JANUARY 2021

Drug Safety Punjab

Monthly Newsletter

26th EDITION

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Provincial Pharmacovigilance Centre (PPC), Provincial Drug Control Unit (PDCU) Punjab,
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DSA-1659 Warfarin and other Anticoagulants: Monitoring of Patients During the COVID-19 Pandemic

Background:

Warfarin, sold under the brand name Coumadin among others, is a medication that is used as an anticoagulant. It is commonly used to treat blood clots such as deep vein thrombosis and pulmonary embolism, and to prevent stroke in people who have atrial fibrillation, valvular heart disease or artificial heart valves.

Problem:

Guidance has been published on monitoring of patients on warfarin and other anticoagulants during the COVID-19 pandemic.

Recommendations:

Healthcare professionals are reminded that:

- Acute illness may exaggerate the effect of warfarin and necessitate a dose reduction; patients on warfarin or other vitamin K antagonists should therefore be asked to tell their GP or healthcare team if they have symptoms of, or confirmed, COVID-19 infection.
- Continued INR (international normalized ratio) monitoring is important in patients taking warfarin or other vitamin K antagonists if they have suspected or confirmed COVID-19 infection, so they can be clinically managed at an early stage to reduce the risk of bleeding.
- Both vitamin K antagonists and direct-acting oral anticoagulants (DOACs) may interact with other medicines and if a patient using these oral anticoagulants is also prescribed antibiotics or antivirals, follow advice in the product information for minimization of risk of potential interactions – this includes INR monitoring in patients taking vitamin K antagonists who have recently started new medicines if patients are switched from warfarin to a DOAC, warfarin treatment should be stopped before the DOACs is started to reduce the risk of over-anticoagulation and bleeding.
- Patients taking vitamin K antagonists should be reminded to carefully follow the instructions for use for anticoagulant medicines (including the patient information leaflet).

Reference:

1. https://www.gov.uk/drug-safety-update/warfarin-and-other-anticoagulants-monitoring-of-patients-during-the-covid-19-pandemic.

A

Advice to Healthcare Professionals

Healthcare Professionals are advised to use Warfarin with caution in patients during the COVID-19 pandemic and any such ADR should be reported to Provincial Pharmacovigilance Centre (PPC), PDCU, Punjab through http://mss.punjab.gov.pk/

DSA-1660 Methotrexate Once Weekly for Autoimmune Diseases: New Measures to Reduce Risk of Fatal Overdose Due to Inadvertent Daily Instead of Weekly Dosing

Background:

Methotrexate is authorized for two different therapeutic areas, each of them with a different administration schedule:

- For the treatment of cancer in which regimens vary and can require daily administration of methotrexate
- For the treatment of autoimmune diseases including rheumatoid arthritis, psoriasis and Crohn's disease, which require once-weekly use

Problem:

In autoimmune conditions and some cancer therapies, methotrexate should be taken once a week; however, MHRA continue to receive reports of inadvertent overdose due to more frequent dosing (including daily administration). New measures have been implemented to prompt healthcare professionals to record the day of the week for intake and to remind patients of the dosing schedule and the risks of overdose.

Recommendations:

Medication errors that lead to taking more than the intended dose (including daily instead of once-weekly dosing) have been identified at all steps in the treatment pathway, including prescribing and dispensing of methotrexate, transfer of care (for example, hospital admission and discharge), and communicating with patients. Healthcare professionals should take into consideration a patient's overall polypharmacy burden when prescribing an oral formulation once-weekly and ensure that the patient is able to comply with once-weekly dosing when prescribing methotrexate.

Reference:

https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency

A

Advice to Healthcare Professionals

- Before prescribing methotrexate, make sure that the patient is able to understand and comply with once-weekly dosing
- Decide with the patient which day of the week they will take their methotrexate and note this day down in full on the prescription
- Inform the patient and their caregivers of the potentially fatal risk of accidental overdose if methotrexate is taken more frequently than once a week; specifically, that it should not be taken daily.

DSA-1661 Nivolumab (Genetical Recombination): Revision of Precautions

Background:

Nivolumab is an antitumor drug and is used for Metastatic Melanoma, Adjuvant Treatment of Melanoma, Metastatic Non-Small Cell Lung Cancer, Advanced Renal Cell Carcinoma, Classical Hodgkin Lymphoma, Squamous Cell Carcinoma of the Head and Neck, Urothelial Carcinoma, Hepatocellular Carcinoma etc.

