وزارة الصحة
Ministry of Health

PHARMACY NEWSLETTER

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A quarterly e-newsletter of the General Administration of Pharmaceutical Care, Therapeutic Affairs Deputyship

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1.1 Formulary New Additions

Esketamine 28 mg/actuation nasal spray

Restricted for the treatment of resistant depression (TRD) in combination with oral antidepressants in adults; should only be available through a restricted program (drug-disease registry) and may only be administered under direct supervision of psychiatry consultant; Dose should not reach 84 mg once weekly.
Prescribing is restricted to consultant psychiatrists
(Central/Controlled Medication)

Coagulation factor VIII LA 500 international units (Esperoct®) injection, 4 mL prefilled pen

Restricted for on demand and prophylaxis of bleeding episodes to prevent or reduce the frequency of bleeding episodes in patients with hemophilia A without inhibitors.
Prescribing is restricted to hematologists (adults and pediatrics)
(Central Medication)

Coagulation factor VIII LA 1000 international units (Esperoct®) injection, 4 mL prefilled pen

Restricted for on demand and prophylaxis of bleeding episodes to prevent or reduce the frequency of bleeding episodes in patients with hemophilia A without Inhibitors.
Prescribing is restricted to hematologists (adults and pediatrics)
(Central Medication)

Coagulation factor IX LA (recombinant/reconstituted) 250 international units (Alprolix®) injection: 5 mL vial

Restricted for on demand and prophylaxis of bleeding episodes to prevent or reduce the frequency of bleeding episodes in patients with hemophilia B without
inhibitors.
Prescribing is restricted to hematologists (adults and pediatrics)
(Central Medication)

Coagulation factor IX LA (recombinant/reconstituted) 1000 international units (Alprolix®) injection: 5 mL vial

Restricted for on demand and prophylaxis of bleeding episodes to prevent or reduce the frequency of bleeding episodes in patients with hemophilia B without inhibitors.
Prescribing is restricted to hematologists (Adults and pediatrics)
(Central Medication)

Semaglutide 0.25 mg/mL injection, 1 mL autoinjector
Semaglutide 0.5 mg/mL injection, 1 mL autoinjector
Semaglutide 1 mg/mL injection, 1 mL autoinjector

Restricted to reduce the risk of major adverse cardiovascular events in adults with T2DM and established cardiovascular disease.
Privilege of prescribing to consultant endocrinology for hospitals use only.
(Central Medication)

Dimeticone 92% scalp application, 50 mL bottle

Carbomer 0.2% (2 mg/g) eye gel

Sodium phosphate dibasic + sodium phosphate monobasic enema

1.2 Formulary Deletions

The following medications were deleted from the formulary. Deletion is effective when stock reaches zero (DWZ)

Coagulation factor VIII [human anti-hemophilic factor] 250 international units injection: vial

Coagulation factor VIII 250 international units injection: 5 mL vial

Coagulation factor VIII (recombinant) 1000 international units injection: powder (vial) + diluent

Coagulation factor VIII (recombinant) 250 international units injection: powder (vial) + diluent

Coagulation factor VIII [human anti-hemophilic factor] 1000 international units injection: powder (vial) + diluent

Coagulation factor IX (recombinant/reconstituted) 250 international units injection: 10 mL vial

Antihemophilic factor IX Recombinant 500 IU vial

Dulaglutide 0.75 mg/0.5 mL injection, 0.5 mL prefilled pen

Dulaglutide 1.5 mg/0.5 mL injection, 0.5 mL prefilled pen

Ascorbic acid 500 mg tablet

Pyrethrins 0.165% + piperonyl butoxide 1.65% shampoo

Hypromellose 2% eye gel

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Aminocaproic acid 1.25 g/5 mL oral liquid

Aminocaproic acid 500 mg tablet

Epoetin beta 1000 international units injection: powder (vial) + diluent

Epoetin beta 30,000 international units injection: powder (vial)+ diluent

AzaTHIOprine 50 mg injection: vial

Muromonab-CD3 5 mg/5 mL injection, 5 mL ampoule

Gas gangrene antitoxin injection, 10 mL ampoule

Sodium aurothiomalate 10 mg/0.5 mL injection, 0.5 mL ampoule

Sodium aurothiomalate 50 mg/0.5 mL injection, 0.5 mL ampoule

Hyoscine butylbromide 10 mg suppository

Phosphate sodium dibasic 60 mg/mL + phosphate sodium monobasic 160 mg/mL enema, 120 mL bottle

