help of media reports, investigative journalism and reports and interventions by civil society organisations. Although multiple vaccines are now approved in India, this article focuses on the two vaccines that were the backbone of the government's rollout i.e., Serum Institute of India's Covishield and Bharat Biotech's Covaxin. While COVID-19 vaccine-related cases continue to be litigated in Indian courts, the article has attempted to include key developments till 31 December 2022.

## II. RIGHT TO HEALTH AND THE AAAQ FRAMEWORK

In *Distribution of Essential Supplies and Services During Pandemic*, *In re*, the SC stated that, "vaccinations being provided to citizens constitute a valuable public good," and pointed out that vaccine access required a, "rational

<sup>8</sup> *Jacob Puliyel v Union of India* 2022 SCC OnLine SC 533.

<sup>9</sup> *Rachana Gangu v Union of India* 2022 SCC OnLine SC 1125.

*method of proceeding in a manner consistent with the right to life (which includes the right to health) under Article 21.*<sup>10</sup> The SC was referring to the long-standing recognition of the right to health as part of the right to life under the Indian Constitution.<sup>11</sup> Over the decades, the courts have continuously evolved various facets of the right to health including access to emergency medical care, essential drugs, drugs for rare diseases, blood safety, standards to be followed in government hospitals, working conditions of healthcare workers, maternal health, sexual and reproductive rights and health as well as the social determinants of health.<sup>12</sup>

India is also signatory to international treaties that recognise the right to health. India's international law obligations under the International Covenant on Economic, Social and Cultural Rights (ICESCR), to which it is a signatory and which enshrines the right to health, are recognised in the *Protection of Human Rights Act, 1993* and in several court decisions.<sup>13</sup> According to Article 12 of the ICESCR, "*States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.*"<sup>14</sup> General Comment 14 issued by the Committee on Economic, Social and Cultural Rights explains in detail the obligations of governments in the fulfilment of this right – both domestically and internationally.<sup>15</sup> The Comment outlines the specific legal obligations of State Parties to "*respect, protect and fulfil*" the right to health.<sup>16</sup> While the right to health casts a duty on the State to take steps towards its full realization i.e., towards a progressive realisation of the right, it also includes core obligations of every State that are accorded the highest priority and which are non-derogable including "*... the prevention, treatment, and control of epidemic, endemic, occupational and other diseases.*"<sup>17</sup>

The Comment notes that the fulfilment of this right rests on the overlapping principles of availability, accessibility, acceptability and quality which have

<sup>10</sup> *Distribution of Essential Supplies and Services During Pandemic, In re* (n 7).

<sup>11</sup> *Vincent Panikurlangara v Union of India* (1987) 2 SCC 165; *Paramanand Katara v Union of India* (1989) 4 SCC 286; *Surjit Singh v State of Punjab* (1996) 2 SCC 336; *Ashok v Union of India* (1997) 5 SCC 10; *State of Punjab v Ram Lubhaya Bagga* (1998) 4 SCC 117.

<sup>12</sup> Kajal Bhardwaj, Veena Johari and Vivek Divan, 'The Right to Health: A Winding Road to Actualization' in Purendra Prasad and Amar Jesani(eds), *Oxford India Studies in Contemporary Society: Health Care Studies in India* (OUP 2018).

<sup>13</sup> See *Navtej Johar v Union of India* (2018) 10 SCC 1 (Supreme Court) and *National Legal Services Authority v Union of India* (2014) 5 SCC 438.

<sup>14</sup> International Covenant on Economic, Social and Cultural Right 1966, art 12.1.

<sup>15</sup> 'CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health (art 12)', (Adopted at the Twenty-second Session of the Committee on Economic, Social and Cultural Rights, Office of the High Commissioner for Human Rights 2000) <<https://www.ref-world.org/pdfid/4538838d0.pdf>> accessed 12 April 2023.

<sup>16</sup> *ibid.*

<sup>17</sup> *ibid.*

come to be known as the ‘AAAQ framework’ (see Figure 1<sup>18</sup>). Some scholars note that the AAAQ framework, “*is an authoritative set of standards,*”<sup>19</sup> that is increasingly applied internationally and nationally.<sup>20</sup> They suggest that with the importance of the AAAQ framework being underscored by governments and health authorities, it is “*emerging as a norm of customary international (health) law.*”<sup>21</sup> While the AAAQ framework lacks precision, “*it helps frame the analysis and debate about how the right to health is guaranteed in the context of COVID-19, and it shows the extent to which countries are prepared to address future crises.*”<sup>22</sup>

AAAQ	Four essential elements of the right to health
Available	Health goods, facilities and services must be <i>available</i> in sufficient quantity everywhere the country. This includes, for example, hospitals, clinics, trained health professionals and essential medicines, as well as underlying determinants, such as safe drinking water and adequate sanitation facilities.
Accessible	Health goods, facilities and services must be <i>accessible</i> to everyone without discrimination. They must be physically accessible, meaning within safe physical reach of all sections of the population, including people with disabilities and people in rural areas. They must be economically accessible, meaning affordable to all.
Acceptable	Health goods, facilities and services must be <i>acceptable</i> , in other words, respectful of medical ethics, including the right to confidentiality, and they must be sensitive to cultures, communities and gender.
Quality	Health goods, facilities and services must be scientifically and medically appropriate and of good <i>quality</i> . The underlying determinants of health, such as water and health education, must be of good quality too.

Figure 1: AAAQ Framework. Figure from Hunt and MacNaughton (2006)

While reviewing various aspects of the government’s vaccine policy, the SC did find violations or the potential for violations of the right to health and other fundamental rights in the government’s procurement policy, in the use of a digital platform as the sole means for accessing the vaccines and in imposing vaccine mandates. These are discussed in greater detail below. This article, however, argues that reviewing the development and rollout of COVID-19

<sup>18</sup> Paul Hunt and Gillian MacNaughton, ‘Impact Assessments, Poverty and Human Rights: A Case Study Using the Right to the Highest Attainable Standard of Health’ (2006) Health and Human Rights Working Paper Series No 6, WHO and UNESCO <[https://www.researchgate.net/publication/237555118\\_Impact\\_Assessments\\_Poverty\\_and\\_Human\\_Rights\\_A\\_Case\\_Study\\_Using\\_The\\_Right\\_to\\_the\\_Highest\\_Attainable\\_Standard\\_of\\_Health](https://www.researchgate.net/publication/237555118_Impact_Assessments_Poverty_and_Human_Rights_A_Case_Study_Using_The_Right_to_the_Highest_Attainable_Standard_of_Health)> accessed 2 May 2023.

<sup>19</sup> Brigit Toebe, Lisa Forman and Giulio Bartolini, ‘Toward Human Rights-Consistent Responses to Health Emergencies: What is the Overlap between Core Right to Health Obligations and Core International Health Regulation Capacities?’ 22 Health and Human Rights Journal 99.

<sup>20</sup> See for instance the judgment of Justice DY Chandrachud in *Navtej Johar v Union of India* (2018) 10 SCC 1 where he notes, “Pursuant to General Comment No. 14, India is required to provide marginalized populations, including members of the LGBTIQ community, goods and services that are available (in sufficient quantity), accessible (physically, geographically, economically and in a non-discriminatory manner), acceptable (respectful of culture and medical ethics) and of quality (scientifically and medically appropriate and of good quality).”

<sup>21</sup> Toebe (n 19).

<sup>22</sup> *ibid.*

vaccines in India through the lens of the AAAQ framework highlights several other areas of concern from a right to health perspective that require greater attention from the SC and the HCs. These 4 principles have been discussed below.

## A. Availability

*“The cumulative number of COVID19 vaccine doses administered in the country has crossed 14.19 Cr today as part of the world’s largest vaccination drive, which completed 100 days yesterday.”*

— Press Information Bureau, 26 April 2021<sup>23</sup>

*“Sankaran Punneri Peroor, 66, took his first dose on March 4 and is running out of time for the second. Several clinics canceled his appointment citing low stocks. On Monday morning, Peroor and his wife were among more than 100 people standing for hours under a scorching sun at the Maasaheb Meenatai Thackeray Hospital in Navi Mumbai. The hospital’s vaccination target for a day is 200. “I managed to get admission in another private clinic which is 10 kilometers away from my residence. But on the vaccination day, the registration itself was canceled,” Peroor said. “I am pursuing all efforts as the coronavirus is spreading like wildfire.””*

— theprint.in, 26 April 2021<sup>24</sup>

*“Nepal launched its vaccination campaign in January and gave shots to 1.9 million people, all provided by India and China. But health experts feared that continuation of the vaccination drive was uncertain after officials had failed to procure more doses from India or any other source. More than 90 developing nations, including Nepal, rely on India – home to the Serum Institute, the world’s largest vaccine maker – for the doses to protect their own populations, but India has*

<sup>23</sup> ‘India’s Cumulative Vaccination Coverage Exceeds 14.19 Crore as the Largest Vaccination Drive Completes 100 Days’ (Ministry of Health and Family Welfare, 2021) <<https://pib.gov.in/PressReleasePage.aspx?PRID=1714035>> accessed 2 May 2023.

<sup>24</sup> PR Sanjai, Dhvani Pandya and Bibhudatta Pradhan, ‘India’s Vaccine Shortage Threatens to Prolong its Covid Crisis’ (*The Print*, 26 April 2021) <<https://theprint.in/health/indias-vaccine-shortage-threatens-to-prolong-its-covid-crisis/646407/>> accessed 2 May 2023.

*now prioritised its own needs as a second wave of the epidemic there rages out of control.”*

— *Al Jazeera, 26 April 2021*<sup>25</sup>

The principle of *availability* requires that public health and health-care facilities, goods and services, and programmes, have to be available in sufficient quantity within a country.<sup>26</sup> While General Comment 14 acknowledges that the nature of these requirements will vary based on numerous factors including the development level of a country, it specifies that adequate hospitals, trained medical staff, and essential drugs must be available. During a majority of the first year of the vaccine rollout programme, vaccines were simply not available in the required quantities, particularly when the government opened up vaccination for everyone over the age of 18.<sup>27</sup> This section explores three issues that impacted the availability of vaccines i.e., procurement, production and wastage, and an additional issue in the context of India’s international obligations on the right to health i.e., exports.

### 1. *Procurement*

COVID-19 vaccination started in India in January 2021 with healthcare workers and frontline workers. Over the next few months, eligibility expanded across different age groups. In its first order, the government ordered only 11 million of the 55 million doses that Serum had already stock piled before approval under tweaked regulatory rules,<sup>28</sup> leading to a temporary halt in production.<sup>29</sup> In Parliament, the Minister of Health stated that procurement initially was aimed only at current requirements rather than projected requirements.<sup>30</sup> Analysts suggest that the government’s approach to procurement was

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<sup>25</sup> ‘Nepal COVID Infections Surge, Fuelled by India’s Mutant Strains’ (*Al Jazeera*, 26 April 2021) <<https://www.aljazeera.com/news/2021/4/26/nepal-covid-infections-surge-fuelled-by-indias-mutant-strains>> accessed 2 May 2023.

<sup>26</sup> ‘CESCR General Comment No. 14: The Right to the Highest Attainable Standard of Health(art 12)’ (n 15).

<sup>27</sup> Ravi Duggal, ‘Covid-19 in India: Vaccine Shortages are Leading to Discrimination in Access’ (*The BMJ Opinion*, 10 August 2021) <<https://blogs.bmj.com/bmj/2021/08/10/covid-19-in-india-vaccine-shortages-are-leading-to-discrimination-in-access/>> accessed 4 April 2023.

<sup>28</sup> Central Drugs Standard Control Organization, Directorate General of Health Services, ‘Notification’ (*Ministry of Health & Family Welfare*) <[https://cdsco.gov.in/opencms/opencms/system/modules/CDSKO.WEB/elements/download\\_file\\_division.jsp?num\\_id=NjMzMzMQ==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSKO.WEB/elements/download_file_division.jsp?num_id=NjMzMzMQ==)> accessed 28 April 2023.

<sup>29</sup> Bharath Manjesh, ‘India Coronavirus Dispatch: Serum Sitting on a Stockpile of 55 mn Shots’ (*Business Standard*, 6 February 2021) <[https://www.business-standard.com/article/current-affairs/india-coronavirus-dispatch-serum-sits-on-55-mn-stockpile-of-shots-121020600646\\_1.html](https://www.business-standard.com/article/current-affairs/india-coronavirus-dispatch-serum-sits-on-55-mn-stockpile-of-shots-121020600646_1.html)> accessed 12 April 2023.

<sup>30</sup> ‘Lok Sabha Questions’ <<http://164.100.47.194/loksabha/Questions/QResult15.aspx?qref=20666&lsno=17>> accessed 12 April 2023.



based on a miscalculation<sup>31</sup> of India's capacity to make COVID-19 vaccines. This miscalculation proved costly not just for India but for the rest of the developing world that was relying on COVID-19 vaccines supply from India.<sup>32</sup>

By April 2021, the government overhauled its cautious approach, placed large orders and unlike previous orders, paid the entire amount upfront.<sup>33</sup> Until this point, the Central government was procuring the vaccines that were then provided through government and private vaccination centres. The following month, vaccination opened up for the 18-44 age group and under the *Liberalised and Accelerated Phase 3 Strategy of the National Covid-19 Vaccination Program*,<sup>34</sup> that came into effect on 1 May 2021, procurement was split between the Central government, State governments and the private sector. While the Central government would continue to procure vaccines for the over 45 age group, procurement for the 18-44 group was left to the State governments. Private sector hospitals were also now allowed to procure and provide vaccines. Manufacturers were asked to reserve 50% of the stock for the Central government, 25% for the state governments and 25% for the private sector.

With little information on the actual manufacturing capacities of the companies, the basis on which orders would be received, and when deliveries would be made, the rollout fell into chaos. State government orders were not being filled,<sup>35</sup> smaller hospitals could not compete with orders from large corporate hospitals<sup>36</sup> and the private sector started offering high-priced deals promising a vaccination with a hotel.<sup>37</sup> Individual States floated global tenders but received

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<sup>31</sup> Neeta Sanghi, 'How the Modi Government Overestimated India's Capacity to Make COVID Vaccines' (*The Wire*, 22 April 2021) <<https://science.thewire.in/health/narendra-modi-government-overestimated-india-covid-vaccine-manufacturing-capacity-shortage/>> accessed 12 April 2023.

<sup>32</sup> GS Mudur, 'How India Landed in Covid Vaccine Mess' (*The Telegraph Online*, 19 April 2021) <<https://www.telegraphindia.com/india/how-we-landed-in-covid-vaccine-mess/cid/1812969>> accessed 28 April 2023.

<sup>33</sup> 'Serum Institute Bharat Biotech to Get 4,500-cr Govt "Advance"' (*The Hindu Business Line*, 19 April 2021) <<https://www.thehindubusinessline.com/news/national/serum-institute-bharat-biotech-to-get-4500-cr-govt-advance/article34361376.ece>> accessed 4 April 2023.

<sup>34</sup> *Government of India Announces a Liberalised and Accelerated Phase 3 Strategy of Covid-19 Vaccination from 1st May (Ministry of Health and Family Welfare*, 19 April 2021) <<https://pib.gov.in/PressReleasePage.aspx?PRID=1712710>> accessed 12 April 2023.

<sup>35</sup> Aishwarya Paliwal, 'Phase 3 Vaccination for 18+ Begins Today but State Say that don't have Vaccine Stock' (*India Today*, 1 May 2021) <<https://www.indiatoday.in/coronavirus-outbreak/story/vaccines-for-all-adults-unlikely-from-tomorrow-states-say-no-stocks-1796605-2021-04-30>> accessed 2 May 2023.

<sup>36</sup> Kaunain Sheriff M, 'Next Up: Ensuring Small Hospitals Get Supply, E-vouchers for Poor' (*The Indian Express*, 8 June 2021) <<https://indianexpress.com/article/india/next-up-ensuring-small-hospitals-get-supply-e-vouchers-for-poor-free-vaccines-pm-modi-7348606/>> accessed 2 May 2023.

<sup>37</sup> 'Covid-19: Government Warns Hotels against Stay-Vaccination Packages' (*Times of India*, 31 May 2021) <<https://timesofindia.indiatimes.com/india/covid-19-government-warns-hotels-against-stay-vaccination-packages/articleshow/83101705.cms>> accessed 12 April 2023.

no responses.<sup>38</sup> The chaos was taken note of by the SC in *In Re: Distribution of Essential Supplies and Services During Pandemic*, where it held that this policy was prima facie arbitrary in its April order. According to the SC:

*“The vaccinations being provided to citizens constitute a valuable public good. Discrimination cannot be made between different classes of citizens who are similarly circumstanced on the ground that while the Central government will carry the burden of providing free vaccines for the 45 years and above population, the State Governments will discharge the responsibility of the 18 to 44 age group on such commercial terms as they may negotiate. Prima facie, the rational method of proceeding in a manner consistent with the right to life (which includes the right to health) under Article 21 would be for the Central Government to procure all vaccines and to negotiate the price with vaccine manufacturers...While we are not passing a conclusive determination on the constitutionality of the current policy, the manner in which the current policy has been framed would prima facie result in a detriment to the right to public health which is an integral element of Article 21 of the Constitution. Therefore, we believe that the Central Government should consider revisiting its current vaccine policy to ensure that it withstands the scrutiny of Articles 14 and Article 21 of the Constitution.”*<sup>39</sup>

The SC remained unconvinced by the government’s explanations for the change in policy and in its May order,<sup>40</sup> reiterated its finding that paid vaccination for the 18-44 group was prima facie arbitrary and irrational. The SC also expressed concerns with the role of the private sector in direct procurement and freedom in pricing. Nudged by the SC, the Central government reverted to central procurement for the States but maintained the new role of the private sector in procuring and providing vaccines albeit with price caps. The SC did not look into this aspect any further. This was unfortunate, because as the SC predicted, private sector procurement created a privileged class of people who could access both public and private sector settings to get a vaccine, while those without the ability to pay often had to wait for days for a slot in the public sector. A similar scenario then played out in the context of precaution/booster doses, which were announced in January 2022 for healthcare and front-line workers, and those above the age of 60 who had co-morbidities. In April 2022, precautionary doses were opened to all persons above the age of 18

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<sup>38</sup> ‘State’s Vaccine Global Tenders Draws a Blank’ (*The Hindu*, 6 June 2021) <<https://www.thehindu.com/news/national/telegana/states-vaccine-global-tenders-draws-a-blank/article34746015.ece>> accessed 12 April 2023.

<sup>39</sup> *Distribution of Essential Supplies and Services During Pandemic, In re* (n 7).

<sup>40</sup> *Distribution of Essential Supplies and Services During Pandemic, In re* (n 7).

only on payment at private centers.<sup>41</sup> Some States announced free precautionary doses at government centres.<sup>42</sup> In July, the central government announced free precautionary doses for all age groups at government centres for 75 days only.<sup>43</sup> Thus, despite the observations of the SC, the government continued to frame policies that discriminated both directly and indirectly against similarly circumstanced people based on their ability to pay.

## 2. *Expanding production*

The chaos in procurement and exports discussed above was directly related to the limited production of the vaccines. It was evident from the very beginning that only two manufacturers would not be able to supply enough doses of the vaccines for the entire nation, especially when they had already entered into agreements to supply COVID-19 vaccines to other developing countries. As vaccine shortages dogged India's vaccine rollout, and given India's co-sponsorship of the TRIPS Waiver proposal,<sup>44</sup> even economically conservative papers demanded that the government buy out Covaxin<sup>45</sup> and various HCs questioned why the government was not using compulsory licensing.<sup>46</sup> In *Distribution of Essential Supplies and Services During Pandemic, In re*, the SC went to great lengths to explain the provisions on compulsory licenses for the government to take note of in deciding its course of action. In its reply, the government stated in its affidavit that the use of compulsory licenses or legal tools would be "counter-productive."<sup>47</sup> The government also put out a '*Myths and Facts*' document<sup>48</sup> stating that compulsory licenses would not be an attrac-

<sup>41</sup> 'Precaution Dose to be now available to 18+ Population Group from 10th April, 2022, at Private Vaccination Centres' (*PIB Delhi*, 8 April 2022) <<https://pib.gov.in/PressReleasePage.aspx?PRID=1814804>> accessed 28 April 2023.

