GOVERNMENT OF INDIA
MINISTRY OF AYUSH

LOK SABHA
UNSTARRED QUESTION NO. 2885
TO BE ANSWERED ON 17TH MARCH, 2023

MARKETING OF FAKE AYUSH PRODUCTS

2885. SHRI VISHNU DAYAL RAM:
MS. RAMYA HARIDAS:

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

(a) whether there has been an increase in fake/misleading products being marketed as AYUSH products and if so, the details thereof;
(b) whether the Government has set up a Pharmacopoeia Commission for Indian Medicine and Homoeopathy and if so, the details of the brands and raw products banned by the Commission;
(c) whether Government has noticed the dubious claims and advertisement of AYUSH products and if so, the details thereof;
(d) whether any protocol or guidelines are in force to restrict AYUSH products only for medicinal use and if so, the details thereof;
(e) the action taken by the Government in cases of false advertising/marketing of products as AYUSH products; and
(f) whether there is a monitoring mechanism in place to prosecute/penalise second-time offenders engaging in false marketing/advertising and if so, the details of such second-time offenders, State-wise?

ANSWER
THE MINISTER OF AYUSH
(SHRI SARBANANDA SONOWAL)

(a) As prescribed in Drugs and Cosmetics Act 1940 and Rules 1945 made thereunder, enforcement of the legal provisions pertaining to Quality Control and issuance of drug license of Ayurveda, Siddha, Unani and Homoeopathic drugs, is vested with the State drug Controllers/ State Licensing Authorities appointed by the concerned State/ Union Territory Government.

State government of Andhra Pradesh (A.P.) has informed that following fake/ misleading products have come to their notice-

i. Vata Nivarini Gulika & Dhanwantari Gulika, manufactured by M/s Ijas Herbals of Kurnool, A.P. (Mfg.License no. R-1909/Ayur.) & M/s Susruta Ayurvedics of Ravulapalem, W.G. Dist. Of A.P. (Mfg. License A-1610/Ayur. for Arhtirits Pains). Casses has been filed under Section 33-E, EE and EEA, the licenses were cancelled and the units have been seized.

ii. Sri Anandaiah's Covid Medicine (P,K,LF & Eye drops) – Activity is stopped and the department has furnished all the relevant documents to Hon'ble High Court of A.P. in connection with a case filled by others.

State government of Kerala has informed that the number of cases filed regarding fake/misleading products has been increased compared to previous years. From 2013, 19 complaints for misleading advertisement and 11 cases for Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954 & Rules there under have been reported.

(b) Yes Sir and Madam. Government of India has merged three organizations namely; Pharmacopoeia Laboratory of Indian Medicine (PLIM), Homoeopathic Pharmacopoeia Laboratory (HPL) [both central government laboratories under Ministy of Ayush and deals the matter pertaining to drug testing and Pharmacopoeial Standardization of drug used in Indian System (Ayurveda, Siddha Unani) of medicine and Homoeopathy respectively] and Pharmacopoeia Commission for Indian Medicine & Homoeopathy an autonomous body under M/o Ayush, and re-established as Pharmacopoeia Commission for Indian Medicine & Homoeopathy (PCIM&H), a subordinate office under Ministry of Ayush vide Gazette Notification No. CG-DL-W-20072020-220580, dated 06.07.2020.

The prime mandate of re-established PCIM&H on behalf of M/o Ayush to lays down Pharmacopoeial Standards and Formulary specifications for ASU&H drugs, which serve as official compendia for ascertaining the identity, purity and strength of the drugs included therein. Further, commission is acting as appellate laboratory for testing of ASU&H drugs.

(c) to (e) Yes. As prescribed in Drugs and Cosmetics Act 1940 and Rules 1945 made thereunder, enforcement of the legal provisions pertaining to Quality Control and issuance of drug license of Ayurveda, Siddha, Unani and Homoeopathic drugs, is vested with the State drug Controllers/

State Licensing Authorities appointed by the concerned State/ Union Territory Government. State/UT Governments are empowered to enforce the provisions of Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954 & Rules there under and Rule 170 of the Drugs & Cosmetics Rules, 1945 pertaining to control and prohibition of misleading advertisements and exaggerated claims of drugs. Accordingly, directives have been issued to the States/UTs for appointing Officers to enter, search any premises or examine or seize any record related to the alleged misleading or improper advertisements and initiate action against the cases of default.

Pharmacovigilance Centres for Ayurveda, Siddha, Unani and Homoeopathy (ASU&H) Drugs set up in different parts of the country under the Central Scheme of Ministry of Ayush are mandated to monitor and report the misleading advertisements to the respective State Regulatory Authorities. A three tier structure comprising of a National Pharmacovigilance Co-ordination Centre (NPvCC), Intermediary Pharmacovigilance Centres (IPvCs) and Peripheral Pharmacovigilance Centres (PPvCs) is established. All India Institute of Ayurveda (AIIA), New Delhi under Ministry of Ayush is the National Pharmacovigilance Co-ordination Centre (NPvCC) for the implementation of the National Pharmacovigilance program for Ayurveda, Siddha, Unani & Homoeopathy drugs. Objectionable advertisements are being reported to the respective State Licensing Authorities by PPvC at regular intervals.

As per the information received from State/UT government, the details of dubious claims and advertisement of AYUSH products and the action taken by the Government in cases of false advertising/marketing of products as AYUSH products are as follows –

S.no.	**Name of the State/UT**	**the details of dubious claims and advertisement of AYUSH products**	**Action taken by the State/ UT Government for false advertising/marketing of products as AYUSH products**
1.	Tamil Nadu	01, misleading advertisement of Thamara-20	• License of Asthra Power Tonic Capsule & Cream of M/ s. Pee Gee Pharma, No. 2/143, Sivadapuram, S.O, Salem - 636 307 had been suspended for one month for illegal advertisement with false claim. • License of Boraxine Ointment of M/ s. Ancient Pharma, Door No. 4/150, Virathanur Road, Ayyanarpuram, Panaiyur Post, Madurai - 625 009 had been suspended for one month for illegal advertisement with false claim.

