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THE ROLE PLAYED FEDERAL/CENTRAL AGENCIES IN APPROVAL, DISTRIBUTION OF COVID VACCINES: AN ADMINISTRATIVE ANALYSIS

- Aseem Mittal & Dhananjay Khurana[1]

ABSTRACT

The COVID 19 pandemic just came in as a surprise in the world. None of the health organization across the globe was able to predict that such disease could arise and be life threatening. It is obvious that it created panic everywhere. All the governments in the world had to implement policies for lockdown, quarantine etc. Soon the World Health Organisation, flagged the need of COVID vaccine in order to protect millions of people who were exposed to the disease. Having trust in immunisations stands fundamental and is profoundly dependent upon the competence of state-run organisations towards conveying the benefits of inoculation, plus to deliver the antibodies steadily and efficaciously. This mandates the work of governments in enhancing reliance in the adequacy as well as wellbeing across successful communication, and also have a belief to get and appropriate the vaccines constructively and even-handedly. Around the world there is a small minority who believe that vaccines are not necessary having anti-vaccination opinions and views, reluctance about COVID-19 inoculation coexists clearly in several nations. Government activities to earn trust will be crucial for their prosperity, and to the rise of stronger social orders after the emergency. This paper will discuss how India catered the need of vaccination, approval and distribution in such tough times. The primary point of discussion would be surrounding the polices enacted by the government. It is important to discuss what laws govern the actions of the government in vaccine creation and what all authorities were allowed to provide relevant approvals. The paper will analyse whether there was misuse of the power delegated to the Central government by the legislature. In order to analyse whether India's administrative framework

[1] Students at Jindal Global Law School

was good or not the paper will also discuss what was the policy adopted by United Kingdom (UK) and a comparison would be drawn between both.

INTRODUCTION

The COVID 19 pandemic just came in as a surprise in the world. None of the health organization across the globe was able to predict that such disease could arise and be life threatening. It is obvious that it created panic everywhere. All the governments in the world had to implement policies for lockdown, quarantine etc. Soon the World Health Organisation, flagged the need of COVID vaccine in order to protect millions of people who were exposed to the disease. Having trust in immunisations stands fundamental and is profoundly dependent upon the competence of state-runorganisationstowards conveying the benefits of inoculation, plus to deliver the antibodies steadily and efficaciously. This mandates the work of governments in enhancingreliance in the adequacy as well as wellbeing across successful communication, and also have a belief to get and appropriate the vaccinesconstructively and even-handedly. Around the world there is a small minority who believe that vaccines are not necessary having anti-vaccination opinions and views, reluctance about COVID-19 inoculation coexists clearly in several nations. Government activities to earn trust will be crucial for their prosperity, and to the rise of stronger social orders after the emergency.This paper will discuss how India catered the need of vaccination, approval and distribution in such tough times. The primary point of discussion would be surrounding the polices enacted by the government. It is important to discuss what laws govern the actions of the government in vaccine creation and what all authorities were allowed to provide relevant approvals. The paper will analyse whether there was misuse of the power delegated to the Central government by the legislature. In order to analysewhether India's administrative framework was good or not the paper will also discuss what was the policy adopted by United Kingdom (UK) and a comparison would be drawn between both.