Recommendations:

Patients should be carefully monitored through periodic liver function tests.

New added adverse reactions

Fulminant hepatitis, hepatic failure, hepatic impairment accompanied by increased levels of AST, ALT, γ-GTP, Al-P as well as bilirubin, etc., hepatitis, and sclerosing cholangitis may occur.

Reference:

https://www.pmda.go.jp/files/000237435.pdf

DSA-1662 Tecentriq (Atezolizumab): A New Identified Risk of Severe Cutaneous Adverse Reactions

Background:

Tecentriq (atezolizumab) is a monoclonal antibody medication designed to bind with a protein called PD-L1 expressed on tumor cells and tumor-infiltrating immune cells, blocking its interactions with both PD-1 and B7.1 receptor. By inhibiting PD-L1, Tecentriq may enable the activation of T cells. It is used to treat urothelial carcinoma, non-small cell lung cancer, triple-negative breast cancer, small cell lung cancer, and hepatocellular carcinoma.

Problem:

Hoffman-La Roche (leading research-focused healthcare company) updated about the new identified risk of severe cutaneous adverse reactions (SCARs) associated with the use of Tecentriq®. SCARs are now considered to be an identified risk for atezolizumab.

Recommendations:

Healthcare professionals are advised to refer suspected cases of SCARs to a dermatologist for further diagnosis and management, to withhold atezolizumab from patients with suspected Stevens Johnson syndrome (SJS) or toxic epidermal necrolysis (TEN) and to permanently withdraw atezolizumab for any grade confirmed SJS or TEN.

Reference:

1. https://www.hsa.gov.sg/
2. https://www.hsa.gov.sg/announcements/dear-healthcare-professional-letter/tecentriq-(atezolizumab)-a-new-identified-risk-of-severe-cutaneous-adverse-reactions

A

Advice to Healthcare Professionals

Healthcare Professionals are advised to use Atezolizumab with caution in patients who have previously experienced a severe or life-threatening skin adverse reaction on prior treatment with other immune-stimulatory anticancer agents and any such ADR should be reported to Provincial Pharmacovigilance Centre (PPC), PDCU, Punjab through http://mss.punjab.gov.pk/

DSA-1663 Montelukast: Increased Risk of Neuropsychiatric Events

Background:

Montelukast belongs to a group of medications called as leukotriene receptor antagonist and is used primarily for asthma, Exercise-Induced Bronchoconstriction (EIB), and Allergic Rhinitis

Problem:

The Health Sciences Agency (HSA) communicates about the neuropsychiatric events caused by Montelukast. The risk benefit assessment of montelukast concluded that the benefits of montelukast for use in allergic rhinitis patients remain favourable if additional precautionary measures are put in place to mitigate the known but rare risk of neuropsychiatric events.

Recommendations:

Healthcare professionals are advised to consider the benefits of treatment and risks of neuropsychiatric effects before prescribing montelukast.

Reference:

1. https://www.hsa.gov.sg/
2. https://www.hsa.gov.sg/announcements/dear-healthcare-professional-letter/advisory-on-restriction-on-the-use-of-montelukast-and-neuropsychiatric-effects

A

Advice to Healthcare Professionals

Healthcare Professionals are advised to restrict the use of Montelukast in the treatment of allergic rhinitis to patients who have inadequate response or are intolerant to alternative and any such ADR should be reported to Provincial Pharmacovigilance Centre (PPC), PDCU, Punjab through http://mss.punjab.gov.pk/

DSA-1664 Systemic and Inhaled Fluoroquinolones: Risk of Heart Valve Regurgitation/Incompetence

Background:

Fluoroquinolones are a class of antibiotics that act by inhibiting 2 enzymes involved in bacterial DNA synthesis, both of which are DNA topoisomerases that human cells lack and that are essential for bacterial DNA replication, thereby enabling these agents to be both specific and bactericidal.

Problem:

European Medicines Agency informs of the risk of heart valve regurgitation/ incompetence associated with fluoroquinolones for systemic and inhalation use. Conditions predisposing to heart valve regurgitation/incompetence include congenital or pre-existing heart valve disease, connective tissue disorders, Turner syndrome, Behçet's disease, hypertension, rheumatoid arthritis, and infective endocarditis.

