



Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs & Drug Control
Department of Pharmacovigilance & Drug Information

HALF-YEARLY PV REPORT

July – December 2020



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1. Introduction

The Department of Pharmacovigilance & Drug Information (DPV&DI), which is the National PV Center (NPVC), greatly appreciate the contribution of all healthcare professionals, patients, pharmaceutical companies and Marketing Authorization Holders (MAHs) to the reporting of suspected adverse drug reaction, quality problems and medication errors.

In this report, the following are covered:

1. Regional PV Centres (RPVC) and Sub-regional PV Centres (S-RPVC) & VigiFlow users (VF)
2. Alerts and Recalls
3. COVID-19
4. Adverse Drug Reaction Reports
5. Quality Problems Reports
6. Medication Error Reports

2. PV Centres and VigiFlow users

During the period from July to December 2020, new regional PV centres (**34**) and sub-regional PV centres (**84**) have been activated. Also, new VigiFlow users are added, with total of (**253**) (Figure 1).

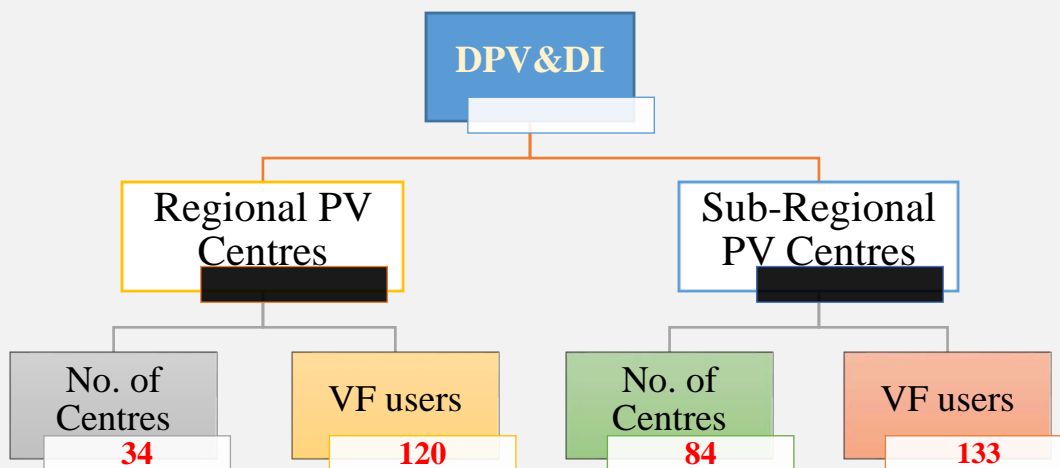


Figure (1): Structure of VigiFlow PV centres and users

3. Alerts and Recalls

The number of Alerts and Recalls issued during this period is (6) and (3) respectively. **Table (1)** shows summary of the Alerts, **while Table (2)** shows the Recalls. Respective circulars can be found at <https://www.moh.gov.om/en/web/dgpadc/-11>.

Table (1): Alerts

Sr	Circular No.	Issue Date	Alert
1	141/2020	29/07/2020	Azithromycin review of QT prolongation in the context of COVID-19 infection
2	142/2020	29/07/2020	Authorised uses of cancer medicine Yondelis unchanged following review of new data.
3	168/2020	06/09/2020	Invokana, Invokamet and Invokamet XR: Boxed warning about risk of leg and foot amputations removed
4	197/2020	25/10/2020	Nonsteroidal Anti-inflammatory Drugs (NSAIDs): Avoid use of NSAIDs in pregnancy at 20 weeks or later.
5	222/2020	29/11/2020	Ferric carboxymaltose (Ferinject): Risk of symptomatic hypophosphatasemia leading to osteomalacia and fractures
6	226/2020	06/12/2020	New product information wording: Fluoroquinolones for systemic and inhalation formulations- Heart valve regurgitation, cervical artery dissection and aortic aneurysm and dissection.

Table (2): Recalls

Sr	Recall No.	Recall Date	Recall	Recall Classification	Recall Level
1	126/2020	07/07/2020	Voluntary Recall/ Batch Recall: Salonpas-Hot Patch	Class III	Retail
2	133/2020	13/07/2020	Voluntary Recall/ All batches: Minirin nasal spray 0.1mg/ml	Class II	Retail
3	236/2020	14/12/2020	Voluntary Recall/ Batch No: A90142: Largactil 50mg/2ml solution for injection	Class II	Wholesale

4. COVID-19

Between July 2020 and December 2020, the DPV&DI received (16) reports for drugs that were used in the treatment of COVID-19 patients (**Table 3**).

The DPV&DI is encouraging all healthcare professionals to report suspected adverse reactions for the drugs that are used in the treatment of COVID-19, and request to include as much details as available to facilitate monitoring and evaluation of these drugs.

Table (3): Drugs used in treatment of COVID-19

Sr	Health Institution	Suspected Drugs	Reported ADR
1	Ibri Hospital- Dhahira	Interferon beta, Lopinavir/Ritonavir, Ribavirin	Abnormal LFTs
2	Ibri Hospital- Dhahira	Interferon beta, Lopinavir/Ritonavir	ALT increased
3	Ibri Hospital- Dhahira	Low molecular weight heparins	Thrombocytopenia
4	DGHS-Dhofar	Hydroxychloroquine, Azithromycin, Tocilizumab, Low molecular weight heparin, Tazocin, Methylprednisolone, Lopinavir/ Ritonavir, Teicoplanin, Frusemide, Meropenem	Atrial flutter, Supraventricular tachycardia
5	Ibri Hospital- Dhahira	Azithromycin	Vomiting
6	Ibri Hospital- Dhahira	Linezolid, Low molecular weight heparin	Thrombocytopenia
7	Ibri Hospital- Dhahira	Favipiravir	ALT increased
8	Sultan Qaboos Hospital-Dhofar	Remdesivir	Abnormal LFTs
9	Sultan Qaboos Hospital-Dhofar	Remdesivir	Abnormal LFTs
10	Ibri Hospital- Dhara	Tocilizumab	ALT high
11	Ibri Hospital- Dhara	Favipiravir	Elevated liver enzyme levels
12	Ibri Hospital- Dhahira	Low molecular weight heparin	Thrombocytopenia
13	Ibri Hospital- Dhahira	Low molecular weight heparin	Thrombocytopenia
14	Ibri Hospital- Dhahira	Favipiravir	Abnormal LFTs
15	DGHS-Sharqiyah South	Clarithromycin	Diarrhoea
16	Sultan Qaboos University Hospital	Dexamethasone	Blood sugar increased

5. Adverse Drug Reactions (ADRs) Reports

The total number of ADR reports received and entered in the national database (VigiFlow) between July and December 2020 was **(855)**, the name of institutions and the numbers of reports are given in **Table (4)**. There were **(63)** reports, which were submitted manually and not yet processed in the VigiFlow, the name of institutions and the numbers of reports are given in **Table (5)**.

From the reporting rate as shown in Table (4), the **highest reporting hospital** is *Sultan Qaboos Hospital-Dhofar* [Total ADR reports **103**] followed by *Ibri Hospital* [Total ADR reports **84**]. The **governorate with the highest number of reports** is *North Sharqiyah*, with **(157)** reports. Among the **private institutions**, *Kims Oman hospital /Pharmacy* is the highest with **(18)** reports.

The patient sex distribution, the age group distribution of patients, the top ten reported drugs, and frequently reported suspected reactions, are depicted as graphs in Fig. **6, 7, 8, and 9** respectively.

The **highest reported drug** is *Metformin* while the **highest reported reaction** is *Allergy*. The reactions classified by System – Organ Classification (SOC), gastrointestinal disorders ranked the highest followed by Nervous system disorders. Top reported drug classes are alimentary tract and metabolism including the antidiabetic drugs followed by Cholesterol reducing agents. For the list of drugs-reactions, refer to Table (9).

Table (4): ADR Reports that are processed in VigiFlow

Region	Institution	No. of reports
Dakhilia (41)	Nizwa Hospital	40
	Lizugh HC	1
Dhahira (99)	Ibri Hospital	84
	Ibri EHC	9
	Dhank HC	2
	Yanqal HC	2
	Tanam HC	1
	Yanqul Hospital	1
Dhofar (109)	Sultan Qaboos Hospital	103
	Tawi Ateer Hospital	2
	Jibiat HC	1
	Midinat Al Haq Hospital	1
	Qeiron Heriti HC	1
	Taqa Hospital	1
Wusta (4)	Hayama Hospital	3
	Najdah HC	1
Buraimi (23)	Buraimi Polyclinic	10
	Buraimi Hospital	9
	Mahdhah HC	2
	Roudha HC	1
	Wadi Al Jizi Hospital	1

Muandam (2)	Dibba Hospital	1
	Khasab Polyclinic	1
Muscat Tertiary Hospitals	Royal Hospital	21
	Khoula Hospital	11
	Field Hospital	1
Muscat (MOH facilities) (49)	Mawaleh HC	13
	Massarah Hospital	12
	Al Hajer HC	6
	Wattayyah HC	4
	North Alkhwair HC	3
	Qurayat EHC	3
	Bowsher EHC	2
	Bowsher HC	1
	Bowsher renal dialysis	1
	Seeb EHC	1
	Muttrah HC	1
	Muscat HC	1
	Quriyat Hospital	1
Batinah North (7)	Sohar Hospital	7
South Batinah (1)	Barka Polyclinic	1
Sharqiyah North (157)	Ibra EHC	43
	Wadi Indam HC	23
	Al Qabil HC	20
	Bidiya Hospital	18
	Sinaw Hospital	13
	Mudhaybi HC	10
	Wadi Naam HC	9
	Miss HC	6
	Ismayya HC	5
	Wadi Bani Khalid Hospital	3
	Samad Hospial	3
	Al Jaza HC	2
	Wadi Dama HC	1
	Ibra Hospital	1
Sharqiyah South (100)	Kamil HC	64
	Ras Al Hadd HC	13
	JBB Ali Hospital	7
	Sur EHC	6
	Wafi HC	2
	Seeq&Sabt HC	2
	JBB Ali EHC	2
	Tiwi HC	2
	Sur Hospital	1
	Specialist Sur Diabetic Center	1
Sultan Qaboos University Hospital		53

Armed Force Hospital		3
ROP Hospital		20
Diwan Polyclinic		43
Private (107)		
Private Pharmacies/Hospital/Clinics	Kims Hospital	18
	Muscat Pharmacy	5
	Star Care Oman	3
	Badr Al Sama Pharmacy	1
	Al Rifaa Hospital	1
	Muscat Hospital	1
Pharmaceutical Companies	Merck	24
	Novartis	21
	Pfizer	4
	Roche	4
	JNJFOC	3
	Baxter	2
	Astellas	1
	Astrazeneca	1
	Takeda	1
	Cheplapharm Arzneimittel	1
	Biogen	1
	Gilead	1
	GSK	1
	ISPEN	1
	Unknown	12
Patient (e Reporting)		1
Vaccines (AEFI) (Dept. of Communicable diseases)		5
Grand Total		855

Table (5): ADR Reports that to be processed in VigiFlow

Institutions/Governorate	Reports no.
Khoula Hospital	60
Hajer HC	2
Ainin HC	1
Total	63

