

Safety Signals Identified by the SFDA

April – June 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
HPV Vaccine	Herpes Virus Infection	Pending	SFDA is validating this potential risk
HPV Vaccine	Colitis Ulcerative	Pending	SFDA is validating this potential risk
Semaglutide	Uremic Syndrome	Pending	SFDA is validating this potential risk
Paclitaxel	Loss Of Consciousness - Pulse Absent	Pending	SFDA is validating this potential risk
Enoxaparin Sodium	Consciousness Fluctuating - Oxygen Saturation Abnormal - Vomiting - Oral Intake Reduced	Pending	SFDA is validating this potential risk
Acetylsalicylic Acid	Gastro-Intestinal Candidiasis	Pending	SFDA is validating this potential risk
Atorvastatin	Gerd	Pending	SFDA is validating this potential risk
Acetazolamide	Polydipsia - Dry Mouth - Dry Throat - Hyperpigmentation Skin - Persistent Headache - Dizziness	Pending	SFDA is validating this potential risk
Rivaroxaban	Breath Odourstomach Irritated Feeling Of - Smelly Breath - Gastrointestinal Disorder - Eructation - Mood Altered	Pending	SFDA is validating this potential risk
Cefazolin	Acute Kidney Injury	Pending	SFDA is validating this potential risk
Pregabalin	Ventricular Septal Defect	Pending	SFDA is validating this potential risk
Delgocitinib	Headache	Pending	SFDA is validating this potential risk
Delgocitinib	Upper Respiratory Tract Infection	Pending	SFDA is validating this potential risk
Delgocitinib	Nasopharyngitis	Pending	SFDA is validating this potential risk
Oxaliplatin	Porto-Sinusoidal Vascular Disorder	Pending	SFDA is validating this potential risk
Oxaliplatin	Hypersplenism	Pending	SFDA is validating this potential risk
Fulvestrant	Lymphopenia	Pending	SFDA is validating this potential risk
Palbociclib	Lymphopenia	Pending	SFDA is validating this potential risk
Dutasteride	Suicidal Behaviour	Pending	SFDA is validating this potential risk
Dutasteride	Suicidal Ideation	Pending	SFDA is validating this potential risk
Finasteride	Suicidal Ideation	Pending	SFDA is validating this potential risk
Finasteride	Suicidal Behaviour	Pending	SFDA is validating this potential risk
Terbinafine	Muscular Weakness	Pending	SFDA is validating this potential risk
Dulaglutide	Lymphoid Tissue Hyperplasia	Pending	SFDA is validating this potential risk
Promestriene	Jaw Dislocation, Muscle Spasms, And Inability To Close The Eyes	Pending	SFDA is validating this potential risk
Risperidone - Brexpiprazole	Mental Confusion / Brain Fog - Hearing Voices In The Head (Auditory Hallucinations) - Social Withdrawal / Withdrawal From Life - Dizziness -	Pending	SFDA is validating this potential risk

	Swelling Of The Forehead - Confusion / Disorientation - Shortness Of Breath - Heart Tightness / Chest Tightness - Muscle Spasms / Seizures (After Injection)		
ALGLUCOSIDAS E ALFA , Hydrocortisone , Azithromycin	Walking disability	Pending	SFDA is validating this potential risk
Sitagliptin Hydrochloride Hydrate	Stress - Allergy	Pending	SFDA is validating this potential risk
Vildagliptin - Metformin Hydrochloride	Palpitation - Skipped beats	Pending	SFDA is validating this potential risk
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Neoplasm - Breast mass	Pending	SFDA is validating this potential risk
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Blood pressure increased	Pending	SFDA is validating this potential risk
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Nasopharyngitis	Pending	SFDA is validating this potential risk
Rituximab , Pyridostigmine , Tacrolimus , Benzoyl Peroxide , Adapalene	Vitiligo	Pending	SFDA is validating this potential risk
Inclisiran	Oxygen consumption decreased - Pneumonia - Blood pressure decreased	Pending	SFDA is validating this potential risk
Nusinersen	Deep vein thrombosis	Pending	SFDA is validating this potential risk
Recombinant Varicella Zoster Virus Surface Glycoprotein E , Influenza Virus Vaccine Polyvalent	Cold flash - Joint injury	Pending	SFDA is validating this potential risk
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Pelvic Fracture	Pending	SFDA is validating this potential risk
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Cardiac Monitoring Abnormal	Pending	SFDA is validating this potential risk

