Registered with the Registrar
of Newspapers for India
under No. 10410

Registered No. PY/44/2018-20
WPP No. TN/PMG(CCR)/WPP-88/2018-20
Dated : 26-8-2019
Price : ₹ 8-00

सत्यमेव जयते

புதுச்சேரி மாநில அரசிதழ்
La Gazette de L' État de Poudouchéry
The Gazette of Puducherry

PART - I

சிறப்பு வெளியீடு **EXTRAORDINAIRE** **EXTRAORDINARY**

அதிகாரம் பெற்ற வெளியீடு | Publiée par Autorité | Published by Authority

விலை : ₹ 8-00 | Prix : ₹ 8-00 | Price : ₹ 8-00

எண்		புதுச்சேரி	திங்கட்கிழமை	2019 ஆம்	ஆகஸ்ட் மீ	26 உ
No.	139	Poudouchéry	Lundi	26	Août	2019 (4 Bhadra 1941)
No.		Puducherry	Monday	26th	August	2019

GOVERNMENT OF PUDUCHERRY

CHIEF SECRETARIAT (HEALTH)

No. 307/H7/Health/2019.

Puducherry, dated 22nd August 2019.

NOTIFICATION

The following Notifications of the Ministry of Health and Family Welfare (Department of Health and Family Welfare), Government of India, New Delhi, published in the Gazette of India, are republished for the general information of the public.

Sl.No.	Notification No.	Date
1	GSR 222 (E)	13-03-2018
2	GSR 277 (E)	23-03-2018
3	GSR 360 (E)	10-04-2018
4	GSR 385 (E)	19-04-2018
5	GSR 408 (E)	26-04-2018
6	GSR 521 (E)	01-06-2018
7	GSR 795 (E)	21-08-2018
8	GSR 729 (E)	01-08-2018
9	GSR 390 (E)	24-04-2018
10	GSR 411 (E)	27-04-2018

M. Sarathi,
Deputy Secretary to Government (Health).

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 13th March, 2018.

G.S.R. 222 (E).—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published, as required under sub-section (I) of sections 12 and sub-section (I) of 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. 302 (E), dated the 30th March, 2017, published in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), 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 were made available to the public on 30th March, 2017;

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 the section 12 and 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 (First Amendment) Rules, 2018.
(2) They shall come into force on the 13th day of September, 2018.

2. In the Drugs and Cosmetics Rules, 1945, in rule 96, in sub-rule (1), in clause (i), in sub-clause (A), for the portion beginning with the words "For this purpose" and ending with the words "name and shall be", the words "For this purpose, the proper name of the drug or fixed dose combination drug other than fixed dose combinations of vitamin and other fixed dose combinations containing three or more drugs, shall be printed or written in a conspicuous manner which shall be in the same font but at least two font size larger than the brand name or the trade name, if any, and in other cases the brand name or the trade name, if any, shall be written in brackets below or after the proper name and shall be" shall be substituted.

[F. No. X.11014/5/2017-DRS]

SUNIL SHARMA, Jt. Secy.

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. 1380(E), dated the 10th November, 2017.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 23rd March, 2018

G.S.R. 277(E).—Whereas the 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 sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) *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. 1357(E), dated the 1st November, 2017 inviting objections and suggestions from all persons likely to be affected thereby before the expiry of 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 copies of the said Official Gazette were made available to the public on 1st November, 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 and section 33 of the said Act, 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 (Second Amendment) Rules, 2018.

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

2. In the Drugs and Cosmetics Rules, 1945, in Schedule H, after serial number 537 and the entries relating thereto, the following serial numbers and entries shall be inserted, namely,-

"538. Alclometasone

539. Beclomethasone

540. Betamethasone

541. Desonide

542. Desoximetasone

543. Dexamethasone

544. Diflorasone diacetate

545. Fluocinonide

546. Fluocinolone acetonide

547. Halobetasol propionate

548. Halometasone

549. Methylprednisone

550. Prednicarbate

551. Triamcinolone acetonide. ".

[F. No. X-11014/14/2017-DRS]

SUNIL SHARMA, Jt. Secy.

Note: The principal rules were published in the Gazette of India vide notification No. F.28-10/45-H (1) dated 21st December, 1945 and last amended vide notification number G.S.R. 222(E), dated 13th March, 2018.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department Of Health And Family Welfare)

NOTIFICATION

New Delhi, the 10th April, 2018.