Figure (6): Patient – Sex Distribution

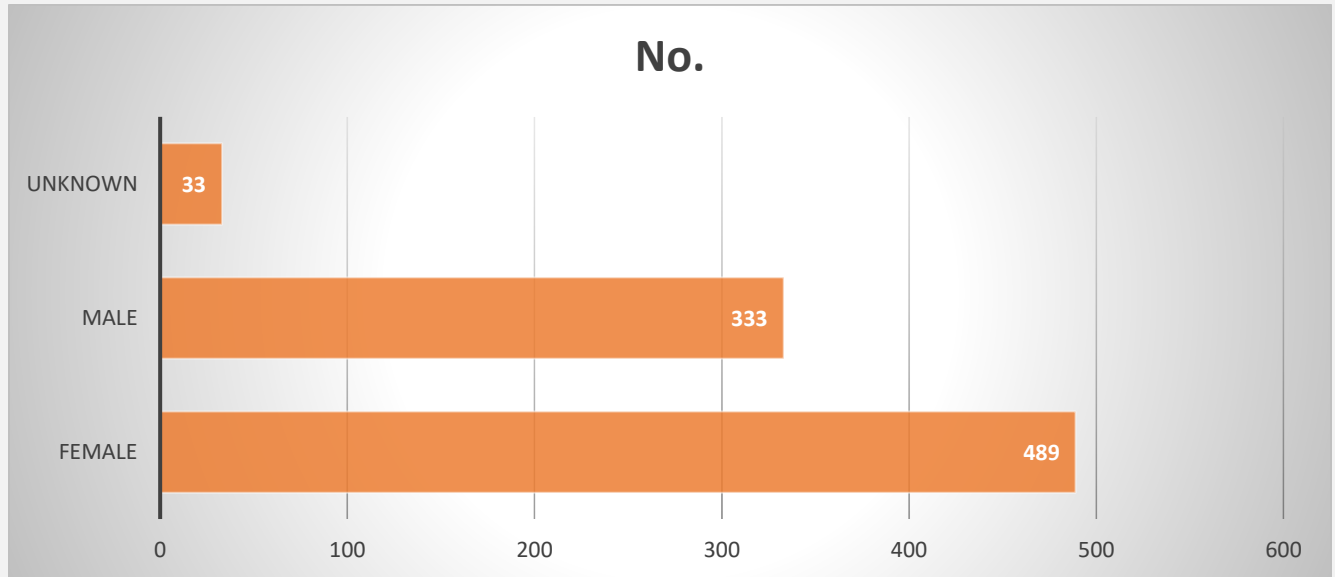


Figure (7): Patient Age Group Distributions

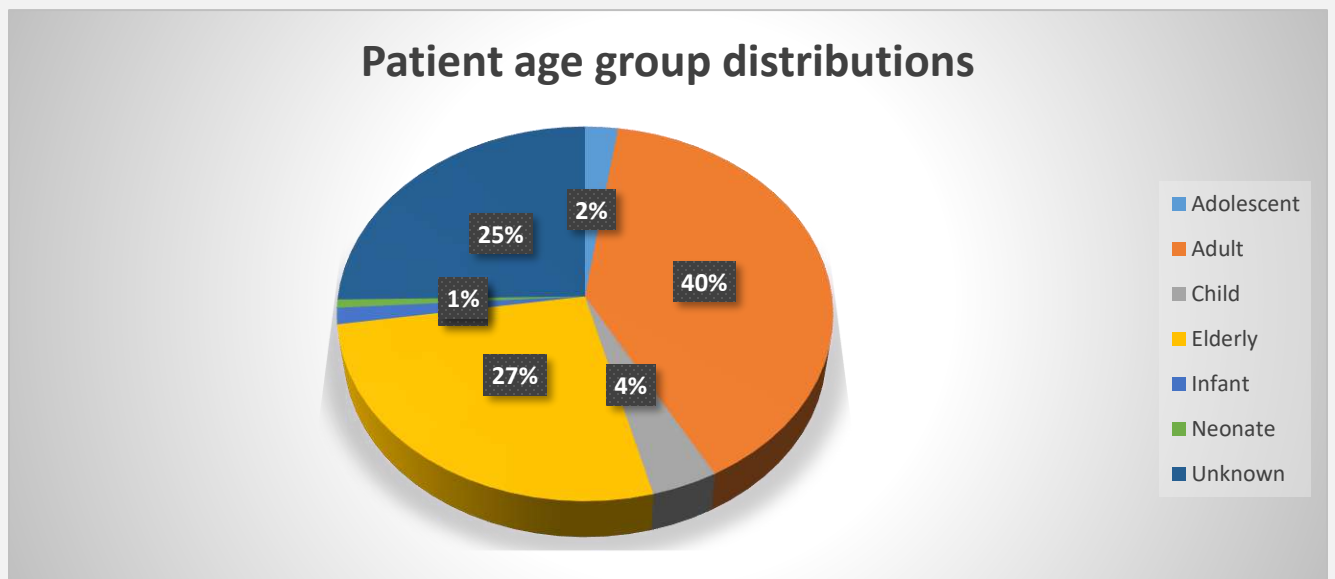


Figure (8): Top Ten Suspected Drugs

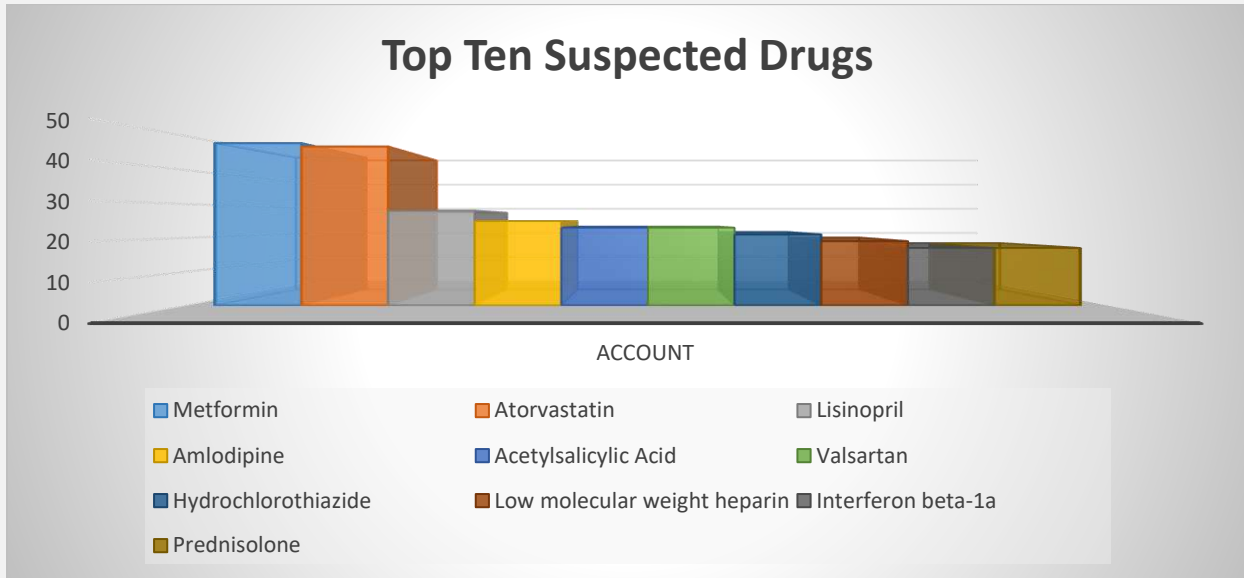
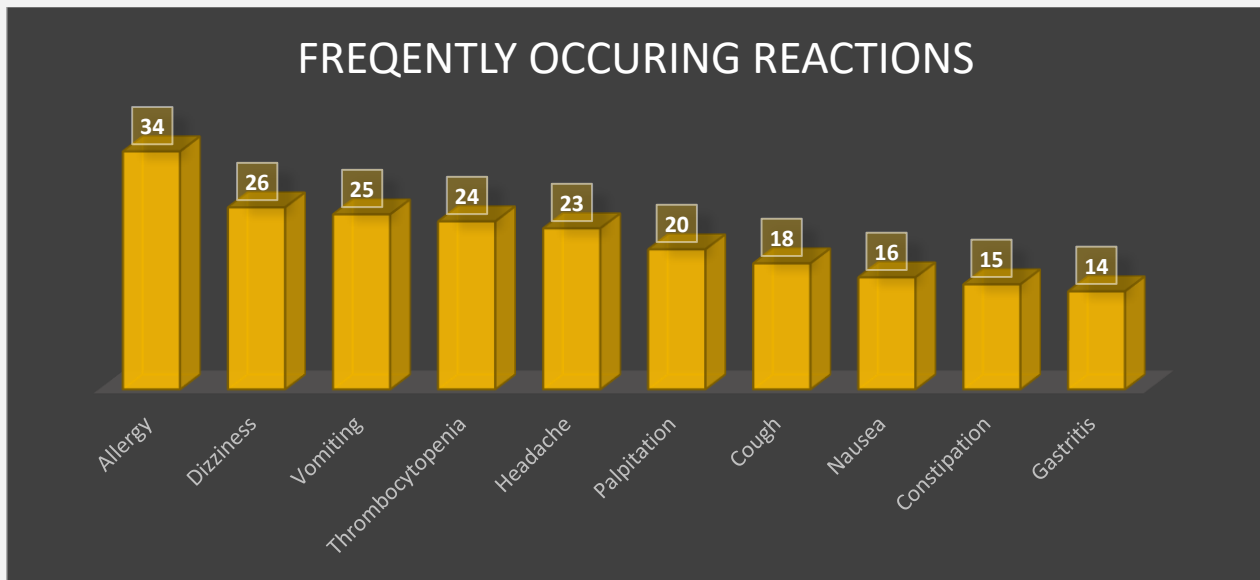


Figure (9): Frequently Occurring Reactions



Note:

Please note that Figure 6 to Figure 9 and Table 9, refer to the ADR reports that are processed in the VigiFlow.

6. Quality Problems Reports (QPR)

There were (86) product quality reports received at the DPV&DI via VigiFlow from government institutions and private sector (Table 6). Table (7) shows the reported quality problems according to dosage forms.