Recombinant Varicella Zoster Virus Surface Glycoprotein E	Convulsions Local - Cerebrovascular Accident - Paralysis	Pending	SFDA is validating this potential risk
Zoledronic Acid , Salbutamol , Ascorbic Acid , Zinc , Calcium Glubionate , Budesonide , Nusinersen	Arm Amputationarm Amputation	Pending	SFDA is validating this potential risk
Natalizumab	Syphilis - Herpes Simplex	Pending	SFDA is validating this potential risk
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Neoplasm - Illness	Pending	SFDA is validating this potential risk
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Breast Cancer	Pending	SFDA is validating this potential risk
Tamsulosin Hydrochloride;Tolt erodine L-Tartrate	Urinary Tract Infection - Efficacy Lack	Pending	SFDA is validating this potential risk
Tirzepatide	Nodule	Pending	SFDA is validating this potential risk
Goserelin, Letrozole , Abemaciclib	Neutropenia - Oestradiol Increased	Pending	SFDA is validating this potential risk
Belimumab Subcutaneous	Hypothyroidism - Eczema - Renal Disorder - Sickle Cell Anaemia	Pending	SFDA is validating this potential risk
Inclisiran	Abdominal Pain	Pending	SFDA is validating this potential risk
Varicella Zoster Vaccine Rge (Cho) , Recombinant Varicella Zoster Virus Surface Glycoprotein E	Plantar Fasciitis	Pending	SFDA is validating this potential risk
Magnesium sulfate , LABETALOL HYDROCHLORID E	Maternal exposure during pregnancy - Premature delivery	Pending	SFDA is validating this potential risk
RECOMBINANT VARICELLA ZOSTER VIRUS SURFACE GLYCOPROTEIN E	Hypertension	Pending	SFDA is validating this potential risk
WARFARIN , Tacrolimus , Prednisone	Ureteritis - Nephritis - Thrombocytopenia - Adenovirus infection	Pending	SFDA is validating this potential risk

Recombinant Varicella Zoster Virus Surface Glycoprotein E	Gastritis - Thyroiditis - Bone Pain - Tongue Ulceration	Pending	SFDA is validating this potential risk
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Fatigue - Palpitations - Headache	Pending	SFDA is validating this potential risk
Tacrolimus	Bronchiectasis - Upper Respiratory Tract Infection	Pending	SFDA is validating this potential risk
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Sciatica - Mobility Decreased	Pending	SFDA is validating this potential risk
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Bladder Neoplasm	Pending	SFDA is validating this potential risk
Prednisone Acetate , Etanercept , Methotrexate Sodium , Tofacitinib Citrate , Leflunomide , Hydroxychloroquin e Sulfate	Immune Reconstitution Inflammatory Syndrome - Myositis	Pending	SFDA is validating this potential risk
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Bursitis	Pending	SFDA is validating this potential risk
Influenza Virus Vaccine Polyvalent , Recombinant Varicella Zoster Virus Surface Glycoprotein E	Thyroiditis - Parotitis	Pending	SFDA is validating this potential risk
Prednisone , Tacrolimus , Mycophenolate Mofetil	Polyomavirus-Associated Nephropathy - Viruria - Adenovirus Infection - Ureteritis	Pending	SFDA is validating this potential risk
Oxymetazoline Hydrochloride;Zinc Sulfate	Tachyphylaxis	Pending	SFDA is validating this potential risk
Oxymetazoline Hydrochloride;Zinc Sulfate	Rhinitis	Pending	SFDA is validating this potential risk
Xylometazoline	Tachyphylaxis	Pending	SFDA is validating this potential risk
Xylometazoline	Rhinitis	Pending	SFDA is validating this potential risk
Alectinib	Hypertriglyceridaemia	Pending	SFDA is validating this potential risk