India's Response to COVID 19: Vaccination Policy

1. Laws governing approval and distribution of vaccine

In India the Drug and Cosmetics act 1940, gives power to the central government to make to "Drug Technical Advisory Board"[2]which will include experts in healthcare who will undergo functions provided in the act. This board has the power to monitor different kinds of drugs and come with new drugs by following standard protocol. Under the Drug and Cosmetics act, the Central Drug Standard Control Organisation (CDSCO) was formed which is responsible for making and conducting trails for vaccines in India[3]. Further, the Drug Controller General of India (DCGI) under the CDSCO is responsible for approval of licenses of vaccines. The CDSCO is the most important authority for creation, approval, and distribution of COVID 19 vaccines in India. During the time of the pandemic the Central government had power to make vaccines and they fast-tracked the process for approvals as well. The Ministry of Health and Family Welfare under the notification dated 18thMay 2020[4] for the first time gave permission to any individual who intends to manufacture and store vaccine for COVID 19 which are under clinical trials can do so by filing an application to the CDSCO in conformity with new drugs and Clinical Trial Rules 2019. The authority to check if a manufacturer complied with the respective laws or not completely lied on CDSCO. Further, the ministry under the notification dated 26th November 2020[5], increased the validity of import licenses for sale and distribution of COVID vaccines. It is important to note that the central government was making such regulations under the power given in section 26B of Drug and Cosmetics act[6]. The central government also constituted the National Expert Group on Vaccine Administration for COVID-19 (NEGVAC), which had the duty to formulate action plan for the distribution of vaccines[7].Finally, the DCGI under the notification dated 15th April 2021[8] gave the guidelines for the approval of vaccine for emergency use to the

[2]DRUG and COSMETICS ACT 1940, sec 1
[3]DRUG and COSMETICS ACT 1940, sec 5
[4]Ministry of Health and Family Welfare, Notification dated: 18th May 2020. Available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjMzMQ== .
[5]Ministry of Health and Family Welfare, Notification dated: 26th November 2020. Available at: https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WEB/elements/download_file_division.jsp?num_id=NjcyMQ==
[6]DRUG and COSMETICS ACT 1940, sec 26B
[7]Ministry of Health and Family Welfare, COVID 19 Vaccine Operational Guidelines, Government of India, 28th December 2020, Available at: https://www.mohfw.gov.in/pdf/COVID19VaccineOG111Chapter16.pdf
[8]Directorate General of Health Services, Guidelines for emergency approval of vaccines, Central Drug Standard Control Organisation, 15th April 2021, Available at: https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/notice15april21.pdf

vaccines approved by US FDA, EMA, UK MHRA, Japan, or those in the approved list of WHO.

The above-mentioned authorities and committees are all managed and controlled at the by the Central government. However, it was also necessary to make task forces at the state level as well to monitor the distribution of vaccines. To cater that need the NEGVAC made the following governance mechanism.

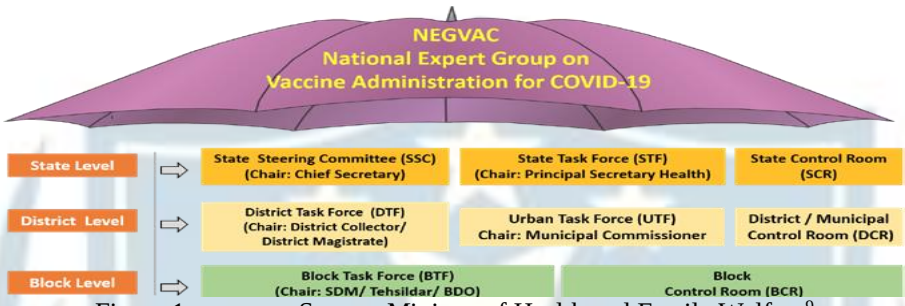

Figure 1 Source: Ministry of Health and Family Welfare[9]

Figure 1 demonstrates different task forces appointed at state and district level who was supposed to administer vaccines in their respective areas and see that there no discrepancy with the distribution of vaccines. Instead of the above-mentioned departments and forces there were many other ministries who was involved in the procedure for a speedy availability and distribution of vaccine. All this on one hand looks to be the perfect plan of action keeping in mind the emergency that COVID 19 created, but on the other hand it raises a red flag as to the power used by the executive i.e., the central government with minimal involvement of the legislature. The next section will analyse the entire mechanism adopted by the central government and try to see how there could be misuse of power and whether there was excessive delegation given by the legislature under the acts mentioned above for the Central government to make all the arrangements to vaccine approval and distribution.

