रजिस्ट्री सं. डी.एल.- 33004/99 REGD. No. D. L.-33004/99

भारत का राजपत्र
The Gazette of India

सी.जी.-डी.एल.-अ.-06062020-219795
CG-DL-E-06062020-219795

असाधारण
EXTRAORDINARY
भाग II—खण्ड 3—उप-खण्ड (i)
PART II—Section 3—Sub-section (i)

प्राधिकार से प्रकाशित
PUBLISHED BY AUTHORITY

सं. 275] नई दिल्ली, शुक्रवार, जून 5 , 2020/ज्येष्ठ 15, 1942
No. 275] NEW DELHI, FRIDAY, JUNE 5, 2020/JYAISHTHA 15, 1942

स्वास्थ्य एवं परिवार कल्याण मंत्रालय

(स्वास्थ्य एवं परिवार कल्याण विभाग)

अधिसूचना

नई दिल्ली, 5 जून, 2020

सा.का.नि. 354(अ).—नई औषधि और नैदानिक परीक्षण नियम, 2019 का संशोधन करने के लिए कतिपय नियमों के निम्नलिखित प्रारूप, जिसे केंद्रीय सरकार औषधि तकनीकी सलाहकार बोर्ड के परामर्श से औषधि और प्रसाधन सामग्री अधिनियम, 1940 (23 के 1940) की धारा 12 की उप-धारा (1) और धारा 33 की उप-धारा (1) द्वारा प्रदत्त शक्तियों का प्रयोग करते हुए, इसके द्वारा प्रभावित होने की संभावना वाले सभी व्यक्तियों की जानकारी के लिए प्रकाशित किया जाता है और एतद् द्वारा सूचना दी जाती है कि उक्त प्रारूप नियमों पर उस तारीख से पंद्रह दिनों की अवधि समाप्त होने पर या उसके बाद विचार किया जाएगा जिस तारीख को इन प्रारूप नियमों को अन्तर्विष्ट करने वाली भारत के राजपत्र की प्रतियां जनता को उपलब्ध कराई जाएगी;

केंद्रीय सरकार द्वारा उपर्युक्त निर्दिष्ट अवधि के भीतर किसी भी व्यक्ति से प्राप्त होने वाली आपत्तियों और सुझावों पर विचार किया जाएगा;

आपत्तियां और सुझाव, यदि कोई हों, तो अवर सचिव (औषधि), स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार, कमरा सं. 414ए, डी विंग, निर्माण भवन, नई दिल्ली - 110011 को अग्रेषित किया जाए अथवा drugsdiv-mohfw@gov.in पर ई-मेल किया जाए।

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 5th June, 2020

G.S.R. 354(E).—The following draft of certain rules to amend the New Drugs and Clinical Trials Rules, 2019 which the Central Government proposes to make, in exercise of the powers conferred by sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) and in consultation with the Drugs Technical Advisory Board is hereby published for information of all persons likely to be affected thereby and notice is hereby given that the said draft rules shall be taken into consideration on or after the expiry of a period of fifteen days from the date on which the copies of the Gazette of India containing these draft rules are made available to public;

Objections and suggestions which may be received from any person within the period specified above will be considered by the Central Government;

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 emailed at drugsdiv-mohfw@gov.in.

DRAFT RULES

1. (1) These rules may be called the New Drugs and Clinical Trials (.....Amendment) Rules, 2020.
   (2) They shall come into force on the date of their final publication in the Official Gazette.
2. In the New Drugs and Clinical Trials Rules, 2019,
   A. In CHAPTER XI, after rule 96, the following shall be inserted, namely:—
   "**96A**. **Application for import of unapproved new drug for Compassionate use for treatment of patients by hospitals or and medical institution**
   1) Notwithstanding anything contained in these rules, a medical officer of a hospital or medical institution may import new drug for compassionate use for treatment of patients suffering from life threatening disease or disease causing serious permanent disability or disease requiring therapy for unmet medical need, which has not been permitted in the country under Chapter X of these rules, but under Phase-III clinical trial in the country or in any other country, by making an application duly certified by the Medical Superintendent of the hospital or Head of the medical institution, as the case may be, to the Central Licensing Authority in Form CT-28
   2) The application under sub-rule (1) shall be accompanied by such other particulars and documents as are specified in Form CT- 28.
   3) The application under sub-rule (1) shall be accompanied by the following details:
      (i) The rationale for the use of the new drug as compassionate use over the available therapeutic options;
      (ii) The criteria for patient selection with description of the patient's disease or condition, including recent medical history and previous treatments of the disease or condition;
      (iii) The method of administration of the drug, dose, and duration of therapy;
      (iv) A description of the manufacturing facility;
      (v) Chemistry, manufacturing, and controls (CMC) information adequate to ensure the proper identification, quality, purity, and strength of the drug;
      (vi) Pharmacology and toxicology information adequate to conclude that the new drug is reasonably safe at the dose and duration proposed for compassionate use, and
      (vii) A description of clinical procedures, laboratory tests, or other monitoring necessary to evaluate the effects of the drug and minimize its risks.

