Drugs and Cosmetics (6th Amendment) Rules, 2010

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homoeopathy (AYUSH)

NOTIFICATION

New Delhi, the 10th August, 2010

*__G.S.R.663(E).—__Whereas the draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published, vide notification of the Government of India in the Ministry of Health and Family Welfare, number G.S.R.377(E), dated 3rd May, 2010, in the Gazette of India, Extraordinary, inviting objections and suggestions from persons likely to be affected thereby before the expiry a period of Forty Five days from the date on which copies of the Official Gazette containing the said notification were made available to the public;

And whereas, the said Gazette was made available to the public on the 4th May, 2010;

And whereas, objections and suggestions received from the public on the said draft rules have been considered by the Central Government;

Now, therefore, in exercise of the powers conferred by section 33-N of the Drugs and Cosmetics Act, 1940 (23 of 1940) the Central Government, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely :-

RULES

1. These rules may be called the **Drugs and Cosmetics (6th Amendment) Rules, 2010.**

   They shall come into force on the date of their publication in the Official Gazette.

2. In the Drugs and Cosmetics Rules, 1945 (herein after referred to as the said rules), after rule 158-A, the following rules shall be inserted, namely:-

158(B) Guidelines for issue of license with respect to Ayurveda, Siddha or Unani drugs.

I.(A). Ayurveda, Siddha Unani Medicines under section 3(a):-

Ayurveda, Siddha or Unani drugs includes all medicines intended for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, and manufactured exclusively in accordance with the formulae described in the authoritative books of Ayurvedic, Siddha and Unani Tibb system of medicine, as specified in the First Schedule;

(B). Patent or Proprietary medicine under section 3(h);

(i) In relation to Ayurvedic, Siddha and Unani Tibb system of medicine of all formulations containing only such ingredients mentioned in the formulae described in the authoritative books of Ayurveda, Siddha or Unani Tibb system of medicines specified in the First Schedule, but does not include a medicine which is administered by parenteral route and also a formulation included in the authoritative books as specified in clause (a);

(ii) **Balya/Poshak/Muqawi/Unavuporutkal/positive health Promoter** formulations having ingredients mentioned in books of First Schedule of the Drugs and Cosmetics Act and recommended for promotional and preventive health.

(iii) **Saundarya Prasadak (Husane afza)/Azhagh-sadhan** formulation having ingredients mentioned in Books of First Schedule of the Drugs and Cosmetics Act and recommended for oral, skin, hair and body care.

(iv) **Aushadh Ghana (Medicinal plant extracts – dry/wet)** extract obtained from plant mentioned in books of First Schedule of the Act including Aqueous or hydro-alcohol.

II.(A) For issue of license to the medicine with respect to Ayurvedic, Siddha and Unani, the conditions relating to safety study and the experience or evidence of effectiveness shall be such as specified in columns (5) and (6) of the Table given below:-

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** Published in the Gazette of India (extraordinary) Part-II, section 3, sub-section (i), vide G.S.R 663(E), dated 10th August, 2010.*

Serial number	Category	Ingredient(S)	Indications(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 Act, 1940	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

(B) For issue of license with respect to Patent or Proprietary medicine. The condition relating to Safety studies and experience or evidence of effectiveness shall be specified as follows:-

Serial number	Category	Ingredient(S)	Indications(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, Unani drug with 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 license with respect to Balya and Poshak medicines the person who applied for license 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 1st 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 license with respect to Saundarya Prasadak (Husane afza/Azhagu Sodhan) the person who applied for license is required to:-

(i) Submit photo-copy of the textual reference of ingredients used in the formulation as mentioned in the book of 1st 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 license with respect to medicine Aushadh Ghana [extract of medicinal plant (dry or wet).

Serial number	Category	Ingredient(S)	Indications(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.	(A1). Aqueous	As per Text	New indication	Not Required	Not Required	Required
3.	(B) Hydro-Alcohol	As per Text	As per Text	Not Required	If Required	Not Required
4.	(B1) Hydro-Alcohol	As specified	New Indication**	Required	If Required	Required
5.	Other than Hydro/Hydro-Alcohol	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 1st schedule books of Drugs & Cosmetics Act 1940.

[No.K.11020/02/2010-DCC (AYUSH)]

S. JALAJA, Secy. (AYUSH)

Foot Note: The Principal rules were published in Official Gazette vide notification No. F.28-10/45-H(I) dated the 21st December, 1945 and the last amended *vide* No. GSR 602(E), dated 19-7-2010.