G.S.R. 360(E).—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published, as required by sub-section(i) of section 12 and sub-section(i) of 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. 429 (E), dated the 2nd May, 2017, published in the Gazette of India, Extraordinary, Part II, section 3, sub-section (i), dated the 2nd May, 2017, inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of thirty 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 said Official Gazette were made available to the public on 2nd May, 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 sections 12 and 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 (Third Amendment) Rules, 2018.

(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 71, in sub-rule (6), for the words "patent or proprietary medicines" at both the places where they occur, the word "drugs" shall be substituted.

3. In the said rules, in rule 71B, for the words "patent or proprietary medicines" at both the places where they occur, the word "drugs" shall be substituted.

4. In the said rules, in rule 76, in sub-rule (7), for the words "patent or proprietary medicines" at both the places where they occur, the word "drugs" shall be substituted.

5. In the said rules, in rule 76A, for the words "patent or proprietary medicines" at both the places where they occur, the word "drugs" shall be substituted.

6. In the said rules, in Schedule D, in the Table, against item 1, under the column "Class of drugs", for the existing entries, the following entries shall be substituted, namely:-

"Substances not intended for medicinal use excluding those intended to be used as drugs after further purification or rendering them sterile.".

[F.No. X.11014/2/2014-DFQC]

SUDHIR KUMAR, Jt. Secy.

Note: The principal rules were published in the Official Gazette *vide* notification No. F.28-10/45-H (1), dated the 21st December, 1945 and last amended *vide* notification number GSR 277(E), dated the 23rd March, 2018.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 19th April, 2018.

G.S.R. 385(E).—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945, was published, as required by sub-section(i) of section 12 and sub-section(i) of 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. 1368 (E), dated the 3rd November, 2017, published in the Gazette of India, Extraordinary, Part II, section 3, sub-section(i) inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of thirty 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 said Official Gazette were made available to the public on 3rd November, 2017;

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 under section 12 and 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 (Fourth Amendment) Rules, 2018.

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

2. In the Drugs and Cosmetics Rules, 1945, in Schedule K, in the Table, for serial number 34 and the entries relating thereto, the following shall be substituted namely,–

Class of Drugs	Extent and Conditions of Exemption
"34. Production of Oxygen 93 per cent. USP or Oxygen 93 per cent. IP, produced from air by the molecular sieve process or Oxygen 93 per cent. supplied from liquid Oxygen, by a hospital or medical institute for their captive consumptions	The provisions of Chapter IV of the Act and the rules made thereunder which require them to be covered by manufacturing licence under the rules, provided that the production facilities shall be open to inspections by an Inspector appointed under the Act, who can, if necessary, take samples for test.".

[F. No. X-11014/17/2017-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 the 21st December, 1945 and last amended vide notification number G.S.R. 360(E), dated the 10th April, 2018.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 26th April, 2018

G.S.R. 408(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 sub-section (1) of 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. 1369(E), dated the 3rd November, 2017, for inviting objections and suggestions from persons likely to be affected thereby before the expiry of a period of thirty 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 said Official Gazette were made available to the public on the 3rd November, 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 and 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 (Fifth Amendment) Rules, 2018.

(2) They shall come into force on the 1st day of November, 2018.

2. In the Drugs and Cosmetics Rules, 1945 (hereinafter to be referred as the said rules), in rule 96, in sub-rule (1), in clause (xi),—

(a) for the portion beginning with the words "In addition to the'' and ending with the words "in the above list:", the following shall be substituted, namely:—

"In addition to the other particulars which are required to be printed or written under these rules, the label of inner most container of the following categories of drugs and every other covering in which the container is packed shall bear a caution or warning, as applicable, depending on whether the drug is covered under Schedule G or Schedule H or Schedule H1 or Schedule X, as specified in rule 97, in legible black coloured font size in a completely red rectangular box without disturbing other conditions printed on the label under these rules, namely:—

Narcotic analgesics, hypnotics, sedatives, tranquillisers, corticosteroids, hormones, hypoglycemic, antimicrobials, antiepileptics, antidepressants, anticoagulants, anti-cancer drugs and all other drugs falling under Schedules G, H, H1 and Schedule X whether covered or not in the above list:

Provided that if any of the drug referred above category is not covered under any of the Schedule, namely, Schedule G, Schedule H, Schedule H1 and Schedule X, the label of inner most container of drugs and every other covering in which the container is packed shall bear caution or warning, as the case may be, applicable for that drugs covered under Schedule H as specified in rule 97.";

(b) In the Proviso, for the words "Provided that", the words "Provided further that" shall be substituted.

