GOVERNMENT OF INDIA
MINISTRY OF AYUSH

LOK SABHA
UNSTARRED QUESTION NO. 2224
TO BE ANSWERED ON 15th DECEMBER, 2023

"Action against Manufacturing of Spurious Drugs"

2224. SHRI KISHAN KAPOOR:

Will the Minister of AYUSH be pleased to state:

(a) the number of complaints received by the Government regarding the manufacturing of spurious AYUSH drugs and products in the country during the last years and the current year, State/UT-wise; and

(b) the action taken/proposed to be taken by the Government against such companies/entities, State/ UT-wise?

ANSWER
THE MINISTER OF AYUSH
(SHRI SARBANANDA SONOWAL)

(a)and (b) 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. 158-B in the Drugs and Cosmetics 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 and Cosmetics 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 of Drugs and Cosmetics Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia.

Further, Provisions related to Spurious Ayurveda, Siddha and Unani drugs are mentioned under section 33EEA, 33EEC, 33-I and 33J of the Drugs and Cosmetics Act, 1940 and Provisions related to Spurious Homoeopathy drugs are mentioned under section 9B, 10, 13, 17B, 18, 27, 31, 36 AB and 36 AC of the Drugs and Cosmetics Act, 1940. As per the information received from various States/UTs governments, the details of the number of complaints received by the Government regarding the manufacturing of spurious AYUSH drugs and products along with the action taken/proposed to be taken by the Government against such companies/entities are at **Annexure-I**.

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Annexure-I

State/ UT-wise details of number of complaints received by the Government regarding the manufacturing of spurious AYUSH drugs and products along with the action taken/proposed to be taken by the Government against such companies/entities are as follows -

<table>
<tr><th>S.no.</th><th>Name of the State/ UT</th><th>Details of number of complaints received</th><th>Details of the action taken/proposed to be taken</th></tr>
<tr><td>1.</td><td>Maharashtra</td><td><table><tr><td>Time period</td><td>No. of Complaint received</td></tr><tr><td>01.04.2022-31.03.2023</td><td>08</td></tr><tr><td>01.04.2023 to till date</td><td>NIL</td></tr></table></td><td><table><tr><td>Time period</td><td>No. of Complaint received</td></tr><tr><td>01.04.2022-31.03.2023</td><td>08 samples were declared NSQ and Prosecutions filed. Investigation under process.</td></tr><tr><td>01.04.2023 to till date</td><td>NIL</td></tr></table></td></tr>
<tr><td>2.</td><td>West Bengal</td><td>08 complaints regarding misbranded and spurious drugs are received in 2023.</td><td>Regarding normal complaints 06 police raids from the office of West Bengal, Licensing Authority had been initiated for adequate action in 2023. 02 complaints are under scrutiny.</td></tr>
<tr><td>3.</td><td>Jharkhand</td><td>Complain of one product (REPL Orthovit Capsule) manufactured by Renovation Exports Pvt. Ltd. Bhugandih has been received.</td><td>Product permission cancelled and Prosecution filed.</td></tr>
<tr><td>4.</td><td>Rajasthan</td><td>NIL</td><td>NIL</td></tr>
<tr><td>5.</td><td>Goa</td><td>NIL</td><td>NIL</td></tr>
<tr><td>6.</td><td>Odisha</td><td>NIL</td><td>NIL</td></tr>
<tr><td>7.</td><td>Puducherry</td><td>NIL</td><td>NIL</td></tr>
<tr><td>8.</td><td>Kerala</td><td>NIL</td><td>NIL</td></tr>
<tr><td>9.</td><td>Karnataka</td><td>NIL</td><td>NIL</td></tr>
<tr><td>10.</td><td>Haryana</td><td>NIL</td><td>NIL</td></tr>
<tr><td>11.</td><td>Delhi</td><td>NIL</td><td>NIL</td></tr>
<tr><td>12.</td><td>Arunachal Pradesh</td><td>NIL</td><td>NIL</td></tr>
<tr><td>13.</td><td>Uttarakhand</td><td>NIL</td><td>NIL</td></tr>
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