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Review Article

CURRENT STATUS OF RULE 170 IN DRUGS AND COSMETICS ACT & RULES, 1940 &1945

Sudhanya V. S[1]*, Prabhat Kumar Dwivedi[2]
*[1]PG Scholar, [2]Professor, Dept of Rasa Shastra and Bhaishajya Kalpana, Govt. Ayurvedic College, Patna, Bihar, India.

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ABSTRACT

Drugs and Cosmetics Act, 1940 (Act 23 of 1940) is a pre-independence Act passed by British Legislature under the Government of India Act, 1935 as the Drugs Act, 1940. The main objective of this act is to regulate the import, manufacture, distribution and sale of Ayurveda, Siddha, Unani drugs. The Drugs and Cosmetic Rule came in existence as a part of force vide Notification No.F.28-10/45 (H) (1), the 21st December, 1945, Department of Health, Government of India, New Delhi. Drugs and Cosmetic Rules, 1945 composed of 19 parts containing 170 rules. The rules 151 to 170 are pertaining to Ayurveda, Siddha, Unani drugs. The review aims to get a transparency regarding the current status of Rule 170 of Drugs and Cosmetic Rule, 1945, as this rule is in a state of uncertainty. Rule 170 and its provisions 0f Drugs and Cosmetic Rules, 1945 mainly deals with the prohibition of misleading advertisement of Ayurveda, Siddha or Unani drugs. On 29th August 2023 the notification from Ministry of Ayush in relation to the omission of Rule 170, creates dilemma in public. In that notification it is clearly stated that, With the power confers under section 33P of Drugs and Cosmetic Act, 1940, all States/UTs licensing authorities are here by directed not to initiate or take action under the Rule of 170 of Drugs and Cosmetic Rules, 1945. Together with this notice it also mentioned that the notification for omissions of Rule 170 and its related provisions mentioned in Drugs and Cosmetic Rules, 1945 will take some time. The letter was issued based on a recommendation from the ASUDTAB and developed based on the existing case regarding the Patanjali products. A part from this in "THE INDIAN GAZETTE" of 2nd February 2024, Ministry of AYUSH notified the draft of certain rules further to amend the Drugs Rules, 1945. In that over the serial number 33 mentions regarding the omission of Rule 170, it is quoted like "The Rule 170 of the principal rules, shall be omitted". As per the objection/opinion received from the public over the drafted rules published by Ministry of Ayush in relation to Drugs and Cosmetic Rules, 1945, a latest notification of "THE INDIAN GAZETTE" (July 2nd of 2024) also suggesting that "Rule 170 shall be omitted". By reviewing this, it is found that still the Rule 170 is not get omitted from the Drugs and Cosmetic Rules, 1945, instead of omission it got neutralised based on the section 33P of Drugs and Cosmetic Act and it is on consideration for omission.

INTRODUCTION

Drugs and Cosmetic Act & Rules is an Act to regulate the import, manufacture, distribution and sale of drugs and cosmetics. The purpose of this Act is to make pharmaceutical and medical technology firms accountable for their carelessness and poor-quality services. It is a pre-independence Act passed as a result of the observations made by Drugs Enquiry Committee and Indian Medical Association as a part of the British misrule providing poor health care system to Indian citizens. The Drugs and Cosmetic Act of 1940 came into being as a result of reports published in the Indian Medical Gazette during the 1920s and 1930s and followed by this on 1945, Drugs and Cosmetic Rules came in existence. For ease of comprehension, the Drugs and Cosmetic Rules have been separated into several sections, each with its own set of rules.

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The present study mainly focusing on the current status of the Rule 170 of Drugs and Cosmetic Rule, 1945. Rule 170 and its provisions clearly state the Prohibition of Misleading advertisement related to Ayurveda, Siddha or Unani drugs. At currently this Rule is in turbulence as a part of the notification came from the Ministry of AYUSH regarding the omission of Rule 170. Beyond that it was clearly stated in that notification, "all State/UTs licensing authorities are hereby directed not to initiate/ take any action under Rule 170 of Drugs and Cosmetic Rules, 1945" and also noted that the "final notification for the omission of this Rule and related provisions mentioned in Drugs and Cosmetic Rules will take some time". Thus, it caused misunderstanding among the public over the rule's omission. The present study aims to get a transparency with reference to the Rule 170 and to know the present status of the Rule 170.