Phosphate sodium dibasic 60 mg/mL + phosphate sodium monobasic 160 mg/mL enema, 60 mL bottle

Etidronate Disodium 300 mg ampoule

Febuxostat 40 mg tablet

Febuxostat 80 mg tablet

Insulin detemir 100 international units/mL injection, 10 mL prefilled injection device

liothyronine sodium 25 microgram tablet

Nateglinide 120 mg tablet

Menadiol 10 mg tablet

Theophylline 60 mg/5 mL oral liquid

Neostigmine metilsulfate 12.5 mg/5 mL injection, 5 mL ampoule

1.3 New Strength and/or Dosage Form Addition

Dolutegravir 50 mg + lamivudine 300 mg tablet

1.4 Indication Expansion

The following medications indication was expanded to pediatrics:

Glecaprevir 100 mg + pibrentasvir 40 mg tablet

Ribavirin 200 mg capsule

Sofosbuvir 400 mg tablet

1.5 NP to P switch

The following medications' status in the formulary was changed to formulary items (planned).
There will be no formulary category as (NP:Not Planned) anymore

RomiPLOStim 250 microgram injection: vial
RomiPLOStim 500 microgram injection: vial
Restricted medication: As 2nd line after the failure of eltrombobag
Privilege of Prescribing to Adult hematologists

Basiliximab 20 mg injection: vial
Restricted to Transplant Centers

Mycophenolic sodium 180 mg tablet: gastro-resistant
Restricted to Transplant Centers

Budesonide 3 mg capsule
Prescribing is restricted to gastroenterologists for Ulcerative Colitis and Chron's disease

Pamidronate disodium 15 mg/5 mL injection: concentrated, 5 mL vial
Restricted to Endocrine and Oncology

Liothyronine sodium 50 microgram tablet
Restricted to hospitals only for adult and pediatrics endocrinology
Prescribing is restricted to endocrinology consultants

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Zoledronic acid 5 mg/100 mL injection: intravenous infusion, 100 mL bottle
Restricted for hospitals only for osteoporosis
Prescribing is restricted to adult Endocrinologists

Sildenafil 20 mg tablet
Prescribing is restricted to pulmonologists for pulmonary hypertension

Diphenyl Cyclopropenone (Dpcp) 206.24 , 5 G White to Tan Powder
Prescribing is restricted to dermatologists

Aprotinin 3000 KI units + calcium chloride 40 micromole + human fibrinogen 91 mg + thrombin-human 500 international units, 2 mL application

Botulism immunoglobulin, human 100 mg injection: vial

Famotidine 20 mg/2 mL injection, 2 mL vial

Repaglinide 2 mg tablet

Pyridoxine hydrochloride 10 mg tablet

CloNIDine hydrochloride 100 microgram tablet

Edetate calcium disodium 1 g/10 mL injection: concentrated, 10 mL ampoule

Fomepizole 1.5 g/1.5 mL injection: intravenous infusion, 1.5 mL vial

Sugammadex 100 mg/1 mL injection, vial

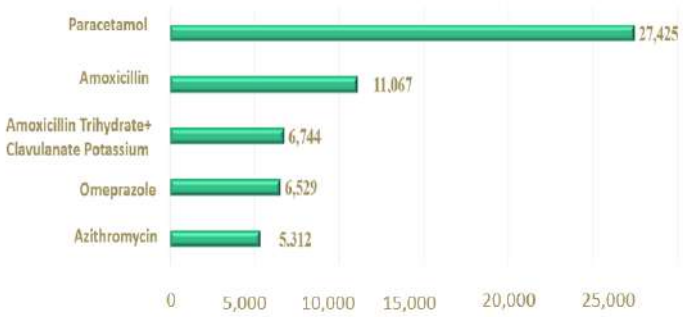
1.6 MOH Formulary Application

For IOS

For Android

2 The Top 5 Most Frequently Reported Medication Errors

The Top 5 reported medication errors through the Ministry of Health Medication Error Reporting System were as follows:



Category B: 57%, Category A: 41.7%, Category C: 1%, Category D: 0.18%, Category E: 0.05%, Category F: 0.05%, Category I: 0.01%, Category G: 0.001%

3 A Case of Extravasation Injury

A 15-years old female known case of global developmental delay, spastic quadriplegia, and failure to thrive, weighing approximately 20kg, with seizure disorder. She presented to the Emergency Department at 07:37 with active seizures, IV cannula G22 was immediately inserted in the right hand at 07:40.

