



# *e-Newsletter*

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# **Materiovigilance Programme of India**

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Indian Pharmacopoeia Commission

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# Training & Education



National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) conducted a training programme on "Overview of Materiovigilance Programme of India" at Fortis Hospital, Okhla, New Delhi on October 13, 2022. Ms. Nikita Mishra, Materiovigilance Associate & Mr. Rohit Sharma, Junior Materiovigilance Associate sensitized the healthcare professionals of Fortis Hospital on Materiovigilance programme and

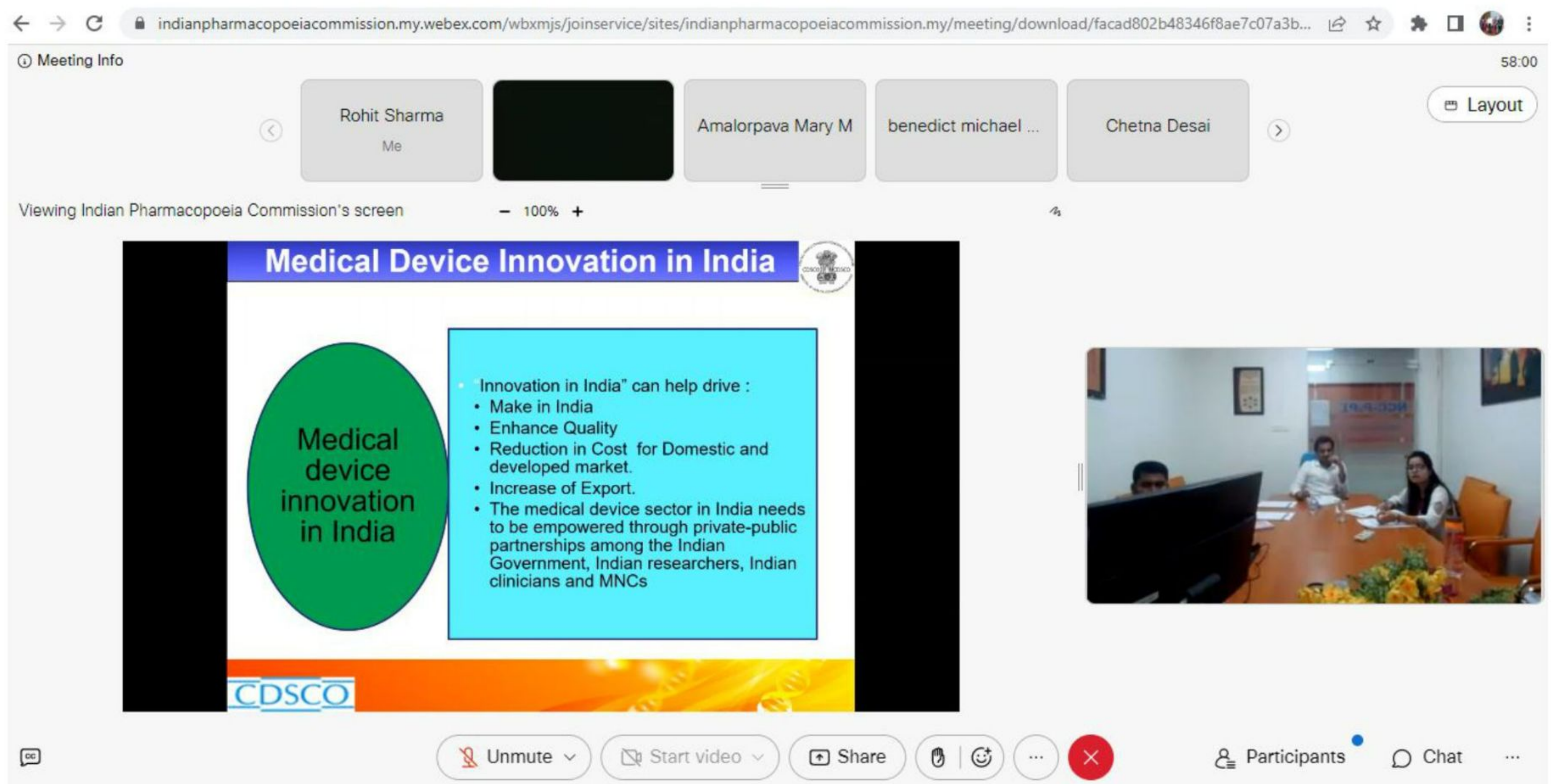
tools for reporting medical device adverse event. In total, 40 healthcare professionals attended this training programme. Overall, this was an interactive training programme that welcomed many questions and queries from the participants. MvPI associates resolved all the queries raised by participants and made them understand about the need of materiovigilance programme in India.



