

Safety Signals Identified by the SFDA

July – September 2026



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
Nintedanib	Oxygen Saturation Decreased - Chest Pain	Pending	SFDA is validating this potential risk
Colecalciferol	Drowsiness	Pending	SFDA is validating this potential risk
Omeprazole	Menstrual Cycle Abnormal	Pending	SFDA is validating this potential risk
Tirzepatide	Thigh Abscess	Pending	SFDA is validating this potential risk
Alfuzosin Hydrochloride	Polyuria	Pending	SFDA is validating this potential risk
Mitomycin	Hepatic Insufficiency	Pending	SFDA is validating this potential risk
Semaglutide	Anorexia Nervosa	Pending	SFDA is validating this potential risk
Dulaglutide	Anorexia Nervosa	Pending	SFDA is validating this potential risk
Liraglutide	Anorexia Nervosa	Pending	SFDA is validating this potential risk
Orforglipron	Anorexia Nervosa	Pending	SFDA is validating this potential risk
Orforglipron	Parosmia	Pending	SFDA is validating this potential risk
Dulaglutide	Parosmia	Pending	SFDA is validating this potential risk
Liraglutide	Parosmia	Pending	SFDA is validating this potential risk
Semaglutide	Parosmia	Pending	SFDA is validating this potential risk
Dexamethasone Sodium Phosphate	Nasopharyngitis	Pending	SFDA is validating this potential risk
Dexamethasone Sodium Phosphate	Pruritus	Pending	SFDA is validating this potential risk
Dexamethasone Sodium Phosphate	Vomiting	Pending	SFDA is validating this potential risk
Orforglipron	Taste Disorder	Pending	SFDA is validating this potential risk
Dulaglutide	Taste Disorder	Pending	SFDA is validating this potential risk
Liraglutide	Taste Disorder	Pending	SFDA is validating this potential risk
Dolutegravir	Loss Of Libido	Pending	SFDA is validating this potential risk
Acetylsalicylic Acid	Hypotension	Pending	SFDA is validating this potential risk
Acetylsalicylic Acid	Bradycardia	Pending	SFDA is validating this potential risk
Dabrafenib	Cerebrovascular Accident	Pending	SFDA is validating this potential risk
Glimepiride	Hyperglycaemic Crisis	Pending	SFDA is validating this potential risk
Apremilast	Hepatitis C Antibody Positive	Pending	SFDA is validating this potential risk
Sitagliptin Hydrochloride Hydrate	Nephrolithiasis	Pending	SFDA is validating this potential risk
Varicella Zoster Vaccine	Cellulitis	Pending	SFDA is validating this potential risk
Metformin Hydrochloride	Gastrooesophageal Reflux Disease	Pending	SFDA is validating this potential risk
Sofosbuvir	Pain in Jaw	Pending	SFDA is validating this potential risk
Levetiracetam	Pain in Jaw	Pending	SFDA is validating this potential risk
Mycophenolate Mofetil	Ureteritis	Pending	SFDA is validating this potential risk
Mycophenolate Mofetil	Adenovirus Infection	Pending	SFDA is validating this potential risk
Mycophenolate Mofetil	Viruria	Pending	SFDA is validating this potential risk
Influenza Vaccine	Parotitis	Pending	SFDA is validating this potential risk
Influenza Vaccine	Thyroiditis	Pending	SFDA is validating this potential risk
Varicella Zoster Vaccine	Parotitis	Pending	SFDA is validating this potential risk

