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Proposed 'Z' Schedule: The review

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Abstract

The Proposed Z Schedule in Pharmacy act 1940 for Amendment Because Strict and Stringent Guidelines For Manufacturing of Ayurvedic, Siddha, Unani and Homeopathic medicines Which may helpful to Export Ayurveda, Siddha, Unani and Homeopathic medicines Outside the Country and Parallely all Parameter that have for Allopathic that Have been Stringent to Siddha, Unani, Ayurvedic and Homeopathic May be necessary or Regulatory Body are Inspect All factory Premises and Manufacturing Unit.

Keywords: Proposed Z schedule, Ayurveda, siddha, Unani drugs, drugs controller

Introduction

Background

The Drugs and Cosmetics Act, 1940 regulates the AYUSH (Ayurveda, Siddha, Unani and Homoeopathic) drugs. Rules 151 to 159 of the Drugs and Cosmetics Rules, 1945 provide the regulatory provisions for grant of licenses to manufacture Ayurveda, Siddha and Unani drugs and promote their safety and quality.

The standards of Ayurveda, Siddha and Unani drugs to be complied with are prescribed in Rule 168 of Drugs and Cosmetics Rules, 1945. Within the provisions of Drugs and Cosmetics Act, 1940, the Central Government can make or amend rules in this regard after consultation with or on the recommendation of the relevant Drugs Technical Advisory Board.

The technical enforcement or implementation related to the evaluation of AYUSH medicines is done by the following bodies:

- Ayurveda, Siddha, Unani Drugs Technical Advisory Board (ASUDTAB – which advises the government on issues related to the drugs,
- Ayurveda, Siddha, Unani Drugs Consultative Committee (ASUDCC – which advises the government on issues related to implementation,
- State licensing authorities who actually look after the testing process of AYUSH drugs to ascertain their purity, safety etc.

Introduction to ASUDTAB

The Central Government shall, by notification in the Official Gazette and with effect from such date as may be specified therein, constitute a Board (to be called the [Ayurvedic, Siddha and Unani Drugs Technical Advisory Board]) to advise the Central Government and the State Governments on technical matters arising out of this Chapter and to carry out the other functions assigned to it by Chapter IVA.

Constitution of ASUDTAB

The Board shall consist of the following members, namely:-

1. The Director General of Health Services, ex officio.
2. The Drugs Controller, India, ex officio.
3. The principal officer dealing with Indian systems of medicine in the Ministry of Health, ex officio.
4. The Director of the Central Drugs Laboratory, Calcutta, ex officio.

5. One person holding the appointment of Government Analyst under section 33F, to be nominated by the Central Government.
6. One Pharmacognocist to be nominated by the Central Government.
7. One Phyto-chemist to be nominated by the Central Government.
8. Four persons to be nominated by the Central Government, two from amongst the members of the Ayurvedic Pharmacopoeia Committee, one from amongst the members of the Unani Pharmacopoeia Committee and one from amongst the members of the Siddha Pharmacopoeia Committee].
9. One teacher in Dravyaguna and Bhaishajya Kalpana, to be nominated by the Central Government.
10. One teacher in ILM-UL-ADVIA and TAKLIS-WA-DAWA-SAZI, to be nominated by the Central Government.
11. One teacher in Gunapadam, to be nominated by the Central Government.
12. Three persons, one each to represent the Ayurvedic, Siddha and Unani drug industry, to be nominated by the Central Government.
13. Three persons, one each from among the practitioners of Ayurvedic, Siddha and Unani Tibb system of medicine, to be nominated by the Central Government].
14. The Central Government shall appoint a member of the Board as its Chairman.
15. The nominated members of the Board shall hold office for three years but shall be eligible for denomination.
16. The Board may, subject to the previous approval of the Central Government, make bye-laws fixing a quorum and regulating its own procedure and conduct of all business to be transacted by it.
17. The functions of the Board may be exercised notwithstanding any vacancy therein.
18. The Central Government shall appoint a person to be Secretary of the Board and shall provide the Board with such clerical and other staff as the Central Government considers necessary.