Recommendations:

Healthcare professionals are advised to use systemic and inhaled fluoroquinolones after careful benefit-risk assessment and after consideration of other therapeutic options in patients at a risk for heart valve regurgitation.

Reference:

1. https://www.ema.europa.eu/en
2. https://www.ema.europa.eu/en/documents/dhpc/systemic-inhaled-fluoroquinolones-risk-heart-valve-regurgitation/incompetence_en.pdf

A

Advice to Healthcare Professionals

Healthcare Professionals are advised to instruct the patients to seek immediate medical attention in case of acute dyspnoea, new onset of heart palpitations, or development of oedema of the abdomen or lower extremities and any such ADR should be reported to Provincial Pharmacovigilance Centre (PPC), PDCU, Punjab through http://mss.punjab.gov.pk/

DSA-1665 Transdermal Fentanyl Patches for Non-cancer Pain: Do Not Use in Opioid-naive Patients

Background:

Fentanyl is an opioid used as a pain medication and together with other medications for anesthesia. Fentanyl is also used as a recreational drug, often mixed with heroin or cocaine. It has a rapid onset and its effects generally last less than two hours. A 12 microgram (µg) per hour fentanyl patch equates to daily doses of oral morphine of up to 45mg a day.

Problem:

The Commission on Human medicines(CHM) did a review that reported serious harm, including fatalities and respiratory depression associated with fentanyl patches in opioid naïve patients.

Recommendations:
Healthcare professionals are advised to use fentanyl patches only in those non cancer patients who have previously tolerated opioids.

Reference:

1. https://www.gov.uk/
2. https://www.gov.uk/drug-safety-update/transdermal-fentanyl-patches-for-non-cancer-pain-do-not-use-in-opioid-naive-patients

A

Advice to Healthcare Professionals

Healthcare Professionals are advised to avoid use of fentanyl patches in opioid-naïve patients (unless other analgesics and opioids are available). Make patients aware of the signs and symptoms and advise them to seek medical attention immediately if overdose is suspected and any related ADR should be reported to Provincial Pharmacovigilance Centre (PPC) PDCU, Punjab through http://mss.punjab.gov.pk/

DSA-1666 Flucytosine: New Contraindication in Patients with DPD Deficiency

Background:
Flucytosine is an antifungal agent. Chemically, it is 5-fluorocytosine, a fluorinated pyrimidine which is a prodrug of 5-flurouracil which is used to treat systemic yeast and fungal infections. It is a white to off-white crystalline powder with a molecular weight of 129.09

Problem:
The Medicine and Healthcare Products Regulatory Agency (MHRA) reported that the use of flucytosine is contraindicated in patients with known complete DPD (dihydropyrimidine dehydrogenase) deficiency due to life threatening toxicity. In patients with partial DPD deficiency, the risk of severe drug toxicity is increased, with the level of toxicity correlating with the extent of DPD deficiency.

Recommendations:
Healthcare professionals are advised to avoid the use of flucytosine in patients with complete or partial DPD deficiency and in case of toxicity, consider stopping treatment with flucytosine.

Reference:

1. https://www.gov.uk/
2. https://www.gov.uk/drug-safety-update/flucytosine-ancotil-new-contraindication-in-patients-with-dpd-deficiency#new-recommendations-following-review

A

Advice to Healthcare Professionals

Healthcare Professionals are advised to avoid use of flucytosine in patients with complete or partial DPD deficiency and any related ADR should be reported to Provincial Pharmacovigilance Centre (PPC) PDCU, Punjab through http://mss.punjab.gov.pk/

SECTION B: TGRP HIGHLIGHTS

DSA-1667 Injection Heparin Related Gastric Bleeding

Background:

Heparin is an anticoagulant (blood thinner) that prevents the formation of blood clots. Heparin is used to treat and prevent blood clots caused by certain medical conditions or medical procedures. It is also used before surgery to reduce the risk of blood clots.

