PHARMACEUTICALS EXPORT PROMOTION COUNCIL OF INDIA

(Set up by Ministry of Commerce & Industry, Govt. of India)

REGULATORY & MARKET PROFILE OF NEPAL

DEMOGRAPHY

SL. No	Parameter	Description
1	Region	Southern Asia
2	Country	Nepal
3	Capital	Kathmandu
4	Population	29,717,587 (July 2018 est.)
5	Population growth rate (%)	1.09% (2018 est.)
6	GDP (purchasing power parity)	$79.19 billion (2017)
7	GDP - real growth rate (%)	7.9% (2017 est.)
8	GDP - per capita (PPP)	$2,700 (2017 est.)
9	Epidemiology	COPD(Chronic obstructive pulmonary disease), Cerebral vascular diseases, HIV/AIDS, Diabetes, Pneumonia
10	Population below poverty line	25.2%(2011 Estimate) (No update)
11	Age structure (%)	0-14 years: 29.54%
		15-24 years: 21.52%
		25-54 years: 37.18%
		55-65 years : 6.42%
		65 & above: 5.34%
Source: CIA World Fact Book updated till July 2018		

NEPAL- PHARMA MARKET REPORT

As per Nepal' Pharmaceutical producers' association there are 50 pharmaceutical companies as its members, 32 of which are certified with WHO-GMP and others in process of it.

The following is the size and forecast of the pharma market in Nepal.

Nepal's Pharmaceutical Market Size in $ billion

Nepal	2017	2018 Estimated	2019
Pharmaceutical sales, USD bn	**0.293**	**0.311**	**0.331**

Acquisitions and Trade events:

Helsinn Group and Glenmark Pharmaceuticals have entered into an exclusive licensing agreement to introduce Akynzeo in India and Nepal. Akynzeo, an oral fixed combination of netupitant 300mg and palonosetron 0.5mg in capsule form, is used for prevention of chemotherapy-induced nausea and vomiting. The licensing agreement with Glenmark for Akynzeo represents Helsinn's first such agreement in India.

Akynzeo was developed by Helsinn, which currently has 20 licensing partners for it in 167 countries. Glenmark will have exclusive marketing rights for Akynzeo in India and Nepal, and has received marketing approval for the drug from the Central Drugs Standard Control Organization.

Torrent has acquired Unichem's Nepal business.

During the year 2017 Nepal has imported $ 239 million worth of Formulation in all including patented. India is the largest importing partner of Nepal(Nepal has imported $ 190 million out of $ 239 million) as far as Pharmaceuticals are concerned. Nepal has imported around 80% its formulation needs from India during the year.

There is no other information available regarding Nepal pharma market.

Statistics:

A) India's Exports

India's Pharmaceutical exports to NEPAL $ Million						
Category	**2015-16**	**2016-17**	**2017-18**	**GR%**	**Contbn%**	**Contbn to Region**
Bulk Drugs and Drug Intermediates	15.94	17.00	20.13	18.42	8.65	8.90
Drug Formulations and Biologicals	126.13	154.27	169.36	9.78	72.76	42.00
Ayush	12.78	15.57	18.48	18.72	7.94	78.79
Herbal Products	0.54	0.77	0.70	-8.95	0.30	5.10
Surgicals	10.11	13.23	15.19	14.83	6.53	39.15
Vaccines	11.36	6.11	8.89	45.38	3.82	15.22
Total	176.86	206.95	232.76	12.47	100.00	30.47

B) Nepal's Imports

Top Ten Importing Partners of Nepal $ Million						
Rank	**Country**	**2015**	**2016**	**2017**	**Gr%**	**Share%**
1	India	141.95	194.41	190.14	-2.20	79.43
2	Switzerland	62.02	21.76	20.85	-4.17	8.71
3	Belgium	0.50	0.18	9.50	5039.63	3.97
4	Bangladesh	1.89	2.11	2.51	18.73	1.05
5	Germany	1.54	1.46	2.35	61.09	0.98
6	China	1.10	1.94	2.25	15.95	0.94
7	USA	42.10	1.39	1.54	11.17	0.64
8	France	1.83	1.35	1.29	-4.17	0.54
9	Netherlands	1.43	1.46	1.28	-12.02	0.54
10	Italy	1.44	0.95	1.26	32.37	0.53
	World	263.46	233.31	239.38	2.60	100.00

India is the largest importing partner of Nepal of finished dosage forms of Pharmaceuticals contributing around 80% to its total imports.