3. In the said rules, in rule 97, in sub-rule (1),—

(i) for clauses (a) to (e), the following clauses shall be substituted, namely:—

"(a) if it contains a drug substance specified in Schedule G, be labeled with following words in legible black coloured font size in completely red rectangular box:

SCHEDULE G PRESCRIPTION DRUG – CAUTION It is dangerous to take this preparation except under medical supervision.

;

(b) if it contains a drug substance specified in Schedule H, be labeled with symbol Rx and conspicuously displayed on the left top corner of the label and shall also be labeled with the following words in legible black coloured font size in completely red rectangular box:

SCHEDULE H PRESCRIPTION DRUG – CAUTION Not to be sold by retail without the prescription of a Registered Medical Practitioner.

;

(c) if it contains a drug substance specified in Schedule H and comes within the purview of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) be labeled with symbol NRx, which shall be in red and conspicuously displayed on the left top corner of the label and shall also be labeled with the following words in legible black coloured font size in completely red rectangular box:

SCHEDULE H PRESCRIPTION DRUG – WARNING To be sold by retail on the prescription of a Registered Medical Practitioner only.

;

(d) if it contains a drug substance specified in Schedule X, be labeled with symbol XRx, which shall be in red and conspicuously displayed on the left top corner of the label and shall also be labeled with the following words in legible black coloured font size in completely red rectangular box:

SCHEDULE X PRESCRIPTION DRUG – WARNING
To be sold by retail on the prescription of a Registered Medical Practitioner only.

;

(c) if it contains a drug substance specified in Schedule H1, be labeled with symbol Rx, which shall be in red and conspicuously displayed on the left top corner of the label and shall also be labeled with the following words in legible black coloured font size in completely red rectangular box:

SCHEDULE H1 PRESCRIPTION DRUG – CAUTION
– It is dangerous to take this preparation except in accordance with the medical advice.
– Not to be sold by retail without the prescription of a Registered Medical Practitioner.

;

(f) if it contains a drug substance specified in Schedule H1 and comes within the purview of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985) be labeled with symbol NRx, which shall be in red and conspicuously displayed on the left top corner of the label and shall also be labeled with the following words in legible black coloured font size in completely red rectangular box:

SCHEDULE H1 PRESCRIPTION DRUG – CAUTION
– It is dangerous to take this preparation except in accordance with the medical advice.
– Not to be sold by retail without the prescription of a Registered Medical Practitioner.

".

4. In the said rules, in Schedule H, in the Note appended thereto, after paragraph 3, the following paragraph shall be inserted, namely:—

"4. The salts, esters, derivatives and preparations containing steroids for topical or external use shall also be covered under this Schedule.".

5. In the said rules, in Schedule K, against serial number 27, for the entries under the column "Class of Drugs", the following shall be substituted, namely:—

"Oral Rehydration Salts (Manufactured as per the following formula):-Composition of the formulation in terms of the amount in g, to be dissolved in sufficient water to produce 1000 ml.

- Sodium Chloride 2.6
- Dextrose (anhydrous) or 13.5
- Dextrose mono-hydrate 14.85
- Potassium chloride 1.5
- Sodium Citrate 2.9. ".

[F.No. X.11014/06/2016-DFQC]
SUDHIR KUMAR, Jt. Secy.

Note: The principal rules were published in the Gazette of India *vide* notification No. F.28-10/45-H (1) dated 21st December, 1945 and last amended *vide* notification number G.S.R. 385(E), dated the 19th April, 2018.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 1st June, 2018

G.S.R. 521(E).—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published as required under sections 12 and 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. 1367(E), dated the 3rd November, 2017, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of thirty 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 were made available to the public on the 3rd November, 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 under sections 12 and 33 of the Drugs and Cosmetics Act, 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 (Sixth Amendment) Rules, 2018.
(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 to be referred as the said rules), in rule 36, in the second proviso, in clause (iii), after the word, figures and letter "Form 12 B", the words "requiring the permit holder to give details of drugs imported and utilised on yearly basis" shall be inserted.
3. In the said rules, in Schedule A, in Form 12B, in paragraph 3, for the words "for a period of six months", the words "till such time as the patient requires the drug as per the prescription of a registered medical practitioner and the permit holder shall submit details of drugs imported and utilised to the licensing authority on yearly basis" shall be substituted.

[F.No. X.11014/13/2017-DRS]

SUDHIR KUMAR, Jt. Secy.