2. Administrative issuein COVID 19 vaccination policy

There existthree organs of a government namely Legislature, Executive and Judiciary. In simple words the legislature makes the law, the executive implements the law, and the judiciary interprets the law. However, it is difficult to make laws and policy in greater details

[9]Ministry of Health and Family Welfare, COVID 19 Vaccine Operational Guidelines, Government of India, 28th December 2020, Available at: https://www.mohfw.gov.in/pdf/COVID19VaccineOG111Chapter16.pdf

since the legislature does not have that much time and most importantly, they lack expertise in different areas. Therefore, it is important for the legislature to delegate its power to the executive. Thisis known as the doctrine of delegated legislation. From the mere definition this doctrine looks very helpful in the sense that it lowers the workload of the legislature. However, there is always a possibility of misuse of power by the executive or sometimes excessive delegation by the legislature itself. The concept of delegated legislation was discussed in the landmark judgment of *in re Delhi laws act case*[10]. This case clarified what exactly was the position delegated legislation in India. Two main conclusions that were drawn in this case was firstly it legitimized legislation of legislative power to the administrative organs and secondly it imposed an outer limit on delegation by the legislature[11]. So, it is understood that the doctrine of delegated legislation applies in India, but the biggest threat is the limit of that delegation and check whether there is not excessive delegation. The court in this case made it clear that the way in which the doctrine of delegated legislation was applied in British constitution cannot be applied similarly in India[12].The reason being that the British constitution gives excessive powers to the administrative body. The 7-judge bench in this case had conflicting opinions regarding the permissible limit for the delegated legislation. Justice FazliAli concluded that the legislature should discharge its legislative functions, it should not abdicate its functions and make a parrel legislature. If that happens then the whole purpose of have the three different organs of the government would be defeated, and executive will get into the shoes of the legislature. With regards to the limits of delegated legislation the court had the opinionthat only non-essential functions should be delegated. There was conflicting opinion on this,JusticeMukherji said that the legislature should make the policy in the act broadly and the executive should make the detailed policy. However, Justice Kania had the opinion that the legislature cannot give power to make detailed policies to the executive. The court could not have any agreement on the same. However, with respect to modifications in policy Justice Fazl stated that if the alteration is not changing the intent of policy, it can be done by the executive[13].

[10]In re Delhi Laws Act, AIR 1951 SC 332.
[11]M P Jain & S N Jain: Principles of Administrative Law, Lexis Nexis, 9th Edition.
[12]M P Jain & S N Jain: Principles of Administrative Law, Lexis Nexis, 9th Edition.
[13]In re Delhi Laws Act, AIR 1951 SC 332.

In the case of COVID 19 vaccination policy there were lots of laws involved that gave powers to the central government to make vaccines, conduct trials and make arrangement for distribution. The Drug and Cosmetics act[14] was the primary legislation that gave power to the central government. However, the act has no mention of provisions with regards to "emergency response and expedited pathways for approvals"[15]. This is the first red flag in the entire vaccination policy. It is true that the intent of the executive was not wrong in coming up all the committees and policies as mentioned above. However, it is a complete misuse of power by the executive. Section 26 B of the act[16] gives power to the central government to regulate or restrict the use of any drug that it feels meets the requirement of an emergency due to an epidemic or natural calamities in "public interest". This clause is firstly too broad and secondly is an example of excessive delegation. The legislature has given full authority to the central government to make laws with regards to drugs in case of emergency. As mentioned above provisions with regards to emergency approval still fails to be a part of the act. Excessive delegation was one of the biggest threats that the court briefly flagged in the case of *In Re Delhi laws act case*[17]. The concept of excessive delegation came up in the case of *Gwalior Rayon silk*[18], in which the debate was whether of doctrine of excessive delegation is maintainable or not. Justice Mathew in this case was of the opinion that indelegation of legislation there should be not any restrictions to the executive[19]. This view if accepted would increase the power of executive substantially. Similar was the view of majority and they believed that the biggest drawback in Mathew's opinion is that this would practically leave the legislature with very minimal power even to repeal an act. Currently, due to the existence of party system in real instance the legislature passes laws only after with consultation with the executive[20]. In true it is the executive that runs the legislature. It is true that in such a scenario it is hard to believe that legislature would ever repeal a law where there would be excessive delegation without the consent of the executive.