96B.Grant of licence for import of new drug for compassionate use:

The Central Licencing Authority may, after scrutiny of information and documents enclosed with the application and such further enquiry, if any, as considered necessary,-

(i) if satisfied, that the requirements of these rules have been complied with, grant permission to import new drug but under clinical trial for compassionate use in Form CT-29;

(ii) if not satisfied with the requirements as referred to in clause (i), reject the application, for reasons to be recorded in writing, within a period of thirty days, from the date of application made under rule 96A.

1) An applicant who is aggrieved by the decision of the Central Licencing Authority under sub-rule (1), may file an appeal before the Central Government within forty-five days from the date of receipt of such rejection and that Government, may, after such enquiry, and after giving an opportunity of being heard to the appellant, dispose of the appeal within a period of sixty working days from the date of filing the appeal.

2) The quantity of any single drug imported on the basis of licence granted under sub-rule (1), shall not exceed one hundred average dosages per patient but in exceptional circumstances and on being satisfied about the necessity and exigency the Central Licencing Authority may allow import of new drugs in larger quantities depending on the condition and requirement of such patient.

96C. Conditions of licence:

1) The import licence granted under rule 96B in Form CT-29 shall be subject to the following conditions, namely:-

(i) The licence shall remain valid for a period of one year from the date it has been issued;

(ii) The licence shall be displayed in the premises of the medical institution including where the new drug is being stocked and used in the office of the Medical Superintendent of the hospital or Head of the medical institution;

(iii) the licencee shall stock the new drug imported under this licence under proper storage conditions;

(iv) the new drug imported under this licence shall be exclusively used for compassionate use;

(v) the registered pharmacist shall maintain a record as specified in Annexure of Form CT-29, countersigned by the Medical Superintendent of the hospital or Head of the medical institution which shall be produced, on demand by the officer authorised by the Central Licencing Authority under these rules;

(vi) the hospital or medical institution referred to in sub-rule (1) of rule 96A, shall submit to the Central Licencing Authority a quarterly_report about the status and stock of new drugs imported, utilized and destroyed;

(vii) where the new drugs imported under licence granted under sub-rule (1) of rule 96B, are left over or remain unused or get damaged or its specified shelf life has expired or has been found to be of sub-standard quality, the same shall be destroyed and the action taken in respect thereof be recorded as referred to in clause (iv) by the registered pharmacist.

96CA.Suspension or cancellation of license to import new drug for the purpose of compassionate use:

(1) Where an importer to whom the license is granted under rule 96B fails to comply with any provision of the Act and these rules, the Central Licencing Authority, may, after giving an opportunity of being heard, by an order, in writing, suspend or cancel the license for such period as considered appropriate either wholly or in respect of some of the substances to which the violation relates.

(2) Where the manufacturer whose license is suspended or cancelled under sub-rule (1) is aggrieved by an order of the Central Licencing Authority, he may, within a period of forty-five days from the receipt of the order, make an appeal to the Central Government in respect of suspension or cancellation of the license and that Government, may, after such enquiry, as deemed necessary and after affording an opportunity of being heard, pass such orders in relation thereto as considered appropriate.

96D. Application for the permission to manufacture new drug for Compassionate use:

1) Where any medical officer of a hospital or medical institution prescribes a new drug for compassionate use for treatment of patients suffering from life threatening disease or disease causing serious permanent disability or disease requiring therapy for unmet medical need, which has not been permitted in the country under Chapter X of these rules, but under Phase-III clinical trial in the country or in any other country, then, such new drug may be approved to be manufactured in limited quantity subject to provisions of these rules.

2) Where any manufacturer intends to manufacture new drug referred to in sub-rule (1), he shall obtain the consent in writing from the patient to whom the new drug has been prescribed under sub-rule (1) or his legal heirs and make an application to the Ethics Committee of the hospital or medical institution, as the case may be, for obtaining its specific recommendation for manufacture of such new drug.

3) After obtaining the recommendation of the Ethics Committee under sub-rule (2), the manufacturer shall make an application in Form CT-30 to obtain the permission, to the Central Licencing Authority for manufacturing the new drug for the purpose of compassionate use.

