GOVERNMENT OF INDIA
MINISTRY OF AYUSH

RAJYA SABHA
UNSTARRED QUESTION NO. 814
TO BE ANSWERED ON 11th FEBRUARY, 2025

"Safety and regulatory oversight of AYUSH medicines"

814 Dr. Fauzia Khan:

Will the Minister of Ayush be pleased to state:

(a) whether the clinical trials are not mandatory for AYUSH drugs, the details of regulatory mechanisms in place to ensure the safety and efficacy of AYUSH drugs before granting approvals for manufacturing and sale;

(b) whether there have been discussions to amend existing regulations to strengthen premarket safety assessments for Ayurvedic and other AYUSH medicines; and

(c) the number of approvals granted based on textual evidence alone without clinical validation in the last five years?

ANSWER

THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYUSH

(SHRI PRATAPRAO JADHAV)

(a)and (b) The term 'clinical trial' as such is not mentioned in the context of Ayurveda, Siddha and Unani drugs related provisions of Drugs Rules, 1945. However, experience or evidence of effectiveness of the ASU drug based on textual rationale, published literature and pilot study is required in support of the claim of indication or use for issue of license in accordance with the provisions of Rule 158 B of the Drugs Rules, 1945. Second Schedule (4A) of the Drugs and Cosmetics Act, 1940 provides for quality standards of Homoeopathic drugs. Conditions for the grant of a license to manufacture Homoeopathic medicines are mentioned under Rule 85E of Drugs Rules 1945.

I. The details of regulatory mechanisms in place to ensure the safety and efficacy of Ayush drugs before granting approvals for manufacturing and sale are as follows:

1. The Drugs & Cosmetics Act, 1940 and Rules made there under have exclusive regulatory provisions for Ayurvedic, Siddha, Unani, and Homoeopathy drugs. Provisions relating to

Ayurveda, Siddha and Unani Drugs are contained in Chapter IVA and Schedule- I of the Drugs and Cosmetics Act, 1940 and in Rules 151 to 169, Schedules E(I), T & TA of the Drugs Rules, 1945. Further, Rules 2dd, 30AA, 67 (C-H), 85 (A to I), 106-A, Schedule K, Schedule M-I of the Drugs Rules, 1945 pertain to Homoeopathic drugs. 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 Rules, 1945 and quality standards of drugs given in the respective pharmacopoeia.

2. 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.
3. Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H)on behalf of Ministry of Ayush lays down the formulary specifications and pharmacopoeial standards for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) drugs which serves as official compendia for ascertaining the quality (identity, purity and strength) of the ASU&H drugs. As per the Drugs & Cosmetics Act, 1940 and rules there under, the compliance to this quality standards are mandatory for the production of ASU&H drugs being manufactured in India.
4. Rule 160 A to J of the Drugs Rules, 1945 provides the regulatory guidelines for approval of Drug Testing Laboratory for carrying out such tests of identity, purity, quality and strength of Ayurvedic, Siddha and Unani drugs as may be required under the provisions of these rules, on behalf of licensee for manufacture of Ayurvedic, Siddha and Unani drugs. As on date, 34 State Drug Testing Laboratories have been supported for strengthening their infrastructural and functional capacity. Further, 106 laboratories are approved or licensed under the provisions of Drugs Rules, 1945 for quality testing of Ayurvedic, Siddha and Unani drugs and raw materials.

II. Ministry of Ayush has constituted Ayurvedic, Siddha and Unani Drugs Technical Advisory Board (ASUDTAB) for the purpose of sub-section (1) of the section 33 C of the Drug and Cosmetics Act, 1940 to advise the Central Government and the State Governments on Technical matters related to Ayurveda, Siddha and Unani drugs. Ministry of Ayush has also constituted

Ayurvedic, Siddha and Unani Drugs Consultative Committee (ASUDCC) for the purpose of the section 33 D of the Drug and Cosmetics Act, 1940 to advise the Central Government, the State Governments and ASUDTAB on the matter related to Ayurvedic, Siddha or Unani drugs.

(c)As per the information received from States/ UTs governments, details of number of approvals granted based on textual evidence alone without clinical validation in the last five years are available at **Annexure-I.**

Annexure-I

State/ UT-wise details of number of approvals granted based on textual evidence alone without clinical validation in the last five years are as follows -

<table>
<tr><th>S.No</th><th>Name of The State/UT</th><th>Details</th></tr>
<tr><td>1)</td><td>Goa</td><td>Number of Product permissions granted in the last 05 years
<table><tr><th>S.No</th><th>year</th><th>Own Mfg. Units</th><th>Loan Mfg. Units</th></tr><tr><td>1</td><td>2020</td><td>09</td><td>18</td></tr><tr><td>2</td><td>2021</td><td>12</td><td>02</td></tr><tr><td>3</td><td>2022</td><td>09</td><td>02</td></tr><tr><td>4</td><td>2023</td><td>11</td><td>03</td></tr><tr><td>5</td><td>2024</td><td>19</td><td>01</td></tr></table></td></tr>
<tr><td>2)</td><td>Tamilnadu</td><td><table><tr><th>S.No</th><th>Year</th><th>No of approval granted based on textual evidence</th></tr><tr><td>1</td><td>2020</td><td>587</td></tr><tr><td>2</td><td>2021</td><td>564</td></tr><tr><td>3</td><td>2022</td><td>643</td></tr><tr><td>4</td><td>2023</td><td>490</td></tr><tr><td>5</td><td>2024</td><td>1232</td></tr></table></td></tr>
<tr><td>3)</td><td>Karnataka</td><td>Approvals are granted only after ascertaining the submission of documents relating to evidence of effectiveness as per Rule 158B of the Drug Rules 1945.</td></tr>
<tr><td>4)</td><td>Andhra Pradesh</td><td>371 Sastric formulations are approved for the last 5 years based on Textual evidences without clinical validations.</td></tr>
<tr><td>5)</td><td>Kerala</td><td>No Medicine approvals had been done from this office without following the provisions in Rule 158 B. 1.B of Drugs Rules 1945.</td></tr>
<tr><td>6)</td><td>Gujarat</td><td>Number of Approval -9765 in last 5 Years as per Rule 158B of the Drugs Rules 1945.</td></tr>
<tr><td>7)</td><td>West Bengal</td><td>Approvals has been granted to ASU medicines as per the existing norms in Drugs and Cosmetics Act which incorporates several factors apart from only textual references e.g. in-house test report (physical & chemical), stability study report, published literature, etc.</td></tr>
<tr><td>8)</td><td>Puducherry</td><td>1051</td></tr>
<tr><td>9)</td><td>Madhya Pradesh</td><td>Nil</td></tr>
<tr><td>10)</td><td>Delhi</td><td>Nil</td></tr>
<tr><td>11)</td><td>Andaman and Nicobar</td><td>Nil</td></tr>
<tr><td>12)</td><td>Manipur</td><td>Nil</td></tr>
<tr><td>13)</td><td>Haryana</td><td>Nil</td></tr>
<tr><td>14)</td><td>Mizoram</td><td>Nil</td></tr>
<tr><td>15)</td><td>Arunachal Pradesh</td><td>Nil</td></tr>
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