PROCEDURE RELATED TO SPECIAL PERMISSION FOR MEDICINE, 2074

For a situation in which a drug is not registered in Nepal but its unavailability poses a risk to the life of a patient, difficulty in treatment, problem in the diagnosis of a disease and may lead to permanent disability, this procedure has been made and implemented pursuant to Good Governance (Management and Operations) Rule, 2065, Rule (9), as it is desirable to make a transparent and clear process for the approval of an import of a drug urgently required for the treatment of a patient, and manage it according to the objective of Drugs Act, 2035, and Drug Registration Rules, 2038.

CHAPTER – 1

Preliminary

1. Short Title and Commencement:

   (1) The name of the procedure is Procedure Related to Special Permission for Medicine, 2074.

   (2) This Procedure shall be in effect from the date of its issue.

2. Definition: Unless the subject or the context means otherwise:

   (A) "Ministry" means the Ministry of Health.

   (B) "Department" means the Department of Drug Administration.

   (C) "Act" means Drugs Act, 2035.

   (D) "Rule" means Drugs Registration Rules, 2038.

   (E) "Committee" means Drug Advisory Committee.

   (F) "Drug" means a substance according to Drugs Act, 2035, Section 2 (A).

   (G) "Special permission" means an approval issued by the Department to import a drug not registered with the Department, but is urgent for a patient.

   (H) "Physician" means a physician registered with the council established according to the law.

   (I) "Drug Evaluation Committee" means a committee constituted according to Section 3.

   (J) "Hospital Pharmacy and Therapeutic Committee" means a committee constituted according to Procedure Related to Hospital Pharmacy Operation, 2072, Section 3.

   (K) "Inspector" means a person qualified according to Drugs Act, 2035, Section 23.

CHAPTER – 2

Drug Evaluation Committee Formation and Function

3. Formation of Drug Evaluation Committee: The Drug Evaluation Committee will constitute the following members to submit its opinion before the Department following a scientific and factual study related to a drug's safety, efficacy, quality and use:

(A)	Division Chief, Management Division Coordinator	
(B)	Senior Quality Controller, National Drug Laboratory	Member
(C)	Division Chief, Registration Division	Member
(D)	Division Chief, Inspection Division	Member
(E)	Senior Pharmacist or Pharmacy Officer nominated by the Director General of the Department	Member-Secretary

A subject matter expert or an employee of the Department working in a relevant section may be invited to join this Committee as an invitee.

4. Committee's Function, Duty and Power: The Committee's function, duty and power shall be as the following.

   (1) For a request for a special permission received from a hospital's Pharmacy and Therapeutic Committee for a new drug, a new combination of drugs and a new dosage form not registered at the Department, for the use for a patient, recommend the Department the said drug with comparative benefit (usefulness, public safety, effectiveness, quality, price suitability, availability).

   Explanation: "New drug" means a new drug that is not registered at the Department, that which is registered at the Department but because it is intended for a new indication, has a new dosage form, new dosage and new route of administration, and that which is registered at the Department as separate formulations but now appear as a fixed dose combination.

   (2) For a request received from a hospital's Pharmacy and Therapeutic Committee for a drug that is registered at the Department, but cannot be imported and made available through a regular process but is very necessary for treatment, recommend the Department on whether a special permission is to be issued or not following the evaluation of the said drug's comparative benefit (usefulness, public safety, effectiveness, quality, price suitability, availability).

   (3) Recommend the Department on a process related to registration or a solution to an existing procedural ambiguity.

   (4) Since the function of this Committee is to provide a recommendation and suggestion to the Department, a decision of this Committee shall only be effective after it is verified by the Director General of the Department.

CHAPTER – 4

Arrangement Regarding Application and Recommendation for Special Permission

5. Arrangement regarding application for special permission:

   (1) A person (importer) can submit an application requesting for a special permission for use for a patient, a drug not registered at the Department, a new combination of drugs, a new dosage form, or a drug registered at the Department but in short supply in the market, with a recommendation from a concerned hospital's Pharmacy and Therapeutic Committee, along

with the drug's comparative benefit (usefulness, public safety, effectiveness, quality, price suitability, availability) and documents according to Schedule 1.

(2) An application registered pursuant to Sub-section (1), must be submitted with the following documents attached along with:

(a) Drug's Summary of Product Characteristics (SPC)

(b) Exporting country and details regarding the drug's registration and use in other countries.

(c) Details of therapeutic benefits and risks over the existing drug.

(d) Details of cost benefit over existing registered drug.

(e) Two levels of prices: Import price and Maximum Retail Price (MRP)

(f) Other scientific reference materials (relevant unbiased scientific research articles, clinical trial reports, etc.).

6. If various government as well as non-government bodies and organisations receive a drug not registered at the Department, then staying within Drug Donation Guideline, an application mentioning quantity, an organization distributing the drug, mode of distribution, etc., may be submitted to the Department.

