

Insights and Commentary from Dentons

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April 2023



MISSING on your WEEKLY DOSE?

Healthcare, Pharma & Life Sciences

Weekly Insights & Updates

21 November 2022

Media reports claiming regulatory approval for COVAXIN was rushed due to political pressure are misleading and fallacious

Media reports have claimed that Bharat Biotech, manufacturer of the indigenous COVID-19 vaccine – COVAXIN, “had to skip certain processes” and “speed up” clinical trials due to political pressure. The reports further claimed that there were several irregularities in the three phases of the clinical trials conducted for the vaccine. These media reports are completely misleading, fallacious, and ill-informed. It is clarified that the Government of India and the national regulator i.e., Central Drugs Standard Control Organization (CDSCO) have followed a scientific approach and prescribed norms in approving COVID-19 vaccines for emergency use authorization. The Subject Expert Committee (SEC) of CDSCO met on 1st and 2nd January 2021. After due deliberations recommendations were made in respect of the Restricted Emergency Approval of the COVID-19 vaccine of M/s Bharat Biotech. Before COVAXIN was approved for restricted emergency use in January 2021, the SEC reviewed the data on safety and immunogenicity of the vaccine and recommended the vaccine for restricted use in emergency in the public interest as an abundant precaution. The approval was given for use in clinical trial mode to have more options for vaccinations, especially in case of infection by mutant strains. The SEC’s approval for the phase 3 clinical trial of the proposed dose of COVAXIN was based on scientific data presented by M/s Bharat Biotech and established practices in this regard. Moreover, the purported “unscientific changes” in clinical trials of COVAXIN, as claimed in the news reports, were made after submissions were made by M/s Bharat Biotech in CDSCO in compliance with the due process and with approval from the DGCI.

[Link to press release](#)

5th Naturopathy Day celebrated across the nation as a future-oriented healthcare system

“Nature is the form of God, we should understand the power, potential, and wealth present in it but sometimes we do not give importance to these things and get surrounded by troubles. If we take care of nature, it will take care of us.” - stated Union Minister of AYUSH Shri Sarbananda Sonowal on 5th Naturopathy Day as he attended an event organized by International Naturopathy Organization (INO), Surya Foundation with the support of Ministry of AYUSH in New Delhi. The video message of Lok Sabha speaker, Shri Om Birla was also played before the gathering.

[Link to press release](#)

India wins Excellence in Leadership in Family Planning (EXCELL) Awards-2022 at International Conference on Family Planning

In a significant development and recognition of the country's efforts in improving access to Modern Family Planning methods, India is the only country to have received the Leadership Awards-2022 in Family Planning (EXCELL) in the 'country category' at the International Conference on Family Planning held in Pattaya city, Thailand.

[Link to press release](#)

Please feel free to reach out to the following members of our Healthcare team for any questions:

Nusrat Hassan, Managing Partner
Pradnesh Warke, Associate Partner

nusrat@linklegal.in
pradnesh.warke@linklegal.in

[View Profile](#)
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FIRM'S RECOGNITION



OUR OFFICES

DELHI

Aiwan-e-Ghalib Complex,
Mata Sundri Lane,
New Delhi – 110 002, India
Tel: +91 11 4651 1000

MUMBAI

21/22, Second Floor,
Free Press House,
Free Press Journal Road,
215, Nariman Point,
Mumbai – 400 021, India
Tel: +91 22 6633 6791 / 6625 2222

BENGALURU

#10, First Floor, 12th Main,
Palace Road,
Vasanth Nagar,
Bengaluru – 560 052, India
Tel: +91 80 4123 1072

HYDERABAD

1st Floor, MC Design House,
Plot No. 27, Rohini Layout,
HITEC City, Madhapur,
Hyderabad – 500 081, India
Tel: +91 40 3516 8987 / 3516 8988

CHENNAI

1B, First Floor 17-A,
Diamond Business Center,
Kalakshetra Road,
Chennai – 600 041, India
Tel: +91 44 4271 9731

NEW YORK

57 West, 57th Street,
4th Floor, New York,
NY – 10019
Tel: (212) 389-6281 / 381-1057



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