Problem:

Provincial Pharmacovigilance Centre Punjab PDCU has received a TGRP-732 report of a 55-year-old female, she presented in hospital with medical history of left ventricular failure, Hepatitis C and Diabetes Mellitus and diagnosed with Non ST elevation Myocardial Infarction. She was prescribed with Tab. Aspirin 150 mg O. D, Tab. Clopidogrel 75mg 1 x O.D, Tab. Atorvastatin 20 mg H.S, Tab. Glyceryl Trinitrate 2.6 mg 1 x B.D. Cap. Cefixime 400mg 1 x O.D, Tab. Moxifloxacin 400 mg 1 x O.D, Inj. Furosemide 40 mg IV x B.D, Tab. Pantoprazole 40 mg x O.D, Inj. Humulin 70/30 According to sliding Scale, Tab. Captopril 25 mg Sublingual B.D. She was administered Inj. Heparin 2.5 ml in 100 ml Normal Saline B.D, on 4th Day of administration she developed bleeding.

However, patient recovered. According to FDA approved drug literature of drug, suspected drug is known to cause bleeding. VigiAccess has the database of Haemorrhage (2470). PPC has categorized this case under POSSIBLE category of WHO-UMC Criteria.

A

Advice to Healthcare Professionals

Healthcare Professionals are advised to monitor patients prescribed with Injection Heparin. Any related ADR should be reported to Provincial Pharmacovigilance Centre (PPC) PDCU, Punjab through http://mss.punjab.gov.pk/

SECTION C: QUALITY ASSOCIATED SAFETY ISSUES (QASI)

DSA-1668 Recall of Parapals Infusion 100ml

Background:

DRAP has initiated a recall of PARAPALS INFUSION 100ML manufactured by M/S Inventor Pharma, Karachi, Vide Letter No. F.No.13-48/2020-QC, Dated: 27th October, 2020. Details of the Medical Product Alert are given below:

Product Name	Generic	Stated Manufacturer	Reg. number	Batch No.
Parapals infusion 100 ml	Paracetamol	M/s Inventor Pharma, Karachi	088360	LI-237

Advice:

- All retailors (Pharmacies, Medical Stores), Whole sellers, Distributors, Health Facilities are directed immediately to stop the dispensation of the products and update to respective area drug inspector regarding their current inventory and consumption record.
- All consumers (Patients, Healthcare Professionals) are directed to stop usage of above mentioned product immediately as it may prone risk to health.

Reference:

- Medical Product Alert, DRAP, Vide Letter No. F.No.13-48/2020-QC

DSA-1669 Drug Recall of Oxiphin 1g Injection

Background:

DRAP has initiated a recall of OXIPHIN 1g Injection manufactured by M/S Kanel Pharmaceuticals, Vide Letter No. F.No.03-48/2020-QC, Dated: 27th October, 2020. It is declared that Aqua-Nov Injection manufactured by M/s Novartana Pharmaceuticals (Pvt.) Ltd., Lahore is present in the combo pack of Oxiphin 1g Injection and the product is declared as "Adulterated and Sub-standard". Details of the Medical Product Alert are given below:

Product Name	Stated Manufacturer	Batch Number
Oxiphin 1g Injection	M/s Kanel Pharmaceuticals, Islamabad.	KG20033
Aqua-Nov Injection	M/s Novartana Pharmaceuticals (Pvt.) Ltd., Lahore.	W-214

Advice:

- All retailors (Pharmacies, Medical Stores), Whole sellers, Distributors, Health Facilities are directed immediately to stop the dispensation of the products and update to respective area drug inspector regarding their current inventory and consumption record.
- All consumers (Patients, Healthcare Professionals) are directed to stop usage of above mentioned product immediately as it may prone risk to health.

Reference:

- Medical Product Alert, DRAP, Vide Letter No. F.No.03-48/2020-QC

DSA-1670 Drug Recall of Aqua-Nov Injection

Background:

DRAP has initiated a drug recall of AQUA-NOV INJECTION manufactured by M/s Novartana Pharmaceuticals (Pvt.) Ltd., Vide Letter No. F.No.03-48/2020-QC, Dated: 27th October, 2020. The product is present in combo pack of product 'Oxiphin 1g injection' (Mfg. by M/s Kannel Pharmaceuticals, Islamabad). Details of the Medical Product Alert are given below:

Product Name	Stated Manufacturer	Batch Number
Aqua-Nov Injection	M/s Novartana Pharmaceuticals (Pvt.) Ltd., Lahore.	W-214

Advice:

- All retailors (Pharmacies, Medical Stores), Whole sellers, Distributors, Health Facilities are directed immediately to stop the dispensation of the products and update to respective area drug inspector regarding their current inventory and consumption record.
- All consumers (Patients, Healthcare Professionals) are directed to stop usage of above mentioned product immediately as it may prone risk to health.