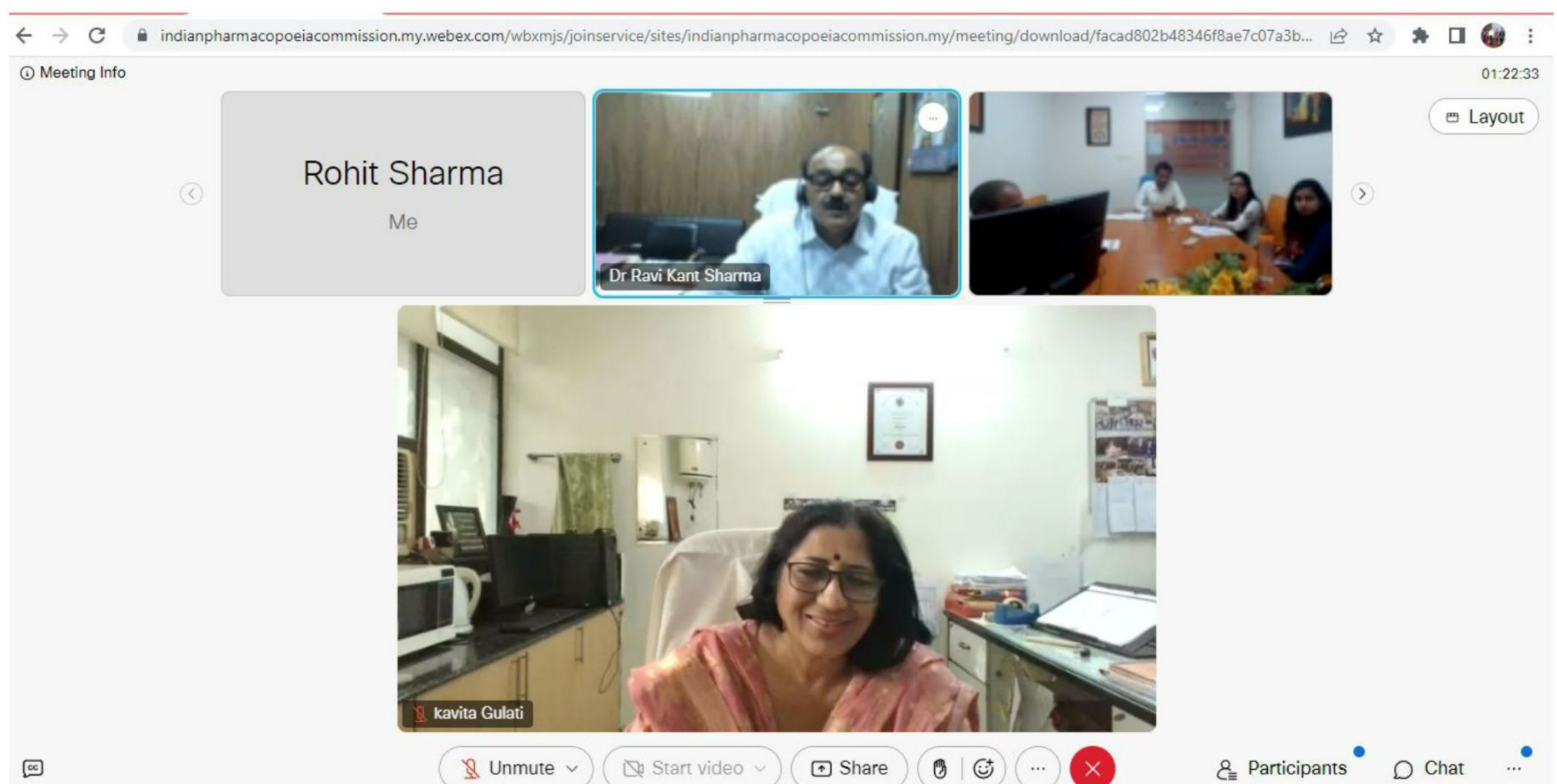


National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) conducted a national conference on "Strengthening of Medical Products Safety surveillance System in North Eastern States of India" on October 19, 2022 at Government Pharmacy College, Sajong, Sikkim. In this conference, Dr. Rajeev Singh Raghuvanshi, Secretary-cum-Scientific, Director presented the special remarks followed by the sessions given by eminent speakers. Speakers from Central Drugs Standard Control Organization, New Delhi, Andhra Pradesh MedTech Zone, Andhra Pradesh, Bureau of Indian Standard, New Delhi, Sree Chitra Tirunal Institute of Medical Sciences, Thiruvananthapuram & Indian Pharmacopoeia Commission participated in this conference and enhanced the knowledge of participants. Conference sessions were interactive due to the queries raised by the participants. Eminent speakers of this conference resolved their queries and enhanced their knowledge. More than 100 participants participated in this conference and enhanced their knowledge on medical device & in-vitro diagnostics safety surveillance.





National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) conducted an induction-cum-training programme for newly identified coordinators on November 9-10, 2022 via digital platform. NCC-MvPI, IPC has recognized 119 new Medical Device Adverse Event Monitoring Centres (MDMCs) pan India. For the seamless functioning of materiovigilance programme at the newly identified centres, NCC-MvPI organized an Induction-cum-training programme for newly identified coordinators, deputy coordinators and materiovigilance associates. The Induction-cum-training programme organized to develop the basic understanding of newly identified coordinators, deputy coordinators, Materiovigilance associates on Medical Device Rules, Materiovigilance Programme, Available tools for Reporting, Post-marketing surveillance and baseline Study of medical devices.