Varicella Zoster Vaccine	Thyroiditis	Pending	SFDA is validating this potential risk
Varicella Zoster Vaccine	Tongue Ulceration	Pending	SFDA is validating this potential risk
Varicella Zoster Vaccine	Bone Pain	Pending	SFDA is validating this potential risk
Varicella Zoster Vaccine	Thyroiditis	Pending	SFDA is validating this potential risk
Varicella Zoster Vaccine	Gastritis	Pending	SFDA is validating this potential risk
Varicella Zoster Vaccine	Paralysis	Pending	SFDA is validating this potential risk
Varicella Zoster Vaccine	Cerebrovascular Accident	Pending	SFDA is validating this potential risk
Varicella Zoster Vaccine	Convulsions Local	Pending	SFDA is validating this potential risk
Tropicamide	Cyanosis - Oxygen Saturation Decreased	Pending	SFDA is validating this potential risk
Sitagliptin Hydrochloride Hydrate	Colon Injury	Pending	SFDA is validating this potential risk
Lornoxicam	Abdominal Pain	Pending	SFDA is validating this potential risk
Sofosbuvir	Speech Disorder	Pending	SFDA is validating this potential risk
Sofosbuvir	Back Pain	Pending	SFDA is validating this potential risk
Sofosbuvir	Myalgia	Pending	SFDA is validating this potential risk
Levetiracetam	Speech Disorder	Pending	SFDA is validating this potential risk
Levetiracetam	Back Pain	Pending	SFDA is validating this potential risk
Atogepant	Disturbance in Attention	Pending	SFDA is validating this potential risk
Atogepant	Nasopharyngitis	Pending	SFDA is validating this potential risk
Atogepant	Paraesthesia	Pending	SFDA is validating this potential risk
Letrozole	Ileus	Pending	SFDA is validating this potential risk
Trametinib	Cerebrovascular Accident	Pending	SFDA is validating this potential risk
Sevoflurane	Acute Encephalopathy in patients carrying the mitochondrial DNA variant m.11232T>C	Pending	SFDA is validating this potential risk
Selpercatinib	Lymphangiectasia Intestinal	Pending	SFDA is validating this potential risk
Atogepant	Insomnia	Pending	SFDA is validating this potential risk
Glimepiride	Gastroenteritis	Pending	SFDA is validating this potential risk
Tacrolimus	Ureteritis	Pending	SFDA is validating this potential risk
Tacrolimus	Viruria	Pending	SFDA is validating this potential risk
Prednisone	Ureteritis	Pending	SFDA is validating this potential risk
Prednisone	Adenovirus Infection	Pending	SFDA is validating this potential risk
Prednisone	Viruria	Pending	SFDA is validating this potential risk
Prednisone	Polyomavirus-Associated Nephropathy	Pending	SFDA is validating this potential risk
Hydroxychloroquine Sulfate	Myositis	Pending	SFDA is validating this potential risk
Hydroxychloroquine Sulfate	Immune Reconstitution Inflammatory Syndrome	Pending	SFDA is validating this potential risk
Leflunomide	Myositis	Pending	SFDA is validating this potential risk
Leflunomide	Immune Reconstitution Inflammatory Syndrome	Pending	SFDA is validating this potential risk
Tofacitinib Citrate	Myositis	Pending	SFDA is validating this potential risk
Tofacitinib Citrate	Immune Reconstitution Inflammatory Syndrome	Pending	SFDA is validating this potential risk
Methotrexate Sodium	Myositis	Pending	SFDA is validating this potential risk
Methotrexate Sodium	Immune Reconstitution Inflammatory Syndrome	Pending	SFDA is validating this potential risk

Etanercept	Immune Reconstitution Inflammatory Syndrome	Pending	SFDA is validating this potential risk
Prednisone Acetate	Myositis	Pending	SFDA is validating this potential risk
Prednisone Acetate	Immune Reconstitution Inflammatory Syndrome	Pending	SFDA is validating this potential risk
Prednisone	Adenovirus Infection	Pending	SFDA is validating this potential risk
Prednisone	Thrombocytopenia	Pending	SFDA is validating this potential risk
Prednisone	Nephritis	Pending	SFDA is validating this potential risk
Prednisone	Ureteritis	Pending	SFDA is validating this potential risk
Tacrolimus	Adenovirus Infection	Pending	SFDA is validating this potential risk
Tacrolimus	Nephritis	Pending	SFDA is validating this potential risk
Warfarin	Adenovirus Infection	Pending	SFDA is validating this potential risk
Warfarin	Thrombocytopenia	Pending	SFDA is validating this potential risk
Warfarin	Nephritis	Pending	SFDA is validating this potential risk
Warfarin	Ureteritis	Pending	SFDA is validating this potential risk
Labetalol Hydrochloride	Premature Delivery - Maternal Exposure During Pregnancy	Pending	SFDA is validating this potential risk
Magnesium Sulfate	Premature Delivery - Maternal Exposure During Pregnancy	Pending	SFDA is validating this potential risk
Abemaciclib	Oestradiol Increased	Pending	SFDA is validating this potential risk
Letrozole	Oestradiol Increased	Pending	SFDA is validating this potential risk
Letrozole	Neutropenia	Pending	SFDA is validating this potential risk
Goserelin	Oestradiol Increased	Pending	SFDA is validating this potential risk
Goserelin	Neutropenia	Pending	SFDA is validating this potential risk
Metformin Hydrochloride; Vildagliptin	Palpitations	Pending	SFDA is validating this potential risk
Brexpiprazole	Chest Discomfort - Dyspnoea	Pending	SFDA is validating this potential risk
Brexpiprazole	Seizure	Pending	SFDA is validating this potential risk
Brexpiprazole	Swelling Face	Pending	SFDA is validating this potential risk
Brexpiprazole	Dizziness	Pending	SFDA is validating this potential risk
Brexpiprazole	Social Avoidant Behaviour	Pending	SFDA is validating this potential risk
Brexpiprazole	Hallucination, Auditory	Pending	SFDA is validating this potential risk
Brexpiprazole	Confusional State	Pending	SFDA is validating this potential risk
Risperidone	Swelling Face	Pending	SFDA is validating this potential risk
Risperidone	Social Avoidant Behaviour	Pending	SFDA is validating this potential risk
Mebeverine; Sulpiride	Dyspepsia	Pending	SFDA is validating this potential risk
Amlodipine	Numbness	Pending	SFDA is validating this potential risk
Levothyroxine	Gastric Ulcer stomach Pain - Vomiting - Ulcer Stomach	Pending	SFDA is validating this potential risk
Risperidone	Hallucination, Auditory	Pending	SFDA is validating this potential risk
Vitamin B Complex	Odor Body	Pending	SFDA is validating this potential risk
HPV Vaccine	Neuropathy Peripheral	Pending	SFDA is validating this potential risk
HPV Vaccine	Polycystic Ovarian Syndrome	Pending	SFDA is validating this potential risk
HPV Vaccine	Complex Regional Pain Syndrome	Pending	SFDA is validating this potential risk
HPV Vaccine	Ovarian Failure	Pending	SFDA is validating this potential risk
HPV Vaccine	Epilepsy	Pending	SFDA is validating this potential risk

