



Jordan Pharmacovigilance Database Analysis

(2010 - 2014)

**Rational Drug Use &
Pharmacovigilance
Department**

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Pharmacovigilance Department**



His Royal Majesty King Abdullah the Second said:

“Improving the quality of the citizen’s life requires proper health care for all people. The healthy citizen who is reassured about his and his family’s health is the one who is capable of working and being productive”.





JFDA General Director, Dr. Hayel Obeidat said:

“We believe that 21st century pharmacovigilance must also include tighter and more regularly monitored post-approval bioequivalence measures. It’s a new and difficult task and calls for better validated methodologies for both data collection and signal prioritization. It is the responsibility of the JFDA to take the leadership role and help educate our various constituencies to the importance of 21st century Phase IV monitoring and interventions.”

Preface:

Rationale drug use and pharmacovigilance department in "Jordan food and drug administration (JFDA)" with the cooperation of Health Hazard Evaluation Committee has analyzed the domestic adverse drug reactions (ADRs) reports which considered the cornerstone of post-marketing surveillance in Jordan in the period (2010-2014).

The ultimate goals of analysis of ADRs database are to identify the most common drugs involved in causing ADRs and the most commonly reported ADRs and to ensure safety of drugs through continuous monitoring of all registered drugs in Jordan. The results of this study will enable the health authority to take an appropriate action toward drugs at the proper time to ensure patient safety and improve public health.

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Abbreviations:

ADR: Adverse Drug Reaction

CIOMS: Council for International Organizations of
Medical Sciences

EMA: European Medicine Agency

EPS: Extrapyrarnidal Symptom

GI: Gastrointestinal

ICP: Intracranial Pressure

JFDA: Jordan Food & Drug Administration

KHCC: King Hussein Cancer Center

LSR: Local Safety Person

PV: Pharmacovigilance

QPPV: Qualified Person for Pharmacovigilance

RDU: Rational Drug Use

RMS: Royal Medical Services

WHO: World Health Organization

Jordan Food and Drug Administration:

Jordan Food and Drug Administration (JFDA) was established in 2003 as an independent public sector institution that is the main national competent authority for ensuring drug safety and efficacy in addition to food safety and quality.

Vision:

To excel regionally and globally as a pioneer in the field of food, medicine and related materials, so as to enhance public health and consumer's confidence.

Mission:

Ensuring food safety and quality, as well as effectiveness, quality and safety of the drug and related material through the application of controlled systems based on the scientific and international standards. Strengthen cooperation with partners and increase citizen awareness of proper handling and use of food and drug.

Core Values:

- Excellence
- Justice
- Loyalty
- Innovation & Creativity
- Transparency
- Initiation
- Teamwork

Pharmacovigilance

Definition:

"The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other medicine- related problem". (WHO, 2002)

Why Pharmacovigilance is important?

Good pharmacovigilance practice will identify the risks in the shortest possible time after the medicine has been marketed and will help to establish and/or identify risk factors. When communicated effectively, this information allows for intelligent, evidence-based prescribing with potential for preventing many adverse reactions and will ultimately help each patient to receive optimum therapy at a lower cost.

The post-marketing assessment of the benefits and risks of medical products can be achieved through collaborative efforts from regulatory bodies, healthcare providers, industry and the patients. Therefore, effective pharmacovigilance systems should communicate with the patients and healthcare professionals to ensure sharing of information related to drug safety.

Pharmacovigilance should be proactive in monitoring their possible consequences.

In order to prevent unnecessary suffering by patients and to decrease the financial loss sustained by the patient due to the inappropriate or unsafe use of medicines, it is essential that a monitoring system for the safety of medicines in Jordan is supported by doctors, pharmacists, nurses and other health professionals in the country.

The JFDA and the Rational Drug Use & Pharmacovigilance Department are committed to improve drug safety through continuous monitoring of adverse drug reactions in Jordan.

Why Pharmacovigilance is needed?

Pharmacovigilance is an important and integral part of clinical research. Both clinical trials safety and post-marketing pharmacovigilance are critical throughout the product lifecycle.

Once released into the market, a medicine leaves the secure and protected scientific environment of clinical trials and is legally set free for consumption by the general population. At this point, most medicines will only have been tested for short-term safety and efficacy on a limited number of carefully selected individuals.

Therefore, it is essential that new and medically still evolving treatments are monitored for their effectiveness and safety under real-life conditions post release. In summary, Pharmacovigilance is needed for:

- Patient safety (maximize benefit, minimize risk) which will be reflected on public health.
- Promoting rational use of medicines and adherence
- Economical concern (Cost – effective drugs)
- Industry requirements.
- Quality concern (Ensuring quality of a product from selection to use).
- Ethics: *"To know of something that is harmful to another person who does not know, and not telling, is unethical."*

Pharmacovigilance History in Jordan

- Pharmacovigilance system was established in 2001.
- WHO membership in 2002.

- In 2006, was the first approval of adverse drug reactions guidelines based on the ICH- Guidelines, which clarify the relation among stakeholders (Health authorities, healthcare providers, industry and patient).
- In 2010, the guidelines were updated according to JFDA/PV post marketing practical experience in Jordan.
- The Head of Pharmacovigilance section joined the Arab Technical Committee for medicines in the Arab League to review the EMA guidelines and came out with the Arab Good Pharmacovigilance Practice Guidelines, in March 2013.
- In February 2014, the pharmacovigilance section and Rational Drug Use Department in JFDA – Drug Directorate were merged into one department called "Rational Drug Use & Pharmacovigilance Department (RDU & PV department)".
- Between (2011-2015) five PV regional centers have been established in the north, middle and south of Jordan to increase the awareness about PV and promote reporting of ADRs; these centers are located at the following sites: Al-Karak

Government Teaching Hospital, Prince Hamzeh Hospital, Pharmacy faculty at Jordan University, King Abdullah University Hospital and Al-Bashir Hospital.

Objectives of Pharmacovigilance:

- To improve patient care and safety in relation to the use of medicines, and all medical and paramedical interventions.
- To improve public health and safety in relation to the use of medicines.
- To detect problems related to the use of medicines and communicate the findings in a timely manner.
- To contribute to the assessment of benefit, harm, effectiveness and risk of medicines
- To encourage the safe, rational and more effective (including cost effective) use of medicines.
- To promote understanding, education and clinical training in pharmacovigilance and its effective communication to health care professionals and the public.

Adverse Drug Reaction (ADR) Reporting System in Jordan:

Adverse Drug Reaction (ADR) is:

"A response to a drug which is noxious and unintended, and which occurs at doses normally used in man for the prophylaxis, diagnosis, or therapy of disease, or for the modifications of physiological function". This definition excludes overdose (either accidental or intentional), drug abuse, treatment failure and drug administration errors.

Adverse Drug Reaction (ADR) Reporting System:

On the basis of WHO reporting system, our system for data collecting, collating and assessment is similar to WHO recommendation and worldwide regulations. This reporting system considered as a useful tool for JFDA for activities such as looking for new safety concerns that might be related to a marketed product, evaluating a manufacturer's compliance to provide us with reports and responding to outside requests for information.

Reporting Methods:

- Online reporting through:

Website: www.jfda.jo

E-mail : jpc@jfda.jo

- Report Forms (JFDA-Yellow Card, CIOMS)

Who reports?

Health Care Professional	Public	Drug Agents & Industries
•Physician	•Patient	•LSR
•Pharmacist	•Relatives	•QPPV
•Nurse		
•Others		

Adverse Drug reactions Database Analysis:

ADRs reports submitted to the Rational Drug Use and Pharmacovigilance department between (2010-2014) were analyzed. Aims of this analysis are to summarize the last 5 years' experience of pharmacovigilance in Jordan through analyzing the Adverse Drug reactions Database, raise awareness on the magnitude of drug safety problems and increase the rational and safe use of drugs, create an ADR database for the Jordan population, and convince healthcare professionals

that reporting of ADRs is part of their professional and moral obligation.

This analysis of ADRs database meant to determine the rate of reporting per year, classes of drugs involved in ADRs, the most common reported drugs, the most common ADRs and system organ classes involved in ADRs.

The total number of ADRs reports received was 428 reports (**Figure 1**). Eighty (80) reports were excluded from the analysis as they are related to quality issue. The rate of reporting increased markedly between (2010-2014). There was about a 5-fold increase in the number of received reports. These results indicate that there is an increase in the awareness about the importance of reporting among healthcare providers in Jordan.