Table (6): QPR (Received through VF)

Sr	Institution	Governorate	No. of QPRs
Ministry of Health			
1	Mawaleh HC	Muscat	4
2	Mazaraa HC	Muscat	2
3	North Al Khwair HC	Muscat	3
4	Seeb EHC	Muscat	1
5	Bama HC	Muscat	1
6	Muscat HC	Muscat	8
7	Qurayat EHC	Muscat	3
8	Qurayat Hospital	Muscat	2
9	Renal Dialysis (Bowsher)	Muscat	1
10	Nizwa Hospital	Dakhliya	4
11	Ibra EHC	Sharqiyah North	16
12	Wadi Indam HC	Sharqiyah North	1
13	Sohar Hospital	Batinah North	3
14	Buraimi Hospital	Buraimi	11
15	Buraimi PC	Buraimi	12
16	Akhdar HC	Dhahira	1
17	Ibri Hospital	Dhahira	2
18	DGHS	Dhahira	1
19	Sultan Qaboos Hospital	Dhofar	1
20	Bukha Hospital	Musandam	1
Public Health Institutions			
21	Royal Oman Police Hospital	Muscat	1
22	Royal Hospital	Muscat	4
Private sector			
23	Merck		1
24	Novartis		1
25	Bayer		1
	Total		86

Table (7): Reported Quality Problems according to dosage forms

Dosage Form	Reported Quality Problem
Parenteral dosage forms	
	Broken ampoule in the original packing.
	Difficult to break ampoules
	Discoloration
	Rusty layer on the metal (top of the vial)
	Difficulty of syringe insertion to the vial
	Air bubbles persist inside the vial
	Red particles inside the powder
	Glass get crushed during opening (pieces will go inside)
	Particles/Impurity found inside ampoules
	Ineffectiveness
	Eroded & deposits at opening point
Oral dosage forms	
	Missing tablet / capsule in sealed strips
	Damaged / broken (tab. & capsule) inside the sealed strips/bottles
	Black/Brown spots on tablets
	Tablet color change
	Tablet dividing difficulty
	Inappropriate sealing of strips (Aluminum foil)
	Mixed aluminum foil silver colour with yellow.
	End of strips found cut.
	Bad odour
	Bad/Metallic taste
	Unpleasant palatability
	Shrunk strips seems to be exposed to heat
	Two different products under the same code
	Empty capsules in a sealed strips
	Leakage of powder from capsule in sealed strips
	Leakage from closed cap screw
	Syrup precipitates
	Insect/Spider found inside the sealed bottle
	Patient / Not Tolerated / Ineffectiveness
	Ineffectiveness for unapproved indication
	Patient complaint due to change of brand/ ineffectiveness.
	Caking of powder/ granules in sachet
	Swollen sachet
	Opened sachet in a sealed back

	Look alike medications – similar packs with inner / outer label
	Missing information on label
	Small font in the label (difficult to read)
	No leaflet / No Arabic instructions
Respiratory (inhaled) dosage forms	
	Product ineffectiveness (No Improvement)
	Leakage of Nebulizer Solution
	Difficult to open
Topical Dosage Forms	
	Product Ineffectiveness
	Packaging material with no medicine / dropper
	Black partials inside the bottle
	Broken bottle
	Look alike medications – similar packs with inner / outer back
	The way of the strength of Atropine Drops 1.0% is printed on the package is error prone.

7. Medication Errors Reports (MER)

The DPV&DI received **(16)** Medication Error reports in this half year (**Table 8**): Fifteen **(15)** reports received from the Royal Hospital and one **(1)** report from Amgen Middle East FZ-LLC. P-method was done to determine the type of errors.

Table (8) Medication Error Reports:

Sr.No.	ME type	No. of reports
1	Prescribing errors	14
2	Administration error	1
3	Overdose (Heparin)	1
	Total	16



Boxed Warning:

Note to all Manufacturing Authorization holders:

Kindly refrain from re - sending the ICSRs listed in this half yearly report again to the DPV&DI channels as it will cause duplication in the reports.

Table (9): List of Drugs- Reactions (July to December 2020)

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
1	Adult	Female	Acetaminophen	Anaphylaxis
2	Child	Male	Acetazolamide	Metabolic acidosis
3	Elderly	Female	Acetylsalicylic Acid	Abdominal pain
4	Elderly	Male	Acetylsalicylic Acid	Difficulty breathing
5	Elderly	Male	Acetylsalicylic Acid	Abdominal mass
6	Elderly	Male	Acetylsalicylic Acid	Dizziness
7	Elderly	Male	Acetylsalicylic Acid	Rash
8	Adult	Male	Acetylsalicylic Acid	Abdominal pain
9	Unknown	Female	Acetylsalicylic Acid	Tremor
10	Unknown	Female	Acetylsalicylic Acid	Tremor
11	Adult	Male	Acetylsalicylic Acid	Breath shortness
12	Adult	Female	Acetylsalicylic Acid	Heartburn
13	Elderly	Female	Acetylsalicylic Acid	Headache
14	Elderly	Male	Acetylsalicylic Acid	Gastrointestinal disorder
15	Elderly	Male	Acetylsalicylic Acid	Nasal bleeding
16	Elderly	Female	Acetylsalicylic Acid	Palpitation
17	Elderly	Female	Acetylsalicylic Acid	Itching
18	Adult	Male	Acetylsalicylic Acid, Clarithromycin, Ceftriaxone	Bleeding
19	Unknown	Male	Acyclovir	Creatinine high
20	Unknown	Unknown	Acyclovir, Cotrimoxazole	Acute graft versus host disease in skin
21	Infant	Female	Adrenaline	Cold extremities
22	Adult	Male	Albumin human, Amiodarone, Meropenem	Thrombocytopenia
23	Child	Unknown	Alglucosidase alfa	Off label use
24	Child	Unknown	Alglucosidase alfa	Off label use
25	Unknown	Male	Allopurinol	Ankle swelling, Joint pain
26	Elderly	Male	Alteplase	Upper gastrointestinal bleeding
27	Elderly	Female	Alteplase	Bleeding
28	Elderly	Male	Alteplase	Ventricular tachycardia
29	Elderly	Male	Aluminum hydroxide/magnesium hydroxide	Chest tightness

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
30	Elderly	Male	Aluminum hydroxide/magnesium hydroxide	Flatulence
31	Elderly	Female	Aluminum hydroxide/Magnesium hydroxide	Nausea
32	Adult	Female	Aluminum hydroxide/Magnesium hydroxide	Vomiting
33	Unknown	Male	Amiodarone hydrochloride	Thyrototoxicosis
34	Adult	Male	Amiodarone, Meropenem, Atorvastatin Piperacillin/ Tazobactam	Deranged liver function tests, Hypokalemia
35	Adult	Male	Amiodarone, Omeprazole, Spironolactone	Hepatotoxicity
36	Adult	Female	Amitriptyline	Sleepy
37	Adult	Female	Amitriptyline	Allergic reaction
38	Elderly	Male	Amlodipine	Edema like
39	Adult	Male	Amlodipine	Insomnia
40	Elderly	Female	Amlodipine	Allergy
41	Unknown	Female	Amlodipine	Dizziness
42	Elderly	Male	Amlodipine	Headache
43	Elderly	Male	Amlodipine	Headache
44	Elderly	Female	Amlodipine	Urinoma
45	Elderly	Female	Amlodipine	Foot oedema
46	Unknown	Female	Amlodipine	Swelling of legs
47	Adult	Female	Amlodipine	Excessive flatulence Uncontrolled hypertension
48	Adult	Female	Amlodipine	Kidney pain, Acidemia
49	Adult	Male	Amlodipine	Atypical angina
50	Elderly	Male	Amlodipine	Headache
51	Elderly	Female	Amlodipine	Edema
52	Elderly	Male	Amlodipine	Ankle swelling
53	Unknown	Male	Amlodipine	Oliguria
54	Adult	Female	Amlodipine	Headache, Tiredness, Heaviness of head
55	Unknown	Female	Amlodipine	Numbness
56	Unknown	Male	Amlodipine	Allergy

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
57	Elderly	Female	Amlodipine	Edema
58	Unknown	Female	Amlodipine besilate, Hydrochlorothiazide, Valsartan	Palpitation
59	Unknown	Female	Amlodipine besilate, Valsartan	Ankle edema
60	Unknown	Male	Amlodipine, Procyclidine	Hyponatremia
61	Adult	Female	Amlodipine/Perindopril	Headache, tired
62	Adult	Male	Amlodipine/perindopril	Headache, tired
63	Adult	Female	Amoxicillin	Allergy
64	Elderly	Male	Amoxicillin	Acidosis
65	Elderly	Male	Amoxicillin	Allergy
66	Child	Male	Amoxicillin	Allergy
67	Adult	Female	Amoxicillin	Acute diarrhea
68	Unknown	Female	Amoxicillin	Gastritis
69	Elderly	Female	Amoxicillin/Clavulanate	Cholestatic jaundice, acute hepatitis
70	Adult	Female	Amoxicillin/Clavulanate	Allergic reaction to drug
71	Unknown	Female	Amoxicillin/clavulanate	Hypersensitivity
72	Unknown	Female	Amoxicillin	Tremor
73	Adult	Female	Amphotericin B	Electrolyte imbalance
74	Child	Male	Amphotericin B	Hypokalemia
75	Adolescent	Female	Amphotericin B	Pulmonary aspergillosis, Acute anaphylactic reaction, Flushing, Back pain
76	Adult	Male	Ampicillin	Allergic skin reaction
77	Unknown	Male	Anakinra	Death, Off label use
78	Adult	Female	Antazoline/Naphazoline	Burning eyes
79	Elderly	Female	Artificial tears	Allergy
80	Elderly	Male	Artificial tears	Burns eyes
81	Elderly	Female	Atenolol	Dizziness
82	Elderly	Female	Atorvastatin	Myopathy
83	Elderly	Female	Atorvastatin	Skin rash
84	Unknown	Female	Atorvastatin	Tinnitus, hearing loss
85	Elderly	Female	Atorvastatin	Sleepiness
86	Elderly	Male	Atorvastatin	Allergy
87	Adult	Male	Atorvastatin	Skin rash

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
88	Elderly	Male	Atorvastatin	Skin rash
89	Unknown	Female	Atorvastatin	Headache
90	Adult	Female	Atorvastatin	Palpitation
91	Unknown	Unknown	Atorvastatin	Myopathy
92	Elderly	Female	Atorvastatin	Excessive flatulence
93	Elderly	Female	Atorvastatin	Nausea
94	Elderly	Female	Atorvastatin	Nausea
95	Elderly	Female	Atorvastatin	Dizziness
96	Elderly	Female	Atorvastatin	Dizziness
97	Elderly	Female	Atorvastatin	Dizziness
98	Elderly	Female	Atorvastatin	Muscle pain
99	Elderly	Male	Atorvastatin	Myopathy
100	Adult	Female	Atorvastatin	Epigastric pain
101	Adult	Female	Atorvastatin	Shivering
102	Adult	Male	Atorvastatin	Muscle weakness
103	Adult	Male	Atorvastatin	Cholesterol high
104	Elderly	Female	Atorvastatin	Chest burning, shortness of breath
105	Unknown	Female	Atorvastatin	Tremor, Acidemia, Appetite lost
106	Adult	Female	Atorvastatin	Bone pain
107	Elderly	Female	Atorvastatin	Headache
108	Unknown	Female	Atorvastatin	Muscular pain
109	Elderly	Female	Atorvastatin	Liver function test increased
110	Adult	Male	Atorvastatin	Bad breath
111	Elderly	Male	Atorvastatin	Constipation
112	Elderly	Female	Atorvastatin	Vomiting
113	Adult	Male	Atorvastatin, Levofloxacin, Allopurinol	Thrombocytopenia
114	Adult	Female	Atorvastatin, Lisinopril, Acetylsalicylic acid	Creatine kinase
115	Adult	Male	Atorvastatin, Paracetamol	Liver function test increased
116	Unknown	Male	Atorvastatin	Muscle pain
117	Elderly	Male	Atorvastatin	Chest pain, acidity
118	Elderly	Female	Atorvastatin	Chest pain
119	Elderly	Female	Atorvastatin	Fatigue, feeling pain
120	Adult	Male	Atorvastatin	Chest pain, acidity

