ANNUAL REPORT 2015

NATIONAL CENTRE FOR ADVERSE DRUG REACTIONS MONITORING, NATIONAL PHARMACEUTICAL CONTROL BUREAU (NPCB)

1. The Malaysian Adverse Drug Reactions Advisory Committee (MADRAC)

The Malaysian Adverse Drug Reactions Advisory Committee (MADRAC) was established in 1987 under the DCA to perform the function of monitoring safety profiles of drugs registered for use in Malaysia.

During MADRAC meetings held once in two months, causality verification is done for all local ADR reports, and all pertinent drug safety issues are discussed to provide DCA with information and recommendations if required.

A total of six (6) MADRAC meetings were held in 2015, with 12,527 adverse drug reaction (ADR) reports presented for verification of causality.

Table 1: List of MADRAC Members (Jan- Dec 2015)

No.	Name and Designation
Ex-officio	
1	**Chairman** En. Tan Ann Ling Director of NPCB
2	**Secretary** Cik Sameerah Shaikh Abdul Rahman Deputy Director, Centre for Post-Registration of Products, NPCB
3	Pn. Anis Talib Secretary of the Drug Control Authority
Committee Members *(Alternate Members)*	
1	Prof. Datuk Dr. Jeyaindran Tan Sri Sinnadurai, PJN, DSSA Deputy Director General of Health (Medical) Ministry of Health Malaysia. *(Dr. Hjh. Rosaida Mohd. Said)*
2	Dr. G.R. Letchuman Ramanathan Head of Department and Senior Medical Consultant (Endocrinology) Hospital Taiping. *(Dr. Padmini Menon)*
3	Dato' Dr. Gun Suk Chyn Head of Department and Senior Medical Consultant (Rheumatology) Hospital Tuanku Ja'afar. *(Dr. Azmillah Rosman)*
4	Dr. Lim Chong Hum Head of Department and Senior Consultant Psychiatrist, Hospital Ampang. *(Dr. Siti Nor Aizah Ahmad)*
5	Dr. Norzila Mohamed Zainudin Senior Consultant Paediatrician, Hospital Kuala Lumpur. *(Dato' Dr. Hussain Imam bin Hj. Muhammad Ismail)*

No.	Name and Designation
6	Dr. Noor Zalmy Azizan binti Mohd. Ali Azizan Senior Consultant Dermatologist, Hospital Kuala Lumpur. *(Dr. Rohna Ridzwan)*
7	Dr. Sunita Bavanandan Consultant Nephrologist, Hospital Kuala Lumpur. *(Dato' Dr. Tan Chwee Choon)*
8	Dr. Rohani Jahis Senior Principal Assistant Director, Prevention of Disease Vaccine/ Food & Water Borne Sector Disease Control Division Ministry of Health Malaysia *(Dr. Jamiatul Aida Md. Sani)*
9	Associate Prof. Datin Dr. Zoriah binti Aziz Pharmacy Department, Medical Faculty, Universiti Malaya. *(Professor Dr. Mohamed Mansor bin Manan)*
10	Pn. Azuana Ramli Ketua Penolong Pengarah Kanan, Cawangan Formulari dan Farmakoekonomik, Bahagian Perkhidmatan Farmasi. *(Pn. Rosliza Lajis)*
11	Dr. Koh Kar Chai Malaysian Medical Association (MMA) *(Dr. Azizan binti Abdul Aziz)*
12	Dr. Steven Chow Federation of Private Medical Practitioners' Association Malaysia (FPMPAM) *(Dr. G. Shanmuganathan)*
13	Ms. Eliza Basir Association of Private Hospitals of Malaysia (APHM) *(Ms. Lee Seng Dee)*
14	En. Wan Mohd. Hamidi Malaysian Pharmaceutical Society (MPS) *(Pn. Bharathi Suresh Chand)*

2. ANALYSIS OF ADR REPORTS

The National Centre received **13,675** ADR reports in 2015 (**Figure 1**), with **12,992** reports sent to the WHO Uppsala Monitoring Centre for inclusion into the WHO database. This figure includes Adverse Events Following Immunisation (AEFI) reports received by NPCB.

In November 2015, the World Health Organisation Collaborating Centre for International Drug Monitoring, Uppsala, Sweden (WHO-UMC), reported that Malaysia was top among low-middle income countries (according to the World Bank classification of economies July 2014) in terms of number of ADR reports submitted per year and population (**Figure 2**).