REGISTRATION AND LICENSING REQUIREMENTS

➢	Regulatory Authority	:	**Department of Drug Administration (DDA)**
➢	Website of regulatory Authority	:	http://www.dda.gov.np/
➢	Fees for Drug Registration	:	Company Approval: NPR. 50,000 Audit Fee: $ 1500 Product registration fee: NPR 2400 & Import recommendation letter: NPR 300
➢	Normal time taken for registration	:	06 Months
➢	Registration Requirement [Dossier Format]	:	Non-CTD
➢	Whether plant inspection is mandatory	:	NO
➢	Requirement of Local agent/ Subsidiary		Local Agent is sufficient
➢	Registration Validity		06 Months

Department of Drug Administration (DDA), Ministry of Health & population, Government of Nepal.

Government of Nepal established Department of Drug Administration (DDA) in 1979 A.D (2036/07/01 B.S.) erstwhile under Ministry of forest & soil conservation and went under Ministry of Health and population after Poush, 2041 B.S. DDA is one of the three departments under Ministry of Health & Population.

Nepal has promulgated the Drug Act 1978, to prohibit the misuse or abuse of medicines and allied pharmaceutical products as well as false or misleading information relating to efficacy and use of drugs and to regulate and control the production, marketing, distribution, export, import, storage and utilization of those drugs which are not safe for the public use, efficacious and of standard quality. To implement & fulfill the aim and objectives of Drug Act 1978 and various regulations are made under it.

In accordance with the objectives of the National Health Policy, 1991, to improve & manage by establishing co-ordination among governmental, non-governmental & private organizations involved in

activities related to medicine production, import, export, storage, supply, sales, distribution, quality assessment, regulatory control, rational use and information flow, the National Drug Policy, 1995 has been implemented. Achieving the aim & objectives of National drug policy is another important area for DDA.

Under the Drug Act 1978, the following rules/regulations & codes have been implemented as supporting tools for the active enforcement of Drugs Act, 1978.

- ✓ Drug advisory committee & consultative council regulation, 2037
- ✓ Drug registration regulation, 2038
- ✓ Inquiry & inspection regulation, 2040
- ✓ Drug standard regulation, 2043
- ✓ Drug donation guidelines have been implemented for the quality assurance of donated drugs
- ✓ Drug sales & distribution codes, 2071
- ✓ Good practice codes for drug production, 2072
- ✓ Medicine registration guidance, 2073

DIVISIONS OF DDA:

(1) Registration Division
- (a) Import and Export Section
- (b) Industry Section
- (c) Pharmacy Registration Section

(2) Management Division
- (a) Training and Drug Information Section
- (b) Planning section
- (c) Administration section

(3) Inspection Division
- (a) Law section
- (b) Import/export section
- (c) Audit section: WHO GMP certification and Recertification related activities.

National Medicine Laboratory:

National medicine laboratory, previously known as Royal Drug Research Laboratory (RDRL) was established in 1964 A.D. It is the principal body of government of Nepal for testing and analysis of drugs. It is a National Drug Control Laboratory. It has various sections like chemical analysis, microbiology, pharmacology & instrumental analysis. The main functions of NML are

- Test and analyze the quality of drug as empowered according to the Drugs Act, 1978.
- Check & evaluate the standard of drug testing laboratories in the country.
- Develop reference standard and make available to the pharmaceutical industries & laboratories.
- Conduct training on Good laboratory practices.
- Audit laboratories of National Pharmaceutical industries.

Medicine Registration Guidance

Import Registration

Medicine Registration Guidance (Issued under Drug Registration Regulation 2038) issued by the Department of Drug Administration, Govt of Nepal on Sep 12, 2017. As per the guidance documents, the following documents are mandatory for registering the medicine from foreign country.

- Compulsory requirement of WHO-GMP certification of the company for concerned drug product intended to be imported in Nepal
- On-site inspection prior to drug product registration for compliance of WHO-GMP guidelines by the company of non-Stringent Regulatory Authority (nSRA) countries
- Compulsory requirement of Notarized copy of Certificate of Pharmaceutical Products (CPP) as prescribed by WHO
- BA/BE report of modified release dosage forms
- Clinical study report on safety and efficacy of new drug
- Drug product specification with quality control parameter, analytical methods and reports with the drug registration application
- Summary Product Characteristics (SPC) requirement for new drug products registration.

