Islamic Republic of Afghanistan
Ministry of Public Health

National Medicine and Healthcare Products Regulatory Authority

National Inspection Checklist for Pharmaceutical Importers

February 2017

USAID
از طرف مردم امریکا

SPS Strengthening Pharmaceutical Systems

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About SPS

The Strengthening Pharmaceutical Systems (SPS) Program strives to build capacity within developing countries to effectively manage all aspects of pharmaceutical systems and services. SPS focuses on improving governance in the pharmaceutical sector, strengthening pharmaceutical management systems and financing mechanisms, containing antimicrobial resistance, and enhancing access to the most efficacious, safe and cost-effective medicines and appropriate use of medicines.

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ABBREVIATIONS AND ACRONYMS

LML	licensed medicine list
MIMMAR	Manufacturing and Importing Medicines and Medical Appliance Regulation, official gazette issue number 916, February, 24, 2007
ML	Medicine Law, official gazette issue number 963, November, 18, 2008
MOPH	Ministry of Public Health
MRG	Medicine Registration Guidelines, 2014
MSH	Management Sciences for Health
NMHRA	National Medicine and Healthcare Products Regulatory Authority
NMP	National Medicines Policy, 2014
NPNCM	National Policy for Narcotic and Controlled Medicines, 2016
NPQAP	National Pharmaceutical Quality Assurance Policy, 2105
NPWMSDPP	National Policy for Waste Management & Safe Disposal of Pharmaceutical Products, 2016
PR	Pharmacy Regulation, official gazette issue number 916,February, 24, 2007
SPS	Strengthening Pharmaceutical Services
TIC	technical in-charge
USAID	US Agency for International Development

FOREWORD

The National Medicine and Healthcare Products Regulatory Authority (NMHRA) was established under the Ministry of Public Health (MOPH) in 2016, with the mission to regulate and control production, importation, exportation, distribution, and use of medicine and health care products to provide access to quality, safe, and efficacious medicines and health products with the objective of development and enforcement of effective standards in order to optimize the safety, efficacy, quality, and affordability of medicines and health products throughout the country. I have the pleasure of introducing the first-ever National Inspection Checklist for the inspection of pharmaceutical importers.

To ensure that the inspection of pharmaceutical importers is carried out with good standards, MOPH initiated the development of the pharmaceutical importers inspection checklist to guide the inspectors. The objective of using the checklist for inspection is to enforce implementation of relevant laws and regulations by importers for ensuring the quality and safety of their practices and pharmaceuticals during procurement, storage, and distribution of medicines and to deliver high-quality services to the population.

To ensure technical quality and appropriateness for the context of Afghanistan, the national inspection checklist was developed by a MOPH-delegated technical committee with the financial and technical support of the Strengthening Pharmaceutical Systems (SPS) Project. MOPH is committed to overseeing implementation of the checklist on all pharmaceutical importers across the country.

The NMHRA in the MOPH wishes to acknowledge the contributions of the individuals who comprised the taskforce for developing the national inspection checklist for pharmaceutical importers. Acknowledgement is given to the following people from NMHRA-MOPH, in particular:

- Pharmacist Mohammad Zafar Barry
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- Pharmacist Mohammad Asef Yari
- Pharmacist Mohammad Osman Zaki

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- Pharmacist Mohamed Basir, Pharmaceutical Regulatory System Program Manager
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- Pharmacist Shiou-Chu (Judy) Wang, Senior Technical Adviser
- Dr. Paul Ickx, Senior Principal Technical Advisor

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Dr. Noor Shah Kamawal
Executive Director
National Medicine and Healthcare Products Regulatory Authority
1395/12/19

LAWS, REGULATIONS, POLICIES, AND GUIDELINES APPLIED IN THIS CHECKLIST

This inspection checklist was developed according to the effective laws and regulations governing pharmaceutical practices and services. The laws and regulations applied in this checklist are listed below with their acronyms.