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
121	Elderly	Female	Atorvastatin	Drowsiness
122	Elderly	Female	Atorvastatin	Rash
123	Elderly	Female	Atorvastatin	Myopathy
124	Elderly	Female	Atorvastatin	Allergy
125	Elderly	Female	Atorvastatin	Dizziness
126	Elderly	Female	Atorvastatin	Chest pain
127	Unknown	Unknown	Atorvastatin	Dizziness
128	Unknown	Unknown	Atorvastatin	burning sensation
129	Neonate	Male	Atropine	Hyperthermia, Erythema
130	Unknown	Female	Ayurvedic preparation NOS	Skin exfoliation
131	Unknown	Female	Azathioprine	ALT increased
132	Adult	Male	Azathioprine, Tacrolimus, Prednisolone	Lymphopenia, Urosepsis, Pancytopenia
133	Elderly	Female	Azithromycin	Raised INR
134	Child	Female	Azithromycin	Vomiting
135	Unknown	Male	Baclofen	Palpitation
136	Child	Male	BCG Vaccine	abscess
137	Infant	Female	BCG Vaccine	Axillary adenitis
138	Adult	Male	Bictegravir, Emtricitabine, Tenofovir, alafenamide	Palpitation, Dry lips, Red eye, Hair loss
139	Adult	Male	Bilastin	Dizziness
140	Elderly	Female	Bisacodyl	Allergy
141	Elderly	Female	Bisoprolol	Constipation
142	Unknown	Female	Bisoprolol	Palpitation
143	Adult	Female	Bisphosphonates	Fever, Appetite lost, Bone pain, Numbness
144	Adult	Male	Brentuximab	Anaphylactic reaction
145	Unknown	Male	Brentuximab vedotin, Bendamustine	Anaphylaxis, Off label use
146	Adult	Female	Cabergoline	Dizziness, Nausea, Chills
147	Neonate	Male	Caffeine Citrate	Tachycardia
148	Unknown	Female	Calcium carbonate, Colecalciferol	Acid dyspepsia
149	Elderly	Female	Candesartan	Coughing
150	Unknown	Unknown	Capecitabine	Jaundice, Intentional use for unlabeled indication, Off label use
151	Unknown	Female	Carbamazepine	Abnormal behavior

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
152	Unknown	Male	Carbamazepine	Hyponatremia
153	Unknown	Male	Carbamazepine	Rash
154	Adult	Female	Carbamazepine	Liver-kidney microsomal antibody, Abdominal pain
155	Adult	Male	Carbamazepine	Aggression, Hyperactivity, Photophobia, Movements involuntary
156	Elderly	Female	Carbimazole	Vomiting
157	Unknown	Female	Carbimazole	Nausea
158	Adult	Female	Carboplatin	Rash purpuric
159	Adult	Female	Carboplatin	Tachycardia, Heartburn, Dizziness
160	Adult	Female	Carvedilol	Dizziness
161	Unknown	Male	Carvedilol	Hypotension
162	Adolescent	Male	Carvedilol	Allergy
163	Unknown	Unknown	Carvedilol	Tachycardia
164	Elderly	Female	Carvedilol	Weakness
165	Elderly	Male	Carvedilol	Drowsiness
166	Elderly	Female	Carvedilol	Bad breath
167	Unknown	Male	Carvedilol, Isosorbide mononitrate, Furosemide, Valsartan, Spironolactone	Hypotension
168	Adult	Female	Carvedilol, Acetylsalicylic acid , Nifedipine, Lisinopril	Giddiness
169	Adult	Female	Caspofungin	Abnormal LFTs
170	Adult	Female	Caspofungin, Cotrimoxazole, Human albumin	Hypokalemia, Hypomagnesaemia, Hypocalcaemia, Thrombocytopenia
171	Adult	Male	Caspofungin, Levetiracetam Low molecular weight heparin	Hepatotoxicity
172	Elderly	Male	Caspofungin, Piperacillin/tazobactam	Toxic epidermal necrolysis
173	Adult	Female	Caspofungin, Vancomycin, Meropenem	Hypokalemia, Deranged liver function tests
174	Infant	Male	Cefixime trihydrate	Allergic skin reaction
175	Adult	Male	Cefotaxime	Urticarial rash
176	Unknown	Female	Cefotaxime sodium	Vomiting
177	Child	Male	Cefotaxime, Chlorpheniramine, Hydrocortisone	Allergy

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
178	Unknown	Female	Ceftazidime	Allergy
179	Adult	Female	Ceftraxone	Itching, Eye redness, Swollen lips Rash on legs
180	Adult	Female	Ceftriaxone	Rash face
181	Adult	Female	Ceftriaxone	Itching, Vomiting
182	Unknown	Male	Ceftriaxone	Toxic epidermal necrolysis
183	Elderly	Female	Ceftriaxone	Tachycardia
184	Elderly	Male	Ceftriaxone	Anaphylaxis, Itchy skin , Dizziness, Hypoxia, Hypotension
185	Unknown	Female	Ceftriaxone	Skin reaction
186	Unknown	Female	Ceftriaxone	Drug allergy
187	Adult	Female	Ceftriaxone, Aspirin, Spironolactone, Frusemide, Carvedilol, Atorvastatin, Clopidogrel, Lisinopril	Acute renal failure
188	Elderly	Male	Ceftriaxone, Azithromycin, Hydroxychloroquine sulfate, Lopinavir/Ritonavir	Off label use
189	Unknown	Male	Ceftriaxone, Azithromycin, Hydroxychloroquine, Lopinavir, Ritonavir, Fentanyl, Midazolam, Cisatracurium, Meropenem, Levofloxacin, Teicoplanin	Cardiopulmonary arrest, Multiple organ failure, Acute lung injury, SARS-CoV-2 infection, Metabolic acidosis, Off label use
190	Child	Male	Ceftriaxone, Dextromethorphan, Hydrocortisone	Allergy
191	Adult	Female	Ceftriaxone	Swelling of lips
192	Elderly	Female	Ceftriaxone	Allergy
193	Adult	Male	Cefuroxime, Ceftriaxone, Clarithromycin, Cinacalcet, Valsartan, Sevelamer	Allergy
194	Unknown	Male	Celecoxib	Vomiting
195	Adult	Female	Celecoxib	Itchy skin
196	Unknown	Male	Celecoxib	Vomiting
197	Unknown	Female	Cephalexin	Tremor
198	Adult	Male	Cephalexin	Itching
199	Unknown	Female	Cerelac Wheat Date	Vomiting
200	Adult	Male	Cetuximab	Itching all over

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
201	Adult	Female	Chlorpheniramine maleate	Sedation
202	Adult	Male	Chlorpheniramine maleate	Dry mouth
203	Elderly	Female	Chlorpheniramine maleate	Asthmatic attack
204	Adult	Male	Chlorpheniramine maleate	Insomnia
205	Adult	Female	Chloroquine	Metabolic acidosis, Drug poisoning, Intentional overdose, Intentional, drug misuse, Cardiac arrest, Dizziness, Speech disorder, Difficulty breathing, Convulsions generalized, Seizure ,Hypotensive ,Hypokalemia, Arrhythmia, Ventricular fibrillation, Sinus tachycardia, T wave flattening of, Defect conduction intraventricular, Ventricular ectopic beats
206	Adult	Female	Chloroquine	Intentional drug misuse
207	Adult	Male	Chlorpromazine	Tachycardia
208	Infant	Male	Ciprofloxacin	Respiratory distress, Tachycardia, Dyspnea, Irritability, Hypoactivity, Cyanosis, Poor peripheral perfusion
209	Unknown	Female	Ciprofloxacin	Diarrhea
210	Adult	Female	Ciprofloxacin	Nausea, Dizziness, Headache
211	Adult	Female	Ciprofloxacin	Erythematous rash
212	Adult	Male	Ciprofloxacin, Amoxicillin/ Clavulanic Acid	Angioedema
213	Adult	Male	Cisatracurium, Levetiracetam	Hypertension
214	Adult	Male	Citalopram	Vomiting
215	Adult	Male	Citalopram	Oedema
216	Adult	Male	Citrizine	Appetite absent
217	Elderly	Female	Clarithromycin	Taste metallic
218	Elderly	Male	Clarithromycin	Diarrhea
219	Unknown	Female	Clarithromycin	Tremor
220	Elderly	Female	Clarithromycin	Chest pain
221	Adult	Female	Clarithromycin	Taste metallic
222	Adult	Male	Clarithromycin	Acute diarrhea
223	Elderly	Male	Clarithromycin, Warfarin	INR increased
224	Elderly	Female	Clomipramine hydrochloride	Headache
225	Unknown	Female	Clonazepam, Paracetamol	QT prolonged

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
226	Unknown	Male	Clonazepam, Procyclidine, Cloxacillin	Thrombocytopenia
227	Adult	Female	Clonazepam, Lamotrigine, Sodium valproate, Folic acid	Epilepsy
228	Adult	Male	Clopidogrel	Dizziness
229	Unknown	Male	Clopidogrel	Skin rash
230	Infant	Female	Cloxacillin/ Clindamycin	Urticaria , itching
231	Elderly	Male	Colchicine	Allergic reaction
232	Elderly	Male	Colistimethate sodium	Acute kidney injury
233	Elderly	Male	Colistimethate sodium, Vancomycin	Acute kidney injury
234	Adult	Male	Cotrimoxazole	Lymphopenia, Thrombocytopenia
235	Adult	Female	Cotrimoxazole, Meropenem, Omeprazole	Anemia
236	Unknown	Unknown	Crizotinib	Facial rash, Neoplasm progression
237	Adult	Male	Cyclosporin, Prednisolone, Mycophenolate	Nephrotoxicity
238	Unknown	Female	Dapagliflozin	Nausea
239	Unknown	Male	Dapagliflozin propanediol monohydrate	Paraphimosis
240	Unknown	Unknown	Daratumumab,Bortezomib, Dexamethasone	Multiple myeloma progression
241	Adult	Female	Deferasirox	Acute kidney injury
242	Unknown	Unknown	Deferasirox	Libido decreased
243	Unknown	Unknown	Deferasirox	Proteinuria
244	Unknown	Unknown	Deferasirox	Eye disorder
245	Unknown	Unknown	Deferasirox	Hair loss
246	Unknown	Unknown	Deferasirox	Chest heaviness
247	Unknown	Unknown	Deferasirox	Pain in arm
248	Unknown	Female	Deferasirox	Fever, Herpes simplex, Flank pain, Shoulder pain, Chest pain (non-cardiac), Epigastric pain, Spleen enlarged, Pain in arm
249	Unknown	Unknown	Deferasirox	GI upset
250	Unknown	Male	Deferasirox	Acute kidney injury, Anaphylactic reaction, Product use in unapproved population
251	Unknown	Male	Deferasirox, Acetaminophen	Bilirubin increased, Incision site pain