(I) Procedural Guideline

(A) Procedure to get approval of Pharmaceutical Manufacturing company:

Any person intended to import drug in Nepal from a new manufacturing company needs to apply for approval of the company with following documents:

- Application by the company (with intention and purpose) on its own letterhead.
- Letter of authority to the importer issued by the responsible person of the company
- Site Master File (*as per PICS guidelines*)
- Up to date manufacturing license.
- List of products intended to be registered in Nepal.
- Letter of warranty
- Latest GMP internal audit report.
- Photocopy of firm registration as wholesaler (*of Nepalese importer*).
- A complete dossier of one product intended to register (*as minimum*).
- Approval letter from the Department on WHO-GMP compliance (*applicable for non SRA (Non-Stringent Regulatory Authority), Non-UN prequalified product and company*)
- Risk evaluation and mitigation strategy including PV and post marketing surveillance

(B) Procedure to obtain product license (Schedule –4E) and Import recommendation letter (Schedule-7)

(a) Pharmaceutical products

An applicant shall apply for drug product registration and import recommendation letter with the following documents as prescribed in the drug registration rule 2038 and directives issued by the Department from time to time:

i. An Application in the form of Schedule 4 'C' (Format enclosed as Annex-I) for product registration as per Drug Registration Regulation of Drug Act 1978
ii. An application in the form Schedule 6 (Format enclosed as Annex-III) for product import recommendation letter as per Drug Registration Regulation of Drug Act, 1978
iii. Up-to-date manufacturing license issued by the concerned Drug Regulatory Authority (Drug License)
iv. Attested copy of valid Certificate of Pharmaceutical Product (CPP) as recommended by WHO (Attested by Drug Regulatory Authority or Notary Public with valid license in Nepal).
v. Detail formulation including excipients, color, flavor, etc.
vi. In case of new drug combination / new molecule (document in the format designed by the Department).
vii. In case of controlled & sustained release dosage forms additional documents as prescribed (as devised by the Department).
viii. BA/BE report (bio waivers can be requested as per bio waiver guidance's mentioned in the following section)
ix. Product specification.
x. Method of Analysis (official compendia methods are accepted however other methods must be validated for precision, accuracy, repeatability/specificity, ruggedness, limit of detection, limit of quantitation. For this, latest WHO guidelines on analytical method validation may be followed and substantiated with report).
xi. Samples of label and carton.
xii. Sample of the product (equivalent quantity as defined by NML for 2 complete tests).
xiii. Analytical report from company's own laboratory and from any of the following Laboratories for the same batch:
    a) Government Laboratory of the exporting country or
    b) National Medicine Laboratory, Nepal; or
    c) From other national or foreign laboratories approved by the Department.
xiv. Real Time Stability Testing Report for the period of claimed shelf-life.
xv. A letter of attorney in favor of the authorized importer (Refer the guidance document for the format)
xvi. Undertaking that the proposed products is not supplied in higher prices than in the exporting country
xvii. Submission of prices of at least 5 competitor brand, this may not be mandatory in case of fewer brands that 5 available in the market

(b) Import recommendation as per rule 4B sub-rule(4):

- Live saving medicines with prescription of medical doctor, when applied with evidences, the department shall issue import recommendation letter for the drug/vaccine/biological product in required quantity.
- The Department shall issue import recommendation letter for Drug/Vaccine/Biological intended to be imported by governmental or nongovernmental agencies through donation*. (Please refer to **Donation Guidelines** in the official webpage)
- The department shall issue import recommendation letter for the drug/vaccine/biological products and quantity intended to be imported through international competitive bidding,
- Following documents are required to issue import recommendation letter as per rule 4B sub-rule (4):
    a) An application with purpose and justification
    b) The prescription of registered practitioner for personal use with quantity (for personal use only).
    c) Recommendation letter with justification by the concerned Drug & Therapeutic Committee (DTC) of the Hospitals (including medical colleges hospitals) and Nursing Homes(for hospital use)
    d) Additional clarification or document as decided by the Drug Evaluation Committee of DDA.
    e) Payment voucher as prescribed in Schedule 14 of the Drug Registration Rule 2038

(II) Application for importation of products and restrictions

Any person fulfilling following requirements may apply for drug product importation in Nepal

- Any Nepali drug wholesale firms registered with DDA authorized by the manufacturing company in foreign company can apply for drug import registration in Nepal
- The company should have issued letter of attorney in favor of the authorized importer
- Authenticated documents as described in the Section 4 above

Restrictions:

- Company not having authorized wholesaler in Nepal
- Those having importation interest outside the provisions mentioned in the departmental communiqué *dated 2071.04.01 in Gorkhapatra daily*
- Those barred by the law of the land

(III) Sample application dossier

WHO-PQ programme has adopted common technical document (CTD) format for product dossier assessment in its focused programme products, which is equally relevant for other products also. Any person applying for new or generic product registration in the department may submit application as prescribed (Schedule-4C and 6) along with the product dossier.

