متطلبات التسجيل و معايير الاعتماد للصيدليات العامة

متطلبات التسجيل ومعايير اعتماد الصيدليات

Version 1.2

مقدمة

يجوز لأى صيدلية عامة التقدم بطلب الحصول على اعتماد الهيئة العامة للاعتماد والرقابة الصحية طالما أنه في وقت تقديم الطلب كانت الصيدلية تحت التشغيل وتقدم خدمات للمجتمع، وتكون الصيدلية على إستعداد لتحمل مسؤولية تحسين جودة الخدمات التي تقدمها.

وبناءا على قانون رقم ١٢٧ لسنة ١٩٥٥ فإن المعايير المذكورة في هذا الدليل هي للصيدليات العامة.

وتهدف عملية إدارة الدواء السليمة الى تعزيز سلامة المرضى كهدف أساسي، فإن متطلبات التسجيل ومعايير الاعتماد إنما تهدف إلى تسليط الضوء على هذا الهدف الأساسي، ويتطلب دعمها بسياسات وممارسات صحيحة علمية، وتحت إشراف ومتابعة من قبل الصيادلة المرخصين لتحمل هذه المسئولية، كما أن معايير الاعتماد تهدف الى رفع مستوى خدمات رعاية المرضى التي نقدمها الصيدلية بشكل مستمر.

نظام تسجيل الصيدليات العامة ببرنامج الاعتماد

استنادا الى قانون رقم ٢ لسنة ٢٠١٨ بشأن نظام التأمين الصحي الشامل و الصادر في يناير ٢٠١٨ ولائحته التنفيذية الصادرة بقرار رئيس مجلس الوزراء رقم ٩٠٩ لسنة ٢٠١٨ في مايو لسنة ٢٠١٨

و في إطار الخطوات الحثيثة والمتلاحقة التي تخطوها الدولة نحو تنظيم القطاع الصحي بما يضمن سلامته واستقراره، وتحسين جودته، وتوكيد الثقة في جودة مخرجات الخدمات الصحية بجمهورية مصر العربية، على كافة المستويات المحلية و الإقليمية والدولية.

فقد قرر مجلس إدارة الهيئة العامة للاعتماد و الرقابة ما يلي

أولا : وضع قواعد وشروط تسجيل واعتماد الصيدليات.

ثانيا: مع مراعاة التدرج الجغرافي في التطبيق , تحتفظ الهيئة العامة للاعتماد و الرقابة الصحية بالحق في البت في تسجيل و اعتماد الصيدليات في كافة أنحاء الجمهورية وفي كافة القطاعات وفقا للقانون ٢ سنة ٢٠١٨

ثالثا : تلتزم الهيئة العامة للاعتماد و الرقابة الصحية بتعريف و تدريب الاطراف المعنية بإجراءات تسجيل وأعتماد الصيدليات وفق خطة محددة و مفهوم لا يتعارض مطلقا مع اي من القواعد الحاكمة لمبدأي الشفافية و تجنب تضارب المصالح.

التزامات عامة من جانب الصيدليات

١. تلتزم الصيدلية بتقديم جميع المعلومات المطلوبة بشكل صحيح خلال فترة التسجيل و الاعتماد.

٢. تلتزم الصيدلية المتقدمة للتسجيل والاعتماد بتحديث المعلومات لدى الهيئة فورا إذا حدث أي تغيير في المعلومات ذات الصلة بتسجيل أو اعتماد الصيدلية بعد أو أثناء إجراءات التسجيل والاعتماد.

٣. تلتزم الصيدلية بإطلاع الهيئة العامة للاعتماد والرقابة على النسخ الأصلية من نتائج وتقارير التقييمات الخارجية للصيدلية.

٤. لا يسمح لاي صيدلية باستعمال شعار الاعتماد للهيئة العامة للاعتماد والرقابة الصحية إلا بعد إشعاررسمي من الهيئة باجتياز الاعتماد بنجاح.

خطوات تسجيل و اعتماد الصيدليات لدى هيئة الاعتماد و الرقابة الصحية

١. تتقدم الصيدلية بطلب التسجيل والاعتماد لدى الهيئة و ذلك عن طريق ملأ و تقديم الاستمارة المخصصة لذلك.

٢. تقوم الهيئة بدراسة الطلب المقدم من الصيدلية.

٣. تقوم الصيدلية صاحبة الطلب بدفع مقابل التسجيل والاعتماد.

٤. تقوم الهيئة بمراجعة الوثائق المستلمة من الصيدلية و التأكد من اكتمالها و مخاطبة الصيدلية لاستكمال و تقويم ما ترى الهيئة ضرورة استكماله و تقويمه من الوثائق اللازمة لإتمام عملية التسجيل

٥. بعد التأكد من اكتمال جميع الوثائق المطلوبة تقوم الهيئة بتحديد موعد لإجراء زيارة للصيدلية للتدقيق و التحقق من البنية و العمليات المرتبطة بالوثائق المقدمة من الصيدلية و تقييم معايير الاعتماد في الصيدلية.