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
252	Unknown	Male	Deferasirox, Acetaminophen	Abdominal pain, Acute gastroenteritis, Anion gap increased, Blood bicarbonate low, Colitis, Constipation, Cough, Dehydration, Diarrhea, Dizziness, Cholelithiasis, Gastritis, Alanine aminotransferase increased, Platelet count high, Hyperacidity, Creatinine increased, Jaundice, Nausea, Non-cardiac chest pain, Post procedural pain, Flank pain Cutaneous, hypersensitivity Vomiting
253	Elderly	Female	Dexamethasone, Low molecular weight heparin	Thyroid function abnormal
254	Child	Female	Dexamethasone	Vomiting
255	Adult	Female	Dexamethasone	Leukocytosis
256	Adult	Male	Dexamethasone	Blood sugar increased
257	Adult	Female	Dexamethasone	Tachycardia
258	Neonate	Female	Diazepam	Neonatal abstinence syndrome
259	Adult	Male	Diclofenac	Itching
260	Adult	Female	Diclofenac	Rash
261	Elderly	Female	Diclofenac	Fatigue
262	Elderly	Male	Diclofenac	Acidosis
263	Elderly	Male	Diclofenac	Allergy
264	Adult	Female	Diclofenac	Epigastric pain
265	Adolescent	Female	Diclofenac	Itchy rash
266	Unknown	Male	Diclofenac	Allergy
267	Unknown	Unknown	Diclofenac	Itching
268	Unknown	Male	Diclofenac	Skin rash
269	Unknown	Male	Diclofenac potassium	Redness of legs, Itching all over
270	Unknown	Female	Diclofenac sodium	Palpitation
271	Adult	Male	Diclofenac sodium	Allergy, Rash, Swelling
272	Unknown	Male	Diclofenac sodium, Levofloxacin	angioedema, itching
273	Adult	Female	Diclofenac, Low molecular weight heparin, Pethidine	Allergy
274	Infant	Female	Dimethicone	Allergy
275	Elderly	Male	Dipyridamole	Headache, Flushing

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
276	Adult	Female	Docetaxel	Tachycardia
277	Elderly	Male	Docetaxel	Neuropathy, Mononeuritis multiplex
278	Elderly	Female	Domperidone	Palpitation
279	Child	Male	Doxorubicin	Anaphylaxis
280	Adult	Female	Doxycycline	gastritis
281	Child	Male	DPT Vaccine	Swelling
282	Adolescent	Female	Dupilumab	Off label use
283	Adult	Female	Dydrogesterone, Mefenamic Acid	Dizziness, Fatigue, Diarrhea, Tachycardia, Anorexia, Insomnia
284	Adult	Male	Efavirenz, Emtricitabine, Tenofovir disoproxil fumarate	Immune reconstitution inflammatory syndrome
285	Adult	Female	efavirenz,emtricitabine, Tenofovir disoproxil fumarate	Maculopapular rash, Sore throat
286	Adult	Female	Eltrombopag	Maternal exposure during pregnancy
287	Unknown	Female	Eltrombopag olamine	Respiratory failure
288	Unknown	Female	Empagliflozin	Angioedema
289	Unknown	Female	Empagliflozin	Urinary tract infection
290	Adult	Male	Emtricitabine, Atorvastatin, Ritonavir	Abdominal pain, Nausea, Fever, Triglycerides high
291	Unknown	Male	Enoxaparin	ALT increased
292	Unknown	Male	Enoxaparin	ALT high
293	Unknown	Unknown	Enoxaparin	Melena
294	Adult	Male	Enoxaparin	Thrombocytopenia
295	Adult	Female	Enoxaparin sodium	thrombocytopenia
296	Elderly	Male	Entecavir monohydrate	Allergy
297	Unknown	Male	Ergocalciferol, Nicotinamide, Pyridoxine hydrochloride, Riboflavin, Thiamine mononitrate	Breath shortness
298	Infant	Female	Erythromycin	Loose motions
299	Adult	Male	Erythromycin	Abdominal pain
300	Adult	Female	Erythropoietin, Atenolol, Folic acid, Omeprazole	Hypertension, Increased number of platelets
301	Adult	Female	Escitalopram	Palpitations, General body pain, Nausea, Abdominal pain
302	Unknown	Male	Esomeprazole	Stool bloody
303	Adult	Female	Esomeprazole	Difficulty breathing

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
304	Unknown	Male	Ethinyl Estradiol/Levonorgestrel, Ferrous Fumarate amoxicillin/clavulanic acid	Facial rash, Rash
305	Unknown	Male	Etoricoxib, Glucosamine, Lansoprazole	Hand swelling
306	Unknown	Female	Everolimus	Ovulation disorder, Polycystic ovary
307	Adult	Female	Famotidine	Heartburn
308	Adult	Male	Famotidine	Nausea and vomiting symptoms
309	Elderly	Male	Favipiravir	ALT increased
310	Elderly	Male	Favipiravir	Deranged liver function tests
311	Elderly	Male	Favipiravir	Elevated liver enzyme levels
312	Adult	Male	Favipiravir	Drug-induced hepatotoxicity
313	Adult	Male	Favipiravir	Abnormal LFTs
314	Adult	Male	Favipiravir	ALT increased
315	Elderly	Male	Favipiravir	ALT high
316	Elderly	Male	Favipiravir	Raised liver enzymes
317	Unknown	Female	Ferric carboxymaltose	Rash
318	Unknown	Female	Ferric carboxymaltose	Rash
319	Adult	Female	Ferrous sulfate	Constipation, nausea
320	Adult	Female	Ferrous sulfate	Constipation
321	Adult	Female	Ferrous Sulfate	Constipation
322	Adult	Female	Ferrous Sulfate	Heartburn
323	Adolescent	Female	Ferrous sulfate/Folic acid	Constipation
324	Adolescent	Female	Ferrous sulfate/Folic acid	Dyspepsia, vomiting
325	Elderly	Female	Ferrous sulfate/Folic acid	Nausea
326	Unknown	Female	Ferrous sulfate/Folic acid	Diarrhea
327	Adult	Female	Ferrous sulfate/Folic acid	Constipation
328	Adult	Female	Ferrous sulfate/Folic acid	Constipation
329	Adult	Female	Ferrous sulfate/Folic acid	Nausea
330	Adult	Female	Ferrous sulfate/Folic acid	Constipation
331	Adult	Female	Ferrous sulfate/Folic acid	Constipation
332	Adult	Female	Ferrous sulfate/folic acid	Constipation
333	Adult	Female	Ferrous sulfate/folic acid	Nausea
334	Elderly	Female	Ferrous Sulphate	Vomiting
335	Adult	Female	Ferrous Sulphate	Constipation

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
336	Elderly	Female	Ferrous Sulphate	Abdominal pain
337	Elderly	Female	Ferrous Sulphate	Abdominal pain
338	Elderly	Female	Ferrous Sulphate	Vomiting
339	Adult	Female	Ferrous Sulphate	Vomiting
340	Adult	Female	Ferrous Sulphate	Heartburn
341	Adult	Female	Ferrous Sulphate/folic acid, Low molecular weight heparin, Paracetamol	Allergy
342	Adult	Female	Ferrous Sulphate	Gastritis
343	Unknown	Male	Filgrastim, Deferasirox piperacillin/ tazobactam, Vancomycin	Premature ventricular contractions, Arrhythmia, Febrile neutropenia, Cellulitis of face
344	Elderly	Male	Finasteride	Rash
345	Elderly	Male	Fluconazole, warfarin	Raised INR
346	Unknown	Female	Flunarizine	Spasm and Cramps
347	Adult	Male	Flunarizine	Depression
348	Adult	Female	Fluphenazine	Schizo-affective type schizophrenia
349	Elderly	Female	Fluticasone	Swelling NOS
350	Adult	Female	Fluticasone	Throat infection, Fungal rash
351	Adult	Female	Fluticasone	Headache
352	Elderly	Female	Fluticasone	Nausea
353	Unknown	Female	Fluticasone propionate	Itchy throat
354	Adult	Female	Fluticasone, Vilanterol	Abnormal breathing
355	Adult	Female	Folic acid	Nausea, vomiting
356	Adult	Female	Folic acid	Breathing difficult
357	Adult	Female	Folic acid	Constipation
358	Infant	Female	Frusemide	Polyuria
359	Child	Female	Frusemide	Hypomagnesemia
360	Adult	Male	Frusemide, Insulin injection biphasic, Meropenem, Atorvastatin, piperacillin/ tazobactam	Hypokalemia
361	Adult	Male	Frusemide, Levetiracetam, Low molecular weight heparins	Nephrotoxicity
362	Unknown	Female	Gabapentin	Acidemia
363	Unknown	Female	Gefitinib	Disease progression

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
364	Unknown	Male	Gemfibrozil	Lethargy
365	Unknown	Unknown	Gentamicin	Balance difficulty
366	Unknown	Female	Gliclazide	Dizziness, Itching, Angioneurotic edema
367	Elderly	Female	Gliclazide	Fatigue
368	Adult	Female	Gliclazide	Palpitation
369	Elderly	Female	Glimepiride	Gastritis
370	Elderly	Male	Glimepiride	Acidosis
371	Elderly	Female	Glimepiride	GI pain
372	Elderly	Female	Glimepiride	Fatigue
373	Elderly	Male	Glimepiride	Hypoglycemia
374	Elderly	Male	Glimepiride	Insomnia
375	Adult	Female	Glucose	Allergy, Itching, Redness
376	Adult	Female	Glycerin	Itching
377	Elderly	Male	Heparin	Thrombocytopenia
378	Elderly	Female	Heparin	Thrombocytopenia
379	Unknown	Female	Hydrochlorothiazide	Tremor
380	Elderly	Female	Hydrochlorothiazide	Hyperuricaemia
381	Elderly	Female	Hydrochlorothiazid	Hyperuricaemia
382	Adult	Female	Hydrochlorothiazide	Headache
383	Elderly	Female	Hydrochlorothiazide	Cough
384	Elderly	Female	Hydrochlorothiazide	Headache
385	Adult	Male	Hydrochlorothiazide	Cough
386	Elderly	Female	Hydrochlorothiazide	Palpitation
387	Adult	Female	Hydrochlorothiazide	Palpitation
388	Elderly	Female	Hydrochlorothiazide	Dizziness
389	Elderly	Female	Hydrochlorothiazide	Headache
390	Elderly	Male	Hydrochlorothiazide	Chest cold
391	Elderly	Female	Hydrochlorothiazide	Abdominal pain
392	Elderly	Male	Hydrochlorothiazide	Headache
393	Elderly	Female	Hydrochlorothiazide	Cough
394	Elderly	Female	Hydrochlorothiazide	Dizziness
395	Elderly	Male	Hydrochlorothiazide	Dizzy
396	Unknown	Female	Hydrochlorothiazide	palpitation