(For further detail of the sample dossier may be referred to WHO guidelines document: WHO technical series 961, Annex 15/ or refer to WHO website.)

(IV) Sample Master File:

WHO guiding document to prepare site master file is given in the WHO Technical Series 961, Annex 14

(V) Stability requirement:

Please refer the Annex-4: Guidelines on Stability of Products, 2007(as amended in 2015) of the Import registration of Medicines registration guidance.

(VI) BA/BE requirement

- ✓ An applicant is required to submit reports on bioavailability and bioequivalenc estudy. The methods and approaches to conduct such studies may be followed as per WHO guidelines or equivalent (US FDA guidance, EU guidance).
- ✓ Bioavailability and BE study is not required for drug products intended to use as IV injection.
- ✓ An applicant can request BCS biowaiver for orally administered solid dosage forms(*detailed guidelines on BCS –based biowaiver and BE study may be refered to WHO Technical Series 937 Annex 7*)
- ✓ Conditions requiring BE study report are:
  - a) Locally applied, systemically acting products
  - b) Non-oral immediate release forms with systemic action
  - c) Modified release products; e.g.; sustained release tablet
  - d) Transdermal products
  - e) Narrow therapeutic drugs, drugs with low bioavailability, non linear kinetics, poor dissolution profile, variable bioavailability/bioequivalence, modified release dosage form having blood steady state concentration such as sodium valproate, valproic acid, carbamazepine, antibiotics etc,
  - f) Oral products intended to be absorbed in the oral cavity
  - g) In-vivo BA/BE profile or in-vitro dissolution profile should be compared with Innovator/leading/comparator brand of the product.

(VII) Conditions when bio waiver can be permitted

Accepted Bio waiver conditions:

- Injectable, ophthalmic and otic solutions- provided that the active and inactive ingredients are qualitatively and quantitatively same as the reference listed drug.
- Oral and topical solutions- provided that differences in inactive ingredients are characterized and do not affect absorption of active ingredient of the product.

- Immediate-release drug products with a determination of efficacy. The regulatory authority may request in vitro dissolution testing for oral solid dosage forms. Examples include acetaminophen and codeine tablets, folic acid tablets, hydrocortisone cream and ointment, triamcinolone ointment, cytarabine injectable and dacarbazine injectables.

- Drugs which are comparatively safer and have wider therapeutic index such as NSAIDs, analgesic, antipyretic and OTC products, the comparative in-vitro dissolution test profile along with real time stability data can also be submitted instead of BA/BE study report.

- BCS class 1 drugs, e.g., metoprolol and few BCS class III drug

- Pharamcopoieal immediate release solid dosage drug products with comparable dissolution profile with comparator drug product (f2 test as per WHO guidelines).

What data required for bio waiver request by the applicant?

- ✓ Drug substance highly soluble over the entire physiological pH range (pH 1.2, pH 4.5 acetate buffer and pH 6.8 phosphate buffer)
- ✓ Drug substance highly permeable
- ✓ Drug product very/ rapidly dissolves rapidly over the entire physiological pH range can be considered for Biowaiver is found equivalent through comparable dissolution profile (f2 test as per WHO guidelines) with reference drug product.

Option 1: ***Very rapidly dissolving products***

- Not less than 85 % of labeled amount are dissolved within 15 min in each of three buffers (pH 1.2, pH 4.5 acetate buffer, pH 6.8 phosphate buffer) – no further profile comparison of T and R is required

Option 2: Rapidly dissolving products

- Not less than 85 % of labeled amount are dissolved within 30 min in each of three buffers (pH 1.2, pH 4.5 acetate buffer, pH 6.8 phosphate buffer)
- Not a drug with narrow therapeutic index
- For Generic products, also demonstrate similar dissolution profiles of test and reference (comparator)
- BCS class I and some BCS III class drug containing products can be considered for biowaiver
- Class III drugs (low solubility, high permeability) with weak acidic properties may be considered based on revised WHO Criteria.

