

Technology Law Analysis

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WHAT DOES LIBERALISATION OF DRONE LAWS MEAN FOR THE PHARMACEUTICAL INDUSTRY?

Over the past few years, drones have come to be used in various industries and for varied purposes including for agri-tech, logistics and last-mile delivery, surveying operations and even disaster response. Specifically in India, the increasing popularity of drones is reflected in the growth rate estimates of the Ministry of Civil Aviation ("MCA") which anticipates India's drone sector to achieve a total turnover of INR 120-150 billion (USD 1.63-2.04 billion) by 2026.¹ The Finance Minister of India's Budget speech of 2022 has also recognised the growing role of drones and seeks to facilitate drone start-ups to enable application of drones as a service in various sectors in the forthcoming years.²

When it comes to the pharmaceutical sector, drones as a service are already becoming fairly common, with a wide variety of use cases. These developments have been largely enabled by the Government's overhaul of the civil drone regime in India through the Drone Rules, 2021 ("New Rules") which were notified on August 25, 2021.³ The New Rules have liberalised the drone sector, incentivising their application in various industries. The Government has simplified the drone registration and certification process, removed express restrictions on foreign owned entities undertaking drone operations in India, enabled carriage of payload, among other measures (our detailed analysis for the New Rules can be accessed [here](#)). Further, a recent notification by the Director General of Civil Aviation ("DGCA") has also removed the requirement of a drone pilot license from the licensing regime.⁴ A pilot certificate issued by the DGCA approved institution would suffice for operating drones.

USE CASES OF DRONES IN THE PHARMACEUTICAL / LIFE SCIENCES INDUSTRY

During the pandemic, the use of drones for last mile delivery has gained immense popularity to address the necessity of accessing healthcare, even more so in remote places. Drones have expedited access not only to drugs and vaccines but also to blood and medical technology. Drones are also being utilised to monitor diseases, tracking their spread and preparing for treatment and prevention. An example of such a study is the tracking of and predicting the transmission of a tropical disease caused by parasitic worms i.e. schistosomiasis.⁵ In a recent feat achieved by a healthcare marketplace Retailio, medicine delivery across 10km distance was completed by the drones while maintaining the cold chain and other necessities.⁶

The various use cases and potential applications of drones in the pharmaceutical industry should create a robust demand on the Indian drone manufacturing industry. Certain legal challenges have also surfaced, given the lacuna in law in catering to certain potential applications as discussed below.

CHALLENGES FACED BY THE INDUSTRY

i. Beyond Visual Line of Sight Operations ("BVLOS")

BVLOS operations could be required in remote diagnosis of patients by use of drones equipped with specialised cameras. Similarly, the use of drones for medicine deliveries,⁷ vaccine deliveries,⁸ controlling vector borne diseases,⁹ etc. would all require drones to be operated in BVLOS ranges. While the New Rules have liberalised the use of drones, they do not expressly provide regulatory guidance for BVLOS operations which are critical for most use cases of drones in the pharmaceutical sector. Presently, BVLOS operations appear to be undertaken only upon receiving approval on a case-to-case basis from the relevant authorities, based on voluntary Standard Operating Procedures (SOP) prepared by the participants.

However, the lack of uniform guidelines could create impediments especially when pharmaceutical businesses are evaluating partnering with drone service providers. Thus, to provide regulatory certainty, it is hoped that the Government provides SOPs in this regard.

ii. Autonomous drone operations

Pharmaceutical deliveries by drones may be undertaken through autonomous means to enable deliveries to remote places. Autonomous deliveries are likely to reduce costs, as well as response and delivery time for pharmaceutical products. However, similar to BVLOS operations, detailed provisions pertaining to autonomous drones are absent from the New Rules. Since autonomous drones do not involve a pilot, it is unclear if any license/certificate is required for autonomous drone operations. This is somewhat of a paradox given that autonomous drones are generally perceived to involve higher risks as compared to remotely operated drones, and the latter require remote pilot certificates for operations.¹⁰

iii. Carriage of payload

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Any kind of delivery operations through drones would entail the carriage of goods/payload. However, the New Rules do not contain guidelines on such operations either, except for restricting certain dangerous goods from being carried on the drones.¹¹ In the absence of guidelines, there is limited clarity on the kind of goods that can be carried, and whether such carriage can be in the BVLOS ranges.