Zolpidem	Tic	Pending	SFDA is validating this potential risk
Zolpidem	Autism Spectrum Disorder	Pending	SFDA is validating this potential risk
Zolpidem	Intellectual Disability	Pending	SFDA is validating this potential risk
Zolpidem	Eating Disorder	Pending	SFDA is validating this potential risk
Diazepam	Tic	Pending	SFDA is validating this potential risk
Diazepam	Attention Deficit Hyperactivity Disorder	Pending	SFDA is validating this potential risk
Diazepam	Autism Spectrum Disorder	Pending	SFDA is validating this potential risk
Diazepam	Intellectual Disability	Pending	SFDA is validating this potential risk
Diazepam	Personality Disorder	Pending	SFDA is validating this potential risk
Diazepam	Eating Disorder	Pending	SFDA is validating this potential risk
Diazepam	Schizophreniform Disorder	Pending	SFDA is validating this potential risk
Burosumab	Hyperparathyroidism	Pending	SFDA is validating this potential risk
Burosumab	Pyrexia	Pending	SFDA is validating this potential risk
Amlodipine	Acute Kidney Injury	Pending	SFDA is validating this potential risk
Amlodipine	Fall	Pending	SFDA is validating this potential risk
Amlodipine	Hyperkalaemia	Pending	SFDA is validating this potential risk
Amlodipine	Hyponatraemia	Pending	SFDA is validating this potential risk
Tirzepatide	Myocardial Infarction	Pending	SFDA is validating this potential risk
Tirzepatide	Cardiac Disorder	Pending	SFDA is validating this potential risk
Prednisolone	Haemolytic Anaemia	Pending	SFDA is validating this potential risk
Prednisolone	Haematochezia	Pending	SFDA is validating this potential risk
Ponatinib	Maternal Exposure During Pregnancy	Pending	SFDA is validating this potential risk
Ponatinib	Congenital Megacolon	Pending	SFDA is validating this potential risk
Axicabtagene Ciloleucel	Brain Oedema	Pending	SFDA is validating this potential risk
Diclofenac	Renal Artery Fibromuscular Dysplasia	Pending	SFDA is validating this potential risk
Naproxen	Renal Artery Fibromuscular Dysplasia	Pending	SFDA is validating this potential risk
Ibuprofen	Renal Artery Fibromuscular Dysplasia	Pending	SFDA is validating this potential risk
Orforglipron	Liver Injury	Pending	SFDA is validating this potential risk
Brexipiprazole	Parkinsonian Crisis	Pending	SFDA is validating this potential risk
Brexipiprazole	Intracranial Aneurysm	Pending	SFDA is validating this potential risk
Methadone	Autism Spectrum Disorder	Pending	SFDA is validating this potential risk
Buprenorphine	Autism Spectrum Disorder	Pending	SFDA is validating this potential risk
Buprenorphine	Attention Deficit Hyperactivity Disorder	Pending	SFDA is validating this potential risk
Pembrolizumab	Mucous Membrane Pemphigoid	Pending	SFDA is validating this potential risk