<sup>42</sup> PTI, 'Delhi Govt Says Free Precaution Doses at its Hospitals Soon' (*The New Indian Express*, 15 April 2022) <<https://www.newindianexpress.com/cities/delhi/2022/apr/15/delhi-govt-says-free-precaution-doses-at-its-hospitals-soon-2442464.html>> accessed 28 April 2023.

<sup>43</sup> 'All Adults to get Free Covid Precaution Dose from Today for Next 75 Days' (*India Today*, 15 July 2022) <<https://www.indiatoday.in/coronavirus-outbreak/vaccine-updates/story/adults-free-covid-precaution-dose-from-today-next-75-days-1975812-2022-07-15>> accessed 28 April 2023.

<sup>44</sup> 'Waiver From Certain Provisions of the Trips Agreement for the Prevention, Containment and Treatment of Covid-19' (*WTO*, 2 October 2020) <<https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True>> accessed 2 May 2023.

<sup>45</sup> 'Buy Out Covaxin's IPR, for World's Sake' (*Economic Times*, 8 March 2021) <<https://economictimes.indiatimes.com/blogs/et-editorials/buy-out-covaxins-ipr-for-worlds-sake/>> accessed 2 May 2023.

<sup>46</sup> KC Gopakumar, 'Kerala High Court seeks Centres Response to Invoke Compulsory Licensing of Covid Vaccines' (*The Hindustan Business Line*, 2 July 2021) <<https://www.thehindubusinessline.com/news/national/kerala-high-court-seeks-centres-response-to-invoke-compulsory-licensing-of-covid-vaccines/article34534257.ece>> accessed 12 April 2023.

<sup>47</sup> *In Re: Distribution of Essential Supplies and Services During Pandemic*, Suo Motu Writ Petition (C) No.3/2021, affidavit dated 09.05.2021 on behalf of the Union of India <[https://www.livewlaw.in/pdf\\_upload/centres-affidavit-in-suo-moto-covid-case-supreme-court-393164.pdf](https://www.livewlaw.in/pdf_upload/centres-affidavit-in-suo-moto-covid-case-supreme-court-393164.pdf)> accessed 28 April 2023.

<sup>48</sup> 'Myths & Facts on India's Vaccination Process' (*PIB Delhi*, 27 May 2021) <<https://pib.gov.in/PressReleasePage.aspx?PRID=1722078>> accessed 2 May 2023.

tive option for vaccine manufacturing, which requires licensing and technology transfer; ironically these were the same arguments used by developed countries and the multinational pharmaceutical industry to oppose India's TRIPS waiver proposal at the WTO.<sup>49</sup>

Review of patents on vaccines reveal a confusing web of multiple patents, often granted to multiple entities creating an extremely difficult pathway for other manufacturers to make the vaccines without infringing several existing patents.<sup>50</sup> While patents may not be the only barrier to vaccine production by other manufacturers, they are certainly a significant barrier. For instance, while patents related to Covishield specifically may not have been filed or granted by mid-2021, it could be protected by an older patent held by Astrazeneca in India on simian and hybrid adenoviral vectors and a patent application on the method for generating a recombinant adenoviral vector.<sup>51</sup> Compulsory licensing and government use provisions enshrined in the Patents Act, 1970 are meant to remedy several adverse consequences of exclusive control over technologies that patents can result in, particularly in terms of availability and affordability.<sup>52</sup> The use of these tools is as much a political act as it is a legal one and it can be argued that the government's formal reluctance to use this tool expressed to the SC and its listing of reasons for not doing so in a press release, severely undermined not only its own domestic policy space but also its international position on the TRIPS Waiver.

The SC also sought details on whether the government had invited expressions of interest for the voluntary licensing of Covaxin. Indeed, the government's explanation that technology transfer and licensing are needed to promote additional vaccine manufacturing has raised the question of why this was not done for Covaxin. The confusion over the intellectual property related to Covaxin<sup>53</sup> was clarified by the government's affidavit filed before the SC, which revealed that the intellectual property is shared between the government and Bharat Biotech, the government receives 5% royalty and its name is required to be printed on the Covaxin bottles.<sup>54</sup> The government informed the

<sup>49</sup> 'Seven Reasons the EU is Wrong to Oppose TRIPS Waiver' (*Human Rights Watch*, 3 June 2021) <<https://www.hrw.org/news/2021/06/03/seven-reasons-eu-wrong-oppose-trips-waiver>> accessed 2 May 2023.

<sup>50</sup> 'A Fair Shot for Vaccine Affordability' (*Access Campaign*, 2017) <[https://www.msfaaccess.org/sites/default/files/2018-06/VAC\\_report\\_A%20Fair%20Shot%20for%20Vaccine%20Affordability\\_ENG\\_2017.pdf](https://www.msfaaccess.org/sites/default/files/2018-06/VAC_report_A%20Fair%20Shot%20for%20Vaccine%20Affordability_ENG_2017.pdf)> accessed 28 April 2023.

<sup>51</sup> 'VaxPal: COVID-19 Vaccines Patent Database' (*Medicines Patent Pool*) <[https://www.vaxpal.org/?product%5B%5D=ChAdOx1+nCoV-19+\(AZD1222\)+0.5+ml&countries%5B%5D=India&page=1](https://www.vaxpal.org/?product%5B%5D=ChAdOx1+nCoV-19+(AZD1222)+0.5+ml&countries%5B%5D=India&page=1)> accessed 2 May 2023.

<sup>52</sup> Patents Act 1970, ss 84-103.

<sup>53</sup> R Ramakumar, 'Whose Intellectual Property is Bharat Biotech's Publicly Funded Covaxin? India Deserves an Answer' (*Scroll.in*, 26 April 2021) <<https://scroll.in/article/993257/why-its-vital-for-indians-to-know-who-owns-intellectual-property-rights-to-bharat-biotechs-covaxin>> accessed 2 May 2023.

<sup>54</sup> *Distribution of Essential Supplies and Services During Pandemic*, In re (n 47).

SC that three of its public sector units (Haffkine Biopharmaceuticals, Indian Immunologicals Limited and Bharat Immunologicals and Biologicals Limited) would be involved in manufacturing of Covaxin.<sup>55</sup> Bolstering public sector manufacturing which had been systematically dismantled over the years<sup>56</sup> could have had important short-term and long-term benefits. However, it remains unclear whether those units eventually manufactured Covaxin.

It is important to note that during a public health emergency, even if the government is taking the aid of the private sector, there are substantial public funds, public investments, human labour and resources that are used to bring out the product on time to curb, or mitigate the emergency in the shortest period of time. It is therefore pertinent that the government involves as many manufacturers as possible, particularly in a country like India with multiple manufacturers,<sup>57</sup> and place in the public domain processes, technical know-how, etc. so that those with the capacity are able to help in the production, manufacturing, distribution of the products. Profits and intellectual property rights ought not to take precedence over the fundamental right to life and health of people.

While the primary context within which demands for the expansion of production arose was domestic needs, two additional factors should have given the government the impetus to use their powers either under the Patents Act 1970 or as joint holders of the intellectual property and co-developers of Covaxin. The first relates to India's international obligations under the right to health discussed in greater detail below; at a time when procurement missteps and a sudden expansion of vaccine eligibility resulted in the stoppage of the vaccine exports from India, it was imperative for the government to explore and use every avenue available to expand production – both for Covishield and for Covaxin. The second factor that should have been taken into account was the emerging information on the increased risk of a particular side-effect of Covishield for young persons, i.e., Thrombosis and Thrombocytopenia Syndrome or TTS. In the one month that the SC and the government went back and forth on the availability and accessibility of COVID-19 vaccines, clear data on this serious and severe AEFI, which had a significant chance

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<sup>55</sup> 'Bharat Biotech Ready to Share COVAXIN Formula with other Manufacturers: Centre' (*Livemint*, 13 May 2021) <<https://www.livemint.com/news/india/bharat-biotech-agrees-to-give-covaxin-formula-to-other-manufacturers-centre-11620906716372.html>> accessed 2 May 2023, and 'Covaxin Production. Three More Firms get the Nod to Produce Covaxin' (*Hindu Business Line*, 16 May 2021) <<https://www.thehindubusinessline.com/news/three-more-firms-get-the-nod-to-produce-covaxin/article34567892.ece>> accessed 2 May 2023.

<sup>56</sup> Vibha Varshney, 'COVID-19 Vaccines: Waiting for Advantage India' (*Down to Earth*, 17 April 2021) <<https://www.downtoearth.org.in/news/health/covid-19-vaccines-waiting-for-advantage-india-76543>> accessed 28 April 2023.

<sup>57</sup> 'List of Licensed Human Vaccine Manufacturing Facilities in India' (CDSCO) <[https://cdsco.gov.in/opencms/export/sites/CDSCO\\_WEB/Pdf-documents/biologicals/facilitiesLIST.pdf](https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/biologicals/facilitiesLIST.pdf)> accessed 2 May 2023.

of resulting in death, had emerged from other countries and many had either stopped the use of the vaccine for the under 40 age group or were at least offering an alternative vaccine. Unlike most developing countries, India did have an alternative to offer in Covaxin, but with half-hearted efforts to expand production beyond the exclusive control of Bharat Biotech, this option could not really be exercised.

### 3. *Vaccine wastage*

India's immunization program had a wide reach and was well-organized prior to the COVID-19 pandemic. In keeping with WHO guidance, the government announced vaccination in phases starting with key priority groups. However, a certain amount of flexibility could have been built into the system to allow extra doses in opened vials to be given to persons outside of the priority groups to avoid vaccine wastage. The Delhi HC noted that as per one report about 44 lakhs vaccines had been wasted out of the 10 crore vaccines allocated to different States, because of the restriction of age and category of people who were entitled to take the vaccine. The court directed the government to devise ways and means to register volunteers who may be below the age of 45 years but above 18 years, who could be called upon to take the residual doses of vaccines, in case the doses are left unutilized after 5 PM every day, and requested the government to modify the Co-WIN app accordingly.<sup>58</sup> Instead of questioning and investigating the wastage caused by the vaccination policy, and checking on pilferage and corruption, in some cases, unfortunately, the blame was placed on healthcare providers. In one case, the anticipatory bail application of a nurse was rejected by the Allahabad HC, for her alleged involvement in the wastage of 29 vaccine doses of COVID-19 vaccines.<sup>59</sup> Vaccine wastage of another kind was reported throughout 2022 in relation to expiries of vaccine stocks. In July 2022, reports suggested that nearly 6 lakh Covishield doses in Maharashtra were likely to expire in the coming months.<sup>60</sup> In November 2022, Bharat Biotech announced that 200 million doses of Covaxin were about to expire.<sup>61</sup> While this wastage has been blamed on low uptake of precaution

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<sup>58</sup> 'Delhi HC on Status of Availability of COVID Beds, Supply of Ventilators, Need of Medical Oxygen and Essential Medications || "Wastage of a Single Dose of Vaccine is a Criminal Waste"' (*SCC Blog*, 21 April 2021) <<https://www.sconline.com/blog/post/2021/04/21/covid-19-7/>> accessed 2 May 2023.

<sup>59</sup> *Niha Khan v State of U.P.* Criminal Misc Anticipatory Bail Application U/S 438 CR.P.C. No. - 12674 of 2021.

<sup>60</sup> Nisha Nambiar, '6 Lakh Covishield Vaccine Doses to Expire in August, Maharashtra Races to Use Up Vials in Time' (*Times of India*, 31 July 2022) <<https://timesofindia.indiatimes.com/city/pune/6-lakh-covishield-vaccine-doses-to-expire-in-august-maharashtra-races-to-use-up-vials-in-time/articleshow/93243024.cms>> accessed 2 May 2023.

<sup>61</sup> Gopavajhala Diwakar, 'Owing to Poor Demand, 50 Million Doses of Covaxin Set to Expire Early 2023' (*The Wire*, 6 Nov 2022) <<https://thewire.in/health/covaxin-50-million-doses-expire-early-2023>> accessed 2 May 2023.

doses, as noted above, precaution doses were initially only available on payment likely dampening the demand for boosters from the very beginning.

#### 4. Exports

Right to health obligations are usually discussed in the domestic or national context. However, the right to health also places international obligations on governments; most often it is the obligation of developed countries that are the subject of these discussions. According to General Comment 14, “[S]tates parties have to respect the enjoyment of the right to health in other countries, and to prevent third parties from violating the right in other countries, if they are able to influence these third parties by way of legal or political means, in accordance with the Charter of the United Nations and applicable international law. Depending on the availability of resources, States should facilitate access to essential health facilities, goods and services in other countries, wherever possible, and provide the necessary aid when required.”<sup>62</sup> With the Indian government recognizing and in fact advertising its role as the key supplier of COVID-19 vaccines for the rest of the developing world, how India’s domestic policy impacted international access to vaccines is worth discussing.

There were international expectations that Serum Institute would be the key supplier of COVID-19 vaccines for developing countries from early on as the manufacturer entered into multiple collaborations with Oxford University, Astrazeneca, the Coalition for Epidemic Preparedness Innovations (CEPI), Global Alliance for Vaccines and Immunisation (GAVI) and the Bill and Melinda Gates Foundation (BMGF) in 2020. BMGF provided at-risk funding of 300 million dollars to Serum for supplying 200 million doses of COVID-19 vaccines to the international COVAX facility.<sup>63</sup> Within days of the national rollout starting, exports from India started with the government’s launch of its “Vaccine Maitri” mission of gifting doses to several neighbouring and friendly countries.<sup>64</sup> By end March 2021, however, both Serum Institute and Bharat Biotech were asked to prioritise domestic supplies as the Delta wave worsened.<sup>65</sup> Even as dismay grew across developing countries with

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<sup>62</sup> General Comment No. 14 (n 15).

<sup>63</sup> ‘New Collaboration Makes Further 100 Million Doses of COVID-19 Vaccine Available to Low- and Middle-income Countries’ (*Gavi The Vaccine Alliance*, 29 September 2020) <<https://www.gavi.org/news/media-room/new-collaboration-makes-further-100-million-doses-covid-19-vaccine-available-low>> accessed 2 May 2023.

<sup>64</sup> Prashasti Singh, “Vaccine Maitri’: Covid vaccine doses from India reach Bhutan, Maldives’ (*Hindustan Times*, 20 January 2021) <<https://www.hindustantimes.com/world-news/vaccine-maitri-covid-vaccine-doses-from-india-reach-bhutan-maldives-101611139314272.html>> accessed 2 May 2023.

<sup>65</sup> Himani Chandna and NayanimaBasu, ‘Prioritise Covid Vaccine Supplies within India Over Exports, Govt Tells Serum & Bharat Biotech’ (*The Print*, 25 March 2021) <<https://theprint.in/health/prioritise-covid-vaccine-supplies-within-india-over-exports-govt-tells-serum-bharat-biotech/628300/>> accessed 2 May 2023.

GAVI's announcement of delays of 90 million doses that were expected from Serum Institute<sup>66</sup>, it is of note that the greatest concern for both Serum and Astrazeneca appeared to be a shipment of 5 million doses destined not for COVAX or other developing countries, but for the UK,<sup>67</sup> which had already cornered a significant portion of international vaccine supplies.<sup>68</sup> The predicted re-start of exports within a few months was upended with the announcement of vaccination being opened up to everyone over the age of 18 in India. According to the WHO, the stoppage of vaccine exports from India affected 91 countries.<sup>69</sup> Exports restarted only about six-months later.<sup>70</sup>

The government of India and many experts have rightly noted that the blame for the international scarcity of COVID-19 vaccines hardly lay at India's doorstep. Not only had developed countries snapped up the majority of vaccine supplies as early as 2020,<sup>71</sup> they actively opposed the TRIPS Waiver proposal by India and South Africa at the WTO that could have cleared the pathway for widespread local production (and continue to oppose the vastly watered-down TRIPS decision on vaccine patents from being extended to diagnostics and therapeutics)<sup>72</sup> and did little to support a global technology transfer initiative by the WHO and the Government of Costa Rica.<sup>73</sup>

However this is not to say that missteps by the government of India did not exacerbate the situation or that there weren't legal, policy and other steps that

<sup>66</sup> PTI, 'Gavi Announces Supply Delays for up to 90 Million Vaccine Doses as India Sees Covid Surge' (*India TV*, 25 March 2021) <<https://www.indiatvnews.com/news/world/covid-vaccine-doses-delayed-gavi-un-vaccine-delivery-program-announcement-india-covid-surge-693545>> accessed 2 May 2023.

<sup>67</sup> PTI, 'Serum Institute Seeks Govt Nod to give 5 Million Vaccine Doses to UK' (*Business Standard*, 23 March 2021) <[https://www.business-standard.com/article/pti-stories/sii-seeks-govt-s-nod-to-give-50l-covishield-doses-to-uk-says-won-t-affect-india-s-vaccination-drive-121032301300\\_1.html](https://www.business-standard.com/article/pti-stories/sii-seeks-govt-s-nod-to-give-50l-covishield-doses-to-uk-says-won-t-affect-india-s-vaccination-drive-121032301300_1.html)> accessed 2 May 2023.

<sup>68</sup> AFP, 'UK Starts Mass Coronavirus Vaccination Programme' (*The Economic Times*, 8 December 2020) <<https://economictimes.indiatimes.com/news/international/business/uk-starts-mass-coronavirus-vaccination-programme/articleshow/79620085.cms?from=mdr>> accessed 2 May 2023.

<sup>69</sup> 'India's Covid Vaccine Export Ban has Affected 91 Countries, Says WHO Chief Scientist' (*Scroll.in*, 1 June 2021) <<https://scroll.in/latest/996305/indias-covid-vaccine-export-ban-has-affected-91-countries-says-who-chief-scientist>> accessed 2 May 2023.

<sup>70</sup> Elizabeth Roche, 'After 6-month pause, India resumes covid vaccine exports' (*Live mint*, 11 October 2021) <<https://www.livemint.com/news/india-restarts-covid-vaccine-export-11633865328184.html>> accessed 2 May 2023.

<sup>71</sup> 'Coronavirus: Rich Nations Snap up Vaccine Stocks in Global Race for Jab' (*The Economic Times*, 17 September 2020) <<https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/coronavirus-rich-nations-snap-up-vaccine-stocks-in-global-race-for-jab/articleshow/78168230.cms>> accessed 2 May 2023.

<sup>72</sup> 'WTO: North Countries Stalemate TRIPS Decision on Diagnostics & Therapeutics' (*TWN*, 19 October 2022) <<https://www.twn.my/title2/health.info/2022/hi221002.html>> accessed 2 May 2023.

<sup>73</sup> Carlos M Correa, 'Expanding the Production of COVID-19 Vaccines to Reach Developing Countries Lift the Barriers to Fight the Pandemic in the Global South' (*South Centre*, 2021) <<https://www.southcentre.int/wp-content/uploads/2021/04/PB-92.pdf>> accessed 2 May 2023.



the government could have taken to expand vaccine production that could have helped ease both domestic and international shortages. As noted above, the initial cautious procurement by the government resulted in a temporary halt in production by Serum Institute. The other decision by the government was a far more significant one i.e., the opening up of vaccination to all those above the age of 18 resulting in a sudden, and by all accounts, unplanned massive expansion of domestic needs, with an immediate adverse impact on international needs.

