GOVERNMENT OF INDIA
MINISTRY OF AYUSH

RAJYA SABHA
UNSTARRED QUESTION NO. 3369
TO BE ANSWERED ON 1ST APRIL, 2025

"Uneven implementation of quality standards across States"

3369. Dr. Fauzia Khan::

Will the Minister of ***Ayush*** be pleased to state:

(a) the reasons for the variance in enforcement of AYUSH drug quality standards, where some States conduct regular inspections while others report no action against substandard medicines;
(b) whether the Ministry plans to implement a uniform, centrally-monitored framework to ensure compliance across all States and Union Territories; and
(c) the number of cases where Ayurvedic or AYUSH medicines have been found to be substandard or adulterated in the past five years, and the actions taken against such manufacturers?

ANSWER
THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYUSH
(SHRI PRATAPRAO JADHAV)

(a)and(b) Ministry of Ayush has implemented centrally-monitored framework for enforcement of Ayush drug quality standards and ensure compliance across all States and Union Territories as below:

1. As prescribed in Drugs and Cosmetics Act, 1940 and Rules made thereunder, enforcement of the legal provisions pertaining to Quality Control and issuance of drug license of Ayurveda, Siddha, Unani and Homoeopathy drugs, is vested with the State Drug Controllers/ State Licensing Authorities appointed by the concerned State/ Union Territory Government. Rule 158-B in the Drugs Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Ayurvedic, Siddha, Unani medicines and Rule 85 (A to I) in the Drugs Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Homoeopathy medicines. It is mandatory for the manufacturers to adhere to the prescribed requirements for licensing of manufacturing units & medicines including proof of safety & effectiveness, compliance with the Good Manufacturing Practices (GMP) as per Schedule T & Schedule M-I for Ayurveda, Siddha, Unani drugs and Homoeopathy drugs respectively of the Drugs Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia.

2. Drug Inspectors collect medicine samples regularly from manufacturing firms or sale shops within their jurisdiction and send them to Drug Testing Laboratory under Drug Control department for quality testing and if any sample is found to be 'Not of Standard Quality', appropriate action is initiated such

as preventing the sale of the products from the market and appropriate legal actions as per Drugs and Cosmetics Act 1940 and Rules made thereunder.

3. Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), a subordinate office under Ministry of Ayush lays down the Formulary specifications and Pharmacopoeial Standards for Ayurveda, Siddha, Unani & Homoeopathic (ASU&H) drugs, which serve as official compendia for ascertaining the Quality Control (identity, purity and strength) of the ASU&H drugs, included therein, as per Drugs & Cosmetics Act, 1940 and Rules made thereunder and compliance to these quality standards are mandatory for the production of ASU&H drug being manufactured, sold and stocked in India.

(c) As per the information received by States/UTs, the number of cases where Ayurvedic or AYUSH medicines have been found to be substandard or adulterated in the past five years and the actions taken against such manufacturers is given at Annexure-1.

Annexure-1

Details of the number of cases of Ayurvedic/AYUSH medicines found to be substandard or adulterated in the past five years, and the actions taken against such manufacturers:

<table>
<tr><th>S. No.</th><th>Name of the State/UT</th><th>No. of cases of Ayurvedic/ Ayush medicines found to be substandard or adulterated</th><th>Action taken against such manufacturers</th></tr>
<tr><td>1.</td><td>Thiruvananthapuram</td><td>107 ayurvedic medicines</td><td>Legal action under Drugs and Cosmetics Act, 1940/ departmental actions has been taken.</td></tr>
<tr><td>2.</td><td>Karnataka</td><td><table><tr><td>Year</td><td>No. of Not of Standard Quality drug</td></tr><tr><td>2020</td><td>23</td></tr><tr><td>2021</td><td>20</td></tr><tr><td>2022</td><td>58</td></tr><tr><td>2023</td><td>7</td></tr><tr><td>2024</td><td>38</td></tr></table></td><td>Not of Standard Quality drugs are recalled from the market and the sale of such drugs is prohibited in the state.</td></tr>
<tr><td>3.</td><td>Chennai</td><td><table><tr><td>Year</td><td>No. of Not of Standard Quality drug</td></tr><tr><td>2020</td><td>121</td></tr><tr><td>2021</td><td>19</td></tr><tr><td>2022</td><td>23</td></tr><tr><td>2023</td><td>36</td></tr><tr><td>2024</td><td>11</td></tr></table></td><td>The products were recalled from the market, suspended for 03 months and suspension was revoked after compliance.</td></tr>
<tr><td>4.</td><td>Uttarakhand</td><td><table><tr><td>Year</td><td>No. of Not of Standard Quality drug</td></tr><tr><td>2020-21</td><td>09</td></tr><tr><td>2021-22</td><td>15</td></tr><tr><td>2022-23</td><td>16</td></tr><tr><td>2023-34</td><td>01</td></tr><tr><td>2024-25 (till date)</td><td>48</td></tr></table></td><td>Action taken as per Drugs and Cosmetics Act, 1940</td></tr>
<tr><td>5.</td><td>Mizoram</td><td><table><tr><td>Year</td><td>No. of Not of Standard Quality drug</td></tr><tr><td>2020-21</td><td>04</td></tr><tr><td>2021-22</td><td>06</td></tr><tr><td>2022-23</td><td>19</td></tr><tr><td>2023-34</td><td>03</td></tr><tr><td>2024-25</td><td>-</td></tr></table></td><td>-</td></tr>
<tr><td>6.</td><td>Odisha</td><td>39</td><td>The suppliers of the medicines were asked to replace the medicines and have been replaced. No such NSQ cases have been detected for licensed Ayurvedic drug manufacturers of the State.</td></tr>
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7.	Goa	01	The matter is under investigation.
8.	Madhya Pradesh	Nil	-
9.	Manipur	Nil	-
10.	Arunachal Pradesh	Nil	-
11.	Puducherry	Nil	-

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