GOVERNMENT OF INDIA
MINISTRY OF AYUSH

RAJYA SABHA
UNSTARRED QUESTION NO. 3048
TO BE ANSWERED ON 28TH MARCH, 2023

BANNING OF DRUGS

3048 DR. V. SIVADASAN:

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

(a) whether Government has taken cognizance of the banning of five drugs namely Divya Madhugrit, Divya Eyegrit Gold, Divya Thyrogrit, Divya BPgrit and Divya Lipidom in the country;
(b) the provisions which are still allowing production and sale of such medicines;
(c) whether it is mandatory to conduct any double-blind pharmacological studies before granting approval to such medicines; and
(d) whether there is any mechanism to prevent the production and distribution of fraudulent drugs in Ayush?

ANSWER
THE MINISTER OF AYUSH
(SHRI SARBANANDA SONOWAL)

(a) and (b) 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 licence 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. 15 instances of misleading advertisements against Madhugrit, 10 instances against Eyegrit Gold, 3 against Thyrogrit, 18 against BPgrit and 7 against Lipidom have been reported by respective peripheral pharmacovigilance centers during the past 8 months. Simultaneously these communications were sent to the respective state licensing authorities by the peripheral pharmacovigilance centers to initiate suitable action.

In the year 2022, Ministry of Ayush had forwarded advertisements of Divya Madhugrit, Divya Lipidom, Divya Eyegrit Gold and Divya BPgrit to Ayurveda & Unani Services, State of Uttarakhand to examine the matter for withdrawal of advertisements.

(c) Rule 158-B in the Drugs and Cosmetics Rules, 1945 provides the regulatory guidelines for issue of licence 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 indication	As per text	New	Not Required	If Required	Required

(II) For issue of licence 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 licence with respect to Balya and Poshak medicines the person who applied for licence 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 licence with respect to Saundarya Prasadak (Husane afza/Azhagu Sodhan) the person who applied for licence 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 formulation;

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

(V) For issue of licence 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.]

(d) Yes Sir. Prohibition and penalty for manufacture and sale of misbranded, adulterated and spurious Ayurvedic, Siddha & Unani drugs have been prescribed under Section 33EEC and 33 I of the Drugs and Cosmetics Act, 1940 respectively.

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