# Drugs and Cosmetics (11th Amendment) Rules, 2017 for Regulation of Homoeopathic Medicines

The Central Government of India, after consultation with the Drugs Technical Advisory Board (DTAB) amended the Drugs and Cosmetics Rules, 1945 for regulating sale of Homoeopathic medicinal products (HMP), making them easily available to users and enhancing safety, quality, efficacy of homoeopathic medicines. The main beneficiaries of these amendments are homoeopathic practitioners, pharmacists, manufacturers & millions of patients in India.

HMP market is witnessing incremental opportunity thus emphasis is laid on maintaining the quality and safety of homoeopathic medicines.

Some objections and suggestions received from the public on the said rules have also been considered by the Central Government thereby putting an end to false and misleading reports about barring homeopathic doctors from selling medicines. Under the amended rules, homoeopathic doctors can continue dispensing medicines from their clinics. The restrictions which are part of existing rules have no amendments. It is also hereby clarified that the dispensing of HMPs in clinic is covered & governed under Homoeopathic Practitioners (Professional Conduct, Etiquette and Code of Ethics) Regulations, 1982[1] by Central Council of Homoeopathy (CCH) not by the provisions of Drugs & Cosmetics Rules, 1945. It states, "*A practitioner of Homoeopathy has a right to prepare and dispense his own prescription.*"

The definition of Homoeopathic medicines was introduced under Drugs & Cosmetics Rules, 1945 on 21st December,1945[2]. Since then, the quality, manufacturing, sale and import are governed by the various provisions of its Acts & Rules. Recently, Government of India had issued an amendment in rules of G. S. R. 80 (E), in the month of November' 2017, these rules may be called the Drugs and Cosmetics 11th Amendment Rules, 2017[3].

The key amendments are in Rule 67, PART VI A, for Sale of Homoeopathic Medicines and in Rule 67C, 67F, 67G, 85E. The highlights are:

- Need of license for exhibiting the Drugs for promotional activities in any fair, which was required in earlier rule, has been removed in this notification. The amendment is beneficial for the homoeopathic products for exhibition, which will promote the awareness and usefulness of homoeopathic medicines. The government envisioned this will have far reaching implication in promoting Homoeopathy and broaden its visibility to public.
- The ambiguous clause about the sale of homoeopathic medicines has now been clarified more precisely. The licensed homoeopathic pharmacy shops, homoeopathic practioners clinics and even allopathic chemist shops can dispense homoeopathic medicines.
- The new rules also throw light upon the requisite qualifications of persons dealing with homoeopathic medicines at pharmacy shops and in manufacturer's sealed packing only except dispensing of medicines in globules, water or milk sugar or as per prescription of a Homoeopathic Medical Practitioner.
- Amendments set the standards for the manufacturers to produce the quality medicines in compliance with Good Manufacturing Practice (GMP). The license will be issued to manufacturers who adhere to GMP of homoeopathic drugs. This amendment takes into

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consideration if the quality and safety of the final product follow applicable regulations.

- Concerns were raised over homoeopathic dilutions prepared from 'back' potencies, expiry date and availability of lesser known, less used drugs in the market by the Industry and doctors from time to time at various platforms like forums, meetings and seminars[44]

This notification resolves these issues, which will have a very significant influence on homoeopathic manufacturing industry. Under paragraph 9, relating to "Expiry Date", homoeopathic dilutions and back potencies are being kept separate from the existing provision of not exceeding 60 months from the date of manufacture.

This notification lays emphasis on increasing and strengthening Homoeopathy in India by fixing the specific and relative qualifications of those dealing with homoeopathic medicines thus restricting the entry of the non-qualified personal dispensing homoeopathic medicines. Giving homoeopathic doctors & practitioners authority to prescribe & dispense their medicines is also significant. Overall the amendments have been welcomed by the manufacturers, homoeopathic practitioners and sellers alike as this will aid availability of quality homoeopathic medicines for the ever-increasing number of patients taking Homoeopathy in India.