7. If a situation for a shortage of an essential drug develops or a shortage is likely to happen due to a special dire circumstance such as a natural disaster, epidemic, an application for a special permission of the drug may be submitted. In this situation, the number of patients determined by the Department will not be applicable.

8. For a drug not registered in Nepal but has been recommended by the Physician as necessary for a patient, an application for a special permission with a prescription attached and a recommended quantity mentioned, needs to be submitted to the Department.

9. If a drug not registered at the Department is to be received by any government or non-government body or organisation through an international competitive bidding, an application with procurement-related documents attached needs to be submitted.

CHAPTER – 5

Arrangement Regarding Approval of Special Permission

10. To be Recommended by the Evaluation Committee: For an application registered as per Section 5 (1), the Evaluation Committee shall recommend to the Department after evaluating a drug on the basis of its comparative benefit (usefulness, public safety, effectiveness, quality, price suitability, availability).

11. To Publish Notice: After the Evaluation Committee submits its recommendation as per Section (10), the Department shall publish a seven-day (7) public notice about the recommended drug's name, quantity, importer, manufacturer, recommending hospital, price on the Department's noticeboard and website for the purpose of informing everyone concerned.

12. Based on the recommendation of the Evaluation Committee as per Section (10), the Department is to provide a special permission according to the format given in Schedule (2) for only the quantity required for a maximum of 100 patients as defined in a treatment protocol.

13. In relation to an application received as per Section (6), (7), (8) and (9), a special permission according to Schedule (2) may be provided after a Departmental decision is made following the completion of a process from the Registration Division as per Drug Registration Rules, 2038, Rule 4 (B), Sub-rule 4.

14. A special permission provided as per Section (12) must be endorsed by a meeting of the Drug Advisory Committee.

15. The drug's consumer price must not exceed its maximum retail price in its exporting country.

16. Validity of Special Permission Letter: A special permission issued by the Department shall be valid only for the fiscal year in which it has been issued.

CHAPTER – 6

Condition for Issuing Special Permission

17. Except when not prohibited by Section (25) of the Act, a special permission for new drugs as defined in Schedule (1) for a quantity required for the purpose of treating patients may only be provided under the following condition:

    (1) A drug to be imported must be registered in the exporting country.

    (2) A drug to be imported is essential for the treatment of a patient's disease and is an alternative to the drug (in terms of usefulness, public safety, effectiveness and price suitability) is not registered in Nepal or is in shortage.

    (3) A concerned drug must be used under the supervision of a concerned Physician of a recommending hospital, however, under a special circumstance, if recommended by the Physician, with a permission from the Department, it may be used in another hospital as well.

    (4) The Inspector appointed by the Department to inspect an area where the drug is stored, details regarding distribution, etc., must be allowed to conduct an inspection without any hindrance.

CHAPTER – 7

Condition When Special Permission are Not Provided

18. A special permission shall not be provided when an application for a special permission has been submitted according to Section (5), Sub-section (1), but the Evaluation Committee cites that a special permission for the requested drug is not necessary as a comparative benefit of the said drug is not established.

19. A special permission shall not be provided for any drug that is manufactured by a domestic drug manufacturer.

20. A special permission shall not be provided for a drug that is registered at the Department, but cannot be imported through a regular processes due to a special circumstance, when the same drug of another manufacturer is registered at the Department and is available in the market.

Miscellaneous

21. The importer must keep full details (imported quantity, date of import, name of the manufacturer, price of the drug, name and address of a patient to whom the drug has been distributed, name of the disease) updated and must submit the details the Department every three (3) months.

22. Notwithstanding what has been stated in Section (20), in case there is problem with the supply of certain lifesaving drugs registered at the Department because their manufacturers have changed, there shall not be any problem to provide permissions to import such drugs mandated by the Drug Advisory Committee from time to time.

SCHEDULE – 1

Application for Special Permission

Date:

Mr. Director General,
Department of Drug Administration, Bijulibazar.

Subject: Request for Special Permission

Since the new drugs detailed below are urgently required for the patients undergoing treatment at ……. Hospital Teaching Hospital/Medical College/Nursing Home for …….. disease, I hereby submit an application for a special permission with necessary documents.

S. No.	Drug's Name	Drug's Active Ingredient	Manufacturing Company's Name and Address	Required Quantity	Import Price	Drug's Maximum Retail Price (MRP)

Applicant

SCHEDULE – 2

Format of Special Permission

Date: ……

Mx. …… Department of Customs,

For treatment of patients undergoing treatment at …….. Hospital/Teaching Hospital/Medical College/Nursing Home being treated for …… disease, …….. Hospital/Teaching Hospital/Medical College/Nursing Home or the importer named …… is given a permission to import the drug(s) detailed below as per the decision of the Department dated …… The validity of this permission letter shall be till the current fiscal year.

S. No.	Drug's Name	Drug's Active Ingredient	Manufacturing Company's Name and Address	Quantity	MRP

Permission letter issuing official's

Signature: ……
Name: ……..
Post: ……...…….