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
397	Unknown	Male	Hydrochlorothiazide, Frusemide, Azithromycin, Omeprazole	Hypokalemia
398	Elderly	Female	Hydrochlorothiazide	Shortness of breath
399	Unknown	Male	Hydrochlorothiazide	Fatigue Distress respiratory, Rash
400	Elderly	Female	Hydrocortisone	Heartburn
401	Adult	Female	Hydrocortisone	Respiratory arrest
402	Unknown	Unknown	Hydrocortisone	Headache
403	Child	Female	Hydrocortisone	Blood sugar increased
404	Adolescent	Female	Hydrocortisone	Blood sugar increased
405	Elderly	Female	Hydrocortisone sodium succinate	Headache
406	Adolescent	Female	Hydroxycarbamide	Mucositis oral
407	Adult	Male	Hydroxychloroquine, Azithromycin	Torsade de pointes, Crackles
408	Adult	Male	Hydroxychloroquine, Azithromycin, Tocilizumab, Low molecular weight, heparin, piperacillin/ tazobactam, Methylprednisolone, Lopinavir/Ritonavir, Teicoplanin, Frusemide, Meropenem	Atrial flutter, Supraventricular tachycardia
409	Adult	Male	Hydroxychloroquine, Lopinavir/ritonavir	Electrocardiogram QTc interval prolonged
410	Unknown	Male	Hydroxychloroquine, Lopinavir/ritonavir	Electrocardiogram QTc interval prolonged
411	Adult	Female	Hydroxyprogesterone	Rash generalized
412	Adult	Female	Hydroxyzine	Vomiting
413	Unknown	Female	Hyoscine-N-butyl bromide	Maculopapular rash
414	Infant	Male	Hyoscine-N-butyl bromide	Urinary retention, Sweating
415	Adolescent	Male	Hyoscine-N-butyl bromide	Constipation
416	Adult	Male	Hyoscine-N-butyl bromide	Mydriasis
417	Adult	Female	Hyoscine-N-butyl bromide	Tachycardia, Dry throat
418	Adult	Female	Ibuprofen	Allergy
419	Unknown	Female	Ibuprofen	Skin rash, Itching, Lip swelling
420	Elderly	Male	Ibuprofen	Tremor
421	Elderly	Male	Ibuprofen	Sensitive skin

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
422	Elderly	Female	Ibuprofen	Epigastric pain
423	Elderly	Female	Ibuprofen	Gastritis
424	Elderly	Male	Ibuprofen	Allergy
425	Unknown	Female	Ibuprofen	Tremor
426	Unknown	Female	Ibuprofen	Tremor
427	Unknown	Female	Ibuprofen	Tremor
428	Adult	Male	Ibuprofen	Puffiness face
429	Child	Female	Ibuprofen	Skin rash
430	Unknown	Female	Ibuprofen	Rash
431	Unknown	Male	Ibuprofen	Allergy
432	Adult	Female	Ibuprofen	Colic
433	Adult	Female	Ibuprofen	Delayed period
434	Elderly	Female	Indapamide	Hyperglycemia
435	Unknown	Male	Indapamide	Visual disturbances, dry mouth, Drowsiness
436	Adult	Male	Insulin Glargine	Feeling hungry
437	Elderly	Female	Insulin Glargine	Mouth ulcer
438	Adult	Female	Insulin Glargine, Metformin, Sitagliptin, Amlodipine/valsartan	Pain in hand, Prick pain
439	Adult	Female	Interferon beta-1a	General body pain, Fever
440	Unknown	Female	Interferon beta-1a	leg Muscle spasms
441	Unknown	Female	Interferon beta-1a	Nauseated, Vomited
442	Adult	Female	Interferon beta-1a	Headache
443	Unknown	Female	Interferon beta-1a	General body pain
444	Adult	Female	Interferon beta-1a	Bruise
445	Unknown	Female	Interferon beta-1a	Injection site redness
446	Adult	Female	Interferon beta-1a	Numbness of lower extremities
447	Adult	Female	Interferon beta-1a	Injection site redness
448	Adult	Female	Interferon beta-1a	Injection site redness
449	Adult	Female	Interferon beta-1a	Multiple sclerosis lesion, Multiple sclerosis relapse
450	Adult	Female	Interferon beta-1a	Numbness of lower extremities
451	Adult	Female	Interferon beta-1a	Hot feeling in feet
452	Adult	Female	Interferon beta-1a	Burning leg
453	Adult	Female	Interferon beta-1a	Spasms, Refusal of treatment by patient

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
454	Elderly	Female	Interferon beta-1a, Lopinavir/Ritonavir	ALT increased
455	Elderly	Male	Interferon beta-1a, Lopinavir/Ritonavir, Ribavirin	Abnormal LFTs
456	Unknown	Male	Iohexol	Rash
457	Adult	Female	Iron	Allergic reaction
458	Adult	Female	Iron	Chest pain
459	Adult	Female	Iron	injection site pain
460	Unknown	Female	Iron ferrous hydroxide	Urticaria
461	Elderly	Male	Isosorbide dinitrate	Esophagus burn
462	Unknown	Female	Isosorbide dinitrate	Headache, Dizziness, Blurred vision
463	Elderly	Female	Isosorbide dinitrate	Palpitation
464	Unknown	Unknown	Ketoconazole	Application site allergy, Application site dryness
465	Adult	Male	Ketoconazole	Allergic skin reaction, Dry skin
466	Unknown	Male	Ketoconazole	ALLERGY, dry skin.
467	Unknown	Unknown	Labetalol	Character change
468	Adult	Female	Labetalol, Acetylsalicylic acid ,Fefol	Itching, rash
469	Adult	Female	Labetalol, ferrous Sulphate/folic acid, Chlorpheniramine	Itching
470	Unknown	Female	Lamotrigine	Depression, Sleep disturbance
471	Adolescent	Male	L-asparaginase	Allergy
472	Adolescent	Female	L-Asparaginase	Allergic reaction, hypotension, desaturation
473	Elderly	Male	Lenalidomide	Itchy rash
474	Adult	Female	Lenalidomide	Skin lesion
475	Elderly	Male	Lenalidomide	Rash
476	Unknown	Male	Levetiracetam	Mood disorder
477	Adult	Female	Levetiracetam	Convulsions
478	Adult	Male	Levetiracetam	Dizziness
479	Adult	Female	Levetiracetam, Gabapentin, Lamotrigine, Folic acid	Abusive behavior
480	Adult	Female	Levetiracetam, Lamotrigine	Memory loss
481	Unknown	Male	Levocetirizine Dihydrochloride	Palpitations

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
482	Unknown	Unknown	Levocetirizine Dihydrochloride	Palpitation
483	Elderly	Male	Levofloxacin	Fatigue
484	Unknown	Female	Levofloxacin	Pruritus
485	Adult	Male	Levofloxacin	Abnormal LFTs
486	Unknown	Male	Levofloxacin	Ligament sprain
487	Unknown	Male	Levofloxacin	Difficulty sleeping
488	Adult	Female	Levothyroxine	Abdominal pain
489	Adult	Female	Levothyroxine	Palpitations
490	Unknown	Female	Levothyroxine	Breath shortness
491	Unknown	Male	Levothyroxine	Breath shortness
492	Unknown	Female	Levothyroxine	Hypothyroidism, Prolapse, Enzyme level increased, Benign neoplasm, Fatigue, Lethargy
493	Unknown	Male	Lidocaine hydrochloride, Tolperisone hydrochloride	Red patches, itching all over body
494	Adult	Male	Linezolid	Thrombocytopenia
495	Elderly	Male	Linezolid	Thrombocytopenia
496	Adult	Male	Linezolid	Thrombocytopenia
497	Elderly	Male	Linezolid, Low molecular weight heparin	Thrombocytopenia
498	Adult	Female	Linezolid, Piperacillin, Low molecular weight heparin	Thrombocytopenia
499	Unknown	Male	Linezolid	Thrombocytopenia
500	Elderly	Female	Lisinopril	Headache
501	Elderly	Female	Lisinopril	Dry cough
502	Elderly	Male	Lisinopril	Dizziness
503	Elderly	Female	Lisinopril	Cough
504	Elderly	Male	Lisinopril	Cough
505	Adult	Female	Lisinopril	Cough
506	Adult	Female	Lisinopril	Cough
507	Unknown	Female	Lisinopril	Cough
508	Adult	Female	Lisinopril	Dry cough
509	Elderly	Male	Lisinopril	Cough
510	Elderly	Male	Lisinopril	Hypokalemia
511	Adult	Male	Lisinopril	Eye redness

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
512	Elderly	Female	Lisinopril	Cough
513	Elderly	Female	Lisinopril	Cough
514	Unknown	Female	Lisinopril	Tremor
515	Unknown	Female	Lisinopril	Tremor
516	Elderly	Male	Lisinopril	Cough
517	Adult	Female	Lisinopril	Dry cough
518	Adult	Female	Lisinopril	Headache
519	Elderly	Female	Lisinopril	Dizziness
520	Unknown	Female	Lisinopril	Tremor
521	Adult	Female	Lisinopril	Persistent dry cough
522	Unknown	Female	Lisinopril	Cough
523	Elderly	Female	Lisinopril	Dry cough
524	Unknown	Unknown	Lisinopril	Dry cough
525	Adult	Female	Lisinopril	Dry cough
526	Unknown	Male	Lisinopril	Skin rash
527	Adolescent	Female	Lisinopril, Tacrolimus	Hyperkalemia
528	Adult	Male	Lopinavir/ritonavir	Amylase high, abdominal pain, nausea
529	Elderly	Female	Lopinavir/ritonavir	Raised liver enzymes
530	Elderly	Female	Loratadine	Prickly heat
531	Unknown	Male	Loratadine	Loss of smell, loss of taste, sensitivity.
532	Unknown	Male	Low molecular weight heparin	Thrombopenia
533	Unknown	Male	Low molecular weight heparin	Thrombocytopenia
534	Elderly	Female	Low molecular weight heparin	Thrombocytopenia
535	Elderly	Male	Low molecular weight heparin	Thrombocytopenia
536	Elderly	Male	Low molecular weight heparin	Platelet count low
537	Adult	Male	Low molecular weight heparin, Levetiracetam Ascorbic acid	Hematuria
538	Unknown	Female	Low molecular weight heparins	Allergy
539	Elderly	Female	Low molecular weight heparins	Thrombocytopenia

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
540	Unknown	Male	Low molecular weight heparins, Levofloxacin, Atorvastatin	Thrombocytopenia
541	Adult	Male	Low molecular weight, heparin, Clarithromycin, Ceftriaxone	Bleeding
542	Adult	Female	Low molecular weight, heparin, Cotrimoxazole, Human albumin	Thrombocythemia
543	Unknown	Female	Mefenamic Acid	Erythematous rash
544	Unknown	Male	Mefenamic acid	Diarrhea, nausea, vomiting
545	Adult	Female	Mefenamic acid	Acidosis
546	Adult	Female	Mefenamic acid	Gastritis
547	Adult	Female	Mefenamic acid	Gastritis
548	Adult	Female	Mefenamic acid	Allergy
549	Unknown	Male	Meropenem	Diarrhea
550	Elderly	Male	Meropenem	Thrombocytopenia
551	Elderly	Male	Meropenem	Renal impairment
552	Adult	Female	Meropenem, Cotrimoxazole, Human albumin	Thrombocytopenia
553	Adult	Male	Meropenem, Omeprazole, Noradrenaline	Increased liver stiffness Deranged liver function tests
554	Adult	Female	Mesalazine	Diarrhea, nausea
555	Unknown	Unknown	Mesalazine	Epigastric discomfort
556	Adult	Male	Metoclopramide	Chest tightness
557	Adolescent	Female	Metoclopramide	Headache, dizziness
558	Adult	Female	Metformin	Headache
559	Adult	Male	Metformin	Dizziness
560	Elderly	Female	Metformin	Stomach pain
561	Elderly	Male	Metformin	Dizziness
562	Elderly	Female	Metformin	Dizziness
563	Elderly	Female	Metformin	Tachycardia
564	Adult	Male	Metformin	Fatigue
565	Elderly	Female	Metformin	Constipation
566	Elderly	Male	Metformin	Hypoglycemia
567	Elderly	Female	Metformin	Palpitation
568	Elderly	Male	Metformin	General body pain
569	Elderly	Female	Metformin	Palpitation

