Government of Nepal
Office of the Prime Minister and the Council of Ministers
(…….. Section)

Singhadurbar, Kathmandu,
Nepal.

Letter number: 42/074
Ch.no: 8278

Date: 2074/02/19

Mx. Secretary,
The Ministry of Health.

I would like to request your kind notice of the following decision by the Legislative Committee, Council of Ministers' meeting held on 2074/02/19.

> "Approve attached herewith, "Directive on Health Technology Product and Equipment, 2074" revised by including subject matters raised during the discussion at today's meeting instead of the directive presented with a proposal, following the decision made at the meeting of the Council of Ministers dated 2074/1/25 "to discuss in Legislative Committee, Council of Ministers, and act according to the decision of the committee" the Ministry of Health's proposal number 31 | 6-074 | 1 | 25 Ma.Pa.Bai.Sa 6-074 with a subject to approve "Directive on Health Technology Product and Equipment, 2074."

Signed
(Rajiv Gautam)
Secretary

DIRECTIVE ON HEALTH TECHNOLOGY PRODUCT AND EQUIPMENT

Since it is desirable to assure the quality of production, export, import or sales and distribution of a Health Technology Product and Equipment, and manage work and action related to their effective monitoring and inspection, the Government of Nepal has made the following directive exercising the rights given by Good Governance (Management and Operations) Act, 2064, Section 45.

1. Short Title and Commencement:

   (1) The name of this directive is, "Directive on Health Technology Product and Equipment, 2074."

   (2) This directive shall come into effect 91 days after the approval by the Government of Nepal.

2. Definitions: In this directive, unless the subject or the context leads to mean otherwise:

   (A) "Drugs Advisory Council" means the Drugs Advisory Council as per Drugs Act, 2035, Section 3.

   (B) "Drugs Advisory Committee" means the Drugs Advisory Committee as per Drugs Act, 2035, Section 4.

   (C) "Certificate" means the certificate granted as per Section 4 or 5.

   (D) "Health Technology Product or Equipment" means those product and equipment as listed in Schedule-1.

   (E) "Ministry" means the ministry under the Government of Nepal looking after subject related to health.

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

   (G) "Recommendation Letter" means the letter of recommendation issued to export or import Health Technology Product or Equipment according to Section 3.

3. Recommendation Letter Should be Taken:

   (1) A person wanting a Recommendation Letter to establish an industry for the production of a Health Technology Product or Equipment or export or import such a product and equipment, must submit an application to the Department in the format according to Schedule-2 for the establishment of a Health Technology Product or Equipment industry, and that according to Schedule-3 for the export or import of such a product or equipment.

   (2) If there is any application received as per Sub-section (1) to the Department, the Department shall inquire such application and issue a Recommendation Letter to the applicant in the format according to Schedule-4 for the establishment of an industry for the production of the Health Technology Product or Equipment, and according to Schedule-5 for the export or import of such a product and equipment.

4. Health Technology Product and Equipment Must be Registered:

   (1) Prior to the sales and distribution of a Health Technology Product or Equipment inside Nepal, a person who produces or imports such a product or equipment inside Nepal, must submit an application to the Department in the format according to Schedule-6.

(2) If an application is received as per Sub-section (1), the Department shall inquire whether or not the Health Technology Product or Equipment mentioned in the application meet the national standard according to Section 8.

(3) If, following the inquiry as per Sub-section (2), the mentioned Health Technology Product or Equipment meets the national standard, the Department shall register such a product or equipment and issue a registration-certificate according to Schedule-7 to the concerned person.

5. Sales Centre, Firm and Shop Must be Registered:

(1) A person who wishes to retail or wholesale a Health Technology Product or Equipment by opening a sales centre, firm or shop must submit an application to the Department in the format according to Schedule-8 to register such a sales centre, firm or shop.

(2) If an application is received as per Sub-section (1), the Department shall register the sales centre, firm or shop and issue a certificate in the format according to Schedule-9 to the applicant.

6. Validity and Renewal of Recommendation Letter and Certificate:

(1) The validity of a Recommendation Letter and Certificate shall be one year from the date of receipt of such Recommendation Letter and Certificate.

(2) A person who wishes to have a Recommendation Letter or Certificate renewed must submit an application to the Department for the renewal of such Recommendation Letter or Certificate one month prior to the end of validity according to Sub-section (1).