She was given two doses of IV lorazepam , 3 mg and 2.3 mg. A second cannula G20 was inserted on the left arm at 08:12.

At 08:20 the pediatric neurologist on-call consulted PICU team, ordered IV phenobarbital at 08:30 which was given at 08:55, not clear through which cannula.

At 09:10, the right-hand cannula was removed due to redness; the ED physician was not informed. Another cannula G22 was inserted in the left arm. The PICU physician documented that the swelling was mainly at the palmar surface with mild bluish discoloration; perfusion and pulse were intact.
He diagnosed this finding as extravasation and asked the nurse to elevate the hand, apply a warm compress, check the pulse with Doppler hourly, and monitor the saturation from the right hand.

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Extravasation is defined as an accidental leakage of any liquid from a vein into the surrounding tissues

Signs and Symptoms of Extravasation

• Complaints of pain, tightness, burning, discomfort at or around the insertion site, catheter tip, or entire venous pathway.

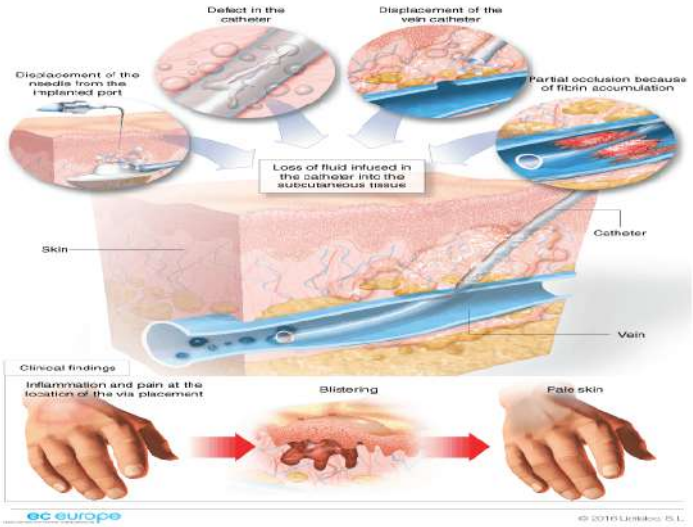
• Swelling at or above the insertion site or increase in size of extremity.

There are two types of medication extravasation:

1. Irritant Medications: Medications that are capable of causing inflammation, irritation or pain at the site of extravasation but rarely cause tissue breakdown. Such as Amphotericin B, Ampicillin, Cefazolin, Ceftriaxone, Clindamycin, …etc.)

2. Vesicants: Medications that are capable of causing pain, inflammation and blistering of the local skin and underlying structures. If left untreated may lead to tissue death and necrosis Such as Acyclovir, Dextrose over 10%, Dopamine, Mannitol 10%-20%, Oxaliplatin, Phenobarbital, …. etc.)

A list of irritant and vesicant medications that are recommended to be administered via central line, please see the below barcode:



Phlebology - Medical illustration - ec-europe. (2022). Retrieved 31 May 2022, from https://www.ec-europe.com/medical-illustration/phlebology

4 Interactions Between Sex Hormones and Epilepsy

There is a complex, bidirectional interdependence between sex steroid hormones and epilepsy; hormones affect seizures, while seizures affect hormones, thereby disturbing reproductive endocrine function. Both female and male sex steroid hormones influence brain excitability. For the female sex steroid hormones, progesterone and its metabolites are anticonvulsants, while estrogens are mainly proconvulsants. Androgens are mainly anticonvulsants, but the effects are more varied, probably because of their metabolism to, among others, estradiol. In addition, antiepileptic drugs (AEDs) can interact both with the epilepsy itself and with hormones. Clinically, the effect of hormones on brain excitability appears as fluctuations in seizure frequency in relation to changes in hormone levels. The results of many clinical studies have been supported by several animal studies that have demonstrated increased seizure frequency after estrogen administration, and decreased seizure frequency after progesterone