٦. إبلاغ المنشأة بموعد زيارة التدقيق و المراجعة قبل فترة لا تقل عن ١٥ يوما من التاريخ المحدد للزيارة.

٧. يقوم فريق من المقيمين / المراجعين بزيارة للتدقيق والمراجعة.

٨. تلتزم الهيئة بإبلاغ الصيدلية بقرار الهيئة خلال فترة لا تزيد عن ١٥ يوم عمل من تاريخ انتهاء الزيارة.

٩. الحالات المختلفة لقرار الهيئة:

أ. قبول تسجيل و اعتماد الصيدلية.

ب. رفض تسجيل و اعتماد الصيدلية.

ج. القبول المشروط لتسجيل و اعتماد الصيدلية و في هذه الحالة يتم تحديد فترة لإكمال المتطلبات وتحديد زيارة اخرى زيارة الفرصة الثانية)و تلتزم المنشأة بتسديد مقابل تلك الزيارة.

١٠. تعتبر شهادة الاعتماد الصادرة من الهيئة العامة للاعتماد و الرقابة الصحية لاغية في حال توفر الأسباب المذكورة في المادة ١٤ من قانون ١٢٧ لسنة ١٩٥٥ وتشمل:

أ. اذا تغير نشاطه و لم يعمل بالتراخيص الممنوحة له.

ب. اذا نقلت المؤسسة من مكانها الى مكان اخر.

ج. اذا تغير صاحب المنشأة مالم يتم اخطار الهيئة و عمل مايلزم.

١١. تتعهد الصيدلية بخطة عمل لربط الصيدلية بنظام التامين الصحي الكترونيا.

١٢. تقدم الصيدلية موافقة كتابيا على الالتزام بتطبيق معايير الاعتماد طوال فترة الاعتماد واستعدادها الدائم للزيارات المعلنة وغيرالمعلنة من الهيئة العامة للاعتماد والرقابة الصحية.

١٣. بما لا يتعارض مع القانون رقم ٢ لسنة ٢٠١٨ بشأن نظام التأمين الصحي الشامل، للهيئة الحق باتخاذ ماتراه مناسبا من إجراءات في حالة عدم التزام الصيدلية بأي من معاييرأو شروط تسجيلها واعتمادها.

Accreditation Decision

For each standard, the score can either be Fully Met (FM), partially met (PM), Not Met (NM), or Not Applicable (NA).

NSR EVALUATION:

- GAHAR is very much focused on individual and community safety.
- There are nine NSR standards.
- A pharmacy has to achieve overall score of 80% or more in NSR category.
- To pass accreditation, the pharmacy cannot score NM for any of these NSR standards.

OVERALL EVALUATION:

GAHAR considers the requirements of licensure, NSR evaluation, and pharmacy standards evaluation during the survey process. The outcome results of all these activities will formulate the registration and accreditation decisions.

The pharmacy is accredited by GAHAR when it meets all the following:

- All the registration information is correct and valid.
- None of NSR standards is scored as NM.
- The pharmacy demonstrates an acceptable level of compliance in each category of accreditation, where the total score is not less than 70%.(except for NSR overall score it should be not less than 80%)
- The pharmacy demonstrates overall acceptable compliance of no less than 80%.

GAHAR has the right to evaluate the risk of the following and decide either to schedule a second visit or to deny accreditation.

Accreditation is at risk or is denied when one or more from the following occurs:

- The registration information is found to be inaccurate when the surveyor team visits the pharmacy.
- Any NSR standard is scored as NM or overall NSR score is less than 80%
- One or more section's (rather than NSR section) total score is less than 70%.
- The overall compliance total score is less than 80%.
- The pharmacy fails to pass the second visit or fails to correct the information when it is requested to do so by GAHAR.

STANDARDS CATEGORIES:

- Pharmacy Licensure Requirements (PLR)
- National Safety Requirements (NSR)
- Pharmacy General Standards
  - Patient's Rights (PRT)
  - Appropriate and Safe Medications (ASM)
  - Prescription Review and Dispensing (PRD)
  - Infection Prevention And Control (IPC)
  - Environment of Care (EC)

APPENDICES:

- Appendix A: Pharmacy Licensure Requirements
- Appendix B: References

A. Pharmacy Licensure Requirements

PLR.1
The pharmacy complies with laws and regulations of licensing requirements for community pharmacies.

Rationale:
Laws and regulations serve many purposes and functions in society. Four principal purposes and functions are: establishing standards, maintaining order, resolving disputes, and protecting liberties and rights. The law is a guidepost for minimally acceptable acts in a society.