The unfortunate developments around vaccine exports from India highlighted another key gap in law and policy. The development of COVID-19 vaccines is based on multiple agreements, licenses and collaborations almost none of which are available in the public domain. Public health groups pointed out concerns with the lack of transparency in these agreements and the dangers of relying on non-transparent commercial arrangements while dealing with a public health emergency. With Serum Institute in particular, health groups noted that the lack of transparency in these agreements meant that there was little information on Serum's legal obligations to export which needed to be taken into account while determining what supplies would actually be available for domestic procurement.<sup>74</sup> This became apparent when Astrazeneca served Serum with a legal notice for failure to supply COVID-19 vaccines internationally.<sup>75</sup> A clause in the contract of particular interest that came to light only because of the export stoppage, was the requirement for Serum to prioritise any supply commitments that Astrazeneca had made.<sup>76</sup>

There is one other aspect that requires some attention and that relates to the actions of Indian manufacturers in the international market. News reports indicate that Serum charged much higher prices to developing countries when supplying bilaterally; for instance, Uganda, a Least Developed Country was reportedly being charged USD 7 per dose in an order it placed with Serum.<sup>77</sup> Bharat Biotech's international dealings have brought forth other aspects such as the allegations of corruption in the negotiations for the supply of Covaxin to Brazil at a high price of USD 15 per dose for a government contract<sup>78</sup> and

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<sup>74</sup> All India Drug Action Network, 'Letter from All India Drug Action Network on Serum Institute of India's Application for Emergency Approval for Covishield' (*Health, Ethics and Law*, 8 December 2020) <<https://fmesinstitute.org/serum-institute-of-indias-application-for-emergency-approval-for-covishield/>> accessed 4 April 2023.

<sup>75</sup> 'SII Receives Legal Notice from AstraZeneca Over Vaccine Delays' (*The Quint*, 8 April 2021) <<https://www.thequint.com/news/india/sii-gets-legal-notice-from-astrazeneca-over-vaccine-delays>> accessed 28 April 2023.

<sup>76</sup> PTI (n 67).

<sup>77</sup> Esther Nakkazi, 'Uganda Defends Price Paid for AstraZeneca COVID19 Vaccine; New Study Suggests Vaccine Could Cut Transmission By Two-Thirds' (*Health Policy Watch*, 3 February 2021) <<https://healthpolicy-watch.news/uganda-defends-astrazeneca-price-says-its-not-higher-than-other-countries/>> accessed 28 April 2023.

<sup>78</sup> Leroy Leo, 'Brazil Suspends \$320 Million Deal with Bharat Biotech for Covaxin' (*Live mint*, 30 June 2021) <<https://www.livemint.com/companies/news/>

the flagging of Good Manufacturing Practice (GMP) concerns by the WHO in April 2022.<sup>79</sup>

The ethical implications of decisions by countries who had vaccine doses to prioritise mass domestic vaccination beyond key vulnerable groups when the vast majority of developing countries had barely even rolled out a small number of first doses to their vulnerable groups, is a hotly debated topic.<sup>80</sup> Vaccine distribution is also at the heart of ongoing negotiations on a Pandemic Treaty.<sup>81</sup> In India's case, arguably the responsibility became acute as exports had in fact started, several developing countries commenced their vaccination drives as first doses had already arrived from India,<sup>82</sup> others put in place rollout plans and host of other actions were taken by multilateral agencies in anticipation of the exports from India.<sup>83</sup> Particularly for those in need of second doses in these countries, a total stoppage of exports from India should have been reconsidered. In the interest of those countries clearly reliant on India, the question of whether India should have continued a gradual expansion of eligibility with a focus on those with co-morbidities instead of a sudden, unrestricted expansion to the 18+ age group is a matter that deserves some reflection. Certainly, as noted in the section on expanding production above, India had an obligation to increase the availability of vaccines by involving other vaccine manufacturers in the production of both the vaccines to meet domestic and international needs.

It is of note that no formal ban on the exports of COVID-19 vaccines was in place during the period that exports were halted indicating that the government

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brazil-suspends-320-million-deal-with-bharat-biotech-for-covaxin-11625073987131.html> accessed 4 April 2023.

<sup>79</sup> 'Suspension of Supply of COVID-19 Vaccine (COVAXIN)' (*WHO*, 2 April 2022) <<https://www.who.int/news/item/02-04-2022-suspension-of-supply-of-covid-19-vaccine-covaxin>> accessed 28 April 2023.

<sup>80</sup> Nancy S Jecker, Aaron G Wightman and Douglas S Diekema, 'Vaccine Ethics: An Ethical Framework for Global Distribution of COVID-19 Vaccines' [2021] *National Library of Medicine* <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7887861/>> accessed 2 May 2023.

<sup>81</sup> Kerry Cullinan, 'Pandemic Treaty 'Zero-Draft' is Out – Proposes WHO Gets 20% of All Pandemic Products to Ensure Equity' (*Health Policy Watch*, 1 February 2023) <<https://health-policy-watch.news/pandemic-treaty-zero-draft-proposes-who-gets-20-of-products/>> accessed 2 May 2023. See also: 'WHO's Pandemic Treaty: Promises of Equity should be Kept' (*The Lancet Global Health*, 1 March 2023) <[https://www.thelancet.com/journals/langlo/article/PIIS2214-109X\(23\)00121-3/fulltext](https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(23)00121-3/fulltext)> accessed 2 May 2023.

<sup>82</sup> 'COVID-19 Vaccine Doses Shipped by the COVAX Facility Head to Ghana, Marking Beginning of Global Rollout' (*WHO*, 24 February 2021) <<https://www.who.int/news/item/24-02-2021-covid-19-vaccine-doses-shipped-by-the-covax-facility-head-to-ghana-marking-beginning-of-global-rollout>> accessed 2 May 2023 and Suhasini Haidar, 'Hit by India's Vaccine Export Ban, Bhutan Seeks Help' (*The Hindu*, 27 June 2021) <<https://www.thehindu.com/news/international/hit-by-indias-vaccine-export-ban-bhutan-seeks-help/article35006213.ece>> accessed 2 May 2023.

<sup>83</sup> 'UNICEF Begins Shipping Syringes for the Global Rollout of COVID-19 Vaccines under COVAX' (*UNICEF*, 23 February 2021) <<https://www.unicef.org/press-releases/unicef-begins-shipping-syringes-global-rollout-covid-19-vaccines-under-covax>> accessed 2 May 2023.

had sufficient informal power to effect changes in the decisions of the vaccine manufacturers. This power could certainly have been exercised to expand the pool of vaccine manufacturers even if the government was reluctant to take any legal steps to force the sharing of technology or intellectual property. It could also be used to increase the government's oversight of the actions of Indian manufacturers abroad. Although India's international obligations on the right to health, at least in so far as increasing and ensuring availability were concerned, did not find mention in the SC's deliberations in *In Re: Distribution Of Essential Supplies And Services During Pandemic*, given the significant impact that India's capacity to produce and supply medical products has internationally, perhaps these aspects should also be taken into consideration in the future.

## B. Accessibility

*Anushi, 26 years of age, registered on the CoWIN platform for her Covid-19 vaccination the very first day registrations were thrown open for those above 18 years. However, she is still waiting for a slot at a government vaccination centre. "I have been trying to get myself and my brother vaccinated but I cannot seem to find any slots at government centres. My parents also need to get their second dose. Private facilities are too expensive," Anushi said... For the 18-45 age group, all 368 government centres...have been suspended for around two weeks now. Meanwhile, people are getting vaccinated in droves at private hospitals. The situation is diametrically opposite to what is happening at government centres. At a private hospital vaccination centre in Delhi, Deepanshu Mehta told India Today, "At government centres, you will get a slot if you are lucky. Otherwise, the wait can be endless. My office requires a vaccination certificate and that is why I got vaccinated at a private hospital. I had to pay a lot but there was no option."*

— *India Today*, 6 June 2021<sup>84</sup>

*Ram Kumari, 26, from Gurugram, Haryana, said: "I didn't even know we had to register on the phone. I don't have a smartphone. My husband has one, but I don't know how to use it." She added: "I want to get the vaccine, and I thought*

<sup>84</sup> Milan Sharma, Aishwarya Paliwal Sushant Mehta, 'With Govt Centres Shut and Private Hospitals Pricy, Delhi's Youngsters Left without Covid Vaccines' (*India Today*, 6 June 2021) <<https://www.indiatoday.in/cities/delhi/story/govt-centres-shut-private-hospitals-delhi-youngsters-left-covid-vaccines-1811389-2021-06-05>> accessed 2 May 2023.

*of going to the government hospital, but it is too far to walk. I have no way of getting there, especially alone.”*

— *The Guardian*, 28 June 2021<sup>85</sup>

*“Last week I had told you that I do not have the figures. Today I have the figures. So if we take the figures from 1 May to 22 September — this is a big qualification, so we are not talking of the entire period of vaccination, we are talking of May, June, July, August, and 22 days of September — roughly 6 per cent doses have been administered in private hospitals and remaining doses have been administered in public health facilities,” Bhushan said while replying to a question from ThePrint.”*

— *The Print*, 23 September 2021<sup>86</sup>

*Only 4,018 people with disabilities have received both doses of COVID-19 vaccine till November 28, as per figures released by the Health Ministry during the ongoing session of Parliament. It added that as per the CoWIN portal, 8,390 people with disabilities received the first dose. As per Census 2011, the differently abled population in India stands at 26.8 million.*

— *The Hindu*, 7 December 2021<sup>87</sup>

The principle of *accessibility* requires that health services, goods and facilities be physically<sup>88</sup> and economically<sup>89</sup> accessible to all without discrimination.

<sup>85</sup> Nayanika Guha, ‘India’s Covid Gender Gap: Women Left Behind in Vaccination Drive’ (*The Guardian*, 28 June 2021) <<https://www.theguardian.com/global-development/2021/jun/28/india-covid-gender-gap-women-left-behind-in-vaccination-drive>> accessed 2 May 2023.

<sup>86</sup> Abantika Ghosh, ‘Private Sector Administered 6% of Covid Vaccines Since May, Maharashtra Tops List, Says Centre’ (*The Print*, 23 September 2021) <<https://theprint.in/india/private-sector-administered-6-of-covid-vaccines-since-may-maharashtra-tops-list-says-centre/738899/>> accessed 2 May 2023.

<sup>87</sup> Bindu Shajan Perappadan, ‘COVID-19 | Only 4,018 People with Disabilities got Both Doses of Vaccine Till November-end’ (*The Hindu*, 7 December 2021) <<https://www.thehindu.com/news/national/only-4018-people-with-disabilities-got-both-doses-of-covid-19-vaccine-till-november-end/article37880304.ece>> accessed 2 May 2023.

<sup>88</sup> “Physical accessibility: health facilities, goods and services must be within safe physical reach for all sections of the population, especially vulnerable or marginalized groups, such as ethnic minorities and indigenous populations, women, children, adolescents, older persons, persons with disabilities and persons with HIV/AIDS. Accessibility also implies that medical services and underlying determinants of health, such as safe and potable water and adequate sanitation facilities, are within safe physical reach, including in rural areas. Accessibility further includes adequate access to buildings for persons with disabilities.” See, CESCR General Comment No. 14: The right to the highest attainable standard of health (art 12) (n 15).

<sup>89</sup> “Economic accessibility (affordability): health facilities, goods and services must be affordable for all. Payment for health-care services, as well as services related to the underlying

Accessibility also includes the right to seek, receive and impart information and ideas concerning health issues. However, accessibility of information should not impair the right to have personal health data treated with confidentiality. These aspects of informational accessibility are discussed later in the context of the principles of acceptability and quality. This section focusses on the issues of prioritisation and discrimination in vaccine access and economic accessibility in terms of vaccine pricing.

## 1. *Prioritisation*

As soon as it became clear that COVID-19 vaccines were likely to be effective and that there would likely be restricted supplies, the WHO's SAGE committee issued guidance for countries to take into account while deciding which population groups would be prioritised in vaccination.<sup>90</sup> India's rollout of COVID-19 vaccines started in January 2021 for healthcare workers and frontline workers, in March 2021 for the 65+ and 45+ (with co-morbidities) age groups and in April 2021 for the entire 45+ age group. In May 2021, eligibility for vaccination was declared for everyone who was 18+. It is this announcement of the sudden expansion of eligibility to all adults that resulted in the most controversy.

In the SC, in *Distribution of Essential Supplies and Services During Pandemic, In re*, the controversy related to the government's departure from centralized procurement and paid vaccinations for this age group. But the very basis of opening up of vaccine eligibility was also questioned and a group of researchers and doctors contended that the move in effect de-prioritised the previously eligible groups noting that, "from 3 May to 5 June 2021, more first doses were administered to people under 45 than over 60, even though at least 77 million people aged 60 remain unvaccinated."<sup>91</sup> Several States facing vaccine shortages announced suspensions of vaccination for the 18+ group to preserve vaccine stock for the 45+ age group.<sup>92</sup> In Chhattisgarh,

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*determinants of health, has to be based on the principle of equity, ensuring that these services, whether privately or publicly provided, are affordable for all, including socially disadvantaged groups. Equity demands that poorer households should not be disproportionately burdened with health expenses as compared to richer households."* *ibid.*

<sup>90</sup> 'WHO SAGE Roadmap for Prioritizing Uses of Covid-19 Vaccines in the Context of Limited Supply' (WHO, 2020) <<https://www.who.int/docs/default-source/immunization/sage/covid/sage-prioritization-roadmap-covid19-vaccines.pdf>> accessed 2 May 2023.

<sup>91</sup> Peter Llyod Sherlock, Nidheesh Manee Kandiyil, Martin McKee, Arokiasamy Perianayagam, Sridhar Venkatapuram, Soumithra Pathare, Aravinda Meera Guntupali, Ramesh Kumar K, Soumitra Ghosh, 'Pandemic Lessons from India: Inappropriate Prioritisation for Vaccination' (*BMJ*, 9 June 2021) <<https://www.bmj.com/content/373/bmj.n1464>> accessed 2 May 2023.

<sup>92</sup> Bhavika Jain, Richa Pinto and Sumitra Debroy, '60+ in Mumbai now Walk in for 2nd Dose 3 Days a Week' (*Times of India*, 13 May 2021) <<https://timesofindia.indiatimes.com/city/mumbai/60-in-city-can-now-walk-in-for-2nd-dose-3-days-a-week/articleshow/82590158.cms>> accessed 2 May 2023; 'Delhi: Vaccination for 18-44 Category Suspended for 5th Day, No COVAXIN for any Age Grp, says AAP MLA' (*Live mint*, 28 May 2021) <<https://www>

given the shortages for the 18-44 group, the government announced three phases for the vaccination of the 18+ group starting with those enrolled in the Antyodaya Anna Yojana, followed by those who were below the poverty line and in the third phase expanding to those above the poverty line. The HC of Chhattisgarh, however, directed the government to earmark vaccines for all the three groups in an equal ratio of 33% instead of the phase-wise approach.<sup>93</sup> Public health activists noted that the approach of the Chhattisgarh government had been in line with WHO's priority groups and that equality in access as directed by the HC would end up undermining equity; what our courts have so eloquently described in the past as substantive equality rather than formal equality.<sup>94</sup>

## 2. *Discrimination*

The SC in *Distribution of Essential Supplies and Services During Pandemic, In re*, found that prima facie the government's procurement policy in providing free vaccines to those above 45 and not to those in the 18-45 age group was discriminatory. However, this was not the only aspect of the vaccine policy that was discriminatory. The COVID-19 vaccine rollout programme appeared to adopt a one-size-fits-all approach. There was scant attention paid to the many vulnerabilities and barriers that keep people away from healthcare. The rollout excluded a large number of differently abled persons, elderly, non-citizens living in India, pregnant women, and others who were unable to register on the app or reach the centres to get the vaccine.

One of the first barriers to access related to the so-called 'digital divide', as reports came in of hardships faced in registering through the Co-WIN application (Co-WIN app). Many people did not have smart phones or even access to the internet to register to get a vaccine. In a *suo motu* petition, the HC of Tripura, issued directions to the State to provide fullest assistance to such persons so that there was no class divide for access to vaccination, and to make a road map for securing vaccination to the majority of the eligible population.<sup>95</sup> Prodded by the SC in its April order in *Distribution of Essential Supplies and Services During Pandemic, In re* the Central government announced walk-in

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livemint.com/news/india/delhi-vaccination-for-18-44-category-suspended-for-5th-day-no-covaxin-for-any-age-grp-says-aap-mla-11622210148892.html> accessed 4 April 2023.

<sup>93</sup> *Suo Motu v State of Chhattisgarh*, 2021 SCC OnLine Chh 1008 (High Court of Chhattisgarh), <<https://www.livemint.com/news/india/delhi-vaccination-for-18-44-category-suspended-for-5th-day-no-covaxin-for-any-age-grp-says-aap-mla-11622210148892.html>> accessed 28 April 2023.

<sup>94</sup> Sulakshana Nandi, 'Chhattisgarh took the Right Step towards Vaccine Equity – But the High Court Blocked it with Quotas' (*Scroll.in*, 9 May 2021) <<https://scroll.in/article/994435/chhattisgarh-took-the-right-step-towards-vaccine-equity-but-the-high-court-laid-down-quotas>> accessed 4 April 2023.

<sup>95</sup> *Court on Its Own Motion*, Writ Petition PIL No. 9 of 2020, High Court of Tripura, Agartala, order dated 31.5.2021.

registrations for the 18-44 age group but only at government centres.<sup>96</sup> In its May order, the SC found that a vaccination policy relying only on a digital portal would create an accessibility barrier for the marginalized and, “*could have serious implications on the fundamental right to equality and the right to health,*” of such persons.

The courts also dealt with cases related to vaccine access for non-citizens. A petition was taken up by the Uttarakhand HC based on a letter by a student stating that people from Nepal who are living in India were unable to register on the Co-WIN app to get vaccinated as they did not have Aadhaar cards.<sup>97</sup> The HC of Rajasthan gave directions to the state government in a *suo motu* petition for Pakistani minority migrants living in the State to be provided with vaccines and food grains. The court issued a set of guidelines that could be followed for varied groups and beneficiaries to avail of the vaccines and directed the state government to chalk out a plan.<sup>98</sup>

The rollout also made little provision for persons with disabilities. Two cases, one in the SC and one in the Bombay HC, are important to examine in this context. The Bombay HC heard a PIL between April 2021 and October 2021 on the need for door-to-door vaccination facilities for senior citizens and specially-abled persons who are unable to reach the vaccination centres. The State contended that the reasons that there was no door-to-door vaccination policy was because of difficulties in managing AEFIs and observing beneficiaries for 30 minutes, vaccine contamination, vaccine wastage and difficulty in maintaining social distancing with elderly who have co-morbidities. The HC on hearing both parties found that such a policy was arbitrary and unreasonable, the elderly are also entitled to protection under Article 21 of the Constitution of India and it was for the State to figure out how to deal with the risks it had identified,<sup>99</sup> and in a series of orders oversaw the establishment of a door-to-door vaccination policy in Maharashtra. The court also asked for a record of AEFIs when the door-to-door vaccination was started and found this concern was unfounded. By the time the case was disposed of in October 2021, the Central government had finally instituted door-to-door vaccination, something it then highlighted in a PIL before the SC asking for similar directions as the Bombay HC case. The case in the SC is ongoing with interim orders citing the right of accommodation under the *Rights of Persons with Disabilities Act, 2016*, noting that only 23,678 persons with disabilities had been vaccinated and

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<sup>96</sup> ‘Walk-in Vaccine Registration for 18-44 Age Group Allowed at Govt-Run Centres’ (*Indian Express*, 24 May 2021) <<https://indianexpress.com/article/india/walk-in-vaccination-at-government-run-centres-now-allowed-for-people-in-18-44-age-group-7328081/>> accessed 4 April 2023.

<sup>97</sup> *In Writ Petition PIL No. 62 of 2021*, suo motu taken up by the Uttarakhand High Court, dated 19.5.2021.