Note: The principal rules were published in the Gazette of India *vide* notification number F.28-10/45-H(1), dated the 21st December, 1945 and was last amended *vide* notification number G.S.R. 408(E), dated the 26th April, 2018.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 21st August, 2018

G.S.R. 794(E).—In exercise of the powers conferred by section 26A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby further amends the notification of the Government of India, Ministry of Health and Family Welfare (Department of Health and Family Welfare) No. G.S.R. 411(E), dated 27th April, 2018 published in Part II - Section 3 - Sub-section (i) of the Gazette of India, Extraordinary, namely,—

In the said notification, in para 1, in sub-para 5, for clauses (v) and (vi), the following clause shall be substituted, namely,—

"(v) The Oxytocin formulations manufactured by the public sector companies or undertakings licensed under the Drugs and Cosmetics Rules, 1945 shall be distributed or sold in accordance with such rules."

[F. No. X.-11014/3/2018-DR]

SUDHIR KUMAR, Jt. Secy.

Note : The principal notification was published in the Gazette of India Extraordinary, Part II, Section 3, ub-section (i) *vide* number G.S.R. 411(E), dated the 27th April, 2018 and was last amended *vide* notification number G.S.R. 602(E), dated the 29th June, 2018.

NOTIFICATION

New Delhi, the 21st August, 2018

G.S.R. 795(E).—Whereas a draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published as required under sections 12 and 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. 763(E), dated the 10th August, 2018, in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), inviting objections and suggestions from persons likely to be affected thereby, before the expiry of a period of 7 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 were made available to the public on the 10th August, 2018;

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

And whereas, circumstances have arisen making it necessary to publish this notification without prior consultation of the Drugs Technical Advisory Board and the consultation shall be made in accordance with section 12 and section 33 of the said Act.

Now, therefore, in exercise of the powers conferred under sections 12 and 33 of the Drugs and Cosmetics Act, 1940, the Central Government 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 (Seventh Amendment) Rules, 2018.

(2) They shall come into force on the First day of September, 2018.

2. In the Drugs and Cosmetics Rules, 1945, —

(a) In Schedule H the entry at serial number 382 relating to Oxytocin shall be omitted;

(b) In Schedule H1 at the end after entry at serial number 46 the following entry shall be inserted, namely,—

"47. Oxytocin ".

[F. No. X.-11014/3/2018-DR]

SUDHIR KUMAR, Jt. Secy.

Note : The principal rules were published in the Gazette of India *vide* notification number F.28-10/45-H(1), dated the 21st December, 1945 and was last amended *vide* notification number G.S.R. 602(E), dated the 29th June, 2018.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 1st August, 2018

G.S.R. 729(E).—Whereas a draft of certain rules to amend the Medical Device Rules, 2017 was published as required under sections 12 and 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 412(E) dated 27.04.2018 in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i) by the Central Government, inviting objections and suggestions from all persons likely to be affected thereby, before the expiry of a period of thirty days from the date on which copies of the said Official Gazette containing the said notification were made available to the public;

And whereas, copies of the Official Gazette containing the said notification were made available to the public on the 27th April, 2018;

And whereas, all objections and suggestions received in response to the said draft notification have been duly considered by the Central Government;

Now, therefore, in exercise of the powers conferred by section 12 and 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, namely:-

1. (1) These rules may be called the Medical Devices (Amendment) Rules, 2018.

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

2. In the Medical Devices Rules, 2017, in the Fourth Schedule, in Part II, in paragraph (ii), for clause (h), the following clause shall be substituted, namely:-

"(h) In case of in-vitro diagnostic medical devices, performance evaluation report by the manufacturer shall be submitted by the applicant:

Provided that when the State Licensing Authority specifically requires for Class B or the Central Licence Authority for Class B, Class C and Class D in-vitro diagnostic medical devices, as the case may be, applicant shall submit the report issued by the central medical devices testing laboratory or a medical device testing laboratory registered under rule 83 or by any laboratory accredited by the National Accreditation Board for Testing and Calibration Laboratories or by any hospital accredited by National Accreditation Board for Hospitals and Healthcare Providers or by any Central Government or State Government Laboratory of any hospital or of any institute, specified by the concerned State Licensing Authority or the Central Licensing Authority.".

[F. No. X.11014/5/2018-DR]

SUDHIR KUMAR, Jt. Secy.

