GOVERNMENT OF INDIA
MINISTRY OF AYURVEDA, YOGA & NATUROPATHY,
UNANI, SIDDHA AND HOMOEOPATHY
(AYUSH)

LOK SABHA
UNSTARRED QUESTION NO.2849
TO BE ANSWERED ON 2ND DECEMBER, 2016

QUALITY CONTROL OF AYURVEDIC MEDICINES

2849. SHRI J.J.T. NATTERJEE:
SHRI PARVESH SAHIB SINGH:

Will the Minister of **AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY (AYUSH)** be pleased to state:

(a) whether the Government has taken any steps in order to ensure nation wide quality control of ayurvedic medicines;

(b) if so, the details thereof and if not, the reasons therefor;

(c) whether certain medicines developed by the Central Council of Research in Ayurvedic Sciences have been embroiled in a controversy as to misleading advertisements in the recent past and if so, the details thereof; and

(d) whether the Government has issued a draft notification related to ban on advertisements for products from the Indian traditional medicine category, if so, the details thereof?

ANSWER
THE MINISTER OF STATE (IC) OF THE MINISTRY OF AYURVEDA,
YOGA & NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY
(SHRI SHRIPAD YESSO NAIK)

(a) & b): Regulatory provisions for Ayurvedic medicines are in place under the Drugs and Cosmetics Act, 1940, which is a Central Act applicable throughout the country. Under this Act, Rules 151 to 159 of the Drugs and Cosmetics Rules, 1945 have specific regulatory provisions for grant of license to manufacture Ayurvedic medicines and ensure their safety, quality and standards by enforcing Good Manufacturing Practices. The standards of Ayurvedic drugs and their shelf life or date of expiry are prescribed in the Drugs and Cosmetics Rules, 1945 and Rule 158-B specifically prescribes the requirement of proof of safety and effectiveness of various categories of Ayurvedic drugs. Compliance to Good Manufacturing Practices (GMP) and submission of evidence of safety and effectiveness are required for obtaining license to manufacture Ayurvedic medicines. Need-based regulatory amendments for imposing effective quality control of Ayurvedic medicines are made in consultation with the Ayurvedic, Siddha and Unani Drugs Technical Advisory Board following a stipulated procedure. Central Government has published Ayurvedic pharmacopoeia in two parts containing quality standards of 645 single

Ayurvedic drugs and 202 Ayurvedic compound formulations. Ministry of AYUSH also provides financial support and guidance to the States for quality control activities related to Ayurvedic drugs and a statutory body in the name of Ayurvedic, Siddha and Unani Drugs Consultative Committee is constituted of members from all States and Central Government to advise in the matters of securing uniformity throughout India in the administration of Drugs & Cosmetics Act, 1940 pertaining to Ayurvedic, Siddha and Unani drugs. In order to facilitate emerging trade and export opportunities for Ayurvedic medicines, voluntary quality certification system is administered by Drugs Controller General of India in accordance with the WHO-GMP and COPP guidelines and by Quality Council of India for granting AYUSH Standard Mark and AYUSH Premium Mark to the eligible products.

(c): An anti-diabetic Ayurvedic formulation, AYUSH-82 for management of Type II Diabetes has developed by the Central Council for Research in Ayurvedic Sciences (CCRAS) has recently been transferred through National Research Development Council, Department of Scientific and Industrial Research, Ministry of Science & Technology & Earth Sciences, Govt. of India to the interested manufacturers for its commercial manufacturing under proprietary category of Ayurvedic drugs. Complaints about the misleading content of the advertisement of this Ayurvedic drug have been forwarded to the concerned State Licensing Authorities for necessary action in accordance with the provisions of Drugs and Magic Remedies (Objectionable Advertisements) Act, 1954 and Drugs & Cosmetics Act, 1940 and rules thereunder.

(d): Notification of the draft rules for prohibition of misleading advertisements of Ayurveda, Siddha and Unani drugs was issued in the Official Gazette vide GSR No. 396(E) dated 4th April, 2016 to amend the Drugs and Cosmetics Rules, 1945. Copy of the notification providing relevant details is **annexed.** Comments of the stakeholders and drug manufacturers have been received on the proposed rules.