(3) If an application is received as per Sub-section (2), the Department shall renew the Recommendation Letter or Certificate following a necessary inquiry.

7. Record Must be Maintained: The Department must keep an up-to-date record of the Recommendation Letter and Certificate issued according to this directive.

8. Determine National Standard:

(1) The Department shall determine a national standard of a Health Technology Product or Equipment.

(2) While determining a national standard as per Sub-section (1) criteria determined by World Health Organisation for a Health Technology Product or Equipment shall be used.

(3) In an event that criteria as per Sub-section (2) are unavailable, a national standard for Health Technology Product or Equipment shall be determined according to the existing international norms.

(4) While determining a national standard as per this Section, effect and risk on human and animal health must also be considered.

9. Must be in Line with National Standard: Any Health Technology Product or Equipment produced, imported and sold and distributed inside Nepal must be according to the national standard as per Section 8.

10. Quality Testing:

    (1) The National Bureau of Standards & Metrology under the Ministry of Industry shall carry out testing with regards to whether or not the quality of a Health Technology Product or Equipment is as per the national standard set according to Section 8.

    (2) If a quality testing according to Sub-section (1) cannot be carried out, such a product or equipment shall be tested by National Medicine Laboratory under the Department or by National Public Health Laboratory.

    (3) If a quality testing according to Sub-section (1) and (2) cannot be done, the quality of such a product and equipment shall be tested by a laboratory of international standard determined by the Department on the recommendation of the Drugs Advisory Council or the Drugs Advisory Committee.

11. Not Allowed to Produce or Import:

    (1) A Health Technology Product or Equipment that does not meet a quality standard as per the national standard according to Section 8 cannot be produced or imported inside Nepal.

    (2) A Health Technology Product or Equipment that has already been used once in any country, is old, repaired or rebuilt cannot be imported or have it imported inside Nepal.

12. Allowed to Export or Import Through an Agent: A person receiving a Recommendation Letter to export and import can export and import a Health Technology Product or Equipment through own's authorized agent.

    Explanation: For the purpose of this Section, an "Authorized Agent" means an individual registered with the Department as own's agent by a person who has received a Recommendation Letter according to Section 3 for the export or import of a Health Technology Product or Equipment.

13. Allowed to Set Maximum Retail Price: The Department shall fix a maximum retail price of a Health Technology Product or Equipment according to a consultation from the Drugs Advisory Council or an advice from the Drugs Advisory Committee, and based on a priority.

14. Allowed to Take Service Fee and Charge: The Department may collect fees charged as per existing law while issuing a Recommendation Letter or Certificate.

15. Testing Charge: If a Health Technology Product or Equipment needs any testing according to this directive, costs incurred for such testing shall be borne by the person who produces or imports such a product or equipment.

16. Allowed to Monitor and Inspect:

    (1) The Department must routinely monitor and inspect the production, export, import, as well as sales and distribution of a Health Technology Product or Equipment.

    (2) For monitoring and inspecting as per Sub-section (1), the Department may determine the monitoring and inspection priority order of a Health Technology Product or Equipment according to the advice from the Drugs Advisory Committee.

17. Action as per Existing Laws:

(1) Action as per existing laws shall be taken against a person operating contrary to this directive.

SCHEDULE-I

[Related to Section 2, Sub-section (D)]

Health Technology Product and Equipment (HTP)

1. Medical non-durables and consumables: Examples: surgical commodities (gauge, bandages, cottons, surgical gloves, catheters, disposable syringes, sutures and catguts, dental fixtures, etc.)

2. Optical appliances. Spectacles, contact lens/solution, sunglasses, intraocular lens, etc.

3. Orthopedic and prosthetic implants/instruments; Examples: Artificial limb, implants like prosthesis, screw plate, nail, rod, orthopedic instruments.

4. Medical devices (durables): Examples: Heart valve, pacemaker, stents, catheter.

5. Medical equipment (life-saving and rehabilitation products): Examples: ventilator, defibrillator, anesthesia machine, oxygen concentrator, walker, wheelchairs, crutches and other rehabilitation aid products, physiotherapy equipment.

6. Medical equipment (invasive diagnostic: Examples: ultrasound, MRI, endoscopy.

7. Medical devices and reagents (radio-imaging and radiotherapy): Example: X-ray, CT scan, C-arm. Other medical equipment: Examples: ECG, EMG, etc.