Reference:

- Medical Product Alert, DRAP, Vide Letter No. F.No.03-48/2020-QC

DSA-1671 Drug Recall of Substandard MB-Chlor Eye Drops

Background:

DRAP has initiated a drug recall of substandard MB-Chlor Eye Drops manufactured by M/S MBL Pharma, Lasbela, Vide Letter No. F.No.03-49/2020-QC, Dated: 26th October, 2020. Details of the Medical Product Alert are given below:

Product Name	Stated Manufacturer	Reg. #	Batch Number
MB-Chlor Eye Drops	M/S MBL Pharma, Lasbela, Baluchistan	024555	177

Advice:

- All retailors (Pharmacies, Medical Stores), Whole sellers, Distributors, Health Facilities are directed immediately to stop the dispensation of the products and update to respective area drug inspector regarding their current inventory and consumption record.
- All consumers (Patients, Healthcare Professionals) are directed to stop usage of above mentioned product immediately as it may prone risk to health.

Reference:

- Medical Product Alert, DRAP, Vide Letter No. F.No.03-49/2020-QC

DSA-1672 Drug Recall of Oxiphin 1g Injection

Background:

DRAP has initiated a recall of OXIPHIN 1g INJECTION manufactured by M/S Kanel Pharmaceuticals, Vide Letter No. F.No.03-47/2020-QC, Dated: 22th October, 2020. It is declared that Water for Injection manufactured by M/S Ammer and Adnan Pharmaceuticals, Lahore is present in the combo pack of Oxiphin 1g Injection and the product is declared as "Adulterated and Sub-standard". Details of the Medical Product Alert are given below:

Product Name	Stated Manufacturer	Batch Number
Oxiphin 1g Injection	M/s Kanel Pharmaceuticals, Islamabad.	KH20002, KH20003, KH20007, KH20011
Water for injection	M/S Ameer and Adnan Pharmaceuticals, Lahore.	WFI-237

Advice:

- All retailors (Pharmacies, Medical Stores), Whole sellers, Distributors, Health Facilities are directed immediately to stop the dispensation of the products and update to respective area drug inspector regarding their current inventory and consumption record.
- All consumers (Patients, Healthcare Professionals) are directed to stop usage of above mentioned product immediately as it may prone risk to health.

Reference:

- Medical Product Alert, DRAP, Vide Letter No. F.No.03-47/2020-QC

DSA-1673 Drug Recall of Water for Injection

Background:

DRAP has initiated a recall of WATER FOR INJECTION manufactured by M/S Ammer and Adnan Pharmaceuticals, Lahore, Vide Letter No. F.No.03-47/2020-QC, Dated: 22th October, 2020. It is declared that Water for Injection is present in the combo pack of Oxiphin 1g Injection and the product is declared as "Adulterated and Sub-standard". Details of the Medical Product Alert are given below:

Product Name	Stated Manufacturer	Batch Number
Water for Injection	M/S Ameer and Adnan Pharmaceuticals, Lahore.	WFI-237

Advice:

- All retailors (Pharmacies, Medical Stores), Whole sellers, Distributors, Health Facilities are directed immediately to stop the dispensation of the products and update to respective area drug inspector regarding their current inventory and consumption record.
- All consumers (Patients, Healthcare Professionals) are directed to stop usage of above mentioned product immediately as it may prone risk to health.

Reference:

- Medical Product Alert, DRAP, Vide Letter No. F.No.03-47/2020-QC

DSA-1674 Recall of Zental Suspension

Background:

DRAP has initiated a recall of ZENTAL Suspension manufactured by M/S GSK Pakistan Limited, Karachi, Vide Letter No. F.No.13-45/2020-QC, Dated: 15th October, 2020. The product is mislabelled as "USP Specifications" instead of "GSK's Specifications". Details of the Medical Product Alert are given below:

Product Name	Stated Manufacturer	Reg. #	Batch Number
Zental Suspension	M/S GSK Pakistan Limited, Karachi.	006730	VH8Y, 2B6X, 3A2F, 3A2L, 4A7N, 4C2T, 576M, 5K2B, CM4R, DJ4U, G39M, HG5R, HZDBQ, K38N, MN3J, NL8H, P33E, RG8G, T58R, TJ4K, UE5J, UE5K, UX4D, UX4E, VP8A, W33U, WR7L, X47X, Y38V, 5D4E, 4L2R, IZDBS, L26AHG5R

Advice:

- All retailors (Pharmacies, Medical Stores), Whole sellers, Distributors, Health Facilities are directed immediately to stop the dispensation of the products and update to respective area drug inspector regarding their current inventory and consumption record.
- All consumers (Patients, Healthcare Professionals) are directed to stop usage of above mentioned product immediately as it may prone risk to health.