- MIMMAR: Manufacturing and Importing Medicines and Medical Appliance Regulation, official gazette issue number 916, February, 24, 2007
- ML: Medicine Law, official gazette issue number 963, November, 18, 2008
- MRG: Medicine Registration Guidelines, 2014
- NMP: Afghanistan National Medicines Policy, 2014
- NPNCM: National Policy for Narcotic and Controlled Medicines, 2016
- NPQAP: National Pharmaceutical Quality Assurance Policy, 2105
- NPWMSDPP: National Policy for Waste Management and Safe Disposal of Pharmaceutical Products, 2016
- PR: Pharmacy Regulation, official gazette issue number 916, February, 24, 2007

SECTION 1. GENERAL INFORMATION

Date of Inspection (Persian/Shamsi calendar)	/ / / (day/month/year)			
Date of Last Inspection (Persian/Shamsi calendar)	/ / / (day/month/year)			
Time Started	_____: _____ am/pm (hour and minutes)			
Type of Inspection (circle one)	Routine/ Comprehensive	Concise	Follow-up	Special
Name of Importer				
Importer Registration/Inauguration Number				
Date of Establishment				
Location	Province: _____ District: _____ Village/town: _____ Street: _____ GPS (latitude) if GPS device available: GPS (longitude) if GPS device available:			
Physical Address				
Telephone Number				
E-mail Address				
Name of the Proprietor				
Name of Technical In-Charge				
Technical In-Charge's Certificate of Practice Number:				

SECTION 2. REGISTRATION CERTIFICATE

Inspect the registration certificates of the importer and the TIC according to the requirements in the indicated laws or regulations. **If the requirements are met, please indicate 1 for yes or passed in the 1 or 0 column; if the requirements are not met, indicate 0 for no or failed.**

	Requirement	1 or 0	Remarks
2.1	Is the importer registration/inauguration certificate/ letter available? (16 MIMMAR 2007)		
2.2	Is the importer registration/inauguration certificate/ letter displayed in a prominent location? (16 MIMMAR 2007)		
2.3	Is the valid certificate of practice of the technical in-charge available? (16 MIMMAR 2007)		
2.4	Is the valid certificate of practice of the technical in-charge displayed in a prominent location? (35 MIMMAR 2007)		
Score for Registration Certificate Index Add up the importer's scores for questions 2.1 to 2.4 and record the score in the space provided in the next column. The range for this index is 0–4.		**Score:** **Score: (/ × 100) = %**	

SECTION 3. LEGALITY OF STOCKED PRODUCTS

Walk through the warehouse and do a general scan of the medicines or products stored or displayed in the warehouse according to the requirements in the indicated laws or regulations. If any suspect medicines are found, collect the samples for quality control (QC) testing and fill the sampling form (Annex 1). If any nonconformity is found, confiscate or quarantine the medicines or products and fill in the Confiscation/Quarantine Form (Annex 2). **Randomly select at least 5 items for inspection. If the requirements are met, please indicate 1 for yes or passed in the 1 or 0 column; if the requirements are not met, indicate 0 for no or failed.**

	Requirements	1 or 0	Remarks
3.1	Are **all** the inspected medicines in accordance with the national LML? (9 ML 2008)		
3.2	Are **all** the inspected medicines registered with the NMHRA (GDPA) and does importer have a registration certificate? (Check and obtain a copy of the registration certificate.) (16 MIMMAR 2007, 5 NMP 2014, and 5 NPQAP 2015)		
3.3	Are there copies of receipts/invoices for the procurement of medicines and medical equipment from manufacturers? (5 NMP 2014 and 15 NPQAP 2015)		
3.4	Are there no counterfeit and substandard medicines found for sale on the importer's premises? (16 MIMMAR 2007 and 7 NPQAP 2015)		
Score for General Inspection and Legality of Stocked Products Index Add up the importer's scores for questions 3.1 to 3.4 and record the score in the space provided in the next column. The range for this index is 0–4.		**Score:** **Score: (/ × 100) = %**	

SECTION 4. PRODUCT LABEL EXAMINATION

Closely examine the product labels according to the requirements in the indicated laws or regulations. **Randomly select at least 5 items for inspection. If the requirements are met, please indicate 1 for yes or passed in the 1 or 0 column; if the requirements are not met, indicate 0 for no or failed.**

