

और प्रसाधन नियम, 1945 के उपबंधों के अनुपालन का निर्धारण एक वर्ष में कम से कम एक बार किया जाएगा।”

(घ) प्ररूप 25च और प्ररूप 28घ में, पैरा 5 के स्थान पर क्रमशः निम्नलिखित पैरा रखा जाएगा, अर्थात्:—

“5. यह अनुज्ञप्ति, जब तक वह इससे पूर्व निलंबित या रद्द नहीं कर दी जाती, स्थायी रूप से विधिमान्य रहेगी। तथापि, अनुज्ञप्ति की शर्तों और ओषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) और ओषधि और प्रसाधन नियम, 1945 के उपबंधों के अनुपालन का निर्धारण एक वर्ष में कम से कम एक बार किया जाएगा।”

(ङ) प्ररूप 28क में, पैरा 3क के स्थान पर निम्नलिखित पैरा रखा जाएगा, अर्थात्:—

“3क. यह अनुज्ञप्ति, जब तक वह इससे पूर्व निलंबित या रद्द नहीं कर दी जाती, स्थायी रूप से विधिमान्य रहेगी। तथापि, अनुज्ञप्ति की शर्तों और ओषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) और ओषधि और प्रसाधन नियम, 1945 के उपबंधों के अनुपालन का निर्धारण एक वर्ष में कम से कम एक बार किया जाएगा।”

(च) प्ररूप 37 में, पैरा 3 के स्थान पर निम्नलिखित पैरा रखा जाएगा, अर्थात्:—

“यह अनुमोदन, जब तक वह इससे पूर्व निलंबित या रद्द नहीं कर दिया जाता, स्थायी रूप से विधिमान्य रहेगा। तथापि, अनुमोदन की शर्तों और ओषधि और प्रसाधन सामग्री अधिनियम, 1940 (1940 का 23) और ओषधि और प्रसाधन नियम, 1945 के उपबंधों के अनुपालन का निर्धारण एक वर्ष में कम से कम एक बार किया जाएगा।”

(छ) प्ररूप 19, प्ररूप 19क, प्ररूप 19कक और प्ररूप 19ग के शीर्षक में क्रमशः “या उसका नवीकरण किए जाने” शब्दों का लोप किया जाएगा।

(ज) प्ररूप 21ग, प्ररूप 21गग, प्ररूप 26, प्ररूप 26क, प्ररूप 26ख, प्ररूप 26च, प्ररूप 26ज, प्ररूप 33 और प्ररूप 33क का लोप किया जाएगा।

(झ) प्ररूप 24, प्ररूप 24क, प्ररूप 24ख, प्ररूप 24ग, प्ररूप 24च, प्ररूप 27, प्ररूप 27क, प्ररूप 27ख, प्ररूप 27घ, प्ररूप 27घक, प्ररूप 31 और प्ररूप 31क में,—

(क) शीर्षक में, “या उसका नवीकरण किए जाने” शब्दों का क्रमशः लोप किया जाएगा;

(ख) पैरा 1 में “अनुदान/नवीकरण” शब्दों के स्थान पर क्रमशः “अनुदान” शब्द रखा जाएगा।

(ञ) प्ररूप 25, प्ररूप 25क, प्ररूप 25ख, प्ररूप 25च, प्ररूप 28, प्ररूप 28क, प्ररूप 28ख, प्ररूप 28घ, प्ररूप 28घक, प्ररूप 32 और प्ररूप 32क में, शर्त 1 में “और प्रवृत्त नवीकरण का कोई प्रमाणपत्र” शब्दों का लोप किया जाएगा।

[फा. सं. एक्स.11014/6/2017-डी.आर.सी.]

कुन्दन लाल शर्मा, संयुक्त सचिव

टिप्पण : मूल नियम भारत के राजपत्र में अधिसूचना सं. एफ. 28-10/45-एच (1), तारीख 21 दिसम्बर, 1945 द्वारा प्रकाशित किए गए थे और उनमें अंतिम संशोधन अधिसूचना सं. सा.का.नि. (अ), तारीख , द्वारा किया गया था।

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION.

New Delhi, the 31st March, 2017

G.S.R. 319(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 sections 12 and 33 of the Drugs

and Cosmetics Act, 1940 (23 of 1940), in consultation with the Drugs Technical Advisory Board, is hereby published as required under the provisions of the said sections 12 and 33, for information of all persons likely to be affected thereby; and notice is hereby given that said draft rules will be taken into consideration on or after the expiry of a period of forty-five days from the date on which the copies of the Official Gazette containing these draft rules are made available to the public;

Objections and suggestions, if any, may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, Room No. 414 A, D Wing, Nirman Bhavan, New Delhi.— 110011 or e-mailed at drugsdiv-mohfw@nic.in;

Objections and suggestions which may be received from any person within the aforesaid period will be considered by the Central Government.