**Table 1: Comprehensive comparison of existing provision of Drugs and Cosmetics Rules, 1945 with the new Drugs and Cosmetics (11th Amendment) Rules, 2017**

| Sr. No. | Existing Rules | Amendments | Advantages |
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| 1. | **Rule 67C** Forms of licences to sell drugs. A license [to sell, stock or exhibit or offer for sale or distribute] Homoeopathic medicines by retail or by wholesale shall be issued in Form 20C or 20D as the case may be. | "*Provided that no license shall be required for exhibiting the Drugs for promotional activities in any fair*". | ● This amendment was required in earlier rule.<br>● This is beneficial for the homoeopathic products for exhibition, which will promote the awareness and usefulness of homoeopathic medicines. |
| 2. | **Rule 67F** Conditions to be satisfied before a licence in Form 20 c or Form 20D is Granted:-for the words "who is in the opinion of the Licensing Authority competent to deal in Homeopathic medicines: | In the said rules, the following shall be substituted, namely: —<br>a) Degree in Homoeopathy from a recognized University; or<br>b) Degree in pharmacy from a recognized University; or<br>c) Bachelor's degree from a recognized University with one-year experience of dealing in Homoeopathic medicines in the premises of a registered Homoeopathic Medical Practitioner or premises holding license in Form 20C or Form 20D"<br>d) Diploma in Homeopathic Pharmacy; or<br>e) Diploma in Homeopathy Medicine and Surgery:" | ● This clearly defined the eligibility for holding license and for sale of homoeopathic medicines.<br>● This step has been taken for the dispensing of quality & standard medicines to the public for efficacious results under the supervision of technically qualified persons.<br>● Since there are around 198 Homoeopathic medical colleges in India, the qualified persons will get more opportunities. |
| 3. | **Rule 67G** For clause (2), The sale of Homeopathic medicines shall be conducted under the supervision of a person, competent to deal in Homoeopathic medicines | "Under the supervision of a person having qualifications referred to in sub-rule (1) of **rule 67F**; and in manufacturer's sealed packing only except dispensing of medicines in globules, water or milk sugar or as per prescription of a Homoeopathic Medical Practitioner." | ● This will deter the non-qualified personal to dispense homoeopathic medicines.<br>● This will check sale of loose/ unsealed medicines.<br>● Will enhance the safety, efficacy and quality of homoeopathic medicines. |

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| **4.** | **Rule 85E,** after **sub-rule (2),** | **Rule 85E,** after **sub-rule 2, 2A (sub-rule has been inserted) "***Certificate of Good Manufacturing Practice.- The certificate of Good Manufacturing Practice tomanufacturers, who comply with the requirements of Good Manufacturing Practices of Homeopathy drugs,as specified in Schedule M-I, shall be issued up to the date of validity of licence"* | ● This amendment set the standards for the manufacturers to produce the quality medicines in compliance with GMP thereby enhancing the effectiveness of the medicine.<br>● Making the adherence to GMP mandatory and hence, getting the certificate of GMP will make the manufacturers |
| **5.** | **Schedule K, serial number 31.** The following Homoeopathic Medicines, Namely:-b, c ,d & e | for serial number 31 and the entries relating thereto, the following has beensubstituted, namely:-<br>**Homoeopathic Medicines,** | ● All the different types of homoeopathic medicines are now substituted with concise terminology reducing the complexity of the document.<br>● Manufacturers will benefit from this amendment. |
| **6.** | **Schedule M-I**<br>● **Paragraph 1** "General requirements"<br>● **Paragraph 2** "Plant and Equipment"<br>● **Paragraph 3** "Requirement of Equipment and Facilities" *the words and figures "stainless steel of grade 304words and figures "shall be separate and shall be 55 square meters for each for basic installations"* | the words "or outside" has been omitted;<br>**sub-paragraph 2.1**, for the word "origins", the word "types" has been substituted;**in sub-paragraph 3.1**<br>(a) in items (v), (vi) and (ix), for the words and figures "stainless steel of grade 304", thewords and figures "stainless steel of **grade not below 304**" shall respectively has been substituted;<br>(b) for the words and figures "shall be separate and shall be 55 square meters for each for basic installations", the words and figures "shall **not be less than** 55 square meters for basic installations" has been substituted; | ● The manufacturers will find these amendments useful leading to production of quality medicines as per GMP norms. |
| | **Sub-paragraph 3.3, in the Notes, in Note (b)***for the words, "neutral glass"*<br>**Sub-paragraph 3.4, in the Notes, in Note (b)** *after the words, "shall be provided"*<br>● **Paragraph 4** "Quality Control Division"<br>● **Paragraph 5** 'Raw Materials' **in clause (a) for item (iv)** *the materials shall be free of inorganic or organic foreign matter"* **in item (v),** *procurement of dry raw material* | for the words, "neutral glass", the words "**neutral glass or stainless steel"** has been substituted**;**<br>the words "**as per therequirements of manufacturing process**" shall be inserted;<br>**sub-paragraph 4.3**, for item "(ii) Dissecting microscope", the item "(ii) Compound microscope" has been substituted<br>**sub-paragraph 5.1** the item "<br>(iv) the materials shall conform to the pharmacopoeial standards;" has been substituted;the words "and should not be more than six months old" has been omitted;the item " | ● By clarifying the specificity of material used, quality standards of homoeopathic medicines is going to improve with this amendment.<br>● Raw material is the starting material of homoeopathic medicines. This starting point must be standardized to come up with the effective and safe homoeopathic medicines. This significant amendment will play an important role for the same. |