Requirements		1 or 0	Remarks
4.1	Are **all** the labels of the inspected medicines printed in at least one of the national languages or English? (2 MRG 2014)		
4.2	Are **all** the labels of the inspected medicines in accordance with the labeling requirements specified in the regulation and/or guidelines? (24 MIMMAR 2007 and 2 MRG 2014)		
4.3	Is the information in **all** the inspected medicines' leaflets in accordance with the requirements specified in the regulation and/or guidelines? (25 MIMMAR 2007 and 2 MRG 2014)		
4.4	Do all the inspected medicines have valid expiry dates? (7 NPQAP 2015)		
Score for Product Label Examination Index Add up the outlet's score for questions 4.1−4.4 and record the score in the space provided in the next column. The range for this index is 0–4.		**Score:** **Score: (/ × 100) = %**	

SECTION 5. MANAGEMENT OF CONTROLLED MEDICINES

Inspect the controlled medicines including physical examinations and storage, as well as documentation of controlled medicines. **If the requirements are met, please indicate 1 for yes or passed in the 1 or 0 column; if the requirements are not met, indicate 0 for no or failed.**

Requirements		1 or 0	Remarks
5.1	Are there lockable cabinet(s) for storage of all controlled medicines (category 2) on the premises? (5 and 12 NPNCM 2016)		
5.2	Is the entire inventory of category 2 controlled medicines kept in a lockable cabinet(s)? (5 and 12 NPNCM 2016)		
5.3	Are all the inspected controlled medicines within their labeled expiry dates? Randomly inspect 3 items. (7 NPQAP 2015)		
Score for Management of Controlled Medicines and other Documentations Index Add up the outlet's score for questions 5.1–5.3 and record the score in the space provided in the next column. The range for this index is 0–3.		**Score:** **Score: (/ × 100) = %**	

SECTION 6. STORAGE CONDITIONS (STORAGE OF PHARMACEUTICAL PRODUCTS)

Inspect the storage conditions at the pharmacy as per the following requirements. **If the requirements are met, please indicate 1 for yes or passed in the 1 or 0 column; if the requirements are not met, indicate 0 for no or failed.**

	Requirements	1 or 0	Remarks
6.1	Is the temperature in the warehouse compatible with drug storage requirements? (15 to 25 °C or, depending on climatic conditions, up to 30 °C) (50 ML 2008)		
6.2	Is there a temperature monitoring device available for recording the temperature within the warehouse? (50 ML 2008) • If yes, how often is the temperature recorded? (select one) Frequency: _____ Irregularly No records		
6.3	Does the warehouse have a functional refrigerator(s) for storing temperature-sensitive items? (38 MIMMAR 2007 and 50 ML 2008)		
6.4	Are any temperature-sensitive medicines found stored or displayed outside the refrigerator(s)? (38 MIMMAR 2007 and 50 ML 2008)		
6.5	Are all the inspected medicines in the refrigerator(s) within their labeled expiry dates? Randomly select 3 items. (7 NPQAP 2015)		
6.6	Is there a temperature monitoring device available for recording the temperature in the refrigerator(s)? (38 MIMMAR 2007 and 50 ML 2008) • If yes, how often is the temperature recorded? (select one) Frequency: _____ Irregularly No records		
6.7	Is there a dedicated area for placement of expired, returned, recalled, and quarantined medicines and if so, is it clearly labeled? (9 NPWMSDPP 2016 and 7 NPQAP 2015)		
Score for Storage Conditions Index Add up the outlet's score for questions 6.1–6.7 and record the score in the space provided in the next column. The range for this index is 0–7.		**Score:** **Score: (/ × 100) = %**	

SECTION 7. GENERAL CONDITION OF THE PREMISES

Is the general condition of the importer's premises considered appropriate in accordance with the following requirements? **If the requirements are met, please indicate 1 for yes or passed in the 1 or 0 column; if the requirements are not met, indicate 0 for no or failed.**