4) The application under sub-rule (3) shall be accompanied by consent in writing from the patient referred to in sub-rule (2) or his legal heirs regarding use of such new drug and such other particulars and documents as are specified in Form CT-30.

5) The application under sub-rule (3) shall be accompanied by the following details:

(i) The rationale for the use of the new drug as compassionate use over the available therapeutic options;

(ii) The criteria for patient selection viz. description of the patient's disease or condition, including recent medical history and previous treatments of the disease or condition;

(iii) The method of administration of the drug, dose, and duration of therapy;

(iv) A description of the manufacturing facility;

(v) Chemistry, manufacturing, and controls (CMC) information adequate to ensure the proper identification, quality, purity, and strength of the drug;

(vi) Pharmacology and toxicology information adequate to conclude that the investigation new drug is reasonably safe at the dose and duration proposed for compassionate use and

(vii) A description of clinical procedures, laboratory tests, or other monitoring necessary to evaluate the effects of the drug and minimize its risks.

96E.Grant of the permission to manufacture new drug for Compassionate use:

(1) The Central Licencing Authority may, after scrutiny of information and documents enclosed with the application and such further enquiry, if any, as considered necessary,-

(i) if satisfied, that the requirements of these rules have been complied with, grant permission to manufacture new drug or compassionate use in Form CT-31;

(ii) if not satisfied with the requirements as referred to in clause (i), reject the application, for reasons to be recorded in writing, within a period of thirty days, from the date of application made under rule 96D.

(2) The quantity of any single new drug manufactured on the basis of permission granted under sub-rule (1) shall not exceed one hundred average dosages per patient but in exceptional circumstances on the basis of the prescription of the medical officer referred to in sub-rule (1) and the recommendation of the Ethics Committee, the Central Licencing Authority may allow the manufacture of such new drug in larger quantity.

96F. Condition of permission: The permission granted under rule 96E in Form CT-31, is subject to the following conditions, namely:-

(i) The permission shall remain valid for a period of one year from the date it has been issued;

(ii) the patient(s) to whom the unapproved new drug is prescribed under sub-rule (1) of rule 96E shall use such new drug under the supervision of the medical officer at the place specified in the permission or at such other places, as the Central Licencing Authority may authorise;

(iii) the manufacturer to whom the permission is granted under sub-rule (1) of rule 96E, shall make use of the new drug only for the purposes specified in the permission and no part of it shall be sold in the market or supplied to any other person, agency, institution or place;

(iv) the manufacturer referred to in clause (iii) shall keep record of the new drugs manufactured, stored and supplied by him to the patient in a register in the format as specified in annexure of Form CT-31

(v) the manufacturer referred to in clause (iii), shall submit to the Central Licencing Authority a quarterly report about the status of the new drugs manufactured, supplied to the authorized patient;

(vi) the manufactured new drugs shall be kept and stored in accordance with the storage conditions specified on its label and supplied to the patient under the supervision of the medical officer referred to in sub-rule (1) of rule 96D or a registered pharmacist duly authorised by him;

(vii) the registered pharmacist shall maintain a record of the full name and address of the patients, diagnosis, dosage schedule, total quantity of drugs received and issued, countersigned by the Medical Superintendent of the hospital or Head of the medical institution which shall be produced, on demand by the officer authorised by the Central Licencing Authority under the Act;

(viii) where the new drug manufactured in accordance with the permission issued under sub-rule (1) of rule 96E, is left over or remain unused or get damaged or its specified shelf life has expired or has been found to be of sub-standard quality, the same shall be destroyed by the manufacturer and the action taken in respect thereof shall be recorded;

(ix) the permission holder shall inform the Central Licencing Authority of the occurrence of any serious adverse event and action taken thereon including any recall within fifteen days of occurrence of such event.

96G. Inspection of manufacturing site of new drug for the purpose of compassionate use:

(1) The manufacturer referred to in rule 96E, shall allow persons authorized by the Central Licencing Authority including the person authorised by the State Licencing Authority to enter the premises where the new drug is being manufactured, stored and supplied, with or without prior notice, to inspect such premises and records, investigate the manner in which the new drug is being manufactured, supplied and to take sample thereof.

96H. Suspension or cancellation of permission to manufacture new drug for the purpose of compassionate use:

(1) Where the manufacturer to whom permission is granted under rule 96E fails to comply with any provision of the Act and these rules, the Central Licencing Authority, may, after giving an opportunity of being heard, by an order, in writing, suspend or cancel the permission for such period as considered appropriate either wholly or in respect of some of the substances to which the violation relates.