MATERIALS AND METHODS

Drugs and Cosmetics Act, 1940 (Act 23 of 1940) is a pre-independence Act enacted by British Legislature under the Government of India Act, 1935 as the Drugs Act, 1940. The Drug Act, 1940 was passed by the central Legislature, when the drug was covered by the list 2 of the 7th schedules of the Government of India Act, 1935.[1] The Drug Act of 1940 was the outcome of a resolution voted by all provincial legislatures giving the Central Legislature the authority to enact laws governing the import, production, distribution, and sale of pharmaceuticals. As the Drugs are enlisted on serial 19th of the concurrent list, hence both the Central Government as well as State Government can legislate.[2] Up to First World War, Indian's access to modern medicine was mostly dependent on imports. In 1927 "Quinine Fraud" had brought control of the quality of drugs need to be sold in India.

In 'August 1930' the Government of India constituted a Drug Enquiry Committee under the Chairmanship of Colonel R.N. Chopra, to investigate into the numerous routes for movement of the adulterated and substandard drugs across the nation and to provide necessary suggestions for control over this mechanism. The committee, in its report submitted in 1931, recommended for enactment of comprehensive all India legislation for the control of drugs and pharmacy either as a combined Act or a separate Drugs Act and Pharmacy Act.[3] Based on this report, the Drugs Act received the assent of the Governor-General in Council on April 10, Act 23 of 1940. The act was, subsequently amended during the year, 1955 (Import Chapter, Patent and Proprietary) and 1960 (Power of Drugs Inspector).

The Drugs Act of 1940 was renamed as the Drugs and Cosmetic Act of 1940 after the term "cosmetics" was added to the Act in 1962. For ease of understanding, all of the provisions under this Act are appropriately divided into five chapters.

The Drugs and Cosmetic Act was passed in 1940 (10th April 1940) aimed to regulate the import, manufacture, distribution and sales of Drugs and Cosmetics, ensuring their safety and efficacy for human use. The Drugs and Cosmetics Act, 1940, is a comprehensive legislation that regulates a wide range of products, including, Allopathic, Homeopathic, Unani, and Siddha drugs as well as on Contraceptives, Creams, lotions, and mosquito repellents, Cosmetics Devices for internal and external use in diagnosis. Under this act, the regulation of manufacture, sale and distribution of drugs is primarily the concern of the state authorities while the central authorities are responsible for approval of new drugs, clinical trials in the country, laying down standards for drugs, control over the quality of imported drugs, coordination of the activities of drug control organization and providing expert advice with a view of bringing about uniformity in the enforcement of drugs and cosmetic act.

Objectives:[4]

- The Drugs and Cosmetic Act 1940 provides the central legislation which regulates import manufacture distribution and sale of drugs and cosmetics in the country.
- To guarantee that the drugs available to the people are safe and efficacious and the cosmetic marketed are safe for use.
- The Drugs and Cosmetic Act supervise the manufacture and import of drugs in to India so that no substandard or spurious drugs get manufactured and imported in and in to the India respectively.
- This act also provides the constitution of two boards namely- the Drug Technical Advisory Board (DTAB) and Ayurvedic, and Unani drugs technical advisory board to advise the central and state governments on technical matters arising out of the administration of this act.
- It also provides the establishment of two drugs consultative committee (DCC) one for allopathic and the other for Ayurvedic, Siddha, Unani drugs to advise the various governments and boards on matters tending to secure uniformity throughout the country in the administration of the act.

Regulations under the Drugs and Cosmetics Act, 1940 (23 of 1940): In excise of the powers granted by Sections 12, 33 and 33N of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government has periodically amended the rules in accordance with the

public interest for the overall quality control of medications. Necessary schedules are also made to these Rules.[5]

1) The Drugs and Cosmetics Rules, 1945 (Amendments),

2) The Medical Devices Rules, 2017 (Amendments)

3) The New Drugs and Clinical Trials Rules, 2019.

4) Cosmetic Rule (2022).

The Drugs and Cosmetics Rules, 1945 (Amendments): Drugs and Cosmetics Rules, 1945 has come in force vide Notification No.F.28-10/45 (H) (1), the 21st December, 1945, Department of Health, Government of India, New Delhi.[6] Drugs and Cosmetics Rules, 1945 has been divided into different Parts with suitable Rules for better understanding and enforcement. Drugs and Cosmetic Rules consist of 170 rules, which has been divided in to 19 parts. Rule 151 to 170 are the rules pertaining to Ayurveda, Siddha or Unani drugs, that is commencing from part 16 onwards of the Drugs and Cosmetic Rule, 1945.