Reference:

- Medical Product Alert, DRAP, Vide Letter No. F.No.13-45/2020-QC

DSA-1675 Drug Recall of Torfen (Ibuprofen 200mg/5ml) Suspension

Background:

DRAP has initiated a drug recall of substandard TORFEN SUSPENSION manufactured by M/S Kaizen Pharmaceuticals, (Pvt.) Ltd., Karachi, Vide Letter No. F.No.03-51/2020-QC, Dated: 10th November, 2020. Details of the Medical Product Alert are given below:

Product name	Stated Manufacturer	Reg. #	Batch number
Torfen Suspension (Ibuprofen 200mg/5ml)	M/S Kaizen Pharmaceuticals, (Pvt.) Ltd., Karachi.	073895	035

Advice:

- All retailors (Pharmacies, Medical Stores), Whole sellers, Distributors, Health Facilities are directed immediately to stop the dispensation of the products and update to respective area drug inspector regarding their current inventory and consumption record.
- All consumers (Patients, Healthcare Professionals) are directed to stop usage of above mentioned product immediately as it may prone risk to health.

Reference:

- Medical Product Alert, DRAP, Vide Letter No. F.No.03-51/2020-QC

DSA-1676 Drug Recall for Kanbact Injection 500mg

Background:

DRAP has initiated a recall of Kanbact Injection 500 MG Manufactured by M/S Kanel Pharmaceuticals, Rawat Islamabad and Xylop 1 % Injection Manufactured by M/S Palpex Pharmaceuticals (PVT.) LTD. Karachi Vide No. F.No.03-42/2020-QC. It is declared that Kanbact 500 mg Injection is present in combo pack of Xylop 1 % Injection and the product is considered Substandard and Adulterated. Details of the medical product are given below:

PRODUCT NAME	STATED MANUFACTURER	BATCH NUMBER
Kanbact Injection	M/S Kanel Pharmaceuticals, Rawat, Islamabad	KH20017
Xylop 1% Injection	M/S Palpex Pharmaceuticals Pvt.Ltd Karachi	BBH06

Advice:

- All retailors (Pharmacies, Medical Stores), Whole sellers, Distributors, Health Facilities are directed immediately to stop the dispensation of the products and update to respective area drug inspector regarding their current inventory and consumption record.
- All consumers (Patients, Healthcare Professionals) are directed to stop usage of above mentioned product immediately as it may prone risk to health.

Reference:

- Medical Product Alert, DRAP, Vide Letter No. F.No.03-42/2020-QC

DSA-1677 Drug Recall for Xylop 1% Injection

Background:

DRAP has initiated a Recall of Xylop 1% Injection Manufactured by M/S. Palpex Pharmaceuticals (PVT.) LTD., Karachi. It is declared that Xylop 1% Injection is present in combo pack of Kanbact 500 mg Injection (Manufactured by M/S Kanel Pharmaceuticals, Islamabad) and the product is considered Substandard and Adulterated. Details of the medical product are given below:

PRODCUT NAME	MANUFACTURER	BATCH NUMBER
Xylop 1% Injection	M/S Palpex Pharmaceuticals (Pvt.)Ltd., Karachi	BBH06

Advice:

- All retailors (Pharmacies, Medical Stores), Whole sellers, Distributors, Health Facilities are directed immediately to stop the dispensation of the products and update to respective area drug inspector regarding their current inventory and consumption record.
- All consumers (Patients, Healthcare Professionals) are directed to stop usage of above mentioned product immediately as it may prone risk to health.

