

SOP No.	Revision	Issue date	Page 1 of 20
SOP-01-001	0	DD/MM/YYYY	
Effective date	Prepared by:		
Standard Operating Procedure	Reviewed by:		
	Authorized by:		

**COSMETICS, DEVICES & DRUGS
REGULATORY AUTHORITY
PROCEDURES**

**STANDARD OPERATING PROCEDURE
FOR
ISSUING WHOLESALE LICENCE**

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Prepared by: Date:	Reviewed by: Date:	Authorized by: Date:	Supersedes No.: Date:
<p>Title: SOP for Issuing Wholesale Licence</p> <p>Department: Law Enforcement Division / Administrative Division</p> <p>Responsibility: Head of the Department</p>			

1. Purpose:

The objective of this SOP is to describe the method for issuing Wholesale Licence.

2. Scope:

This SOP applies for issuing a wholesale licence annually as specified in CDD regulations.

3. Responsibility:

It is the responsibility of the Chief Food & Drugs Inspector to ensure timely issuing of licence following inspection of the premises.

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4. Procedure

4.1 Metropolitan Area

- 4.1.1 Importer / wholesaler submits application [Annexure 1: Schedule VIII, Form A] to the Health Management Assistant (1) of the Pharmacy Licence issuing section of CDDA.
- 4.1.2 Health Management Assistant (1) date stamp and opens a file with a unique Number/filed into the existing file.
- 4.1.3 Health Management Assistant (1) refers the application to CF&DI. C/FD&I forwards the file to F&DI (1).
- 4.1.4 F& DI (1) will inspect premises [Annexure2: Checklist for the inspection of Pharmacies] and forwards the report with the recommendations [Annexure 3] to Health Management Assistant (1).
- 4.1.5 Health Management Assistant (1) refers the file to the Health Management Assistant (2) who is in – charge the data base to clarify whether the Pharmacist is already registered in some other place. Health Management Assistant (2) checks, minute and return the file to the Health Management Assistant (1).

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- 4.1.6 When pharmacist is newly employed to the relevant pharmacy, he/she is called for certificate verification and the recommendation is given after the interview.
- 4.1.7 If the recommendation given by the F&DI is satisfactory, Health Management Assistant (1) issues payment letter (Annexure 4: Fee). If not satisfies the applicant is notified.
- 4.1.8 Applicant makes payment to the shroff counter of the Ministry of Health and obtains the yellow receipt. The yellow Receipt is date stamped and submits to Health Management Assistant (1).
- 4.1.9 Health Management Assistant (1) attaches the yellow receipt and attach the licence to be typed (Annexure 5: Schedule VIII, Form B) to the file and sends to the typist.
- 4.1.10 Typist types licence No ,Owner’s name & address ,Issuing date, Date of payment, Yellow receipt no, File No, Date of typed, Name of the Pharmacist and his/her registration number with 2 copies.
- 4.1.11 Typist refers the file to the Senior Health Management Assistant to affix the photograph of the Pharmacist on the form ‘B’ and attaches a photocopy of the typed form ‘B’.

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- 4.1.12 Senior Health Management Assistant submits the file to the F&DI section for checking.
- 4.1.13 The Chief F&DI refers the file to the F&DI who assigned for this purpose.
- 4.1.14 The F&DI checks all relevant documents in the file with guidance of a check list (Annexure 6) and checks whether all relevant documents are in the order and recommends to issue the licence (Annexure 7).
- 4.1.15 CF&DI maintains a register and enters the necessary information in the register and forward the file to D/MT&S for signature.
- 4.1.16 D/MT& S will sign and forward to Health Management Assistant (2).
- 4.1.17 Health Management Assistant (2) will issue the wholesale Licence to the applicant while attaching a copy to the file and sending the other copy to the data entry operator.
- 4.1.18 The data entry operator enters the required data in the database and return to the Health Management Assistant (2) to bind the certificates separately.

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4.2) Other areas

- 4.2.1 Applicant refers duly filled new/renewal application to respective Regional Director of Health Services (RDHS).
- 4.2.2 RDHS refers the application to F&DI concern for his recommendation.
- 4.2.3 F&DI carries out an inspection of the place and after inspecting, F&DI forwards his recommendation to RDHS.
- 4.2.4 RDHS forwards the application with his recommendation to D/MT&S.
- 4.2.5 D/MT&S forwards the application to the F&DI section.
- 4.2.6 The application is entered in a register maintained at the F&DI section.
- 4.2.7 F&DI forward the application to the Health Management Assistant (1). Health Management Assistant (1) opens a file with a unique Number/ filed into the existing file.