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
570	Elderly	Female	Metformin	Acidosis
571	Elderly	Female	Metformin	Nausea
572	Elderly	Female	Metformin	Gastritis
573	Adult	Female	Metformin	Insomnia
574	Unknown	Female	Metformin	Heartburn
575	Elderly	Female	Metformin	Nausea
576	Adult	Female	Metformin	Acidosis
577	Adult	Female	Metformin	Glycosylated hemoglobin high
578	Elderly	Female	Metformin	Burn esophageal
579	Elderly	Female	Metformin	Nephropathy
580	Elderly	Female	Metformin	Gastritis
581	Adult	Male	Metformin	Heartburn
582	Adult	Female	Metformin	Gastritis
583	Elderly	Male	Metformin	Diarrhea
584	Adult	Male	Metformin	Hyperacidity
585	Unknown	Male	Metformin	Vomiting
586	Elderly	Female	Metformin	Plasma acidosis
587	Adult	Female	Metformin	Abdominal spasm
588	Adult	Male	Metformin	Flatulence
589	Adult	Male	Metformin	Gastritis
590	Adult	Male	Metformin	Heartburn
591	Elderly	Female	Metformin	Heartburn
592	Adult	Female	Metformin	Gastritis
593	Elderly	Male	Metformin	Pain epigastric
594	Elderly	Female	Metformin	Diarrhea
595	Adult	Female	Metformin	Dyspepsia
596	Unknown	Unknown	Metformin	Dyspepsia
597	Adult	Male	Metformin	Hyperacidity
598	Adult	Female	Metformin	Allergic reaction
599	Adult	Female	Metformin	Vitamin B12 deficiency
600	Adult	Female	Metformin	Vitamin B12 deficiency
601	Elderly	Female	Metformin	UTI
602	Adult	Female	metformin	Hyperacidity
603	Unknown	Female	Metformin hydrochloride, Sitagliptin phosphate monohydrate, Cholecalciferol	Febrile neutropenia

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
604	Child	Female	Metformin hydrochloride, Dopamine hydrochloride, Propranolol	Metformin associated lactic acidosis, Poor peripheral perfusion, Bradycardia, Hypotensive, Hyperkalemia, Lethargic, Creatinine increased, Hyperglycemia, Drug toxicity, Off label use in unapproved age group
605	Unknown	Female	Metformin Hydrochloride/ Vildagliptin	Vomiting
606	Child	Female	Metformin, Propranolol	Impaired renal function,, Hyperkalemia, Lactic acidosis, Off label use
607	Adult	Female	Metformin, Vildagliptin	Constipation
608	Elderly	Female	Metformin/Vildagliptin	Nausea
609	Unknown	Female	Metformin/Vildagliptin	Vomiting
610	Unknown	Female	Metformin/Vildagliptin	Vomiting
611	Unknown	Male	Metformin/Vildagliptin	Palpitation
612	Child	Male	Methotrexate	Painful rash
613	Adult	Male	Methyldopa, Calcium carbonate, Nifedipine	Deranged liver function tests
614	Adult	Female	Metoclopramide	Acute dystonia
615	Adult	Female	Metoclopramide	Acute dystonia
616	Elderly	Male	Metoclopramide	Acute dystonia
617	Adult	Female	Metoclopramide	Movements abnormal
618	Adult	Female	Metoclopramide	Tongue dystonia, Trismus, Dizziness, Shortness of breath
619	Adult	Male	Metronidazole	Gastritis
620	Adult	Female	Metronidazole	Gastritis
621	Adult	Male	Metronidazole	Vomiting
622	Elderly	Male	Metronidazole	Oral thrush
623	Infant	Female	Midazolam	Bradypnea, Developmental regression, Hepatosplenomegaly, Seizure, Bicytopenia
624	Child	Male	Midazolam	Hypotension
625	Adult	Male	Midazolam, Levetiracetam	Hypertension
626	Adult	Female	Misoprostol	Diarrhea, Epigastric pain
627	Adult	Female	Misoprostol	Headache Breathing difficult Epigastric pain

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
628	Unknown	Female	Misoprostol	Chills, Dizziness, Nausea
629	Adult	Female	Misoprostol	Diarrhea, Shivering
630	Adult	Female	Misoprostol	Shivering
631	Adult	Female	Misoprostol	Watery diarrhea
632	Adult	Female	Misoprostol	Watery diarrhea
633	Adult	Male	Montelukast	Palpitation
634	Child	Female	Morphine	Urticaria
635	Adult	Female	Moxifloxacin	Off label use Drug use for unapproved indication
636	Unknown	Male	Moxifloxacin	Itching
637	Unknown	Female	Moxifloxacin hydrochloride	Vomiting, diarrhea
638	Elderly	Female	Multivitamin	Dizziness
639	Unknown	Male	Mycophenolate	Diarrhea
640	Unknown	Male	Mycophenolate	Diarrhea
641	Unknown	Male	Mycophenolate	Diarrhea
642	Adult	Male	Mycophenolate mofetil, Prednisolone, Tacrolimus	Anemia, Thrombocytopenia
643	Adult	Male	Mycophenolate, Everolimus, Prednisolone, Amlodipine	Hyperlipidemia, Hypokalemia
644	Adult	Female	Mycophenolate, ferrous Sulphate/folic acid, Alfacalcidol	Nephrotoxicity
645	Adult	Female	Mycophenolate, Lisinopril, Prednisolone	Gastrointestinal tract biopsy, Diarrhea
646	Unknown	Female	Mycophenolate, Prednisolone, Tacrolimus	Loose motions
647	Adult	Male	Mycophenolate, Tacrolimus, Prednisolone	Sepsis, Pancytopenia, Lymphopenia, Hematuria
648	Adult	Female	Naproxen, Clomipramine Hydrochloride	Numbness, Gastrointestinal upset
649	Unknown	Male	Natalizumab	Skin red, Skin rash
650	Adult	Female	Nitrofurantoin	Discoloration urine
651	Adult	Male	Noradrenaline, Metoclopramide, Hydrocortisone, Lisinopril, Carvedilol, Atorvastatin, Acetylsalicylic acid	Nephrotoxicity
652	Elderly	Female	Norethindrone	Headache
653	Adult	Female	Norethindrone	Hair loss

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
654	Adult	Female	Norethindrone	Neonatal insufficient breast milk syndrome
655	Adult	Female	Norethindrone	Low back pain
656	Adult	Female	Norethindrone	Bleeding
657	Unknown	Female	Octreotide acetate	Blurred vision, Cataract, Migraine, Visual acuity reduced, Visual disturbances
658	Unknown	Male	Olanzapine	Neutropenia, Hyperprolactinemia, Hyperprolinemia
659	Elderly	Female	Olanzapine	Dysphasia
660	Unknown	Male	Olmesartan, medoxomil	Tinnitus
661	Adult	Female	Omeprazole	Abdominal pain
662	Elderly	Female	Omeprazole	Abdominal pain
663	Adult	Female	Omeprazole, Cotrimoxazole, Human albumin	Anemia, Thrombocytopenia
664	Unknown	Male	Omeprazole, Levofloxacin, Allopurinol	Thrombocytopenia
665	Adult	Male	Omeprazole, Tigecycline, Colistin	Thrombocytopenia
666	Elderly	Female	Omperazole	Epigastric pain & acidity
667	Adult	Female	Ondansetron, Promethazine, Pethidine	Allergy
668	Adult	Female	Oxaliplatin	Shortness of breath, Chest tightness, Rash
669	Adult	Male	Oxaliplatin	Drug toxicity
670	Adult	Female	Paracetamol	Poisoning
671	Adult	Female	Paracetamol	Swelling
672	Unknown	Female	paracetamol	mild itching in hand, swelling in hand, redness in hand
673	Adult	Female	Paracetamol	Itching, Shortness of breath, Flushing
674	Unknown	Female	Paracetamol	Itching
675	Child	Female	Paracetamol	Allergic reaction
676	Adolescent	Female	Paracetamol	Abdominal pain, nausea, vomiting, dizziness, lethargic
677	Elderly	Female	Paracetamol	ALT high
678	Adult	Female	Paracetamol, Acetylsalicylic acid, Nifedipine, Lisinopril	Nephrotoxicity

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
679	Adult	Male	Paracetamol, Proguanil, Ethanol	Metabolic acidosis, Drug poisoning, Violence, Weakness, Breathing difficult, Hypotension, General physical health deterioration, Drowsiness, Vomiting, Nausea, Headache, Agitation, Respiratory arrest, Confusion, Hypokalemia Defect conduction intraventricular, Seizures, Intentional drug misuse, Intentional overdose, Acute overdose
680	Adult	Female	Paracetamol, Tramadol, Ranitidine, Lisinopril, Clopidogrel, Atorvastatin, Carvedilol, Frusemide, Spironolactone, Acetylsalicylic acid	Acute renal failure
681	Unknown	Female	Pegylated liposomal doxorubicin hydrochloride	Febrile neutropenia
682	Unknown	Female	Pegylated liposomal doxorubicin hydrochloride	Febrile neutropenia
683	Adult	Male	Penicillin, Acetylsalicylic acid, Atenolol	Allergy
684	Adolescent	Male	Pentamidine isethionate	Shortness of breath, Tachycardia, Giddiness, Generalized itching, Pain, Hypotension
685	Infant	Female	Pentavalent vaccine	Swelling of injection site
686	Adult	Female	Perindopril	Dry cough
687	Adult	Female	Perindopril	Dry cough
688	Adult	Female	Perindopril arginine / Amlodipine besilate	Dry cough
689	Adult	Female	Perindopril arginine / Amlodipine besilate	Palpitation
690	Adult	Male	Perindopril arginine/Amlodipine besilate	Tinnitus
691	Unknown	Male	Perindopril arginine/Indapamide/ amlodipine.	hypokalemia, hyponatremia
692	Unknown	Female	Perindopril/Indapamide, sertraline	Hyponatremia
693	Child	Male	Phenobarbital	Skin rash
694	Child	Female	Phenobarbitone	Maculopapular rash, Pyrexia, Hemoglobin low

