Regulatory Procedure

REGISTRATION, LICENSING AND OTHER LEGAL REQUIREMENTS TO IMPORT DRUGS (INCLUDING VETERINARY DRUGS) INTO PAKISTAN

Small and Medium Enterprises Development Authority

Ministry of Industries & Production

Government of Pakistan

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March 2006

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1. INTRODUCTION OF SMEDA

The Small and Medium Enterprise Development Authority (SMEDA) was established with the objective to provide fresh impetus to the economy through the launch of an aggressive SME development strategy.

Since its inception in October 1998, SMEDA had adopted a sectoral SME development approach. A few priority sectors were selected on the criterion of SME presence. In depth research was conducted and comprehensive development plans were formulated after identification of impediments and retardants. The all-encompassing sectoral development strategy involved overhauling of the regulatory environment by taking into consideration other important aspects including finance, marketing, technology and human resource development.

SMEDA has so far successfully formulated strategies for sectors, including fruits and vegetables, marble and granite, gems and jewellery, marine fisheries, leather and footwear, textiles, surgical instruments, transport and dairy. Whereas the task of SME development at a broader scale still requires more coverage and enhanced reach in terms of SMEDA's areas of operation.

Along with the sectoral focus a broad spectrum of services are now being offered to the SMEs by SMEDA, which are driven by factors like enhanced interaction amongst the stakeholders, need based sectoral research, over the counter support systems, exclusive business development facilities, training and development for SMEs and information dissemination through wide range of publications.

2. ROLE OF SMEDA LEGAL SERVICES CELL

The Legal Services Cell [LSC] is a part of Business Development Division of SMEDA and plays a key role in providing an overall facilitation and support to SMEs. The LSC provides guidance based on field realities pertaining to SMEs in Pakistan and other parts of the world.

LSC believes that information dissemination among the SMEs on the existing regulatory environment is of paramount importance and it can play a pivotal role in their sustainable development.

In order to facilitate SMEs at the Micro Level LSC has developed user-friendly systems, which provide them detail description of the Laws, and Regulations including the process and steps required for compliance.

The purpose of this document is to provide SMEs with information pertaining to registration / licensing and other legal requirements to import drugs in Pakistan. Entrepreneurs interested in enhancing their understanding about the procedures can also use the document and documentation required to comply with registration / licensing procedure. For convenience of the readers sample of various forms and important addresses are also included.

3. DISCLAIMER

Information in this document is provided only for general information purpose and on an "as is" basis without any warranties of any kind. Use of this information is at the user's sole risk. SMEDA assume no responsibility for the accuracy or completeness of this information and shall not be liable for any damages arising from its uses."

4. Overview:

The Drugs Act, 1976 is a law which controls the manufacturing and import of drug (including veterinary medicine) in Pakistan. Under power conferred by the said Act, the Government has also made the Drugs (Licensing, Registration and Advertising) Rules, 1976 and the Drugs (Import and Export) Rules, 1976 to control the import of drugs into Pakistan.

Under the said Act and the rules a person requiring to import drugs ((including veterinary medicine) have to fulfill certain requirements and follow the procedure given in the rules.

5. Registration of Drug

The Act requires that all finished drugs should be registered with the Drug Registration Board before their sale in the market. Finished drug means a drug that has undergone all stages of production and is ready for use.

6. Application for Registration

An application for registration of a drug shall be made in Form 5-A (Form 5A is attached herewith) in duplicate to the Drug Registration Board addressed to its Secretary. It is pertinent to mention that a separate application is required to be made for each drug.

7. Fee for Registration

The application for registration shall be accompanies by a fee of:

a) Rupees one thousand for the registration of new drug;
b) Rupees five hundred for the registration of any other drug

8. Procedure on Application for Registration

Before registering a new drug for which the research work has been conducted in other countries and its efficacy, safety and quality has been established therein, the Registration Board requires the investigation on such pharmaceutical, pharmacological and other aspects, to be conducted and clinical trials to be made as are necessary to establish its quality and, where applicable, the biological, availability, and its safety and efficacy to be established under the local conditions:

9. Certificate of Registration

After necessary investigation and on satisfaction, the board shall issue registration certificate to the applicant. A certificate of registration shall, unless earlier suspended or cancelled, be in force for a period of five years from the date

of Registration of the drug and may thereafter be renewed for periods not exceeding 5 years at a time.

