



National Human Rights Commission

Minutes of the Open House Discussion on Measures to Curb Spurious Medicines in India

The National Human Rights Commission (NHRC), India, convened an Open House Discussion on **Measures to Curb Spurious Medicines in India** on February 25, 2026, at Manav Adhikar Bhavan, New Delhi. The meeting was chaired by Dr. Justice Bidyut Ranjan Sarangi, Hon'ble Member, NHRC, and attended by Smt. Vijaya Bharathi Sayani, Hon'ble Member, NHRC; Shri Rajiv Jain, Former Member, NHRC; Shri Bharat Lal, Secretary General; Smt. Anupama Nilekar Chandra, Director General (Investigation); Shri Joginder Singh, Registrar (Law); Joint Secretaries Shri Samir Kumar and Smt. Saidingpuii Chhakchhuak, along with other officials of the Commission.

2. A distinguished gathering comprising representatives from regulatory authorities, law enforcement agencies, the pharmaceutical industry, and subject-matter experts participated in the discussion. The Open House Discussion was organized in hybrid mode, and the list of participants is **annexed**.



3. At the outset, **Shri Samir Kumar, Joint Secretary, NHRC**, welcomed all participants to the Open House Discussion and underscored the urgent need to address the growing menace of spurious and substandard medicines in the country. He referred to a recent enforcement action carried out on 23rd February near Patna, where authorities raided a fake drug manufacturing unit and seized large quantities of counterfeit medicines and packaging materials, thereby exposing the organised and systematic nature of such illegal operations.



4. In this context, he outlined the four key focus areas of the Open House Discussion; i.) reviewing the existing legal and regulatory framework; ii.) examining the public health risks and consequences of spurious and substandard medicines; iii.) exploring how technology can be leveraged to enhance transparency and traceability in regulatory processes; and iv.) identifying best practices to strengthen oversight mechanisms and emphasized that the deliberations would be outcome-oriented to generate concrete and actionable recommendations.

5. In his opening remarks, **Shri Bharat Lal, Secretary General, NHRC**, welcomed the participants and set the tone for deliberations by underscoring that although the discussion is focused on spurious drugs but both spurious and substandard medicines adversely impact the right to life and health, calling for coordinated institutional action to combat the menace. Emphasizing that citizens consume medicines in good faith, trusting the state's obligation to safeguard life and dignity, he cautioned that any breach may result in violation of human rights of the victims. Stressing that 'medicines must heal, not harm,' he also highlighted the clear distinction between 'spurious drugs' in different manifestations defined under Section 17-B of the Drugs and Cosmetics Act, 1940 and 'substandard drugs' which refer to authorized products that fail to meet quality standards or specifications. Citing the National Survey on Drugs, he noted that about 10% of government samples were found to be substandard.

6. Shri Lal further pointed out that spurious drugs are produced and distributed as part of criminal activity with no clearly identifiable manufacturer, which requires criminal investigation, whereas manufacturers of substandard drugs can be traced. He said that the NHRC has been very proactively taking *suo motu* cognizance of such reported incidents of rights violation due to alleged consumption of spurious medicines. In this context, he referred to one of the recent notices sent in October 2025 to the Governments of Madhya Pradesh, Rajasthan and Uttar Pradesh and to Union health and regulatory authorities following media reports of children allegedly succumbing after consuming contaminated cough syrups. The Commission directed a comprehensive supply-chain investigation and

mandated state laboratories to submit sample test reports, underscoring the urgency of coordinated regulatory action.



7. He further stated that the circulation of counterfeit medicines remains a serious reality and poses a direct threat to public health and safety. He emphasized that the most affected victims are often children and economically vulnerable sections of society who depend heavily on public healthcare systems and affordable medicines.



8. **Justice (Dr.) Bidyut Ranjan Sarangi, Hon'ble Member, NHRC** and chair of the Open House Discussion, framed the issue within the constitutional guarantee of the Right to Life under Article 21. He observed that the right to health is inherent in the right to life and dignity, and therefore, the circulation of spurious medicines constitutes a direct infringement of fundamental human rights. He acknowledged that legislative frameworks such as the Drugs and Cosmetics Act, 1940, provide regulatory mechanisms to ensure drug safety and quality; however, he questioned whether enforcement and implementation are sufficiently robust to effectively curb the menace. He noted that despite various beneficial government schemes and the expansion of healthcare access across the country, persistent

gaps in monitoring, compliance, and enforcement continue to undermine the intended outcomes of these initiatives.