(2) Where the manufacturer whose permission is suspended or cancelled under sub-rule (1) is aggrieved by an order of the Central Licencing Authority, he may, within a period of forty-five days from the receipt of the order, make an appeal to the Central Government in respect of suspension or cancellation of the permission and that Government, may, after such enquiry, as deemed necessary and after affording an opportunity of being heard, pass such orders in relation thereto as considered appropriate.

96I. Licence to manufacture new drug for compassionate use under the Drugs and Cosmetics Rules, 1945:

(1) After obtaining permission under rule 96E, the person intending to manufacture a new drug for compassionate use, shall make an application for grant of licence to manufacture the new drug under the provisions of the Act and the Drugs and Cosmetics Rules, 1945.

(2) The application referred in sub-rule (1) shall be accompanied by the permission in Form CT-31 obtained by the applicant from the Central Licencing Authority to manufacture the new drug.

Explanation: For the purpose of these rules, compassionate use means use of new drug, which has not been permitted in the country under Chapter X of these rules, but under Phase-III clinical trial in the country or in any other country, for diagnosis, treatment, mitigation or prevention any life threatening disease or disease causing serious permanent disability or disease requiring therapy for unmet medical need under a treatment protocol."

B. In the EIGHTH SCHEDULE, after the Form CT-27, following shall be inserted, namely:-

"**FORM CT-28**

APPLICATION FOR GRANT OF LICENCE TO IMPORT NEW DRUG FOR COMPASSIONATE USE BY HOSPITAL OR MEDICAL INSTITUTION

I/We, ...*(name and address of the applicant)* of M/s ..... hereby apply for grant of licence to import new drug for compassionate use or expanded access in a hospital or medical institution.

The details of the application are as under:

1. Name of Medical officer/Applicant:	
2. Nature and constitution of applicant: (proprietorship, partnership including limited liability partnership, company, society, trust, other to be specified) (Hospital or Medical Institution)	
3.(i) Corporate or registered office address including telephone number, mobile number, fax number and e-mail id: (ii) Applicant's address including telephone number, mobile number, fax number and e- mail id: (iii) Address for correspondence:	
4. Details of new drugs to be imported [As per Annexure].	
5. Particulars of overseas Manufacturer, Manufacturing sites [As per Annexure].	
6. Details of the patient and disease [As per Annexure].	
7. I hereby state and undertake that: (i) I shall comply with all the provisions of the Drugs and Cosmetics Act, 1940 and Chapter IX of the New Drugs and Clinical Trials Rules, 2019. (ii) The new drug to be imported from M/s..... shall be used exclusively for the purpose of compassionate use and no part of it shall be diverted to the domestic market. 8. A legal undertaking stating that the unapproved new drug to be imported shall be used for the treatment of the patient for the disease mentioned below only and no part of it shall be sold in the market is enclosed herewith.	

Place:

Digital Signature

Date:

(Name and designation)

Annexure:

Details of new drug:

Names of the new drug:	
Therapeutic class:	
Dosage form:	
Composition:	
Indications:	
Quantity:	

Details of manufacturer and manufacturing site:

Name and address of manufacturer (full address with telephone, fax and e-mail address of the manufacturer)	
Name and address of manufacturing site (full address with telephone, fax and e-mail address of the manufacturing site)	

Details of patient:

Name of the patient:	
Disease name:	

Certificate

Certified that the unapproved new drug specified above for import is urgently required for the treatment of patients suffering from ..... and that the said drug is not available in India.

Place..... Signature

Date..... Medical Superintendent of the Government Hospital or Head of Medical Institution

[Stamp]

FORM CT-29

LICENCE TO IMPORT NEW DRUG FOR THE PURPOSE OF COMPASSIONATE USE BY HOSPITAL OR MEDICAL INSTITUTION

Licence Number:_____

The Central Licencing Authority hereby grants licence to_____ (Name and full address with contact details of the applicant) to import new drug as per protocol number dated_____ for compassionate use in the _____ (Name and full address with contact details of the Hospital) . [As per Annexure].

2. This licence is subject to the conditions prescribed in Chapter IX of the New Drugs and Clinical Trials Rules, 2019.

3. This licence shall, unless previously suspended or revoked, be in force for a period of one year from the date of its issuance.

4. Details of overseas manufacturer and manufacturing site under this licence.

Serial number	Name and address of manufacturer (full address with telephone, fax and e-mail address of the manufacturer)	Name and address of manufacturing site (full address with telephone, fax and e-mail address of the manufacturing site)

5. The licencee shall maintain the record of imported new drugs [As per Annexure].

Place: .....

