Checklist for Company Registration

1.	Application by the importer for Company registration
2.	Application by the Company on its letterhead.
3.	Letter of Authority to the importer (ANNEX 2)
4.	Site Master File (as per PICS guidelines/WHO Guidelines)
5.	Notarized Copy of Up to date manufacturing license
6.	List of Products Intended to be registered in Nepal
7.	Letter of Warranty (Annex 3)
8.	Latest GMP internal audit report
9.	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

1.	An Application in the form of *Schedule 4 'C'(DDA document)*
2.	An application in the form *Schedule 6 (DDA document)*
3.	Notarized Up-to-date manufacturing license issued
4.	Notarized Copy of Valid COPP as recommended by WHO
5.	Detail formulation including excipients, colour, flavour, etc.
6.	In case of new drug combination / new molecule (*document in the format designed by the Department*).
7.	BA/BE if non pharmacopeial and modified release
8.	Product Specification
9.	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. N.	Name of Documents
1.	Application for renewal of 4 E and 7
2.	Original 4 E and 6
3.	Notarized COPP
4.	Notarized Valid Mfg. Lic
5.	Notarized Valid GMP
6.	Sample
7.	Annual Product Review
8.	Stability information
9.	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)

र्मित

श्रीमान महानिदशकज्यू,
औषधि व्यवस्था बिभाग,
काठमाडौं|

बिषय : औषधिको तुलनात्मक मुल्य पेश गरेको बारे |

उपरोक्त सम्बन्धमा हाम्रो फमबाट आयात गरिने .....(देशको नाम)..... को .....(उत्पादकको नाम) .... बाट उत्पादित ..... (औषधिको BRAND NAME)..... को औषधि तहाँ विभागमा दता प्रयोजनका लागि पेश गरेकोमा बजारमा उपलब्ध देहाएका उत्पादकहरुबाट उत्पादित तपसिल अनुसारका औषधिहरुको BRAND NAME, GENERIC NAME, STRENGTH र DOSAGE FORM को प्रति ईकाई बजार मुल्य (MRP) बजारमा उपलब्ध भए अनुसारको यसै आवेदन साथ पेश गरेको व्यहोरा अनुरोध छ|

मुल्यको बिबरण

S.N	MANUFACTURER'S NAME	BRAND NAME	GENERIC NAME	STRENGTH	DOSAGE FORM	MRP/NRS
1						
2						
3						
4						
5						

<u>आवेदक</u>
नाम:
पद:
फमको नाम:
सहा
कायालय को छाप

To,
The Director General
Department of Drug Administration
Bujulibazar, Kathmandu,Nepal

Subject: Commitment for Price.

Respected Sir,

We from…… are marketing our drug products in Nepal since the last……(Date) our prices for drug product are at per with product prices in India.

We assure your department that we will keep product prices in Nepal at per or lower than in India, and in any scenario nepal price will not increase the price we offer in our country india.
The current MRP for following new drug proposed to be registered are as below
We will communicate in written for any changes in price

S.N	PRODUCT NAME	PACK SIZE	MRP PER UNIT INR	MRP PER UNIT NPR
1				
2				
3				
4				
5				

Thanking you

Sincerely yours

मिति:-

श्रीमान महानिदशकज्यू,
औषधि व्यवस्था बिभाग,
काठमाडौं|

बिषय : औषधिको मुल्य पेश गरेको बारे |

उपरोक्त सम्बन्धमा हामी फमबाट आयात गरिने .....(देशको नाम)..... को ...".....(उत्पादकको नाम) .... बाट उत्पादित ..... (औषधिको BRAND NAME)..... को औषधि तहाँ विभागमा दता / नबिकरण/ सिफारिस प्रयोजनका लागि देहायको ढाँचामा सो औषधिका प्रति ईकाई मुल्य .....(ने.रु. □□) □ि□□ □ □□□□ □□ □□□□ छौ सो मा कुनै संसोधन भएमा त्यस विभागको पूव स्वीकृति लिई मात्र गन व्यहोरा anurodanurodhanurodha□□□□□ □□ □□□□नेपाल सरकार मन्त्रिपरिषद्को मिति □□□□/□□/□□ निणयले औषधि □□, □□□□ □□ □□□ □□ ले दिएको अधिकार प्रयोग गरि मिति □□□□/□□/□□ मा नेपाल राजपत्रमा प्रकाशित औषधिहरुको सुचिमा उल्लेख भएका औषधिहरुको अधिकतम खुद्रा मूल्य (MRP) □□□□□□ □□□□ ि□त्र □□□□ द□□□□ □□□□□ □|

सो भन्दा बढी अधिकतम खुद्रा मूल्य(MRP) राखेर बिक्रि बितरण गरेको पाईएमा प्रचलित कानुन बमोजिम एवं विभागबाट हुने निणयमा हामीलाई मन्जुरी छ |

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Documents Required for Import of Intra Ocular Lenses (IOL)

1. Application by Importer
2. Application by Company
3. Manufacturing License
4. Site Master File (SMF)
5. ISO 9000 : 2000 Certificate
6. EC Directives 93/42/EEC Annex II- CE Certification
7. ISO 13485 : 2003 (Quality Management System of the Industry)
8. ISO 11979 : 1999 (Standard of the Product)
9. Quality Manual
10. Sources of the Materials used in the Lens
11. Authority Letter from the Manufacturer
12. Test Report of the Lens
13. Letter of Warranty
14. Unit Price

Documents Required for Import of Radioactive Substances

1. Application by Importer
2. Industry Registration Certificate
3. Company Registration Certificate
4. Approval letter from Government Agency for handling radioactive substances.
5. Material Safety Data Sheet
6. Performa Invoice
7. License from authorized Atomic Energy Regulatory Board
8. Standard Operating Procedures for Transport, Handling, Storage and Disposal.
9. Radiation Protection Manual
10. Consumption Report