Efforts are also being taken to increase the **quality of ADR reports** by educating reporters on the importance of providing complete and accurate information in order to ensure usefulness of reports. The WHO-UMC measures report quality using the 'Documentation Grading - Completeness Score' system. Malaysia obtained an average score of 0.45 from 2010-2013, and has successfully increased this to 0.63 in 2014, and **0.72 in 2015**.

The NPCB ADR reporting form for healthcare professionals has been updated as part of our continual efforts to increase the quality of ADR reports received in Malaysia (**Figure 3**).

New features of the updated form include:

- New columns: seriousness of reaction, type of report (initial/ follow-up);
- More specific column headings;
- A reminder to state patient pregnancy status, allergies, hepatic/renal dysfunction, where relevant.
- Full contact details for NPCB;
- Marked mandatory fields to be completed;
- An ADR Reporting Guide.

Detailed analysis of the ADR reports received in 2015 is shown in **Appendix 1**.

3. STRENGTHENING THE PHARMACOVIGILANCE OF VACCINES

The NPCB received 1,369 Adverse Events Following Immunisation (AEFI) reports in 2015, 1,094 (79.9%) involving the Human Papilloma Virus (HPV) vaccine, while the remaining 275 AEFI reports (20.1%) involved other vaccines registered in Malaysia. Active surveillance is conducted for this vaccine since it was introduced into the National Immunisation Programme in 2010. The majority of the adverse events reported via this active surveillance programme have been non-serious, and HPV vaccination in Malaysia continues to be a safe programme for prevention of cervical cancer.

Type of Adverse Events

For HPV vaccines, a total of 2,032 adverse events were reported in 2015. The MedDRA System Organ Class (SOC) 'General Disorders and Administration Site Conditions' such as injection site pain, injection site swelling, injection site erythema and fever contributed the most reports (66.0%).

For vaccines other than HPV, a total of 565 adverse events were reported in 2015. 'General Disorders and Administration Site Conditions' contributed the most reports (54.2%), followed by 'Skin and Subcutaneous Tissue Disorders' (13.8%) and 'Nervous System Disorders' (9.0%).

Vaccine Pharmacovigilance Committee and Safety Expert Group

In line with the role of NPCB in monitoring the safety of vaccines, especially in handling and monitoring AEFI, NPCB has taken over the "*Jawatankuasa Kecil Farmakovigilans Keselamatan Vaksin* (JKFKV)" from the Pharmaceutical Services Division since February 2015. The committee was renamed as the 'Vaccine Pharmacovigilance Committee (JFV)' and new members have been appointed, continuing the close collaboration with the Public Health division.

NPCB also began the process of establishing a Vaccine Safety Expert Group (JPKV) in 2015. The role of this group is to make the final decision regarding the causal relationship between a vaccine and serious AEFI cases which require further discussion.

4. TESTING OF SUSPECTED ADULTERATED PRODUCTS

The NPCB receives ADR reports with samples of products, mainly for traditional medicines, food and cosmetics, sent in by consumers or healthcare professionals who suspect adulteration. The NPCB conducts tests on these samples to identify suspected adulterants including steroids, antihistamines, NSAIDs, or slimming agents.

Among the products sent for laboratory testing following reports of ADRs in 2015, a total of **48 products tested positive** for various adulterants. These were all unregistered traditional products or products classified as food, and information on the adulterants detected was conveyed to the Pharmacy Enforcement Division for further action. **Table 2** shows the list of products and adulterants detected.

