

MINISTRY OF FINANCE

(Department of Revenue)

NOTIFICATION

New Delhi, the 13th July, 2010

S.O. 1661(E).—In exercise of the powers conferred by section 9 read with sections 4 and 76 of the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985), the Central Government hereby makes the following rules further to amend the Narcotic Drugs and Psychotropic Substances Rules, 1985, namely:-

1. Short title and commencement. - (1) These rules may be called the Narcotic Drugs and Psychotropic Substances (Amendment) Rules, 2010.
(2) They shall come into force on the date of their publication in the official Gazette .

2. Insertion of rule 33A. - In the Narcotic Drugs and Psychotropic Substances Rules, 1985 (hereinafter referred to as the said rules), after rule 33, the following rule shall be inserted, namely:-

“33A. Sale of opium derivatives from the Government Opium Factories.- (1) The Government Opium Factories may sell the opium derivatives only if the buyer produces a valid quota allocation under rule 67E.

(2) Every buyer of a opium derivative under sub-rule (1), shall provide information to the Chief Controller of Factories regarding its utilization, or any other related matter in such form and within such time as may be indicated by the Chief Controller of Factories.”.

3. Amendment of rule 36:- In rule 36 of the said rules; (a) in sub-rule 2A, the words ‘from Indian opium’ shall be omitted.

(b) after sub-rule 2A, the following sub-rule shall be inserted, namely:-

“(2B) If, in the opinion of the Central Government, the licensee fails to fulfill the purpose for which he is issued a licence under sub-rule (2A) or the terms and conditions of the licence, the Central Government may, after giving the licensee a reasonable opportunity of being heard, cancel the licence.”.

4. Insertion of new rule 36A.- After rule 36 of the said rules, the following rule shall be inserted, namely:-

“36A. Manufacture of natural manufactured drugs from poppy straw. - (1) Notwithstanding anything contained in rule 36, if the Central Government is of the opinion that it is in public interest to do so, the Narcotics Commissioner or any other officer authorised by the Central Government in this behalf may issue a licence in

Form No.3A on such terms and conditions as may be specified in the licence to manufacture poppy straw concentrate from poppy straw.

(2) The licensee may also manufacture morphine, codeine, thebaine, dionine, dihydrocodeinone, dihydrocodone, acetyldihydrocodeine, acetyldihydrocodeinone, dihydromorphine, dihydromorphinone, dihydrohydroxycodone, pholcodeine and their respective salts from the poppy straw concentrate manufactured under sub-rule (1).

(3) If, in the opinion of the Central Government, the licensee fails to fulfill the purpose for which he is issued a licence under sub-rule (1), or the terms and conditions of the licence, the Central Government, may, after giving the licensee a reasonable opportunity of being heard, cancel the licence.”

5. Amendment of rule 37.- In rule 37 of the said rules, in sub-rule (2), for the word ‘fifty’, the words ‘five thousand’ shall be substituted and the words ‘or sub-rule (2A) of rule 36’ shall be omitted.

6. Amendment of rule 39. - (1) Rule 39 shall be re-numbered as sub-rule (1) thereof, and in sub-rule (1) as so re-numbered the words “rule 36 or” shall be omitted.

(2) After sub-rule (1), the following sub-rule shall be inserted, namely:-

“(2) Licence referred to in sub-rule (2A) of rule 36 and rule 36A shall be issued subject to the condition that before commencing of the manufacture, the licensee shall obtain the licences required as per the Drugs and Cosmetics Act, 1940(23 of 1940) from the authority in-charge of drug control in the State and the licence issued by the State Government under section 10 of the Act, or any other licence required under any other law for the time being in force.”

7. Amendment of rule 54:- In rule 54 of the said rules, the following proviso shall be inserted, namely:-

“Provided that nothing in this rule shall apply to import of morphine, codeine, thebaine and their salts by manufacturers notified by the Government, for use in manufacture of products to be exported or to imports of small quantities of morphine, codeine and thebaine and their salts not exceeding a total of 1 kilogram during a financial year for analytical purposes by any importer notified by the Government, after following the procedure under rule 55 and subject to such conditions as may be specified in the import certificate issued in Form No.4A.”

8. Amendment of rule 55. - In rule 55 of the said rules, -(1), in sub-rule (1), after the words letters and figure, “Form. No. 4” the words letters and figure, “or Form No.4A, as the case may be” shall be inserted.