9. Smt. Vijaya Bharathi Sayani, Hon'ble Member, NHRC, reflected on the human cost of substandard treatment. She recalled how a member of her family suffered permanent loss of eyesight due to improper treatment and the use of poor-quality medicines. She said that the issue needs to be urgently addressed by placing in place strengthened oversight and accountability mechanisms in the pharmaceutical ecosystem.

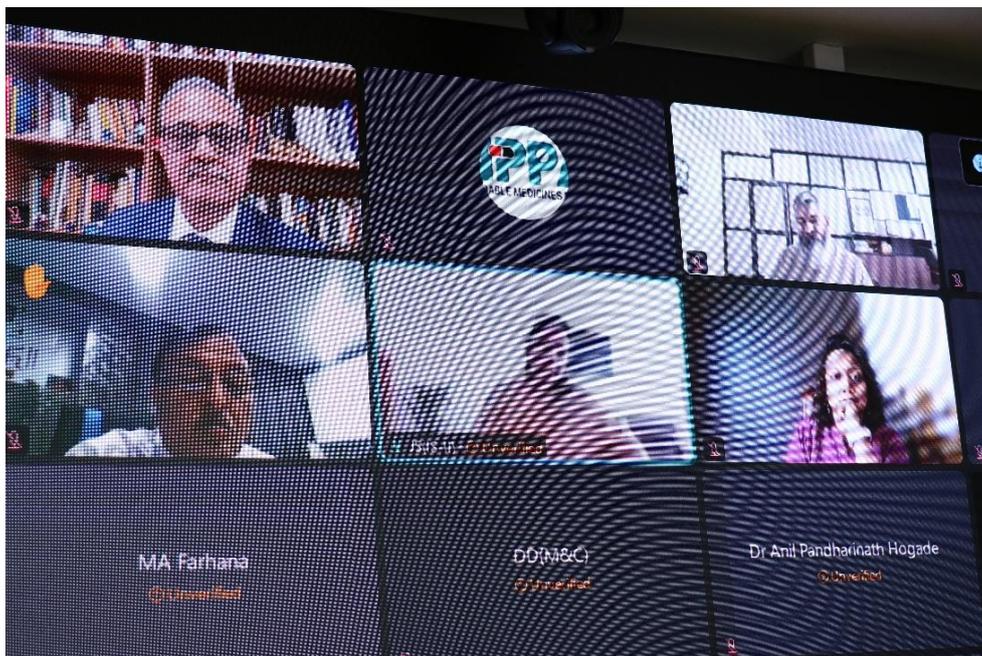
10. Shri Rajiv Jain, Former Member, NHRC, focused on legal, technological, and enforcement-related measures necessary to curb the menace of spurious medicines. He referred to relevant statutory provisions under the Drugs and Cosmetics Act, 1940 and the Bharatiya Nyaya Sanhita, 2023, particularly provisions relating to cheating, forgery, and enhanced penalties. He emphasized the need for time-bound adjudication of drug-related offences and suggested the establishment of special courts dedicated to such cases. He observed that while minimum punishments are prescribed under the existing law, effective enforcement remains inconsistent. He recommended the creation of a national databank of offenders and a centralised recall mechanism to ensure swift market withdrawal of identified spurious products.



11. He further suggested technological interventions such as mandatory QR codes for certain categories of drugs, blockchain-enabled supply chain tracking, integration with GST databases, consumer verification applications, AI-based anomaly detection in batch production, and real-time public disclosure of repeat offenders. He highlighted the importance of empowering consumers through awareness campaigns and verification systems and stressed the need for coordination among enforcement agencies including police, customs, GST authorities, and cybercrime units. He also advocated for whistleblower protection, surprise inspections, digital audit trails, and asset forfeiture mechanisms for repeat offenders, along with international cooperation to address cross-border dimensions of the problem.