8. Laboratory equipment, reagents and kits for in-vivo and in-vitro tests, at pathological: Examples: ELISA reader, HPLC, infrared spectrophotometer, UV spectrophotometer, pH meter, etc.

9. Laboratory equipment, reagents and kits for in-vivo and in-vitro tests, at pharmaceutical laboratories: Examples: ELISA reader, HPLC, infrared spectrophotometer, UV spectrophotometer, pH meter, etc.

10. In-vivo and in-vitro diagnostic chemicals, reagents and kits.

11. Nutritional/food supplements not regulated by Drugs Act or Food Act like multivitamins, multi-minerals, antioxidants, etc.

12. Common pharmaceutical products for oral and topical use not regulated by Department of Drug Administration (DDA) as over-the-counter (OTC) medicines.

13. Cosmetic items though are not health products: They can be hazardous to health. Examples: materials used for beautification, cosmetic and toiletries, ornaments with molybdenum, arsenic and heavy metal contamination.

14. Supportive devices, accessories and consumables for medical equipment: Examples: ECG paper, ultrasound paper, x-ray film, x-ray chemicals, back-up UPS for medical devices, stabilizer back-up for medical devices, lead glass, lead sheet to protect from radiation hazards, etc.

15. Radioisotopes and accessories for nuclear medicines.

16. Blood and blood components, blood bags, test list/reagent, chemical, instruments, storage and component separate device/machine/equipment, etc.

17. Home health care product like glucometer, pregnancy test kit, BP monitors, thermometer, etc.

SCHEDULE-2

[Related to Section 3, Sub-section (1)]

Application Format for the Recommendation Letter for the Establishment of a Health Technology Product or Equipment Industry

Mx. Director General,
Department of Drug Administration.

Subject: To Receive Recommendation Letter for the Establishment of a Health Technology Product or Equipment Industry.

Dear Sir/Madam,

Since it is my/our intention to establish the following industry for Health Technology Products or Equipment, I/we submit an application with the following details for a Recommendation Letter in accordance with the Directive on Health Technology Product or Equipment, 2074, Section 3, Sub-section (1).

1. Proposed Health Technology Product or Equipment Industry's:
   (A) Name:
   (B) Location for establishment: (give details of the district, name of municipality or rural municipality and ward no.)
   (C) Estimated capital and its source:
   (D) Report on preliminary study regarding the establishment attached or not?
   (E) Project map showing area of establishment attached or not?

2. Detail of the Health Technology Product or Equipment to be Produced by the Proposed Industry:
   (A) Detail of necessary raw materials and their source:
   (B) If machinery is required, then its detail as much as possible:
   (C) Detail of the building or house where the Industry is to be established:

Applicant's, -
Signature:
Name, Surname:
Address:
Date:

SCHEDULE-3

[Related to Section 3, Sub-section (1)]

Application Format for the Recommendation Letter for the Export or Import of the Health Technology Product or Equipment

Mx. Director General,
Department of Drug Administration.

Dear Sir/Madam,

Since wanting to receive a Recommendation Letter for the export or import of the following Health Technology Product or Equipment, I/we submit this application in accordance with the Directive on Health Technology Product or Equipment, 2074, Section 3, Sub-section (1).

Detail of Health Technology Product or Equipment Wanting to Export or Import:

S. No.	Name	Form/Type	Manufacturing Country	Exporting or Importing Country	Quantity	Remarks
1						
2						
3						
4						
5						
6						
7						

Applicant's, -
Signature:
Name, Surname:
Address:
Date:

SCHEDULE-4

[Related to Section 3, Sub-section (2)]

Format for the Recommendation Letter for the Establishment of the Health Technology Product or Equipment Industry

Government of Nepal
Ministry of Health
Department of Drug Administration

This Recommendation Letter has been issued showing the following details to establish the following Health Technology Product or Equipment industry in accordance with the Directive on Health Technology Product or Equipment, 2074, Section 3, Sub-section (2).

1. Health technology product or equipment industry recommended to be established:

   (A) Name:

   (B) Location for establishment:

   (C) Estimated capital:

2. Detail of the Health Technology Product or Equipment to be produced by the industry:

Name	Form/Type	Remarks

Recommendation Letter Issuing Official's, –
Signature:
Name, Surname:
Post:
Date:
Official Stamp:

SCHEDULE-5

[Related to Section 3, Sub-section (2)]

Format for the Recommendation Letter for the Export/Import of the Health Technology Product or Equipment

Government of Nepal
Ministry of Health
Department of Drug Administration

This Recommendation Letter has been issued showing the following detail for the export/import of the Health Technology Product or Equipment in accordance with the Directive on Health Technology Product or Equipment, 2074, Section 3, Sub-section (2).