Table 2: Adulterants Detected in Samples of Products Suspected to Cause ADRs

No.	Product Name	Adverse Reactions Reported	Adulterants Detected
1	Air Haruan Ajaib	Skin striae	Dexamethasone
2	Baschi Quick Slimming Capsule	Delirium	Sibutramine
3	Bio Belut Putih	Appetite increased, moon face top, weight increase	Dexamethasone
4	Black Bear	Unexpected therapeutic benefit	Chlorpheniramine
5	Blood Purification Capsule	Blood cortisol decreased, cushingoid	Ibuprofen
6	Cobra X	Myocardial infarction	Sildenafil
7	Creative Health Resources Creative Nutrition	Unexpected benefit	Dexamethasone, Chlorpheniramine
8	F.O.B	Blood creatinine increased, hepatic enzyme increased	Niacinamide, Dexamethasone, Cyproheptadine
9	Ho Fook Yew Bone - Urat	Cushingoid, cortisol decrease, lethargy	Dexamethasone, Chlorpheniramine
10	Homeopathic Liquid Medication (HAT Tuanku Mizan)	Blood cortisol decreased, drug withdrawal syndrome	Dexamethasone
11	Jamu Ajaib	Hypoadrenalism	Dexamethasone.
12	Kapsul Asam Urat KBM	Upper gastrointestinal haemorrhage	Dexamethasone, Chlorpheniramine
13	Kapsul Resdong Gali	Unexpected therapeutic benefit, feeling of warmth	Dexamethasone, Chlorpheniramine
14	Kopi Jantan +++	Energy increased	Sildenafil
15	Linzi Dong Mai Tan	Cushingoid	Betamethasone
16	Maajun Mutiara	Drug withdrawal syndrome	Indomethacin
17	Maajun Selasih	Lethargy, breath shortness, sinus bradycardia	Dexamethasone, chlorpheniramine
18	Maajun Wali Sembilan	Drug withdrawal syndrome, weight gain, cataract	Dexamethasone
19	Madura	Sepsis, hypokalaemia, cortisol decreased	Dexamethasone

No.	Product Name	Adverse Reactions Reported	Adulterants Detected
20	Majun Mutiara	Unexpected therapeutic benefit, energy increase	Dexamethasone
21	Majun Mutiara	Cushingoid, skin striaes	Dexamethasone
22	Makjun 1001 Rahsia	DRESS syndrome	Dexamethasone
23	Mu Gua Wan	Cushing's syndrome	Dexamethasone, Chlorpheniramine
24	Myanmar Traditional Medicine Pink White Tab	Hypertonia, ataxia, chorea, tremor	Cyproheptadine
25	N3 Beauty Care Beauty Cream	Skin hypopigmentation	Hydroquinone, Tretinoin
26	N3 Beauty Care Toner 2	Skin hypopigmentation	Hydroquinone, Tretinoin
27	Pai Du Tong Jin Ju Ning Dan	Drug withdrawal syndrome, Cushingoid	Dexamethasone
28	Pil Penawar Raja Saraf Original Pekisa	Bipolar disorder	Dexamethasone
29	Pill Pembersih Darah	Fluid retention	Ibuprofen
30	POLLA Whitening Cream	Skin hypopigmentation	Hydroquinone, Tretinoin
31	Porcupine Bezoar Stone	Unexpected therapeutic benefit	Dexamethasone
32	Red Capsule KK Beserah 5244	Hepatic enzymes increased	Dexamethasone, Chlorpheniramine
33	Roots	Unexpected therapeutic benefit	Tadalafil
34	Sear Heang Tienchi Tu Chung Wan	Erythroderma	Dexamethasone, Chlorpheniramine
35	Shexiang Zhuangu Wan	Diabetes mellitus inadequate control	Dexamethasone
36	Shueh Lian Dan	Lethargy, cushingoid, oedema legs	Dexamethasone, Chlorpheniramine
37	Skyline Al Taqwa Juice	Cortisol decreased	Dexamethasone
38	Super Resdong	Hepatitis	Dexamethasone, Chlorpheniramine
39	Tain Ma Tu Chung Seven Leave Ginseng	Hepatitis acute	Dexamethasone
40	TCM HRPB LJW 2	Drug withdrawal syndrome	Dexamethasone, Cyproheptadine, Chlorpheniramine
41	TCM HTAJ 5326	Blood glucose increased	Dexamethasone
42	TCM Temple White Round Tablet	Coombs positive haemolytic anaemia	Prednisolone, Paracetamol
43	TCM Wing Onn Trading Black Pill	Addisonian crisis	Dexamethasone, Chlorpheniramine
44	TCM Wing Onn Trading Powder	Addisonian crisis	Chlorpheniramine, Piroxicam

No.	Product Name	Adverse Reactions Reported	Adulterants Detected
45	Tian Ma Du Zhong Wan	Cushingoid	Betamethasone, Chlorpheniramine
46	Tian Ma Tu Chung Seven Leave Ginseng	Lower limb oedema, abdominal distension, oedema periorbital	Dexamethasone
47	Ubat Kampung Kota Bahru	Unexpected benefit	Phenylbutazone, Paracetamol
48	Yellow Colour Cream (CPF Johor)	Fatigue, rash papular	Mercury

5. STRENGTHENING DATA ANALYSIS AND SIGNAL DETECTION

The new NPCB pharmacovigilance (PV) system started being used by PV staff in December 2015. The system for use by product registration holders, healthcare professionals and consumers is still under development.