5 Good Pharmacy Practice

Good health is a fundamental right for individuals and societies. Limited access to quality medical products, lack of trained healthcare professionals, unaffordable cost of care and low standards of health education, are all obstacles to community health and welfare. Quality pharmaceutical service is essential to patients, community health, and well-being. Therefore, the WHO and FIP (International Pharmaceutical Federation) have emphasized the role and importance of pharmaceutical care, and have developed standards for pharmacy care called "Good Pharmacy Practice" (GPP). GPP is the practice of pharmacy that responds to the needs of the people who use the pharmacist's care, and provides optimal, evidence-based pharmaceutical care.

Main Requirements of GPP :

- A pharmacist's primary responsibilty must be the health and welfare of the patient and society.
- The primary responsibility is to deliver medications to patients, as well as updated medication information and counselling.

- Pharmacists must monitor the effects of medication use and make required interventions. This includes providing updated reports about ADRs and drug-drug interactions, medication errors, defects in product quality and detection of counterfeit products.
- Pharmacists must play an integral role in promoting rational and economic prescribing, dispensing and medication use.
- All objectives of pharmacy services must be relevant to the patient, clearly defined, and properly conveyed.
- Multidisciplinary teamwork among all healthcare providers is key to patient safety.

Implementing these and other GPP measures enhances the traditional role of the pharmacist to become a provider of modern pharmaceutical care in a comprehensive, proactive and patient-centric approach.

6 Pharmacists Working Toward Patient-Centered Care

Pharmacy services have evolved beyond basic medicine supply to become more patient-centered and caring services. Pharmacists collaborate with other healthcare practitioners to improve patients' quality of life and obtain the best clinical results.

An excellent professional relationship and communication between pharmacists and patients must be developed and maintained to achieve that goal. The pharmacist should also retain a caring approach and use his expertise and knowledge as a medication expert to enhance the health and satisfaction of the patients.

Knowing what patients are looking for can help pharmacists become better practitioners while also increasing patient satisfaction. Considering this patient's need can assist the pharmacist in moving the profession toward a visible patient-centered model in which the patient (or caregiver) is fully involved in all aspects of medication-related care, such as prescriptions, over-the-counter medications, supplements, and other services.

In pharmaceutical care, pharmacists should encourage patients to seek education and counseling and should eliminate barriers to providing it.

Patient satisfaction is an essential component of healthcare quality. Improved communication, convenience, and civility can lead to increased use of health care services and, as a result, improved results. High satisfaction encourages favourable health behaviours such as compliance and provider continuity. Patients who are satisfied with their overall treatment are more likely to take their medications properly and less inclined to switch from one healthcare practitioner to another.

7 G6PD Deficiency and medications: To give or not to give!

G6PD is a genetic disorder caused by inherited mutations of the X-linked gene G6PD resulting from a structural defect in an enzyme called glucose-6-phosphate dehydrogenase that affects red blood cells, which carry oxygen from the lungs to the tissues throughout the body. In affected individuals red blood cells break down prematurely.

Medications and medication classes likely to be UNSAFE in moderate to severe G6PD deficiency (Up to date): *
-Dapsone (diaminodiphenyl sulfone)
-Fluoroquinolones (ciprofloxacin, moxifloxacin): Levofloxacin is not listed because some cases of hemolytic anemia with levofloxacin have been associated with a positive Coombs test.

-Methylene blue (methylthioninium chloride): Methylene blue is a component of some combination urinary tract products.
-Nitrofurantoin
-Primaquine
-Sulfonylureas (eg, glyburide [glibenclamide])

* Applies to Class I, II, and III G6PD variants. However, note that there is marked variability in reports. This list is based on evidence supporting a clear association with drug-induced hemolysis. Individual characteristics (ie, degree of G6PD deficiency, dose, presence of infection) will determine actual safety or injury. Medications known to be unsafe in G6PD deficiency that are no longer in clinical use are excluded from this list. In cases where the patient truly requires the medication and G6PD status is unknown, it may be appropriate to administer and monitor closely.