DRAFT RULES

1. These rules may be called Drugs and Cosmetics (_____Amendment) Rules, 2017.
2. In the Drugs and Cosmetics Rules, 1945 (hereinafter referred to as the said rules), in rule 59,—
 - (a) in sub-rule (2), the words “or renewal” shall be omitted.
 - (b) sub-rule (4) and the proviso thereto shall be omitted.
3. In the said rules, in rule 62B, in sub-rule (2), in the proviso, the words “or renew” shall be omitted.
4. In the said rules, in rule 62C,—
 - (a) in sub-rule (1), the words “or renewal”, shall be omitted;
 - (b) the proviso thereto shall be omitted.
5. In the said rules, for rule 63, the following rule shall be substituted, namely:—

“63. Duration of licence.—(1) A licence issued in Form 20, 20A, 20B, 20BB, 20F, 20G, 21, 21A, 21B and 21BB shall remain valid, if licensee deposits a licence retention fee referred to in sub-rule (2) before the expiry of a period of every succeeding five years from the date of its issue, unless, it is suspended or cancelled by the licensing authority.

(2) The licence retention fee referred to in sub-rule (1) shall be equivalent to the respective fee required for the grant of such licence.

(3) If the licensee fails to pay licence retention fee on or before the due date as referred to in sub-rule (1), he shall be liable to pay licence retention fee along with a late fee calculated at the rate of two per cent. of the licence fee for every month or part thereof up to six months, and in the event of non-payment of such fee, the licence shall be deemed to have been cancelled.”
6. In the said rules, rules 63A and 63B shall be omitted.
7. In the said rules, in rule 64,—
 - (a) the words “or renewed” wherever they occur shall be omitted;
 - (b) in sub-rule (2),—
 - (i) the words “or renewing” shall be omitted;
 - (ii) in first proviso, the words “or renew” shall be omitted.

8. In the said rules, in rule 65, the words “or renewal” at both the places where they occur shall be omitted.
9. In the said rules, after rule 65A, the following new rule shall be inserted, namely:—
“65B. Inspection for verification of compliance.—The licensing authority shall cause inspection, by the Inspector appointed under the Act, of each premises licensed under this Part, to verify the compliance with the conditions of licence and the provisions of the Act and these rules at least once in a year.”.
10. In the said rules, in rule 68A,—
 (a) in the marginal heading, the words “or Renewal” shall be omitted;
 (b) the words “or renewed” at both the places where they occur shall be omitted;
 (c) the words “or renewal” where they occur shall be omitted;
 (d) in sub-rule (2), clause (iii) shall be omitted;
 (e) the words “or renew” at both places where they occur shall be omitted.
11. In the said rules, in rule 69,—
 (a) in sub-rule (1), the words “or renewal” shall be omitted;
 (b) in sub-rule (2), the words “or for the purpose of renewal of the licence” wherever they occur shall be omitted;
 (c) sub-rule (3) shall be omitted.
12. In the said rules, in rule 69A, in sub-rule (1),—
 (a) the words “or renewal” shall be omitted;
 (b) the proviso thereto shall be omitted.
13. In the said rules, in rule 71,—
 (a) in the marginal heading, the words “or renewal” shall be omitted;
 (b) the words “or renewed” shall be omitted.
14. In the said rules, in rule 71A,—
 (a) in the marginal heading, the words “or renewal” shall be omitted;
 (b) the words “or renewed” shall be omitted.
15. In the said rules, in rule 71B,—
 (a) in the marginal heading, the words “or renewal” shall be omitted;
 (b) the words “or renewed” shall be omitted.
16. In the said rules, for rule 72, the following rule shall be substituted, namely:—
“72. Duration of licence.—
 (1) A licence issued in Form 25, Form 25B, Form 25F, Form 28, Form 28B and Form 28D shall remain valid if the licensee deposits a licence retention fee referred to in sub-rule (2) before the expiry of a period of every succeeding five years from the date of its issue, unless, it is suspended or cancelled by the licensing authority.
 (2) The licence retention fee referred to in sub-rule (1) shall be equivalent to the respective fee required for the grant of such licence.
 (3) If the licensee fails to pay licence retention fee on or before the due date as referred to in sub-rule (1), he shall be liable to pay licence retention fee along with a late fee calculated at the rate of two per cent. of the licence fee for every month or part thereof up to six months, and in the event of non-payment of such fee, the licence shall be deemed to have been cancelled.”.
17. In the said rules, the rules 73 and 73A shall be omitted.