The highlights of the new system include:

- ICH E2B compatible format allowing ease of data transfer between databases, such as NPCB data submission to WHO, and receipt of ADR reports from product registrations holders;
- Automated safety signal generation using an in-built algorithm;
- User-friendly data extraction system which allows customised queries;
- To be integrated with the Pharmacy Information System (PhIS) and Clinic Pharmacy System (CPS). This will further enhance electronic submission of ADR reports nationwide, with an expected increase in the number of reports received from public healthcare facilities.

6. MONITORING DRUG SAFETY ISSUES

In 2015, a total of **82 drug safety issues** were identified through environmental screening. Following review, **16 issues** were presented at MADRAC meetings to determine the appropriate risk minimisation measures [**Table 3**]. The majority of these issues resulted in updates to the package insert safety information, such a tightening of indications or additional contraindications. Regulatory actions for five (5) of these issues were proposed to the DCA, resulting in DCA directives issued to ensure package inserts of all generic products containing the affected active ingredients are updated with the required safety information.

Besides that, review and approval of **safety-related updates** to product package inserts were carried out for 246 products (95%) out of 259 applications received.

Table 3: Drug Safety Issues Discussed by MADRAC

MADRAC Meeting Date	Product name (active Ingredient) & Safety Issue	MADRAC Recommendation/ Resulting Actions				
		DCA Directive	PI Update	DHPC or MTIK	Publication of article	Further review
12 Feb	Bromhexine dan Ambroxol: Risk of Serious Cutaneous Adverse Reactions (EM and SJS)					✓

MADRAC Meeting Date	Product name (active Ingredient) & Safety Issue	MADRAC Recommendation/ Resulting Actions				
		DCA Directive	PI Update	DHPC or MTIK	Publication of article	Further review
16 Apr	Paracetamol: Update of label, prescribing information and RiMUP with warning on risk of serious cutaneous adverse reactions	✓	✓		✓	
	Domperidone: Update of package insert information to restrict use following the risk of cardiovascular adverse effects	✓	✓	✓	✓	
	Hydroxyethyl starch (HES)-containing products: Restriction of use to minimise the risk of mortality and kidney injury		✓		✓	
	Hydroxyzine: Risk of abnormal heart rhythm (QT prolongation and torsades de pointes)				✓	✓
	Zopiclone: Reduction of starting dose to reduce the risk of next-day impairment					✓
	Pentaxim® vaccine: Discussion of Two Case Reports					✓
18 Jun	Singulair® (montelukast): Update of prescribing information regarding the risk of thrombocytopenia	✓	✓		✓	
	Ibuprofen: Risk of serious cardiovascular adverse effects including heart attack and stroke with use of high doses (2400mg/day)					✓
	Testosterone: Increased risk of cardiovascular adverse effects and stroke		✓		✓	
20 Aug	Diclofenac (systemic formulations): Update of package insert with information on the risk of cardiovascular advers effects	✓	✓		✓	
	Forxiga® (dapagliflozin), canagliflozin and empagliflozin: Risk of diabetic ketoacidosis during treatment with sodium glucose co-transporter 2 (SGLT2) inhibitors			✓	✓	✓
8 Oct	Locabiotal® (fusafungine): Risk of serious allergic reactions, including anaphylactic reactions				✓	✓
	Dipeptidyl peptidase-4 (DPP-4) Inhibitors: Risk of severe and disabling arthralgia				✓	✓
17 Dec	Azithromycin: Update of package insert with information on the risk of QT prolongation and Drug Reaction	✓	✓		✓	