<sup>98</sup> *Suo Motu v. Union of India &anr.*, D.B. Civil WP no. 10075 of 2017, order dated 27.5.2021.

<sup>99</sup> *Dhruti Kapadia v Union of India* 2021 SCC OnLine Bom 659.

directing the Central government to call for suggestions on strengthening the framework for vaccination of the disabled.<sup>100</sup>

Persons in care homes and custodial settings were also not accounted for. In a case relating to conditions in mental healthcare homes, the SC gave interim orders to all the States and Union Territories to lay down a time schedule to facilitate vaccination of people lodged in the mental health care institutions and their care givers, and provide a progress report.<sup>101</sup> The Uttarakhand HC, recognizing that the uptake of vaccinations in the prisons has been low, passed orders to drastically increase the uptake of vaccinations.<sup>102</sup>

The lack of gender sensitivity in the vaccine policy was raised before the SC by the Delhi Commission for Protection of Child Rights, which contended that the exclusion of pregnant and lactating women from the vaccination drive was discriminatory and violative of Articles 14, 15 and 21 of the Constitution of India.<sup>103</sup> The petitioners contended that there was medical evidence available to show that the vaccines were safe for pregnant and lactating women, a fact that was also endorsed by the Federation of Obstetrics and Gynecological Societies of India, stating that they should also be given COVID-19 vaccines to protect themselves and their children.<sup>104</sup> As pregnant and lactating women were included in the vaccination drive during the pendency of the petition, additional concerns raised by the Petitioner on the manner of declaration of pregnancy or lactation and for tracking AEFIs were considered policy level submissions requiring experts with domain knowledge and the SC asked for these to be submitted to the government for their consideration. Additionally, the SC dismissed an intervention in the case asking for stoppage of vaccination for pregnant and lactating women, stating that the decision of the government was based on guidance from the WHO and other domain experts and that, “*this Court cannot take medical decisions regarding the safety of COVID-19 vaccination among pregnant and lactating persons.*”<sup>105</sup>

### 3. Pricing

The pricing of vaccines has been a critical issue with the sale and administration of the vaccines through the private sector. When private sector hospitals were roped in at the beginning of the rollout in the administration of the vaccines, the government announced a price cap of Rs. 250 (Rs. 150 as vaccine

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<sup>100</sup> *Evava Foundation v Union of India* Writ Petition (Civil) No. 58 of 2021, Supreme Court, interim order dated 23.02.2022.

<sup>101</sup> *Gaurav Kumar Bansal v Dinesh Kumar* 2018 SCC OnLine SC 3522, interim order dated 01.09.2021.

<sup>102</sup> *Omveer Singh v State of Uttarakhand* 2021 SCC OnLine Utt 561.

<sup>103</sup> *Delhi Commission for Protection of Child Rights v Union of India* 2021 SCC OnLine SC 3143.

<sup>104</sup> *ibid.*

<sup>105</sup> *ibid.*



charge and Rs. 100 as service charge) for administering the vaccine. The real issue with pricing arose when vaccination was opened up for the 18-44 age group. At this stage, while the government negotiated lower prices for itself,<sup>106</sup> pricing in the private sector presented several problems.

From the beginning of the rollout, vaccine manufacturers complained about the low government procurement prices. Serum stated that while they were making profits, they were unable to make super profits to invest in expansion.<sup>107</sup> When the government opened up vaccination for the 18+ age group, the companies were given a free hand to set the price at which the vaccine would be sold to the States and to the private sector as long as this was disclosed upfront. Both Serum and Bharat announced three sets of prices with the lowest for the Central government, a higher band for State governments and the significantly higher prices for the private sector.<sup>108</sup>

As noted in the section on procurement above, the SC found the Central government's policy discriminatory but its nudging only resulted in the Central government reverting to centralized procurement for the Central and State roll-outs. Private sector procurement at higher prices was maintained. The price for both vaccines to the government was Rs. 150 per dose. Prices to the private sector were Rs. 600 for Covishield and Rs. 1200 for Covaxin. Reports of widely varying high prices being charged across large corporate hospitals and cities<sup>109</sup> resulted in the government stepping in to cap prices (taking into account GST and a Rs. 150 service charge) at Rs. 780 for Covishield and Rs. 1410 for Covaxin per dose in the private sector.<sup>110</sup> By the time precaution doses were announced both companies had reduced their price to Rs. 255 per dose for the private sector.<sup>111</sup> It is interesting to note that the Maximum Retail Prices (MRP) for both vaccines have never been announced. It is also worth noting that estimates suggest that with high volumes, the production of adenovirus vector vaccines should cost between Rs. 12.26 to Rs. 18.80 per dose

<sup>106</sup> Affidavit on behalf of the Union of India (n 47).

<sup>107</sup> NDTV, “‘Making Profit, But not Enough to Reinvest,’ Says Adar Poonawalla to NDTV” (*YouTube*, 6 April 2021) <[https://www.youtube.com/watch?v=T6gSk0GsQE4&ab\\_channel=NDTV](https://www.youtube.com/watch?v=T6gSk0GsQE4&ab_channel=NDTV)> accessed 4 April 2023.

<sup>108</sup> Rhythma Kaul, ‘Covaxin Price Dropped to 400 for States; Still 1,200 for Pvt Hospitals’ (*Hindustan Times*, 29 April 2021) <<https://www.hindustantimes.com/india-news/covaxin-price-dropped-to-rs-400-for-states-still-rs-1-200-for-pvt-hospitals-101619705802978.html>> accessed 4 April 2023.

<sup>109</sup> Rema Nagarajan, ‘At Rs 700-Rs 1,500, Price of Covid Vaccine in India’s Private Sector Among Costliest’ (*Times of India*, 10 May 2021) <<https://timesofindia.indiatimes.com/india/at-rs700-rs1500-price-of-covid-vaccine-in-indias-private-sector-among-costliest/articleshow/82509814.cms>> accessed 4 April 2023.

<sup>110</sup> Special Correspondent, ‘Government Caps Prices of COVID-19 Vaccines at Private Hospitals’ (*The Hindu*, 8 June 2021) <<https://www.thehindu.com/news/national/high-cost-of-vaccination-at-private-hospitals-unacceptable-paul/article34763106.ece>> accessed 4 April 2023.

<sup>111</sup> Priyanka Sharma, ‘Bharat Biotech, Serum Institute Reduce Covid Booster Dose Price to 225’ (*Live mint*, 9 April 2022) <<https://www.livemint.com/news/india/bharat-biotech-serum-institute-reduce-covid-booster-dose-price-to-rs-225-11649503209141.html>> accessed 4 April 2023.

depending on the process used.<sup>112</sup> Factoring in post-production and delivery costs, the price of a viral vector vaccine like Covishield should be closer to the median price of Rs. 65.38 per dose paid by countries for other vaccines.<sup>113</sup> While there are no estimates for inactivated vaccines, experts suggest the cost to Bharat Biotech for producing and supplying Covaxin should be between Rs. 60 – 100.<sup>114</sup> This suggests that both companies were already making significant profits at the government's procurement price. Reports show massive revenue increases for both companies for 2021-22,<sup>115</sup> which begs the question of whether in a pandemic, the extremely high private sector pricing of both vaccines was at all justified.

The SC highlighted another factor while discussing the higher prices in the private sector and raised the pertinent question of how the government's funding of COVID-19 vaccine research and development was being reflected in the private sector prices. The SC noted that the government spent ₹11 crore on Covishield clinical trials and that Serum had not invested in the vaccine's R&D and it had spent ₹35 crore on Covaxin clinical trials where it shared the R&D and the IP with Bharat Biotech.<sup>116</sup> Some analysts believe even these amounts are an underestimate.<sup>117</sup> This was really the only data on the arrangements between the government and the manufacturers that was made available in the public domain and efforts to access more information through RTI applications have been futile.<sup>118</sup> Apart from the investments disclosed in the SC affidavits, there have been reports of an additional ₹900 crore R&D grant for vaccines by the government. However, details on who has received these

<sup>112</sup> Rafael G Ferreira, Neal F Gordon, Rick Stock, Demetri Petrides, 'Adenoviral Vector COVID-19 Vaccines: Process and Cost Analysis' (*MDPI*, 18 August 2021) <<https://www.mdpi.com/2227-9717/9/8/1430#B58-processes-09-01430>> accessed 4 April 2023.

<sup>113</sup> Olivier J Wouters, 'Challenges in Ensuring Global Access to COVID-19 Vaccines: Production, Affordability, Allocation, and Deployment' (*The Lancet Global Health*, 13 March 2021) <[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)00306-8/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00306-8/fulltext)> accessed 28 April 2023.

<sup>114</sup> Himani Chandna, 'Bharat Biotech Promised Shot Cheaper than Bottled Water. But Covaxin is 3rd Costliest in World' (*The Print*, 14 June 2021) <<https://theprint.in/india/bharat-biotech-promised-shot-cheaper-than-bottled-water-but-covaxin-is-3rd-costliest-in-world/677108/>> accessed 28 April 2023.

<sup>115</sup> 'Serum Institute of India Continues to Lead in Indian Biopharmaceutical Industry Survey 2022' (*Bio Spectrum*, 11 April 2023) <<https://www.biospectrumindia.com/features/18/22925/serum-institute-of-india-continues-to-lead-the-indian-biopharmaceutical-industry-survey-2022.html>> accessed 28 April 2023.

<sup>116</sup> *Distribution of Essential Supplies and Services During Pandemic, In re*, (n 47).

<sup>117</sup> R Ramakumar, 'As Indian Government Offers Some Answers on Covaxin Patent Rights, More Questions Emerge' (*Scroll.in*, 12 May 2021) <<https://scroll.in/article/994763/as-indian-government-offers-some-answers-on-covaxin-patent-rights-more-questions-emerge>> accessed 28 April 2023.

<sup>118</sup> Aniket Aga and Chitraganda Choudhary, 'Modi Govt Keeps Financial Deal with Bharat Biotech Secret, Covaxin Among World's Costliest Vaccines' (*Article 14*, 16 November 2021) <<https://article-14.com/post/modi-govt-keeps-financial-deal-with-bharat-biotech-secret-covaxin-among-world-s-costliest-vaccines--619317364e311>> accessed 2 May 2023.

grants and how much remain vague.<sup>119</sup> It is also worth noting that estimates suggest that 97-99% of funding for the Oxford vaccine, which was licensed to Serum Institute through Astrazeneca, came from public and charitable sources till Autumn 2020.<sup>120</sup> As noted previously, BMGF provided at-risk funding of 300 million dollars to Serum Institute which included a price ceiling of USD 3 per dose.<sup>121</sup> Additionally, the US NIH also revealed that the adjuvant used in Covaxin was developed with their funding.<sup>122</sup>

It appeared that the risks of investing in a vaccine candidate were minimized for the private sector and taken on by the government and funding agencies. Despite the rapid and significant amount of this public and philanthropic investment, pharmaceutical companies appear to have largely retained control over the production, supply and prices of the vaccines. Despite the SC's pointed questions in this regard, high prices continued to be charged in the private sector for COVID-19 vaccines and as noted previously, the SC did not return to this issue.

### C. Acceptability

*“...because Ritu was a normal child it didn't even occur to me that I have to go to a paediatrician and ask if there are any potential side effects of this and even at the vaccination centres there was no information put up, nothing of concern...it was just by word of mouth that I hear from others that you might expect high fever the next day or body pains but that should subside within a few days. That was the only information we had. We both, Ritu and I got our vaccines on the 29<sup>th</sup> of May around 9.30 am and we both got Covishield...*

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<sup>119</sup> E Kumar Sharma, 'Where did the Govt's Rs 900 Crore R&D Grant for COVID Vaccine Development Go?' (*Financial Express*, 14 April 2021) <<https://www.financialexpress.com/lifestyle/health/where-did-the-govts-rs-900-crore-rd-grant-for-covid-vaccine-development-go/2232734/>> accessed 2 May 2023; See also Department-Related Parliamentary Standing Committee on Science and Technology, Environment, Forests and Climate Change, *Demands for Grants (2021-2022) of the Department of Biotechnology (Demand No. 89) (342nd Report, 2021)*.

<sup>120</sup> Samuel Cross, 'Who Funded the Research Behind the Oxford-AstraZeneca COVID-19 Vaccine?' (*BMJ*) <<https://gh.bmj.com/content/6/12/e007321>> accessed 2 May 2023.

<sup>121</sup> 'Serum Institute of India to Produce up to an Additional 100 Million Covid-19 Vaccine Doses for India and Low-and Middle-Income Countries in 2021' (*Serum Institute of India Pvt. Ltd.*, 29 September 2020) <[https://www.seruminstitute.com/news\\_sii\\_gavi\\_bmgf.php](https://www.seruminstitute.com/news_sii_gavi_bmgf.php)> accessed 2 May 2023.

<sup>122</sup> 'Adjuvant Developed with NIH Funding Enhances Efficacy of India's COVID-19 Vaccine' (*National Institutes of Health*, 29 June 2021) <<https://www.nih.gov/news-events/news-releases/adjuvant-developed-nih-funding-enhances-efficacy-indias-covid-19-vaccine>> accessed 2 May 2023.

*...the early hours of June 5<sup>th</sup> around 3.30 am...she woke up saying mama my head is really hurting...I feel as if lice are crawling all over my head...she woke up around 12 or 12.30, this was still the 5<sup>th</sup> of June...she said her left thumb was really, really sore...one of the small toes on her left foot was also hurting...finger tips are tingling and they feel numb...palms are kind of itchy...it was the 7<sup>th</sup> of June and I had been giving her avil for two days [on doctor's advice] and she wasn't better so we took her for bloodwork. She started noticing spots under the skin on her palm...around 9 in the night got a call... from Vijay Diagnostics...her platelets are extremely low...the next day [on the video call with the GP at Apollo and after re-test confirmed low platelets] the doctor said no need to panic...then my uncle who is a retired doctor who sent me a link about covishield and blood clots...I didn't have the knowledge to think this was life threatening...*

*...around 6 in the evening on 8<sup>th</sup> June, Ritu started getting a headache... shooting pain... started throwing up...every 20-30 minutes...it was around 10.30 in the night...we rushed her to Apollo...neurologist said get her an MRI...technician said there is a problem in her brain get her admitted right away...doctor came around 6.30 am...said she seems to have a clot in her brain...within a few hours she got seizures right in front of our eyes...she was put on the ventilator...she went in for a surgery, a craniotomy...this all happened on the 9<sup>th</sup> of June. 10<sup>th</sup> of June...doctor said your daughter has CVST [cerebral venous sinus thrombosis]...50% chance of her survival...yes clots happen but you see symptoms over a month...but the way your daughter got it...it started like a drizzle but became a storm...*

*...the next few days they did every possible test to see if she had an underlying condition, they couldn't find anything to link it to...in between I heard from the doctors this could be a vaccine induced thrombocytopenia...around 15<sup>th</sup> of June they said we tried everything...there's no brain signals...and at this point we consider her brain dead...I didn't trust them...how can she be brain dead in 6 days...toughest decision in my entire life to just let her go...so we could continue in the process of Jeevan dan [organ donation]...at 1.30 am on 20<sup>th</sup> June they took her to the operation theatre...somehow the government got involved and delayed our discharge...they didn't give us the result of the autopsy...*

*...recently we found out about AEFI and tried to file but we found vaccination department had reported it...when I talked to people, to doctors they say it's one in one million, one in one lakh but ask the person, the family member who have lost...even one in million is not true...in some countries its one in 26,000...I think it all depends on the transparency of the country so we are not being transparent...after this happened to us I feel it should not happen to any other parent...its devastating...an 18 year old lost her life for no reason...I hear from some doctors it's a rare adverse event...the benefit outweighs the risk...what does that mean...doesn't that one life have any value? All I'm saying is people need to be educated. We didn't know about any of this. If I had known that Covishield could cause such an issue...I could have done something if I was informed...and maybe she would have still been living...that lack of information...it's what is really missing...that is the main thing we want to push for, the information and the warning...I don't think people realise how life threatening the blood clots could be..."*

*Excerpts taken from Pavan Omtri & Rachna Gangu,  
AEFI Testimonial, Rithaika, Age 18, Hyderabad,  
19 November 2021<sup>123</sup>*

The principle of *acceptability* requires that all health facilities, goods and services must be respectful of medical ethics and be culturally appropriate as well as being designed to respect confidentiality and improve the health status of those concerned.<sup>124</sup> This section focusses on two key aspects of medical ethics which are free and informed consent and that of privacy and confidentiality.

## 1. *Consent*

Any medical intervention requires the consent of the individual. It is well established now that “*every human being of adult years and sound mind has a right to determine what shall be done with his body*”<sup>125</sup> and that consent is an important aspect of vaccination.<sup>126</sup> Consent for immunization and the balancing of individual autonomy with public health concerns has been the subject of much debate in recent years with increasing trends in some countries

<sup>123</sup> Awaken India Movement 2 (AIM) ‘AEFI Testimonial 3: Rithaika, Age 18, Hyderabad’ (YouTube, 19 November 2021) <[https://www.youtube.com/watch?v=dTEtofvwptc&ab\\_channel=AwakenIndiaMovement2%28AIM%29](https://www.youtube.com/watch?v=dTEtofvwptc&ab_channel=AwakenIndiaMovement2%28AIM%29)> accessed 2 May 2023.

<sup>124</sup> General Comment No. 14 (n 15).

<sup>125</sup> *Schloendorff v Society of New York Hospital* (1914) 211 NY 125.

<sup>126</sup> Richard Griffith, ‘Obtaining Consent for Immunization of Adults’ (*Human Vaccines and Immunotherapeutics*, 30 November 2015) <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4962744/>> accessed 4 April 2023.

of parents refusing some vaccinations for their children.<sup>127</sup> In India, the controversy surrounding HPV vaccines raised issues of informed consent.<sup>128</sup> For COVID-19 vaccines, there are several aspects that are both similar and distinct from pre-pandemic debates; perhaps the biggest difference is the speed at which COVID-19 vaccines were developed, tested and approved and the evolving information inter alia on safety signals, adverse events, length of protection, differences in protection with the emergence of newer variants, possibly varying levels of protection in certain populations, impact on transmission and impact on disease severity, hospitalization and death as the vaccines were and continue to be administered in unprecedented numbers across entire populations – pediatric, adolescent and adult. The matter of voluntariness is discussed below in the context of mandates. How consent is taken is another crucial aspect and how informed consent should have been insured in the case of COVID-19 vaccines is the second issue explored in this section.

## 2. *Vaccination Certificates and Mandates*

From the beginning the government maintained that vaccination was going to be purely voluntary. However, people who were vaccinated with both doses of the vaccine received certificates of being vaccinated, which later created a privileged class of people who had to access to public services and settings. High Courts across the country found themselves dealing with a range of discriminatory policies based on vaccination status. The Guwahati HC held that the policy of issuing permits to development workers in both public and private sector to only those persons who were vaccinated was violative of Article 14 by discriminating between vaccinated and unvaccinated persons in the absence of evidence that vaccination prevented infection or transmission.<sup>129</sup> It also directed the modification of rules for the re-opening of the schools and colleges that required vaccination of teaching and non-teaching staff to include those who choose not to be vaccinated and instead opted for testing every 15 days.<sup>130</sup> The Delhi HC directed the government to pay an unvaccinated teacher who was unable to take the vaccine due to allergies, his monthly salaries in a petition seeking reinstatement and removal of “on leave” status.<sup>131</sup> The HC of Manipur directed the State authorities not to deny supply of PMGKAY food grains to beneficiaries yet to be vaccinated.<sup>132</sup> In some cases, courts asked the

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<sup>127</sup> Daniel R Bronfin, ‘Childhood Immunization Controversies: What are Parents Asking?’ (*National Library of Medicine*, 3 August 2008) <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3096324/>> accessed 4 April 2023.