Table 1: Drug and Cosmetic Rules 1945[7]

Part I	Preliminary
Part II	The Central Drugs Laboratory
Part III	Rules 9 to 20
PART IV	Import and Registration
Part V	Government Analysts, Inspectors, Licensing, Authorities and Controlling Authorities
Part VI	Sale of Drugs Other than Homeopathic Medicines
Part VI A	Sale of Homeopathic Medicines
Part VII	Manufacture For Sale or for Distribution of Drugs other than Homeopathic Medicines
Part VIII	Manufacture for Examination, Test or Analysis
Part IX	Labelling and Packing of Drugs other than Homeopathic Medicines
Part X	Special Provisions Relating to Biological and Other Special Products
Part XA	Import of Manufacture of New Drug for Clinical Trials or Marketing
Part XB	Requirement for the Collection, Storage, Processing and Distribution of Whole Human Blood, Human Blood Components by Blood Banks and Manufacture of Blood Products.
Part XI	Exemptions
Part XII	Standards
Part XIII	Import of Cosmetics
Part XIV	Manufacture of Cosmetic for Sale or for Distribution
Part XV	Labelling, Packing and Standards of Cosmetics
Part XV Part XV A	Manufacture for sale of Ayurvedic (Including Siddha) or Unani Drugs Approval of Institution for Carrying Out Test on Drugs & Cosmetics and Raw Materials used in their Manufacture on Behalf of Licensees for Manufacture for Sale of Drugs & Cosmetics
Part XVII	Labelling, Packing And Limit Of Alcohol In Ayurvedic (Including Siddha) Or Unani Drugs
Part XVIIA	Approval of Institute to carry out test On ASU Drugs and Raw Materials used in their Manufacture Behalf of Licenses
Part VIII	Government Analysis and Inspectors For Ayurvedic (Including Siddha) Or Unani Drugs
Part XIX	Standard of Ayurvedic, Siddha and Unani Drugs

In the year 2018, the present answering respondent vide gazette notification no. G.S.R. 1230 (E) on 24-12-2018 notified the rule 170 of the drugs and cosmetic rule, 1945 regarding prohibition of advertisement of Ayurvedic, Siddha or Unani drugs. Rule 170 comes under PART XIX of Drugs and Cosmetic Rule, 1945.The provisions aimed to prevent the advertisement of ASU drugs without the clearance from the relevant licensing authority of the state. As per this Rule;[8]

1. Ayurvedic, Siddha or Unani drugs, shall not participate in the publication of any advertisement relating to any drug for the use of diagnosis, cure,

mitigation, treatment or prevention of any disease, disorder, syndrome or condition.

2. The Ayurvedic, Siddha or Unani drug shall be advertised for the purpose other than specified in sub-rule (1) after the allotment of the Unique Identification Number.
3. The manufacturer of the Ayurvedic, Siddha or Unani drug shall apply for the Unique Identification Number for the advertisement issued or aired Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, Govt. of India Page 203 of 874 before this notification, within the period of three months from the date of the publication of this notification.
4. The application for advertisement shall be rejected if,
   - It is incomplete; or
   - The intended advertisement does not contain the contact details of the manufacturer; or
   - The contents of the advertisement directly or indirectly tantamount to vulgarity or obscenity; or
   - It refers to any Ayurvedic, Siddha or Unani drug in terms which suggest or calculated to lead to the use of that drug or medicine for the enhancement of height and dimensions or capacity of performance of male or female sexual organs; or
   - It depicts photographs or testimonials of celebrities or government officials; or
   - It refers to any Government or Autonomous organization of the Government; or
   - It gives a false impression about the true character of Ayurvedic, Siddha or Unani drug; or
   - It makes a misleading or exaggerated claim about the effectiveness of the said drug.
5. The application for allotment of the Unique Identification Number for an advertisement shall be submitted in Form 26 E-4 to the State Licensing Authority or Drug Controller specifying therein the claims such as textual references, rationale from the authoritative books, indication(s) or use(s), evidence regarding safety, effectiveness and quality of the drug.
6. The application fee of rupees one thousand per advertisement shall be deposited along with Form 26E-4 and other supporting documents. Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, Govt. of India Page 204 of 874
7. The application for the advertisement shall be submitted to the Licensing Authority of the State where the corporate office of the manufacturer is located, in case the Ayurvedic, Siddha or Unani drug is licensed for manufacturing in more than one State.
8. The State Licensing Authority shall process the application (if required, in consultation with the concerned technical experts) for disposal within thirty days from the date of receipt of application along with complete information and shall allot Unique Identification Number for the advertisement.
9. The manufacturer of Ayurvedic, Siddha or Unani drug may appeal to the State AYUSH or Health Secretary for the direction in case the application for allotment of Unique Identification Number under sub-rule (8) is not disposed of within the period of 30 days.
10. The applicant shall furnish the required information to the Licensing Authority or Drugs Controller as and when called for, failing which the application shall be rejected and the application fee shall stand forfeited.
11. The State Licensing Authority or Drugs Controller on being satisfied with the application or otherwise, shall record and convey in Form 26 E-5 the recorded contents of advertisement, reasons for rejection of application or any clarification required from the applicant.
12. The advertisement recorded by the Licensing Authority or Drugs Controller in Form 26 E-5 shall be valid till the date of validity of license to manufacture for sale of that drug and can be renewed thereafter.
13. An appeal may be filed before the Central Government against the decision of the State Licensing Authority under sub-rule (11) and the order of Central Government shall be final and binding on the appellant and the State Licensing Authority.
14. The State Government may notify in the Official Gazette the officers of Ayurvedic, Siddha or Unani system to undertake the monitoring of the advertisements of Ayurvedic, Siddha or 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 Central Drugs Standard Control Organization, Ministry of Health and Family Welfare, Govt. of India Page 205 of 874 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.
15. The State Licensing Authority may suspend or cancel the license of the manufacturer of the