Requirements		1 or 0	Remarks
7.1	Does the importer operate at the address as registered for the business? (14 MIMMAR 2007)		
7.2	Does the importer have a warehouse for storing medicines? (38 MIMMAR 2007 and 50 ML 2008)		
7.3	Are the walls, floors, and ceiling in good condition without signs of humidity, mold, and cracking? (38 MIMMAR 2007 and 50 ML 2008)		
7.4	Is the entire warehouse area clean? (38 MIMMAR 2007 and 50 ML 2008)		
7.5	Is there a ventilation system, and is it functional? (38 MIMMAR 2007 and 50 ML 2008)		
Score for General Condition of the Premises Index Add up the outlet's score for questions 7.1–7.5 and record the score in the space provided in the next column. The range for this index is 0–5.		**Score:** **Score: (/ × 100) = %**	

SECTION 8. STAFF AND SERVICES

Are the staff and services of the importer considered appropriate in accordance with the following requirements? **If the requirements are met, please indicate 1 for yes or passed in the 1 or 0 column; if the requirements are not met, indicate 0 for no or failed.**

Requirements		1 or 0	Remarks
8.1	Is the TIC present at the company on the day of the inspection? (35 MIMMAR 2007)		
8.2	Do the importer's invoices contain the following information? (21 PR 2007) • Name of medicine (generic and brand with strength and dosage form) • Manufacture and expire dates • Quantity • Batch number • Manufacturer • Date of transaction • Sign and stamp of the company		
8.3	Is the percentage of profit in accordance with the provisions of the law? (**The importer's profit in sales of medicine and medicinal products must not be more than 10% of the purchase price.**) (31 MIMMAR 2007)		
8.4	Does the importer have a stamp? (14 MIMMAR 2007)		
8.5	Does the importer have a standard signboard? (14 MIMMAR 2007)		
Score for Staff and Services Index Add up the importer's score for question 8.1 to 8.5 and record the score in the space provided in the next column. The range for this index is 0–5.		**Score:** **Score: (/ × 100) = %**	

SECTION 9. REFERENCE MATERIALS

Please ask the importer staff to present the following reference materials. This section is not scored.

Requirements		Yes	No	Remarks
9.1	Valid/effective Afghan Medicines Law (Official Gazette Number 963 2008)	√		
9.2	Valid/effective Manufacturing and Importing Medicines and Medical Appliance Regulation (Official Gazette Number 916 2007)	√		
9.3	Valid National Licensed Medicines List, 2014		√	
9.4	Valid National Essential Medicines List, 2014		√	
9.5	Updated National Medicines Policy, 2014		√	
9.6	Updated National Pharmaceutical Quality Assurance Policy, 2015		√	
9.7	Updated National Policy for Narcotic and Controlled Medicines, 2016		√	
9.8	Updated National Policy for Waste Management and Safe Disposal of Pharmaceutical Products, 2016		√	
9.9	Updated Foreign Pharmaceutical Manufacturing Companies Registration Guideline, 2014 available		√	
9.10	Updated Medicines Registration Guideline, 2014 available		√	

SECTION 10. SCORING

Please fill in the scores for Sections 2–8 into the following table and determine the overall compliance score in the Result column.

Date	Sectional scores obtained (%)							Total score (A)	Total points (B)	Result (%) (A/B*100)
	2	3	4	5	6	7	8			
This inspection (date)										
Last inspection (date)										
% point change										

Note: Please make two copies (use carbon paper for writing or make a photocopy if possible) for Sections 11−15. The inspectors keep the original copy and give the duplicate copy to the importer. Advise the proprietor and the TIC to file it in a designated folder for records and actions and for future inspections.

SECTION 11. ANY OTHER OBSERVATIONS AND REMARKS

Provide information about any observations in addition to the information obtained in the checklist, if available. Use a separate sheet if the space provided is not enough.

SECTION 12. RECOMMENDATIONS AND ACTIONS

From the inspection results, identify the most critical issues for correction or improvements, such as registration, legality or quality of products, etc. If regulatory measures or penalties should be applied, specify it in the "Actions agreed to take and timeline" column. Use carbon paper to duplicate this section and give one copy to the pharmacy for taking actions and follow-up.