Reference:

- Medical Product Alert, DRAP, Vide Letter No. F.No.03-42/2020-QC

DSA-1678 Medical Product Recall of Azomax 500mg FCT

Background:

DRAP has initiated a voluntary recall of Azomax 500 MG FCT Manufactured by M/S GSK Consumer Healthcare Pakistan Limited, Jamshoro for M/S Novartis Pharma Pakistan Limited, Karachi due to potential mix up that can pose potential safety risk to the patient. Details of the medical product are given below:

PRODUCT NAME	MANUFACTURER	BATCH NUMBER
Azomax 500 mg FCT	M/S GSK Consumer Healthcare Pakistan Limited, Jamshoro	LJ2L

Advice:

- All retailors (Pharmacies, Medical Stores), Whole sellers, Distributors, Health Facilities are directed immediately to stop the dispensation of the products and update to respective area drug inspector regarding their current inventory and consumption record.
- All consumers (Patients, Healthcare Professionals) are directed to stop usage of above mentioned product immediately as it may prone risk to health.

Reference:

- Medical Product Alert, DRAP, Vide Letter No. F.No.13-57/2020-QC

DSA-1679 Medical Product Recall of Caflam 50mg SCT

Background:

DRAP has initiated a Voluntary Precautionary Recall of Caflam 50 mg SCT Manufactured by M/S GSK Consumer Healthcare Pakistan Limited, Jamshoro for M/S Novartis Pharma (Pakistan) Limited, Karachi due to potentially compromised product quality. Details of the medical product are given below:

PRODUCT NAME	MANUFACTURER	BATCH NUMBER
Caflam 50 mg SCT	M/S GSK Consumer Healthcare Pakistan Limited, Jamshoro	W72G

Advice:
All retailors (Pharmacies, Medical Stores), Whole sellers, Distributors, Health Facilities are directed immediately to stop the dispensation of the products and update to respective area drug inspector regarding their current inventory and consumption record. All consumers (Patients, Healthcare Professionals) are directed to stop usage of above mentioned product immediately as it may prone risk to health.

Reference:
- Medical Product Alert, DRAP, Vide Letter No. F.No.13-58/2020-QC

DSA-1680 Medical Product Recall of Fenaclod Injection

Background:
DRAP has initiated a Drug Recall of Adulterated and Substandard Fenaclod Injection REG. NO.050475 Manufactured by M/S Epoch Pharmaceuticals Karachi. Details of the medical product are given below:

Product Name	REG. NO	BATCH NO	MFG DATE	EXP.DATE	MANUFACTURER
Fenaclod Injection	050475	039	10-2019	10-2021	M/S Epoch Pharmaceuticals Karachi

Advice:
- All retailors (Pharmacies, Medical Stores), Whole sellers, Distributors, Health Facilities are directed immediately to stop the dispensation of the products and update to respective area drug inspector regarding their current inventory and consumption record.
- All consumers (Patients, Healthcare Professionals) are directed to stop usage of above mentioned product immediately as it may prone risk to health.

Reference:
- Medical Product Alert, DRAP, Vide Letter No. F.No.03-44/2020-QC

DSA-1681 WHO Medical Product Alert N°6/2020-Falsified Fluzone Quadrivalent Influenza Vaccine

Background:
WHO Medical Product Alert N°6/2020 relates to three different batches of confirmed Falsified Fluzone Quadrivalent Influenza Vaccine Identified in Mexico and reported to WHO on 16 October,2020. Details of the medical product are given below:

Product Name	Fluzone Quadrivalent Influenza Virus Vaccine		
Stated Manufacturer	Sanofi Pasteur		
Expiry Date	ENE 22	ENE 22	ENE 22
Batch Number	EUH2174AC	EUH071AB	E0H071AB

Advice:
- All retailors (Pharmacies, Medical Stores), Whole sellers, Distributors, Health Facilities are directed immediately to stop the dispensation of the products and update to respective area drug inspector regarding their current inventory and consumption record.

- All consumers (Patients, Healthcare Professionals) are directed to stop usage of above mentioned product immediately as it may prone risk to health.

