Islamic Republic of Afghanistan
Ministry of Public Health

National Medicine and Healthcare Products Regulatory Authority

National Inspection Checklist for Retail Pharmacies

February 2017

Table of Contents

Forward

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 Retail Pharmacies for the inspection of retail pharmacies.

To ensure that the inspection of retail pharmacies is carried out with good standard, MoPH initiated the development of the retail pharmacies 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 retail pharmacies 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 retail pharmacies 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 retail pharmacies. Acknowledgement is given to the following people in particular:

1. Pharmacist Mohammad Zafar Barry, NMHRA-MoPH
2. Pharmacist Sayed Asadullah Akhlaqizada, NMHRA-MoPH
3. Pharmacist Sayed Nazir Hussain Hashemi, NMHRA-MoPH
4. Pharmacist Mir Padshah Zohori, NMHRA-MoPH
5. Pharmacist Muhammad Naeem Yaqoby, NMHRA-MoPH
6. Pharmacist Mohammad Ibrahim Arab, NMHRA-MoPH
7. Pharmacist Mohammad Hanif Nabavi, NMHRA-MoPH
8. Pharmacist Zekria Fatehzada, NMHRA-MoPH
9. Pharmacist Mohammad Asef Yari, NMHRA-MoPH
10. Pharmacist Mohammad Osman Zaki, NMHRA-MoPH

The NMHRA would also like to thank the following technical advisors of the SPS project who provided technical support to the development and formulation of the checklist:

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

I wish to commend the SPS project funded by the US Agency for International Development (USAID) and implemented by Management Sciences for Health (MSH) for their tremendous technical support. I also thank the National Inspection Checklists Development Task Force members and all those who contributed to the development of this checklist.

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 the Pharmacy				
Pharmacy Inauguration Number				
Date of Establishment				
Type of Pharmacy Registered (circle one that applies)	First class	Second class	Third class	Other
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 pharmacy 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 pharmacy registration/inauguration certificate/ letter available in the pharmacy? (20 PR, 2007)		
2.2	Does the pharmacy registration/inauguration certificate /letter displayed in a prominently visible location? (20 PR, 2007)		
2.3	Does the valid certificate of practice of the technical in-charge available? (20 PR, 2007)		
2.4	Does the valid certificate of practice of the technical in-charge displayed in a prominently visible location? (20 PR, 2007)		
2.5	Does the Technical in-charge's education qualification comply with the registered classification of the pharmacy? (9 PR, 2007) If the certificate is not available for inspection, indicate "**N/A**" in the "1 or 0" column.		
Score for Registration Certificate Index Add up the outlet's score for question "**2.1**" to "**2.5**" and record the score in the space provided in the next column. The range for this index is "**0 – 5**". (**If the question # 2.5 not observed, the range for this index is "0–4"**)		**Score: ( )** **Score: (/ X 100) = %**	

3. Legality of Stocked Products

Walk through the pharmacy and do a general scan of the medicines or products stored or displayed in the pharmacy 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" (Annex2). **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	There are no narcotic substances (Annex 4) and alcoholic beverages found for sale in the pharmacy. (44 ML, 2008)		
3.3	There are no counterfeit and substandard medicines found for sale in the pharmacy. (44 ML, 2008)		
3.4	There are no any non-medical items found for sale in the pharmacy. (2 and 18 PR, 2007)		
3.5	Are there copies of receipts/invoices for the procurement of medicines and medical equipment from importers/ wholesalers? (21 PR, 2007 and section 15 NPQAP, 2015)		
3.6	Do the inspected medicine purchased form registered importers and wholesalers (21 PR, 2007) (21 PR, 2007 and section 15 NPQAP, 2015)		
Score for Legality of Stocked Products Index Add up the outlet's score for question "**3.1**" to "**3.6**" and record the score in the space provided in the next column. The range for this index is "**0–6**"		**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 outlet'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.**

Requirements		1 or 0	Remarks
5.1	Is there at least one lockable cabinet for the storage of all the controlled medicines (category 2) in the pharmacy? (Section 5 and 15 of NPNCM, 2016)		
5.2	Are the entire category 2 controlled medicines kept in the lockable cabinet? (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)		
5.4	Does the pharmacy have a controlled medicine registration book? (15 and 35 PR, 2007)		
5.5	Do the control medicines and narcotic prescriptions entered correctly into the registration book? (15 PR, 2007) (Inspect the most recent prescriptions) **(If the answer to # 5.4 is NO, answer "N/A" to this question)**		
5.6	Are the prescriptions for narcotic medicines (category 2) securely kept to prevent access by unauthorized persons? (15 PR, 2007)		
Score for Management of Controlled Medicines Add up the outlet's score for question "**5.1**" to "**5.6**" and record the score in the space provided in the next column. The range for this index is "**0 – 6**" (**If the question # 5.5 not observed, the range for this index is "0 – 5"**)		**Score: ( )** **Score: (/ X 100) = %**	

