Islamic Republic of Afghanistan
Ministry of Public Health

National Medicine and Healthcare Products Regulatory Authority

National Inspection Checklist for Pharmaceutical Importers

February 2017

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The National Medicine and Healthcare Products Regulatory Authority (NMHRA) was established under the Ministry of Public Health (MoPH) in 2016, with the mission of "access to quality, safe and efficacious medicines and health products through regulation and control of production, importation, exportation, distribution and use, 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 to introduce 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 standard, MoPH initiated the development of the pharmaceutical importer's inspection checklist to guide the inspectors. The objective of using the checklist for inspection is to enforce the implementation of the relevant law and regulations by the importers for assuring the quality and safety of their practices and the pharmaceuticals during procurement, storage, and distribution medicines; and delivering high quality services to the population.

To ensure technical quality and appropriate to the local context, 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 oversee the 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 the development of the national inspection checklist for pharmaceutical importers. Acknowledgement is given to the following people in particular:

1. Pharmacist Mohammad Zafar Barry, NMHRA-MoPH
2. Pharmacist Sayed Asadullah Akhlaqizada, NMHRA-MoPH
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8. Pharmacist Zekria Fatehzada, NMHRA-MoPH
9. Pharmacist Mohammad Asef Yari, NMHRA-MoPH
10. Pharmacist Mohammad Osman Zaki, NMHRA-MoPH

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1. Pharmacist Mohamed Basir, Pharmaceutical Regulatory System Program Manager
2. Pharmacist Sohail Nazari, Pharmaceutical Regulatory System Technical Officer
3. Pharmacist Mohammad Zafar Omari, Chief of Party,
4. Pharmacist Shiou-Chu Judy Wang, Senior Technical Adviser, SPS in USA
5. Dr. Paul Ickx, Senior Principal Technical Advisor, SPS in France

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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 is 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:

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

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 devices available: GPS (Gratitude) if GPS devices 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:				

2. Registration Certificate

Inspect the registration certificates of the importer and the technical in-charge according to the requirements in the indicated laws or regulations. **If the requirements are met, please indicate "1" for Yes or Passed; if the requirements are not met, indicate "0" for No or Failed in the "1 or 0" column.**

	Requirement	1 or 0	Remarks
2.1	Does the importer registration/inauguration certificate/letter available? (16 MIMMAR, 2007)		
2.2	Does the importer registration/inauguration certificate/letter displayed in a prominently visible location? (16 MIMMAR, 2007)		
2.3	Does the valid certificate of practice of the technical in-charge available? (16 MIMMAR, 2007)		
2.4	Does the valid certificate of practice of the technical in-charge displayed in a prominently visible location? (35 MIMMAR, 2007)		
Score for Registration Certificate Index Add up the importer's score for question "**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: (/ X 100) = %**	

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 QC test 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; if the requirements are not met, indicate "0" for No or Failed in the "1 or 0" column.**

	Requirements	1 or 0	Remarks
3.1	Are all the inspected medicines in accordance with the National Licensed Medicines List? (9 ML, 2008)		
3.2	Are all the inspected medicines registered with the NMHRA (GDPA) and have a registration certificate? (**check and obtain a copy of registration certificate**) (16 MIMMAR 2007, section 5 of NMP, 2014, section 5 of NPQAP, 2015)		
3.3	Are there copies of receipts/invoices for the procurement of medicines and medical equipment from manufacturers? (NMP, 2014 and NPQAP, 2015)		
3.4	There are no counterfeit and substandard medicines found for sale in the warehouse. (16 MIMMAR 2007 and section 7 NPQAP, 2015)		
Score for Legality of Stocked Products Index Add up the importer's score for question "**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: (/ X 100) = %**	

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; if the requirements are not met, indicate "0" for No or Failed in the "1 or 0" column.**

	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? (Section 2 of 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 section 2 of MRG, 2014)		
4.3	Is the information of all the inspected medicines' leaflets in accordance with the requirements specified in the regulation and/or guidelines? (25 MIMMAR, 2007 and section 2 of MRG, 2014)		
4.4	Are all the inspected medicines in valid shelf lives? (Section 7 NPQAP, 2015)		
Score for Product Label Examination Index Add up the importer's score for question "**4.1**" to "**4.4**" and record the score in the space provided in the next column. The range for this index is "**0 – 4**"		**Score: ( )** **Score: (/ X 100) = %**	

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; if the requirements are not met, indicate "0" for No or Failed in the "1 or 0" column. (If the importer is not involved in importation of controlled medicines, this section is not applicable)**

Requirements		1 or 0	Remarks
5.1	Is there lockable cabinet(s) for the storage of all the controlled medicines (category 2) in the warehouse? (Section 5 and 15 of NPNCM, 2016)		
5.2	Are the entire category 1 controlled medicines kept in the lockable cabinet(s)? (Section 5 and 15 of NPNCM, 2016)		
5.3	Are all the inspected controlled medicines in valid shelf lives? **Randomly inspect 3 items**. (Section 7 of NPQAP, 2015)		
Score for Management of Controlled Medicines Index Add up the importer's score for question "**5.1**" to "**5.3**" and record the score in the space provided in the next column. The range for this index is "**0–3**".		**Score: ( )** **Score: (/ X 100) = %**	