The importer shall also issue a warranty in Form 2-A (Form 2-A is enclosed herewith) for any drug indented or sold by him for the purpose of re-sale or distribution.

10. Import of drugs into Pakistan

According to the Drugs (Import and Export) Rules, 1976, there are four different modes to import drugs into Pakistan:

1. Import of finished drugs
2. Import of drugs other than the finished drugs
3. Import of small quantities of drugs for the purpose of clinical trial, examination, test or analysis.
4. Import of drugs for personal use

There are different requirements to import of drugs for all above modes which requirements are provided below one by one.

11. Procedure to import of finished drugs

Import license is not required to import finished drugs, however, as per the Drugs (Import and Export) Rules, 1976, the following requirements have to be fulfilled by the importer to import finished drugs: --

(i) the importer must possesses a license to sell by way of retail, wholesale, the drug he wants to import and has adequate facilities for proper storage to preserve its properties. The license to sell is issued by the provincial government.

(ii) Within fifteen days of establishing the letter of credit, the importer must intimate about such import on Form I (Form 1 is enclosed herewith) to an officer authorised by the Federal Government in this behalf.

(iii) the drug should be imported in containers intended for retail sale or supply to hospitals, dispensaries or such other institutions.

(iv) The drugs should be imported against indents issued by the authorized indentors or local agents of the manufacturers.

(v) To import finished drugs in bulk containers the importer is required to possesses a license for re-packing and obtain permission in writing to such import from an officer authorized by the Federal Government in this behalf. As per rule 4 of the said rules an application in Form 1 is

required to be submitted to the Central Licensing Board addressed to its Secretary to obtain license to manufacture drugs by way of repacking.

12. Procedure to import drugs other than the finished drugs

An import license is required to import drugs other than the finished drugs. To obtain import license, an application in Form 2 (enclosed herewith) is required to be submitted to the licensing authority. The said application should be accompanied by a fee of fifty rupees and by an undertaking in Form 3 (enclosed herewith), signed by or on behalf of the manufacturer from whom the drugs are to be imported.

A single application shall be made, and a single licence shall be required, in respect of the import of more than one drug or class of drugs manufactured by the same manufacturer:

Provided that if a manufacturer from whom the drugs are to be imported has two or more premises manufacturing the same or different drugs a separate application shall be made, and a separate licence shall be required, in respect of the drugs manufactured in each such premises.

13. Issuance of License

Upon receipt of the said application, the licensing authority, after confirmation of meeting all the requirements, shall issue license in Form 5 (enclosed herewith) to import drugs other than the finished drugs which license shall be valid for two years unless earlier suspended or cancelled. To obtain the said license importer is required to comply with the following conditions: --

(i) the manufacturer shall at all times observe the under-taking given by him or on his behalf in Form 3 (enclosed herewith);
(ii) the licensee shall allow the licensing authority or any person authorised by it in this behalf to enter, with or without prior notice, any premises where the imported drug is stocked to inspect the means, if any, employed for testing the drug and to take samples;
(iii) the licensee shall on request furnish to the licensing authority from every batch of each drug or from such batch or batches as the licensing authority may from time to time specify as sample in such quantity as the licensing authority may consider adequate for any examination, test or analysis required to be made, and the license shall, if so required furnish full protocols of the tests, if any which have been applied;

(iv) the licensee shall ensure proper storage facilities for preserving the properties of the imported drug;

(v) the licensee shall maintain a complete record of utilization of the imported drug, showing particulars of the substance manufactured from it and such further particulars, if any as the licensing authority may specify and such record shall be open to the inspection of licensing authority or any person authorised in this behalf by the licensing authority

(vi) the licensee shall comply with such further requirements, if any applicable to the holders of import licences, as may be specified in any rules that may be made afterwards under the Act in this behalf and of which the licensing authority has given to him not less than three months notice.