12. **Ms. Nishtha Tiwari, Joint Secretary, Ministry of Home Affairs**, raised concerns regarding the misuse of prescription medicines and emphasized the need for a strong end-to-end mechanism to monitor the pharmaceutical supply chain and ensure accountability. She noted that the issue has come to the attention of the Ministry and that efforts are underway to address it.

13. In a comprehensive presentation, **Dr. Keshav Kumar, Special Rapporteur, NHRC**, emphasized the need for a robust, intelligence-driven monitoring and oversight framework to address the prevalence and distribution of counterfeit medicines. He recommended periodic assessments to evaluate the public health impact of such drugs, along with systematic audits of pharmaceutical supply chains to identify structural vulnerabilities. Strengthening supply chain analytics, enhancing security at important transit and storage points, and developing data-backed tracking mechanisms were highlighted as essential measures. He further proposed the establishment of coordinated central and state-level task forces comprising representatives from regulatory authorities, NHRC, industry, law enforcement, and forensic experts to ensure rapid response and localized intervention. He also underscored the importance of strengthening the regulatory framework through mandatory QR codes, barcodes, holographic authentication systems, and recruitment of drug inspectors across states, alongside enhanced legal scrutiny and human rights framing of the issue.

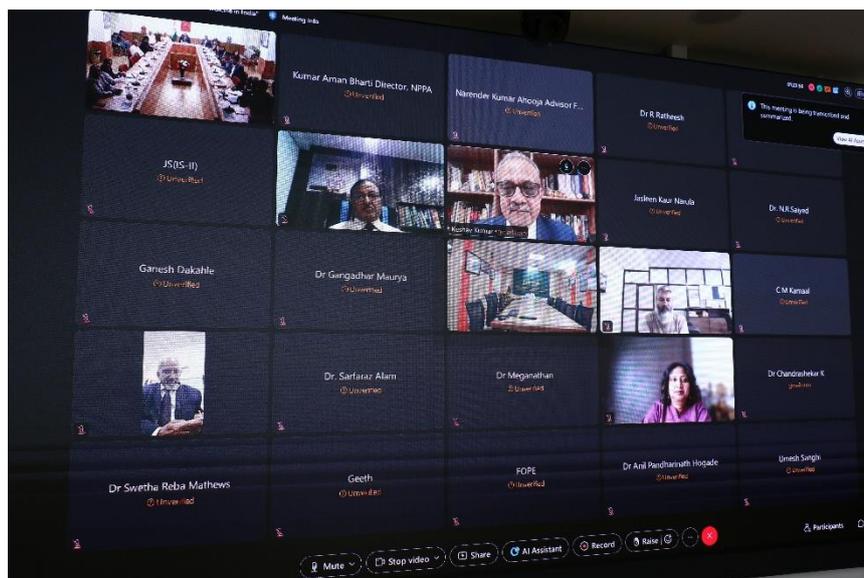


14. **Ms. Anupama James, National Investigation Agency (NIA)**, emphasised the need for coordinated efforts between local police authorities and Drug Control Administrations to effectively combat the menace of spurious medicines.

15. **Ms. Sai Ahlladini Panda, Member Secretary, National Pharmaceutical Pricing Authority (NPPA)**, stated that NPPA is responsible for fixing the prices of scheduled medicines and monitoring the pricing of non-scheduled medicines. She further highlighted the need for greater enforcement by the Central Drugs Standard Control Organization (DCGI)

and State Licensing Authorities. She emphasised the preventive aspect and suggested that NPPA can hold workshops with agencies undertaking such work in coordination with State Governments. She also underlined the need for more IEC activities, wherein NPPA can also be a part.

16. Shri Om Prakash Sadhwani, Joint Commissioner, Food and Drug Administration (FDA), highlighted that the primary responsibility for curbing the menace rests with the Central Drugs Standard Control Organization, State Drug Control Organizations, and manufacturers. While a support system exists, he emphasized the need for stronger coordination, particularly as most major cases are detected at the state level and states lack jurisdiction beyond their boundaries, highlighting the requirement for structural and interstate coordination mechanisms. He stressed the importance of a multipronged approach, including strengthening of DCAs, involvement of police in investigations, and enhanced coordination among enforcement agencies, manufacturers, civil society, and NGOs. He further underscored the need for capacity building through HRD initiatives, specialized training programs on investigation and technological aspects, and strengthening drug testing laboratories.