(VIII) Clinical study requirements

An applicant for multisource generic products needs to submit product dossier in a format prescribed (currently WHO guidelines as per *Generic Guidelines_PDS_CTD* format is accepted) and for new products ICH guidelines as recommended in M4E may be followed.

Validity period product license, recommendation letter and certificate:

Product License, Drug registration certificate and the Recommendation letter for the importation of drug shall remain valid for two years from the date of its issue.

Renewal of licenses, Recommendation Letter and Certificate

Each license, recommendation letter and certificate shall be got renewed for each year within thirty five days of the expiry of its validity period.

If the renewal is not made within the specified time limit mentioned above, and an application is made, setting out the reasons for the failure to have renewal, within three months after the date of expiry of the time limit, the Department shall make renewal by charging an additional fee of twenty five percent of the renewal fee. The license, recommendation letter or certificate not renewed even within that time limit shall ipso facto be invalid.

Imported product registration certificate (Schedule-4E) (Enclosed as Annex-II)

- Application for renewal of Schedule-4E
- Original Schedule-4E
- compliance with terms and condition of Schedule-4E
- Valid certificate of pharmaceutical products (Notarized and in the format as recommended by WHO Valid licenses issued by the exporting country's regulatory authority
- Payment voucher as per Schedule 14 (Enclosed as Annex-V) of Drug Registration Regulation

Drug product Import/ export recommendation letter (Schedule-7) (Enclosed as Annex-IV)

- Application-Schedule-6
- Original product registration certificate Schedule-5 (for export only, applicable for products manufactured in the country)
- Original product registration certificate (Schedule-4(E)
- Valid certificate of pharmaceutical products (Notarized and in the format as recommended by WHO)
- Valid licenses issued by the exporting country's competent regulatory authorities
- Approval of variations made during the period
- Valid WHO-Good Manufacturing Practices certificate or equivalent from SRA as applicable issued from the concerned competent authority
- Sample of drug product to be renewed
- Evidence of export to SRA(s) in case of drug product registered under conditions of export to SRA country.
- Payment voucher as per Schedule 14 of Drug Registration Regulation
- Annual Product Review
- Stability information's in case of changes with report of data logger sheets.
- Declaration on ADR reporting on the product

Re-registration of the drug product (Schedule 4E) and re-issue of import recommendation letter (Schedule7)

The products which are registered in the Department but the importer failed to renew within 125 days after the validity period can still renew their drug product registration certificates and import recommendation letter upon payment of fines as prescribed and after furnishing following documents. If the manufacturer has not renewed its products licenses or recommendation letters for last two years, the company will not be considered for renewal of its products. The pending fees and fines will be recovered from the company on outstanding revenue.

- Up to date drug product manufacturing license issued in favour of the manufacturer.
- Notarized copy of valid Certificate of Pharmaceutical Product (CPP).
- Approval of variations during the period.
- If substantive variations were done document supporting expiration period
- Method of Analysis.
- Valid GMP certificate issued by DDA or competent authority of the exporting country.

Variations in licenses, recommendation letter, product specification/standards

- The applicant shall apply with scientific justification of any variation required to be done in the master/batch formula and composition, such variation if found justified shall be allowed in the drug manufacturing license, such variation should be mentioned in the drug marketing authorization certificate/ import registration also for this, following documents are required:

  - Variation requested and justification
  - Revised product specification (with proposed variations)
  - Analytical test report from own testing laboratory
  - Product sample with labelling specimens

- Variation of Name of the industry and address shall be made if application for such variation along with evidences of changes made at company registrar's office, department of industry and department of cottage industry are submitted at the department.

Import recommendation letter in case of non-registered medicine

- Medicine(s) as per the prescription of registered practitioner for personal use of patient.
- Medicine(s) recommended by the Drug & Therapeutic Committee (DTC) of the hospitals (including medical colleges) and nursing homes for hospital use.

ANNEX-I

Schedule-4C_

(Relating to Sub-rule (1) of Rule 4B)

Application for drug import registration certificate

The Administrator,
Department of Drugs Administration.