Ayurvedic, Siddha or Unani drug as per the provisions of Rule 159, in case the directions given by the said authority is not complied.

16. The Central Government shall, in the public interest, prohibit any advertisement of the Ayurvedic, Siddha or Unani drugs, by notification in the Official Gazette.]

In the present scenario Rule 170 become questionable, because less than a month after the new rule 170 was gazetted, several manufacturers went to court against it on January 2019 in the Delhi High Court.[9] The High Court had accepted the Unions submission that the Advisory Board would be requested to re-examine the insertion of Rule 170 before its notification. On March 15, 2021 decision of omitting Rule 170 is taken by ASUDTAB after recommendation by an expert committee of the Ayush ministry. The meeting held by ASUDTAB on June 27 of 2022 suggests that the omission of Rule 170 is not required.[10] Beyond this, in relation with Patanjali Ayurveda case (2022) over the publication of misleading advertisement that maligned allopathy, particularly during the COVID pandemic, and falsely claimed that its own ayurvedic products could completely cures certain diseases also questions the sustainability of Rule 170 in Drugs and Cosmetic Rule, 1945. In view of this case, Ministry of Ayush sent the letter to all State/UT Licensing authorities regarding the omission of Rule 170 and its related provisions as a part of the meeting conducted on 25th May 2023 at New Delhi. The notice was published on the date 29th of August 2023 and it was issued based on a recommendation from the Ayurvedic, Siddha or Unani Drugs Technical Advisory Board. This decision was based on the powers conferred under Section 33P Drugs and Cosmetic Act ,1940. In that letter it is instructing them not to initiate or take action under Rule 170, however, the final notification for omission of Rule 170 and its related provisions mentioned in Drugs and Cosmetic Rules, 1945 will take some time.[11] The formal notification of the Rule had not been published by that time. Today, the issue was listed for consideration regarding the broader concern of misleading health claims made by Fast- Moving Consumer Goods and drug companies through advertisements, along with the Unions decision to remove the Rule 170 from the 1945 rules.[12] On May 2024 the central Government informed the Supreme court that it will "forthwith" withdraw the letter sent by the Ministry of Ayush to all state/UT Licensing authorities.[13] But after that, there was no such notification on the Gazette of India regarding the withheld of the decision taken by the Ministry of Ayush.

The affidavit submitted by the joint secretary of the Ayush Ministry highlighted that approximately 8 – 9 writ petitions challenging Rule 170 had been filed before various High courts. But there was no judgement received for none of these cases.[14] The Additional Solicitor General (ASG) sought to emphasize that the Delhi High Court had urged reconsideration of the matter concerning Rule 170. However, the bench expressed concern over this assertion, questioning how the government could issue a letter restricting the implementation of the law when the final decision regarding its omission had not been made. Ultimately the ASG assured that the letter would be withdrawn "forthwith". But till now there is no decision came pertaining to Rule 170.[15]