17. Dr. N. R. Saiyad, Deputy Commissioner, Food and Drug Control Administration (FDCA), Gujarat, focused on actionable measures to address the issue. He emphasized that a strong information network, including informal channels, is essential for detection, along with fast communication and prompt inter-district coordination to ensure successful outcomes. He highlighted the importance of tools and technology, including data verification systems to authenticate licenses and enable on-the-spot identification, and suggested the possible use of AI for improved detection and efficiency. He stressed the need for awareness and regular information exchange among distributors and manufacturers. He also outlined mechanisms for complaint handling, including a designated contact person, online grievance systems, and toll-free numbers.

18. Shri Prashant Reddy T., Lawyer and author of The Truth Pill, referred to media-reported cases and pointed out that incidents such as deaths due to contaminated

intravenous fluids in Karnataka and West Bengal do not fall within the legal definition of 'spurious drugs' but constitute law and order issues. He observed that, as per government statistics, the incidence of spurious drugs is not very significant, citing a 2017 nationwide survey by the National Institute of Biologicals, Noida, in which only 13 out of approximately 47,000 samples were classified as spurious. He stated that penalties for spurious drugs are stringent, thereby reducing incentives for counterfeiters.

19. Dr Bhoomika Patel, Dean, School of Pharmacy, National Forensic Sciences University (NFSU), emphasized the need for a comprehensive track-and-trace system focusing on two key aspects of protecting India's global pharmaceutical reputation and ensuring patient safety in the domestic market. She suggested the adoption of QR code/barcode-based tracking mechanisms, similar to delivery tracking models used in e-commerce platforms, to build an integrated ecosystem for authentication across the supply chain. She also stressed the need for punitive action against violations, revision of the export strategy, and engagement of start-up companies for developing and implementing appropriate technological solutions. She mentioned that India produces 20% of the world's generic medicines, serves 219 countries. Track and trace is a solution given even by IDMA.



20. Dr. P. K. Sharma, Professor and Head, Department of Pharmacology, SLB Medical College, highlighted several major concerns requiring urgent attention. He suggested using medical colleges in the whole process. The issue is of checking quality and medical colleges have department of pharmacology, labs it could be used well. He stated that the quality of medication remains a significant issue and emphasized the need to establish quality control laboratories and conduct routine checks, particularly in pharmacology colleges. He further noted the necessity of raising awareness among medical authorities, as many doctors remain unaware of these concerns, and stressed the importance of sensitizing medical students to issues relating to drug quality and safety.

21. Prof. (Dr.) Yogendra Kumar Gupta, President, AIIMS Kalyani, underscored the need to address the root causes of spurious medicines. He identified three broad categories: accidental production, which is unintentional; deliberate economic offences; and non-

compliance with Good Manufacturing Practices. He emphasized the importance of early vigilance and the establishment of risk-based surveillance mechanisms to create effective early warning systems. He also highlighted the need for close coordination between the Centre and the States, particularly in matters relating to licensing, and called for greater awareness among all stakeholders, including doctors and patients. He observed that while regulatory frameworks exist, implementation often falls short, and greater synergy between the Centre and the States is essential.

22. Shri Ankit Gupta, President, Authentication Solution Providers Association (ASPA), emphasised the importance of incorporating both overt and covert security features in medicines and advocated for a combination of physical and digital solutions. He referred to a report published by ASPA in collaboration with CRISIL in 2022 on the state of counterfeit medicines in India, which indicated that cases of counterfeit medicines increased by 20 per cent between 2018 and 2020, and that 25 per cent of consumers had purchased counterfeit pharmaceutical products at least once.