PLR.1

Evidence of Compliance
The pharmacy shows evidence of complying with each item in the license requirements, which are listed in Appendix A, for verification.

B. National Safety Requirements

NSR.1

The patient safety rules in pharmacy are well-followed by developing and implementing policies and procedures that include, but are not limited to:

NS.1.1 Accurate, standardized patient and prescription identification.

NSR.1.2 Standardized processes for dealing with telephone communication.

NSR.1.3 Proper hand hygiene, whenever indicated.

Rationale:
Addressing the most common and critical identified areas to prevent adverse events and to ensure awareness of patient safety within the pharmacy.

Survey process:
Patient safety policies and procedures will be reviewed and checked for all of the standard's components. Pharmacy staff will be interviewed to ensure awareness of policy and procedure of patient and prescription identification.

The policy and practice should cover how the staff handles telephone communications and staff awareness of proper hand washing.

NSR.1.1

Evidence of Compliance

a. The pharmacy develops and implements a policy and procedure that explains the two identifiers that are used to assure the correct patient for the correct prescription.

b. The policy includes special circumstances when the prescription owner is not available at the time of dispensing and the precautions that should be taken by the pharmacist.

NSR.1.2

Evidence of Compliance

a. The pharmacy has a policy on telephone communication.

b. The pharmacy does not accept telephone orders for chemotherapeutic agents, high-alert medications, or controlled medications.

NSR.1.3

Evidence of Compliance

a. The pharmacy develops and implements a policy explaining the proper method of hand hygiene based on evidence-based techniques.

b. Washing hand thoroughly with soap and water, or using an alcohol rub before mixing or preparing medications.

c. Having adequate supplies needed for handwashing.

NSR.2

Policies and Procedures for medication management safety are developed and implemented, including, but not limited to:

- Preventing errors from high-alert medications
- Preventing errors from look-alike/sound-alike (LASA) medications

Rationale:

Standardization and consistency of safe medication-related practices require developing and implementing policies and procedures which foster and support the culture of avoiding all harm to the patient.

Survey Process:

- The medication management safety policies and procedures are reviewed and checked for including the standard's components.
- Staff members are interviewed to check for full awareness of the mentioned policies and procedures.

NSR.2

Evidence of Compliance:

a. The pharmacy has a policy identifying the high-alert medications and their storage and dispensing precautions.
b. The pharmacy has a policy identifying LASA medications along with their storage and dispensing precautions.

NSR.3

High-alert medications and LASA medications are identified; measures are taken during storing and dispensing them to minimize the risk of medication error.

Rationale:

Identification and differentiation is an error reduction strategy. Inappropriate management of high-alert medication and LASA medications could lead to fatal medication errors.

Survey Process:

- Review the updated list of high-alert medications and LASA medications.
- Interview pharmacists and check if they understand how to minimize the risks associated with these types of medication.
- Observe, at the pharmacy, the labelling of LASA medications.

NSR.3

Evidence of Compliance

a. The pharmacy develops a list of high-alert medications in the pharmacy and updates it at least annually (and whenever needed) based on its data and national and international recognized organizations such as the Institute of Safe Medication Practice and the World Health Organization.
b. The pharmacy develops lists of LASA medications in the pharmacy and updates at least annually (and whenever needed) based on its data and national and international recognized organizations such as the Institute of Safe Medication Practice and the World Health Organization.
c. The pharmacy has a procedure that defines the storage and labelling of high-alert medications.
d. The pharmacy has a procedure that defines the storage and labelling of LASA medications.
e. The pharmacy procedure defines the steps of verification while preparing high-alert medication, LASA medications, and before dispensing.

NSR.4 The pharmacy has a system for labelling medications, solutions, and substance containers when preparing or mixing substances.

Rationale:

Labelling of substance containers assists healthcare professionals to identify the correct medicine and substances at all times, and reduce the risk of medication errors when preparing or mixing substances.

Survey Process:

To be observed at the mixing area and on patient medicines to make sure that medication containers are clearly labelled with their contents, the date the product was first opened, and the manufacturer's expiration date (whenever applicable).

NSR.4

Evidence of Compliance

a. Medications and chemicals used to prepare medications or those present in the preparation area are accurately labelled with contents, quantities, volume, expiration dates, and warnings.

b. The staff are aware of the process of labelling

NSR.5

Processes are used to ensure that medications are maintained within proper conditions, which include identification of storage temperature and humidity ranges, continuous temperature/humidity monitoring procedures, and methods that assure the presence of these conditions during medication transfer from distributor to pharmacy.

Rationale:

It is essential to maintain the stability of the medicine to ensure that each medicine will give its expected effect.