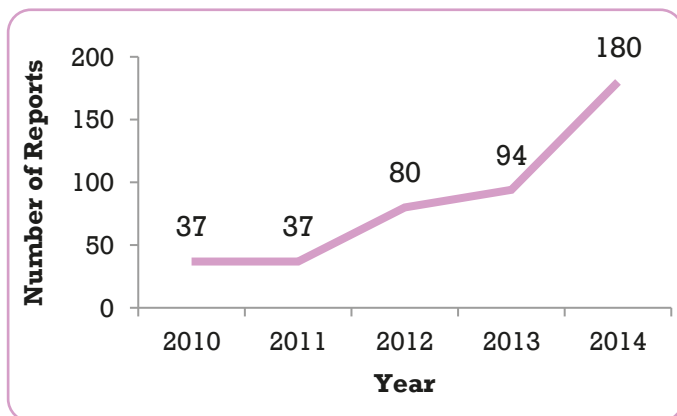


Figure 1. Number of ADR Reports/Year.

Number of ADR Reports/Drug Class:

Seventeen classes of drugs were involved in causing ADRs. The most common classes were Antineoplastics (37.6%), Immunomodulators (14.1%) and Antibiotics (10.3%) (**Table 1, Figure 2**).

Classes of Drugs	Total No. of reports (348)	percentage %
Antineoplastics	131	37.6%
Immunomodulator	49	14.1%
Antibiotics	36	10.3%
Analgesics	23	6.6%
Antihypertensives	19	5.5%
Antivirals	15	4.3%
Antiepileptics	13	3.7%
Anticoagulants	9	2.6%
Antidiabetics	9	2.6%
Corticosteroids	7	2%
Antihyperlipidemic	4	1.1%
Hormones	4	1.2%
Antipsychotics	2	0.6%
vitamins & iron	2	0.6%
Anti-acne	2	0.6%
Peptic Ulcer-healing	2	0.6%
Antidepressants	1	0.3%
Others	20	5.7%

Table 1. Number of ADR reports /Drug Class

Figure 2 shows the percentage of drug classes causing ADRs. The 10.8% represents the following classes of drugs (antihyperlipidemics, hormones, antipsychotics, vitamins & iron, anti-acne, peptic ulcer-healing, antidepressants) and others.

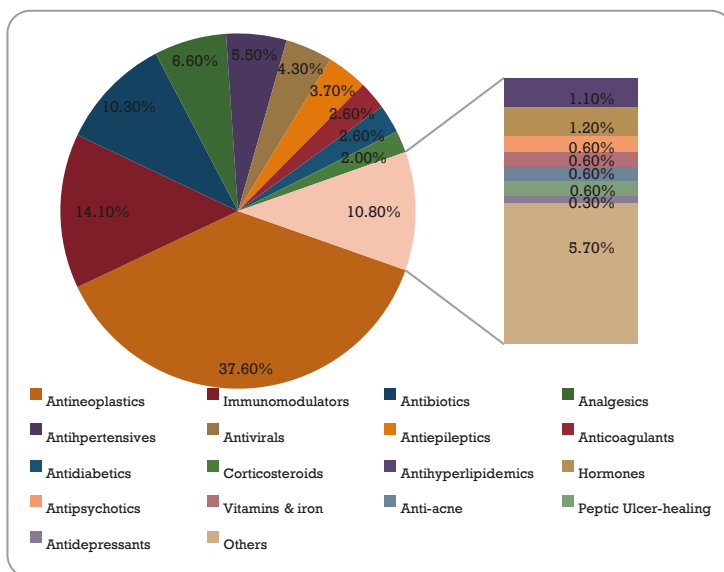


Figure 2. Percentage of ADR reports /Drug Class

Classes of drugs involved in causing ADRs:

Looking at **(Figure 3)**, you can identify the most common drug causing ADRs in each drug class.

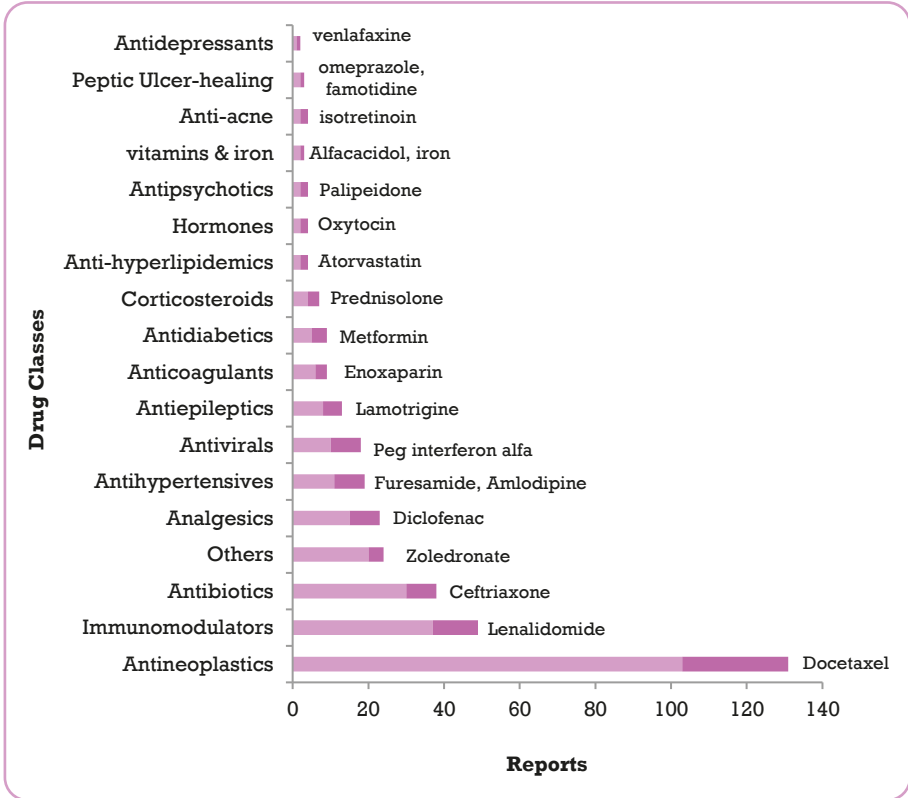


Figure 3. The most common drug causing ADR in each class.

1. Antineoplastics:

Antineoplastics were the first group of drugs involved in causing ADRs, 131 reports (37.6%). The most common antineoplastic drugs were docetaxel (28) reports (21.4%), followed by oxaliplatin (15) reports (11.5%) (**Figure 4**).

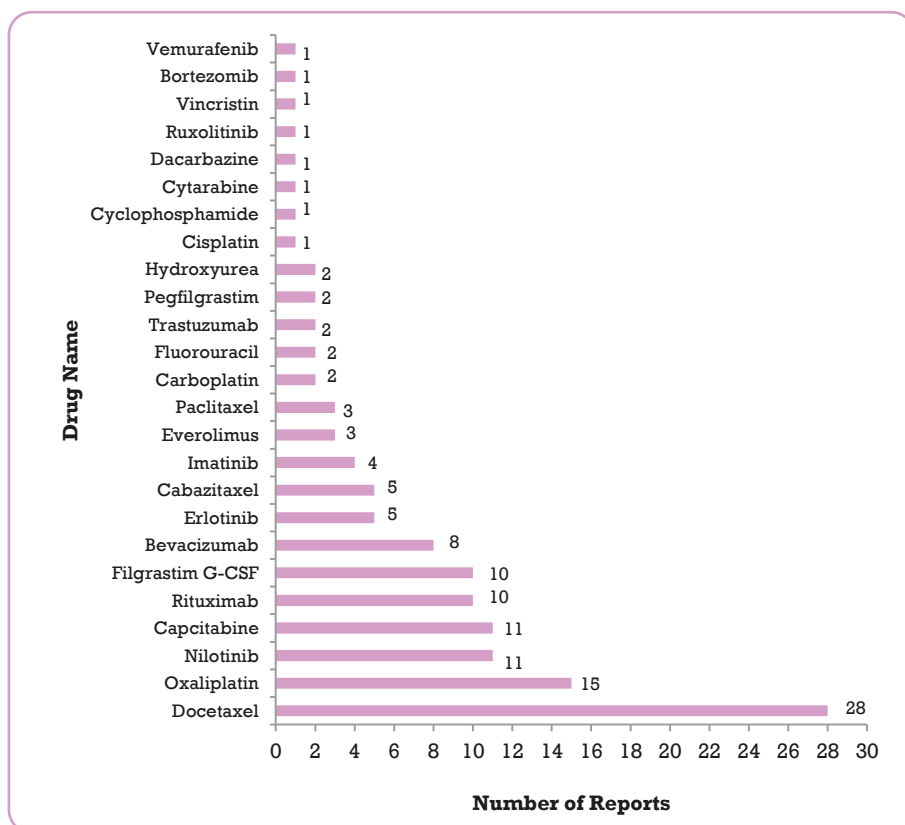


Figure 4. Number of Reports of Antineoplastic Drugs

2. Immunomodulators:

Immunomodulators were the second group of drugs involved in ADRs, 49 reports (14.1%). The most commonly drugs were lenalidomide (24.5%), and thalidomide (20.4%) (**Figure 5**).