<sup>128</sup> Ganapati Mudur, ‘Indian MPs Criticize HPV Vaccination Project for Ethical Violations’ (*BMJ*, 6 September 2013) <<https://www.bmj.com/content/347/bmj.f5492>> accessed 4 April 2023.

<sup>129</sup> *Madan Mili v Union of India* 2021 SCC OnLine Gau 1503.

<sup>130</sup> *Kohima v State of Nagaland* 2021 SCC OnLine Gau 1170.

<sup>131</sup> *R.S. Bhargava v State (NCT of Delhi)* 2022 SCC OnLine Del 3076.

<sup>132</sup> *Thangjam Santa Singh v State of Manipur* 2021 SCC OnLine Mani 309.

government to rethink these policies or to reconsider individual cases<sup>133</sup> while some found in favour of vaccine mandates.<sup>134</sup>

In *Jacob Puliyel*, the SC examined the issue of vaccine mandates in some detail. While noting the importance of vaccination, the SC analysed the scope of right to privacy, and reiterated that “*nobody can be forcefully vaccinated as it would result in bodily intrusion and violation of individual’s right to privacy, protected under Article 21 of the Constitution of India*”.<sup>135</sup> Referring to the *Puttaswamy* judgement, the judgment highlighted the three requirements to be fulfilled by the State while placing restraints on the right to privacy to protect legitimate interests of the State – (a) there must be a law in existence to justify encroachment of privacy; (b) aim of the State should fall within the framework of Article 14, which should not be arbitrary; and (c) the means that are adopted by the State are proportional to the object to be achieved that needs to be fulfilled by the law. The SC concluded that (a) Bodily integrity is protected under Article 21, and no individual can be forced to be vaccinated; (b) Personal autonomy involves individual determination of their own life, medical treatment, etc.; (c) Persons not keen on being vaccinated, can avoid vaccination, however, if they are likely to spread infection to others or contribute to the mutation of the virus or burden public health infrastructure, thereby affecting communitarian health at large, the Government can regulate such public health concerns by imposing certain limitations on individual rights that are reasonable and proportionate to the object to be fulfilled.

Noting that the government did not present any evidence to indicate that the transmission of the virus by unvaccinated persons was greater than by vaccinated persons, the SC held that in the present scenario vaccine mandates should not be enforced. This remains a very narrow ground identified by the SC which went on to caution that if the situation changed and the evidence of the impact of unvaccinated persons on different aspects of the pandemics changed then the government could impose restrictions. Unfortunately, the SC appears to accept a binary classification between vaccinated and unvaccinated persons which it may be argued is in itself arbitrary as it does not consider other aspects such as prior infection, the use of masks and other measures that impact transmission and disease severity.

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<sup>133</sup> “*The compulsory vaccination policy of the Indian Air Force was challenged in the court, wherein directions were given to the Air Force to consider the case of an unvaccinated employee and not to take any coercive action against the petitioner for not being vaccinated, as vaccination was purely voluntary.*” *Yogendra Kumar v Indian Air Force* 2021 SCC OnLine Guj 1197.

<sup>134</sup> *Sanil Narayanan v State of Kerala* 2021 SCC OnLine Ker 11608.

<sup>135</sup> *Jacob Puliyel v Union of India* (n 8).

### 3. *Informed consent*

Informed consent is generally required for medical interventions, as the person has a right to know the benefits, risks, alternatives, etc., and take an informed decision on whether to take the medical treatment or undergo the procedure or not. In the medical context, informed consent is considered a powerful tool to balance the unequal relationship between a healthcare provider and a patient. While consent may be written or verbal, express or implied, it must always be informed. In several countries, including India, consent for mass or routine vaccinations is considered to be implied as the people themselves go to the vaccination center.<sup>136</sup> Whether implied consent for routine vaccinations is sufficient to assume that such consent is also informed is an issue that has arisen even before the pandemic. In the case of COVID-19 vaccines, a stronger case can be made for express consent as (i) people trust the vaccines approved by the authorities and submit themselves to taking the vaccine, (ii) approaching the center to take the vaccine even though this would mean implied consent, does not mean that the person is aware of the risks, side effects, adverse events, that may occur, even if they are rare and when to see timely medical help in such cases; (iii) while giving emergency approvals, even the authorities also do not know all the adverse events or side effects that the vaccines may cause.

When the COVID-19 vaccines were approved and first rolled out, there were two documents released by the government in January 2021: an operational guide<sup>137</sup> and a communications guide.<sup>138</sup> The only mention of consent in these documents related to the use of peoples' images in communication campaigns. Identifying vaccine hesitancy as a key issue, the documents place greater emphasis on promoting the benefits of the vaccines and while awareness related to AEFIs is included in these documents there is no real consent process envisaged. Interestingly, the rather confusing approval given to Covaxin in "clinical trial mode" (discussed below) resulted in the creation of an information sheet, a screening sheet, and an informed consent form that could have provided the framework for ensuring informed consent for all COVID-19 vaccines;<sup>139</sup> to be clear the argument here is not for paperwork. Often debates around informed consent focus on written forms when in fact

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<sup>136</sup> Veena Johari, 'Identifying Ethical Issues in Development of Vaccines and in Vaccination' (2017)2 (2) Indian Journal of Medical Ethics <<https://ijme.in/articles/identifying-ethical-issues-in-the-development-of-vaccines-and-in-vaccination/?galley=html>> accessed 4 April 2023.

<sup>137</sup> 'COVID-19 Vaccines Operational Guidelines' (Ministry of Health and Family Welfare) <<https://main.mohfw.gov.in/newshighlights-31>> accessed 4 April 2023.

<sup>138</sup> 'COVID-19 Vaccine Communication Strategy' (Ministry of Health and Family Welfare) <<https://www.mohfw.gov.in/pdf/Covid19CommunicationStrategy2020.pdf>> accessed 4 April 2023.

<sup>139</sup> 'Restricted Use of COVAXIN Under Clinical Trial Mode' (Indian Council of Medical Research, 11 January 2021) <<https://www.mohfw.gov.in/pdf/Version4PDFCOVAXINImplementationPlan11Jan2021.pdf>> accessed 4 April 2023.



informed consent is a process.<sup>140</sup> Arguments have been made against informed consent processes over concerns that these can be time-consuming. From a practical point of view, the sheer number of people being vaccinated meant that people were spending hours at vaccination centers; the concern over immediate allergic reactions meant that people were observed for an additional 30 minutes post-vaccination. It may be argued that this scenario was a missed opportunity as it provided a reasonable amount of time where a creative, thoughtful, empathetic, and balanced informed consent process for COVID-19 vaccination could have taken place; most crucially people could have been provided with correct and timely information to support AEFI reporting and recording.

The importance of informed consent in the case of COVID-19 vaccines is now before the SC in *Rachana Gangu v Union of India*.<sup>141</sup> The case has been brought by the parents of two girls who passed away after taking Covishield. In the case of the first petitioner's daughter who was 19 years old, she received the vaccine on 29 May 2021 and passed away on 19 June 2021 from Thrombosis and Thrombocytopenia Syndrome (TTS). This AEFI assessment found that her death was linked to the vaccine. It is of note that in the months before vaccination was opened up for the 18+ group, some countries in Europe paused the vaccination drive to investigate the AstraZeneca vaccine, due to reports of blood clots, or risk of thromboembolic events post-vaccination. This appeared to be a particular risk for young people. By May 2021, in less than 4 months of vaccination in India, 498 serious and severe AEFIs had been reported of which 26 cases were reported to be "potential thromboembolic events following the administration of the Covishield vaccine."<sup>142</sup> On 17 May 2021, the government issued an advisory to healthcare service providers on the identification and treatment of TTS with a recurring message that the risk was "minuscule."<sup>143</sup> Although this advisory mentions ongoing investigations in other countries, it fails to mention that the UK, the only other country using the Astrazeneca vaccine as widely as India had in April decided to offer under-30s an alternative,<sup>144</sup> and well before this advisory was issued had increased the age limit to under-40s who would be offered an alternative to the

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<sup>140</sup> Jennifer O'Neill, 'The COVID-19 Vaccine, Informed Consent and the Recruitment of Volunteers' (*Journal of Medical Ethics*, 23 November 2020) <<https://blogs.bmj.com/medical-ethics/2020/11/23/the-covid-19-vaccine-informed-consent-and-the-recruitment-of-volunteers/>> accessed 4 April 2023.

<sup>141</sup> 2022 SCC OnLine SC 1125.

<sup>142</sup> 'Bleeding and Clotting Events Following COVID Vaccination Miniscule in India' (*PIB Delhi*, 17 May 2021) <<https://pib.gov.in/PressReleasePage.aspx?PRID=1719293>> accessed 2 May 2023.

<sup>143</sup> Government of Odisha, Health & Family Welfare Department, 'File No. PT2-HFW-SCH-I-MISC-0023-2020-15621/H' <<https://health.odisha.gov.in/sites/default/files/2021-12/Advisory-diagnosis-treatment-Thrombosis-Thrombocytopenic-26052021.pdf>> accessed 2 May 2023.

<sup>144</sup> Nick Triggle, 'Covid: Under-30s Offered Alternative to Oxford-AstraZeneca Jab' (*BBC News*, 7 April 2021) <<https://www.bbc.com/news/health-56665517>> accessed 2 May 2023.

Astrazeneca vaccine due to the risk of TTS.<sup>145</sup> Health experts noted that this advisory was hardly circulated or widely advertised by the government.<sup>146</sup>

The second petitioner's daughter received the vaccine on 8 June 2021 and passed away on 10 July 2021. In this case, the cause was considered to be Multisystem Inflammatory Syndrome in Children/Adults (MIS-C/A) and considered an Adverse Event of Special Interest (AESI) but with no definitive evidence of a link with COVID-19 vaccines. With representations from the parents to the government going unanswered, the parents filed the writ petition seeking a thorough investigation into their daughters' deaths and for the investigation report to be shared with them, the preparation of a protocol for early detection of COVID-19 vaccine AEFIs like the ones suffered by their daughters and for compensation from the government. The critical argument made by the petitioners was that there was no informed consent taken and neither they nor their daughters were informed of the possible severe AEFI from the vaccine before it was administered.

The SC noted that ordinarily, they would have asked the petitioners to seek other remedies as there may be basic questions of fact to be ascertained to bring the case within the framework of medical negligence. But given the documents filed, the lack of any response from the government and the directions sought, the SC directed the government to file its reply.<sup>147</sup> To the dismay of health groups and legal experts,<sup>148</sup> the government in its reply has taken the position that,

*“the concept of informed consent is inapplicable to the voluntary use of a drug such as a vaccine...vaccine beneficiary always has the option to access even more information about the vaccine and its possible adverse effect from the health workers at the vaccination site or their doctor before making an informed decision on their own....once a vaccine beneficiary who has access to all relevant information, voluntarily chooses to enter a vaccination center and receive*

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<sup>145</sup> James Gallagher, 'Under 40s to be Offered Alternative to AZ Vaccine' (*BBC News*, 7 May 2021) <<https://www.bbc.com/news/health-57021738>> accessed 2 May 2023.

<sup>146</sup> Taran Deol, 'COVID-19: Activists Slam Centre's Affidavit Washing Hands Off Compensation for Vaccine Mortality' (*Down to Earth*, 1 December 2022) <<https://www.downtoearth.org.in/news/health/covid-19-activists-slam-centre-s-affidavit-washing-hands-off-compensation-for-vaccine-mortality-86296>> accessed 2 May 2023.

<sup>147</sup> *Rachana Gangu v Union of India* 2022 SCC OnLine SC 1125 affidavit dated 23.11.22 on behalf of the Union of India.

<sup>148</sup> Taran Deol, 'COVID-19: Activists Slam Centre's Affidavit Washing Hands Off Compensation for Vaccine Mortality' (*Down to Earth*, 1 December 2022) <<https://www.downtoearth.org.in/news/health/covid-19-activists-slam-centre-s-affidavit-washing-hands-off-compensation-for-vaccine-mortality-86296>> accessed 2 May 2023.

*vaccination, the question of a lack of informed consent does not arise.*<sup>149</sup>

Not taking informed consent from vaccinees, is a breach of their right to autonomy and right to take an informed decision on whether to take the risks of the vaccine or to take the risk of acquiring the disease. The government's arguments, in this case, attempt to stand the concept of informed consent on its head by placing the responsibility of ascertaining benefits and risks on the shoulders of the vaccine beneficiary instead of the government or healthcare provider. This is an extraordinary position taken by the government as it not only attempts to negate its liability but also that of the manufacturers.

#### 4. *Privacy and Confidentiality*

The right to privacy and confidentiality has been guaranteed under the Constitution of India. Although breaches of vaccination data<sup>150</sup> have been reported they have simply been dismissed by the government instead of being investigated.<sup>151</sup> When it was launched, the Co-WIN app had no specific privacy policy. In June 2021, the Delhi HC directed the government to upload a privacy policy within 4 weeks.<sup>152</sup> In September 2021, the government announced a new feature on the app that would reveal a person's vaccination status to a third party. As pointed out by experts, this violated the privacy policy that was eventually uploaded on Co-WIN which limited access to a person's data only to government agencies and for specific purposes.<sup>153</sup> The new feature would also in effect exacerbate the many concerns raised above with vaccine certificates. In addition, the data of persons who used their Aadhaar numbers to register and get vaccinated appear to be feeding into the automatic creation of Health IDs with little information on the purpose of these IDs, absolutely no consent, informed or otherwise taken from those who registered on the Co-WIN app and no information in the public domain on safeguards and restrictions on the use of these Health IDs.<sup>154</sup>

<sup>149</sup> *Rachana Gangu v Union of India* 2022 SCC OnLine SC 1125 affidavit dated 23.11.22 on behalf of the Union of India.

<sup>150</sup> 'Massive Public Health Data Leak Puts Personal Data of Scores of Citizens at Risk | The Probe Investigation' (*The Probe*, 31 January 2022) <<https://theprobe.in/massive-public-health-data-leak-puts-personal-data-of-scores-of-citizens-at-risk-the-probe-investigation/>> accessed 4 April 2023.

<sup>151</sup> Adam Ang, 'India Dismisses CoWIN Vaccination Data Leak' (*Healthcare IT News*, 24 January 2022) <<https://www.healthcareitnews.com/news/asia/india-dismisses-cowin-vaccination-data-leak>> accessed 4 April 2023.

<sup>152</sup> *Manisha Chauhan v State (NCT of Delhi)* 2021 SCC OnLine Del 1018.

<sup>153</sup> 'Read our Joint Letter with C-Help & FMES to NHA on CoWIN's Updated API #SaveOurPrivacy' (*Internet Freedom Foundation*) <<https://internetfreedom.in/read-our-joint-letter-with-c-help-fmes-to-nha-on-cowins-updated-api/>> accessed 28 April 2023.

<sup>154</sup> Sarthak Dogra, 'Took Covid Vaccine Using Aadhaar? Your National Health ID has been Created without Your Permission' (*India Today*, 24 May 2021) <<https://www.indiatoday.in/>

## D. Quality

*“I got my first [Covishield] shot on October 8 and the second shot on November 6. The participant in Chennai reported sick on October 11. Why didn’t they tell us about it? This case came out only because the participant threatened to file a suit. Who knows how many such cases have actually happened that we don’t even know about,” asked Anil Hebbar, adding that he would have taken the second dose anyway but feels it was the duty of those involved to inform all the participants... “They are saying they didn’t tell me because they thought I might get scared. Now my doctor is saying the serious adverse event was not caused by the vaccine. But what if it was causally linked? Should she not have waited to find that out before giving all of us the second dose?” asked Hebbar. He added that he has lost friends to Covid-19 and has seen his 85-year-old mother, a cancer survivor, live in fear of being infected, which impelled him to volunteer. “I participated hoping that could help bring out a vaccine faster. But I am shocked by the company threatening to sue a participant like me,” said Hebbar.”*

— *Times of India*, 2 December 2020<sup>155</sup>

*“Rajesh Panti, 45, a survivor of the Bhopal gas tragedy, said when he received the first [Covaxin trial] dose, he was not asked whether he was taking any medicine. Chillaar said he takes medication for diabetes every morning, but was not asked at the hospital whether he had any underlying health issues. Sarita Jathav, 26, said she is pregnant, but was only told that pregnant women couldn’t take the vaccine when she went to take her second dose, which she did not receive... Chillaar...said that when hospital administrators called to check on him following the shot, he told them that he was having neck problems. They told him to come in for treatment, but when he did, he said he was told to pay more than 3,000 rupees (\$41).”*

*CNN*, 26 February 2021<sup>156</sup>

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technology/features/story/took-covid-vaccine-using-aadhaar-your-national-health-id-has-been-created-without-your-permission-1806470-2021-05-24> accessed 28 April 2023.

<sup>155</sup> ‘Adverse Event Kept a Secret, Vaccine Volunteers Feel Betrayed’ (*Times of India*, 2 December 2020) <<https://timesofindia.indiatimes.com/india/adverse-event-kept-a-secret-vaccine-volunteers-feel-betrayed/articleshow/79521198.cms>> accessed 2 May 2023.

<sup>156</sup> Esha Mitra and Julia Hollingsworth ‘More than a Dozen Slum Residents in an Indian City say they Thought they were being Vaccinated. They were Part of Clinical Trials’ (*CNN*, 26

*“We also spoke to Venugopalan Govindan, a resident of Coimbatore in Tamil Nadu, whose daughter Karunya Venugopalan died on July 10, 2021... developed complications post getting a Covishield jab...later diagnosed with multisystem inflammatory syndrome (MIS-A). “This is a known side effect of the Covid vaccine, according to The Brighton Collaboration. But my daughter was not diagnosed properly for a long time,” said Venugopalan, adding that filing an AEFI was a taxing process for him. “I rang up the Serum Institute of India right after Karunya was hospitalised. Post this, a doctor from SII called me up and I was told that this (MIS-A) was not a side-effect of the vaccine,” he said. AEFIs initially could be reported only through the vaccine manufactured or through the District Immunisation Officer. Venugopalan said he got to file it only after he reached out to an AEFI committee zonal in-charge through Twitter, in September. “The causality analysis of her death, however, was done only on November 18, 2021. We found it out only when we checked out the MoHFW website. No one had intimated anything to us,” he said.”*

— *The Hindu*, 5 January 2023<sup>157</sup>

The element of *quality* requires that health facilities, goods, and services must be scientifically and medically appropriate, of good quality, and in the case of medical products like drugs and vaccines, must be scientifically approved.<sup>158</sup> There are several aspects to be considered in the scientific approval of COVID-19 vaccines. This section explores the legal and ethical concerns that arose during the clinical trials of Covishield and Covaxin as well as the key issue of adverse events following immunization (AEFI) that have arisen during the government rollout of the vaccines.

The development and approval of COVID-19 vaccines in India have taken place within a complex web of laws, rules, regulations, and guidelines and through multiple regulatory agencies. The safety, efficacy, and quality of COVID-19 vaccines in India are regulated by the *Drugs and Cosmetics Act, 1940*, and various rules and regulatory bodies under the Act. Of particular importance are the provisions in the *New Drugs and Clinical Trial Rules, 2019 (NDCTR)*. Drafted in response to a public interest litigation in the SC

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February 2021) <<https://edition.cnn.com/2021/02/25/asia/india-vaccine-trials-covid-ethics-intl-dst-hnk/index.html>> accessed 2 May 2023.

<sup>157</sup> Parvathi Benu, ‘A Close Look at Low Rate of Covid Vaccine Side Effects in India’ (*Hindu Business Line*, 5 January 2023) <<https://www.thehindubusinessline.com/data-stories/data-focus/a-close-look-at-low-rate-of-covid-vaccine-side-effects-in-india/article66329777.ece>> accessed 2 May 2023.

<sup>158</sup> General Comment No. 14 (n 15).

highlighting gaps in the clinical trial regulatory framework,<sup>159</sup> the NDCTR contains detailed provisions covering a range of issues related to the research and development of medical products including accelerated and expedited processes and for the payment of compensation in case of injury or death during clinical trials.