Survey Process:

The pharmacy shall demonstrate how they keep their medications and products safe and provide proper temperature for the room, refrigerator, and freezer. Also, the pharmacy must document the humidity level readings in special forms during storage and transfer of the medicine.

NSR.5

Evidence of Compliance

a. The pharmacy has a policy and procedure on the proper storage of regular medications and nutrition products.
b. Medications are stored in a way to avoid mixing labels showing the drug name and expiry date.
c. No medications are stored directly on the floor (a minimum of ten centimetres is left to manage spills). Medications are not stacked so high as to block sprinklers or come in contact with overhead lights or pipes.
d. There is an appropriate storage area for regular medications with controlled temperature, 24 hours a day, seven days a week.
e. The refrigerator's temperature is kept at optimal levels.
f. The freezer's temperature is kept at optimal levels.
g. Temperature is continually monitored, checked, and documented on the 24-hour chart.
h. Temperature records are kept for at least a year.
i. All antiseptics, disinfectants, and medications for external use are stored separately from enteral and injectable medications.
j. The "first expiry/first out" (FEFO) principle is followed.
k. All medication storage areas are inspected at least monthly by the pharmacist according to the pharmacy policy to ensure proper storage of medications. The inspection includes, but is not limited to, stock level, expiry date, and storage conditions.
l. Expired and damaged medications are clearly labelled and separated from other drugs until their removal and proper destruction.
m. Light-sensitive medications are to be defined and stored correctly.
n. Ensure that appropriate humidity is maintained between 30-60%, and there is proper documentation in a special form designed for it. These forms are kept in a special file.
o. There is a clear and defined mechanism in the policy on how to deal with an electric power outage or out-of-range temperature of the medication refrigerators and freezers, to ensure the integrity of the affected medications before their possible reuse.
p. Make sure there are only medications in the refrigerator and no other unsuitable materials such as food or drink.

NSR.6

Procedures outline how recalls are handled, including notification, removal from stock, documentation, disposal of products, and when and how patients and providers are contacted.

Rationale: Drug recall is made by a manufacturing company or by the MOH when there is a significant risk associated with that specific drug's use.

Survey Process: Review the policy and ensure that the staff understands the process, what they should do with the medicine that is still in the pharmacy, and how they will deal with the patient that received this recalled medicine. The pharmacy should show the letter of recall and any communication accordingly.

NSR.6
Evidence of Compliance

a. The policy states how and when to contact the patient(s) who received the withdrawn medicine batch.
b. Pharmacists are aware of the policy.
c. Temporary storage space is provided until the company receives the withdrawn medicine.
d. Clear guidance to pharmacists is provided as a clear sign indicating "medicine is withdrawn."

NSR.7

There is a well-structured and implemented fire and smoke safety plan that addresses prevention, early detection, response and safe exit when required, and includes at least the following:

- Frequency of inspecting fire detection and suppression systems, including documentation of the inspections.
- Maintenance and testing of fire detection and abatement systems in all areas.
- Documentation requirements for staff training in fire response and evacuation.

Rationale:

The pharmacy must have an ongoing assessment of compliance with the pharmacy fire safety requirements and National Civil Defence regulations to effectively identify and mitigate risks.

Survey Process:

- Review the fire safety plan ongoing evaluation, pharmacy fire safety inspections, and fire system maintenance.
- The fire alarm should be effectively working.
- Firefighting and smoke containment should comply with civil defence requirements.
- A review plan of testing in the forms of drills should be in place.
- All staff should be trained in fire safety.

NSR.7

Evidence of Compliance

a. Pharmacy complies to National Civil Defense regulations.
b. Maintenance and testing of fire prevention, early detection and abatement systems in all areas.
c. The pharmacy has a no-smoking policy which is rigorously enforced.
d. A no-smoking sign is posted inside the pharmacy.
e. Pharmacy staff are aware of the no-smoking policy and fire control procedures and evacuation.

NSR.8

There is a well-structured and implemented plan for hazardous materials (Hazmat) and waste management for the use, handling, storage, and disposal of hazardous waste, addressing at least the following:

- Safety and security requirements for handling and storage.
- Requirements for personal protective equipment.
- Procedures and interventions to implement following spills and accidental contact or exposures.
- Disposal per applicable laws and regulation.
- Labelling of hazardous materials and waste.
- Monitoring data on incidents to allow corrective actions.

Rationale:

The pharmacy should have a hazmat and waste management program that addresses different requirements. The pharmacy environment, staff, patients, relatives, and vendors should be safe from hazardous material exposure and waste at all times.

Survey process:

- Review the hazardous material and waste management program to make sure that it covers all safety requirements of hazardous materials, safe storage, handling, spills, required protective equipment, and waste disposal in accordance to the national laws and regulations.
- Review the hazardous material and waste disposal plan, hazardous material, and waste inventories, as well as Material Safety Data Sheet (MSDS), and inspect hazardous material labelling and storage in addition to waste collection, segregation storage, and final disposal.