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
695	Child	Male	Phenoxymethylpenicillin	Vomiting
696	Elderly	Female	Phenytoin	Sleepiness
697	Adult	Male	Phenytoin	Thrombophlebitis arm
698	Adult	Male	Phenytoin	High cholesterol
699	Elderly	Female	Pioglitazone	Dizziness
700	Elderly	Female	Pioglitazone	Swelling of legs
701	Child	Male	piperacillin/ Tazobactam	Vomiting
702	Elderly	Male	piperacillin/ Tazobactam	Itching
703	Adult	Female	piperacillin/ Tazobactam	Itching
704	Infant	Male	piperacillin/ Tazobactam	Nephrogenic diabetes insipidus, Polyuria
705	Child	Male	piperacillin/ Tazobactam	Itching, Respiratory distress
706	Child	Female	piperacillin/ Tazobactam	Allergic reaction
707	Adult	Male	Piperacillin/ Tazobactam, Levofloxacin, Allopurinol	Thrombocytopenia
708	Adult	Male	piperacillin/ tazobactam, Omeprazole, Human albumin	Deranged liver function tests
709	Adult	Male	piperacillin/ tazobactam, Tigecycline, Colistimethate	Thrombocytopenia
710	Unknown	Male	piperacillin/tazobactam	Nephrotoxicity
711	Unknown	Female	Piperacillin/tazobactam	Shortness of breath, Nausea
712	Unknown	Male	Piperacillin/tazobactam, Dopamine, Metronidazole	Torsade de pointes, Serum potassium decreased
713	Neonate	Female	Pneumococcal 13 valent vaccine	Generalized macular rash
714	Adult	Unknown	Potassium chloride, Cotrimoxazole, Human albumin	Hyperkalemia
715	Adult	Male	Prazosin	Dizziness
716	Elderly	Male	Prazosin	Leg oedema
717	Unknown	Female	Prednisolone	Shortness of breath
718	Unknown	Male	Prednisolone	Encapsulating peritoneal sclerosis
719	Adult	Male	Prednisolone, Lisinopril, Mycophenolate	Hypocalcemia
720	Adult	Male	Prednisolone, Tacrolimus Acetylsalicylic acid, Atorvastatin	Hyperglycemia
721	Adult	Male	Pregabalin	Dizziness

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
722	Unknown	Female	Procyclidine, Risperidone	Hyperprolactinemia
723	Unknown	Female	Promethazine, Lactulose, Procyclidine	Prolactin increased
724	Adult	Female	Pyridostigmine	Blurred vision
725	Adult	Male	Rabeprazole	Allergic skin reaction
726	Unknown	Male	Remdesivir	Abnormal LFTs
727	Unknown	Male	Remdesivir	Abnormal LFTs
728	Unknown	Female	Ribociclib succinate	Headache
729	Adult	Male	Rifampicin, Isoniazide, Cyclosporine	Drug toxicity
730	Adult	Female	Rifampicin, Isoniazide, Pyrazinamide, Ethambutol	Liver function test increased
731	Adult	Female	Risperidone	Hyperprolactinemia
732	Adult	Female	Risperidone	Schizophreniform disorder
733	Unknown	Male	Risperidone	Diarrhea
734	Adult	Female	Risperidone	Insomnia
735	Adult	Unknown	Rituximab	Itching, Swelling, Breathlessness, Throat discomfort
736	Child	Female	Rituximab	Headache, Vomiting
737	Adult	Male	Rituximab, Methotrexate	Neutropenia
738	Elderly	Male	Rivaroxaban	Hematuria
739	Adolescent	Female	Rivaroxaban, Atorvastatin, Frusemide, Amlodipine	Nephrotoxicity
740	Adult	Male	Rocuronium bromide	Skin rash
741	Adult	Female	Rosuvastatin	Chest pain
742	Adult	Male	Rosuvastatin	Palpitation
743	Unknown	Female	Rosuvastatin	Muscle pain, Joint pain
744	Adult	Female	Saccharated iron oxide	Shortness of breath, palpitation
745	Adult	Female	Salbutamol	Chest pain
746	Adult	Female	Salbutamol	Allergic asthma, dizziness
747	Child	Female	Salbutamol	Tachycardia
748	Adult	Male	Salbutamol, Ipratropium bromide, Meropenem, Frusemide, piperacillin/ tazobactam	Hypokalemia
749	Unknown	Female	Sevelamer	Allergy
750	Neonate	Male	Similac	Vomiting
751	Unknown	Male	Similac	Vomiting

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
752	Adult	Female	Sitagliptin	Vertigo
753	Adult	Female	Sitagliptin	Fatigue
754	Elderly	Female	Sitagliptin	Weakness
755	Unknown	Male	Sitagliptin	Mild acute pancreatitis
756	Unknown	Male	Sitagliptin	Allergic rash
757	Child	Male	Sodium chloride	Throat sore
758	Adult	Male	Sodium valproate, Levetiracetam, Lamotrigine	Hyperammonemia
759	Unknown	Female	Sodium valproate	GI upset
760	Unknown	Female	Sodium valproate	Extrapyramidal symptoms
761	Unknown	Female	Sodium valproate, Clonazepam	Hyponatremia
762	Neonate	Female	Solutions for parenteral nutrition	Extravasation
763	Unknown	Male	Somatropin	Joint pain
764	Unknown	Male	Somatropin	Pain during injection
765	Unknown	Male	Somatropin	Pain during injection
766	Adolescent	Male	Somatropin	Brain tumor
767	Elderly	Female	Spirolactone, Potassium chloride, Frusemide	Impaired renal function
768	Adolescent	Female	Sulfasalazine	Urticated rash
769	Unknown	Female	Sumatriptan	Pain
770	Unknown	Female	Sumatriptan	Headache
771	Adult	Male	Tacrolimus, Prednisolone, Calcium carbonate	Sepsis
772	Adult	Female	Tacrolimus, Prednisolone, Mycophenolate	Hypomagnesemia, Neurotoxicity
773	Adult	Male	Tacrolimus, Prednisolone, Mycophenolate	Hypomagnesemia
774	Adult	Female	Tacrolimus, Prednisolone, Mycophenolate	Hypomagnesemia
775	Adult	Male	Tacrolimus, Prednisolone, Mycophenolate mofetil	Deranged liver function tests
776	Unknown	Unknown	Tacrolimus, Rituximab	Graft versus host disease in gastrointestinal tract
777	Adult	Male	Tenofovir	Fanconi syndrome
778	Elderly	Female	Theophylline	Convulsions, Hypokalemia, Jerky movement NOS
779	Adult	Female	Thyroxine	Dyspepsia

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
780	Unknown	Female	Thyroxine	Weight gain
781	Unknown	Male	Tigecycline	Nausea, Vomiting, Diarrhea
782	Adult	Female	Tigecycline, Ipratropium bromide, Bromhexine	Hepatotoxicity
783	Adult	Male	Tigecycline, Omeprazole, Human albumin	Deranged liver function tests
784	Adult	Female	Tigecycline, Vancomycin, Meropenem	Deranged liver function tests
785	Adult	Male	Tocilizumab	Allergy, Flushing, Itching, Burning sensation
786	Adult	Male	Tocilizumab	Rash, Itching
787	Elderly	Female	Tocilizumab	ALT high
788	Unknown	Unknown	Tofacitinib citrate	Hyperkalemia
789	Elderly	Female	Topiramate	Renal colic
790	Adult	Female	Tramadol	Vomiting
791	Adult	Female	Tramadol	Vomiting, Dizziness
792	Child	Male	Tramadol	Vomiting
793	Elderly	Male	Tramadol	Hypotension
794	Adult	Female	Tramadol	Nausea
795	Unknown	Female	Tramadol	Nausea
796	Adult	Male	Tramadol, Metoclopramide	Supraventricular tachycardia
797	Adult	Female	Tramadol, Ranitidine, Ibuprofen	Allergy
798	Elderly	Female	Triprolidine / pseudoephedrine.	Abdominal pain
799	Elderly	Female	Triprolidine / pseudoephedrine.	Sedation excessive
800	Unknown	Female	Triptorelin acetate	Anaphylactic reaction
801	Child	Female	Triptorelin acetate	Anaphylactic reaction
802	Adult	Male	Valganciclovir	Cytopenia
803	Adult	Male	Valsartan	Cough
804	Elderly	Female	Valsartan	Fatigue, dizziness
805	Adult	Male	Valsartan	Dizziness
806	Elderly	Female	Valsartan	Dizziness
807	Elderly	Female	Valsartan	Allergy
808	Elderly	Female	Valsartan	Dry cough
809	Elderly	Male	Valsartan	Hoarseness of voice
810	Adult	Male	Valsartan	Cough

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
811	Elderly	Female	Valsartan	Headache, drowsiness, body ache
812	Adult	Female	Valsartan	Headache
813	Adult	Male	Valsartan	Headache
814	Elderly	Female	Valsartan	Cough
815	Unknown	Female	Valsartan	Irritant cough
816	Elderly	Female	Valsartan	Dizziness
817	Elderly	Female	Valsartan	Drowsiness
818	Unknown	Unknown	Valsartan	Uncontrolled hypertension
819	Elderly	Female	Valsartan	Coughing
820	Adult	Female	Valsartan	Palpitation
821	Unknown	Female	Valsartan	Nausea
822	Unknown	Male	Valsartan	Palpitation, Chest pain, Headache
823	Adult	Female	Valsartan	Cough
824	Elderly	Female	Valsartan	Cough
825	Unknown	Male	Valsartan	Palpitation, Headache, Acidemia
826	Adult	Male	Vancomycin	Skin reaction
827	Unknown	Female	Vancomycin	Red man
828	Unknown	Male	Vancomycin	Red man
829	Adult	Female	Vancomycin	Red man syndrome, Fever
830	Adult	Male	Vancomycin	Nephrotoxicity
831	Elderly	Female	Vancomycin	Itching, Rash
832	Adolescent	Female	Vancomycin	Skin rash, Headache, Hypotension
833	Child	Male	Vancomycin	Allergy
834	Adult	Male	Vancomycin	Shortness of breath
835	Unknown	Female	Vancomycin	Elevated liver enzyme levels
836	Elderly	Female	Vancomycin, Ceftriaxone, Piperacillin/Tazobactam, carbapenem	Cutaneous symptom
837	Adult	Male	Vancomycin, Metoclopramide, Hydrocortisone	Nephrotoxicity
838	Adult	Male	Vancomycin, Paracetamol	Allergy
839	Adult	Male	Vildagliptin	Flatulence
840	Child	Male	Vincristine	Neuropathy
841	Elderly	Female	Vitamin B1/ B6/ B12	Nausea
842	Adult	Female	Voriconazole	Hyperkalemia
843	Elderly	Female	Warfarin	Nasal bleeding

S.No	Age group	Sex	Drug name (WHODrug)	Reaction / event (MedDRA)
844	Adult	Male	Warfarin	Raised INR
845	Elderly	Male	Warfarin	Epistaxis
846	Adult	Female	Warfarin	Supratherapeutic INR
847	Elderly	Female	Warfarin	Raised INR
848	Adolescent	Male	Warfarin	Raised INR
849	Elderly	Male	Warfarin	Raised INR
850	Elderly	Male	Warfarin	Bleeding
851	Adult	Male	Warfarin	Bleeding
852	Adult	Male	Warfarin	Raised INR
853	Unknown	Male	Warfarin, Famotidine	Anticoagulant effect increased
854	Unknown	Unknown	Intrauterine contraceptive device	Acne
855		Male	Metformin	Blood glucose abnormal, Suspected counterfeit product