(2) After sub-rule (3), the following sub-rule shall be inserted, namely:-

“(4) No import certificate shall be issued unless a fee of rupees one thousand has been paid.”

9. Amendment of rule 58:- In rule 58 of the said rules, after sub-rule (3), the following sub-rule shall be inserted, namely:-

“(4) No export authorisation shall be issued unless a fee of rupees one thousand has been paid.”

10. Insertion of rule 65A- After rule 65 of the said rules, the following rule shall be inserted, namely:-

“65A. - Sale, purchase, consumption or use of psychotropic substances. - No person shall sell, purchase, consume or use any psychotropic substance except in accordance with the Drugs and Cosmetics Rules, 1945 Rules.”

11. Insertion of new rules 67 D and 67E.- After rule 67C, the following Chapter and rules shall be inserted, namely:-

CHAPTER VIII

REPORTS, RETURNS AND ESTIMATES UNDER INTERNATIONAL CONVENTIONS

67D. Submission of reports and returns under international conventions. - (1) All reports and returns which are required to be submitted under any international convention, shall be submitted to an international agency by such officer the Central Government may, by notification in the Official Gazette, appoint in this behalf from time to time.

(2) The officer appointed under sub-rule (1), may call for such inputs as may be necessary to submit the returns under sub-rule (1), from the Narcotics Commissioner, the Chief Controller of Factories or any other officer of the Central Government or any State Government indicating the format in which the information is required and the time by which it is required.

(3) The officer from whom inputs have been called for under sub-rule (2), shall provide all inputs which are sought and which are available with him in the format in which it has been called for and within the time indicated in sub-rule (2) and shall also indicate the information not maintained by him or not available.

67E. Estimates and quotas.- (1) If, estimates of requirement of any narcotic drug have to be submitted under any international convention, resolution or commitment, the same shall be submitted to an international agency by such officer the Central Government may, by notification in the Official Gazette, appoint in this behalf from time to time.

(2) The estimates for use and consumption of narcotic drugs approved by international agencies for India shall be allotted as quotas to users within the country by such officer as may be notified by the Central Government by notification in the Official Gazette from time to time.

(3) The users to whom such quota is allotted shall not exceed the quota allotted to him and shall submit to the officer appointed under sub-rule (2), such statistics of consumption and use of the narcotic drugs and within such time as may be indicated by the officer.”

12. Insertion of new Form No.3A.- After Form No.3 of the said rules, the following Form shall be inserted, namely,-

Form No.3A

[See rule 36A]

Licence No..... Date of issue.....

M/s..... is hereby licenced to manufacture concentrate of poppy straw and the following manufactured drugs on the premises situated at.....

Name of the drug

Quantity

(i)

(ii)

(iii)

2. The licence shall be in force *from*..... *to*.....

The licence is subject to the conditions stated below and to such other conditions as may be specified in the rules for the time being in force under the Narcotic Drugs and Psychotropic Substances Act, 1985 (61 of 1985).

Date.....

Signature.....

Designation.....

Conditions of Licence

- (a) This licence shall not be transferable;
- (b) The licensee shall manufacture concentrate of poppy straw from the poppy straw produced in the fields licenced for the purpose;
- (c) This licence and any certificate of renewal in force shall be kept on the approved premises and shall be produced at the request of an officer detailed for the purpose by the Licencing Authority;
- (d) The licensee shall ensure that the drugs that he manufactures are as per the specifications laid down by or under the Drugs and Cosmetics Act, 1940;
- (e) The licensee shall, if he desires, submit applications for renewal of his licence at least thirty days before the expiry of his licence;

- (f) The licensee shall inform the Licencing Authority in writing in the event of any change in the constitution of the firm operating under the licence. Where any change in the constitution of the firm takes place, the current licence shall be deemed to be valid for a maximum period of three months from the date on which the change takes place or normal expiry of the licence whichever is earlier unless in the meantime, a fresh licence has been taken from the Licencing Authority in the name of the firm with the changed constitution;
- (g) The licensee shall be fully responsible to ensure the security of the factory premises and ensure that no diversion takes place in them;
- (h) The licensee should provide security equipment such as surveillance cameras and other facilities as may be specified by the Narcotics Commissioner to ensure security on the fields;
- (i) The licensee should report to the Narcotics Commissioner if he finds any farmer lancing or diverting;
- (j) The licensee shall keep the Central Bureau of Narcotics informed of all matters relating to cultivation, production, transport, etc. of poppy straw and changes in agricultural practices;
- (k) The licensee shall defray the cost of the Central Bureau of Narcotics staff posted to supervise the cultivation of opium for production of poppy straw and production of concentrate of poppy straw at such rates as may be decided by the Government from time to time;
- (l) The licensee shall notify well before the sowing season, the price which they are willing to pay for the pods;
- (m) The licensee should identify and enter into agreements with the farmers who are willing to cultivate opium poppy for production of poppy straw for sale to the licensee;
- (n) The farmers with whom the licensee has entered into agreements will be licenced to grow opium poppy subject to such verifications as may be felt necessary by the Narcotics Commissioner;
- (o) Such other conditions as may be specified by the Narcotics Commissioner from time to time.