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Annexure

THE GAZETTE OF INDIA : EXTRAORDINARY [PART II—SEC. 3(i)] MINISTRY OF AYURVEDA, YOGA AND NATUROPATHY, UNANI, SIDDHA AND HOMOEOPATHY NOTIFICATION New Delhi, the 4th April, 2016 G.S.R 396(E).—The following draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, which the Central Government proposes to make in exercise of the powers conferred by section 33-N of the Drugs and Cosmetics Act, 1940 (23 of 1940), is hereby published as required by the said section, for the information of all persons likely to be affected thereby and notice is hereby given that the objections or suggestions of the stakeholders on the said draft rules will be taken into consideration after the expiry of a period of forty-five days from the date on which copies of the Official Gazette in which this notification is published, are made available to the public. Any objection or suggestion, which may be received from any person with respect to the said draft rules within the period specified above, will be taken into consideration by the Central Government. The objections or suggestions, if any, may be addressed to the Secretary, Ministry of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH), AYUSH Bhawan, 'B' – Block, GPO Complex, INA, New Delhi-110023. DRAFT RULES 1. (i) These rules may be called the Drugs and Cosmetics (5th Amendment) Rules, 2016. (ii) They shall come into force after their final publication in the Official Gazette. 2. In the Drugs and Cosmetics Rules, 1945, - (i) after rule 169, following rule shall be inserted, namely:- "170 Prohibition of advertisements of Ayurveda, Siddha and Unani drugs.- (1) Manufacturer of Ayurvedic, Siddha and Unani drugs or his agent acting in his behalf shall not take any part in the publication of any advertisement referring to any drug in terms which suggest or calculated to lead to the use of that drug for the diagnosis, cure, mitigation, treatment or prevention of any disease, disorder or condition as given below: (i) Appendicitis (ii) Baldness and greying of hair (iii) Blindness (iv) Bust creams or breast development (v) Cancer or Tumour (vi) Cataract (vii) Change of foetal sex (viii) Chikungunya (ix) Cirrhosis (x) Complexion or fairness (xi) Diabetes mellitus (xii) Deafness ¹Hkkx IIµ[k.M 3(i)º Hkkjr dk jkti=k % vlk/kj.k 7 (xiii) Dengue (xiv) Encephalitis (xv) Gall stones (xvi) Gangrene (xvii) Genetic and congenital disorders (xviii) Goitre (xix) Height enhancement (xx) Hepatitis 'B' and 'C' (xxi) Hernia (xxii) HIV / AIDS (xxiii) Hydrocele (xxiv) Hypertension (xxv) Hysteria (xxvi) Mental Retardation (xxvii) Myocardial infarction (xxviii) Parkinson's disease (xxix) Schizophrenia (xxx) Sexual organ growth (xxxi) Sexual power, desire or performance enhancement (xxxii) Stammering (xxxiii) Sterility and Infertility (xxxiv) Rheumatic Heart Disease (xxxv) Tuberculosis (xxxvi) Valvular heart disease (xxxvii) Varicose Veins (2) The manufacturer of the Ayurvedic, Siddha and Unani drugs may advertise the drug as per the contents noted or recorded by the State Licensing Authority or Drugs Controller. (3) The application for making advertisement of any Ayurvedic, Siddha and Unani Drug shall be submitted to the State Licensing Authority in Form 26 E4 specifying therein the claims such as textual references, rationale from the