6. Storage Conditions (Storage of Pharmaceutical Products)

Inspect the storage conditions at the warehouse as per the following requirements. **If the requirements are met, please indicate "1" for Yes or Passed; if the requirements are not met, indicate "0" for No or Failed in the "1 or 0" column.**

Requirement		1 or 0	Remarks
6.1	Is the temperature in the warehouse compatible with drug storage requirements? (15 to 25^{o}C or depending on climatic conditions up to 30^{o}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 that applies) 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	There are no 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) in valid shelf lives? **Randomly select 3 items**. (Section 7 of 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 that applies) Frequency: _____; Irregularly; No Records;		

Requirement		1 or 0	Remarks
6.7	Is there a dedicated area for placement of expired, returned, recalled and quarantined medicines and if such area is clearly labeled? (NPWMSDPP, 2016, and section 7 of NPQAP, 2015)		
Score for Storage Conditions Index Add up the importer's score for question "**6.1**" to "**6.7**" and record the score in the space provided in the next column. The range for this index is "**0 – 7**"		**Score: ( )** **Score: (/ X 100) = %**	

7. General Condition of the Premises

Dose the general condition of the premises of the warehouse considered appropriate in accordance with the following requirements? **If the requirements are met, please indicate "1" for Yes or Passed; if the requirements are not met, indicate "0" for No or Failed in the "1 or 0" column.**

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

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; if the requirements are not met, indicate "0" for No or Failed in the "1 or 0" column.**

Requirement		1 or 0	Remarks
8.1	Is the technical in-charge present at the company on the day of the inspection? (35 MIMMAR, 2007)		
8.2	Does the invoice of the importer has the following information: (21 PR, 2007) - Name of medicine (generic & brand with strength & dosage form) - Manufacture and expire date - Quantity - Batch number		

	- Manufacturer - Date of transaction - Sign and stamp of the company		
8.3	Does the percentage of profit sell in accordance with the provisions of the law? (**the profit of importer in sales of medicine and medicinal products must not be more than 10% of purchase price**) (31 MIMMAR, 2007).		
8.4	The importer has stamp? (14 MIMMAR, 2007)		
8.5	The importer has a 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: (/ X 100) = %**	

9. Reference Materials

Please ask the company staff to present the following reference materials. There is no need to score for this section.

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

10. Scoring

Please fill the scores of sections "**2 – 8**" into the following table and determine the overall compliance score in the "Result":

Date	Sectional Scores Obtained (%)							Total Score (Obtain "A")	Total Points (B)	Result (%) (A/B*100)
	2	3	4	5	6	7	8			
This Inspection										
Last Inspection										
% of Changes										

Note: Please fill the following fields in two copies (use carbon paper for writing, or make a photocopy if possible). The inspectors keep the original copy, and give the importer the duplicated copy. Advise the proprietor and the technical in-charge to file it in a designated folder for records and actions, and for future inspections.

11. Any Other Observations and Remarks

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

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 measure or penalty should be applied, specify it in the "**Action Agreed to Take and Timeline**". Use a carbon paper to duplicate this section, give one copy to the importer for taking actions and follow-up.

Name of the Importer: _____ Date:_____

Address:

No.	Issues Required Attention and Correction	Actions Agreed to Take and Timeline
1		
2		
3		
4		
5		
6		

13. Owner's/Technical In-Charge Declaration

I ( ) the owner, and ( ) the technical in-charge of the said importer, certify that the information and observations made in this from during the inspection of the importer were true and correct; and the identified issues and corrective actions were communicated and agreed.

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

14. Time Completed

Document the time when the inspection is finished, including completing the checklist, collecting samples for QC test and confiscation, scoring for this inspection, and communication with the proprietor and the technical in-charge.

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

15. Names and Signatures of Inspectors

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

Acknowledge the proprietor, the technical in-charge, and other importer staff for their assistance for the inspection.

Annexes:

Annex 1. Suspect Medicine Sample Collection for Quality Test

Fill the sample collection form in two copies. 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 column of "**Total Quantity Quarantined**".

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

Suspect Medicine Sample Collection for Quality Test

Name of the Importer									
Date					**Address:**				
Name of the Proprietor			**Signature**		**Name of the Technical in-charge**			**Signature**	
S/No	**Generic Name**	**Brand Name**	**Batch No**	**Mafg 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
Post-Market Services Integration Directorate
Inspection and Enforcement of Law and Regulation Department

Quarantine and Confiscation Form

Fill the Confiscation/Quarantine Form in two copies. The inspectors keep the original copy, and give the importer the duplicated copy. The importer should file it in a designated folder for records.								
Name of the Importer								
Date			**Address**					
Name of the Proprietor		**Signature:**	**Name of the Technical in-charge**			**Signature:**		
Please select the appropriate option according to your purpose of use.						1. Quarantine 2. Confiscation		
S/No	**Generic Name**	**Brand Name**	**Batch No**	**Mafg 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. List of Category 2 Medicines which are in the LDL Controlled Medicine List

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

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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.

USAID
از طرف مردم امریکا

SPS Strengthening Pharmaceutical Systems