

**MINISTRY OF HEALTH AND FAMILY WELFARE**  
**(Department of Health and Family Welfare)**  
**NOTIFICATION**

New Delhi, the 27th October, 2017

**G.S.R. 1337(E).**—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published, as required under sub-section (1) of section 12 and section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) *vide* notification of the Government of India in the Ministry of Health and Family Welfare (Department of Health and Family Welfare) number G.S.R. 319(E), dated the 31<sup>st</sup> March, 2017, in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), dated the 31<sup>st</sup> March, 2017, inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of forty-five days from the date on which the copies of the Official Gazette containing the said notification were made available to the public;

And whereas copies of the Gazette containing the said notification were made available to the public on 31<sup>st</sup> March, 2017;

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

Now, therefore, in exercise of the powers conferred by section 12 read with section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

1. (1) These rules may be called the Drugs and Cosmetics (Tenth Amendment) Rules, 2017.
- (2) They shall come into force on the date of their publication in the Official Gazette.
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, in sub-rule (1),-
  - (a) 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 Forms 20, 20A, 20B, 20BB, 20F, 20G, 21, 21A, 21B or Form 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, not less than once in three years or as needed as per risk based approach.”.

10. In the said rules, in rule 68A,-

- (a) in the marginal heading, the words “or Renewal” shall be omitted;
- (b) in sub-rule (1), the words “or renewed, as the case may be,” 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) in sub-rule (3), the words “or renewed” shall be omitted;
- (f) 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;

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- (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 and Form 25F 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 excluding inspection fee paid for grant of 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 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 excluding inspection fee paid for grant of 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 a licence in Form 25 or Form 25A or Form 25B or Form 25F is granted, the licensing authority shall cause the establishment in which the manufacture of drugs is proposed to be conducted or being conducted to be inspected jointly by the Drugs Inspectors appointed by the Central Government and the State Government under this Act who shall examine the establishment intended to be used or being used for the manufacture of drugs.

(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 not less than once in three years or as needed as per risk based approach.”.

**20.** In the said rules, rule 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,-

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(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, 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.-** (1) Before a licence in Form 28 or Form 28A or Form 28B or Form 28D or Form 28DA, is granted the licensing authority or Central Licence Approving Authority, as the case may be, shall cause the establishment in which the manufacture of drugs is proposed to be conducted or being conducted to be inspected jointly by the Drugs Inspectors appointed by the Central Government and the State Government under this Act, who shall examine the establishment intended to be used or being used for the manufacture of drugs.

(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, not less than once in three years or as needed as per risk based approach.”.

**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,-

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(a) in sub-rule (1), the words “or renew” shall be omitted;

(b) in 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 excluding inspection fee paid for grant of 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 a licence in Form 32 or Form 32A or Form 33 is granted, the licensing authority shall cause the establishment in which the manufacture of cosmetics is proposed to be conducted or being conducted to be inspected jointly by the Drugs Inspectors appointed by the Central Government and the State Government under this Act, who shall examine the establishment intended to be used or being used for the manufacture of cosmetics.

(2) The premises licensed under sub-rule (1) shall be inspected jointly by Inspector 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, not less than once in three years or as needed as per risk based approach.”.

**40.** In the said rules, in rule 150B,-

(a) in the sub-rule (1), the words “or renewal” shall be omitted;

(b) in second proviso threto shall be omitted.

**41.** In the said rules, in rule 150C,-

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

(b) in sub-rule (2), the words “or renewed” shall be omitted.

**42.** In the said rules, for rule 150D, the following rule shall be substituted, namely:-

**“150D.Duration of approval.-** (1) A licence issued under Form 37 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.”.

**43.** 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 not less than once in three years or as needed as per risk based approach.”;

(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 not less than once in three years or as needed as per risk based approach.”;

(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 not less than once in three years or as needed as per risk based approach.”;

(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 not less than once in three years or as needed as per risk based approach.”;

(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 not less than once in three years or as needed as per risk based approach.”;

(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 not less than once in three years or as needed as per risk based approach.”;

(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, Form 33A and Form 38 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;

(k) In Form 36,-

(a) In the heading, the words “or renewal” shall be omitted;

(b) In paragraph (1), the words “or renewal” shall be omitted.

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

SUDHIR KUMAR, Jt. Secy.

**Note:** The principal rules were published in the Official Gazette *vide* notification No. F. 28-10/45-H (1) dated 21<sup>st</sup> December, 1945 and last amended *vide* notification number G.S.R. 327(E), dated 3<sup>rd</sup> April, 2017.