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- 4.2.8 Health Management Assistant (1) refers the file to the Health Management Assistant (2) who is in – charge the data base to clarify whether the Pharmacist is already registered in some other place. Health Management Assistant (2) checks, minute and return to the Health Management Assistant (1).
- 4.2.9 When pharmacist is newly employed to the relevant pharmacy, he/she is called for certificate verification and the recommendation is given after the interview.
- 4.2.10 If the recommendation given by the F&DI, after the certificate verification, Health Management Assistant (1) issues payment letter (Annexure 6: Fee). If not satisfies the applicant is notified.
- 4.2.11 Applicant makes payment to the shroff counter of the Ministry of Health and obtains the yellow receipt. The yellow Receipt is date stamped and submits to Health Management Assistant (1).
- 4.2.12 Health Management Assistant (1) attaches the yellow receipt and attach the licence to be typed (Annexure 7: Schedule VIII, Form B) to the file and sends to the typist.

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- 4.2.13 Typist types licence No ,Owner’s name & address ,Issuing date, Date of payment, Yellow receipt no, File No, Date of typed, Name of the Pharmacist and his/her registration number with 2 copies.

- 4.2.14 Typist refers the file to the Senior Health Management Assistant to affix the photograph of the Pharmacist on the form ‘B’ and attaches a photocopy of the typed form ‘B’.

- 4.2.15 Senior Health Management Assistant submits the file to the F&DI section for checking.

- 4.2.16 The Chief F&DI refers the file to the F&DI who assigned for this purpose.

- 4.2.17 The F&DI checks all relevant documents in the file with guidance of a check list (Annexure 4) and checks whether all relevant documents are in the order and recommends to issue the licence (Annexure 5).

- 4.2.18 CF&DI maintains a register and enters the necessary information in the register and forward the file to D/MT&S for signature.

- 4.2.19 D/MT& S will sign and forward to Health Management Assistant (2).

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4.2.20 Health Management Assistant (2) will issue the wholesale Licence to the applicant while attaching a copy to the file and sending the other copy to the data entry operator.

4.2.21 The data entry operator enters the required data in the database and return to the Health Management Assistant (2) to bind the certificates separately.

ANNEXURE "1"

Form A

Regulation 56

SCHEDULE VIII

APPLICATION FOR LICENCE TO SELL DRUGS (BY WHOLESALE)

I/We of hereby apply for a licence to deal in drugs by (wholesale) on premises situated at
.....

Date :

Signed :

Name and Address :

Designation of applicant :

Details Required :

Is licensee a registered pharmacist ; Or.

Is the Transaction carried out on behalf of licensee by a registered pharmacist :

Name and address of registered pharmacist :

Registration No. :

Storage facilities available in the premises :

Refrigerator :

Deep freezer :

Air conditioning :

Name and qualification of person (s) supervising distribution and preservation of drug.

Has a licence been issued before and revoked by the Drugs Authority.

ANNEXURE “2”

Form No-

INSPECTION OF PHARMACIES			
Check List			
01	Date of inspection-/...../.....	Business Registration No-.....	
02	MOH Area-	RDHS Division.....	A.G.A Division-.....
03	Name & Address of the Pharmacy- Tele: Fax: e.mail:	
04	Name & Address of the Owner	I.D No.....
05	Pharmacy is licensed	Yes- <input type="checkbox"/> No- <input type="checkbox"/>	License No -
		Expired- Y / N	Date of issue -/..../.....
		License Fee has paid- Y / N	License is exhibited Yes- <input type="checkbox"/> No- <input type="checkbox"/>
06	Pharmacist is present	Yes- <input type="checkbox"/> No- <input type="checkbox"/>	Pharmacist's license is exhibited-Yes- <input type="checkbox"/> No- <input type="checkbox"/>
07	Name & Address of the Pharmacist	Registered No-
08	No of Pharmacy Assistants / Dispensers employed-	Male-.....	Female-.....
Building & Layout			
09	Location of the Pharmacy	Satisfactory- <input type="checkbox"/> Fair- <input type="checkbox"/> Unsatisfactory- <input type="checkbox"/>	
		Remarks-	
10	Condition of the building	Air conditioned- Yes- <input type="checkbox"/> No- <input type="checkbox"/>	Light & Ventilation Sufficient- <input type="checkbox"/> Not suffic- <input type="checkbox"/>
		Ceiling is fixed- Yes- <input type="checkbox"/> No- <input type="checkbox"/>	Floor area (approx)- s.f Sufficient- <input type="checkbox"/> Not sufficie <input type="checkbox"/>
		Condition of walls- Satisfactory- Y / N	
		Any evidence of fungal or mould growth- Y / N	
11	Overall condition of the building-	Satisfactory- <input type="checkbox"/> Fair- <input type="checkbox"/> Unsatisfactory- <input type="checkbox"/>	Waiting area for consumers- Available- Y / N