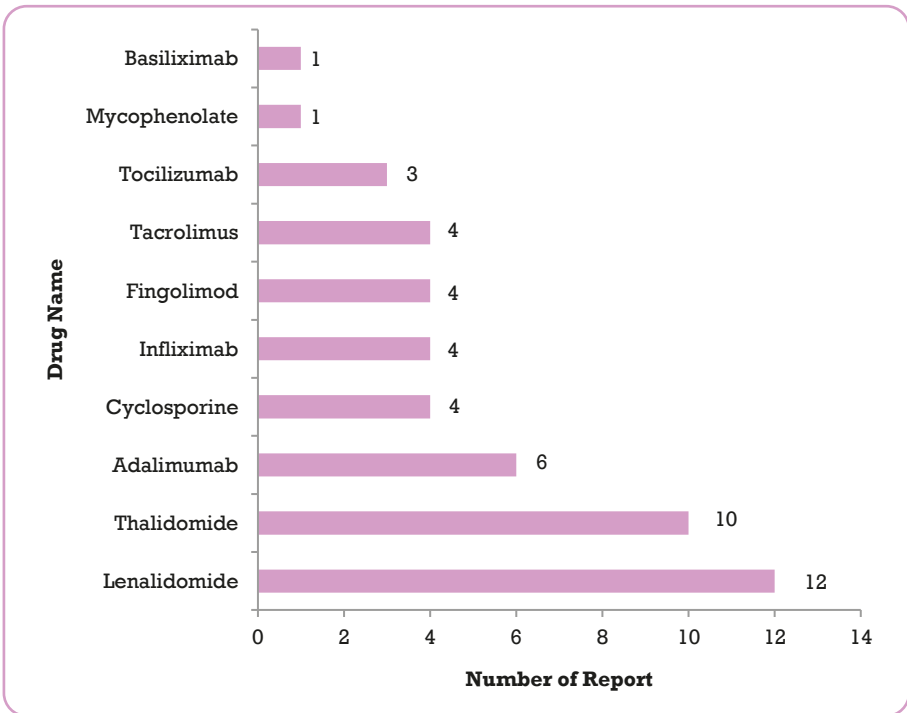


Figure 5.Number of Reports of Immunomodulators

3. Antibiotics:

Antibiotics were the third group of drugs involved in causing ADRs, 36 reports (10. 3%). The most common drugs were ceftriaxone (8) reports, vancomycin (6) reports, and doxycycline (4) reports (**Figure 6**).

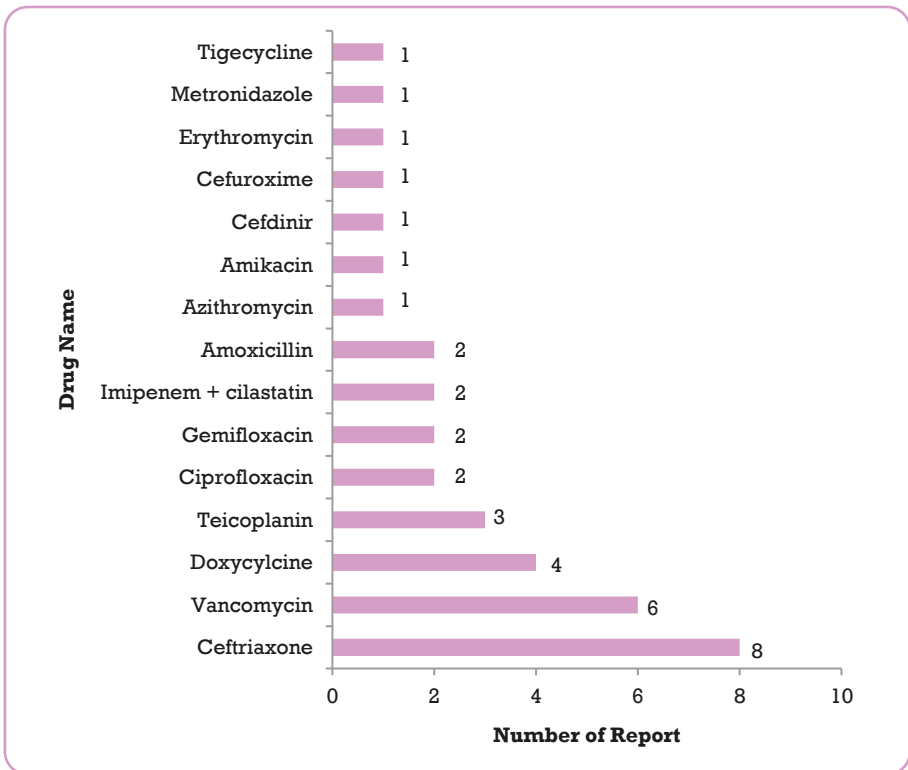


Figure 6. Number of Reports of Antibiotics

4. Analgesics:

Analgesics were the fourth group of drugs causing ADRs, 23 reports (6.6%). The most common drugs were diclofenac (8) reports, aspirin (4) reports and paracetamol (3) reports (**Figure 7**).

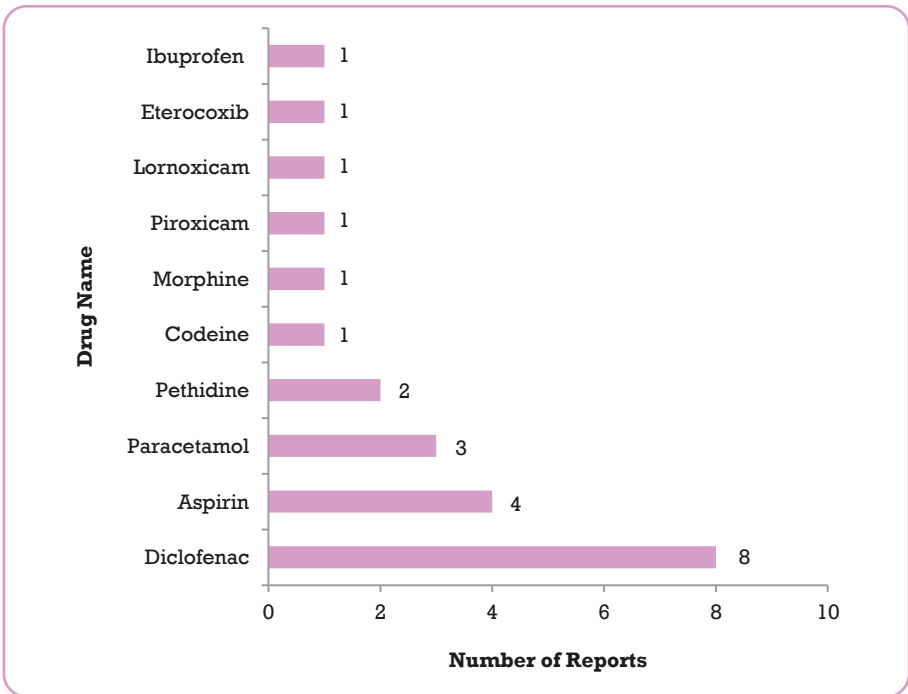


Figure 7. Number of Reports of Analgesics

5. Antihypertensives:

The Antihypertensive drugs were involved in 19 reports (5.5%). The most common drugs were amlodipine (4) reports, furosemide (4) reports, and irbesartan (3) reports (**Figure 8**).