Date: .....

Central Licencing Authority

Stamp

Annexure:

Details of clinical trial site or bioavailability or bioequivalence study centre:

Names and address:	
Ethics committee details:	
Name of investigator:	

FORM CT-30

APPLICATION FOR GRANT OF PERMISSION TO MANUFACTURE NEW DRUG FOR COMPASSIONATE USE OR EXPANDED ACCESS

I/We, ...*(name and full address of the applicant)* of M/s ..... hereby apply for grant of permission to manufacture new drug for compassionate use in hospital or medical institution.

The details of the application are as under:

1. Name of Medical officer/Applicant:	
2. Nature and constitution of applicant: (proprietorship, partnership including limited liability partnership, company, society, trust, other to be specified) (Hospital or Medical Institution)	
3.(i) Corporate or registered office address including telephone number, mobile number, fax number and e-mail id: (ii) Manufacturer's address including telephone number, mobile number, fax number and e- mail id:	

(iii) Address for correspondence:	
4. Details of new drugs to be manufactured [As per Annexure].	
5. Particulars of overseas Manufacturer, Manufacturing sites [As per Annexure].	
6. Details of the Medical officer and Government Hospital and Medical Institution.	
7. Copy of recommendation of the ethics committee and consent from the patient in accordance with Rule 81 of the Regulation of New Drugs and Clinical Trials Rules 2019 are hereby enclosed.	
8. A legal undertaking stating that the new drug to be manufactured shall be used for the Purpose of compassionate use of the patient for the disease mentioned below only and no part of it shall be sold in the market is enclosed herewith.	

Place:

Digital Signature

Date: (Name and designation)

Annexure:

Details of new drug:

Names of the new drug:	
Therapeutic class:	
Dosage form:	
Composition:	
Indications:	
Quantity:	

Details of manufacturer and manufacturing site:

Name and address of manufacturer (full address with telephone, fax and e-mail address of the manufacturer)	
Name and address of manufacturing site (full address with telephone, fax and e-mail address of the manufacturing site)	

Details of the government hospital or government medical institution and patient:

Name of the hospital or medical institution:	
Address of the hospital or medical institution:	
Name and address of the patient:	
Disease name:	

Certificate

Certified that the new drug specified above for manufacture is urgently required for the compassionate use in patients suffering from ..... and that the said drug is not available in India.

Place..... Signature

Date..... Medical Superintendent of the Government Hospital or Head of Medical Institution

[Stamp]

FORM CT-31

PERMISSION TO IMANUFACTURE NEW DRUG FOR THE PURPOSE OF COMPASSIONATE USE

Licence Number:_____

The Central Licencing Authority hereby grants permission to_____ (Name and full address with contact details of the applicant) to manufacture new drug as per protocol number dated_____ for compassionate use use in the _____ (Name and full address with contact details of the Hospital) . [As per Annexure].

2. This licence is subject to the conditions prescribed in Chapter XI of the New Drugs and Clinical Trials Rules, 2019 under the Drugs and Cosmetics Act,1940

3. This licence shall, unless previously suspended or revoked, be in force for a period of one year from the date of its issuance.

4. Details of manufacturer and manufacturing site under this permission.

Serial number	Name and address of manufacturer (full address with telephone, fax and e-mail address of the manufacturer)	Name and address of manufacturing site (full address with telephone, fax and e-mail address of the manufacturing site)

5. The licencee shall maintain the record of the new drugs manufactured. [As per Annexure].

Place: ..... Central Licencing Authority

Date: ..... Stamp

Annexure:

Details of new drug manufactured:

Names and address:	
Ethics committee details:	
Name of investigator:	

Details of unapproved new drug manufactured:

Serial number	Date of manufacture	Licence number	Name of the new drug	Quantity manufactured

Details of record of patient history:

Licence number	Name of the new drug	Patient name	Diagnosis detail with date	Disease name	Dosage schedule

Details of reconciliation of new drug manufactured:

Date	Name of the new drug	Licence No.	Quantity manufactured	Quantity supplied	Quantity Remained	Supplied to	Quantity – left over or remain unused or got damaged or expired or found of sub standard quality	Action taken

”

[F. No. X.11035/167/2020-DR]

Dr. MANDEEP K BHANDARI, Jt. Secy.

Note: The principal rules were published in the Gazette of India *vide* notification number G.S.R. 227(E), dated the 19th March, 2019.

Uploaded by Dte. of Printing at Government of India Press, Ring Road, Mayapuri, New Delhi-110064
and Published by the Controller of Publications, Delhi-110054.