18. In the said rules, for rule 73AA, the following rule shall be substituted, namely:—

“73AA. Duration of loan licence.-

- (1) A licence issued in Form 25A, Form 28A and Form 28DA shall remain valid if licensee deposits a licence retention fee referred to in sub-rule (2) before the expiry of a period of every succeeding five years from the date of its issue, unless, it is suspended or cancelled by the licensing authority.
- (2) The licence retention fee referred to in sub-rule (1) shall be equivalent to the respective fee required for the grant of such licence.
- (3) If the licensee fails to pay licence retention fee on or before the due date as referred to in sub-rule (1), he shall be liable to pay licence retention fee along with a late fee calculated at the rate of two per cent. of the licence fee for every month or part thereof up to six months, and in the event of non-payment of such fee, the licence shall be deemed to have been cancelled.”.

19. In the said rules, after rule 73AA, the following new rule shall be inserted, namely:—

“73AB. Inspection for grant of licence and verification of compliance.-

- (1) Before the grant of licence under Form 25, Form 25A, Form 25B, Form 25F, Form 28, Form 28A, Form 28B, Form 28D and Form 28DA, the premises shall be inspected jointly by Inspectors appointed by the Central Government and the State Government under this Act.
- (2) The premises licensed under sub-rule (1) shall be inspected jointly by Inspector appointed by the Central Government and State Government to verify the compliance with the conditions of licence and the provisions of the Act and these rules at least once in a year.”.

20. In the said rules, the rules 73B shall be omitted.

21. In the said rules, in rule 75,—

- (a) in sub-rule (1),—
 - (i) the words “or renewal” and “or for the purpose of renewal of licences” shall be omitted;
 - (ii) the proviso thereto shall be omitted;
- (b) in sub-rule (2),—
 - (i) the words “or renewal” and “or for the purpose of renewal of licences” shall be omitted;
 - (ii) the second proviso thereto shall be omitted;
- (c) in sub-rule (3),—
 - (i) the words “or renewal” and “or for the purpose of renewal of licences” shall be omitted;
 - (ii) the proviso thereto shall be omitted.

22. In the said rules, in rule 75A,—

- (a) in sub-rule (1),—
 - (i) the words “or renewal” and “or for the purpose of renewal of licences” shall be omitted;
 - (ii) the proviso thereto shall be omitted;
- (b) in sub-rule (1A),—
 - (i) the words “or renewal” and “or for the purpose of renewal of licences” shall be omitted;
 - (ii) the proviso thereto shall be omitted;

23. In the said rules, in rule 76,—

- (a) in the marginal heading, the words “or renewal” shall be omitted;

- (b) in the opening portion, the words “or renewed” shall be omitted.
24. In the said rules, in rule 76A, in the marginal heading, the words “or renewal” shall be omitted.
25. In the said rules, rule 77 shall be omitted.
26. In the said rules, in rule 79,—
- (a) in the marginal heading, the words “or renewal” shall be omitted;
- (b) the words “or renewed” shall be omitted.
27. In the said rules, the rules 83, 83A and 83AA shall be omitted;
28. In the said rules, in rule 84A,—
- (a) in the marginal heading, the words “or renewed” shall be omitted;
- (b) the words “or renew” shall be omitted.
29. In the said rules, after rule 84B, the following new rule shall be inserted, namely:—
- “**84C. Inspection for verification of compliance.**—The Central Licence Approving Authority or the licensing authority, as the case may be, shall cause inspection of each establishment licensed under this Part jointly by the Inspectors appointed by the Central Government and the State Government under the Act, to verify the compliance with the conditions of licence and the provisions of the Act and these rules at least once in a year.”.
30. In the said rules, in rule 85, in sub-rule (2), the words “or renewed” shall be omitted.
31. In the said rules, in rule 138,—
- (a) in sub-rule (1), the words “or renewal” and “or for the purpose of renewal of licence” shall be omitted;
- (b) sub-rule (2) shall be omitted.
32. In the said rules, in rule 138A,—
- (a) in sub-rule (1), the words “or renewal” shall be omitted;
- (b) sub-rule (2) shall be omitted.
33. In the said rules, in rule 139,—
- (a) in the marginal heading, the words “or renewal” shall be omitted;
- (b) in the opening portion, the words “or renewed” shall be omitted.
34. In the said rules, in rule 139AA,—
- (a) in the marginal heading, the words “or renewal” shall be omitted;
- (b) the words “or renewed” shall be omitted.
35. In the said rules, in rule 139AC,—
- (a) in sub-rule (1), the words “or renew” shall be omitted;
- (b) the sub-rule (2), the words “or renewed” shall be omitted.
36. In the said rules, in rule 139AE, the words “or renew” shall be omitted.
37. In the said rules, for rule 140, the following rule shall be substituted, namely:—
- “**140. Duration of licence.**—(1) A licence issued under Form 32, Form 32A and Form 33 shall remain valid if the licensee deposits a licence retention fee referred to in sub-rule (2) before the expiry of period of every succeeding five years from the date of its issue, unless, it is suspended or cancelled by the licensing authority.