Reference:

- Medical Product Alert, DRAP, Vide Letter No. F.No.13-56/2020-QC

DSA-1682 Drug Recall of Penro Injection 1000mg

Background:

DRAP has initiated a DRUG RECALL of Penro Injection 1000mg claimed to be manufactured by M/S Bosch Pharmaceuticals (PVT.) LTD, Karachi. It has been declared **SPURIOUS**. Details of the medical product is given below:

Product Name	Penro Injection 1000 mg
Registration Number	042107
Batch Number	PO200678
Manufactured By	M/S Bosch Pharmaceuticals (PVT.) LTD, Karachi

Advice

- All retailer (Pharmacies, Medical Store), Whole sellers, Distributors, Health Facilities are directed immediately to stop the dispensation of the products and update to respective area drug inspector regarding their current inventory and consumption record.
- All consumers (Patients, Healthcare Professionals) are directed to stop usage of above mentioned product immediately as it may prone to risk health

Reference

- DRAP Letter No: F.No.13-62/2020-QC

DSA-1683 Drug Recall of Various Products Declared Substandard by Drug Testing Laboratories in Month of October

Background:

DRAP has initiated RECALL of various products. These products have been declared SUBSTANDARD. Details of the medical product is given at Page No. 15.

Advice

- All retailer (Pharmacies, Medical Store), Whole sellers, Distributors, Health Facilities are directed immediately to stop the dispensation of the products and update to respective area drug inspector regarding their current inventory and consumption record.
- All consumers (Patients, Healthcare Professionals) are directed to stop usage of above mentioned product immediately as it may prone to risk health.

Reference

- DRAP Letter No: F.No.03-60/2020-QC

Sr. No.	Product Name	Batch No.	Mfg. by
1.	Bronil Syrup	HF.307	M.s Star Laboratories (Pvt) Ltd.
2.	-do-	HF.306	-do-
3.	-do-	HF.260	-do-
4.	-do-	HF.232	-do-
5.	-do-	HF.231	-do-
6.	Liskodyl 120 Syrup	484-20	M/s Lisko Pakistan (Pvt.) Ltd.
7.	Amcoride 120ml Syrup	483-20	-do-
8.	Liskodryllin Syrup	279-20	-do-
9.	Large Volume Solutions Renacarb Solution for Bicarbonate hemodialysis concentrate	110757	M/S. Synchro Pharmaceuticals
10.	-do-	110802	-do-
11.	-do-	110796	-do-
12.	Syrup Maltida-D	L20G065	M/s. Synchro Pharmaceuticals
13.	Baxfen 120 ml Suspension	BXN.026	M/S. Baxter Pharmaceuticals
14.	-do-	BXN.025	-do-
15.	Zee-met Infusion	2068765	M/s. Shahzeb Pharmaceuticals
16.	-do-	205887	-do-
17.	Syncon Capsule	C-285	M/s. Synchro Pharmaceuticals
18.	Cyzit Suspension (Dry powder for suspension)	20E023	M.s Searle IV Solutions (Pvt.) Ltd
19.	Surgical Bandages	63B20	M/s. Cotton Craft Pvt. Ltd.
20.	Zentel Suspension 10 ml	LV9U	M/s GlaxosmithKline Pakistan Limited
21.	-do-	LV9U	-do-
22.	Opth-Carb	148	M/s. Opth –Pharma (Pvt) Ltd
23.	Askprol 120ml	20AS009	M/s. Citi Pharma (Pvt.) Ltd
24.	-do-	20AS010	-do-
25.	-do-	20AS008	-do-
26.	Bendazole	Y-778	M/s.Stanely Pharma
27.	Zamclo Tablet	ZC-0007	M/s. Zamko Pharmaceuticals (Pvt.) Ltd
28.	Zentel Suspension	F43C	M/s GlaxosmithKline Pakistan Limited
29.	-do-	FX9X	-do-
30.	-do-	VS7F	-do-
31.	Requin Tablet	RQ078	M/s. Qintar Pharmaceuticals
32.	Paranol Suspension 100ml	PS 012	M/s. Perfect Pharma (Pvt.) Ltd
33.	Surgical Cotton Bandage 6.5cm×4m	0488	M/s. Paktex Industries, Kamoke
34.	Crepe Bandage	392	-do-
35.	Weldof Tablet 50mg	503	M/s. Welmed Pharma Industries
36.	Xepra Tablet	XP 010	M/s. Qintar Pharmaceuticals
37.	Esoser Tablet 40mg	059	M/s. Panacea Pharmaceuticals
38.	Titan Injection 1000mg	9054	M/s. Macter International
39.	Sytx Suspension 250mg/5ml	685	M/s. Saaf Pharma Industries
40.	B-Panta Tablets	T 0174	M/s. Well borne Pharmachem and Biological Industries