[14]DRUG and COSMETICS ACT 1940, sec 1
[15]Dinda, Amit Kumar; Tripathi, Santanu Kumar; John, Bobby,*Revisiting regulatory framework in India for accelerated vaccine development in pandemics with an evidence-based fast-tracking strategy*, Indian Journal of Medical Research,August 2020 ,Volume 152 ,pg 156-163.
[16] DRUG and COSMETICS ACT 1940, sec 26B
[17]In re Delhi Laws Act, AIR 1951 SC 332
[18]Gwalior Rayon Co. v Asst. Commr. of Sales Tax, AIR 1974 SC 1660
[19]Gwalior Rayon Co. v Asst. Commr. of Sales Tax, AIR 1974 SC 1660
[20]M P Jain & S N Jain: Principles of Administrative Law, Lexis Nexis, 9th Edition.

This is exactly what is happening in the case of COVID 19 vaccine policy in relation to approval and distribution. The government under its power under section 26 B of the act[21] is constantly making laws, policies, committees, and most importantly fast track committees to make vaccine available. On one hand it is a national emergency but on the other hand legislature is completely out of equation. Figure 1 shows that central government regulated NEGVAC has made so many fast-track booths for vaccine administration which is problematic as the problem is keeping check on their functioning. Most importantly the parliament was not even considered for consent with regards to vaccine approvals. The Rajya Sabha in its report no. 229 which was presented on 2nd February 2021lays down what government "informed" the parliament with regards to Management of COVID 19 pandemic and related issues[22]. In the report the parliament mentions the timeline that which government gave with regards to vaccine trials and steps made for approval. The notification for approval has been discussed above. This shows how the opinion of Justice Mathews is being applied and what the majority in the case of *Gwalior Rayon silk*[23] feared. There is complete excessive delegation by thelegislature. The provisions that were laid in *In Re Delhi actcase*[24] have failed and it is visible that legislature have sort of delegated even its essential functions.

Comparative Analyses of India's and UK's COVID 19 Vaccination Policy

In UK researchers and scientists have been following the development since the beginning of 2020. The House of Lords along with royal assent passed the Coronavirus Act 2020 on 25th March 2020[25]. The act gives the UK Government emergency powers to deal with the spread of the virus further it gives them the powertowards restrictingand suspending public assemblies, to isolate individuals thought to have beenstruck by COVID-19, and also to facilitate or relax few guidelines in a scope of areas to confinethe transmission of the infection.The COVID-19 plan UK pursued was a local community led partnership between

[21]DRUG and COSMETICS ACT 1940, sec 26B
[22]Rajya Sabha, Report 229: Management of COVID 19 Pandemic and Related Issues, Parliament of India, 2ndFebruary, Page 22, Available on: https://rajyasabha.nic.in/rsnew/Committee_site/Committee_File/ReportFile/15/143/229_2021_2_15.pdf
[23]Gwalior Rayon Co. v Asst. Commr. of Sales Tax, AIR 1974 SC 1660
[24] In re Delhi Laws Act, AIR 1951 SC 332
[25]Department of Health, *Coronavirus Act Analysis, How the Coronavirus Act has helped the Departments response to the Coronavirus (COVID-19) Pandemic*, available at https://www.health-ni.gov.uk/coronavirus-act-analysis (Accessed on 3 March 2020).