Sir,

I/we have made this application, setting out the following details and affixing a stamp of five rupees hereto, to obtain the drug import registration certificate, pursuant to Sub-section (2) of Section 8A. of the Drugs Act, 2035(1978) and Subrule (1) of Rule 4B of the Drugs Registration Rules, 2038 (1981).

1. Drug of which import registration certificate is intended to be obtained:
   - (a) Name:
   - (b) System:
   - (c) Group and sub-group:
   - (d) Composition:
   - (e) Active ingredient and quantity (per unit):
   - (f) Expiry date:
   - (g) Pharmacopoeia standard:
   - (h) Retail price:
   - (i) Laboratory having conducted analysis and test, and the analysis and test report issued by that laboratory and date thereof:

2. Other details:
   - (a) Whether the product specification setting down the size, color, measurement or weight, taste and flavor of drug, method of packing and details mentioned in its label is attached or not:
   - (b) Whether the method of analyzing and testing the drug is attached or not:
   - (c) Whether the label, cartoon and sample of drug are attached or not:

Applicant's:
Signature:
Name and surname:
Address:
Date:

ANNEX-II

Schedule-4E_
(Relating to Sub-rule (3) of Rule 4B)

Drug import registration certificate

Import registration certificate number:

Sir,

The drug import registration certificate has bee issued, setting out the following details, pursuant to Sub-section (2) of Section 8A of the Drugs Act, 2035(1978) and Sub-rule (3) of Rule 4B. of the Drugs Registration Rules, 2038(1981).

1. Of the drug:
   (a) Name:
   (b) System:
   (c) Group and sub-group:
   (d) Composition:
   (e) Active ingredient and quantity (per unit):
   (f) Expiry date:
2. Manufacturer's:
   (a) Name:
   (b) Address and country:
3. Fees received for the import registration certificate: Rs.---
4. Validity period of certificate:

Import registration certificate obtainer's:

Name and surname:

Address:

Import registration certificate receivers:

Signature:

Name and surname:

Address:

Date:

Certificate issuing officer's:

Signature:

Name and surname:

Designation: Date:

Note bene: Prior approval has to be obtained from the Department if any alteration is to be made in the product specification and label submitted to the department and in the above mentioned details:

Amendment to the certificate

Date	**Details of Amendment**

Renewal

Period of extension of validity		Fees	Officer's signature	Remarks
From	To			

ANNEX-III

Schedule-6

(Relating to Sub-rule (1) of Rule 5)

Application for drug export/import recommendation letter

The Administrator,
Department of Drugs Administration.

Sir,

Whereas, I/we intend to obtain a recommendation letter to export/import the following drug;

Now, therefore, I/we have made this application, setting out the following matters and affixing a stamp of one rupee hereto, to obtain the recommendation letter.

Drug to be exported/imported							
S.No	Name	System	Group or subgroup	Standard Composition	Active ingredient's		Name of manufacturing company and country
					Name	Quantity	

Applicant's:

Signature:

Name and surname:

Address:

Date:

ANNEX-IV

Schedule-7
(Relating to Sub-rule (2) of rule 5)
Drug export/import recommendation letter

This recommendation letter is hereby issued, setting out the following matters, to export/import the following drug, subject to the Drugs Act, 2035(1978) and the Drugs Registration Rules, 2038 (1981).
1.

Drug to be exported/imported							
S.No	Name	System	Group or subgroup	Standard Composition	Active ingredient's		Name of manufacturing company & country
					Name	Quantity	

2. Recommendation letter obtainer's:
   (a) Name and surname:
   (b) Address:
3. Validity period of recommendation letter:
4. Recommendation letter Receivers:
   Signature:
   Date:

Recommendation letter issuing officer's:
Signature:
Name and surname:
Designation:
Date:

(The matters to be written on the reverse side of this recommendation letter.)

Renewal of the recommendation letter

Recommendation Letter					Remarks
Validity extension period		Renewing officer's signature and date	Renewal fees	Department's Seal	
From	To				

ANNEX-V

Schedule-14

(Relating to Sub-rule (2) of Rule 3, Sub-rule (2) of Rule 4, Sub-rule (2) of Rule 4A, Sub-rule (3) of Rule 4B, Sub-rule (2) of Rule 5, Sub-rule (2) of Rule 6, Sub-rule (2) of Rule 7, Sub-rule (2) of Rule 8, Rule 9, and Sub-rule (2) of Rule 10)