Ifinatamab Deruxtecan	Pneumonia Aspiration	Pending	SFDA is validating this potential risk
Iron Sucrose	Seizure - Dystonia - Myalgia - Tremor - Ataxia	Pending	SFDA is validating this potential risk
Rosuvastatin	Chest Pain - Suffocation Feeling - Muscle Pain - Acid Reflux (Oesophageal) - Fatigability Generalized - Headache	Pending	SFDA is validating this potential risk
Inclisiran	Ldl/Hdl Ratio Increased	Pending	SFDA is validating this potential risk
Inclisiran	Memory Impairment	Pending	SFDA is validating this potential risk
Rosuvastatin	Hypertension - Headache - Dizziness - Loss Of Balance - Nausea	Pending	SFDA is validating this potential risk
Folinic Acid	Behaviour Disorder	Pending	SFDA is validating this potential risk
Folinic Acid	Social Problem	Pending	SFDA is validating this potential risk
Rivaroxaban	Subdural Haematoma	Pending	SFDA is validating this potential risk
Calcium Carbonate	Blood Urea Nitrogen Increased	Pending	SFDA is validating this potential risk
Epinephrine	Potassium Decreased	Pending	SFDA is validating this potential risk
Melphalan	Tumor Lysis Syndrome	Pending	SFDA is validating this potential risk
Ferrous Sulfate	Swelling Arm - Numbness In Hands, Forearms, Elbows	Pending	SFDA is validating this potential risk
Hydroxychloroquin e	Hyperacidity	Pending	SFDA is validating this potential risk
Alprostadil	Platelet Count Increased	Pending	SFDA is validating this potential risk
Bisoprolol	Hyperglycemia	Pending	SFDA is validating this potential risk
Calcium Carbonate	Urinary Frequency	Pending	SFDA is validating this potential risk
Dacarbazine	Hypersensitivity - Seizure - Sob	Pending	SFDA is validating this potential risk
Desvenlafaxine	Myalgia	Pending	SFDA is validating this potential risk
Empagliflozin	Alp Increased	Pending	SFDA is validating this potential risk
Alfacalcidol	Joint Pain	Pending	SFDA is validating this potential risk
Acetylcysteine	Blood Urea Nitrogen Increased	Pending	SFDA is validating this potential risk
Indapamide	Memory Impairment - Muscle Weakness - Weakness Generalised - Arthralgia - Myalgia	Pending	SFDA is validating this potential risk
Frovatriptan	Weight Gain	Pending	SFDA is validating this potential risk
Glimepiride	Hyperglycaemic Crisis - Gastroenteritis - Vomiting	Pending	SFDA is validating this potential risk
Hpv Vaccine	Systemic Lupus Erythematosus	Pending	SFDA is validating this potential risk
Levetiracetam - Sofosbuvir	Myalgia - Back Pain - Jaw Pain - Speech Disorder	Pending	SFDA is validating this potential risk
Prednisolone	Epistaxis	Pending	SFDA is validating this potential risk
Atezolizumab	Anorexia Nervosa	Pending	SFDA is validating this potential risk



Hpv Vaccine	Hepatitis	Closed	validation process ended
Hpv Vaccine	Anogenital Warts	Closed	validation process ended
Influenza A(H5n1) Vaccine	Dyspnea - Persistent Fever	Closed	validation process ended
Royal Jelly;Vitamins Nos	Shaking - Shortness Of Breath	Closed	validation process ended
Glimepiride - Metformin	Hyperglycemia	Closed	validation process ended
Influenza A(H5n1) Vaccine	Influenza	Closed	validation process ended
Metformin Hydrochloride - Sitagliptin Hydrochloride Hydrate	Hyperglycemia	Closed	validation process ended
All Other Therapeutic Products	Acute Kidney Injury	Closed	validation process ended
All Other Therapeutic Products	Hypotension	Closed	validation process ended
Vaccines	Palpitation - Arrhythmia - Thyroid Disorder - Hand Pain	Closed	validation process ended
Vaccines	Chest Inflammation	Closed	validation process ended
Immunoglobulin Human Normal	Respiratory Abnormality, Unspecified	Closed	validation process ended
Amitriptyline	Lethargy	Closed	validation process ended
Piperacillin;Tazobactam	Anaphylactic Shock - Tachycardia - Sweating - Hypotension - Generalised Itching - Tachypnoea	Closed	validation process ended
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Influenza	Closed	validation process ended
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Vaccination Failure	Closed	validation process ended
Covid-19 Vaccine Astrazeneca	Optic Neuropathy	Closed	validation process ended
Rituximab	Vitiligo - Alopecia Universalis	Closed	validation process ended
Dolutegravir Emtricitabine , Tenofovir Alafenamide Fumarate	HIV Viraemia	Closed	validation process ended

