Ministry of Health and Family Welfare

Union Health Secretary Chairs High-Level Meeting with States/UTs on Quality and Rational Use of Cough Syrups

Emphasizes strict compliance with the Revised Schedule M by all drug manufacturers; Thorough exercise of identification of non-compliant units be undertaken and strict action be taken against them

States exhorted to ensure rational use of cough syrups, particularly among children, as most coughs are self-limiting and do not require pharmacological treatment

States and UTs advised to ensure enhanced surveillance, timely reporting by all health facilities, wider dissemination of the community reporting tool of IDSP-IHIP, and strengthened inter-state coordination for early reporting and joint action

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In view of recent concerns relating to the quality and administration of cough syrups, the Union Ministry of Health and Family Welfare convened a high-level meeting under the chairmanship of the Union Health Secretary, Smt. Punya Salila Srivastava with all States and Union Territories to review compliance with drug quality norms and promote the rational use of cough syrups, especially in paediatric populations. The matter had been earlier reviewed by Union Minister of Health & Family Welfare, Shri J.P. Nadda, who had directed that the matter may be discussed with States/UTs to ensure necessary actions.

The meeting was attended by Shri Amit Agarwal, Secretary, Dept. of Pharmaceuticals, Ministry of Chemicals and Fertilizers ;Dr Rajiv Bahl, Secretary, Dept. of Health Research and DG, ICMR; Dr Sunita Sharma, Director General of Health Services (DGHS); Dr Rajeev Raghuvanshi, Drugs Controller General of India (DCGI); Dr Ranjan Das, Director, National Centre for Disease Control (NCDC); Additional Chief Secretaries/Principal Secretaries/Secretaries (Health), Drugs Controllers, Directors of Health/Medical Services, Mission Directors (NHM) from all States and Union Territories and senior officials of the Union Health Ministry.

The discussions centered on three key agenda points:

1. **Compliance with Schedule M and other G.S.R. provisions** relating to quality standards in drug manufacturing units;
2. **Rational use of cough syrups in children**, including the need to avoid irrational combinations and inappropriate formulations; and
3. **Strengthening regulation of retail pharmacies** to prevent sale and misuse of such formulations.

The meeting follows recent reports of child deaths in Chhindwara, Madhya Pradesh, allegedly linked to contaminated cough syrups. The Metropolitan Surveillance Unit (MSU), Nagpur, established under the Pradhan Mantri–Ayushman Bharat Health Infrastructure Mission (PM-ABHIM), had reported a cluster

of cases and related deaths to IDSP, NCDC from a Block in Chhindwara District, Madhya Pradesh. Chhindwara, Madhya Pradesh..

Taking cognizance of the situation, a Central team of experts comprising epidemiologists, microbiologists, entomologist and drug inspectors from the National Centre for Disease Control (NCDC), National Institute of Virology (NIV) and Central Drugs Standard Control Organisation (CDSCO) visited Chhindwara and Nagpur and undertook a detailed analysis of the reported cases and deaths in coordination with Madhya Pradesh State Authorities. Various clinical, environmental, entomological, and drug samples were collected and sent to NIV Pune, Central Drug Laboratory (CDL) Mumbai, and NEERI Nagpur for laboratory testing.

Preliminary findings ruled out common infectious diseases except for one positive case of Leptosprirosis. 19 medicine samples which had been consumed by children were collected from treating private practitioners and nearby retail stores. The chemical analysis so far indicates that out of 10 samples analyzed till date 9 meet quality standards. However, one of them viz cough syrup ‘Coldrif’ contains DEG beyond permissible limit. Subsequently, regulatory action has been taken by Tamil Nadu – FDA on the Unit which is located in Kancheepuram, Tamil Nadu. Cancellation of the manufacturing license has been recommended by CDSCO based on inspection findings. Criminal proceedings have also been initiated.

The Union Health Secretary emphasized strict compliance with the Revised Schedule M by all drug manufacturers. States were also advised to ensure rational use of cough syrups, particularly among children, as most coughs are self-limiting and do not require pharmacological treatment. The advisory issued by the DGHS on the rational use of cough syrups in paediatric populations was also discussed.

It was also informed that Risk-Based Inspections (RBI) have been initiated across 19 manufacturing units in six States to identify systemic gaps and strengthen quality assurance mechanisms. States and UTs were also advised to ensure enhanced surveillance, timely reporting by all health facilities (both government and private), wider dissemination of the community reporting tool of IDSP-IHIP, and strengthened inter-state coordination for early reporting and joint action in the context of outbreak response and unusual health events.

Dr Rajiv Bahl stated that children should not be prescribed cough syrups or any combination of drugs to prevent any side-effects. Dr Bahl also highlighted that the National Joint Outbreak Response Team is already functional, ensuring effective coordination between different Central organizations like NCDC, ICMR, etc which can assist states in need. He also advised states to strengthen coordination between their agencies for rapid response to any calamity.

Dr Sunita Sharma highlighted the need for rational use of cough syrup for pediatric population. She informed that cough medications have minimal proven benefit in children but carry significant risks. She underlined the need for checking all medications to avoid combined overdose and checking concentration of drugs. Dr Sharma also informed that guidelines in this regard will also be formulated shortly for parents, pharmacists and doctors and shared with the states.

Dr Rajeev Raghuvanshi reiterated the need for drug manufacturing units to strictly comply to the Revised Schedule M for Good Manufacturing Practices (GMP). He noted that certain firms which applied for the government's infrastructure upgradation scheme has been given an extension till December 2025 and urged states to strictly implement the revised GMP norms.

Department of Pharmaceuticals informed that a number of manufacturing units have started availing of the Revamped Pharmaceuticals Technology Upgradation Assistance Scheme (RPTUAS) for GMP upgradation.

Principal Secretary (Health), Rajasthan informed that their investigation so far indicates that the 4 deaths were not linked to quality of the cough syrup and that an awareness generation campaign is being conducted for rational use of paediatric formulation. However, by way of abundant caution various regulatory actions have been undertaken. Further investigations are being conducted.

Secretary, Medical Education (Maharashtra) informed that the children admitted in various medical institutions in Nagpur are being treated with the best possible health care.

States/UTs also apprised the Ministry of their ongoing efforts and achievements in strengthening drug quality control and administration, and shared best practices adopted in their jurisdictions.

Secretary, Health and Family Welfare stressed upon the importance of enhanced surveillance and wider dissemination of the community reporting tool of IDSP, timely reporting by all health facilities, and strengthened inter-state coordination.

The Union Health Ministry reaffirmed its commitment to ensuring the highest standards of drug quality and patient safety, and directed all States and UTs to take swift, coordinated and sustained action to prevent recurrence of such incidents.

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