HPV Vaccine	Cervix Carcinoma	Pending	SFDA is validating this potential risk
HPV Vaccine	Breast Neoplasm	Pending	SFDA is validating this potential risk
HPV Vaccine	Osteoarthritis	Pending	SFDA is validating this potential risk
Rituximab	Acute Myeloid Leukaemia	Pending	SFDA is validating this potential risk
Semaglutide	Taste Disorder	Closed	Validation process ended
Apremilast	Secondary Syphilis	Closed	Validation process ended
Apremilast	Penile Squamous Cell Carcinoma	Closed	Validation process ended
Apremilast	Pityriasis Rubra Pilaris	Closed	Validation process ended
Apremilast	Ephelides	Closed	Validation process ended
Apremilast	Keratoacanthoma	Closed	Validation process ended
Apremilast	Granuloma Annulare	Closed	Validation process ended
Apremilast	Latent Tuberculosis	Closed	Validation process ended
Apremilast	Uterine Disorder	Closed	Validation process ended
Apremilast	Palmoplantar Pustulosis	Closed	Validation process ended
Apremilast	Tenosynovitis	Closed	Validation process ended
Apremilast	Mycobacterium Tuberculosis Complex Test Positive	Closed	Validation process ended
Apremilast	Enthesopathy	Closed	Validation process ended
Rituximab	Acute Myeloid Leukaemia	Closed	Validation process ended
Tacrolimus	Adenovirus Infection	Closed	Validation process ended
Tacrolimus	Ureteritis	Closed	Validation process ended
Niraparib	Vasculitis	Closed	Validation process ended

Table 2. List of Quarterly Validated Signals

Active Ingredient	Adverse Event	Status	Outcome
Measles Vaccine;Mumps Vaccine;Rubella Vaccine	Decreased Eye Contact	Closed	Refuted
Apremilast	Secondary Syphilis	Closed	Refuted
Apremilast	Penile Squamous Cell Carcinoma	Closed	Valid
Apremilast	Pityriasis Rubra Pilaris	Closed	Refuted
Apremilast	Ephelides	Closed	Refuted
Apremilast	Keratoacanthoma	Closed	Monitored
Apremilast	Granuloma Annulare	Closed	Refuted
Apremilast	Latent Tuberculosis	Closed	Valid
Apremilast	Uterine Disorder	Closed	Monitored
Apremilast	Mycobacterium Tuberculosis Complex Test Positive	Closed	Valid
Apremilast	Enthesopathy	Closed	Valid
HPV Vaccine	Systemic Lupus Erythematosus	Closed	Valid
Rituximab	Vitiligo - Alopecia Universalis	Closed	Refuted