13. Insertion of new Form No. 4A. - After Form No. 4 of the said rules, the following form shall be inserted, namely:

FORM.No.4A

[See rules 54 and 55]

(Official seal of the Issuing authority)

2676 GI/10-4

Official Seal of the Issuing Authority

S.No.....

F.No.....

MINISTRY OF FINANCE
(GOVERNMENT OF INDIA
(DEPARTMENT OF REVENUE)

CERTIFICATE OF OFFICIAL APPROVAL OF IMPORT UNDER THE PROVISIO
TO RULE 54

(The Narcotic Drugs and Psychotropic Substances rules, 1985)

_____, (The Issuing Authority) being empowered to issue Import
Certificate under the Narcotic Drugs and Psychotropic Substances Rules, 1985,
hereby, approves the importation into India of the following consignments of narcotic
drugs:

- (1) _____;
- (2) _____;
- (3) _____.

By M/s.....from M/s.....
..... to manufacture formulations for export/for analytical purposes (strike out
whichever is not applicable) subject to the following conditions:-

Conditions of import certificate

- (i) The consignment containing the drugs shall be imported before
_____ by _____ to (airport/sea-port) in India.
- (ii) If the import is for manufacture of formulations for export, the manufacturer
shall. -
 - (a) ensure that no part of the drug imported under this certificate shall be sold
or used to manufacture formulations for domestic sale;
 - (b) ensure that the formulations manufactured out of the drug imported
against this certificate shall not be diverted for domestic sale;

(c) furnish to the Narcotics Commissioner and the Drugs Controller General of India details of export of drugs on completion of export along with documentary evidence such as shipping bills, bills of lading and invoices;

(d) obtain transport permit from their State Excise authority/State Food and Drugs Administration permitting transport of their consignment from port of entry to the factory premises;

(e) maintain separate accounts of actual quantity of narcotic drug imported, formulations produced, consignments dispatched and the quantity lying in balance;

(f) submit a monthly return of receipt/import, consumption and export of the narcotic drug to the Narcotics commissioner;

(g) follow the procedures prescribed in rules 42, 45, 46 and 47 for security arrangements, maintenance of accounts and submission of returns, possession, sale and distribution of formulations manufactured from the drugs imported under this certificate.

3. Any quantity of morphine, codeine, thebaine and their salts or finished formulations for export that have not been utilized shall be surrendered to the Government Opium and Alkaloids Works.

4. This document is for _____ (The authority to whom and the purpose for which it is being sent to be indicated).

5. The certificate is not valid unless it bears the Official Seal of the Issuing Authority on the top right hand corner.

[F. No. N-11012/1/2009-NC-II]

SATYA NARAYANA DASH, Under Secy.

Note : Principal notification was published in the Gazette of India Part II, Section 3, Sub-section(i) vide No.G.S.R.837 (E), dated 14th November, 1985 and subsequently amended vide notifications G.S.R. 639(E) dated 13th October, 1985 S.O.786 (E) dated 26th October.1992, S.O.599 (E) dated 10th August.1993, G.S.R.748(E) dated 14th December,1993,G.S.R 543 dated 24th October,1994, G.S.R.82 dated 14th February,1995, G.S.R 556(E)dated 14th July.1995, G.S.R.25(E) dated 12th January.1996, G.S.R.509(E) dated 4th November.1996, G.S.R 350(E) dated 25th June.1997, G.S.R 214(E) 19th March.2002, G.S.R 763(E) dated 14th November,2002, GSR 115(E) dated 21st February.2003, G.S.R 129(E) dated 26th February.2003, G.S.R.217(E) dated 17th March.2003, G.S.R 95(E) dated 4th February,2004, G.S.R.736(E) dated 22nd December.2005, G.S.R.639[E] dated 13th October.2006, and G.S.R.2[E] dated First February.2008.