National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI) in association with Ruby Hall Clinic, Pune conducted a national conference on "Strengthening medical product safety surveillance" at Sheraton Grand Hotel, Pune on November 12, 2022. In total, 150 participants including healthcare professionals, medical device industry and students attended the national conference. Mr. Om Prakash Sadhwani, Mr. Pramod Kumar, Dr. Parvesh Mehra, Mr. Manish Soni, Ms. Nikita Mishra were the speakers for the conference. All the sessions

of the conference were interactive that raised many queries from the participants and the speakers resolved all the queries asked by the participants. Conference sessions followed by the panel discussion, eminent speakers Mr. Om Prakash Sadhwani, Mr. Pramod Kumar and Ms. Nikita Mishra were the panellist and answered all the questions asked in the panel discussion.





# *MvPI participation in Indian Pharma Expo*

- IPC Team had set up a stall in Indian Pharma Expo from September 30 to October 01, 2022 at Pragati Maidan, New Delhi to showcase the resource material of IPC. Mr. Rohit Sharma, MvPI representative also took part in the event and made aware the visitors about Materiovigilance programme.
- An event on Global Digital Health Summit: Expo & Innovation Awards organized by Global Digital Health Summit on October 28 & 29, 2022 at Vigyan Bhawan, New Delhi with a theme on "Digital Health for All". Mr. Rohit Sharma, MvPI representative attended the conference and enhanced the knowledge on connectivity of healthcare services at digital platform such as Telemedicine, Ayushman Bharat Digital Mission, Google Health, e-sanjeevani application.