Fees			
SN	**Description**	**Initial fees Rs.**	**Renewal fees Rs.**
1.	For the recommendation letter for the establishment of an industry pursuant to Sub-rule (2) of Rule 3.	200/-	-
2.	For the product license pursuant to Sub-rule (2) of Rule 4 .	200/-	50/-
3.	For the sale and distribution registration certificate pursuant to Sub-rule (2) of Rule 4A.	100/-	50/-
4.	For the import registration certificate pursuant to Sub-rule (2) of Rule 4B.	200/-	100/-
5.	For the export/import recommendation letter pursuant to Sub-rule (2) of Rule 5.	200/-	100/-
6.	For the shop registration certificate pursuant to Sub-rule (2) of Rule 5:		
	(a) Capital not exceeding fifty thousand rupees	200/-	100/-
	(b) Capital from fifty thousand one rupees to one hundred thousand rupees	500/-	250/-
	(c) Capital from one hundred thousand one rupees to five hundred thousand rupees	1000/-	500/-
	(d) Capital exceeding five hundred thousand one rupees	2000/-	1000/-
7.	For the publicity and advertisement license pursuant to Sub-rule (2) of Rule 7:		
	(a) For the license for publicity and advertisement	5000/-	2500/-

Fees			
SN	**Description**	**Initial fees Rs.**	**Renewal fees Rs.**
	through television		
	(b) For the license for publicity and advertisement through printing or other media	2000/-	1000/-
8.	For the clinical trial license pursuant to Sub-rule (2) of Rule 8.	5000/-	-
9.	For duplicate copies of license, certificate and recommendation letter pursuant to Sub-rule (2) of Rule 10.		
	(a) For the first time	50/-	-
	(b) For the second time or each time more than that	100/-	-

Checklist for Company Registration

01	Application by the importer for Company registration
02	Application by the Company on its letterhead.
03	Letter of Authority to the importer
04	Site Master File (as per PICS guidelines/WHO Guidelines)
05	Notarized Copy of Up to date manufacturing license
06	List of Products Intended to be registered in Nepal
07	Letter of Warranty
08	Latest GMP internal audit report
09	Photocopy of updated Wholesale registration
10	Complete Dossier of one product intended to register
11	WHO GMP certificate from concern regulatory authority
12	Product registration and market authorization in SRA countries
13	REMS (Risk Evaluation and Mitigation Strategy) including PV(Pharmacovigilance) and post Marketing Surveillance
14	Approval letter from DDA on WHO GMP compliance (applicable for Non SRA, Non UN prequalified products and company)

Checklist for Product Registration

01	An Application in the form of *Schedule 4 'C'(DDA document)*
02	An application in the form *Schedule 6 (DDA document)*
03	Notarized Up-to-date manufacturing license issued
04	Notarized Copy of Valid COPP as recommended by WHO
05	Detail formulation including excipients, colour, flavour, etc.
06	In case of new drug combination / new molecule (*document in the format designed by the Department*).
07	BA/BE if non pharmacopeial and modified release
08	Product Specification
09	Method of Analysis
10	Monograph if pharmacopoeia
11	Analytical Method Validation if non pharmacopoeial
12	Samples of label and carton
13	Sample of the product
14	Analytical report from Company's own laboratory.
15	Analytical report from Independent laboratory (authorized)
16	Real time stability (Zone IVb) of two batches for claimed shelf life
17	Letter of Attorney (Annex 5)
18	Price commitment for lower price than exporting company
19	Comparative Price of at least 5 bands if available
20	Company inspection report of DDA if audited

Checklist for Product Renewal

S.No	**Name of Documents**
01	Application for renewal of 4 E and 7
02	Original 4 E and 6
03	Notarized COPP
04	Notarized Valid Mfg. Lic
05	Notarized Valid GMP
06	Sample
07	Annual Product Review
08	Stability information
09	Declaration on ADR
10	Price to importer, wholesaler, retailer and MRP
11	Approval of variation made under the period
12	Evidence of export to SRA in case of company registered under SRA export
13	COA (Certificate of analysis)

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Details of importing country embassy in India: **https://in.nepalembassy.gov.np/**

Contact details of Indian Embassy abroad: **http://www.indembkathmandu.gov.in/**

List of Local Pharma Associations:

Nepal Pharmaceutical Association www.npa.org.np
info@npa.org.np

Association of Pharmaceutical Producers of Nepal(APPON) http://www.nepalb2b.com/