On the positive side, given the lack of specific language in the New Rules, the Government appears to have enabled carriage of goods (unless specifically prohibited). This further incentivises pharmaceutical companies to undertake deliveries of goods by use of drones. Based on the comments of the Minister of Civil Aviation stating that drone taxis may soon become a reality under the New Rules, drone ambulances could similarly be yet another use case for the pharmaceutical industry.¹² However, creating regulatory certainty from an operational perspective would be a welcome and necessary move

iv. Safety Concerns

While the New Rules are encouraging for various players to explore drones in the pharmaceutical sector, there does appear to be a general lack of framework regarding the operation of drones from a safety and security perspective especially for BVLOS operations. In the absence of uniform SoPs, there continues to be a lack of clarity as to what would be the base standards from safety/ security- perspective. SoPs would guide drone manufacturers to inbuild certain safety/security by design features to ensure preparedness of the industry for undertaking such operations.

CONCLUSION

Drones have tremendous potential for application in the pharmaceutical industry while being utilised for emergency response to delivery drug, vaccines and even organs to remote places. The application of drones coupled with the liberalised drone laws, could enable greater access to medical and healthcare needs of the citizens. BVLOS operations could form an integral part of the healthcare/pharmaceutical industry but it is recommended that base SOPs/guidelines are issued to lay down the operating framework of BVLOS operations. By doing so, the industry would have regulatory certainty which will in turn help stakeholders in planning their operations and relationships with other stakeholders in both the drones and pharmaceutical sectors. Such SOPs / guidelines would also ensure preparedness of the drone manufacturing industry in catering to the robust demand created in various sectors in a timely manner.

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You can direct your queries or comments to the authors

¹ Indian Drone Industry Reaching the Skies, available at: <https://www.ibef.org/blogs/indian-drone-industry-reaching-the-skies> (Last accessed on February 16, 2022).

² Budget 2022-23, available at https://www.indiabudget.gov.in/doc/Budget_Speech.pdf (Last accessed on February 16, 2022)

³ Available at <https://egazette.nic.in/WriteReadData/2021/229221.pdf> (Last accessed on February 14, 2022).

⁴ Available at: <https://egazette.nic.in/WriteReadData/2022/233331.pdf> (Last accessed on February 16, 2022).

⁵ Available at: <https://www.pnas.org/content/116/46/23182> (Last accessed on February 14, 2022).

⁶ Retailo launches drone delivery for medicine across India, available at: <https://www.pymnts.com/healthcare/2022/retailo-launches-drone-delivery-for-medicine-across-india/> (Last accessed on February 16, 2022).

⁷ Available at: <https://www.pymnts.com/healthcare/2022/retailo-launches-drone-delivery-for-medicine-across-india/> (Last accessed on February 15, 2022).

⁸ ICMR's drone based vaccine delivery model launched, available at: <https://www.thehindu.com/news/national/icmr-drone-based-vaccine-delivery-model-launched/article36821258.ece> (Last accessed on February 15, 2022).

⁹ Mumbai BMC uses drone to control vector-borne diseases as cases surge, available at: <https://www.india.com/maharashtra/mumbai-bmc-uses-drone-to-control-vector-borne-diseases-as-cases-surge-4938864/> (Last accessed on February 15, 2022).

¹⁰ Drone (Amendment) Rules, 2022, available at: <https://egazette.nic.in/WriteReadData/2022/233331.pdf> (Last accessed on February 16, 2022)

¹¹ Rule 27 of the New Rules provides that *"No person shall carry or cause or permit to be carried in any unmanned aircraft to, from within or over India, any arms, ammunitions, munitions of war, implements of war, explosives and military stores, except with the written permission of the Central Government or any other person authorised by the Central Government in this behalf and subject to the terms and conditions of such permission."* Further, Rule 28 of the New Rules prohibits the carriage of dangerous goods on unmanned aircraft unless such operation is in compliance with the Aircraft (Carriage of Dangerous Goods) Rules, 2003.

¹² Available at: <https://www.livemint.com/news/india/taxis-in-the-air-to-be-a-reality-soon-under-new-drone-policy-aviation-minister-11629974892279.html> (Last accessed on August 28, 2021).

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