Name of the Importer: _____ Date:_____

Address:

No.	Issues that require attention and correction	Actions agreed to take and timeline
1		
2		
3		
4		
5		
6		

SECTION 13. OWNER'S/TECHNICAL IN-CHARGE DECLARATION

I ( ) the owner and ( ) the TIC of said importer certify that the information and observations recorded on this form during the inspection of the importer were true and correct and that the identified issues and corrective actions were communicated and agreed.

Proprietor of Importer	**Technical in-charge**
Name:	**Name:**
Signature:	**Signature:**
Date:	**Date:**

SECTION 14. TIME COMPLETED

Document the time that the inspection was finished, including completing the checklist, collecting samples for QC testing and confiscation, scoring for this inspection, and communicating with the proprietor and the TIC.

Time completed	**Hour : minute** am / pm

SECTION 15. NAMES AND SIGNATURES OF INSPECTORS

Name(s) of Inspector(s)	Designation(s)	Signature(s)	Date

Acknowledge the proprietor, the TIC, and other importer staff for their assistance during the inspection.

ANNEX 1. SUSPECT MEDICINE SAMPLE COLLECTION FOR QUALITY TEST

The sample collection form should be filled in duplicate. The inspectors keep the original copy and give the importer the duplicated copy. The importer should file it in a designated folder for records. If quarantine is required, fill the "Total quantity quarantined" column.

Ministry of Public Health
National Medicine and Healthcare Products Regulatory Authority
Head of Integration of Post-Market Services
Laws and Regulation Inspection and Enforcement Department

Suspect Medicine Sample Collection for Quality Testing

Name of importer									
Date		**Address**							
Name of proprietor			**Signature**		**Name of TIC**			**Signature**	
S/no	**Generic name**	**Brand name**	**Batch no**	**Mfg date**	**Exp date**	**Quantity**	**Manufacturer**	**Importer**	**Total quantity quarantined**
1									
2									
3									
4									
5									
6									

Samples collected by (inspector): _____ Signature: _____

Samples collected by (inspector): _____ Signature: _____

ANNEX 2. QUARANTINE AND CONFISCATION FORM

Ministry of Public Health
National Medicine and Healthcare Products Regulatory Authority
Head of Integration of Post-Market Services
Laws and Regulation Inspection and Enforcement Department

Quarantine and Confiscation Form

Fill 2 copies of the quarantine and confiscation form. The inspectors keep the original copy and give the importere the duplicate copy. The importer should file it in a designated folder for records.			
Name of importer			
Date	**Address**		
Name of proprietor	**Signature**	**Name of TIC**	**Signature**
Please select the appropriate reason for sampling. 1. Quarantine 2. Confiscation			

S/no	Generic name	Brand name	Batch no	Mfg date	Exp date	Manufacturer	Importer	Total quantity quarantined
1								
2								
3								
4								
5								
6								

Confiscated or Quarantined by (inspector): _____ Signature: _____

Confiscated or Quarantined by (inspector): _____ Signature: _____

ANNEX 3. CATEGORY 2 MEDICINES IN THE LML CONTROLLED MEDICINE LIST

	Category 2 substances	**Controlled medicines in LML 2014 that are derived from category 2 substances**
1	Fentanyl	Fentanyl 0.05 mg/ml in 2-ml ampoule injection solution
2	Methadone	• Methadone 10 mg/ml in 1-ml ampoule injection • Methadone 10 mg/ml, oral solution • Methadone 10 mg tablet • Methadone 5 mg/ml, oral solution • Methadone 5 mg tablet
3	Morphine	• Morphine hydrochloride 10 mg/ml in 1-ml ampoule, injection • Morphine sulfate 10 mg/ml in 1-ml ampoule, injection
4	Opium	Opium tincture 10% oral solution
5	Pethidine medium A, B, C	• Pethidine 100 mg tablet • Pethidine 50 mg tablet • Pethidine 50 mg/ml, injection ampoule