Note : The principal rules were published in the Gazette of India *vide* notification number G.S.R 78(E), dated the 31st January, 2017.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 24th April, 2018

G.S.R. 390(E).—Whereas the Central Government is satisfied that the use of the drug Oxytocin and its formulation in any name or manner is likely to involve certain risk to human beings and animals and that it is necessary and expedient to prohibit the import of the said drugs in the public interest.

Now, therefore, in exercise of the powers conferred by Section 10A of the Drugs and Cosmetics Act, 1940 (23 of 1940), the Central Government hereby makes the following amendment in the notification of the Government of India in the Ministry of Health and Family Welfare No. G.S.R. 577(E), dated the 23rd July, 1983, namely:—

In the table below to the said notification, after serial number 11 and the entry relating thereto, the following serial number and entry shall be inserted, namely:—

"12. Oxytocin and its formulation in any name or manner.".

[F. No. X.11014/2/2018-DR]

SUDHIR KUMAR, Jt. Secy.

Note : The principal notification was published in the Gazette of India vide G.S.R. 577(E), dated the 23rd July, 1983 and last amended by G.S.R. 433(E), dated the 7th June, 2012.

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 27th April, 2018

G.S.R. 411(E).—Whereas the Hon'ble High Court of Himachal Pradesh, Shimla, has, in its judgment dated 15.3.2016 in CWPIL No. 16 of 2014 titled 'Court on its own motion' versus State of Himachal Pradesh and others, observed that there is large scale clandestine manufacture and sale of the drug Oxytocin leading to its grave misuse, which is harmful to animals and humans;

And whereas, the said Hon'ble High Court also observed that the feasibility of restricting the manufacture of Oxytocin only in public sector companies and also restricting and limiting the manufacture of Oxytocin by companies to whom licenses have already been granted should be considered;

And whereas, the Drugs Technical Advisory Board constituted under section 5 of the Drugs and Cosmetics Act, 1940 (23 of 1940) considered the said issue in its meeting held on the 12th February 2018 and recommended that Oxytocin formulations for human use be regulated and restricted to be supplied only to registered hospitals and clinics in public and private sector to prevent misuse of the said drug;

And whereas, the Central Government, on the basis of the recommendations of the said Board and after examination of the matter, is satisfied that unregulated and illegal use of the drug Oxytocin is likely to involve risk to human beings or animals and that in the public interest it is necessary and expedient to regulate and restrict the manufacture, sale and distribution of the drug Oxytocin in the country to prevent its misuse by unauthorised persons or otherwise;

Now, therefore, in exercise of the powers conferred by section 26A of the said Act, and in supersession of the notification number G.S.R. 29(E) dated 17th January, 2014, the Central Government hereby directs that the drug Oxytocin shall be manufactured for sale or for distribution or sold in the manner specified below, namely:-

(i) The manufacture of Oxytocin formulations for domestic use shall be by public sector undertakings or companies only and the label of the product shall bear barcodes.

(ii) The manufacture of Oxytocin formulations for export purposes shall be open to both public and private sector companies and the packs of such manufacture for exports shall bear barcodes.

(iii) The manufacturers of active pharmaceutical ingredient of Oxytocin shall supply the active pharmaceutical ingredient only to the public sector manufacturers licensed under the Drugs and Cosmetics Rules, 1945 for manufacture of formulations of the said drug for domestic use.

(iv) The manufacturers of active pharmaceutical ingredient of Oxytocin shall supply the said active pharmaceutical ingredient to the manufacturers in public and private sector licensed under the Drugs and Cosmetics Rules, 1945 for manufacture of formulations of the said drug for export purpose.

(v) The Oxytocin formulations manufactured by the public sector companies or undertakings licensed under the Drugs and Cosmetics Rules, 1945 for domestic use shall supply the formulations meant for human and veterinary use only,-

(a) to the registered hospitals and clinics in public and private sector directly; or

(b) to the Pradhan Mantri Bhartiya Janaushadhi Pariyojana (PMBJP) and Affordable Medicines and Reliable Implants for Treatment (AMRIT) outlets or any other Government entity which may be specified by the Central Government for this purpose in the country which shall further supply the drug to the registered hospitals and clinics in public and private sector.

(vi) The Oxytocin in any form or name shall not be allowed to be sold through retail Chemist.

2. This notification shall come into force on the first day of July 2018.

[F. No. X.11014/3/2018-DR]

SUDHIR KUMAR, Jt. Secy.

---

online publication at **"https://styandptg.py.gov.in"**
Published by The Director, Government Press
Printed at: Government Central Press, Puducherry.
Posted at: Puducherry HPO on every Tuesday