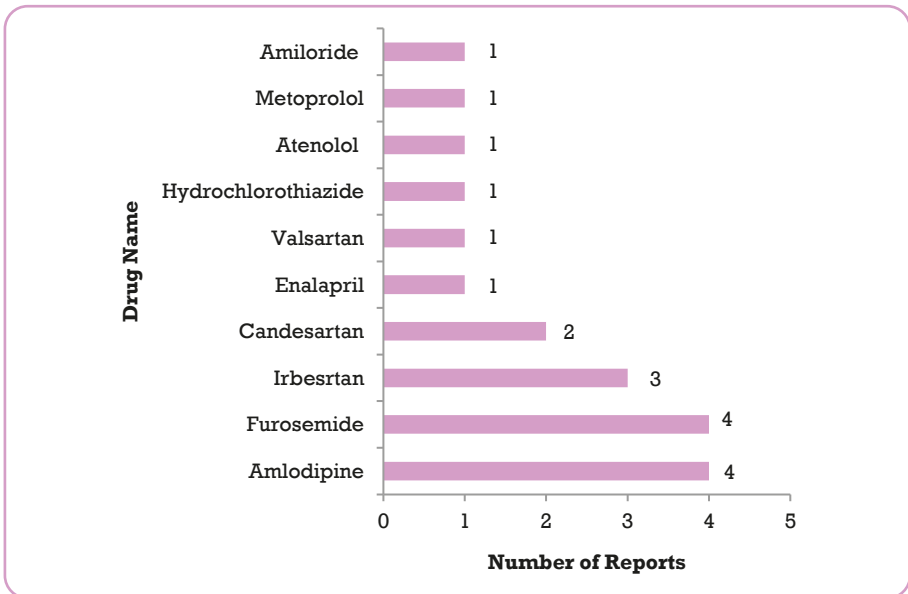


Figure 8. Number of Reports of Antihypertensives

6. Antivirals:

Antiviral drugs were involved in 15 reports (4.3%). The most common drugs were peg interferon alfa-2a (8) reports and valganciclovir (2) reports (**Figure 9**).

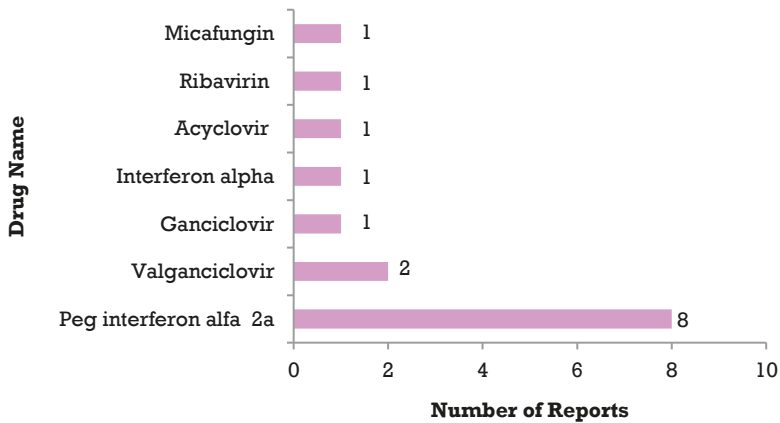


Figure 9. Number of Reports of Antivirals

7. Antiepileptics:

Antiepileptic drugs were involved in 13 reports (3.7%). The commonest drugs were lamotrigine (5) reports, carbamazepine (3) reports and topiramate (2) reports (**Figure 10**).

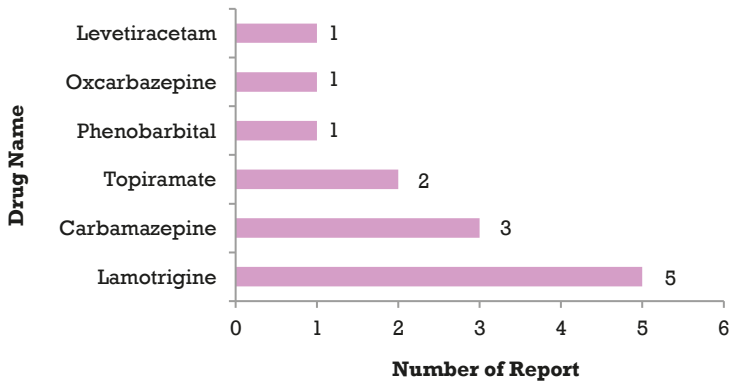


Figure 10. Number of Reports/Antiepileptics

8. Anticoagulants & Fibrinolytics:

Anticoagulants and fibrinolytics were involved in 9 reports (2.6%). The most common drugs were enoxaparin (3) reports, unfractionated heparin, bemiparin Na and streptokinase were involved in (2) reports each (**Figure 11**).

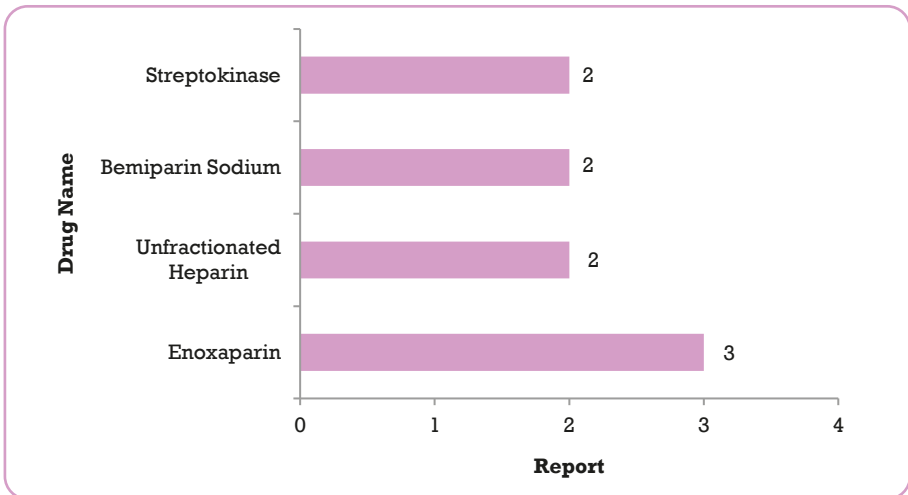


Figure 11. Number of Reports of Anticoagulants and Fibrinolytics

9. Antidiabetics:

Antidiabetic drugs were involved in (9) reports (2.6%). The most common drugs were vildagliptin (5) reports, and insulin, (3) reports (**Figure 12**).

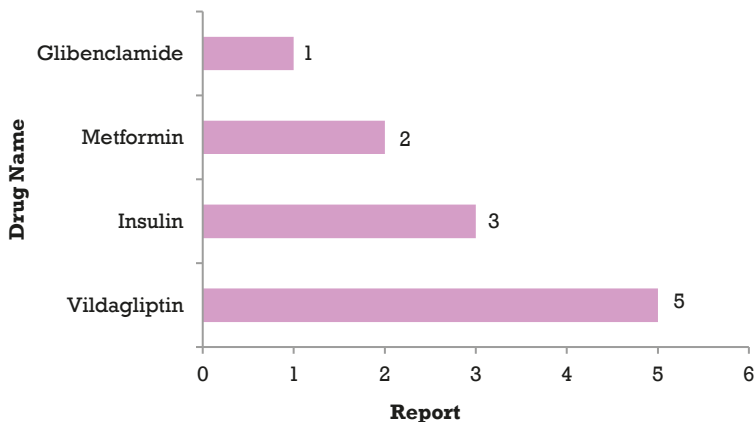


Figure 12. Number of Reports of Antidiabetics

10. Corticosteroids:

Corticosteroids were involved in 7 (2%). The most common drug was prednisolone (3) reports (**Figure 13**).