Recombinant Varicella Zoster Virus Surface Glycoprotein E	Pelvic Fracture	Closed	Refuted
Rituximab	Alopecia Universalis - Vitiligo - Acne - Depression - Skin Depigmentation	Closed	Refuted
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Neoplasm - Illness	Closed	Refuted
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Breast Cancer	Closed	Refuted
Benralizumab	Oxygen Saturation Decreased - Infection - Nasal Congestion - Oropharyngeal Pain - Sputum Culture - Bone Pain - Pain in Extremity	Closed	Refuted
Burosumab	Carbon Dioxide Increased - Blood Sodium Decreased	Closed	Refuted
Benralizumab	Dyspnoea - Cough - Sputum Increased	Closed	Refuted
Zolpidem	Schizophrenia	Closed	Refuted
Brexpiprazole	Carotid Artery Disease	Closed	Refuted
Belimumab	Wound	Closed	Refuted
Benralizumab	Nasal Polyps	Closed	Refuted
Atezolizumab	Paraesthesia	Closed	Valid
Prednisolone	Cutaneous Vasculitis	Closed	Refuted
Paracetamol	Dyspnoea	Closed	Refuted
Levothyroxine	Hyperlipidaemia	Closed	Refuted
Meloxicam	Insulin Resistance	Closed	Refuted
Tadalafil	Pyrexia - Vertigo - Gastroesophageal Reflux Disease	Closed	Monitored
Multivitamins, Combinations	Odour Body	Closed	Refuted
Colistimethate Sodium	Hypomagnesemia	Closed	Valid
Nemolizumab	Erythema Multiforme	Closed	Refuted
Golimumab	Meningitis	Closed	Refuted
Roflumilast	Pancreatitis	Closed	Valid
Linagliptin	Cardiac Failure	Closed	Refuted
Vemurafenib	Sepsis	Closed	Valid
Prucalopride	Suicidal Ideation	Closed	Valid
Dimenhydrinate	Toxic Epidermal Necrolysis	Closed	Valid
Vemurafenib	Cardiac Failure	Closed	Valid
Ferrous Sulfate	Pruritus	Closed	Refuted
Ofatumumab	Central Nervous System Infection	Closed	Valid
Gentamicin	Rash Maculo-Papular	Closed	Refuted
Darbepoetin Alfa	Bone Marrow Disorder	Closed	Refuted
Oxaliplatin	Excoriation - Diarrhea	Closed	Refuted
Semaglutide	Optic Ischaemic Neuropathy	Closed	Valid
Lixisenatide	Optic Ischaemic Neuropathy	Closed	Refuted
Cabozantinib	Cardiac Failure	Closed	Refuted
Leflunomide	Rheumatoid Lung	Closed	Valid
Ofloxacin Hydrochloride	Endophthalmitis	Closed	Monitored



Yellow Fever Vaccine	Malaria	Closed	Refuted
Lacosamide	Hyponatremia	Closed	Refuted
Ibuprofen	Lip Swelling	Closed	Refuted
Valsartan	Hyperacidity	Closed	Refuted
Lithium	Aphasia	Closed	Refuted
Metformin	Gastrooesophageal Reflux Disease	Closed	Refuted
Metformin	Hypomagnesaemia	Closed	Refuted
Metformin	Blood Urea Increased	Closed	Refuted
Rivaroxaban	Respiratory Failure	Closed	Valid
Sildenafil	Hemianopia	Closed	Valid
Teriparatide	Colon Cancer	Closed	Refuted
Levothyroxine	Dry Mouth	Closed	Refuted
Levothyroxine	Fluid Retention	Closed	Refuted
Interferon Beta-1a	Amnesia	Closed	Refuted
Interferon Beta-1a	Nervousness	Closed	Refuted
Interferon Beta-1a	Hypoacusis	Closed	Refuted
Glibenclamide;Metformin	Hyperchlorhydria	Closed	Refuted
Entecavir	Chromaturia	Closed	Refuted
Deferasirox	Chronic Myeloid Leukaemia	Closed	Refuted
Dabigatran	Sepsis	Closed	Valid
Calcium Gluconate	Hypokalaemia	Closed	Refuted
Alprostadil	Pulmonary Haemorrhage	Closed	Refuted
Agomelatine	Amnesia	Closed	Refuted
Vincristine	Cardiac Failure Acute	Closed	Refuted
Bisoprolol	Protein Urine Present	Closed	Refuted
Dapagliflozin	Sarcopenia	Closed	Refuted
Tafamidis	Sepsis	Closed	Refuted
Warfarin	Heat Cramps	Closed	Refuted
Metformin	Back Pain	Closed	Refuted
Bisoprolol	Blood Albumin Decreased	Closed	Refuted
Doxycycline	Gingival Bleeding	Closed	Refuted
Paracetamol	Bilirubin Elevated	Closed	Refuted
Benralizumab	Pulmonary Function Test Abnormal	Closed	Refuted
Benralizumab	Gait Disturbance	Closed	Valid
Cladribine	Muscle Twitching	Closed	Refuted
Dupilumab	Azoospermia	Closed	Refuted
Avelumab	Purpura Fulminans	Closed	Refuted
Dupilumab	Dyspepsia	Closed	Refuted
Doxycycline	Fatigue	Closed	Refuted
Quetiapine	Drug Reaction With Eosinophilia And Systemic Symptoms	Closed	Refuted
Tenofovir Alafenamide	Insomnia - Depression - Dizziness	Closed	Refuted
Adalimumab	Injection Site Pain - Injection Site Redness - Injection Site Erythema - Arthralgia	Closed	Refuted
Gefitinib	Cardiac Failure	Closed	Valid