The latest gazette notification regarding the constitution of ASUDTAB was published on 28th July, 2011 (S.O. 1776 (E)).

Sub-committees of ASUDTAB

Department of AYUSH has constituted five sub-committees under the Ayurveda Siddha Unani Drugs Technical Advisory Board as follows

- The first Sub Committee will examine Schedule 'Z' and other relevant notifications.
- The second Sub Committee is formed to evaluate the proposed Retail Sale License for ASU Drugs.
- The third Sub Committee would review the Model Laboratory Practices for testing of ASU drugs.
- The fourth Sub Committee is formed to amend First Schedule of Drugs & Cosmetics Act, 1940 for the list of Authoritative ASU Books.
- The fifth Sub Committee is to examine Shelf life of ASU Medicines.

Schedule 'Z'

The draft of Schedule Z as prepared by the sub-committee of Ayurveda, Siddha, Unani Drug Technical Advisory proposed to make clinical trials mandatory for all the patent

or proprietary) medicines so as to examine the shelf life of ASU medicines. The revised version of the Schedule Z of the good clinical practices for clinical trials on ASU medicines as issued by the Department of AYUSH was faced vehement opposition from the AYUSH drug industry. The AYUSH drug industry considered the revised Schedule Z as highly unreasonable at the part of the ministry of AYUSH. The AYUSH drug industry suggested that implementation of the provisions of Schedule Z shall have a detrimental effect on the AYUSH formulation market.

Authoritative ASU Books

The AYUSH drug industry use authoritative ASU Books for manufacturing Ayurvedic classical formulations. The first schedule mentions 101 authoritative ASU books for the purpose of the manufacturing. In the year, the ministry of AYUSH invited suggestions/ inputs for including ASU Books in the first schedule. In this regard, the ministry of AYUSH should plan to include books like *Kaiydeva Nighantu*, *Shaligram Nighantu* and *Sodhala Nighantu* in the first schedule of Authoritative ASU Books as these books give account of rare Ayurvedic medicinal plants.

State Technical Committee (STC- ASU)

Recently the ministry of AYUSH proposed to set up state level technical committee to advice governments on technical matters. A proposal in this regard has been made by the ASUDTAB in the draft rules framed by the ministry for the amendment of D&C Rules. The draft rules to be inserted in the amendment of the Drugs and Cosmetics Rules, 2016 proposes that all the state governments must constitute a 'State Technical Committee (STC- ASU) for Ayurveda, Siddha and Unani Drugs' to advise the state government on technical matters related to licensing and quality control of ASU drugs.

Once the Committee comes into effect, the state licensing authority should consult the State Technical Committee for licensing of all the drugs defined under Section 3 (a) of the D & C Act. As per the draft notification, the state licensing authority has to dispose of the application of the manufacturer within two months from the date of submission with all required documents. The state technical Committee is constituted under Rule 152 A (6) of the D&C Rules. Further, it is proposed that the state licensing authority should be supported by Drug Testing Lab accredited by the National Accreditation Board or a Laboratory approved under the Drugs and Cosmetics Rules, 1945.

Future trends

Once State Technical Committees shall start functioning at the state level, it shall be easy for the ASUTAB to monitor that the state licensing authority are abiding by the provisions of the D&C Act. ASU Drug Consultative Committee has already being functioning with representatives from Centre, State and the Union territories. Recently, National Pharmacovigilance Consultative Committee for ASU Drugs (NPCC-ASU) has been proposed. If, ASUTAB, ASUDCC and NPCC-ASU collaborate in near future, it shall deliver the desirable results for the Ayurvedic drug industry.

Reference

1. The role of Ayurvedic Siddha and Unani Drugs Technical Advisory Board in ASU Drug Industry <https://ayushnext.ayush.gov.in/detail/writeUps/the-role-of-ayurvedic-siddha-and-unani-drugs-technical-advisory-board-in-asu-drug-industry#:~:text=The%20role%20of%20Ayurvedic%20Siddha%20and%20Unani%20Drugs%20Technical%20Advisory%20Board%20in%20ASU%20Drug%20Industry>