- (2) The licence retention fee referred to in sub-rule (1) shall be equivalent to the respective fee required for the grant of such licence.
- (3) If the licence holder fails to pay licence retention fee on or before the due date as referred to in sub-rule (1), he shall be liable to pay licence retention fee along with a late fee calculated at the rate of two per cent. of the licence fee for every month or part thereof up to six months, and in the event of non-payment of such fee, the licence shall be deemed to have been cancelled.”.
- 38.** In the said rules, rules 141, 141A and 141AA shall be omitted.
- 39.** In the said rules, after rule 143, the following new rule shall be inserted, namely:—
- “143A. Inspection for grant of licence and verification of compliance:—**
- (1) Before the grant of licence under Form 32, Form 32A and Form 33, the premises shall be inspected jointly by Inspectors appointed by the Central Government and the State Government under the Act.
- (2) The premises licensed under sub-rule (1) shall be inspected jointly by Inspectors appointed by the Central Government and the State Government to verify the compliance with the conditions of licence and the provisions of the Act and these rules at least once in a year.”.
- 40.** In the said rules, in Schedule A,—
- (a) in Form 20, Form 20A, Form 20B, Form 20BB, Form 21, Form 21A, Form 21B, Form 21BB, Form 25B and Form 32, for paragraph 2, the following paragraph shall respectively be substituted, namely:—
- “2. The licence unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed at least once in a year.”;
- (b) in Form 20F, Form 20G, Form 25, Form 28DA and Form 32A, for paragraph 3, the following paragraph shall respectively be substituted, namely:—
- “3. The licence unless sooner suspended or cancelled shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed at least once in a year.”;
- (c) in Form 25A, Form 28 and Form 28B, for paragraph 4, the following paragraph shall respectively be substituted, namely:—
- “4. The licence, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed at least once in a year.”;
- (d) in Form 25F and Form 28D, for paragraph 5, the following paragraph shall respectively be substituted, namely:—
- “5. The licence, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed at least once in a year.”;
- (e) in Form 28A, for paragraph 3A, the following paragraph shall be substituted, namely:—
- “3A. The licence, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed at least once in a year.”;
- (f) in Form 37, for paragraph 3, the following paragraph shall be substituted, namely:—

“3. The approval, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of approval and the provisions of the Drugs and Cosmetics Act, 1940 (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed at least once in a year.”;

- (g) in Form 19, Form 19A, Form 19AA and Form 19C, in the heading, the words “OR RENEWAL” shall respectively be omitted;
- (h) Form 21C, Form 21CC, Form 26, Form 26A, Form 26B, Form 26F, Form 26H, Form 33 and Form 33A shall be omitted;
- (i) in Form 24, Form 24A, Form 24B, Form 24C, Form 24F, Form 27, Form 27A, Form 27B, Form 27D, Form 27DA, Form 31 and Form 31A,—
 - (a) In the heading, the words “OR RENEWAL” shall respectively be omitted;
 - (b) in paragraph 1, for the words “grant/renewal”, the words “grant” shall respectively be substituted;
- (j) in Form 25, Form 25A, Form 25B, Form 25F, Form 28, Form 28A, Form 28B, Form 28D, Form 28DA, Form 32 and Form 32A, in condition 1, the words, “and any certificate of renewal in force” shall be omitted.

[F. No. X. 11014/6/2017-DRC]

K. L. SHARMA, Jt. Secy.

Foot note: The principal rules were published in the Official Gazette vide notification No. F.28-10/45-H (1) dated 21st December, 1945 and last amended vide notification number G.S.R. (E) dated