14. Procedure to import small quantities of drugs

Similarly the import of drugs other than the finished drugs, import license is also required to import of small quantities of drugs for the purpose of clinical trial, examination, test or analysis. To obtain the said license an application in Form 4 (enclosed herewith) is required to be submitted. Upon receiving the said application, the licensing authority may require from the applicant such other particulars to be supplied as it may consider necessary. License is be issued by the licensing authority in Form 6 (enclosed herewith) for the period of two years subject to the following conditions: --

(a) the licensee will use the drug exclusively for the purpose for which it has been imported and at the place specified in the licence, or at such other place as the licensing authority may from time to time authorise;

(b) the licensee shall allow the licensing authority or any person authorised by it in this behalf to enter, with or without prior notice, the premises where the drugs are kept and to inspect the premises and investigate the manner in which the drugs are being used and to take samples thereof;

(c) the licensee shall keep record of, and shall report to the licensing authority, the drugs imported under the licence, together with the quantities imported, the date of importation and the name of the manufacturer;

(d) the licensee shall comply with such further requirements if any, applicable to the holders of licences for clinical trial, examination, test or analysis as may be specified in any rule made afterwards under the Act and of which the licensing authority has given to him not less than one month's notice.

15. Other General requirements to import all types of drugs

Apart from specific requirements as describe above there are some other general requirements which have to be comply with to import all types of drugs. Following are these general requirements: --

(i) Every drug shall be produced in sufficient quantity so as to ensure its regular and adequate supply in the market. In case of an imported drug, the importer in Pakistan shall ensure regular and adequate supply of the drug in Pakistan.

(ii) the importer shall maintain a record of all sales by way of wholesale made by him of the imported drugs, and such record shall be open to the inspection by any person authorised in this behalf.

(iii) the importer shall maintain an inspection book on which a member of the Registration Board or of the licensing authority or an Inspector shall record proceedings of each of his visits, his impressions and the defects notified by him and such inspection book shall be signed by him as well as the licensee or his authorised agent;

(iv) the importer shall ensure that the import of each batch of a drug is accompanied by—

a. a batch certificate in Form 7 (Form 7 is enclosed herewith) from the competent health authority or any other such agency of the country of export or from the manufacturer;
b. a copy of the test report of the drug from the competent health authority or any other such agency of the country of export or from the manufacturer;

(v) the importer shall allow any person authorised in this behalf to enter, with or without prior notice, any premises where the imported drugs are stocked, to inspect the storage facilities and to take samples for testing ;

16. Procedure at Customs Ports

(i) Clearance Certificate

No drug is released from the customs unless a clearance certificates has been obtained by the importer from an officer authorised in this behalf by the Federal Government. To obtain clearance certificate, the importer, shall on receipt of information of arrival of the consignment of drugs at the port of importation report in Form 8 (Form 8 is enclosed herewith) alongwith three copies of the invoice to the officer authorised by the Federal Government to grant clearance.

(ii) Sampling by the Customs Authority

If the Collector of Customs or an officer authorised by him has reason to suspect that any drug does not comply with the provisions of the Act or the rules made thereunder, he may, or if requested by as officer authorised in this behalf by the Federal Government shall, take samples of any drugs from the consignment and forward them to the officer-in charge of the laboratory appointed for the purpose by the Federal Government and may detain the drugs from the consignment of which samples have been taken until the report of the officer-in charge of the said laboratory on such samples is received.

Provided that if the importer gives an undertaking in writing not to dispose of the drugs without the consent of the Collector of Customs and to return the consignment or such portion thereof as may be required, the Collector of Customs shall make over the consignment to the importer. If an importer who has given an undertaking is required by the Collector of Customs to return the consignment or any portion thereof, he shall return the consignment or portion thereof within ten days of receipt of the notice.

(iii) Procedure in case of Non-remediable contravention

If the officer-in-charge of the laboratory appointed for the purpose by the Federal Government reports to the Collector of Customs that the samples of any drug in a consignment do not conform to the specification or that the drug contravenes in any other respect the provisions of the Act or the rules made thereunder and that the contravention is such it cannot be remedied by the importer, the Collector of Customs shall communicate the report forthwith to the importer who shall within two months of his receiving the communication, either export all the drugs of that description in the consignment to the country from which they were imported or surrender them to the Federal Government for disposal in such manner as it may deem fit.

Provided that the importer may, within fifteen days of the receipt of the report make a representation against the report to the Collector of Customs who shall forward the representation with a further sample to the licensing authority or, as the case may be, the Registration Board which after obtaining, ff necessary, the report of the .officer-in-charge of the Federal Drugs Laboratory, shall pass orders thereon which shall be final.