23. Shri Harish K. Jain, Federation of Pharma Entrepreneurs and Shri Narendra Ahojja (FOPE), stated that spurious medicines largely arise from the activities of unlicensed and anti-social elements and should be addressed as a law-and-order issue. He recommended appointing a nodal officer, not below the rank of Superintendent of Police, to coordinate with the Drugs Controller and highlighted regulatory gaps in identifying spurious drugs and regulating the online sale of prescription medicines. He also noted that licensed manufacturers are often victims of such activities and should be treated as witnesses rather than accused persons. They emphasized that packaging remains inadequately covered under existing drug regulations. He recommended bringing all forms of packaging under drug control laws, requiring printers to obtain appropriate licences, and penalizing non-compliant entities. He also suggested incorporating Good Distribution Practices into the regulatory framework and regulating e-pharmacy platforms.

24. Shri Chandrashekar Ranga, Joint Drugs Controller, Drugs Controller General of India (DCGI), highlighted several operational challenges faced by drug inspectors in addressing

cases of spurious medicines. He noted that while drug inspectors are empowered under Section 22 of the Drugs and Cosmetics Act, 1940, to conduct search and seizure operations, they do not possess summoning powers and are unable to independently pursue interstate networks. He further explained that investigations often stall due to non-cooperation from accused persons and the absence of enforcement powers comparable to those available to police authorities. In certain instances, following judicial observations, police agencies have been reluctant to register FIRs independently, creating practical difficulties in effecting arrests and securing custody. He also drew attention to infrastructural constraints, including the lack of vehicles, storage facilities for seized goods, inadequate laboratory capacity in several States, and the absence of dedicated task forces to investigate cases of spurious drugs.



25. In his concluding remarks, **Shri Bharat Lal, Secretary General, NHRC**, thanked the participants and requested written inputs for working out actionable recommendations. He underscored the need for categorizing actionable points based on whether they are within the mandate of the NHRC and/ or require coordination with other government agencies.

List of Participants

National Human Rights Commission, India

- i.) Dr. Justice Bidyut Ranjan Sarangi, Hon'ble Member, NHRC
- ii.) Smt. Vijaya Bharathi Sayani, Hon'ble Member
- iii.) Shri Rajiv Jain, Former Member, NHRC
- iv.) Shri Bharat Lal, Secretary General, NHRC
- v.) Smt. Anupama Nilekar Chandra, Director General (Investigation), NHRC
- vi.) Shri Joginder Singh, Registrar (Law), NHRC
- vii.) Shri Samir Kumar, Joint Secretary, NHRC
- viii.) Smt. Saidingpuii Chhakchhuak, Joint Secretary, NHRC
- ix.) Dr. (Ms.) Rajul Raikwar, Consultant (Research), NHRC
- x.) Ms. Kopal Khare, Junior Research Consultant, NHRC

Representatives from the Government and Other Organizations

- i.) Nishtha Tiwari, Joint Secretary, Ministry of Home Affairs
- ii.) Dr. Keshav Kumar, Special Rapporteur, NHRC
- iii.) Shri P. Krishnamurthy, Chairman, National Pharmaceutical Pricing Authority
- iv.) Ms. Sai Ahlladini Panda, Member Secretary, National Pharmaceutical Pricing Authority
- v.) Ms. Anupama James, AIG, National Investigation Agency
- vi.) Shri Chandrashekhar Ranga, Joint Drugs Controller, Drugs Controller General of India
- vii.) Shri Om Prakash Sadhwani, Joint Commissioner (Retd.), FDA
- viii.) Dr. N.R. Saiyad, Deputy Commissioner, Food and Drug Controller Administration (FDCA)
- ix.) Dr. Ilyas K.P.A., Deputy Director, Bureau of Police Research and Development (BPR&D)
- x.) Shri Shridhar Dube Patil, FDA Commissioner, Government of Maharashtra.
- xi.) Dr. Bhoomika Patel, Dean, School of Pharmacy, NFSU
- xii.) Dr. P.K. Sharma, Professor and Head, Department of Pharmacology, SLB Medical College
- xiii.) Prof (Dr.) Yogendra Kumar Gupta, President, AIIMS Kalyani
- xiv.) Dr. Jitha, Professor, Government Medical College, Kerala.
- xv.) Shri Ankit Gupta, President, ASPA
- xvi.) Shri Harish K. Jain, National President, Federation of Pharma Entrepreneurs (FOPE)
- xvii.) Shri Narendra Ahooja, Regulatory Advisor, FOPE
- xviii.) Shri Sandeep Sikaria, FOPE