NSR.8

Evidence of Compliance

a. The pharmacy does not store chemical substances (e.g. formalin, methanol) for distribution to a laboratory, doctor's office, or hospital.

b. A list of all present hazardous chemicals should be available to all pharmacists in the pharmacy.

c. All caustic or hazardous chemicals and other non-drug substances are clearly labelled and stored on low shelves separate from all other medications.

d. The label must show the health, flammability, reactivity, and physical hazards associated with the substance. The National Fire Protection Association (NFPA) rating system must be used to show these ratings.

e. All existing labels on containers of hazardous substances must remain intact. The labels must be legible.

f. All staff dealing with hazardous materials are aware of information concerning the dangers of those materials, and MSDS are accessible and updated.

C. Patient's Rights

PRT.1

The practice of pharmacy provides patient care services in an environment that maintains patient privacy and confidentiality, supports patient education, and encourages the patient to ask questions.

Rationale:

Patient privacy, particularly during counselling, is important. Confidentiality for patient counselling and medication therapy management services must be provided. Patients are encouraged to ask questions about the medications they are receiving and receive education on medication use.

PRT.1

Evidence of Compliance:

a. An area/space for patients to receive counselling and education services is available, ensuring patient privacy with a clear sign indicating "counselling/education."

b. The pharmacy has a patient/family education policy that is consistent with its mission, services, and patient population.

c. The pharmacist, according to their job description, has a responsibility to give adequate information regarding the reasons for use, the expected benefits of the treatment, any special warnings during the treatment, the most likely side effects and what to do when they occur, and any other information that the pharmacist deems necessary in an easily understood language.

d. Patients are instructed on the proper use and maintenance of any devices dispensed from the pharmacy (e.g. glucose monitors, injectable pens, spacers used with inhalers).

e. The price appears clearly on the medication package.

PRT.2

Patient's rights to listening and responding effectively to his/her complaints.

Rationale:

The pharmacy has a system on patient complaints that includes taking complaints from the patient, then registering and documenting the action and time frame for resolving complaints.

PRT.2

Evidence of Compliance:

a. There is a system in documenting patient complaints received by phone or in the pharmacy.
b. Here is an ongoing analysis report, at least quarterly, as part of the pharmacy quality program.

PRT.3

Patient rights to be provided with suitable educational aids that help patients with disabilities to understand the pharmacological information.

Rationale:

Patient education should identify those who have special needs populations, and the education offered to them in a manner that they can understand. A clear explanation of what counselling consists of how to take and store the medication, possible side effects, interactions with other medications, and how it would benefit them. The pharmacy may have special posters or any other tool which can help the purpose of patient education.

PRT.3

Evidence of Compliance:

a. There are uniform approaches and educational materials that could be used by all pharmacists.
b. Staff are aware of the proper usage of these materials.

PRT.4

The pharmacy informs patients and families about their rights and responsibilities in a manner and language they can understand.

Rationale:

A pharmacy should respect the right of patients to have the prerogative to determine what information regarding their medication would be provided. All pharmacists are knowledgeable about patient rights and can describe to the patients their rights and responsibilities in a simple language.

PRT.4

Evidence of Compliance:

a. Information about patient rights and responsibilities is clearly shown to be seen and read by all customers.

b. The staff are aware of patients' rights and responsibilities.

D. Appropriate and Safe Medications

ASM.1

Medications are provided in the pharmacy per the requirements of the national laws and regulations of the Ministry of Health.

Rationale:

Medication use in the pharmacy should comply with applicable laws and regulations in Egypt. Medication is under the direction and supervision of a licensed pharmacist at all times.

ASM.1

Evidence of Compliance:

a. MOH-registered medications are the only medications allowed to be available within the pharmacy.

b. Medications are dispensed under the supervision of licensed pharmacists at all times.

c. The staff are aware of elements both previous elements.

ASM.2

Medications are available from reliable sources.

Rationale:

The pharmacy has a process to determine the reliable sources for medication and medical devices. Also, the pharmacy is required to have a process to identify medications, medical supplies, and medical devices that are provided from improper sources. Any detected issues with this process should be immediately notified.

ASM.2

Evidence of Compliance:

a. The pharmacy develops and Implements a policy defining the Product Safety and Supplier Integrity process, which require to refrain from dealing with counterfeit, smuggled, or damaged medicines or recalled medicines or samples provided by pharmaceutical companies.
b. The policy should contain a clear system which states that it is prohibited to deal with unregistered dealers, brokers, online medication sources, or subagents.
c. The pharmacy has a system to monitor their employees in dealing with these cases.
d. Medication quality issues are reported to MOH.
e. The staff are aware of their roles in this process.