Quetiapine	Fracture	Closed	Refuted
Lixisenatide	Urinary Tract Infection	Closed	Refuted
Anastrozole	Memory Impairment	Closed	Refuted
Cefotaxime	Drug Reaction With Eosinophilia And Systemic Symptoms	Closed	Valid
Ketamine	Suicidal Ideation	Closed	Refuted
Dapagliflozin	Phimosis	Closed	Refuted
Hyaluronate Sodium	Eye Infection Bacterial	Closed	Refuted
Diphtheria Vaccine Toxoid;Hepatitis B Vaccine;Hib Vaccine;Pertussis Vaccine Acellular;Polio Vaccine Inact;Tetanus Vaccine Toxoid	Eye Movement Disorder - Rigidity Of Limbs - Eye Rolling	Closed	Refuted
Cytarabine	Leukaemia	Closed	Refuted
Prednisolone	Neutropenia	Closed	Refuted
Tacrolimus	Hypoalbuminaemia	Closed	Refuted
Tamsulosin	Bladder Discomfort	Closed	Refuted
Dulaglutide	Thyroid Cancer	Closed	Refuted
Lenvatinib	Adrenal Insufficiency	Closed	Valid
Dextrose	Hypoglycaemia	Closed	Refuted
Bisoprolol	Hyperphosphataemia	Closed	Refuted
Bisoprolol	Leucopenia	Closed	Refuted
Metformin	Cough	Closed	Refuted
Metformin Hydrochloride	Syncope	Closed	Refuted
Pegaspargase	Tachycardia	Closed	Refuted
Elasmeran	Electric Shock Sensation	Closed	Valid
Metformin Hydrochloride	Hot Feeling in Feet	Closed	Refuted
Olanzapine	Obsession	Closed	Refuted
Valsartan	Dry Mouth	Closed	Refuted
Alendronic Acid;Calcium Carbonate	Hypoglycaemia	Closed	Refuted
Tozinameran	Vitiligo	Closed	Refuted
Tozinameran	Vulval Ulceration	Closed	Refuted
Tozinameran	Pneumococcal Sepsis	Closed	Refuted
Tozinameran	Arrhythmia	Closed	Refuted
Tozinameran	Acute Leukaemia	Closed	Refuted
Tozinameran	Parosmia	Closed	Refuted
Tozinameran	Cardio-Respiratory Arrest	Closed	Refuted
Tozinameran	Sepsis	Closed	Refuted
Tozinameran	Ear Swelling	Closed	Refuted
Senna Alexandrina	Tinnitus	Closed	Refuted
Ergocalciferol	Pain in Extremity	Closed	Refuted
Cefazolin	Rash Maculo-Papular	Closed	Refuted
Zoledronic Acid	Mucosal Inflammation	Closed	Refuted



Measles Vaccine;Mumps Vaccine;Rubella Vaccine	Autism Spectrum Disorder	Closed	Refuted
Radium Ra 223 Dichloride	Back Pain	Closed	Valid
Febuxostat	Autoimmune Haemolytic Anaemia	Closed	Refuted
Rifampicin	Blood Alkaline Phosphatase Increased	Closed	Valid
Budesonide	Breath Odour	Closed	Refuted
Furosemide	Gangrene	Closed	Refuted
Teriparatide	Death	Closed	Refuted
Fexofenadine	Loss Of Consciousness	Closed	Refuted
Ampicillin	Consciousness Fluctuating	Closed	Refuted
Etanercept	Glomerulonephritis Rapidly Progressive	Closed	Refuted
Teriparatide	Gait Disturbance	Closed	Refuted
Furosemide	Haematuria	Closed	Refuted
Sitagliptin	Dyspnoea	Closed	Refuted
Teriparatide	Cerebrovascular Accident	Closed	Refuted
Prednisolone	Dry Eye	Closed	Refuted



Thank 
you