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12	General cleanliness	Satisfactory- <input type="checkbox"/>	Unsatisfactory- <input type="checkbox"/>
Storage of Pharmaceuticals			
13	Arrangement of drugs-	Alphabetical order- <input type="checkbox"/>	Categorical order- <input type="checkbox"/>
15	Drugs are protected from Dust / Direct sunlight/leakages Yes- <input type="checkbox"/> No- <input type="checkbox"/>	Direct contact with floor / roof- Yes- <input type="checkbox"/> No- <input type="checkbox"/>	Evidence of applying F.E.F.O-Yes- <input type="checkbox"/> No- <input type="checkbox"/>
16	Water supply- Available <input type="checkbox"/> No- <input type="checkbox"/>	Hand washing facilities- Available - <input type="checkbox"/> No- <input type="checkbox"/>	
Temperature control			
17	<u>Room temperature</u> at the time of inspection-	(1)..... ..C	(2)..... C (3).....C
Cold Chain Maintenance	Monitoring of temperature is done- Yes- <input type="checkbox"/> No- <input type="checkbox"/>	<u>Place of storing of Vaccines/Hormones/A.sera</u> <ul style="list-style-type: none"> • Separate refrigerator- <input type="checkbox"/> Temp- C • Common refrigerator- <input type="checkbox"/> Temp-.....C • Bottler Cooler- <input type="checkbox"/> • Others- <input type="checkbox"/> Specify-..... • No of refrigerators available-..... 	
	Instrument used to monitor temperature- Thermometer- <input type="checkbox"/> Other- <input type="checkbox"/> Specify-.....		
	Arrangements of drugs inside the fridge- Satisfactory- <input type="checkbox"/> Unsatisfactory- <input type="checkbox"/>		
Documentation			
18	Prescription register is maintained- Yes- <input type="checkbox"/> No- <input type="checkbox"/> Date of last entry-.....	Remarks	
19	Register for Dangerous Drugs/Corex D Available- Yes- <input type="checkbox"/> No- <input type="checkbox"/> Not relevent- <input type="checkbox"/>	Health Ministry correspondence file- Yes- <input type="checkbox"/> No- <input type="checkbox"/>	
20	Invoice file maintained- Yes- <input type="checkbox"/> No- <input type="checkbox"/>	Price list available- Yes- <input type="checkbox"/> No- <input type="checkbox"/>	
Dispensing of Drugs			
21	Proper instructions are given(after observation) Yes- <input type="checkbox"/> No- <input type="checkbox"/>	Labeling of medicines dispensed – Satisfactory- <input type="checkbox"/> Unsatisfactory- <input type="checkbox"/>	
22	A system of verification of dispensed drugs available- Yes- <input type="checkbox"/> No- <input type="checkbox"/>		
23	Found possession of-		
	Expired drugs- Yes- <input type="checkbox"/> No- <input type="checkbox"/>	Unregistered drugs- Yes- <input type="checkbox"/> No- <input type="checkbox"/>	
	State logo marked drugs- Yes- <input type="checkbox"/> No- <input type="checkbox"/>	Prohibited drugs- Yes- <input type="checkbox"/> No- <input type="checkbox"/>	
	Spoilt/Damaged drugs- Yes- <input type="checkbox"/> No- <input type="checkbox"/>		

SOP for the procedure for issuing wholesale licence

24	Observations-
25	Remarks-

.....
Signature of Authorized Officer
Date- / /

.....
Signature of -Seller/Owner/Pharmacist/Manager
Date- / /

ANNEXURE “3”

My No:
Food & Drugs Inspector
Office of the D/MT&S

Director/MT&S,

Recommendations for Sale Drugs by Retail/Wholesale and New/Renewal of Licences

Herewith I am submitting my recommendation of licence for the sale of drugs by

..... pharmacy.