ASM.3 There is a well-developed and implemented process of dealing with expired or near-expired medications.

Rationale:

The pharmacy has a system to identify the nearly-expired or expired medications by establishing the FEFO principle, and has a process to isolate these items from the use or mixing with other medications by keeping them in a separate shelf or closed cabinet and labelling them till they are removed properly.

ASM.3 Evidence of Compliance:

a. The policy defines near-expired or expired medication.
b. Pharmacists are aware of the policy.
c. Temporary storage space is provided until the company receives the expired or near expired medicine.
d. Clear guidance to the pharmacists is established by providing a clear sign indicating “Expired Medicine."

ASM.4

Collaboration and effective communication with the prescribing doctors in case of medications unavailability.

Rationale:

The pharmacy implements policy and procedure on proper communication related to medication shortage and outage to prescribers and discussing the available alternatives. The pharmacist shall suggest to the prescribing physician, if possible, the substitution of a therapeutically equivalent item from the pharmacy stock.

ASM.4 Evidence of Compliance:

a. The pharmacy implements a policy on proper communication with the prescribers.
b. The pharmacist and prescriber should agree on the substitutes of medicine in case of medication being out of stock.
c. There is a register to document these communications accurately and promptly.

ASM.5

The existence of an information system for medications and other chemicals can be used for both physicians and members of the public.

Rationale:

The pharmacy should have information sources that can support the work to be done in a safe environment. This source must be a reliable, authoritative, comprehensive, and up-to-date source of drug information. It could be an electronic or an updated drug information manual. All the questions shall be documented and kept in a folder to be used as a reference for any concern that could arise later.

ASM.5

Evidence of Compliance:

a. A reliable source of information that can support the pharmacist to answer the questions from physicians or customers is available in the pharmacy.
b. The pharmacy has a standardized form that can document the caller information, question, and answer, and use read back technique.
c. The form is kept in a file for review.

E. Prescription Review and Dispensing

PRD.1

The medication prescription is reviewed for appropriateness.

Rationale:

A patient's prescription should be reviewed for appropriateness before dispensing by a licensed pharmacist. The pharmacist must utilize their knowledge, discretion, expertise, and pharmacovigilance on the appropriateness review included in the evidence of compliance (b.).

PRD.1

Evidence of Compliance:

a. The pharmacy develops and implements a policy on appropriateness review.

b. Appropriateness review could include:
   - Evaluating the conformity of the patient's diagnosis with the prescribed medication.
   - Ensuring there is no overlap between drugs.
   - Ensuring the life and food habits of the patient do not conflict with the medication before dispensing.
   - Verifying the correct name, correct diagnosis, and correct medicine, dose, frequency, route of administration and duration, correct weight and calculation for doses that depend on weight.
   - Medication use is clear.
   - No allergy, duplication, or interaction.

c. Communicate with the prescriber in case of the inappropriateness of prescription, and document this intervention in a special form for prescription review.

d. The pharmacists are aware of this process.

PRD.2 The pharmacy has a system for storing and dispensing controlled medications according to the relevant laws and regulations.

Rationale:

The pharmacy should have a written implemented policy referring to the laws and regulations' requirements as related to controlled medications storing and dispensing. The pharmacy aims to comply with the Ministry of Health rules and regulations concerning procurement, handling, storage, dispensing, documentation, and disposal of expired items.

A prescription review must be done before dispensing. The review must ensure the prescription completeness with the name of the patient, diagnosis, date, time, medication, dose, frequency, route, the quantity for dispensing, and the physician signature and their stamp.

PRD.2

Evidence of Compliance

a. The pharmacist dispenses controlled medications using forms and steps as per laws and regulations.
b. Processes are used to ensure that inventory control is adequate to detect theft or diversion and include investigating and reporting suspicious events to the authority.
c. The staff are aware of the process' steps and forms.

PRD.3

The pharmacy has a medication error reporting and adverse drug reaction system.

Rationale:

A formal process should be established to report both hazardous situations that could lead to an error in the pharmacy and actual errors in the prescription or unexpected adverse drug reaction which occurred to the patient. The policy should define possible medication errors, adverse drug reactions, and actions that should be taken accordingly with a detailed description of that reporting system. Human error, an investigation is undertaken to uncover any pre-existing performance shaping factors (e.g. task complexity, workflow, time availability/urgency, experience, training, fatigue, stress) and other environmental conditions, system design attributes, behavioural choices, or design flaws that allowed the error to happen and reach the patient. One of the pharmacists in the pharmacy should be responsible for enhancing the detection of medication errors, overseeing the analysis of their causes, coordinating an effective error-reduction plan, and reporting the cases to authority whenever required. The pharmacy management should show the leadership support to the staff who were involved in the error, and encourage them to report on the special format the medication error or adverse drug reaction that was reported by the patient.