Although the NDCTR had been notified just a year earlier, the COVID-19 outbreak led to further changes in the regulatory framework for clinical trials. Beginning in March 2020, the CDSCO regularly issued notifications on regulatory pathways for clinical trials related to COVID-19.<sup>160</sup> Timely guidance was also issued in April 2020 by ICMR in the *National Guidelines for Ethics Committees Reviewing Biomedical & Health Research, During the COVID-19 pandemic (ICMR COVID-19 Guidelines)*.<sup>161</sup> For the first time ever, electronic consent from trial participants was allowed. The Guidelines address a multitude of issues related to clinical trials; conflicts of interest, post-research access and benefit sharing, communication of research findings to individuals and communities, need for appropriate safety, funds, care, and compensation, expeditious review processes for clinical trials for new drugs/compassionate use, etc.

Of great importance to this discussion is ICMR's 2017 guidance<sup>162</sup> providing for monitored emergency use of unregistered and experimental interventions (MEURI) in case of an outbreak of an infectious disease that was also included in the ICMR COVID-19 Guidelines. MEURI approvals are subject to a list of precautions: thorough scientific review followed by an ethics review locally or by a national level ethics committee (EC); tackling public concerns and ensuring oversight by a local EC; the use of Good Manufacturing Practice (GMP) products and making rescue medicines or supportive treatment accessible; the meticulous documentation of therapeutic processes including adverse events; fast track research and possible sharing of data on safety and efficacy for further research; the importance of the consent process which must be carried out with care; and community engagement and ensuring the fair distribution of scarce supplies.<sup>163</sup>

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<sup>159</sup> *Swasthya Adhikar Manch v Union of India* (2014) 14 SCC 788 (Supreme Court).

<sup>160</sup> See Ministry of Science & Technology Department of Biotechnology, *Rapid Response Regulatory Framework to Deal with Applications for COVID 19 Vaccine Development* (Office Memorandum, BT/03/27/2020-PID, 2020). <[https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=NTk1NA==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NTk1NA==)> accessed 4 April 2023.

<sup>161</sup> 'National Guidelines for Ethics Committees Reviewing Biomedical and Health Research During COVID-19 Pandemic' (ICMR, 2020) <[https://main.icmr.nic.in/sites/default/files/guidelines/EC\\_Guidance\\_COVID19\\_06\\_05\\_2020.pdf](https://main.icmr.nic.in/sites/default/files/guidelines/EC_Guidance_COVID19_06_05_2020.pdf)> accessed 4 April 2023.

<sup>162</sup> 'National Ethical Guidelines for Biomedical and Health Research Involving Human Participants' (ICMR, 2017) <[https://ethics.ncdirindia.org/asset/pdf/ICMR\\_National\\_Ethical\\_Guidelines.pdf](https://ethics.ncdirindia.org/asset/pdf/ICMR_National_Ethical_Guidelines.pdf)> accessed 4 April 2023.

<sup>163</sup> 'National Guidelines for Ethics Committees Reviewing Biomedical and Health Research During COVID-19 Pandemic' (n 161).

As the development of COVID-19 vaccines progressed, further regulatory changes were introduced. Trial phases for some of the vaccine candidates were clubbed to expedite the trials<sup>164</sup> and in April 2021, the government replaced the requirement for local trials with “post-approval parallel bridging trials” for vaccines approved in the United States, European Union, United Kingdom, Japan or those approved for WHO’s Emergency Use Listing.<sup>165</sup>

The rapid changes to time-tested regulatory pathways should have been balanced with strict clinical trial oversight by the CDSCO, in particular, related to the rights and well-being of clinical trial participants and heightened transparency and accountability standards post-approval. Interestingly, in March 2020 the CDSCO issued a notice for all stakeholders highlighting the “paramount importance” of the protection of the rights of clinical trial participants in ongoing clinical trials even where adhering to all protocols may have been made difficult by the pandemic.<sup>166</sup> Unfortunately, as the desperation for vaccine candidates increased, this balance was never achieved as can be seen from the discussion below.

### 1. *Ethical Concerns with the Covishield and Covaxin Trials*

The clinical trials for Covishield and Covaxin raised different ethical issues. In the case of Covishield, a key ethical issue was how reports of adverse events were dealt with. In September 2020, due to safety concerns, AstraZeneca, in the UK, paused their Phase 3 trial of the vaccine candidate ChAdOx-nCoV-19, to allow an independent committee to investigate an unexplained illness in one of the trial participants - transverse myelitis – inflammation of the spinal cord.<sup>167</sup> The trials in India were paused only after the DCGI sent a notice to Serum Institute.<sup>168</sup> After AstraZeneca re-started the trials in the UK and provided an explanation that it was a rare occurrence, the DCGI

<sup>164</sup> ‘Restricted use of Covaxin under Clinical Trial Mode’, *Implementation Plan issued by Bharat Biotech and ICMR* <Version4PDFCOVAXINImplementationPlan11Jan2021.pdf (mohfw.gov.in)> accessed 4 April 2023.

<sup>165</sup> Directorate General of Health Services CDSCO (Public Relations Office), *Guidance for approval COVID-19 Vaccines in India for restricted use in emergency situation which are already approved for restricted use by US FDA, EMA, UK MHRA, PMDA Japan or which are listed in WHO Emergency Use Listing (EUL)* (Notice, X-11026/07/2020-PRO, 2021) <[https://cdsco.gov.in/opencms/export/sites/CDSCO\\_WEB/Pdf-documents/notice15april21.pdf](https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/notice15april21.pdf)> accessed 4 April 2023.

<sup>166</sup> Directorate General of Health Services CDSCO, *Conduct of Clinical Trial in Present Situation Due to Outbreak of COVID-19 Reg.* (Notice, F. No.- DCGI/MISC/2020 (104), 2020). <[https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=NjM2Mg==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjM2Mg==)> accessed 4 April 2023.

<sup>167</sup> See Eric Sagonowsky, ‘How does AstraZeneca’s Trial Pause Affect other COVID-19 Vaccines? Analysts Weigh in’ (*Fierce Pharma*, 9 September 2020) <<https://www.fiercepharma.com/vaccines/how-does-astrazeneca-s-trial-pause-affect-other-covid-19-vaccines-analysts-weigh>> accessed 4 April 2023.

<sup>168</sup> Bindu Shajan Perappadan, ‘Coronavirus | Serum Institute Pulled up for not Pausing Vaccine Trial’ (*The Hindu*, 9 September 2020) <<https://www.thehindu.com/sci-tech/health/>>

issued another notice to conduct the trials carefully and to provide additional information in the informed consent form.<sup>169</sup> In November 2020 a young business consultant in India, who was part of the Covishield trial sent a legal notice to Serum Institute claiming he developed severe neurological conditions after taking the first dose of the vaccine in October, after which he was hospitalized for 15 days of which 8 days were in the intensive care unit.<sup>170</sup> The trial was not halted either by Serum or the DCGI. Instead of assuring the participant that they would inquire and provide compensation and treatment, Serum threatened to file a defamation suit of Rs.100 crore on the participant for a “malicious and misconceived” link of his adverse event to the vaccine.<sup>171</sup>

In December 2020 news reports quoted the DCGI’s announcement that an independent committee had concluded that the trial participant’s adverse event was not linked to the vaccine.<sup>172</sup> Serious adverse events during clinical trials are usually reported to the DCGI, the concerned Ethics Committees (EC), and the Sponsors by the Principal Investigators (PI) of the trial. The assessment of relatedness is conducted by the EC and the DCGI, and a committee appointed by the DCGI, based on the records available, and the opinion of the PI. The participant is not a part of the process of assessment. The ECs, DCGI, or any other authority or committee are not mandated to involve the participant or their relatives (in case of death) in the process of assessing the relatedness of the adverse event to the investigational product. If relatedness is established, then the participant is entitled to compensation based on a formula as stated in the NDCTR.<sup>173</sup> In the case of the Covishield trial participant, while the media carried the news of the DCGI’s announcement that relatedness was not established, details of the investigation, the reports and documents assessed by the committee, or its final report have not been placed in the public domain. The trial participant filed a writ petition for compensation before the Madras High

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coronavirus-serum-institute-pulled-up-for-not-pausing-vaccine-trial/article32565181.ece> accessed 4 April 2023.

<sup>169</sup> ‘Serum Institute of India gets DCGI Nod to Resume Clinical Trial of Oxford Covid-19 Vaccine’ (*Times of India*, 16 September 2020) <<https://timesofindia.indiatimes.com/india/serum-institute-of-india-gets-dcgi-nod-to-resume-clinical-trial-of-oxford-covid-19-vaccine/articleshow/78136760.cms>> accessed 4 April 2023.

<sup>170</sup> Sanjay Kumar, ‘Malicious and Misconceived. Indian Vaccine Producer Hits Back at Complaint from Trial Volunteer’ (*Science*, 2 December 2020) <<https://www.science.org/content/article/malicious-and-misconceived-indian-vaccine-producer-hits-back-complaint-trial-volunteer>> accessed 4 April 2023.

<sup>171</sup> *ibid.*

<sup>172</sup> ‘DCGI Finds no Link between Covid Vaccine Shot, “Adverse” Reaction: Report’ (Business Standard, 2 December 2020) <[https://www.business-standard.com/article/current-affairs/dcgi-finds-no-link-between-covid-vaccine-shot-adverse-reaction-report-120120201293\\_1.html](https://www.business-standard.com/article/current-affairs/dcgi-finds-no-link-between-covid-vaccine-shot-adverse-reaction-report-120120201293_1.html)> accessed 4 April 2023

<sup>173</sup> New Drugs and Clinical Trials Rules, Chapter VI read with Schedule Seventh <[https://cdsco.gov.in/opencms/export/sites/CDSCO\\_WEB/Pdf-documents/NewDrugs\\_CTRules\\_2019.pdf](https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf)> accessed 4 April 2023.



Court which admitted the matter and issued notice in February 2021.<sup>174</sup> The matter remains pending.

On 21 December 2020, a Covaxin trial participant died 9 days after taking the trial shot. Restricted emergency use approval for Covaxin was given approximately two weeks after this death on 3 January 2021. Information about the death and other details were not made public either by Bharat Biotech or the regulatory authorities and only emerged through media reports.<sup>175</sup> It was only in reaction to those reports, that on 9 January 2021, Bharat Biotech issued a press release stating that the death was not linked to the vaccine.<sup>176</sup> There is no record that the trial was stopped after this death was reported to Bharat Biotech and while the circumstances of the death were being investigated. And again, no details of who conducted the investigation and how are in the public domain. As a bioethics expert noted, “*India’s expert panel also recommended Covaxin for approval in January, but the death of Maravi happened in December 2020. The drug regulator ought to explain whether the expert panel knew of this death and had factored it in when they gave emergency approval to this vaccine.*”<sup>177</sup>

News of the Covaxin trial death unearthed other ethical issues, as at some trial sites, the vaccine candidate was given to vulnerable populations without taking proper informed consent.<sup>178</sup> After the Bhopal Gas Tragedy, the world’s deadliest industrial accident at the Union Carbide factory, victims including second and third generations and those living around the area continue to be adversely affected by contaminated water, and many have been born with and live with myriad health conditions.<sup>179</sup> In a letter to the Prime Minister and Health Minister, survivors of the Union Carbide disaster detailed the multiple ethical violations at the Covaxin trial sites that recruited gas tragedy victims or those living in the affected area including the manner of recruitment of vulnerable people for the trial including monetary inducements, violations of

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<sup>174</sup> *Asif Riaz v Govt. of India* W.P. No. 3346 of 2021 (Madras High Court).

<sup>175</sup> PTI, ‘Man Dies Days after Participating in Covaxin Covid-19 Vaccine Trial in Bhopal’ (*Deccan Herald*, 9 January 2021) <<https://www.deccanherald.com/national/man-dies-days-after-participating-in-covaxin-covid-19-vaccine-trial-in-bhopal-937050.html>> accessed 4 April 2023.

<sup>176</sup> ‘Covaxin Bhopal Statement’ (*Bharat Biotech*, 9 January 2021) <<https://www.bharatbiotech.com/images/press/covaxin-bhopal-statement.pdf>> accessed 28 April 2023.

<sup>177</sup> Anoo Bhuyan, ‘How Covaxin Trial Participants in Bhopal were Mised’ (*The Wire*, 14 January 2021) <<https://science.thewire.in/health/peoples-hospital-bhopal-covaxin-clinical-trials-exploitation-ethics-ground-report/>> accessed 4 April 2023.

<sup>178</sup> *Ibid.* Anoo Bhuyan, ‘How Covaxin Trial Participants in Bhopal were Mised’ (*The Wire*, 14 January 2021) <<https://science.thewire.in/health/peoples-hospital-bhopal-covaxin-clinical-trials-exploitation-ethics-ground-report/>> accessed 4 April 2023.

<sup>179</sup> Hannah Ellis-Petersen, ‘Bhopal’s Tragedy has not Stopped’: The Urban Disaster Still Claiming Lives 35 Years on’ (*The Guardian*, 8 December 2019) <<https://www.theguardian.com/cities/2019/dec/08/bhopals-tragedy-has-not-stopped-the-urban-disaster-still-claiming-lives-35-years-on>> accessed 28 April 2023.

informed consent processes, the lack of follow up and treatment and failures in reporting of adverse events including the death of the trial participant.<sup>180</sup> The letter asked for urgent intervention in stopping the trial at these trial sites and for the setting up of an investigation. Multiple organizations and individuals echoed the demands of the gas tragedy victims and wrote to the authorities at the Centre and the State demanding that, “*the trial sponsors, Bharat Biotech and ICMR, must take full responsibility for the serious, unconscionable and unlawful lapses in the Bhopal trial.*”<sup>181</sup> Regrettably, no action was taken nor were the ethical lapses at the Bhopal trial sites ever investigated.

These and other ethical issues<sup>182</sup> relating to the trials were raised time and again not by the regulator or the institutional mechanisms put in place to oversee trials but by participants and health groups. It is imperative that clinical trials are conducted meticulously and in a transparent manner even in the emergency caused by the coronavirus. Data transparency in clinical trials is now well-established internationally.<sup>183</sup> The large amounts of government funding, and grants from international funding agencies, for the trials and manufacturing of the vaccine candidates, made it even more important for the government and the manufacturers to be open and transparent in their dealings. It was also important to speak the truth about the data relating to the vaccine candidates. In this regard, the protocols, end-points of the trials, the anonymized data collected, case report forms, informed consent forms, tests, and results conducted to analyze the safety and efficacy of the vaccine candidates ought to have been placed in the public domain.<sup>184</sup>

While the government, regulatory bodies, and ICMR largely shunned right to information (RTI) requests related to COVID-19 vaccines, the SC,

<sup>180</sup> ‘Irregularities and Ethical Violations in the Conduct of the Clinical Trial for Bharat Biotech’s COVAXIN’ (*Health, Ethics and Law*, 12 January 2021) <<https://fmesinstitute.org/blog-20-heal-institute-ijme-covid-19-insights-jan-11-2021/#:ZFHgH3ZBxD8>> accessed 28 April 2023.

<sup>181</sup> ‘Covid-19 Insights: Analysis from Ethics, Human Rights and Law Perspectives’ (*Health, Ethics, and Law*, 2021) <<https://fmesinstitute.org/wp-content/uploads/2021/01/Blog-202.pdf>> accessed 28 April 2023; see ‘Stop Bharat Biotech’s COVAXIN trial in Bhopal – 42 Organizations and 189 Citizens Demand Investigation’ (*Kractivism*, 14 January 2021) <<https://www.kractivist.org/stop-bharat-biotechs-covaxin-trial-in-bhopal-42-organizations-and-189-citizens-demand-investigation/>> accessed 28 April 2023.

<sup>182</sup> See for eg, Angana Chakrabarti, ‘Scientists Oppose Placebo Trials for Covid Vaccines, Call them ‘Unethical, Inappropriate’’ (*The Print*, 10 March 2021) <<https://theprint.in/health/scientists-oppose-placebo-trials-for-covid-vaccines-call-them-unethical-inappropriate/618664/>> accessed 28 April 2023.

<sup>183</sup> “A wide range of institutions, from pharmaceutical companies, government agencies, trade organizations, journals and non-for-profit organizations, have acknowledged the importance of data sharing, including the release of deidentified individual participant data. Many policies, regulations and platforms now exist to facilitate data access, including landmark transparency policies from the European Medicines Agency (EMA) and Health Canada.” Sarah Tanveer, ‘Transparency of COVID-19 Vaccine Trials: Decisions without Data’ (*BMJ Evidence-Based Medicine*) <<https://ebm.bmj.com/content/27/4/199>> accessed 28 April 2023.

<sup>184</sup> *ibid.*

unfortunately, also did not seize the opportunity to bring greater transparency and access to clinical trial data. In the *Jacob Puliye* case, the Petitioner sought directions for the government to make public the segregated data of the clinical trials for the vaccines being administered under emergency use approval in India.<sup>185</sup> The SC, however, considered that the detailed legal regime covering clinical trials and the minutes of the Subject Expert Committee (SEC) meetings to have sufficient data for the citizens to know. Although the SC examined legal and judicial examples from other countries on clinical trial data transparency, it stated that disclosure requirements in India were covered by the existing law and held that “*in light of the statutory regime, we do not see it fit to mandate the disclosure of primary clinical trial data, when the results and key findings of such clinical trials have already been published.*”<sup>186</sup>

“*Restricted Use for Emergency Situation,” “Clinical Trial Mode” and “Conditional Market Authorization”*”

The discussion above in relation to the clinical trials for the two vaccines and the lack of access to data is linked to the approval process; this is the statutory process the SC refers to in *Jacob Puliye* above while denying the prayer for greater clinical trial data transparency. Usually, the analysis of the data collected during trials is done by a Data Safety Monitoring Board (DSMB), which is constituted by the Sponsor of the trials but requires members of the Board to be independent. The data is then presented to the DCGI and the concerned SEC, who decide on further action, provide recommendations on approval of the vaccine candidates, or the need to gather more data, etc. The minutes of the meetings of the SEC are usually available in the public domain. The DCGI, based on the recommendation of the SEC, may approve the vaccine candidate or drug in question.

As noted above, due to the nature of the emergency, various requirements related to the development and approval of COVID-19 medical products were relaxed. These changes should have been matched with increased efforts at transparency by the regulatory authorities. Instead, minutes of the COVID SEC were not published for several months.<sup>187</sup> Additionally, the names, qualifications, affiliations, conflicts of interest, influences, etc. of the members of the DSMB board and the COVID SEC have not been placed in the public domain, making it difficult to determine if conflicts of interest, bias, or lack of expertise affected decision making. The minutes that were finally uploaded only captured the final decision and provided scant details of the kind of data presented

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<sup>185</sup> *Jacob Puliye v Union of India* (n 8).

<sup>186</sup> *ibid*; *Jacob Puliye v Union of India* 2022 (n 8).

<sup>187</sup> Raghendra Shukla, ‘Lack of Transparency in Subject Expert Committee Formed for Approval of COVID-19 Drugs: AIDIAN’ (*Healthwire*, 1 July 2020) <<https://www.healthwire.co/lack-of-transparency-in-subject-expert-committee-formed-for-approval-of-covid-19-drugs-aidian/>> accessed 28 April 2023.

before them, who analyzed the data, what were the clinical end-points, what were the tests conducted, and the results to reach the conclusions, were there other factors that could have influenced the results, what were the adverse events experienced by the participants, how were they managed, etc. This was particularly important due to the unusual nature of approvals that were granted to COVID-19 vaccines i.e. ‘restricted use for emergency situation’, ‘restricted use for emergency situation in clinical trial mode’, and most recently ‘conditional market authorization.’

