

New Delhi, 18<sup>th</sup> May 2023

To,  
Dr. Rajeev Singh Raghuvanshi  
Drugs Controller General of India, CDSCO  
Ministry of Health and Family Welfare, DGHS, GoI  
FDA Bhavan, ITO, Kotla Road, New Delhi -110002

**Subject: 'Monitoring & Mentoring Model for Post-market Surveillance' of Digital Health Products & Services**

Dear Dr. Rajeev ji,  
Namaste

India's digital health market has shown remarkable growth, with an estimated valuation of INR 524.97 Bn in 2021, projected to reach INR 2,528.69 Bn by 2027. With start-ups foraying into Digital Domain, and the advent of artificial intelligence, and the fast-emerging field of digital therapeutics, the pharmaceutical industry has also increased its research and development to introduce innovative digital health products. The Central Drugs Standard Control Organization (CDSCO), as the pharmaceutical industry regulator, has taken commendable steps to facilitate growth and research in this sector.

However, the digital health market currently faces challenges due to the absence of a comprehensive regulatory framework. This ambiguity has created grey areas that impede the potential growth of digital health products in international markets or cause unintended harm and, in extreme cases, could be fatal. To ensure the sustainable development of this sector and to avoid potential unintended harm, it is crucial to address these uncertainties promptly.

Among these challenges, the most critical and urgent issue is the absence of a post-market surveillance mechanism for digital health products. Currently, there is no reporting mechanism or registry where consumers can file complaints in case of adverse events related to these products. This lack of an effective surveillance mechanism not only hampers consumer confidence but also poses potential risks to public health and safety.

As a leading think-tank in the healthcare sector, Health Parliament and our partner organization, International Patients' Union, propose to the CDSCO the establishment of a robust post-surveillance mechanism for digital health products and services. Such a mechanism would serve multiple purposes. Firstly, it would empower consumers to make informed choices by providing them with a platform to report adverse events and share their experiences, which we intend to do through the International Patients' Union.

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Secondly, it would furnish real-time data to policymakers and regulators, enabling them to address emerging issues promptly and make data-driven decisions.

We believe that the CDSCO, with its expertise and dedication to public health, is well-positioned to drive this crucial initiative. We believe that we can create a unique 'Monitoring & Mentoring Model for Post-market surveillance' of Digital Health Products & Services jointly between Health Parliament & CDSCO to ensure 'Regulation & Innovation' thrive in the digital Health Ecosystem, supporting the entrepreneurs in their journey.

We look forward to witnessing the CDSCO's proactive steps, and at Health Parliament, we remain at your disposal to co-lead this initiative, given our competence and global partnerships in the digital health domain.

With best regards

**Dr. Rajendra Pratap Gupta**  
**Founder**  
**Health Parliament**  
**International Patients' Union**

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