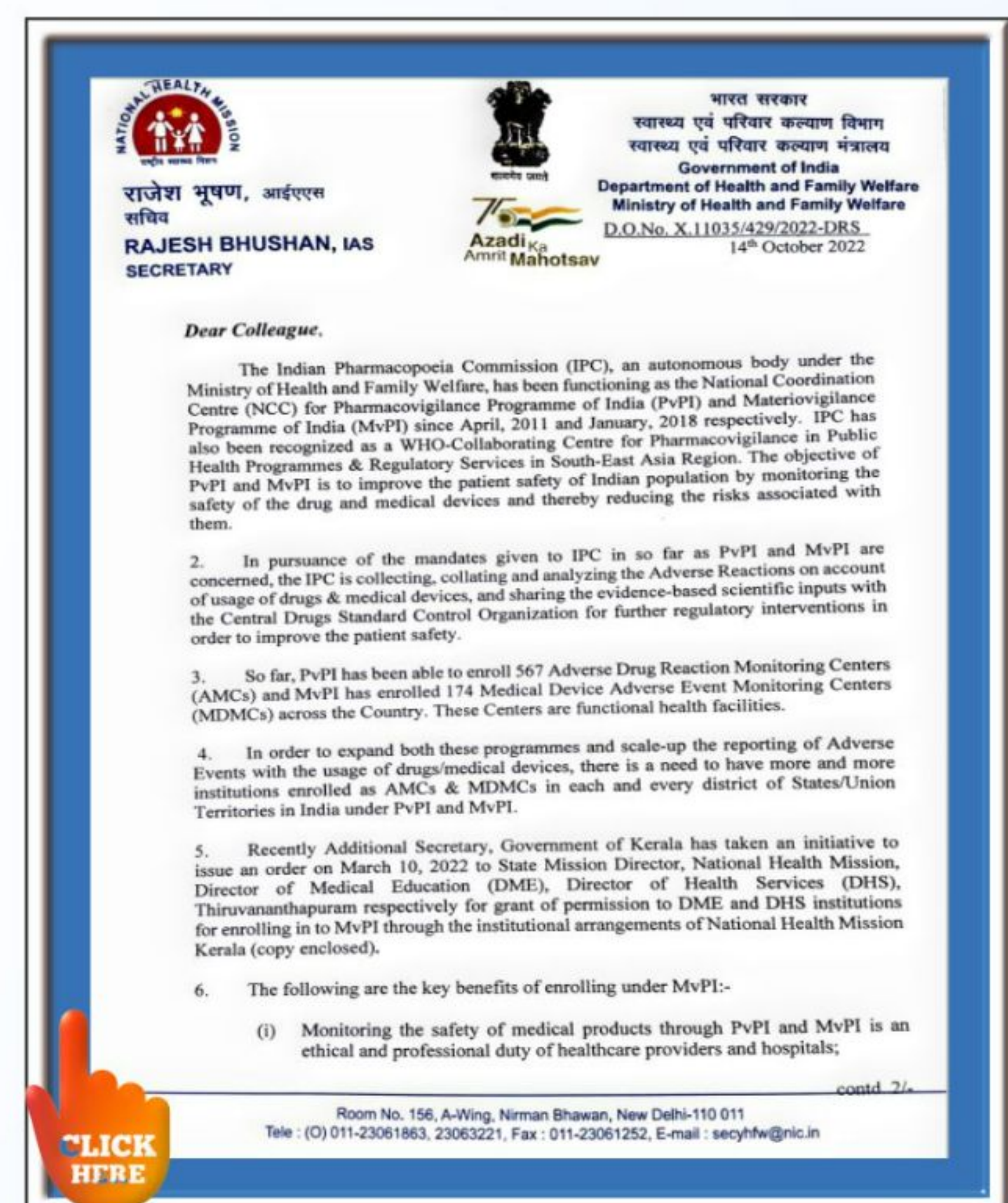




***Government of Puducherry has issued an order to medical superintendents and head of the institutions/hospitals to enroll and report medical device adverse events to Materiovigilance programme of India.***

**Government of India**  
**Department of Health & Family Welfare**  
**Ministry of Health and Family Welfare**

*Secretary, Ministry of Health and Family welfare,  
Government of India has issued a letter to  
State Secretaries regarding the enrollment of  
district level hospitals/institutions under  
Materiovigilance programme of India.*