Detail of Health Technology Product or Equipment Recommended to be Exported/Imported:

S. No.	Name	Form/Type	Manufacturing Country	Exporting or Importing Country	Quantity	Remarks
1						
2						
3						
4						

Recommendation Letter Issuing Official's, –
Signature:
Name, Surname:
Post:
Date:
Official Stamp:

SCHEDULE-6

[Related to Section 4, Sub-section (1)]

Application Format for the Certificate for the Sales and Distribution of the Health Technology Product or Equipment

Mx. Director General,
Department of Drug Administration.

Dear Sir/Madam,

Since wanting to receive a Certificate for the sales and distribution of the following Health Technology Product or Equipment, I/we submit this application showing the following detail in accordance with the Directive on Health Technology Product or Equipment, 2074, Section 4, Sub-section (1).

Detail of Health Technology Product or Equipment Wanting to Sale and Distribute:

S. No.	Name	Form/Type	Remarks
1			
2			
3			
4			
5			
6			
7			

Applicant's, –
Signature:
Name, Surname:
Address:
Post:
Date:

SCHEDULE-7

[Related to Section 4, Sub-section (3)]

Format for the Certificate for the Sales and Distribution of the Health Technology Product or Equipment

Government of Nepal
Ministry of Health
Department of Drug Administration

Certificate for the Sales and Distribution of the Health Technology Product or Equipment

The registration-certificate, showing the following detail, has been issued as per the Directive on Health Technology Product or Equipment, 2074, Section 4, Sub-section (3) after conducting necessary inquiry on the application received on the date …… to receive a Certificate for the purpose of the sales and distribution of the Health Technology Product or Equipment.

Detail of Health Technology Product or Equipment Registered for Sales and Distribution:

S. No.	Name	Form/Type	Remarks
1			
2			
3			
4			
5			
6			
7			

Certificate Issuing Official's, –
Signature:
Name, Surname:
Post:
Date:
Official Stamp:

SCHEDULE-8

[Related to Section 5, Sub-section (1)]

Application Format for the Certificate for the Operation of Sales Centre, Firm or Shop for the Health Technology Product or Equipment

Mr. Director General,
Department of Drug Administration.

Dear Sir,

Since wanting to receive a Certificate for the registration of the following sales centre/firm/shop for the sales and distribution of the following Health Technology Product or Equipment that I/we submit this application showing the following detail in accordance with the Directive on Health Technology Product or Equipment, 2074, Section 5, Sub-section (1).

1. Detail of the Sales Centre, Firm or Shop for the Sales and Distribution of the Health Technology Product or Equipment:

Name	**Location**	**Owner's Name, Surname**		**Owner's Address**	**Estimated Capital**	**Remarks**
		1				
		2				

2. Type of Sales and Distribution of the Health Technology Product or Equipment: Retail/Wholesale

Applicant's, –
Signature:
Name, Surname:
Address:
Date:

SCHEDULE-9

[Related to Section 5, Sub-section (2)]

Format for the Certificate for the Operation of Sales Centre/Firm/Shop for the Health Technology Product or Equipment

Government of Nepal
Ministry of Health
Department of Drug Administration

Certificate for the Operation of Sales Centre/Firm/Shop for Health Technology Product and Equipment

This Certificate, showing the following detail, has been issued as per the Directive on Health Technology Product or Equipment, 2074, Section 5, Sub-section (2) as per the application received on the date …… to receive a Certificate for operation of a sales centre/firm/shop for the purpose of the sales and distribution (wholesale/retail) of the Health Technology Product or Equipment.

1. Detail of the Sales Centre/Firm/Shop for the Sales and Distribution of the Health Technology Product or Equipment:

Name	**Location**	**Owner's Name, Surname**		**Owner's Address**	**Estimated Capital**	**Remarks**
		1				
		2				

2. Type of Sales and Distribution of the Health Technology Product or Equipment: Retail/Wholesale

Certificate Issuing Official's, –
Signature:
Name, Surname:
Post:
Date:
Official Stamp: