GOVERNMENT OF INDIA
MINISTRY OF AYUSH

RAJYA SABHA
UNSTARRED QUESTION NO.1443
TO BE ANSWERED ON 20TH DECEMBER, 2022

HEALTH HAZARDS DUE TO USAGE OF TRADITIONAL SYSTEMS OF MEDICINE

1443 # SHRI VIVEK THAKUR:

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

(a) whether advertisements of health products are shown on television by resorting to various traditional systems of medicine like Ayurveda, etc. and whether these products also have any approval from the Drug Controller General of India;

(b) whether the use of such products have been shown to have caused health hazards as they have a direct effect on the liver or kidneys and also because most of the products do not have the certification of benefits and safety for human body;

(c) whether Government is planning to frame rules or laws to ban such products; and

(d) if so, by when, and if not, the reasons therefor?

ANSWER
THE MINISTER OF AYUSH
(SHRI SARBANANDA SONOWAL)

(a) to (d): 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.

Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Rules thereunder encompass the provisions for prohibition of misleading advertisements and exaggerated claims of drugs and medicinal substances including AYUSH medicines, which appear in the print and electronic media and Government has taken note thereof. Central Government has notified insertion of Rule 170 in the Drugs & Cosmetics Rules, 1945 on 24th December, 2018 specifically for controlling inappropriate advertisements of Ayurvedic, Siddha and Unani medicines.

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.

Rule 158-B in the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for issue of license to manufacture Ayurvedic, Siddha, Unani medicines which are as follows –

(I) For issue licence to the medicine with respect to Ayurvedic, Siddha and Unani, the conditions relating to safety study and the experience or evidence of effectiveness are follows -

S.no.	*Category*	*Ingredient (s)*	*Indication (s)*	*Safety study*	*Experience/Evidence of Effectiveness*	
(1)	(2)	(3)	(4)	(5)	(6)	
					Published Literature	**Proof of Effectiveness**
1	(A) Ayurveda, siddha and Unani drugs, given in 158 B as referred in 3(a)	As per text	As per text	Not Required	Required	Not Required
2	(B) Any change in dosage form of Ayurveda, siddha and Unani drugs, as described in section 3 (a) of the Drugs and Cosmetics	As per text	As per text	Not Required	Required	Not Required
3	(C) Ayurveda, siddha and Unani drugs, referred in 3(a) to be used for new	As per text	New	Not Required	If Required	Required

	indication					

(II) For issue of license with respect to Patent or Proprietary medicine, the condition relating to Safety studies and experience or evidence of effectiveness are as follows:-

Sl.no.	*Category*	*Ingredient (s)*	*Indication (s)*	*Safety study*	*Experience/Evidence of Effectiveness*	
(1)	(2)	(3)	(4)	(5)	(6)	
					Published Literature	Proof of Effectiveness
1	Patent or Proprietary medicine	As per text	Textual Rationale	Not Required	Of Ingredients	*Pilot study as per relevant protocol for Ayurveda, siddha and Unani drugs
2	Ayurveda, siddha and Unani drugswith any of the ingredients of Schedule E(1) of the Drugs and Cosmetics Act, 1940	As per text	Existing	Required	Required	Required

(III) For issue of license with respect to Balya and Poshak medicines the person who applied for license is required to submit the following:

(i) Photo-copy of the textual reference of ingredients used in the formulation as mentioned in the book of Ist schedule;

(ii) Conduct safety studies in case the product contains of any of the ingredients as specified in the Schedule E (1), as per the guidelines for evaluation of Ayurveda Siddha and Unani Drugs formulations;

(iii) For textual indications the safety and effectiveness study is not required.

(IV) For issue of license with respect to Saundarya Prasadak (Husane afza/Azhagu Sodhan) the person who applied for license is required to:-

(i) Submit photo-copy of the textual reference of ingredients used in the formulation as mentioned in the book of Ist schedule;

(ii) Conduct safety studies, in case the formulation contains of any of the ingredients as specified in the Schedule E (1), as per the guidelines for evaluation of Ayurveda, Siddha and Unani formul ation;

(iii) For textual indications the safety and effectiveness study is not required.

(V) For issue of license with respect to medicine Aushadh Ghana extract of medicinal plant (dry or wet).

Sl. no.	*Category*	*Ingredient (S) I*	*Indication (s)*	*Safety study*	*Experience/Evidence of Effectiveness*	
(1)	(2)	(3)	(4)	(5)	(6)	
					Published Literature	Proof of Effectiveness
1	(A) Aqueous	As per text	As per text	Not Required	Not Required	Not Required
2	(Al). Aqueous	As per text	New Indication**	Not Required	Not Required	Required
3	(B) HydroAlcohol	As per text	As per text	Not Required	If Required	Not Required
4	(B1) HydroAlcoho	As specified	New Indication**	Required	If Required	Required
5	Other than Hydro/ HydroAlcohol	As specified	As specified	Required Acute, Chronic, mutagenicity and teratogenicity	If Required	Required

* The standard protocol will also include concept of Anupan, Prakriti &Tridosh etc. published by Central Research Councils Ayurveda, Siddha, Unani and other Government/Research Bodies.

** New indication means which is other than mentioned in Ist schedule books of Drugs & Cosmetics Act 1940.]

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. The identified centers under this program report instances of misleading advertisements to the respective state licensing authorities for suitable action against the defaulters.

As per the information received from States/ UTs, no ASU&H product have been reported for causing health hazards.

******