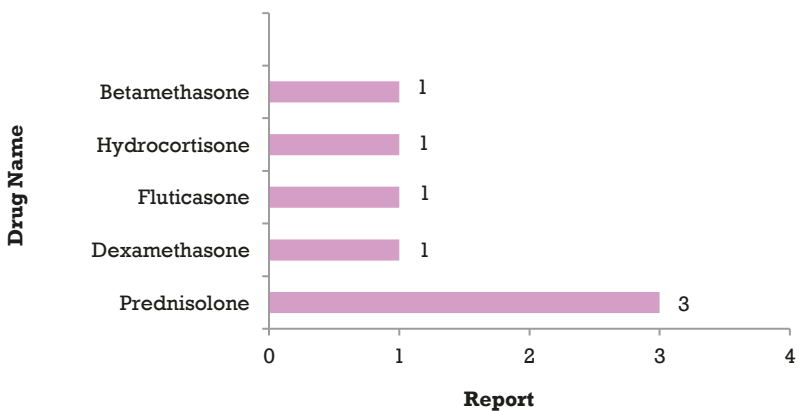


Figure 13. Number of Reports/Corticosteroids

Other classes of drugs

For other Classes of drugs, the number of received reports is as the following:

11. **Antihyperlipidemics:**(4) reports
Atorvastatin (2), gemfibrozil (1),
simvastatin (1).
12. **Hormones:**(4) reports
Oxytocin(2), levothyroxine(1),
progesterone (1)
13. **Antipsychotics:** (2) reports
Paliperidone (2)
14. **Vitamins & Iron:**(2) reports
Alfacalcidol (1), iron (1)
15. **Anti – acne:** (2) reports
Isotretinoin (2)
16. **Peptic ulcer healing:**(2) reports
Omeprazole (1), famotidine (1)
17. **Antidepressants:**(1) report
Venlafaxine (1)

18. Others:

- The following drugs were involved in (2) ADR reports each:

Immunoglobulin, atracurium, zoledronic acid.

- The following drugs were involved in (1) ADR report each:

Cyclopentolate, omalizumab, brimonidine, misicrom, salbutamol, hydroxychloroquine, deferasirox, rifampicin, epoetin beta, ibandronic acid, midazolam, guaifenesin, pseudoephedrine, chlorpheniramine.

System Organ Classes involved in ADRs:

System Organ Classes involved in ADRs were classified according to MedDRA terminology. The total number of all ADRs is (417). The most common systems were skin and subcutaneous with 80 ADRs representing (19.2%), gastrointestinal with 69 ADRs representing (16.5%) and nervous system with 48 ADRs representing (11.5%) (**Table 2**).

System Organ Class	Total No. of reports (417)	percentage (%)
Skin & Subcutaneous	80	19.2%
Gastrointestinal	69	16.5%
Nervous	39	11.5%
Blood	39	9.4%
Respiratory	31	7.4%
General Disorder	31	7.4%
Musculoskeletal	30	7.2%
Vascular	21	5%
Endocrine	16	3.8%
Cardiac	15	4.3%
Renal & Urinary	10	2.8%
Hepatobiliary	9	2.5%
Immune	8	2.3%
Metabolic	7	2%
Psychiatric	4	1.1%
Infections	3	0.8%
Eye	2	0.7%
Ear	1	0.3%

Table 2. System organ classes involved in ADRs

(Figure 14) shows the most commonly reported ADR per system.

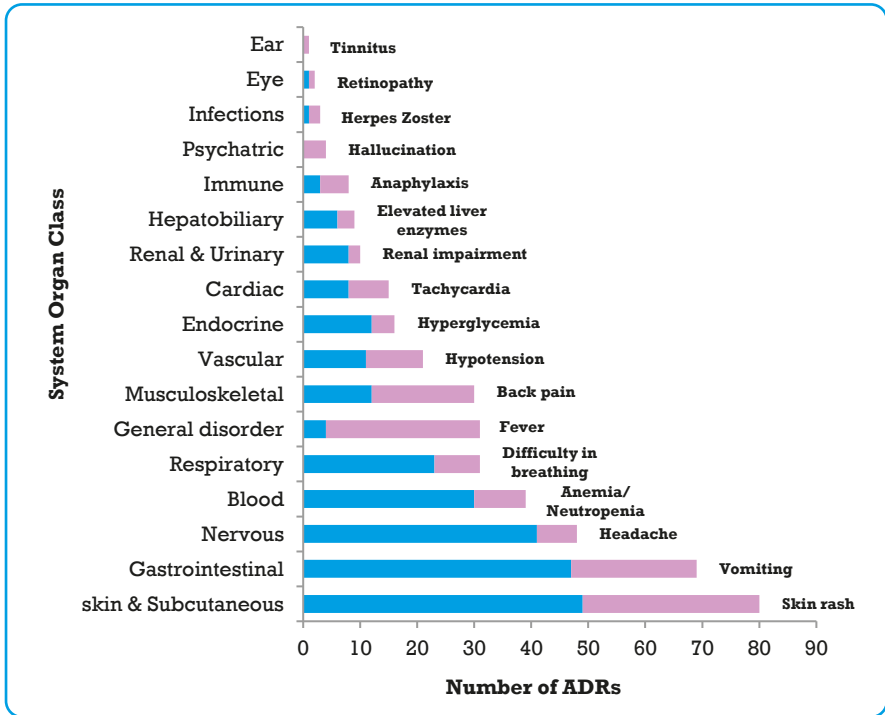


Figure 14. The most common ADR/ System Organ Class

1) Skin & Subcutaneous System:

The skin and subcutaneous system was involved in 80 ADRs (19.2%). The most common reactions were skin rash, redness and itching (**Figure 15**).

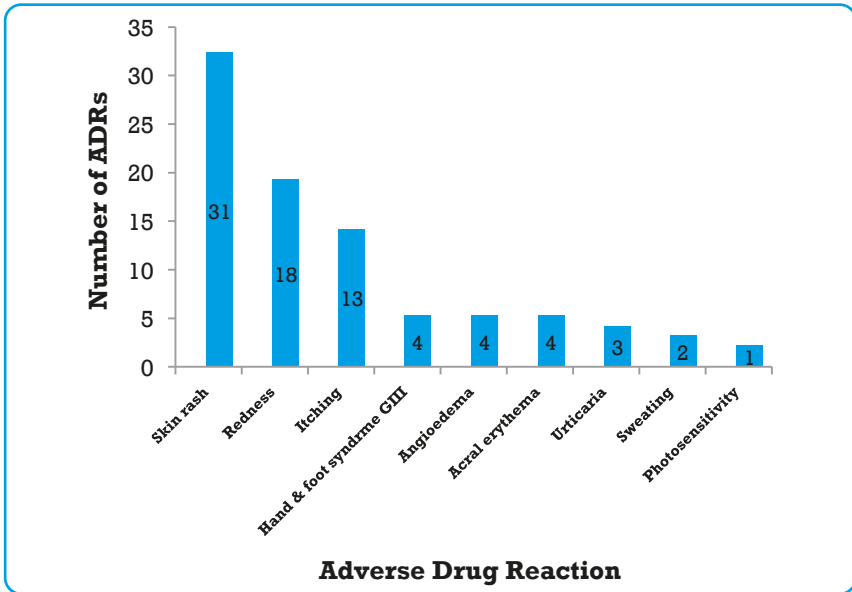


Figure 15. Number of ADRs of Skin & Subcutaneous

2) Gastrointestinal System:

The gastrointestinal system was involved in 69 ADRs (16.5%). The most common reactions were vomiting, diarrhea, gastrointestinal bleeding and duodenal ulcer (**Figure 16**).

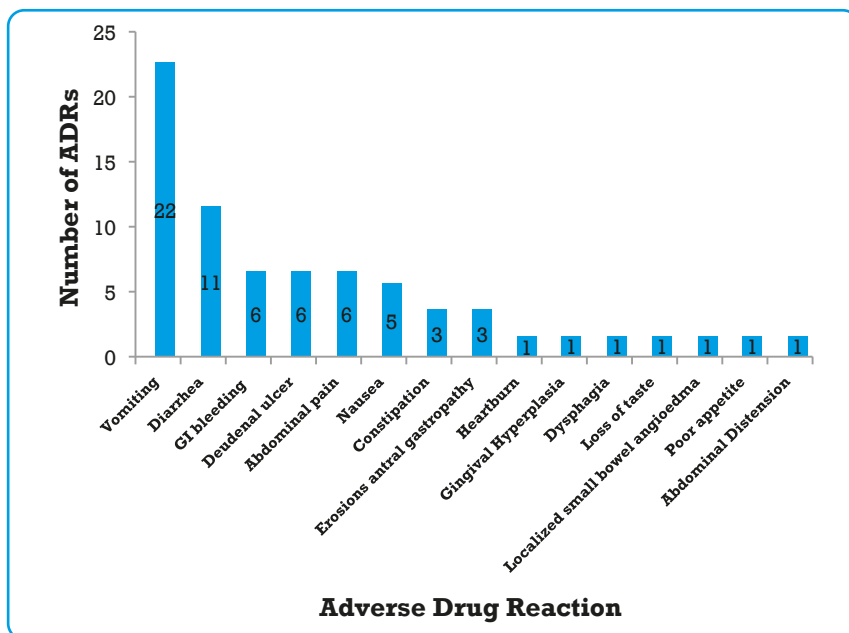


Figure 16. Number of ADRs of Gastrointestinal System

3) Nervous System:

The nervous system was involved in 48 ADRs (11.5%). The most common reactions were headache, convulsions, generalized weakness, and numbness (**Figure 17**).