Recombinant Varicella Zoster Virus Surface Glycoprotein E	Influenza	Closed	validation process ended
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Influenza	Closed	validation process ended
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Cancer Staging	Closed	validation process ended
Rituximab	Alopecia Universalis - Vitiligo - Acne - Depression - Skin Depigmentation	Closed	validation process ended
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Influenza	Closed	validation process ended
Brexucabtagene Autoleucel	Cytokine Release Syndrome - Graft Versus Host Disease	Closed	validation process ended
Brexucabtagene Autoleucel	Cytokine Release Syndrome - Immune Effector Cell-Associated Neurotoxicity Syndrome - Cytomegalovirus Infection Reactivation	Closed	validation process ended
Dupilumab	Skin Burning Sensation	Closed	validation process ended
Mepolizumab	Pyrexia - Fatigue - Lethargy	Closed	validation process ended
Insulin Human Isophane	Blood Glucose Increased - Diabetic Ketoacidosis	Closed	validation process ended
Benralizumab	Oxygen Saturation Decreased - Infection - Nasal Congestion - Oropharyngeal Pain - Sputum Culture - Bone Pain - Pain In Extremity	Closed	validation process ended
Burosumab	Carbon Dioxide Increased - Blood Sodium Decreased	Closed	validation process ended
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Movement Disorder - Injection Site Swelling - Injection Site Warmth	Closed	validation process ended
Hyaluronic Acid	Eye Redness - Irritation Eye - Burning Eyes	Closed	validation process ended
Dupilumab	Pain - Gastroesophageal Reflux Disease - Chest Pain	Closed	validation process ended
Semaglutide	Dry Mouth - Fatigue - Sleep Disorder - Breath Odour	Closed	validation process ended
Semaglutide	Polydipsia	Closed	validation process ended
Cladribine	Hypersensitivity - Pain In Extremity	Closed	validation process ended
Upadacitinib	Dermatitis Atopic	Closed	validation process ended



Lorlatinib	Malignant Neoplasm Progression - Non-Small Cell Lung Cancer	Closed	validation process ended
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Herpes Zoster	Closed	validation process ended
Semaglutide	Miscarriage Of Partner - Polyuria - Dry Mouth - Maternal Exposure During Pregnancy - Breath Odour	Closed	validation process ended
Palivizumab	Respiratory Syncytial Virus Infection	Closed	validation process ended
Meloxicam , Candesartan Cilexetil , Levothyroxine , Mirabegron	Activities Of Daily Living Assessment	Closed	validation process ended
Mepolizumab	Condition Aggravated - Hyposmia	Closed	validation process ended
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Renal Stone Removal	Closed	validation process ended
Mepolizumab	Dry Throat - Flank Pain	Closed	validation process ended
Dupilumab	Vitiligo - Skin Depigmentation	Closed	validation process ended
Influenza Virus Vaccine Polyvalent , Recombinant Varicella Zoster Virus Surface Glycoprotein E	Influenza Like Illness	Closed	validation process ended
Semaglutide	Increased Appetite - Weight Loss Poor	Closed	validation process ended
Empagliflozin	Hypersensitivity - Hyperglycaemia	Closed	validation process ended
Topiramate - Levetiracetam	Seizure	Closed	validation process ended
Hyaluronate Sodium	Dry Eye - Eye Redness - Eye Irritation - Headache	Closed	validation process ended
Ivabradine	Flushed Chest - Sensation Of Heat - Dyspnea - Dizziness - Nausea	Closed	validation process ended
Mepolizumab	Cough - Bronchial Hyperreactivity - Laryngeal Discomfort - Multiple Allergies	Closed	validation process ended
Semaglutide	Weight Increased	Closed	validation process ended
Semaglutide	Weight Loss Poor	Closed	validation process ended
Semaglutide	Anger - Stress - Mood Swings	Closed	validation process ended
Semaglutide	Sinus Disorder - Condition Aggravated - Hypotension	Closed	validation process ended
Letrozole , Abemaciclib	Malignant Neoplasm Progression - Diarrhoea - Nausea - Neutropenia	Closed	validation process ended