PRD.3

Evidence of Compliance:

a. The pharmacy has a policy that defines medication errors and adverse drug reactions.

b. The pharmacy has a clear, well-defined reporting system.

c. The pharmacist documents the received complaints which are related to wrongfully-prescribed medication, wrongfully-dispensed medications, errors discovered during a prescription review or appearance of severe allergic reactions after use of the medicine. The pharmacy should inform the authorities whenever indicated.

d. The staff can demonstrate the process easily and clearly.

PRD.4

When dispensing medications without their original packaging, attention must be given to the factors that adversely affect the effectiveness of the medicine.

Rationale:

The pharmacy should have a policy defining the few cases that require dispensing medications without their original containers or boxes. The policy should define the handling process.

PRD.4

Evidence of Compliance

a. The pharmacy has a policy defining the accepted circumstances for medication dispensing without their original packages.

b. The policy defines the required repacks and labels and to ensure that the medication has complete dispensing information label.

PRD.5

The pharmacy has a well-developed and implemented process of dealing with returned medications.

Rationale:

The pharmacy should give enough information about the conditions of acceptance or non-acceptance of the returned medications. The pharmacists should ask about the reason for returning the medication, and how the patient or customer handled /stored it. Any doubt of the medication safety or integrity should always be excluded first.

PRD.5

Evidence of Compliance

a. The pharmacy develops and implements a policy of returned medications, defining the conditions of validity such as the integrity of the package, storage in proper temperature, etc.)

b. The staff are aware of the returned medication process (including acceptance and non-acceptance).

F. Infection prevention and control

IPC.1

The pharmacy has a well developed and implemented infection prevention and control processes.

Rationale:

The pharmacy should have a policy and procedure guiding infection prevention and control processes to keep the pharmacy safe from the risk of infection.

IPC.1

Evidence of Compliance:

a. The required refrigerator and freezer temperatures are maintained by continuous monitoring of the records.

b. Food and beverages are not kept in the medications refrigerators.

c. Medications are stored under permissible temperatures and humidity.

d. Cleanliness of the place of preparation and dispensing areas is maintained all the time.

e. All working surfaces (e.g. benches, tables, preparation surfaces, and counting trays) are cleaned and wiped with 70% isopropyl alcohol at the start of the working day, or whenever needed.

f. Medications storage shelves should be free of dust.

g. There is a system for the proper disposal of medical waste.

h. Staff are aware of the essentials of infection prevention and control within the pharmacy.

IPC.2

When preparing medications, the pharmacy has a well-developed and implemented process for that.

Rationale:

Preparing medications is a critically sensitive process. It should be done aseptically and precisely. Otherwise, the patient will be harmed. Compliance to this practice is critical when medications are being prepared within the pharmacy.

IPC.2

Evidence of Compliance

a. Clean water and disinfectant soap are available.

b. Hand hygiene is strictly followed in case of medication preparation.

c. The staff are aware of when and how to wash their hands properly.

G. Environment of Care

EC.1

The pharmacy is a secure place for medications, staff, and customers.

Rationale:

Community pharmacists are well aware of prescription-drug diversion and the many ways in which pharmaceuticals—in particular, controlled substances are diverted for criminal purposes: robbery and internal theft by employees. Good pharmacy security combines physical, policy, and technological approaches to safeguard pharmaceutical agents and help protect against theft and diversion.

- For policy, complying with MOH rules in controlled medication is mandatory. The policy should define who is authorized to deal with controlled medications, and who is authorized to prepare and dispense medications. Also, staff in the pharmacy should carry the work ID with name and position title.
- Basic security systems in pharmacies that guard against physical loss of controlled substances and prevent theft by employees include safes, locked cabinets, camera systems, and alarms.
- Video cameras should cover entrances, exits, high-risk areas such as the pharmacy counter, and dispensing areas. Data-storage devices can be housed in secured cabinets or at an off-site location.

- Work environment habits such as limiting direct physical access to designated dispensing areas and other critical locations and requiring strong protocol procedures for access are tactics that can help to minimize physical security threats in pharmacies.
- All prospective employees should be screened by verifying licenses.

EC.1

Evidence of Compliance:

a. There is a security system for the pharmacy to close its doors, and there is a video camera surveillance system or any other security system installed within the pharmacy to guard against theft.

b. Controlled medications are kept behind securely locked safes.

EC.2 There is a well-developed and implemented plan in case of power disruptions.

Rationale:

The pharmacy should have a policy aiming to set up an alternative in case of short term or long-term failure of power supply. The policy shall describe what the pharmacy would do in specific scenarios, such as the place to which medicines requiring low-temperature storage will be transferred, for how many hours these medications would be kept there, and possible communications to fix an interruption of power supply.