the government, local authorities and healthcare workers[26]. UK being one of the frontrunners in the development of vaccines had worked on developing a vaccination for the Middle East Respiratory Syndrome (MERS) in 2016[27] with the help of raising capital from the UK Vaccine Network (UKVN). This technology was reused to foster a COVID-19 vaccine by raising funding from the National Institute for Health Research (NIHR) and UK Research and Innovation (UKRI)[28]. With the help of this noteworthy funding and a quick and notable exploration into this field the UK have endorsed their vaccines by the Medicines and Healthcare items Regulatory Agency (MHRA), subsequent to satisfying their severe guidelines of security, quality, and adequacy. April 2020 was when the UK government set up the Vaccine Task Force (VTF) to guarantee that the population of the country would have admittance to a protected and compelling antibody against COVID-19. The method VTF took empowered various phases of the antibodies development course to happen rapidly and in equal, while never compromising severe security, quality and viability norms. The goal was to make the vaccines accessible to everyone on an urgent basis and produce them in large amounts. The Joint Committee on Vaccination and Immunisation (JCVI) is a body that advises the government of the four nations within the UK regarding vaccinations, anticipations and avoidance of diseases. They also look antibody security, adequacy and check out at the effect and cost viability of inoculation procedures[29]. They advised the government that the COVID-19 vaccine plan should prevent the spread of the virus and reduce the mortality rate.However, the VTF has been the backbone of providing vaccines to the whole country altogether.

Looking at the difference between India and UK we can see that UK'S action plan is much more viable than India's. India having multiple bodies across different states which is not the ideal way to move forward, the power of checks and balances becomes very hard especially with the size of our country and population. UK having 2-3 bodies to handle the full nation is a much more viable option as each committee has a different power, from

[26]OECD, *Enhancing Public Trust in COVID-19 vaccination: The Role of Governments* (10th May 2021). Available at https://www.oecd.org/coronavirus/policy-responses/enhancing-public-trust-in-covid-19-vaccination-the-role-of-governments-eae0ec5a/ (Accessed on 3 March 2022).
[27]Department of Health and Social Care (2021) *UK COVID-19 Vaccines Delivery Plan*. Available at https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/951928/uk-covid-19-vaccines-delivery-plan-final.pdf (Accessed on 3 March 2022).
[28]*Ibid* at para 2.1
[29]UK Health and Security Agency, *The roles of the MHRA and JCVI in COVID-19 vaccines* (2December 2020)Available at https://ukhsa.blog.gov.uk/2020/12/02/the-roles-of-the-mhra-and-jcvi-in-covid-19-vaccines/ (Accessed on 4 March 2022).

giving advice to the rollout of vaccines. Unlike India the UK Government had a fixed set of rules and regulations, the legislature, executive and judiciary all worked hand in hand to fight of this pandemic. The existence of Corona act 2020 clarifies the point that legislature was duly made a part when different sets of rules, polices and committees were made. It can be concluded from the framework of UK that legislature only gave non-essential functions to executive, exactly what *In Re Delhi act case* indented to achieve. It is important to note that legislature does not want to be part of policies which includes technical knowledge. The purpose of legislature is to make laws that are in public interest and then executives while executing can get in experts from different fields.

CONCLUSION

The entire paper discussed various aspects of vaccination policy of India. The timeline of various guidelines show that the central government was committed in approving and distribution of vaccine in timely manner. There is doubt in the intention of government. However, in a parliamentary system where the role of legislature is clearly defined. If executive takeover the rule making power, then the purpose of the entire parliamentary system is defeated. In the case of covid policy as discussed above, the Central government had a free hand in making laws and the legislature was merely informed. As proven above there was way too much of excessive delegation and that should be seen as a threat for the coming years as well. The courts through there judgments have tried in giving clarity with regards to delegated legislation and excessive delegation. It is the duty of the executive to perform activities in its powers and legislature should repeal laws which they feel was made without taken them into consideration. This might make the administrative system more transparent and accountable at the same time.