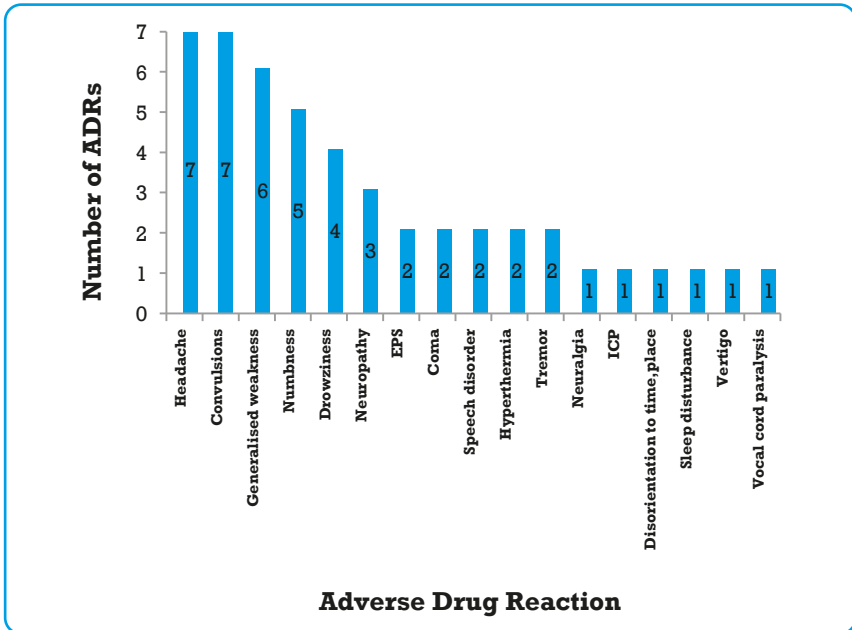


Figure 17. Number of ADRs of Nervous System

4) Blood and lymphatic System:

The ADRs of blood and lymphatic system was 39 ADRs (9.4%). The most common reactions were anemia, neutropenia, thrombocytopenia (**Figure 18**).

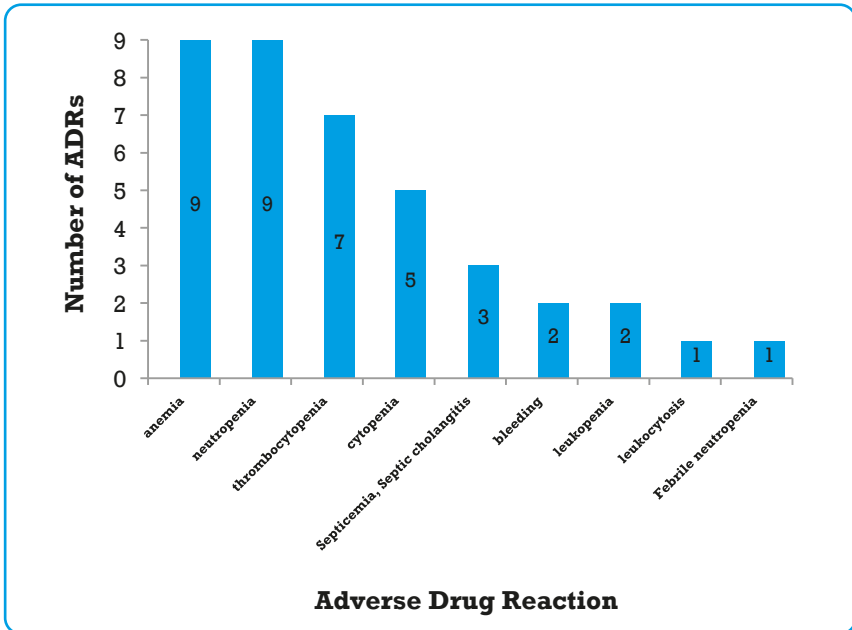


Figure 18. Number of ADRs of Blood System

5) Respiratory System:

The respiratory system was involved in 31 ADRs (7.4%). The most common reactions were difficulty in breathing, cough and Respiratory Depression (**Figure 19**).

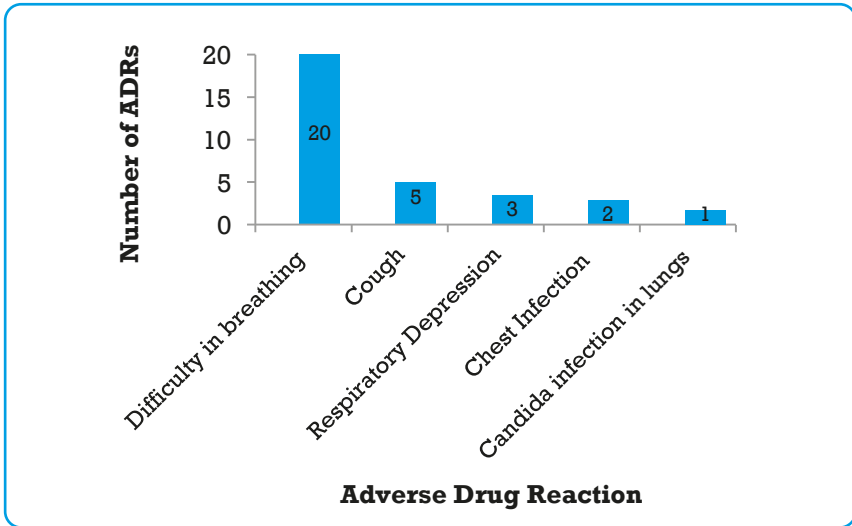


Figure 19. Number of ADRs of Respiratory System

6) General Disorders:

The general disorders were involved in 31 ADRs (7.4%). The reactions were fever (27) reports and chills (4) reports **Figure 20**.

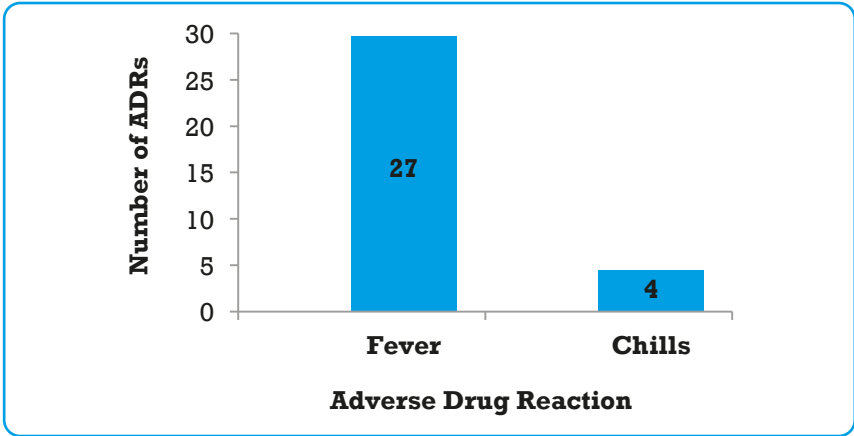


Figure 20. Number of ADRs of General Disorder

7) Musculoskeletal System:

The ADRs of musculoskeletal system were 30 (7.2%). The most common reaction was back pain 19 reports. (**Figure 21**)

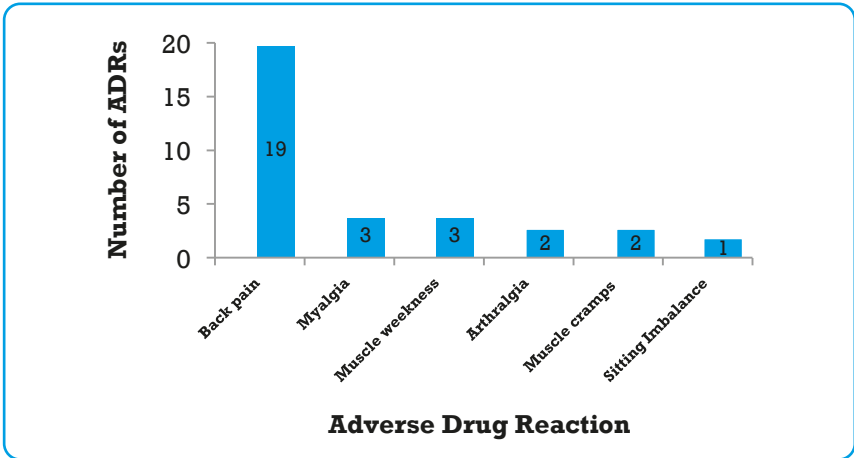


Figure 21. Number of ADRs of Musculoskeletal System

8) Vascular System:

The vascular system was involved in 21 ADRs (5%). The most common reactions were hypotension and hypertension (**Figure 22**).

