

Safety Signals Identified by the SFDA

July – September 2025



Signal Detection Section
National Pharmacovigilance Center



“A signal is defined by the SFDA as reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information. A signal is a hypothesis together with data and arguments and it is important to note that a signal is not only uncertain but also preliminary in nature”

Introduction

This periodic report contains the detected potential signals by Saudi Food and Drug Authority National Pharmacovigilance Center. The objective of sharing this information is to increase the transparency and effective communication between SFDA and its stakeholders. This list intended to support Marketing Authorization Holders, healthcare professionals, and researchers in identifying and addressing newly detected potential signals, thereby contributing to improved public health and patient safety.

Table 1. List of Quarterly Detected Signals

Active Ingredient	Adverse Event	Status	Outcome
VANCOMYCIN	Redness - Swelling NOS - Swelling face	Pending	SFDA is validating this potential risk
GENTAMICIN	Maculopapular rash	Pending	SFDA is validating this potential risk
PARACETAMOL	Tinnitus	Pending	SFDA is validating this potential risk
PARACETAMOL	Vomiting	Pending	SFDA is validating this potential risk
PARACETAMOL	Itching all over - Rash all over - Redness of eyes - Oxygen saturation decreased	Pending	SFDA is validating this potential risk
ONDANSETRON	Cough	Pending	SFDA is validating this potential risk
Onasemnogene abeparvovec	Hepatic cytolysis	Pending	SFDA is validating this potential risk
Onasemnogene	Pneumonia	Pending	SFDA is validating this potential risk
AXICABTAGENE CILOLEUCEL	Serum ferritin increased	Pending	SFDA is validating this potential risk
etranacogene	Arthralgia	Pending	SFDA is validating this potential risk
TISAGENLECLEUCEL-T	Pneumonia	Pending	SFDA is validating this potential risk
VITAMINS, OTHER COMBINATIONS	Intestinal infection due to other organism, not elsewhere classified - Fever - Fatigue - Stomach ache - Cyst	Pending	SFDA is validating this potential risk
DIPHTHERIA TOXOID, TETANUS TOXOID, BORDETELLA PERTUSSIS ANTIGENS, FILAMENTOUS HAEMAGGLUTININ, POLIO VIRUS INACTIVATE TYPE 1 MAHONEY 40 DAGU, POLIO VIRUS INACTIVATE TYPE 2 MEF-1 8 DAGU, POLIO VIRUS INACTIVATE TYPE3 SAUKETT 32 DAGU, HEPATITIS B SURFACE ANT	Abscess	Pending	SFDA is validating this potential risk
NUSINERSEN SODIUM	Diabetes mellitus	Pending	SFDA is validating this potential risk
GLYCERYL TRINITRATE	Irradiation cystitis	Pending	SFDA is validating this potential risk
IMMUNOGLOBULIN, NORMAL HUMAN	Dry mouth - Feeding disorder - Weight decreased - Abdominal pain - Dehydration	Pending	SFDA is validating this potential risk
LEVETIRACETAM	Shock	Pending	SFDA is validating this potential risk
LABETALOL	Ischaemia intestinal	Pending	SFDA is validating this potential risk

TROPICAMIDE	Bradycardia	Pending	SFDA is validating this potential risk
TROPICAMIDE	Cyanosis - Oxygen saturation decreased	Pending	SFDA is validating this potential risk
PARACETAMOL	Hypokalaemia -Shortness of breath - Dyspnea - Hypokalemia	Pending	SFDA is validating this potential risk
PERINDOPRIL	Anxiety - Panic attacks - Dizziness	Pending	SFDA is validating this potential risk
METFORMIN	Gastro-intestinal Behcet disease	Pending	SFDA is validating this potential risk
LABETALOL	Ischemic colitis	Pending	SFDA is validating this potential risk
ONDANSETRON	Pruritus - Respiratory distress - Vomiting - Dizziness - Anaphylaxis - Itching - Respiratory distress - Vomiting	Pending	SFDA is validating this potential risk
DARBEPOETIN ALFA	Bone marrow disorder	Pending	SFDA is validating this potential risk
CILTACABTAGENE AUTOLEUCCEL	Progressive multifocal leukoencephalopathy	Pending	SFDA is validating this potential risk
SULFASALAZINE	Idiopathic intracranial hypertension	Pending	SFDA is validating this potential risk
DATOPOTAMAB DERUXTECAN	Anaphylactic reaction	Pending	SFDA is validating this potential risk
BOSUTINIB	Cutaneous vasculitis	Pending	SFDA is validating this potential risk
EXENATIDE	Hepatocellular carcinoma	Pending	SFDA is validating this potential risk
LIRAGLUTIDE	Hepatocellular carcinoma	Pending	SFDA is validating this potential risk
SOMATROPIN	Dizziness - Hospitalisation	Pending	SFDA is validating this potential risk
LUSPATERCEPT	Cauda equina syndrome - Extramedullary haemopoiesis	Pending	SFDA is validating this potential risk
MEPOLIZUMAB	Stroke volume - Retinal detachment - Fall - Loss of consciousness - Pain	Pending	SFDA is validating this potential risk
CEFAZOLIN	Jaw swelling	Pending	SFDA is validating this potential risk
OCTREOTIDE	Hyperkalaemia	Pending	SFDA is validating this potential risk
IBRUTINIB	Hyperpigmentation skin	Pending	SFDA is validating this potential risk
EPTINEZUMAB JJMR	Cardiac failure - Abortion	Pending	SFDA is validating this potential risk
PREGABALIN	Gastric ulcer	Pending	SFDA is validating this potential risk
CISPLATIN	Dysuria	Pending	SFDA is validating this potential risk
Shingrix Vaccine	Pancreatic abscess - Liver abscess - Muscle abscess	Pending	SFDA is validating this potential risk

Table 2. List of Quarterly Validated Signals

Active Ingredient	Adverse Event	Status	Outcome
Onasemnogene abeparvovec	Hypercalcaemia	Closed	Valid
Onasemnogene abeparvovec	Hyperglycaemia	Closed	Refuted
ESCITALOPRAM	Hypocalcaemia	Closed	Refuted
LIXISENATIDE	Hepatocellular carcinoma	Closed	Refuted
DULAGLUTIDE	Hepatocellular carcinoma	Closed	Refuted
TIRZEPATIDE	Hepatocellular carcinoma	Closed	Refuted
SEMAGLUTIDE	Hepatocellular carcinoma	Closed	Refuted
DESOGESTREL	Meningioma	Closed	Valid
ADALIMUMAB	Osteonecrosis	Closed	Valid
DUPILUMAB	Pemphigoid	Closed	Refuted
BENRALIZUMAB	Optic neuritis - Arthralgia	Closed	Refuted
BARICITINIB	Fracture	Closed	Valid
UPADACITINIB	Fracture	Closed	Valid
TISAGENLECLEUCEL-T	Pneumonia	Closed	Valid



Thank 
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