Benralizumab	Dyspnoea - Cough - Sputum Increased	Closed	validation process ended
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Viral Infection	Closed	validation process ended
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Pneumonia - Gas Poisoning - Allergy Test - Oral Allergy Syndrome - Dry Mouth - Cough - Fatigue	Closed	validation process ended
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Fatigue - Inguinal Hernia Repair	Closed	validation process ended
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Cough	Closed	validation process ended
Semaglutide	Increased Appetite	Closed	validation process ended
Nintedanib Esilate	Pneumonia - Nausea - Chest Discomfort - Cough	Closed	validation process ended
Tacrolimus	Upper Respiratory Tract Infection - Bronchiectasis	Closed	validation process ended
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Influenza	Closed	validation process ended
Recombinant Varicella Zoster Virus Surface Glycoprotein E	Hernia Repair - Fatigue	Closed	validation process ended
Etanercept , Adalimumab	Death - Anaphylaxis Treatment	Closed	validation process ended
Dupilumab	Sleep Disorder Due To A General Medical Condition	Closed	validation process ended
Tirzepatide	Efficacy Lack - Pruritus - Erythema - Allergic Reaction	Closed	validation process ended
Zolpidem	Attention Deficit Hyperactivity Disorder	Closed	validation process ended
Spinraza	Pyrexia	Closed	validation process ended
Semaglutide	Constipation - Abdominal Pain	Closed	validation process ended
Semaglutide	Nausea - Hunger	Closed	validation process ended
Ceftriaxone	Skin Rash - Blurred Vision - Nausea - Vomiting	Closed	validation process ended
Montelukast Sodium	Seizure	Closed	validation process ended
Semaglutide	Diarrhoea - Sepsis - Lymphadenitis	Closed	validation process ended



Semaglutide	Vomiting - Weight Loss Poor	Closed	validation process ended
Semaglutide	Gastroesophageal Reflux Disease - Alopecia	Closed	validation process ended
Liraglutide	Vomiting - Nausea - Food Poisoning	Closed	validation process ended
Burosumab	Seizure	Closed	validation process ended
Semaglutide	Nausea - Hyperthyroidism	Closed	validation process ended
Belimumab	Wound	Closed	validation process ended
Benralizumab	Memory Impairment	Closed	validation process ended
Levetiracetam	Hepatic Failure	Closed	validation process ended
Semaglutide	Hair Disorder	Closed	validation process ended
Inclisiran	Death	Closed	validation process ended
Ofatumumab	Maternal Exposure During Pregnancy	Closed	validation process ended
Benralizumab	Nasal Polyps	Closed	validation process ended
Paracetamol	Abdominal Pain - Diarrhoea - Pyrexia - Sweating Fever - Appetite Disorder	Closed	validation process ended
Lactulose	Nausea - Psychiatric Symptom Nos - Lethargy - Fatigue	Closed	validation process ended
Covid-19 Vaccine	Health Assessment Questionnaire Score Decreased - Female Infertility	Closed	validation process ended
Paracetamol	Persistent Headache	Closed	validation process ended
Vancomycin	Cough - Sob - Cyanosis	Closed	validation process ended
Metformin	Syncope	Closed	validation process ended
Mirtazapine	Ear Pain	Closed	validation process ended
Ondansetron	Ileus	Closed	validation process ended
Mefenamic Acid	Anaphylactic Shock - Itching - Rash - Shortness Of Breath	Closed	validation process ended
Indapamide	Incontinence	Closed	validation process ended
Fluvoxamine	Blurred Vision	Closed	validation process ended
Azathioprine	Rheumatic Arthritis Acute	Closed	validation process ended
Calcium Carbonate	Blood Urea Nitrogen Increased	Closed	validation process ended
Atorvastatin	Swelling Of Toes	Closed	validation process ended
Clopidogrel	Hyperacidity	Closed	validation process ended
Empagliflozin	Euglycemic Diabetic Ketoacidosis	Closed	validation process ended
Enoxaparin	Anemia	Closed	validation process ended
Aciclovir	Blood Urea Nitrogen Increased	Closed	validation process ended
Vincristine Sulfate	Hyper Bilirubinaemia	Closed	validation process ended
Escitalopram	Swelling - Redness - Shingles - Fever	Closed	validation process ended



Quetiapine	Seizures - Hallucinations - Suicidal Behavior - Insomnia	Closed	validation process ended
Empagliflozin	Weight Gain - Nausea	Closed	validation process ended
Semaglutide	Motion Sickness - Hyperosmia	Closed	validation process ended