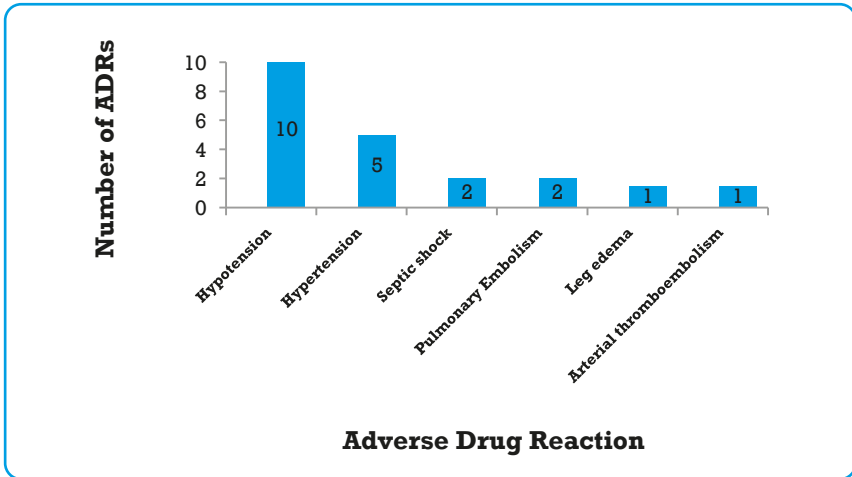


Figure 22. Number of ADRs of Vascular System

9) Endocrine System:

The endocrine system was involved in 16 ADRs (3.8%). The most common reactions were hyperglycemia and hypoglycemia (**Figure 23**).

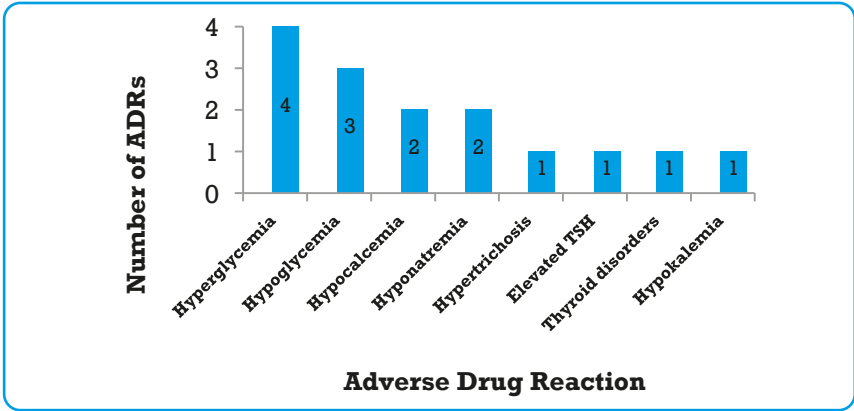


Figure 23. Number of ADRs of Endocrine System

10) Cardiac System:

The cardiac system was involved in 15 ADRs (3.6%). The most common reaction was for palpitation (**Figure 24**).

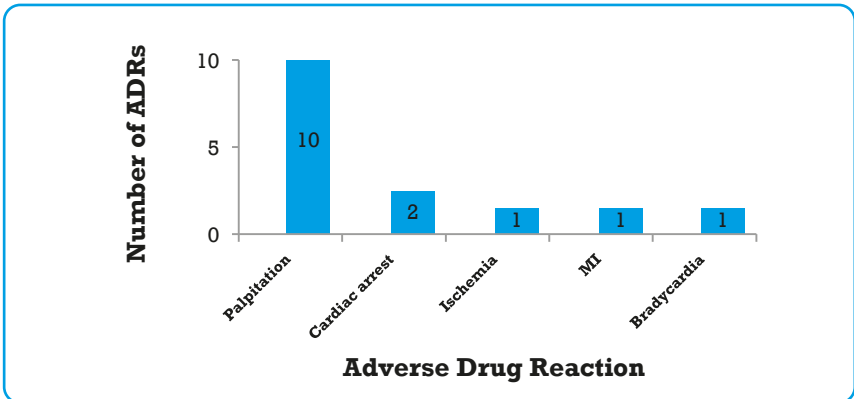


Figure 24. Number of ADRs of Cardiac System

11) Renal & Urinary System:

The renal and urinary system was involved in 10 ADRs (2.4%). The most common reactions were renal impairment and hematuria (**Figure 25**).

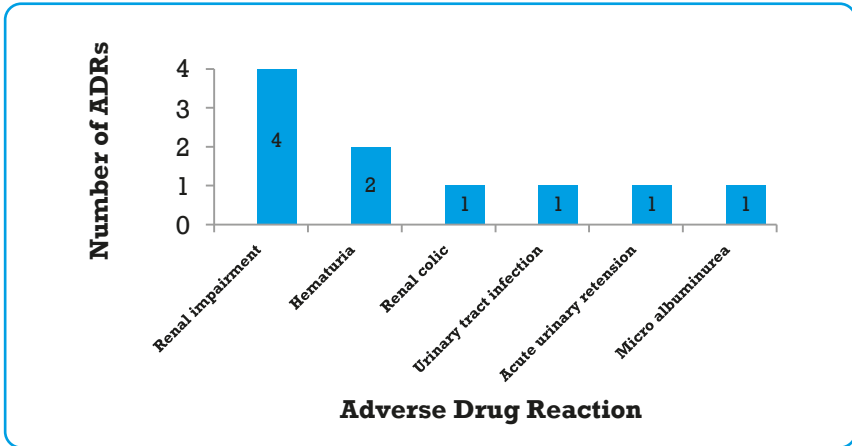


Figure 25. Number of ADRs of Renal & Urinary System

12) Hepatobiliary System:

The hepatobiliary system was involved in 9 ADRs (2.2%). The most common reactions were elevation of liver enzymes, biliary colic and Cigler-najjar syndrome (**Figure 26**).

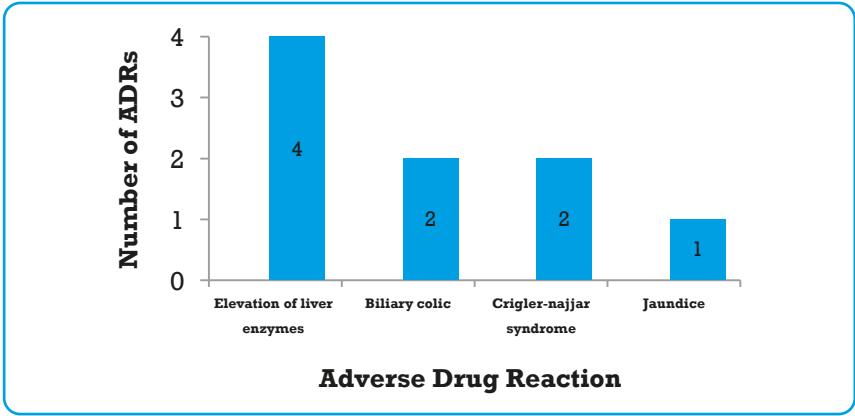


Figure 26. Number of ADRs of Hepatobiliary System

13) Immune System:

The immune system was involved in 8 ADRs (1.9%). The commonest reaction was anaphylaxis (Figure 27).

