

Drugs Advisory Council and Drugs Advisory Committee Formation Rules, 2037(1970)

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In exercise of the powers conferred by Section 40 of the Drugs Act, 2035(1978), Government of Nepal has framed the following Rules.

1. **Short title and commencement:** (1) These Rules may be called as the “Drugs Advisory Council and Drugs Advisory Committee Formation Rules, 2037(1970).”
(2) These Rules shall come into force immediately.
2. **Definitions:** Unless the subject or the context otherwise requires, in this Regulation:
 - (a) “Act” means the Drugs Act, 2035(1978).
 - (b) “Council” means the Drugs Advisory Council formed pursuant to Rule 3.
 - (c) “Committee” means the Drugs Advisory Committee formed pursuant to Rule 5.
3. **Formation of Drugs Advisory Council:** (1) For the purposes of Section 3 of the Act, there shall be formed a Drugs Advisory Council consisting of the following members:
 - (a) Honorable Minister for Forests or Chairperson
Minister of State for Forests
 - (b) Member, National Planning Member
Commission
 - (c) Secretary, Ministry of Forests Member

- (d) Secretary, Ministry of Finance Member
- (e) Secretary, Ministry of Health Member
- (f) Secretary, Ministry of Industry and Commerce Member
- (g) Chief, Drugs Research Laboratory Member
- (h) Three persons nominated by Government of Nepal from amongst the persons having knowledge on drugs Member
- (i) Administrator, Department of Drugs Administration of Member Secretary

(2) The term of office of the members nominated pursuant to Clause (h) shall be Three years; and Government of Nepal may, if it so wishes, re-nominate them or remove them from office even prior to expiration of their term of office.

(3) The Council may, if it considers necessary, invite any native or foreign expert or any officer to attend as an observer the meeting of the Council.

(4) Government of Nepal may, if it considers necessary, make alteration or changes in the number of members, by a Notification publishes in the Nepal Gazette.

- 4. Functions, duties and powers of Council:** (1) It shall be the duty of the Council to provide advice to the Government of Nepal on theoretical and administrative matters relating to drugs, taking into account of the main object to protect the national interest and make the country self-reliant by checking the import based production process and being more dependent on indigenous herbs etc.

(2) In addition to providing advice pursuant to Clause (1), the Council may also provide advice to the Government of Nepal on the following matters:

- (a) To formulate required policies on, inter alia, the development, research, production, sale, distribution, consumption, export and import of the drugs,
- (b) To formulate programme corresponding to the determined policies,
- (c) To make provision of administrative and technical matters for the implementation of the formulated programme,
- (d) To make coordination and harmonization amongst various offices of the Government of Nepal,
- (e) To fix price of drugs,
- (f) To fix basic matters on patents of drugs,
- (g) To prohibit the production, sale, distribution, storage and transportation of any drugs,
- (h) To give recognition to any native or foreign research laboratory or laboratory, if so required, for purposes of test or analysis of drugs and similar other activities,
- (i) To take necessary action on complaints filed with the Government of Nepal on drug related matters,
- (j) To implement the Act or the rules framed under the Act or to resolve problems that come across in the course of implementation.

5. **Formation of Drugs Advisory Committee:** (1) For the purposes of Section 4 of the Act, there shall be formed a Drugs Advisory Committee consisting of the following members:

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| (a) Secretary at the Ministry for Forests | Chairperson |
| (b) Administrator, Department of Drug Administrator | Member |
| (c) Director General, Department of Health Services | Member |
| (d) Director, Nepal Standards Fixation Committee | Member |
| (e) Chief, Drugs Research Laboratory | Member |
| (f) Representative, Ministry of Law and Justice | Member |
| (g) Representative, Nepal Medical Association | Member |
| (h) Representative, Nepal Pharmaceutical Association | Member |
| (i) Representative, Chemists and Druggists Association | Member |
| (j) Three persons nominated by Government of Nepal from amongst the persons having gained knowledge on drugs | Member |
| (k) One senior officer designated by the Department of Drug Administration | Member Secretary |

(2) The term of office of the members nominated pursuant to in Clause (j) of sub-rule (1) shall be Three years; and Government of Nepal may, if it so wishes, re-nominate them or remove them from office even prior to expiration of their term of office.