(iv) Procedure in case of remediable contravention

If he officer-in- charge of the laboratory appointed for the purpose by the Federal Government reports to the Collector of Customs that the samples of any drug contravene in any respect the provisions of the Act or the rules

made thereunder and that the contravention is such that it can be remedied by the importer, the Collector of Customs shall communicate the report forthwith to the importer and permit him to import the drug on his giving an undertaking in writing not to dispose of that drug without remedying the said contravention.

(v) Inspection by the Inspector

A Federal Inspector or a person authorised in this behalf by the Federal Government may physically inspect the consignment and draw samples from each batch for test and analysis as may be necessary and, if the consignment has been released by the customs, may order the importer not to sell or offer for sale or dispose of the drug for a reasonable period not exceeding one month with a view to obtain a test report:

Provided that the Federal Inspector or such authorised officer may prohibit the disposal of a drug for a longer period if he has sufficient reason to believe that the import, in any way, is in contravention of any or the provision of the Act or the rules made under the Act, in which case the importer shall not dispose of that drug until a certificate authorising the sale of the batch has been issued to him.

17. Import duty on import of drugs

Import duty on import of drugs is levied in percentage form. There are different percentages on different types of drugs as per its specification. Chapter 30 of the Pakistan Custom Tariffs deals with the import duty of pharmaceutical products. You may check custom duty in the said chapter as per specification of your drugs by clicking to the following link (http://www.cbr.gov.pk/budget2006/Tariff/Tariff.pdf). Normally import duty on drugs ranges from 5 to 25 percent.

18. Important Addresses

Address of Drug Registration Board
The Drugs Controller
Ministry of Health
Government of Paksitan, Islamabad

Address of Medical Testing Lab:
CENTRAL DRUG TESTING LAB.
Director / Govt. Analyst
Central Drugs Labortories
Building No. 4. Block 'B', S.M.C.H.S.
Karachi
Phone No. 92-21-4382979
92-21-4383079

FORM-5 (A)
[See rule 26 (1)]

APPLICATION FORM FOR REGISTRATION OF AN IMPORTED DRUG.

I/We _____of _____hereby apply for registration of

the drug, namely-_____details of which are enclosed.

Dated_____
Singed_____

Place_____

ENCLOSURES OF THE APPLICATION FOR REGISTRATION OFA DRUG

1. Name, address and status of the applicant:
2. Name and address of the manufacturer:
3. Name of the drug:
   (a) Generic / International non-proprietary name.
   (b) Proprietary name, if any.
4. Name of drug under which it is proposed to be sold:
5. Dosage form of the drug:
6. Composition of the drug stating quantity of each active and non-active ingredients per unit dose percentage of total formulation:
7. Proposed dosage:
   (a) For adults (b) Children by age group
   (c) Infants (d) Special groups
8. Main Pharmacological group to which the drug belongs:
9. Proposed route of administration:
10. Pharmacological and clinical data:
    (a) Recommended clinical use and the claim to be made for the drug.
    (b) Contra-indications.
    (c) Toxicity & side-effects.
    (d) Any directions for use to be included in the labelling warnings and precautions in use; symptoms of over dosage should be given along-with the treatment including antidotes, where required.
11. Specifications with details of analytical procedure not (not required in case of a drug for which the pharmacopoeia standards recognized under the Drugs Act, 1976 are claimed):
12. Bio-availability studies:
13. Stability studies:
14. Proposed shelf life with storage conditions, if any:
15. Type of container:

16. Labelling: (Specimen to be enclosed along with a sample and undertaking to refrain from counterfeiting shall also be submitted):
17. Proposed C & F and maximum retail price (incase of imported drug):
18. Justification:
19. Certificate regarding sale and G.M.P. in the country of origin (in English and on Form-5 (C):
20. Certificate of registration by F.D.A. of USA, Committee on Safety of Medicines of U.K. or corresponding agencies of France, West Germany, Japan, Sweden and Denmark:
21. Patent number, if any, with date and its date of expiry:
22. Undertaking to manufacture drug locally within two years. If it is not possible, the reasons thereof.