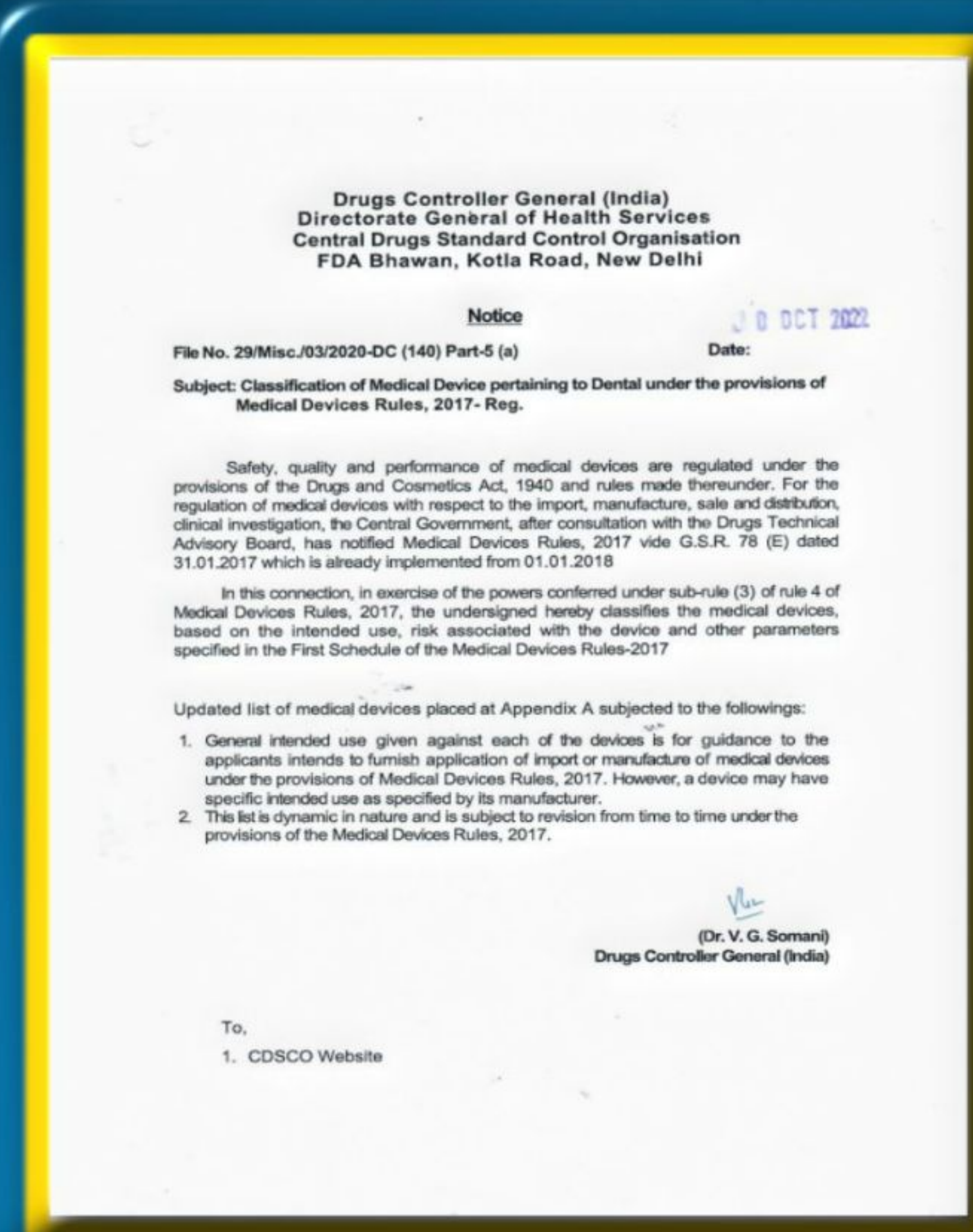
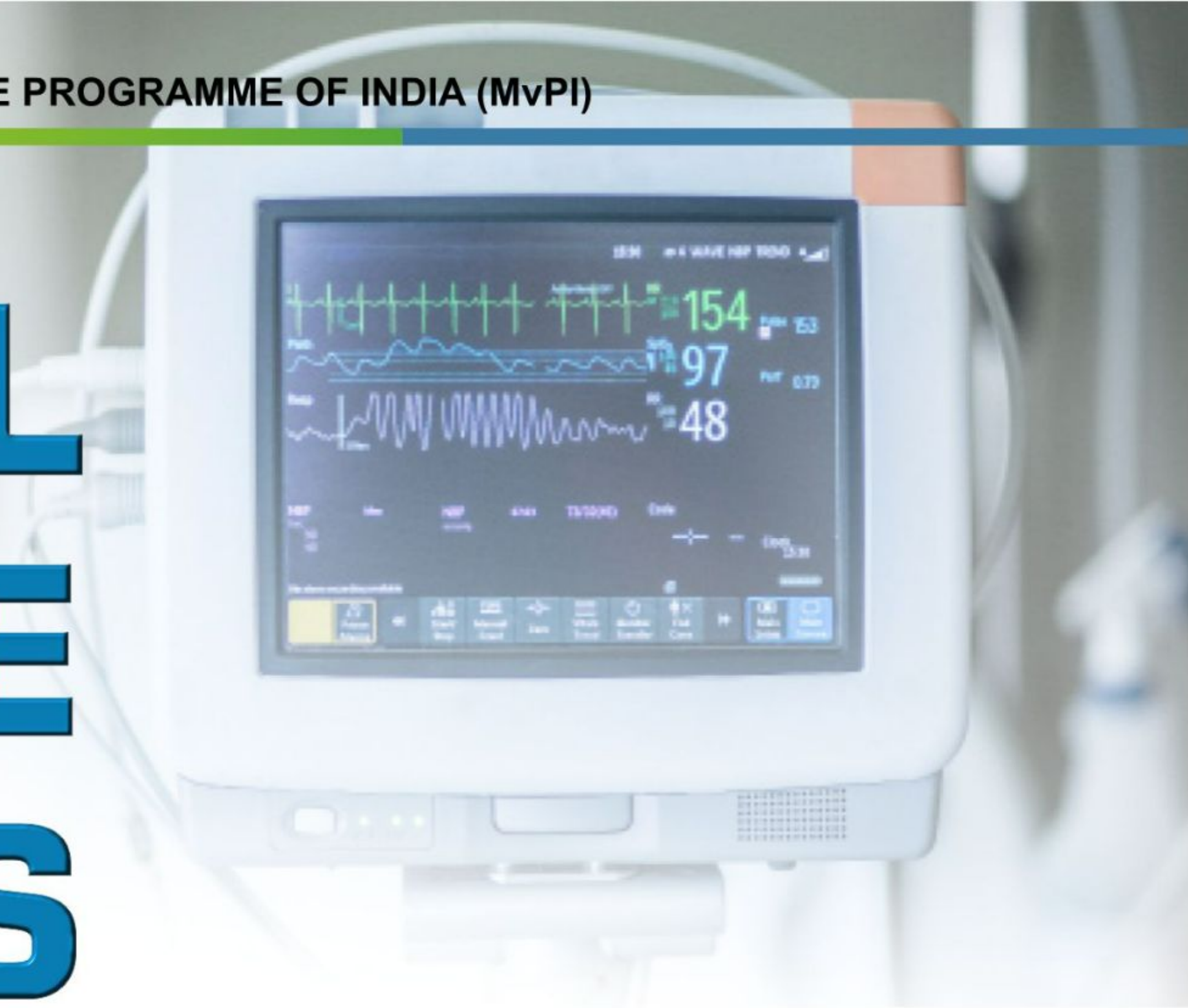
**National Health Systems Resource Centre**  
**Ministry of Health and Family Welfare**  
**Government of India**