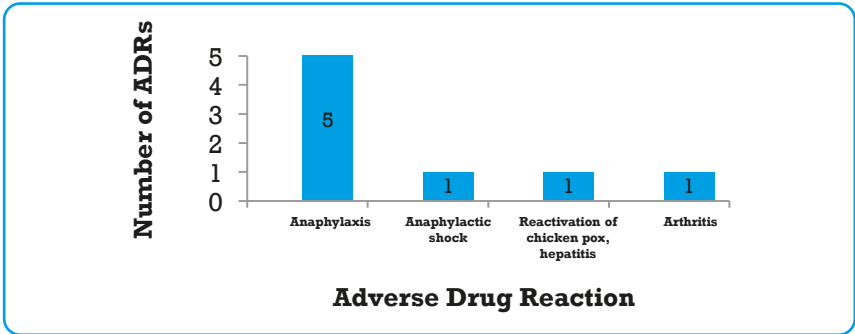


Figure 27. Number of ADRs of Immune System

14) Psychiatric (1%):

Hallucinations appear in 4 reports

15) Infections (0.7%):

Herpes zoster was involved in 2 reports and mucositis in 1 report

16) Eye (0.5%):

Retinopathy reported once and eyelid edema once

17) Ear (0.2%):

Tinnitus in 1 report.

Conclusion:

PV is a system to monitor the safety and effectiveness of medicines and other pharmaceutical products. PV can help minimize the risk of harm by ensuring that medicines are used appropriately and health care providers have the information they need to make decision about medicines. All health care providers should realize that reporting of ADRs is part of their professional responsibility and to be active in the culture of safety. The success of PV system in Jordan depends upon government support and public awareness on need to report suspected ADRs.

Annexes:

- **Annex I: Resources (Websites)**
- **Annex II: Yellow Card – Arabic**
- **Annex III: Yellow Card – English**

Annex I: Resources:

- **JFDA domestic ADRs Reports**

- **Websites:**

- **World Health Organization (WHO)**

A great deal of information is available here, including access to WHO publications.

<http://www.who.int/>

- **The Uppsala Monitoring Centre (UMC)**

This site provides very useful information about practical pharmacovigilance including definitions and advice on pharmacovigilance policy.

<http://www.who-umc.org/>

- **European Medicines Agency (EMA)**

This is a useful resource on product information, current issues and regulatory actions.

<http://www.emea.europa.eu>

- **Food and Drug Administration (FDA), USA**

This is a useful resource on product information, current issues and regulatory actions.

<http://www.fda.gov/>

- **Jordan Food and Drug Administration (JFDA)**

This is a useful resource on product information, current issues and regulatory actions.

www.jfda.jo

Annex II: Yellow Card – Arabic

نموذج رصد الآثار الجانبية للأدوية المشتبه بحدوثها والمشاكل المتعلقة بالاستحضارات الصيدلانية ملاحظة: المعلومات المتعلقة بشخص كل من المبلغ، المريض، المؤسسة المعنية ستبقى سرية						
رقم الملف الطبي: <input type="checkbox"/> ذكر <input type="checkbox"/> أنثى - الوزن: _____ - الطول: _____ - العمر: _____ سنة الأثر الأول من اسم المريض: <input type="checkbox"/> الأثر <input type="checkbox"/> من الأدوية جملتها: <input type="checkbox"/> نعم <input type="checkbox"/> لا - إذا كنت تعمل لمرحلة؟						
اسم الدواء (الأدوية (الاسم التجاري) التي يتناولها المريض	اسم المصنع ورقم التسجيل	شكل الدواء وطريقة استخدامه	الجرعة والتكرار	تاريخ ابتداء تناول الدواء	تاريخ توقف تناول الدواء	بواقي استعمال الدواء
1 -						
2 -						
3 -						
4 -						
5 -						
6 -						
الآثار الجانبية المشتبه بحدوثها والمشاكل المتعلقة بالدواء (نفس في ذاتية الدواء، عيوب تصنيعية... الخ)						
1 -						
2 -						
3 -						
ملاحظات: (تاريخ سابق متعلق بالمريض، حساسية، استعمال مسبق للدواء..... الخ) .						
أيعت الأثر والآثار الجانبية: - بل تعت الأثر والآثار الجانبية خطيرة؟ <input type="checkbox"/> نعم <input type="checkbox"/> لا - إذا كنت خطورة، فما هي: <input type="checkbox"/> وفاة المريض (تاريخ الوفاة: _____) سبب الوفاة: _____ <input type="checkbox"/> تهديد الحياة للمريض <input type="checkbox"/> تناول مستقل <input type="checkbox"/> بفترة مدة إقامة المريض في المستشفى <input type="checkbox"/> وفاة مستشفية <input type="checkbox"/> ظهور عيب خلقي <input type="checkbox"/> تهتك الحرم (أخرها: _____) - مدة المريض يوم كتابة التقرير: <input type="checkbox"/> شفاء تام <input type="checkbox"/> الشفاء التام متوقع <input type="checkbox"/> شفاء مع ظهور ناس وبقي <input type="checkbox"/> وفاسد <input type="checkbox"/> غير معروف النتائج <input type="checkbox"/> تهتك الحرم (أخرها: _____)						
- هل أو إيقاف استخدام أي من الأدوية المشتبه بها؟ <input type="checkbox"/> نعم <input type="checkbox"/> لا - إذا كنت الإجابة نعم، أي أدوية تم إيقافها؟ - هل توقف الأثر الجانبي بعد توقف استخدام الدواء؟ <input type="checkbox"/> نعم <input type="checkbox"/> لا - آخر معروف - ما هو الأثر والآثار الجانبية التي توقفت؟ <input type="checkbox"/> بعد إعادة تناول؟ <input type="checkbox"/> آخر معروف						
- اسم المبلغ وصفه الوظيفي: (طبيب، طبيب أسنان، صيدلي، ممرض) : _____ - عنوان العمل: _____ تاريخ المبلغ: _____ رقم الهاتف: _____ الصلوق: _____ - البريد: _____ البرية الإلكتروني: _____ رقم الفاكس: _____						
- شخص بالمؤسسة العامة للغذاء و الدواء - تاريخ استلام التقرير: _____ رقم التقرير الخاص بالمرجع: _____						
ملاحظة: عند وجود الحاجة إلى حجز أكبر، أرفق تقرير آخر						

Annex III: Yellow Card – English

Pharmacovigilance Report Form						
Report of Suspected Adverse Drug Reaction and Medical Related Problem						
Note: Identities of Reporter, Patient and Institution will remain confidential						
- Patient's Medical Record: _____ <input type="checkbox"/> Male Weight: _____ Kg Height: _____ cm Age: _____ Years						
- Patient's Name/Initials: _____ <input type="checkbox"/> Female Pregnant? _____ <input type="checkbox"/> Yes <input type="checkbox"/> No Which trimester? _____						
Drugs by Brand Name	Manufacturer & Batch no.	Drugs Form & Route	Strength & Dose	Started on	Stopped on	Indications
Suspected Drugs	1-					
	2-					
	3-					
Other Drugs	1-					
	2-					
	3-					
Suspected reaction/ Product Related Problem (Low efficacy, manufacturing defects, etc.)				Date of onset	Duration of reaction	
1-						
2-						
3-						
Comments (e.g. relevant history, allergies, previous exposure to the drug, etc).						
- Consequences of suspected reactions:- Serious: <input type="checkbox"/> Yes <input type="checkbox"/> No. If serious please indicate the seriousness of reaction (s). <input type="checkbox"/> Death (Date of death _____ Cause of death _____) <input type="checkbox"/> Life threatening <input type="checkbox"/> Hospitalization <input type="checkbox"/> Leading to congenital anomaly <input type="checkbox"/> Persistent disability <input type="checkbox"/> Prolongation of hospitalization <input type="checkbox"/> Other serious consequences (Specify _____)						
- Outcome On The Day of Report: <input type="checkbox"/> Recovered fully <input type="checkbox"/> Recovered with reduced function <input type="checkbox"/> Unknown consequence <input type="checkbox"/> Full recovery is expected <input type="checkbox"/> Death <input type="checkbox"/> Other (Specify _____)						
- Was Suspected Drug(s) Discontinued? <input type="checkbox"/> Yes <input type="checkbox"/> No. If yes, which drug(s)? _____						
- Did reaction(s) disappear after discontinuation of suspected drug(s)? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown, if yes which reaction (s)? _____						
- Did reaction(s) reappear after reintroduction of suspected drug(s)? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown						
- Reporter's Name & Status (Physician, Dentist, Pharmacist, Nurse)					Office Address:	
Date: _____			P.O. Box: _____		Phone: _____	
Reporter's Signature: _____			E-mail: _____		Fax: _____	
For Jordan Food and Drug Administration.						
Date of receiving the report: _____						
Program report No.: _____						
Note: In case there is additional information you can attach extra form.						



“Side effects may include loss of appetite, job, home and family.”

PHARMAC

Keeping our eyes open



VIGILANCE

and our medicines safe