(3) The Committee may, if it considers necessary, invite any native or foreign expert or any officer to attend as an observer the meeting of the Committee.

(4) Government of Nepal may, if it considers necessary, make alteration changes (modification) in the number of members, by a notification publishes in the Nepal Gazette.

6. Functions, duties and powers of Committee: (1) It shall be the duty of the Committee to give advice to the Department of Drugs Administration on technical matters as to the research, development and control of drugs.

(2) In addition to giving advice pursuant to sub-rule (1), the Committee may also give advice on the following matters:

- (a) To formulate the standards of drugs, fix other scientific and technical methods for the related test or analysis,
- (b) To prepare Nepal pharmacopeias and other related literatures,
- (c) To give recognize to pharmacopeias or literatures of other countries for purposes of work until the pharmacopeias or literatures as referred to in Clause (b) are approved and enforced by the Government of Nepal,
- (d) To formulate codes for purposes of doing, or causing to be done, the following acts:
 - (1) To produce, dispense, sell, distribute, export, import, transport, storage and consume any drugs or ingredients thereof so that such drugs or ingredients are publicly safe, efficacious and qualitative,
 - (2) To prevent the improper use or misuse of drugs or ingredients thereof,
 - (3) To prevent false or misleading publicity or advertisement on the use and utility of drugs or ingredients thereof,

- (4) To return the drugs which are not publicly safe, effective and qualitative proposed to be or already sold and distributed to the manufacturer of such drugs,
- (5) To issue by the manufacturer of a drug a guarantee letter that the drug is publicly safe, effective and qualitative, prior to the sale and distribution of the drug,
- (6) To safely retain narcotic and poisonous drugs, sell and distribute such drugs and maintain records of the drugs so sold and distributed and prescribe format thereof,
- (e) To prepare basic matters on classification of systems and groups or sub-groups of drugs, and prescribe necessary terms on the production, sale, distribution, export, import, use, storage and consumption of the drugs as per such classification,
- (f) To give recognition to pharmacists or persons having experiences on drugs,
- (g) To prescribe qualifications of and give recognition to professionals,
- (h) To form sub-committees of any member or member secretary or members of the Committee for the performance of the functions prescribed by the Committee.

7. **Meeting, decision and procedures of Council or Committee:** (1) The Council or Committee shall meet as required in such place and time as specified by the chairperson.

(2) The presence of more than half the members of the total number of members of the Council or Committee shall be deemed to constitute a quorum.

(3) The meeting of the Council or Committee shall be presided over by the chairperson and by the vice-chairperson in the absence of the chairperson, and by the person selected by the members present at the meeting from amongst themselves, in the absence of both the chairperson and the vice-chairperson.

(4) A majority opinion shall prevail at the meeting of the Council or Committee. In the event of a tie, the person presiding over the meeting may exercise the casting vote.

(5) The decisions of the Council or Committees shall have to be recorded by the member secretary in the minute's book.

(6) The decisions of the Council or Committees shall be authenticated by the member secretary.

(7) Other procedures relating to the meeting of the Council or Committee shall be as determined by the Council or Committee itself.

8. **Meeting allowances:** The Government of Nepal shall give the meeting allowances, as prescribed, to the non-governmental members who attend the meeting of the Council or Committee.
9. **Liaison with Government of Nepal:** In making contact with the Government of Nepal, the Council do so through the Ministry of Forest.
10. **Modus operandi of Council and Committee:** The Department of Drugs Administration shall make arrangements for the operation of the Council and the Committee.