The notification came in THE GAZETTE OF INDIA from Ministry of Ayush, on 2nd February, 2024- notified regarding the draft of certain rules further to amend the Drugs Rules, 1945, which the central government proposes to make, in exercise of the powers conferred by section 33-N of the drugs and cosmetic act, 1940 (23 of 1940) and after consultation with Ayurveda, Siddha, Unani drug Technical Advisory Board. According to this notification if there is any objection or suggestions regarding the draft rules will be taken in consideration after the expiry of a period of thirty days from the date on which copies of the official gazette in which this notification is published, are made available to the public. Objections and suggestions which may be received from any person within the period specified above will be considered by the central Government. In this draft rule, it is notified on the serial number 33 that "The Rule 170 of the principal rules, shall be omitted".[16] As per the objection/opinion received from the public over the drafted rules published by Ministry of Ayush in relation to Drugs and Cosmetic Rules, 1945, a latest notification of "THE INDIAN GAZETTE" (July 2nd of 2024) also suggesting that "Rule 170 shall be omitted".[17]

DISCUSSION

The Drugs and Cosmetic Acts 1940 and Rules 1945 was passed with objective of regulating the manufacture, import, sales and distribution of drugs and cosmetics. The main objective of the act is to avoid substandard of drugs in order to maintain high standard of medical treatment. There are 2 schedules to act and 25 Schedules to rules. Drugs and Cosmetic rules have been divided in to 19 parts containing 170 rules. Out of this 170 Rules, Rule starting from 151 to 170 is applicable for Ayurveda, Siddha or Unani drugs. Rule 170 was added later in the year of 2018, which was mainly against the misleading advertisement of Ayurveda, Siddha or Unani drugs. This rule ensures the accuracy and safety of the promotional materials

related to these traditional medicinal products. In the present scenario the Rule 170 become a controversial as it got omitted during the year 2023 by the meeting held between the ministry of Ayush and ASU Drug Technical Advisory board under the section of 33P of Drugs and Cosmetic Act 1940.It was notified that all states/UTs licensing authorities are hereby directed to not to initiate/take any action under the rule 170 of Drugs and Cosmetic Rules, 1945.However, the final notification for omission of Rule 170 and its related provisions mentioned in Drugs and Cosmetics Rules, 1945 will take some time. It creates a dilemma in public regarding the omission of the Rule 170, whether it is completely omitted or not?

As far as my study, it may conclude that the Rule 170 is not exactly omitted from the Drugs and Cosmetic Rule 1945, instead of that as per the section 33P in Drugs and Cosmetic Act, 1940 the rule got neutralised, that means the authorities can't take action with respect to this rule according to the current scenario. In the Gazette of India (2024), the Ministry of Ayush notified the draft of certain rules further to amend the Drugs Rules, 1945, which the central government proposes to make, in exercise of the powers conferred by section 33N of the Drugs and Cosmetic Act, 1940 and after consultation with ASU Drug Technical Advisory Board. In this Gazette notification it is given that "The rule 170 of the principal rules, shall be omitted, and it is left for public objections/opinions for a period of 30 days. In consideration with public opinions and objections related with drafted rule notification, currently on July 2nd of 2024 the Ministry of Ayush in "THE INDIAN GAZETTE" notified that "Rule 170 shall be omitted" through the power conferred by section 6(2), 12, 33, and 33N of the Drugs and Cosmetic Act, 1940 (23 of 1940), and on consultation with the Ayurveda, Siddha, Unani Drugs Technical Advisory Board. From this it is clearly understood that till the date of February 2nd 2024 the Rule 170 is not omitted from drugs and cosmetic rules instead of that it got neutralised and omission is on consideration. The latest notification came in relation to the rules further to amend on Drugs Rule, 1945, on July 2nd 2024 by the Ministry of Ayush in the "THE INDIAN GAZETTE" clearly states that the "Rule 170 shall be omitted". My studies have revealed that, based on the latest notification came from Ministry of Ayush give utterance to the omission of Rule 170, but the final notification is yet to come which states the complete omission of Rule 170.

CONCLUSION

This study throws light on the current status of Rule 170 of Drugs and Cosmetic Rule, 1945. Initial stage of the notification issued by the Ministry of Ayush creates lots of uncertainty regarding the status of Rule 170. But through this study it is found that as per the latest notification (July 2nd 2024) issued by Ministry of Ayush in the "THE INDIAN GAZETTE" after the consideration of public opinion and objections by the Central Government in regards with the amendment of further rules in Drugs Rule, 1945, the 'Rule 170 shall be omitted'. In light of these information, it is clearly understood that the Rule 170 will be going to omit and the final notification is yet to come.

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***Address for correspondence**
Dr. Sudhanya V. S
PG Scholar,
Dept of Rasa Shastra & Bhaishajya Kalpana,
Govt. Ayurvedic College, Patna.
Email: vssudhanya@gmail.com