CHECK LIST
Regarding Drug Registration Applications for Import

1. Application on the prescribed Form.5-A under the Drugs (Licensing, Registering & Advertising) Rules, 1976 is required.
2. Name, address and status of the applicant /manufacturer.
3. Name of the drug: -
   (a) Generic/International non-proprietary name.
   (b) Proprietary name, if any.
4. Name of the drug under which it is proposed to be sold.
5. Dosage form of the drug/Proposed dosage of the drug (Adults, Children by age group, Infants, Special groups).
6. Composition of the drug stating quantity of each active and non active ingredients per unit dose or percentage of total formulation.
7. Main Pharmacological group to which the drug belongs.
8. Proposed route of administration.
9. Pharmacological and clinical data: -
   (a) Recommended clinical use and the claim to be made for the drug.
   (b) Contra-indications.
   (c) Toxicity & Side effects.
   (d) Any directions for use to be included in the labeling warnings and precautions in use;
   Symptoms of overdose along with the treatment including antidotes, where
   required.
10. Complete specifications with details of analytical procedures.
11. Description of the method of manufacture and quality control with details of equipments.
12. Bio-availability/Stability studies conducted.
13. Proposed shelf life with storage conditions, if any.
14. Type of container/Package/Pack size(s).
15. Labeling, as required under the Drugs (labeling & packing) Rules, 1986.Specimen to be closed along with the two finished samples of the drug (s) and an undertaking to refrain from counterfeiting.
16. Justification.
17. Proposed C&F and M.R.P demanded. Prices of exact/therapeutic equivalent drugs along with their composition, strength & brand name, already available in the Pakistan market.
18. Availability, Marketing and Registration status as well as Export of the drug to other countries, especially in this region (India, Bangladesh, Serilanka etc.), with export C&F price.
19. Free Sale Certificate & G.M.P. certificate (in original) from the regulatory authority in the country of origin as per approved format of the W.H.O.

20. Certificate of registration by FDA of USA, Committee on Safety of Medicines of U.K.or corresponding agencies of France, West Germany, Japan, Sweden and Denmark
21. Patent number, if any, with date of its expiry.
22. Undertaking to manufacture the drug locally within two years, if it is not possible, valid reasons therefore.
23. Sole agency agreement with the manufacturer abroad.
24. Credentials of the company duly endorsed by the Pakistan Embassy/Consulate office in the country of export.
25. International price comparison (for New Drug)
26. Research papers published in internationally recognized journals. (For New Drug)
27. Treasury Challan of Rs. 15000/- (in original) being the registration fee to be deposited in Federal Government treasury under the head of account:-

    C-Non Tax Revenue
    C02-Receipts from Civil Administration and other Functions.
    C028-Social Services.
    C02841-Health-Other Receipts

28. Five copies of registration dossier for Biological Committee.
29. Four copies of registration dossier/technical data/literature of the drug for Expert Opinion.

FORM 2A
(See rules 19 and 30)

Warranty under Section 23(I)(i) of the Drugs Act, 1976

I.....being a person resident in Pakistan, carrying on business at (full address) ..... under the name of.....(and being an importer/indenter/authorised agent of .....), do hereby give this warranty that the drugs here-under described as sold/indented by me/specified and contained in the bill of sale, invoice, bill of lading or other document describing the goods referred to herein do not contravene in any way the provisions of section 23 of the Drugs Act, 1976.
Dated (Signed)

1. Name(s)• of the drug(s):
(i)
(ii) Batch number(s)

2. Description of bill of sale, invoice, bill of lading or other document (if any).

Signed .....

FORM 1
[See rule 3 (ii)]

INTIMATION REGARDING IMPORT

I/We ……..…….. of ……..... have established the letter of credit to conduct import of drug(s) details of which are as follows:--

(i) Name of the drug(s) ----------

(ii) Drug Registration number(s) ----------

(iii) Name and address of Manufacturer ----------

(iv) Name and address of exporter ----------

(v) Date of establishing L/C ----------

(vi) Quantity to be imported ----------

(vii) Rate per unit ----------

(viii) Total C & F value ----------

(xi) Mode of shipment ----------

(x) Expected date of arrival ----------

(xi) Nature of Drugs Sale License ----------

Date---------- Signed----------

FORM 2
[See rule 6 (1)]

APPLICATION FOR LICENSE TO IMPORT DRUG(S)

I/We ----------hereby apply for import of drug(s) specified below

manufactured by---------- of----------.

NAME OF DRUG(S) ----------.