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| | **in clause (b)** *for item "(i) a small twig of the plant with leaves shall be available if the part used isbark of the plant;"*<br>***for item "(vi)*** *the materials shall be in open mesh bags or in suitable material whichpermits the passage of air inside;*<br>***for item "(vi)***<br>*each consignment of the material shall be accompanied by a statement of thesupplier's name; name of the plant with description of the part supplied; thePharmacopoeial reference, place of collection/harvest,* ***date and time of collection*** *and packaging and weight"* | (i) the raw materials of plant origin shall be as perpharmacopoeia;" has been substituted;The item "<br>(vi) fresh herbs shall be stored in open mesh bags and materials in closed containers;" has been substituted.*The word "date and time of collection" has been omitted* | |
| | • **Paragraph 6 sub-paragraph 6.4** *Formulation (Compound formulation)*<br>• **Paragraph 9** 'Expiry Date'*, Not exceeding sixty (60) months from the date of manufacture.* | *Formulation (Compound formulation) has been omitted.relating to 'Expiry Date', for the words "date of manufacture", the words "date of manufacture except Homoeopathic dilutions and back potencies, if preserved underhygienic conditions."* shall be substituted. | • This amendment has been made to maintain the essence of homoeopathic principle of back potency, which is also conditioned with the storage and preservation under hygiene, so that the mother tinctures do not deteriorate and contain the medicinal value during preservation.<br>• It will also resolve the problem of non-availability of raw drug material for preparation of mother tincture, lesser known, lesser used drugs. |

This amendment will revolutionize the sale of HMPs in India as its implication are widespread and will make homoeopathic medicines easily available to public. The vision behind these amendments is to aid manufacturers to make quality homoeopathic medicines and make homoeopathic medicines available in far flung /remote areas through allopathic chemist shop as OTC products.

## References


1 *http://www.cchindia.com/homoeopathic-practitioners-professional-conduct-etiquette-code-of-ethics-regulations-1982-as-amended-upto-july-2014/*

2 *http://cdsco.nic.in/writereaddata/Drugs&CosmeticAct.pdf*

3 *http://www.egazette.nic.in/WriteReadData/2017/180174.pdf*

4 *Kaur H, Chaudhary A, Khurana A, Hoover T, van Haselen R, Manchanda RK. World integrated medicine forum on the regulation of homoeopathic medicinal products: National and global strategies. Indian J Res Homoeopathy [serial online] 2017 [cited 2018 Feb 7]; 11:123-35. Available from: http://www.ijrh.org/text.asp?2017/11/2/123/207662*



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