EC.2 Evidence of Compliance:

a. The pharmacy has an applicable plan which contains the measures that are taken in case of power or disruptions

b. The staff are familiar with the plan measures.

Appendix- A

Pharmacy License Requirements for Verification

التحقق من اشتراطات التراخيص للصيدليات

١. رخصة الصيدلية , وأن تكون معلومات الرخصة مطابقة للمعلومات التي سيتم تدقيقها من فريق لجنة الأعتماد

٢. رسم هندسي معتمد من مهندس نقابي طبقا لأخر تعديل على الرخصة

3. يجب ألا تقل مساحة الصيدلية عن ٢٥ متر مربع ولا يقل الارتفاع عن ٢,٦ متر

٤. تتوفر في الصيدلية اشتراطات البناء الواردة في قرار وزير الصحة رقم ٣٨٠ لسنة ٢٠٠٩

٥. تعهد بتوفير كل ماهو مسجل و مصرح بتداوله وفقا لاحكام قانون مزاولة مهنة الصيدلة مثال وليس للحصر : المستحضرات الصيدلية والمستحضرات الغذائية التي لها صفة علاجية والمستلزمات الطبية ذات الاستخدام الواحد و مستحضرات التجميل و كل ماورد في المادة رقم ١ من قرار وزير الصحة والسكان رقم ١٧٤ لسنة ١٩٩٩ بشأن استيراد المستحضرات الصيدلانية والمستلزمات الطبية و مستحضرات التجميل و غيرها وان تكون من خلال مستوردين معتمدين وعدم تداول الادوية غير المسجلة أومجهولة المصدر وفقا للقوانين المنظمة لذلك

٦. جميع العاملين من الصيادلة مرخصين لاداء العمل . وتقديم الشهادات الصحية الخاصة بعمال المناولة بالصيدلية.

٧. التقدم ببيان العاملين من صيادلة وعمال وغيرهم وعقود العمل الخاصة بهم

٨. كتابة اسم الصيدلية بخط واضح واسم صاحب الصيدلية باللغة العربية واسم المديرالمسئول في لوحة واضحة على الصيدلية

٩. يتم تداول الأدوية المؤثرة في الحالة النفسية ، وتداول أدوية المخدرات و الجدول داخل الصيدليات العامة والخاصة وفقا لنص القرار رقم ٤٨٧ لسنة ١٩٨٥ الخاص بتنظيم تداول تلك الأدوية والقانون رقم ١٧٢ لسنة ٢٠١١ ويشترط أن تباع هذه الأصناف بدفتر معتمد، ومرقم من إدارة الصيدلة بمديرية الشؤون الصحية تبين به الكميات الواردة والمنصرفة.

١٠. تخصيص مكان امن و محكم الغلق للادوية المؤثرة على الحالة النفسية و الادوية المراقبة و المخدرة

١١. اقرار باتباع و الالتزام بمتطلبات التعامل بجدول رقم ٦) المواد القابلة للالتهاب والمواد المفرقعة و الخطرة (في القانون رقم ١٢٧ لسنة ١٩٥٥

١٢. تخصيص مكان منفصل لتخزين المنتجات او الادوية المنتهية الصلاحية و مسجل عليه لافتة أدوية منتهية الصلاحية – ليست للاستعمال

١٣. أن يكون المكان جيد التهوية والإضاءة

١٤. توفر مورد للمياه النقية العمومية للصيدلية

١٥. أن تكون صرف المخلفات في المجاري العمومية حسب الرسم الهندسي المعتمد من السلطة .الصحية المختصة و طبقا لقرار وزير الصحة رقم ٣٨٠ لسنة ٢٠٠٩

١٦. أن تزود المنشأة بالوسائل والأدوات الصحية اللازمة للتخلص من القمامة.

١٧. شهادة من إدارة الدفاع المدني و الحريق بتوفر الاشتراطات اللازمة لحماية الصيدلية من اخطار الحريق

١٨. تتقدم بتعهد بالالتزام بتنفيذ الاشتراطات الفنية والصحية المحددة بالقانون رقم ١٢٧ لسنة ١٩٥٥ او بأي تعديل صدر لاحقا من الجهات المشرعة فيما يخص مزاولة مهنة الصيدلة

Appendix- B

References:

1. Egyptian Ministry of Health rules and regulations.
2. World Health Organization - Educational Materials for Medication Safety 2016.
3. Joint Commission International Hospital Standards 2016.
4. Canadian Accreditation Standards on Medication Management 2019.
5. ISMP Medication Safety Self-Assessment for Community /Ambulatory Pharmacies 2017.
6. Australian Commission on Safety and Quality in Healthcare – Medication Safety 2019.