In January 2021, both Serum Institute and Bharat Biotech received “restricted use for emergency situation” approvals for their vaccine candidates, Covishield and Covaxin, respectively. This is not the first time that such approval has been given; for instance, in the past, such approvals were given for two MDR TB medicines by the DCGI. However, the DCGI’s approval for Covaxin created a new category i.e. “restricted use in an emergency situation under clinical trial mode”.<sup>188</sup> Covaxin had not completed Phase III trials, and approval was given based on data received from the Phase I and II clinical trials that enrolled a small number of participants. There was speculation that the rushed approval for the fully indigenous vaccine was in service to India’s image of self-sufficiency as Serum Institute’s candidate was the result of foreign collaboration.<sup>189</sup> Just two months later, in March 2021, Covaxin was given “restricted use in emergency situation” approval and was no more in “clinical trial mode”.<sup>190</sup>

The initial approvals generated considerable controversy. On 1 January 2021, the COVID SEC had only recommended the approval of Covishield and asked Bharat Biotech to complete its trials before approval could be recommended.<sup>191</sup> However, the very next day, the same COVID SEC recommended Covaxin for approval as well albeit in clinical trial mode.<sup>192</sup> The

<sup>188</sup> ‘Restricted use of Covaxin under Clinical Trial Mode’ (n 164).

<sup>189</sup> Priyanka Pulla, ‘How Covaxin became a Victim of Vaccine Triumphalism’ (*Livemint*, 27 May 2021) <<https://www.livemint.com/science/news/how-covaxin-became-a-victim-of-vaccine-triumphalism-11622022760541.html>> accessed 28 April 2023.

<sup>190</sup> ‘Covaxin Out of Clinical Trial Mode, Granted Restricted Emergency use of Authorization’ (*Times of India*, 11 March 2021) <<https://timesofindia.indiatimes.com/india/covaxin-out-of-clinical-trial-mode-granted-restricted-emergency-use-authorisation/article-show/81453563.cms>> accessed 28 April 2023.

<sup>191</sup> Directorate General of Health Services CDSCO, ‘Recommendations of the SEC Meeting to Examine COVID—19 Related Proposals under Accelerated Approval Process Made in its 134th Meeting held on 01.01.2021 CDSCO, HQ New Delhi’ (*CDSCO*) <[https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common\\_download.jsp?num\\_id\\_pk=MTMwMQ==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=MTMwMQ==)> accessed 28 April 2023.

<sup>192</sup> Directorate General of Health Services CDSCO, ‘Recommendations of the SEC Meeting to Examine COVID-19 Related Proposals under Accelerated Approval Process made in its 135th Meeting held on 02.01.2021 CDSCO, HQ New Delhi’ (*CDSCO*) <[https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common\\_download.jsp?num\\_id\\_pk=MTMwMA==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/common_download.jsp?num_id_pk=MTMwMA==)> accessed 28 April 2023.

announcement<sup>193</sup> of the approvals on 3 January 2021 by the DCGI led to much consternation among public health activists,<sup>194</sup> the scientific community,<sup>195</sup> and healthcare workers who were first in line to get vaccinated<sup>196</sup> and even led to a public spat between Serum Institute and Bharat Biotech that played out across news channels before they issued a joint press release burying the hatchet.<sup>197</sup>

Even as health groups critiqued the approval process, the courts seemed reluctant to inquire into whether there was a breach of the integrity of the processes and whether they had the sanctity of the law. A petition filed before the Karnataka HC raising questions on the approvals was dismissed with costs as the court opined that the petition was not in the public interest.<sup>198</sup> In *Jacob Puliyeel*, the SC examined the legal regime governing clinical trials and drug regulation and largely relying on information submitted by the government concluded that these provisions were followed and did not inquire further into the processes followed for granting the approvals.

In January 2022, yet another new form of approval was announced by the DCGI when it gave “conditional marketing authorization” for Covishield and Covaxin. According to the government’s press release, “*Conditional Market Authorization*” is a new category of market authorization that has emerged during the current global pandemic COVID19. The approval pathways through this route are fast-tracked with certain conditions to enhance the access to certain pharmaceuticals for meeting the emerging needs of drugs or vaccines.”<sup>199</sup> Among the conditions attached to this approval is the requirement for submission of complete trial data from abroad, provision of vaccines through the national rollout and registered through Co-WIN, and submission of AEFI data. In April 2022, the WHO suspended the emergency use approval

<sup>193</sup> ‘Press Statement by the Drugs Controller General of India (DCGI) on Restricted Emergency Approval of COVID-19 Virus Vaccine’ (*Ministry of Health and Family Welfare*, 3 January 2021) <<https://pib.gov.in/PressReleaseDetail.aspx?PRID=1685761>> accessed 28 April 2023.

<sup>194</sup> ‘Drug Activist Group AIDAN Raises Concerns over EUA for COVAXIN’ (*Express Pharma*, 4 January 2021) <<https://www.expresspharma.in/drug-activist-group-aidan-raises-concerns-over-eua-for-covaxin/>> accessed 4 April 2023.

<sup>195</sup> R Prasad, ‘Indian Scientists Divided Over Nod for Covaxin’ (*The Hindu*, 15 January 2021) <<https://www.thehindu.com/sci-tech/science/scientists-divided-over-restricted-use-approval-for-covaxin/article61740753.ece>> accessed 4 April 2023.

<sup>196</sup> ‘Vaccination Drive: Fewer Takers for Covaxin among Healthcare Workers’ (*Times of India*, 22 January 2021) <<https://timesofindia.indiatimes.com/india/vaccination-drive-fewer-takers-for-covaxin-among-healthcare-workers/articleshow/80395554.cms>> accessed 4 April 2023.

<sup>197</sup> Himani Chandna, ‘After Public Spat, Bharat Biotech & SII Jointly Pledge Smooth Roll out of Covid Vaccines’ (*The Print*, 5 January 2021) <<https://theprint.in/health/after-public-spat-bharat-biotech-sii-jointly-pledge-smooth-roll-out-of-covid-vaccines/579773/>> accessed 4 April 2023.

<sup>198</sup> *Mathew Thomas v Govt. of India*, WP No. 9242 of 2021 (DM-RES-PIL), order dated 26.5.2021 available at <<https://indiakanoon.org/doc/14588988/>> accessed 4 April 2023.

<sup>199</sup> ‘National Regulator Approves “Conditional Market Authorization” of Two COVID19 Vaccines— Covaxin and Covishield’ (*Ministry of Health and Family Welfare*) <<https://pib.gov.in/PressReleasePage.aspx?PRID=1792956>> accessed 2 May 2023.

it had given to Covaxin due to deficiencies in good manufacturing practices (GMP).<sup>200</sup> In November 2022, in response to news reports that quoted a Bharat Biotech executive stating that there was pressure for the early approval of Covaxin, Bharat Biotech revealed that Phase III trials were commenced even before Phase II data was available raising more questions about the entire approval process for the vaccine. None of these developments appear to have affected the conditional approval given to Covaxin.

Perhaps the biggest question in these evolving approval processes, not just for Covishield and Covaxin, but for the additional COVID-19 vaccines (including for use in children and adolescents) that have received approvals in India for use as either primary doses or as precaution doses/boosters<sup>201</sup> is whether the MEURI safeguards included in ICMR's COVID-19 Guidelines were fully and properly applied. With the lack of any detailed information in the public domain, independent scrutiny in this regard by public health or legal experts, bioethicists, health activists or the scientific community has not been possible.

## 2. COVID-19 vaccine-related AEFIs

India's Universal Immunization Program (UIP), which targets almost 57 million people each year to vaccinate newborns and their mothers, has a well-developed AEFI, tiered surveillance system at the district, state, and national levels with committees set up at each tier.<sup>202</sup> For the COVID-19 vaccine rollout, the government set up a Special Group comprising specialists like a cardiologist, neurologist, pulmonary medicine specialist, & an obstetrician-gynecologist to assess the causality of COVID-19 vaccine AEFIs. Several months into the vaccine rollout however, data regarding AEFIs were not available and a group of doctors, lawyers, social workers, and journalists wrote to the government to release this data<sup>203</sup> as media reports highlighted post-vaccination deaths that were being attributed to cardio-vascular problems or brain stroke.<sup>204</sup>

<sup>200</sup> 'Suspension of Supply of COVID-19 Vaccine (COVAXIN)' (*WHO*, 2 April 2022) <<https://www.who.int/news/item/02-04-2022-suspension-of-supply-of-covid-19-vaccine-covaxin>> accessed 28 April 2023.

<sup>201</sup> Directorate General of Health Services CDSCO, 'Approved COVID-19 Vaccines as on 08.07.2022' (*CDSCO*) <[https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download\\_file\\_division.jsp?num\\_id=ODc2OQ==](https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=ODc2OQ==)> accessed 28 April 2023.

<sup>202</sup> Revised AEFI Guidelines: Executive Summary, *Ministry of Health and Family Welfare* (Revised Guidelines) <<https://main.mohfw.gov.in/sites/default/files>> accessed 4 April 2023.

<sup>203</sup> Hamza Lakdawala, 'Doctors, Lawyers, Journalist, and Social Workers Write to Centre again: Share details of 65 Covid Vaccine-Related Deaths and Adverse Events', (*The Leaflet*, 22 March 2021) <<https://theleaflet.in/doctors-lawyers-journalists-and-social-workers-write-to-centre-again-share-details-of-65-covid-vaccine-related-deaths-and-adverse-events/>> accessed 4 April 2023.

<sup>204</sup> Veena Johari, 'Why the Secrecy Around Vaccine Deaths and Data Relating to Serious Adverse Events?' (*The Leaflet*, 22 March 2021) <<https://theleaflet.in/why-the-secrecy-around-vaccine-deaths-and-data-relating-to-serious-adverse-events/>> accessed 4 April 2023.

Eventually, the assessment reports of these AEFIs started getting uploaded on the MOHFW website.<sup>205</sup> However, the reports are listed haphazardly and contain minimal information. No details are provided as to the process of assessment, how they have arrived at the conclusion of causality, and whether documents, papers, reports, autopsy reports, etc. were available for them to scrutinize before concluding their findings. The AEFI reports essentially provide the classification of the AEFIs; for instance, one report released in August 2021, revealed 78 cases of AEFIs investigated by the Special Group.<sup>206</sup> They found 48 cases to have a causal association with the vaccination of which 28 were product-related reactions and 20 were anxiety-related reactions. They found 22 cases with inconsistent causal association – that is not linked to the vaccination and 7 cases in the indeterminate category that included 2 deaths and 1 death was in the unclassifiable category. As causality is linked to liability and given the social benefits arising from individual vaccination, AEFIs categorized as indeterminate, or inconclusive, which is due to lack of evidence, should be presumed to have a causal connection to give the benefit of the doubt to persons facing the AEFI or to the relatives of the person who has died.

AEFI cases were also taken by some courts. In a petition filed before the Allahabad HC, the Petitioner claimed that her husband went blind due to the COVID-19 vaccine.<sup>207</sup> The petition was disposed of with an observation to make a fresh representation with all relevant medical papers before the District Magistrate. In another petition, the Madras HC ordered an autopsy of a 40-year-old conservancy worker who was vaccinated and whose health subsequently started deteriorating and he collapsed and died while on his way to the healthcare facility.<sup>208</sup>

In the *Jacob Puliyel* case, the Petitioner sought directions from the court for information related to AEFIs to be placed in the public domain to identify the occurrence of those adverse events, such as blood clots, strokes, and take adequate steps to prevent or mitigate the occurrence of such adverse events.<sup>209</sup>

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<sup>205</sup> AEFI Reports, *Department of Health and Family Welfare* <<https://main.mohfw.gov.in/Organisation/Departments-of-Health-and-Family-Welfare/immunization/ae-fi-reports>> accessed 4 April 2023.

<sup>206</sup> *ibid.*

<sup>207</sup> Sparsh Upadhyay, 'Man Allegedly Goes Blind Due To COVID Vaccine: Allahabad HC Directs DM to Decide on Wife's Representation Seeking Compensation' (*Livelaw*, 30 June 2021) <<https://www.livelaw.in/news-updates/wife-compensation-husband-goes-blind-covid-vaccine-allahabad-hc-directs-dm-decide-representation-176548>> accessed 4 April 2023.

<sup>208</sup> Jegadeeswari Pandian, 'Alleged Vaccine Death: Madurai Bench asks if Autopsy was Performed as Per Guidelines' (*Indian Express*, 4 February 2021) <<https://www.newindianexpress.com/states/tamil-nadu/2021/feb/04/alleged-vaccine-death-madurai-bench-asks-if-autopsy-was-performed-as-per-guidelines-2259623.html>> accessed 4 April 2023.

<sup>209</sup> *Jacob Puliyel v Union of India* (n 8).

Many countries had collected and reported AEFI data systematically.<sup>210</sup> In response, the government submitted that they were not conducting a detailed assessment and were conducting a rapid review and assessment of all AEFIs reported through a well-defined mechanism. The Apex court did not question the process of collection of the AEFI reports or the assessment of the same. However, the Court while stating that there is an imminent need for the collection of adverse events and wider participation of people, directed the Union of India to facilitate reporting of suspected adverse events by individuals and private doctors through Co-WIN, and for the reports to be made publicly accessible after giving unique identification numbers, and without listing personal and confidential data of persons reporting.<sup>211</sup>

Unfortunately, this order from the SC to simplify AEFI reporting came in mid-2022 while the majority of AEFIs likely occurred during the peak of the vaccine rollout in 2021. As of 19 November 2022, 92,114 AEFI cases had been reported from 219.86 crore vaccine doses (0.0042%) of which 2782 were serious and severe AEFIs (0.00013%).<sup>212</sup> Even these significant numbers of AEFIs likely do not reflect reality given that the majority of vaccinations took place with Covishield and AEFI rates from the equivalent Astrazeneca vaccine in countries like the UK were far higher.<sup>213</sup> The likely underreporting of AEFIs in India has drawn concern from public health experts<sup>214</sup> and should concern the government as well. As noted by the WHO, “*effective spontaneous reporting of adverse events following immunization (AEFI) is the first step to making sure that vaccine products are safe and are being safely administered.*”<sup>215</sup> For those who suffer serious and severe AEFIs, this reporting would have been critical to their ability to access early, effective, and possibly life-saving treatment. The lapses in this regard should be a cause for serious reflection within the government and regulatory authorities.

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<sup>210</sup> ‘Reported Adverse Events’ (CDC, 13 January 2023) <<https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html>> accessed 28 April 2023 makes the adverse event data available at and have set up a Vaccine Adverse Event Reporting system/ portal that is available at <<https://vaers.hhs.gov/>> accessed 28 April 2023. Also, the European Medicines Agency makes public the adverse reactions available at <<https://www.adrreports.eu/en/index.html>> accessed 28 April 2023. The government in Canada also makes public the side effects following vaccination available at <<https://health-infobase.canada.ca/covid-19/vaccine-safety/summary.html>> accessed 28 April 2023.

<sup>211</sup> *Jacob Puliyel v Union of India* (n 8).

<sup>212</sup> Affidavit of Union of India filed in the *Rachna Gangu case*, <<https://awakenindiamovement.com/rachna-gangu-vs-uo-i-wpcivil-1220-of-2021-case-for-vaccine-compensation-in-sc/>> accessed 2 May 2023.

<sup>213</sup> Karina Soboleva, ‘Geographical distribution of TTS cases following AZD1222 (ChAdOx1 nCoV-19) vaccination’ (*The Lancet Global Health*, 2022) <[https://www.thelancet.com/journals/langlo/article/PIIS2214-109X\(21\)00545-3/fulltext](https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(21)00545-3/fulltext)> accessed 4 April 2023.

<sup>214</sup> Nisha Nambiar, ‘Increased under-reporting of AEFI Events a Worry: Experts’ (*Times of India*, 20 November 2021) <<https://timesofindia.indiatimes.com/city/pune/increased-under-reporting-of-ae-fi-events-a-worry-experts/articleshow/87807072.cms>> accessed 4 April 2023.

<sup>215</sup> ‘Reporting form for AEFI’ (*WHO*, 13 April 2021) <<https://www.who.int/publications/m/item/reporting-form-ae-fi>> accessed 4 April 2023.



### 3. Compensation and liability for COVID-19 vaccine AEFIs

When serious and severe AEFIs do occur and are linked to the vaccine, questions of liability and compensation arise. This question of liability has been central to the development and rollout of COVID-19 vaccines. After the initial approvals, in the orders placed by the government for Covishield and Covaxin, the government refused to provide the indemnity initially demanded by the manufacturers.<sup>216</sup> When it emerged that the government might consider giving indemnity to foreign vaccine manufacturers who were refusing to supply their vaccines without the indemnity, Serum demanded that all manufacturers should have the same rules.<sup>217</sup> Eventually, the government decided against providing any indemnity preferring to rely on local vaccines.<sup>218</sup> For those suffering adverse events, the government maintained that they would have to approach the manufacturers for compensation.<sup>219</sup>

Processes for liability and compensation for injuries related to medical products are complicated in India involving criminal laws or criminal provisions in the *Drugs and Cosmetics Act, 1940*, or civil laws like tort law and the *Consumer Protection Act, 2019*. Such cases require considerable financial resources and usually stretch over decades. For those suffering from AEFIs, the fact that the adverse event is not caused by a defect or negligence in manufacturing but is inherent to the vaccine may complicate matters for individuals and families further. And in a context where a vaccine manufacturer threatened a clinical trial participant who faced adverse events with enormous damages and defamation cases, people suffering AEFIs are unlikely to file cases against the manufacturers.

By the time of the *Rachana Gangu* case, the government had further diluted the question of liability for AEFIs not just for itself but also for the manufacturers by arguing that the voluntary nature of vaccination negated any liability

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<sup>216</sup> Leroy Leo, 'No Indemnity for Vaccine Makers in Purchase Pacts' (*Livemint*, 13 January 2021) <<https://www.livemint.com/news/india/no-indemnity-for-vaccine-makers-in-purchase-pacts-11610475232075.html>> accessed 4 April 2023.

<sup>217</sup> 'India Close to giving Indemnity to Foreign Vaccine Makers Like Pfizer: Report' (*Livemint*, 10 June 2021) <<https://www.livemint.com/news/india/india-close-to-giving-indemnity-to-foreign-vaccine-makers-like-pfizer-report-11623321981463.html>> accessed 4 April 2023; see also 'Serum Institute Seeks Indemnity, Says "Same Rules for all": Sources' (*NDTV*, 9 June 2021) <<https://www.ndtv.com/india-news/serum-institute-seeks-indemnity-against-liabilities-says-rules-should-be-same-for-everyone-sources-2455161>> accessed 4 April 2023.

<sup>218</sup> Abantika Ghosh and Moushumi Das Gupta, 'India Unlikely to give Indemnity to Foreign Vaccines, may Consider only if Shortage Persists' (*The Print*, 7 August 2021) <<https://theprint.in/health/india-unlikely-to-give-indemnity-to-foreign-vaccines-may-consider-only-if-shortage-persists/710493/>> accessed 4 April 2023.