***Executive Director, National Health System & Resource System, New Delhi has issued a letter to all MDs National Health Mission States/ Union Territories to enroll & report under Materiovigilance programme.***



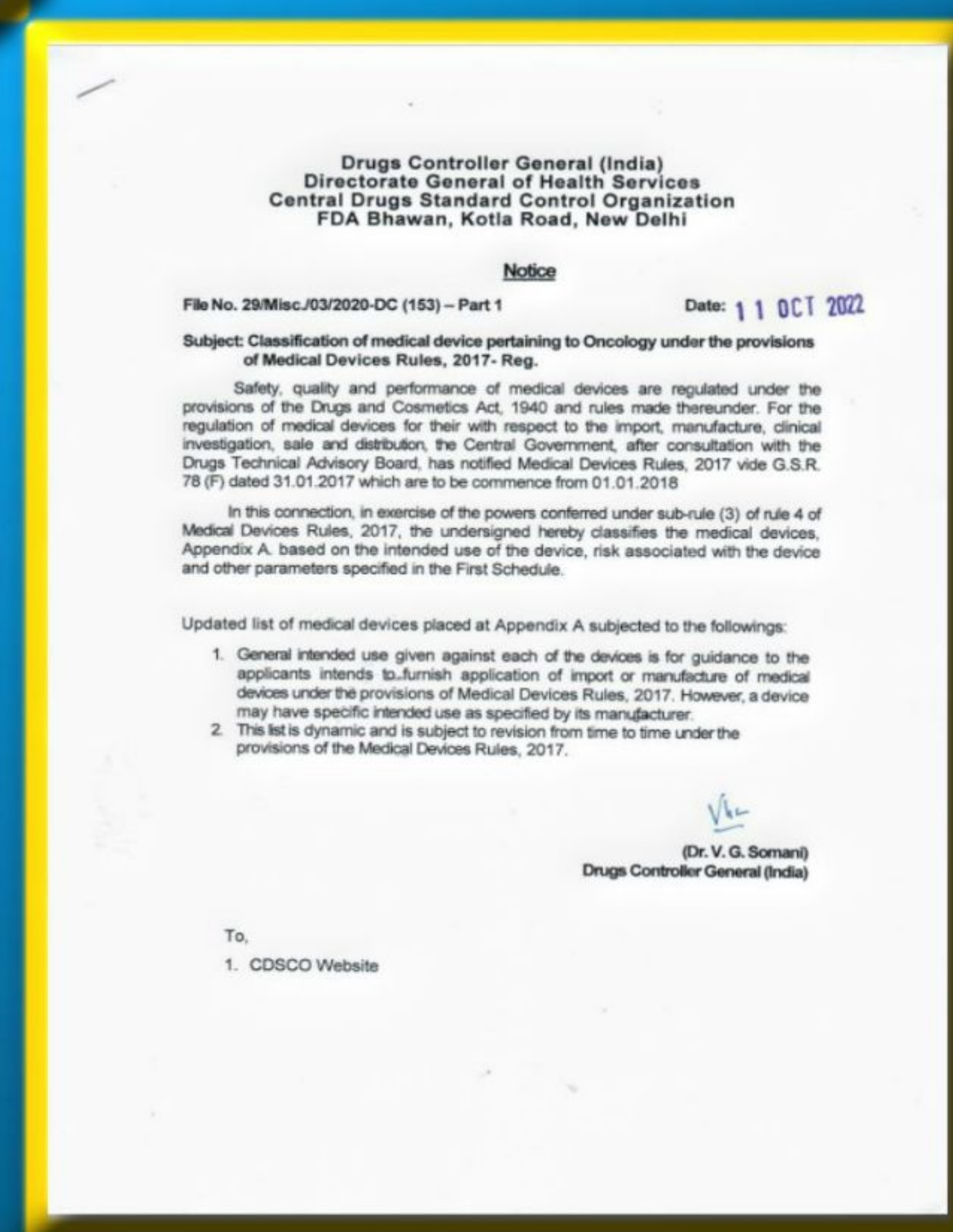


# MEDICAL DEVICE UPDATES



**Classification of  
medical devices  
pertaining to Dental  
under the provisions of  
Medical Device  
Rules, 2017.**

**Classification of  
medical devices  
pertaining to Oncology  
under the provisions of  
Medical Device  
Rules, 2017.**





## *Recommendation to Central Drugs Standard Organization (CDSCO)*

- National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI), IPC has sent recommendation to CDSCO about loss of capture, high capture threshold & lead dislodgement Issue associated with Pacing lead for their information & necessary action at their end.
- National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI), IPC has sent recommendation to CDSCO about Malfunctioning of Incubator associated with Infant Incubator for their information & necessary action at their end.
- National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI), IPC has sent recommendation to CDSCO about Non-functioning of cord clamps associated with Umbilical cord clamp for their information & necessary action at their end.
- National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI), IPC has sent recommendation to CDSCO about Balloon Deflation Issue associated with Coronary Stent System for their information & necessary action at their end.
- National Coordination Centre - Materiovigilance Programme of India (NCC-MvPI), IPC has sent recommendation to CDSCO about Plate Breakage associated with Mandibular Reconstruction (Plate) for their information & necessary action at their end.





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*We have started a journey of Materiovigilance, for saving patient's lives*