Glader, B. (2022, March 23). Diagnosis and management of glucose-6-phosphate dehydrogenase (G6PD) deficiency. Uptodate

8 Pharmacists Role in the Management of Patients with Chronic Kidney Disease

Chronic Kidney Disease (CKD) is a major health problem, requiring early detection and treatment to delay the progression. When disease progresses to a stage where kidney failure occurs, patients are required to start renal replacement therapies, either through dialysis or transplantation. Patients who have undergone organ transplantation are also required to take a multitude of medications and adherence to these medications is essential to avoid graft rejection and unnecessary medical costs. Medication-related problems are common among dialysis patients. Non-adherence to prescribed oral medications is also a common issue with mean reported rates as high as 67%. Over the last decades, pharmacists play an important role in optimizing medication therapy for patients with CKD.

Most frequent interventions performed by pharmacists for the CKD patients:

-Medication profile review to address potential drug-related problems.
-Pharmacotherapeutic interventions to optimize medication therapy.
-Medication reconciliation upon admission and discharge.
-Obtaining the patient's allergy and medication histories.
-Continually assessing the drug therapy for efficacy and adverse effects, using laboratory results.
-Management of other comorbidities, adjustments of doses, and recommendations relating to medications that are eliminated renally.
-Educating patients on the importance of medications in chronic kidney disease, adherence to drug regimens, and the potential risks associated with nephrotoxic medications.

9 Medication Safety Training Program

A medication safety program was developed under the supervision of the General Administration of Pharmaceutical Care (MOH) and in collaboration with the Saudi Pharmaceutical Society (SPS). The program has different modules which is accredited by the Saudi Commission for Health Specialists to be given at a four days period by expert speakers in the field. It aims to train medication safety officers in different hospitals all over the kingdom on the important pillars in medication safety.

Objectives of the Program:

• Participate in the ongoing hospital/pharmacy medication safety projects and activities.
• Review and understand the process for implementing corrective actions for medication-related errors at the individual and aggregate event levels and how this information is utilized and communicated to staff.
• Become familiar with CBAHI & Joint Commission international medications and pharmacy related standards.
• Participate in the pharmacy joint commission continuous compliance team activities and inspection visits.
• Identify medication management best practices that can add value to a hospital's practice add increase medication safety and quality of care.
• Participate in reviewing/updating medication safety-related policies.
• Review the pharmacy quality indicators and performance indicators.

Number of trained medication safety officers (December,2021)
325

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10 When Should Pharmacists Consider Pill Boxes for Patient Counseling?

A pill box is a container used to organize medication doses for a certain length of time, it is very helpful if there are different medications that need to be arranged to improve medication adherence and safe administration. Although many people repackage their medicines into pill boxes, only few pharmacists highlight the safe use of pillboxes during counseling session.

Why is it a concern?

An elderly female patient is using a pillbox to help her keep track of the huge quantities of medicines that she is taking for her kidney transplant, including Cyclosporin capsules . She arranged all her pills in a pill organizer, after few months she suffered from rejection symptoms which is believed it was related to changing of original packaging of Cyclosporin, which lead of ethanol (a required ingredient for solubility of cyclosporin) to vaporize out of the soft capsule when removed from the foil packaging. Although the leaflet stated " stored in the original package in order to protect from moisture" a pharmacist didn't counseled her to do so.

This case highlights that not all medications can be stored in a pill box. In general, the original container protects some medication from heat, air, light and/or moisture. Exposure to these elements may affect the stability of the formulation and/or the active ingredient, which can alter the effectiveness and safety of the medicine.

When Noticing Polypharmacy, Consider Pillboxes!

If the patient is taking more than 3 medications, it is recommended to include the safe use of pillbox during the counseling session. For example, the patient should be advised to keep Methotrexate in a separate compartment from other pills. Proper counseling on how to arrange the pills, and what instructions need to be taken before filling the box will help increase medications effectiveness, preventing errors and contaminations.

Mark your Calendars

It is an opportunity to step up national and international efforts to raise awareness of the global burden of viral hepatitis and influence fundamental changes in community awareness of vaccines, tests, and treatment.

As healthcare providers, always remember that hepatitis medications have various drug-drug interactions. Always be sure to ask patients about medications they are taking, check their medication history, and select the best modification if needed.

Let's activate "World Hepatitis Awareness Day" on July 28th