- 01. Name of the Applicant :
.....
- 02. Address of the Applicant :
.....
- 03. Address of the premises :
.....
- 04. Storage facilities (whether adequate and equipped with proper storage facilities)
:
- 05. Name of the registered pharmacist :
- 06. Registration number of the pharmacist :
.....
- 07. Prescription book :
.....
- 08. Recommended period : *From*/...../...../ *To*
...../...../.....
- 09. Recommendation :
.....
.....
.....

..... Date:/...../.....
Signature of the Authorized Officer

ANNEXURE “4”

The fee for the issue of a wholesale licence is Rs. 6,000/=.
The fee for the issue of a amended wholesale licence is Rs. 1,000/=.

ANNEXURE “5”

Form B

Regulation 58

SCHEDULE VIII

LICENCE TO SELL DRUGS (BY WHOLESALE)

Licence Number :

M/s. is/are hereby licensed to deal in drugs (wholesale) on premises situated at

This licence is subject to the conditions prescribed in regulation 60 of the Drugs Regulations made under the Cosmetics, Devices and Drugs Act, No.27 of 1980 as amended by Act, No.38 of 1984 and shall be in force for a period of one year from the date of issue unless earlier suspended or cancelled.

Date of issue :

.....
Authority

Form C

SCHEDULE VIII

Regulation 61

APPLICATION FOR RENEWAL OF LICENCE TO DEAL IN DRUGS (WHOLESALES/RETAIL)

I/We of
hereby apply for renewal of licence to deal in drugs by (wholesale/retail) on premises situated at
Expiry date of last registration :

Signed :

Name and Address :

Designation of applicant :

Date :

ANNEXURE “6”

Checklist developed in Sinhala language.

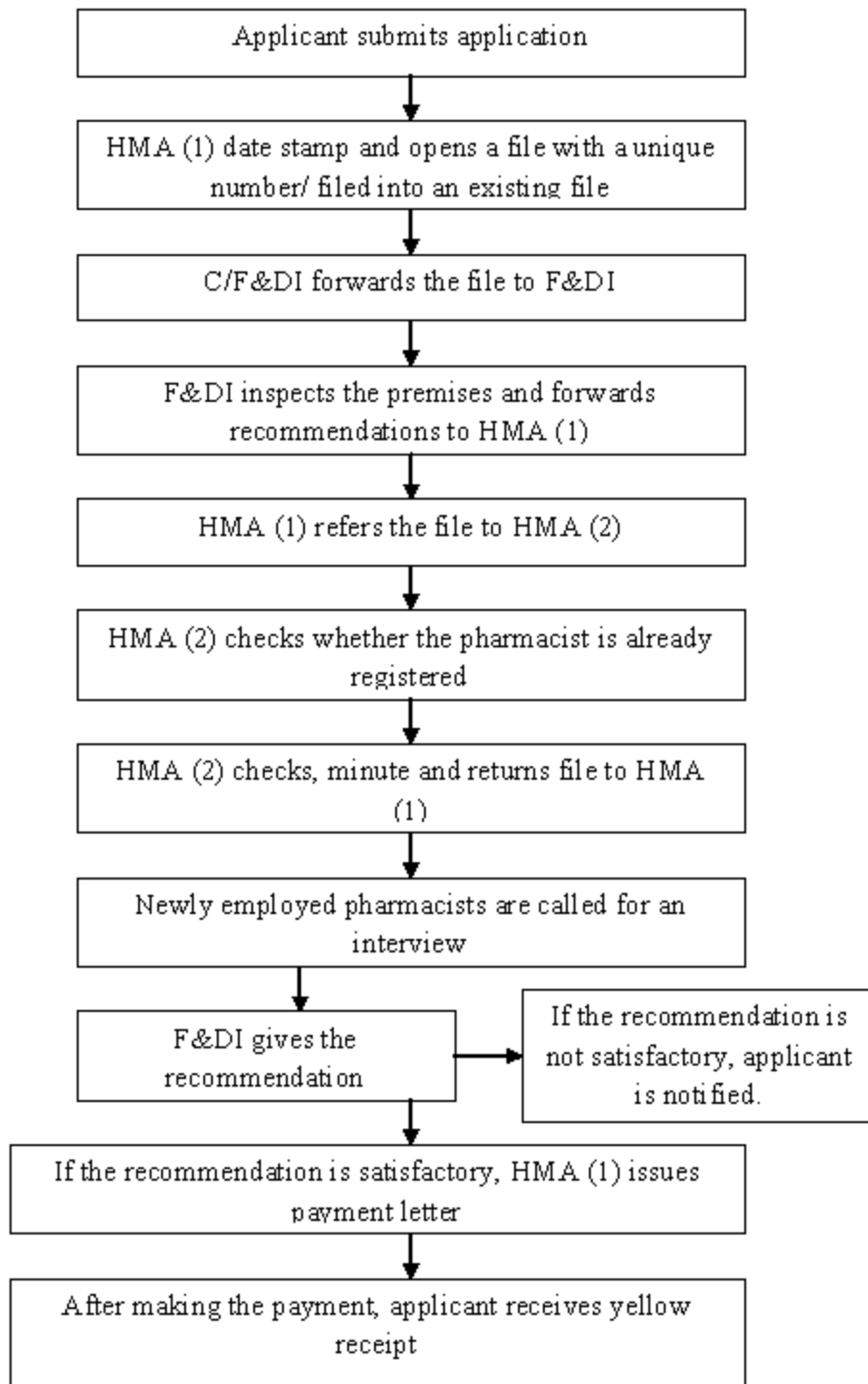
ANNEXURE “7”