I/We----------enclose herewith an undertaking in Form 3 signed by or on behalf of the manufacturer as required by the rule under the Drugs Act, 1976.

FORM 3

[See rule 5 (1)]

FORM OF UNDERTAKING TO ACCOMPANY AN APPLICATION FOR LICENSE TO IMPORT DRUGS

Whereas----------of----------intends to apply for a license under the Drugs (Import and Export) Rules, 1976, for the import into Pakistan of the drug(s) specified below manufactured by us. We----------of----------hereby give this undertaking that:

(1) the said applicant has made a contract with us for import of drug(s) mentioned in the undertaking;

(2) we declare that we are bonafide licensed manufacturer of the drugs covered under this undertaking at the premises specified below and we shall report change, if any, in the said premises;

(3) we shall comply with the conditions imposed on a license by the rules under the Drugs Act, 1976 and such other requirements as may the laid down by the Government of Pakistan in this behalf;

(4) the drug(s) mentioned below conform(s) to the provisions or the Drugs Act, 1976, and the rules made thereunder.

NAME OF THE DRUG(S) ----------

Particulars of the premises where manufacture is carried on.

Date---------- Signature of Manufacturer----------

FORM 5

(See rule 7)

LICENSE TO IMPORT DRUG(S)

Number of license----------M/s---------- of---------- is/are hereby licensed to import into Pakistan during the period for which this license is in force the drug(s) specified below, manufactured by----------of----------.

2. This license is subject to the conditions prescribed in the Drugs Act, 1976 and shall be in force for a period of two years from the date stated below unless it is sooner suspended or cancelled under the said Rules:

Name of Drug(s) to which this license applied:
(1) ----------
(2) ----------
(3) ----------
Date---------- Licensing Authority----------

FORM 4

[See rule 6 (3)]

APPLICATION FOR LICENSE TO IMPORT DRUGS FOR THE PURPOSE OF CLINICAL TRIAL, EXAMINATION, TEST OR ANALYSIS

I/We----------of----------by occupation----------hereby apply for a license to import the drug(s) analysis at----------and I/We undertake to comply with the conditions applicable to the license under rule 12 of the Drugs (Import and Export) Rules, 1976.

Name of drug(s)---------- Quantities----------

Manufactured by----------

Date---------- Signature----------

Name and address of applicant ----------

FORM 6

[See rule 7]

LICENSE TO IMPORT DRUG(S) FOR CLINICAL TRIAL, EXAMINATION, TEST OR ANALYSIS

No. of license----------M/s----------of---------- is/are hereby licensed to import from----------the drug(s) specified below for the purpose of clinical trial, examination test or analysis at----------or in such other place as the licensing authority may from time to time authorise.

2. This license is subject to the condition prescribed in rule 12 of the Drugs (Import and Export) Rules, 1976, and such other conditions as may be prescribed by the Federal Government in this behalf.

3. This license shall, unless, previously suspended or cancelled, be in force for a period of two years from the date specified below:

Name(s) of drug(s) with quantities which may be imported

Date---------- Licensing Authority----------

FORM 7
[See rule 14 (d) (I)]

BATCH CERTIFICATION

Name and Registration No. of drug ----------
Batch number of drug ----------
Name and address of the Manufacturer ----------
Date of Manufacture ----------
Date of expiry, if any ----------

It is hereby certified that the above-mentioned drug (s) has/have been manufactured and labelled in conformity with the provisions of the Drugs Act, 1976, and the rules made thereunder.

It is further certified that this/these drug (s) has/have been manufactured under a valid permit/license issued by the competent Health or any other authority to manufacture this/these drug(s).

Signed ----------
Name, designation and official seal of the Signatory ----------
Place and date ----------

FORM 8

[See rule 14 (f)]

Intimation of arrival of consignment (s) of imported drug (s) other than those imported for personal use.

Name and address of importer. ----------

Status (whether commercial importer or industrial consumer). ----------

Drugs Manufacturing License No (in case of industrial consumer). ----------

Drug Import License No. (in case of industrial consumer). ----------

C.C.I., &E License No. with date and value of the License. ----------

Import Policy Order applicable. ----------

Name and address of exporter/manufacturer. ----------

Name of drug (with dosage form for finished drug) Drug Registration No. finished drug Rate (for C & F/F.O.B.) Packing Quantity Total Value ----------