<sup>219</sup> 'Govt: No Provision to Compensate the Vaccinated in Case of Adverse Events' (*Times of India*, 6 April 2021) <<https://timesofindia.indiatimes.com/india/govt-no-provision-to-compensate-the-vaccinated-in-case-of-adverse-events/articleshow/81923434.cms>> accessed 2 May 2023.

for side effects. The government further hardened this position arguing that even informed consent or the lack of it was irrelevant as long as the vaccine was taken voluntarily. While the *Rachana Gangu* Petitioners are (rightly) arguing for fixing government responsibility for an abject failure in informed consent processes, it may be worth also considering whether the government and manufacturers should be liable for AEFIs as a matter of strict liability given that vaccination is as much a social good as it is for individual benefit. The government's response in the *Rachana Gangu* case on the matter of compensation states that strict liability should not be considered as the government only administered the national vaccine rollout, the vaccines were produced by third parties and had gone through regulatory review and were globally considered safe and effective. In such a scenario, according to the government, "*holding the State directly liable to provide compensation under the narrow scope of strict liability for extremely rare deaths occurring due to AEFIs from the use of vaccines may not be legally sustainable.*"<sup>220</sup>

No matter how rare a serious adverse event is, it adversely affects the life of an individual and their family. Further, if the adverse events are rare, and have occurred in a small population, there is no reason why the manufacturers of the vaccines cannot pay compensation to those who have been adversely affected post-vaccination. As seen earlier, a significant portion of the financial risks for research and development and conducting clinical trials for the two COVID-19 vaccines was shouldered by the government and funding agencies. The government also purchased the vaccines from the manufacturers and also allowed them to sell the vaccines in the private sector for a significant profit. The lack of any mechanism for compensation for AEFIs was taken note of by the Parliament Standing Committee on Health in its September 2022 report related to COVID-19; the Standing Committee "strongly" recommended that, "*the Ministry... create a clear framework of vaccine liability for the manufacturer in case of AEFI so that adequate compensation can be provided to the aggrieved individuals.*"<sup>221</sup> The Kerala HC has also directed the National Disaster Management Authority and the MOHFW to formulate a compensation policy for those who have died due to vaccine side effects.<sup>222</sup>

But the government too cannot absolve its responsibility in paying compensation for AEFIs or even for AESI, because (a) the COVID-19 vaccines were developed by the manufacturers with the help of the government and government funds, and funds from other agencies; (b) the vaccines were given fast

<sup>220</sup> Affidavit of Union of India filed in the *Rachana Gangu* case (n 147).

<sup>221</sup> Department-Related Parliamentary Standing Committee on Health and Family Welfare, *137<sup>th</sup> Report on Vaccine Development, Distribution Management and Mitigation of Pandemic COVID-19*, Rajya Sabha Secretariat, New Delhi, September 2022/Asvina, 1944 (SAKA) <[https://sansad.in/getFile/rsnew/Committee\\_site/Committee\\_File/ReportFile/14/160/137\\_2022\\_12\\_12.pdf?source=rajyasabha](https://sansad.in/getFile/rsnew/Committee_site/Committee_File/ReportFile/14/160/137_2022_12_12.pdf?source=rajyasabha)> accessed 2 May 2023.

<sup>222</sup> *Sayeeda K.A. v Union of India* 2022 SCC OnLine Ker 4514.

track approval, and all AEFI or AESI relating to the vaccines were not documented or recorded or found in the clinical trials that took place on small populations over a small period of time while AEFI can emerge over a much longer period of time and across a much larger population; (c) the vaccines were administered as part of a national vaccine rollout whether in the public or private sectors with strict government control in matters of registration, pricing, dosing, and other aspects as well as strong government messaging that the vaccines were safe and urging individuals to get vaccinated. Even the argument of 'voluntariness' during the height of the vaccine rollout by the government is questionable as the SC order striking down vaccine mandates came over a year and a half into the vaccine rollout.

In light of these considerations, the government and the manufacturers of the vaccines should be jointly and severally liable for persons experiencing serious adverse events, or even death, and in the interest of justice, they would be duty-bound to pay compensation for the same.

There is some international experience in this regard and vaccine injury compensation programs do exist in other countries,<sup>223</sup> and no-fault compensation programs were also established by UNICEF<sup>224</sup> and as part of COVAX, which in theory should also cover India but it is unclear how a person would know if their vaccine came through COVAX or government procurement.<sup>225</sup> Reports suggest that these programs have not been easy for individuals and families to access and compensation payments are often delayed.<sup>226</sup> For India, in consultation with individuals and families who have suffered serious and severe AEFIs as well as health groups and other experts, the government should as a matter of urgency establish a compensation fund that includes contributions from the manufacturers; the mechanism should be generous, empathetic and easy to use. This mechanism should also give the benefit of

<sup>223</sup> Randy G Mungwira and Others, 'Global Landscape Analysis of No-Fault Compensation Programmes for Vaccine Injuries: A Review and Survey of Implementing Countries' (*Plos One*, 21 May 2021) <<https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0233334>> accessed 2 May 2023 and Institute of Medicine, 'Appendix E: Vaccine-Injury Compensation in other Countries' in *Vaccine Supply and Innovation* (National Academies Press 1985) <<https://www.ncbi.nlm.nih.gov/books/NBK216811/>> accessed 2 May 2023.

<sup>224</sup> 'COVID-19 Vaccine Facility No-Fault Compensation Scheme' (*ESIS*) <<https://c19vaccinenfc.com/>> accessed 2 May 2023.

<sup>225</sup> 'No-Fault Compensation Programme for COVID-19 Vaccines is a World First' (*WHO*, 22 February 2021) <<https://www.who.int/news/item/22-02-2021-no-fault-compensation-programme-for-covid-19-vaccines-is-a-world-first>> accessed 2 May 2023.

<sup>226</sup> Jacqui Wise, 'UK Makes First Payments to Compensate Injury or Death from Vaccines' (*BMJ*, 24 June 2022) <<https://www.bmj.com/content/377/bmj.o1565>>; Mary Ward, 'Thousands left waiting for compensation after claims of COVID-19 vaccines injury' (*The Sydney Morning Herald*, 16 April 2023) <<https://www.smh.com.au/national/thousands-left-waiting-for-compensation-after-claims-of-covid-19-vaccine-injury-20230413-p5d03y.html>> accessed 2 May 2023; Karin Larsen, '\$2.8 Million Paid out so Far by Vaccine Injury Support Program' (*CBC News*, 6 January 2023) <<https://www.cbc.ca/news/canada/british-columbia/covid-19-vaccine-injuries-compensation-canada-1.6704655>> accessed 2 May 2023.

the doubt to victims in cases where the causal link to vaccinations for serious and severe AEFIs or AESIs cannot be determined for a lack of evidence and give compensation even in such cases. Finally, such a mechanism should not preclude legal action by individuals and families who suffer AEFIs or AESIs that can be linked to negligence or other lapses on the part of the government and/or the manufacturers as in the *Rachana Gangu* case in the SC or the case before the Bombay HC filed by a father who argues that the government and the manufacturers should be liable in the death of his daughter who, as a health professional, was compelled to take Covishield in the first month of the national rollout.<sup>227</sup>

### III. CONCLUDING REMARKS

It is said that “*a courtroom trial is to law what a laboratory experiment is to science – the primary methods of establishing facts.*”<sup>228</sup> Both law and science are based on evidence, even though the techniques for the collection of evidence are different, the integrity of the process is vital for both.<sup>229</sup> The pandemic exposed the loss of integrity in collecting evidence, both by science and the law, particularly as seen in the case of vaccines. The integrity of the scientific process was severely undermined by a lack of transparency, independent collection of data and information, and the impaired accountability of institutions established to protect scientific rigor. Legislative and policy-making has seen arbitrary, sweeping actions by the government with little to no accountability. The failure to take the process of AEFI reporting seriously and to treat and compensate those who suffer from AEFIs has been particularly disheartening, as those who suffer from these AEFIs do so in the public interest that underlies mass vaccination.

There were umpteen opportunities for the Courts (the custodians of justice, the protectors of rights and liberties), to intervene, hold the government accountable, uphold rights and liberties, and set right the arbitrary, unscientific decisions of the government that abrogated the right to life and other fundamental rights of its people. While the SC and several HCs did pass orders directing the Central and State governments to correct arbitrary, unreasonable, and problematic vaccine and vaccination policies, far too often, explanations offered by the executive for the decisions, commissions, and omissions that violated rights, including the right to life, health, and healthcare have been taken at face value.

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<sup>227</sup> Sharmeen Hakim, ‘Death Due to Alleged Side Effects of Covid Vaccine: Doctor’s Father Files Plea in Bombay HC, Seeks Rs 1,000 Crore Compensation’ (*Livewlaw*, 1 February 2022) <<https://www.livewlaw.in/news-updates/bombay-high-court-covid-19-vaccine-death-due-to-side-effect-1-crore-compensation-190899>> accessed 2 May 2023.

<sup>228</sup> Lee Loevinger, ‘Review: Science and Legal Rules of Evidence’ (1992) 32 *Jurimetrics* 487.

<sup>229</sup> *ibid.*

Although courts played a far more active, and perhaps in some cases even activist role, during the pandemic - a welcome break from the near total retreat of the constitutional courts from the heydays of public interest litigation in the 1980s and 1990s - in nearly every decision, the courts have gone to pains to explain that the proceedings before them were not adversarial and they are not interfering in policy-making and identified narrow areas of inquiry. Most courts relied on a strategy of nudging government policy away from the violation of rights with delayed, mixed results. In several cases, it has taken multiple hearings and interim orders over several months to achieve these outcomes; some cases are still pending. With cases pending for decades in our courts, this may seem to be a period of relatively quick resolution of cases. However, in a health emergency where every day that a decision was delayed or a bad policy remained in effect had an impact on the lives and health of millions, these delays were costly.

In some instances, despite the nudging of the courts, the government persisted with policies the courts found prima facie untenable and the courts let these policies stand as in the case of private sector procurement and pricing of vaccines despite the SC's concerns. As the Bombay HC noted when the State government persisted with its travel restrictions on unvaccinated persons, *"The hope and trust reposed by us in the Committee that it would take a decision, which is reasonable and not in derogation of the Fundamental Rights of the citizens guaranteed by Article 19(1)(d), stand belied. We were utterly mistaken...In hindsight, we feel that...it would have been appropriate if we had struck down the further orders... in the exercise of our suo motu powers instead of, in accordance with judicial discipline, permitting the Committee to take a fresh decision. This decision of the Committee, in the circumstances, is unexpected, to say the least."*<sup>230</sup>

Another worrying aspect of court hesitancy in these cases, was the delay in taking up and hearing certain matters even though the courts admitted them and issued notice. In a public interest litigation pending before the SC on AEFIs, the court is reported to have said that *"we have to look at the countervailing benefits of vaccination. We cannot send a message that there are some problems with the vaccination. The WHO has spoken in favour of vaccines, and countries across the world are doing it. We cannot just doubt it"*.<sup>231</sup> Similarly, although the *Jacob Puliyel* petition was filed in August 2021, at the height of the vaccine rollout, the SC remained reluctant to pass any order in

<sup>230</sup> *Sohan Rajeve Agate v State of Maharashtra* 2022 SCC OnLine Bom 882 <<https://indiankanoon.org/doc/59335163/>> accessed 4 April 2023.

<sup>231</sup> Mehal Jain, "We Cannot Just Cast Doubt on Vaccination": Supreme Court on Plea Seeking Investigation on Deaths Allegedly Linked to Vaccination' (*Livelaw*, 26 November 2021) <<https://www.livelaw.in/top-stories/supreme-court-covid-vaccination-plea-seeking-follow-up-deaths-adverse-effects-186345>> accessed 4 April 2023; Reported conversations during the hearing of the case *Ajay Kumar Gupta v Union of India*, WP(s) (C) No.588/2021.

the petition due to the “fear” that it would lead to “vaccine hesitancy.”<sup>232</sup> The final order in the case was passed in May 2022 and while it made an important direction for the government to allow individuals to report AEFIs, this order came far too late in the 1.5-year-old vaccine rollout.<sup>233</sup> Unfortunately, the hesitancy argument appears to have clouded the vision of the courts in these crucial cases.

The repeated concern of the courts that they should not interfere or appear to interfere in policymaking or their hesitation in hearing certain matters could have been balanced to some extent by insisting on higher standards of transparency and accountability in policymaking. Deficiencies in policies could have been addressed then through measures and orders to strengthen accountability and transparency as well-established methods of democratic checks and balances – in access to information, clinical trial data, detailed minutes of meetings where policies were deliberated, details of decision-making bodies, their members and their proceedings - yet here too the courts hesitated instead trusting the government to identify and consult the right experts or determine when and what information should be available in the public domain severely undermining any independent scrutiny of the government’s actions.

The urgent need for the courts to have supported demands for transparency and accountability also arose from the government’s myopic approach to COVID-19 vaccines resulting in an almost total lack of public consultation and involvement of public interest and public health groups at every stage. Participation is a key tenet of the right to health where governments are required to consult with and ensure the participation of affected communities in decision-making. The documentation of policy lapses, violations of clinical trial norms, the exclusion of various marginalized groups from vaccination, attempts at vaccine price gouging in the private sector, and the recording of AEFIs have largely been done by health groups and community representatives on the ground. It is striking that in many cases, the courts almost acted like a post-box for public interest submissions and grievances and had to repeatedly ask the government to consider petitions as representations and provide responses in writing, in a time-bound manner. In a Constitutional democracy, this should have been a matter of course and hardly something for constitutional courts to continuously arbitrate and seek hearings for the people before the government.

In a rather poignant section of the April order in the *Distribution of Essential Supplies and Services During Pandemic, In re* case, the SC speaks of

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<sup>232</sup> Sohini Chowdhury, ‘If Vaccine Mandates are not Proportionate to Personal Liberty, We will go into it : Supreme Court’ (*Livelaw*, 29 November 2021) <<https://www.livelaw.in/top-stories/supreme-court-covid-19-vaccination-mandates-imposed-implead-states-186563>> accessed 4 April 2023.

<sup>233</sup> *Distribution of Essential Supplies and Services During Pandemic, In re*, 2021(n 7).

the role of courts in creating and preserving collective memory. The SC quotes the following passage from the book *History, Memory, and the Law*:

*“Because the litigated case creates a record, courts can become archives in which that record serves as the materialization of memory. Due process guarantees an opportunity to be heard by, and an opportunity to speak to, the future. It is the guarantee that legal institutions can be turned into museums of unnecessary, unjust, undeserved pain and death. The legal hearing provides lawyers and litigants an opportunity to write and record history by creating narratives of present injustices, and to insist on memory in the face of denial.”*<sup>234</sup>

Indeed, the perusal of court records along with news reports, civil society interventions, and records created by individuals on social media for this article, captured to some extent the pain and anguish of the pandemic and the injustices brought forth by legal responses to it. The SC went on to observe that through the proceedings, “we hope to not only initiate a dialogue so as to better tackle the current COVID-19 pandemic but also to preserve its memory in our public records, so that future generations may evaluate our efforts and learn from them.”<sup>235</sup> There can be little disagreement with this sentiment. But learning from the pandemic is as much a responsibility of our generation as it might be for future generations. There is near global consensus that given the extent of environmental degradation, humanity will face many more pandemics in the coming years as viruses and other pathogens continue to spill over into the human population. The fraught exercise of law and policy-making and judicial oversight during the COVID-19 pandemic must be documented, analyzed, and reflected on as a matter of some urgency. This article presents the right to health and the AAAQ framework as an important and useful foundation for the government and the judiciary to reflect and review the decisions and actions of the past three years; as a possible basis to begin to understand the injustices and inequities of these pandemic years. The old and much-used adage that those who do not learn from history are bound to repeat it takes on a special urgency in our increasingly fragile world as the very real and direct impact of failing to learn these lessons is on the lives and health of millions - now and in the future.

## ANNEX 1

COVID-19 Vaccines in India: A Brief Timeline	
January 2020	Genomic structure of the betacoronavirus, i.e., SARS-CoV2 is revealed.

<sup>234</sup> *Distribution, In re case (n 7).*

<sup>235</sup> *Distribution, In re case (n 7).*

April 2020	ICMR isolates SARS-COV-2 virus and announces public-private partnership with Bharat Biotech to develop a vaccine candidate.
April 2020	Serum Institute announces collaboration with Oxford University on a vaccine candidate.
June 2020	Serum Institute announces agreements with Astrazeneca to produce the Oxford vaccine and with Novovax for its vaccine (known as Covovax in India).
August 2020	Serum Institute announces agreements with CEPI (Coalition for Epidemic Preparedness Innovations), GAVI (Global Alliance for Vaccines) and BMGF (Bill and Melinda Gates Foundation) for global supplies.
September 2020	Nearly 30 vaccine candidates are at various stages of development right from pre-clinical, to Phase I, II, or III in India.
January 2021	Both Serum Institute and Bharat Biotech receive approvals from the DCGI. Serum received 'restricted use in emergency situation' approval. Bharat Biotech's vaccine, Covaxin, was given "restricted use in emergency situation under clinical trial mode" as Phase III trials were still ongoing.
January 2021	Vaccination is announced for healthcare workers and frontline workers. The Central government procures and distributes the vaccines to State governments.
February 2021	International supply of Indian COVID-19 vaccines begins.
March 2021	On completion of Phase III trials, Covaxin's approval is no longer in "clinical trial mode".
March 2021	The rollout is extended to those above the age of 65 and to those above the age of 45 who also had specified co-morbidities. The Central government ropes in the private sector for distribution while it continued to procure and distribute vaccines to the States as well as private hospitals. A cap of Rs. 250 was imposed for private hospitals to charge as fees for administering the vaccines.
March 2021	Serum and Bharat Biotech are asked to prioritise domestic supplies as the Deltawave worsens.
April 2021	All those above the age of 45 became eligible for vaccination.
May 2021	All those above the age of 18 become eligible for vaccination. Procurement is changed with the Central government continuing to procure and distribute vaccines only for 45+ age group leaving it to State governments to procure for the 18-44 age group. The private sector is allowed to independently procure and vaccinate all eligible age groups. Manufacturers are asked to reserve capacity of 50 : 25 : 25 for the Centre, States and private sector respectively.
April 2021	In the <i>Suo Moto</i> case, the SC finds the change in procurement likely to prima facie violate the right to health recognized as part of the right to life under Article 21 of the Indian Constitution.



May 2021	SC reiterates its finding of prima facie violation of the right to health with the new procurement policy.
July 2021	After the SC order, the Centre announced it would procure 75% of capacity and distribute to States while the private sector would procure 25%. The price for both vaccines to the government was Rs. 150. Prices in the private sector were capped at Rs. 780 for Covishield and Rs. 1410 for Covaxin per dose.
October 2021	Exports of Indian COVID-19 vaccines resume.
January 2022	All those between the ages of 15-18 become eligible for vaccination with Covaxin. "Precautionary" doses i.e. a third dose for healthcare and frontline workers and those above the age of 60 who had co-morbidities are also announced. The third dose could be taken 9 months after the second dose and could only be of the same vaccine as the primary series.
January 2022	Covishield and Covaxin receive 'conditional marketing authorization.'
March 2022	All those between the ages of 12-14 become eligible for vaccination with Corbevax (and later with Covavax). For the 12-17 age group, the government procures and provides Covavax and Corbevax while the 15-18 age group can also access Covaxin either from the government or in the private sector.
April 2022	Precautionary doses are opened to all persons above the age of 18 only on payment at private centers. Some States announced free precautionary doses at government centres.
May 2022	SC finds vaccine mandates unconstitutional in the <i>Jacob Puliyel</i> case subject to some conditions and orders the government to allow AEFI reporting by individuals and private doctors and for public access to such records while preserving privacy.
July 2022	Free precautionary doses for all age groups are announced at all government centres for a period of 75 days only. At the end of the 75 days, States with stocks remaining are allowed to continue free provision while stocks last.
August 2022	SC issues notice for reply to the Central government in the <i>Rachana Gangucase</i> on the deaths of two girls post-vaccination.
November 2022	AEFIs recorded: 92,114 AEFI cases had been reported from 219.86 crore vaccine doses (0.0042%) of which 2782 were serious and severe AEFIs (0.00013%)
December 2022	Number of vaccinations: Total vaccinations: 2,20,06,25,208; Dose 1: 1,02,71,66,278; Dose 2: 95,11,41,127; Precaution Dose: 22,23,17,803.
December 2022	Vaccines approved: 10 COVID-19 vaccines including 4 for use in children and adolescents, have received approvals in India for use as either primary doses or as boosters/precaution doses. Two vaccines, Covishield and Covaxin, have received 'conditional marketing authorization' while the others have received 'restricted use in emergency situation' use approval.