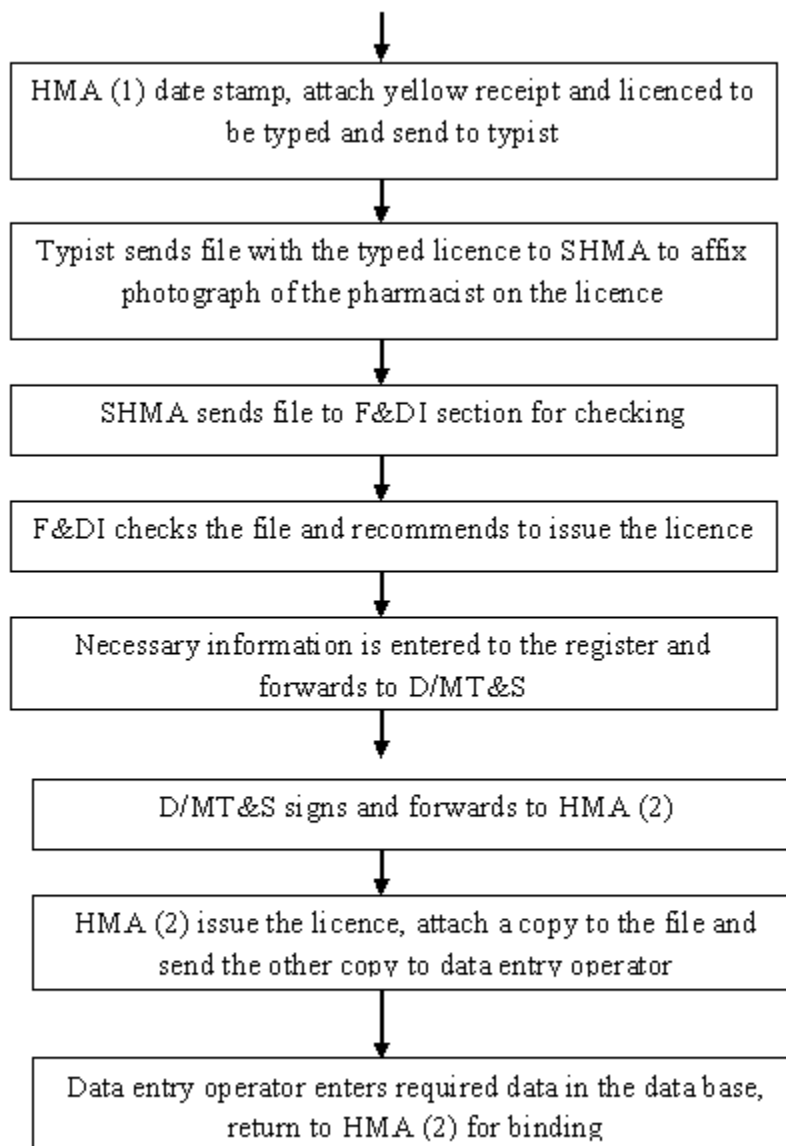
Checked the file, All the important documents are in order. Licence may be issued / not issued.

.....

.....

Flow Chart for Issuing Wholesale Licence at Metropolitan Area





Flow Chart for Issuing Wholesale Licence at Other Areas