Table 2. List of Quarterly Validated Signals

Active Ingredient	Adverse Event	Status	Outcome
HPV Vaccine	Hepatitis	Closed	Refuted
HPV Vaccine	Anogenital warts	Closed	Refuted
Burosumab	Seizure	Closed	Refuted
Benralizumab	Memory Impairment	Closed	Refuted
Ofatumumab	Maternal Exposure During Pregnancy	Closed	Refuted
Omalizumab	Acquired Haemophilia	Closed	Valid
Cetirizine Hydrochloride	Rash	Closed	Refuted
Cefadroxil	Redness - Erythema	Closed	Valid
Potassium Chloride	Arrest Cardiac	Closed	Valid
Rosuvastatin	Peripheral Coldness	Closed	Valid
Chlorpromazine	Short Of Breath	Closed	Refuted
Acetylsalicylic Acid	Heartburn	Closed	Refuted
Nifedipine	Reflex Tachycardia	Closed	Refuted
Aflibercept	Palmar-Plantar Erythrodysesthesia Syndrome	Closed	Refuted
Fluoxetine	Deafness	Closed	Refuted
Levetiracetam	Acute Kidney Injury	Closed	Refuted
Loratadine	Drowsiness	Closed	Refuted
Nusinersen Sodium	Diabetes Mellitus	Closed	Refuted
Levetiracetam	Shock	Closed	Refuted
Pregabalin	Gastric Ulcer	Closed	Refuted
Docetaxel	Vomiting - Nausea - Hoarseness - Throat Pain - Mouth Ulcer	Closed	Refuted
Omeprazole	GI Bleed	Closed	Refuted
Goserelin	Suicidal Behaviour	Closed	Refuted
Tirzepatide	Optic Ischaemic Neuropathy	Closed	Refuted
Exenatide	Sleep Disorder	Closed	Refuted
Yellow Fever Vaccine	Cerebral Haemorrhage	Closed	Refuted



Bisoprolol	Hypercholesterolemia	Closed	Refuted
Sitagliptin	Hypertension	Closed	Refuted
Sitagliptin	Dysphagia	Closed	Refuted
Ciclosporin	Pleural Effusion	Closed	Refuted
Carbamazepine	Encephalopathy	Closed	Valid
Azathioprine	Optic Neuritis	Closed	Valid
Levetiracetam	Stroke - Ischemic Stroke	Closed	Refuted
Alfacalcidol	Heartburn	Closed	Refuted
Tirzepatide	Myocardial Infarction	Closed	Refuted
Ezetimibe	Abdominal Distension	Closed	Refuted
Ezetimibe	Blood Potassium Abnormal	Closed	Refuted
Insulin	Consciousness Decreased - Spasm Muscle	Closed	Refuted
Azathioprine	Non-Cirrhotic Portal Hypertension	Closed	Valid
Atezolizumab	Thrombotic Microangiopathy	Closed	Refuted
Somatropin	Osteonecrosis	Closed	Refuted
Denosumab	Drug-Induced Liver Injury	Closed	Refuted
Alectinib	Pancreatitis	Closed	Refuted
Bupivacaine Hydrochloride	Drug Ineffective	Closed	Refuted
Afatinib	Growth Of Eyelashes	Closed	Refuted
Cefuroxime Axetil	Heart Rate Irregular - Sob (Shortness Of Breath) - Heartbeats Irregular	Closed	Refuted
Aripiprazole	Memory Impairment	Closed	Valid
Dabrafenib	Recall Phenomenon	Closed	Refuted
Apremilast	Diverticulitis	Closed	Valid
Apremilast	Enthesopathy	Closed	Refuted
Anastrozole	Synovial Cyst	Closed	Refuted
Amiodarone	Acute Kidney Injury	Closed	Valid
Cefazolin	Hypotension	Closed	Valid
Levothyroxine	Dry Mouth	Closed	Refuted
Levothyroxine Sodium	Constipation	Closed	Refuted
Linagliptin	Dizziness	Closed	Refuted
Linagliptin	Stomach Ache	Closed	Refuted
Dulaglutide	Depression	Closed	Refuted
Aciclovir	Leukemia	Closed	Refuted
Tozinameran	Acute Respiratory Distress Syndrome	Closed	Valid



Tozinameran	Acute Kidney Injury	Closed	Valid
Tozinameran	Still's Disease	Closed	Valid
Paracetamol	Enzyme Activity Increased	Closed	Refuted
Sacubitril;Valsartan	Chest Pain	Closed	Refuted



Thank 
you