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; 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 pharmacy compatible with drug storage requirements? (15 to 25^{o}C or depending on climatic conditions up to 30^{o}C) (17 PR, 2007 and 50 ML, 2008)		
6.2	Is there a temperature monitoring device available for recording the temperature within the pharmacy? (17 PR, 2007 and 50 ML, 2008) • If yes, how often is the temperature recorded? (select one that applies) Frequency: _____; Irregularly; No Records;		
6.3	Does the pharmacy have a functional refrigerator(s) for storing temperature-sensitive items? (17 PR, 2007 and 50 ML, 2008)		
6.4	There are no any temperature-sensitive medicines found stored or displayed outside the refrigerator(s). (17PR, 2007 and 50 ML, 2008)		
6.5	Are all the inspected medicines in the refrigerator in valid shelf lives? **Randomly select 3 items**. (Section 7 of NPQAP, 2015)		

Requirement		1 or 0	Remarks
6.6	Is there a temperature monitoring device available for recording the temperature in the refrigerator? (17 PR, 2007 and 50 ML, 2008) • If Yes, How often is the temperature recorded? (select one that applies) Frequency: _____; Irregularly; No Records;		
6.7	Is there a dedicated area for placement of expired, returned, recalled and quarantined medicines and if such area is clearly labeled? (NPWMSDPP, 2015 and section 7 of NPQAP, 2015)		
Score for Storage Conditions Index Add up the outlet'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 pharmacy 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 retail pharmacy operates at the address as registered for the business. (7 PR, 2007)		
7.2	The space available should be compliant with the registered classification of a retail pharmacy? (19 ML, 2008) - First class Pharmacy 53 square meters - Second class Pharmacy 43 square meters - Third class Pharmacy 38 square meters - Others 24 square meters		
7.3	The pharmacy is not used as a physician's clinic. (9 PR, 2007)		
7.4	The walls, floors, and celling are in good condition without signs of humidity, mold, and cracking. (17 PR, 2007 and 50 ML, 2008)		
7.5	The entire pharmacy area is clean. (18 PR, 2007)		
7.6	There is a ventilation system, and it is functional. (17 PR, 2007)		
Score for General Condition of the Premises Index Add up the outlet's score for question "**7.1**" to "**7.6**" and record the score in the space provided in the next column. The range for this index is "**0 – 6**"		**Score: ( )** **Score: (/ X 100) = %**	

8. Staff and Services

Are the staff and services of the pharmacy 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 pharmacy on the day of the inspection? (3 PR, 2007)		
8.2	Does the technical in-charge wear a clean white uniform? (26 PR, 2007)		

8.3	Does the technical in charge give clear and understandable instructions and necessary information to patients/customers regarding the prescribed or dispensed medicines? (26 PR, 2007) **If the observation did not occur, score "N/A"**		
8.4	Does the prescription of dispensed medicine have the price written on the top and has it been stamped? (26 PR,2007) **If the observation did not occur, score "N/A"**		
8.5	Does the percentage of profit sell in accordance with the provisions of the law? (**the profit of pharmacy in sales of medicine and medicinal products cannot be more than 15% of purchase price**) (17 ML, 2008) **IF the observation did not occur, score "N/A"**		
8.6	Does the pharmacy have a medicine register for the medicines other than controlled medicines? (15 and 35 PR, 2007)		
8.7	The retail pharmacy has stamp? (35 PR, 2007)		
8.8	The retail pharmacy has a standard signboard? (35 PR, 2007)		
Score for Staff and Services Index Add up the outlet's score for question "**8.1**" to "**8.8**" and record the score in the space provided in the next column. The range for this index is "**0 – 8**". (**If the question # 8.3, 8.4 and 8.5 not observed, the range for this index is "0 – 5"**)		**Score: ( )** **Score: (/ X 100) = %**	

9. Reference Materials

Please ask the pharmacy 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 Pharmacy 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 Afghan National Formulary, 2015			
9.6	A copy of updated National Standard Treatment Guidelines, 2013			
9.7	A copy of updated National Medicines Policy, 2014			
9.8	A copy of updated National Pharmaceutical Quality Assurance Policy, 2015			
9.9	A copy of updated National Policy for Narcotic and Controlled Medicines, 2016			
9.10	A copy of updated National Policy for Waste Management and Safe Disposal of Pharmaceutical Products, 2016			

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 pharmacy 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, qualification of technical in-charge, legality or quality of products, accountability of controlled medicines, 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 pharmacy for taking actions and follow-up.

Name of the Pharmacy: _____ Date:_____

Address:

No.	Issues Required Attention and Correction	Actions Agreed to Take and Timeline
1		
2		
3		
4		
5		
6		
7		

13. Owner's/Technical In-Charge Declaration

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

Proprietor of Pharmacy	**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 pharmacy 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 pharmacy the duplicated copy. The pharmacy 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 Pharmacy									
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 pharmacy the duplicated copy. The pharmacy should file it in a designated folder for records.			
Name of the Pharmacy			
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

This publication is made possible by the generous support of the American people through the US Agency for International Development (USAID), under the terms of leader with associate cooperative agreement number 306-A-00-11-00532-00 under leader award number GHN-A-00-07-00002-00. This document was developed with the technical supports of Management Sciences for Health through Strengthening Pharmaceutical Systems (SPS). The contents are the responsibility of National Medicine and Healthcare Product Regulatory Authority (NMHRA) - Ministry of Public Health (MoPH) of the Islamic Republic of Afghanistan and do not necessarily reflect the views of USAID or the United States Government.

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