authoritative books, scientific evidence regarding safety, efficacy and quality of the drug. (4) The application fee of rupees one thousand per advertisement shall be deposited along with Form 26 E4 and other supporting documents: Provided that the Ayurvedic, Siddha and Unani drug is manufactured and licensed in more than one State, the application for the advertisement shall be submitted to the Licensing Authority or Drugs Controller of the State where the corporate office of the manufacturer is located. 8 THE GAZETTE OF INDIA : EXTRAORDINARY [PART II—SEC. 3(i)] (5) Application for the advertisement may be rejected, if its contents directly or indirectly tantamount to vulgarity or obscenity or gives a false impression about the true character of Ayurvedic, Siddha and Unani drug or make a misleading or exaggerative claim about the effectiveness of the said drug. (6) The State Licensing Authority or Drugs Controller may process the application (if required, in consultation with the concerned technical experts) for disposal within thirty days from the date of receipt of application and may allot unique identity number to the intended advertisement. (7) The applicant shall furnish the required information to the Licensing Authority or Drugs Controller as and when called for, failing which the application may be rejected and the application fee shall stand forfeited. (8) The State Licensing Authority or Drugs Controller on being satisfied with the application or otherwise, shall record and convey in Form 26 E5 the recorded contents of advertisement, reasons for rejection of application or any clarification required from the applicant. (9) The advertisement recorded by the Licensing Authority or Drugs Controller in Form 26 E5 shall be valid till the date of validity of license. (10) An appeal may be filed before the Central Government against the orders of the State Licensing Authority or Drugs Controller under sub-rule (8) and the decision of Central Government shall be final and binding on the appellant and the State Licensing Authority or Drugs Controller. (11) State Government may notify in the Official Gazette the officers of Ayurvedic, Siddha and Unani system to monitor the surveillance of the advertisements of Ayurvedic, Siddha and Unani drugs in the print, electronic, internet and audio-visual media and maintain printed register as well as online register of the advertisements with appropriate entries including those found inappropriate or invalid and action taken against such faulty advertisements and the State Government shall provide information of the advertisements to the Central Government on quarterly basis and also as and when sought by the Central Government. (12) Central Government may give specific directions to the State Government in public interest for banning, suspending or cancelling advertisement of Ayurvedic, Siddha and Unani drug, which is found prima facie not to be appropriate.", (ii) in Schedule A, after Form 26 E3, the following Forms shall be inserted, namely:- "FORM 26 E4 [See Rule 170] Application Form for Advertisement of Ayurvedic, Siddha and Unani drug (Note: Application may be made only for one advertisement) 1. I …… (name of the applicant with designation) am the authorised signatory of……(name and full address of the manufacturing company) License number……. valid up-to ……hereby apply for consideration of following contents of the intended advertisement: Name of the Ayurvedic/

Siddha/ Unani drug Contents of the advertisement including picture/audio/video (s) (Enclose copy) Reference of indication(s) Language of advertisement Medium of advertisement (print/electronic/ internet/ audio-visual) 2. The prescribed fee of rupees one thousand has been deposited to the Government under the head of account…….and the relevant Treasury Challan is enclosed herewith. ¹Hkkx IIµ[k.M 3(i)º Hkkjr dk jkti=k % vlk/kj.k 9 3. Copies of the following documents are attachedi) Valid license ii) References of indications/claims iii) Proof of safety iv) Proof of efficacy v) Quality standards vi) Any other (please specify) a. … b. … c. … Date…… Signature…….. (Applicant) Address and contact details FORM 26 E5 [See Rule 170] State Licensing Authority or Drugs Controller for Ayurveda, Siddha and Unani Drugs Name of the State or Union territory ……. [Note: Out of (a), (b) and (c) paras, only one shall be ticked and filled] It is recorded that M/s.....(Name of the manufacturer/company) situated at……. …….(Address), is holding Ayurvedic / Siddha / Unani drug manufacturing License Number……valid upto…….... and it is conveyed that- (a) Following contents of the intended advertisement for the …….(name of the drug) are noted in the register vide Identity Number……..(Name of the State/ number/ year):- "…… …… ……..” The advertisement contents as above are valid till the validity of the current license. Invalid advertisement or any distortion in the contents of advertisement shall be liable for legal action as per rules. (b) Following clarification with relevant supporting information is needed within thirty days of issue of this communication, failing which application shall be declined and application fee forfeited.- ---------- ---------- 10 THE GAZETTE OF INDIA : EXTRAORDINARY [PART II—SEC. 3(i)] (c) Application dated …….is hereby declined due to following reason(s)- ---------- ---------- ---------- ---------- Note: The permission shall not be reflected or shown in the advertisement in any form. Date: Seal of issuing Officer (Signature and Name) State Licensing Authority/ Drug Controller Name of State or Union Territory". [F.No.K.11024/03/2013-DCC (AYUSH)] JITENDRA SHARMA, Jt. Secy. Foot Note.—The Principal Rules were published in Official Gazette of India vide Notification No. F.28-10/45-H(I), dated 21st December, 1945 and was last amended vide notification G.S.R. No. 313(E), dated 16th March, 2016. Uploaded by Dte. of Printing at Government of India Press, Ring Road, Mayapuri, New Delhi-110064 and Published by the Controller of Publications, Delhi-110054.