<table>
<tr><td></td><td></td><td></td><td>• License of Segro Plus Capsule, Musli Segro Capsule & Kamana Capsule of M/ s. Shankaralaya Herbals Pvt Ltd, No. 9, 10th Cross Street, Mangalanagar, Chennai - 116 had been suspended for one month for illegal advertisement with false claim.</td></tr>
<tr><td>2.</td><td>Karnataka</td><td>Drug Inspectors have issued 1409 notices to erring advertisers for the misleading claims in their advertisements.</td><td>Government officers have been notified under Section (8) of Drugs & Magic Remedies (OA) Act, 1954 to initiate action against advertisers issuing misleading and objectionable advertisement.</td></tr>
<tr><td>3.</td><td>Maharashtra</td><td>73 objectionable advertisements of Ayush products have been detected since 2020.</td><td><table><tr><td>Action taken since 2020</td><td>No. of manufacturing companies</td></tr><tr><td>Notice issued, investigation in progress</td><td>28</td></tr><tr><td>Manufacture informed that they have stopped advertisement</td><td>11</td></tr><tr><td>Objectionable contents removed</td><td>10</td></tr><tr><td>Investigation in progress</td><td>08</td></tr><tr><td>Prosecution filed</td><td>13</td></tr><tr><td>No contravention of DMR observed</td><td>02</td></tr><tr><td>Stock seized and investigation under process</td><td>01</td></tr></table></td></tr>
<tr><td>4.</td><td>Manipur</td><td colspan="2">08 misleading advertisement noticed by PPvC.</td></tr>
<tr><td>5.</td><td>Kerala</td><td>Ayurveda Drug inspectors are constantly monitoring for any dubious claims and advertisement. From 2013, 19 complaints of advertisements have been noticed.</td><td>Legal action to 11 manufacturers has been taken against false advertising/ marketing of Ayurveda, Siddha and Unani products</td></tr>
<tr><td>6.</td><td>Mizoram</td><td>NIL</td><td>NIL</td></tr>
<tr><td>7.</td><td>Odisha</td><td>NIL</td><td>NIL</td></tr>
<tr><td>8.</td><td>Puducherry</td><td></td><td>Nodal officer has been appointed for the Drugs & Magic Remedies (OA) Act, 1954.</td></tr>
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<tr><td>9.</td><td>Gujarat</td><td colspan="3"><table>
<tr><th>Year</th><th>No. of advertisement in respect of DMR Act, 1954.</th><th>Warning issued</th><th>Show Cause notice issued</th><th>Sent for inquiry/ referred</th></tr>
<tr><td>2020</td><td>24</td><td>11</td><td>8</td><td>5</td></tr>
<tr><td>2021</td><td>6</td><td>-</td><td>2</td><td>4</td></tr>
<tr><td>2022</td><td>4</td><td>-</td><td>2</td><td>2</td></tr>
</table></td></tr>
<tr><td>10.</td><td>Andaman & Nicobar</td><td colspan="2">One advertisement with dubious claim of Ayush Product over Internet (by the manufacturer based in Haryana State) has been noticed.</td><td>• Matter has been reported to intermediary pharmacovigilance Centre jamnagar and PPvC, Haryana to take up with the concerned authority.
• Regular awareness programs on DMR (OA) Act, 1954 have been conducted by PPvC Port Blair.</td></tr>
<tr><td>11.</td><td>Uttar Pradesh</td><td colspan="2">04 dubious claims/ advertisement have been noticed.</td><td>Cognizance of the case, direction have been to the concern authority for taking necessary action against the defaulters and alleged manufacturing/ advertisers under the DMR (OR) Act, 1954 and Drugs & Cosmetics Act, 1940.</td></tr>
<tr><td>12.</td><td>Andhra Pradesh</td><td colspan="2">NIL</td><td>As per the provisions of DMR (OR) Act, 1954</td></tr>
<tr><td>13.</td><td>Jammu & Kashmir</td><td colspan="3">There is no separate Ayush Drug Controlling Authority which can monitor herbal drug companies and any misleading / objectionable advertisements under Ayush sector.</td></tr>
<tr><td>14.</td><td>Delhi</td><td colspan="2">NIL</td><td>NIL</td></tr>
<tr><td>15.</td><td>Tripura</td><td colspan="2">NIL</td><td>NIL</td></tr>
<tr><td>16.</td><td>Goa</td><td colspan="2">NIL</td><td>NIL</td></tr>
<tr><td>17.</td><td>Lakshadweep</td><td colspan="2">NIL</td><td>NIL</td></tr>
<tr><td>18.</td><td>Ladakh</td><td colspan="2">NIL</td><td>The department will act against the false advertisement / marketing of product as AYUSH product.</td></tr>
<tr><td>19.</td><td>Meghalaya</td><td colspan="2">NIL</td><td>NIL</td></tr>
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(f) State/UT Governments are empowered to enforce the provisions of Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954 & Rules there under and Rule 170 of the Drugs & Cosmetics Rules, 1945 pertaining to control and prohibition of misleading advertisements and exaggerated claims of drugs. As per section 7 of Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954 -

Whoever contravenes any of the provisions of this Act [or the rules made there under] shall, on conviction, be punishable –

a) in the case of a first conviction, with imprisonment which may extend to six months, or with fine, or with both;

b) in the case of a subsequent conviction, with imprisonment which may extend to one year, or with fine, or with both.

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