MADRAC Meeting Date	Product name (active Ingredient) & Safety Issue	MADRAC Recommendation/ Resulting Actions				
		DCA Directive	PI Update	DHPC or MTIK	Publication of article	Further review
	with Eosinophilia and Systemic Symptoms (DRESS)					
	Forxiga® (dapagliflozin), canagliflozin, empagliflozin, luseogliflozin: Risk of acute kidney injury and serious urinary tract infection, including pyelonephritis and urosepsis, with sodium glucose co-transporter 2 (SGLT2) inhibitors					✓

Key:
DHPC: Direct Healthcare Professional Communication
MTIK: Early safety issue communication (*makluman terkini isu keselamatan*)

7. SAFETY MONITORING OF NEWLY REGISTERED PRODUCTS

Newly registered products, namely New Chemical Entities (NCEs) and biologic products are required to submit Periodic Benefit-Risk Evaluation Reports/ Periodic Safety Update Reports (PBRERs/ PSURs) for the first five years post-registration. PBRERs/ PSURs contain information on the product safety profile in countries where it is registered, and any changes or new findings related to product safety. In 2015, a total of 264 PBRERs/ PSURs involving 162 products were assessed, resulting in implementation of package insert changes for 18 products (11.1%) to ensure that they contain the latest safety information.

Risk management plans (RMPs) are also submitted by product registration holders to NPCB when there is any concern about a risk affecting the benefit-risk balance of a product. In 2015, 28 RMPs involving 26 registered products were reviewed. Package insert safety updates were initiated for one product based on the information in the RMP to maintain product safety. Besides that, the NPCB conducted pre-registration RMP evaluation, as well as provided consultation and advice to the product registration holders prior to implementation of RMPs for some biologic products.

8. DRUG SAFETY COMMUNICATION

In 2015, the NPCB published and distributed three (3) issues of the MADRAC Bulletin and five (5) issues of Reaksi drug safety newsletter to highlight drug safety issues to local healthcare professionals and international regulatory agencies

An **electronic mailing list** was also established in 2014 for all healthcare professionals in an effort to ensure wider and faster spread of the information. This mailing list currently consists of more than 1,800 individuals, including doctors, dentists, pharmacists, nurses, assistant medical officers and assistant pharmacists.

Besides the publications, a total of five (5) **Direct Healthcare Professional Communications** (DHPCs) were approved by the NPCB for distribution in 2015. These were issued by the product registration holders to highlight important changes in the prescribing information, safety profile or use of a product.

Three (3) **early safety issue communications** were distributed in 2015 containing important safety updates involving intravenous succinylated gelatin infusion products, metoclopramide and domperidone.

One (1) **press release** was prepared regarding unregistered traditional products associated with recurrent ADR reports. Drug safety communication was also carried out through product alerts or circulars, and feedback to ADR reporters.

Besides that, **Consumer Medication Information Leaflets (RiMUPs)** are reviewed and approved by the Pharmacovigilance Section, to be uploaded on the NPCB website for use by consumers or healthcare professionals. As of the end of 2015, there are RiMUPs for 1,100 products available for download from the website.

9. OTHER ACTIVITIES

Training

Over the past four years, NPCB has conducted training sessions all across Malaysia on ADR report analysis and causality assessment. In 2015, training was held in the northern region (covering Penang, Kedah and Perlis) and Sabah, involving more than 100 pharmacists. Such training is in-line with the future plan for causality assessment to be done at reporter institution level, for verification by the NPCB.

Besides causality assessment training, there were 15 training programmes conducted or presentations delivered, including at private healthcare facilities such as Subang Jaya Medical Centre (SJMC) and the National Heart Institute (IJN). These aimed to increase awareness on the importance of reporting, improve the quality of ADR reporting, and train reporters to perform causality assessment.

Several international delegates visited the NPCB for training in pharmacovigilance, namely from the Myanmar Pharmacovigilance Centre, Tanzania Food and Drug Administration, and Thailand Mahidol University.

Strengthening Pharmacovigilance by the Pharmaceutical Industry

The pharmaceutical industry also plays a big role in ensuring the safety of medicinal products in Malaysia. On 3 August 2015, the NPCB conducted a training session entitled “Preparing for Pharmacovigilance (PV) Inspection” for participants from the industry. Topics covered included updates on the Malaysian Pharmacovigilance Guidelines, establishing a PV Unit and the role of a PV Officer in the industry, as well as an introduction to the practice of PV audit and inspection, which will be implemented in phases.

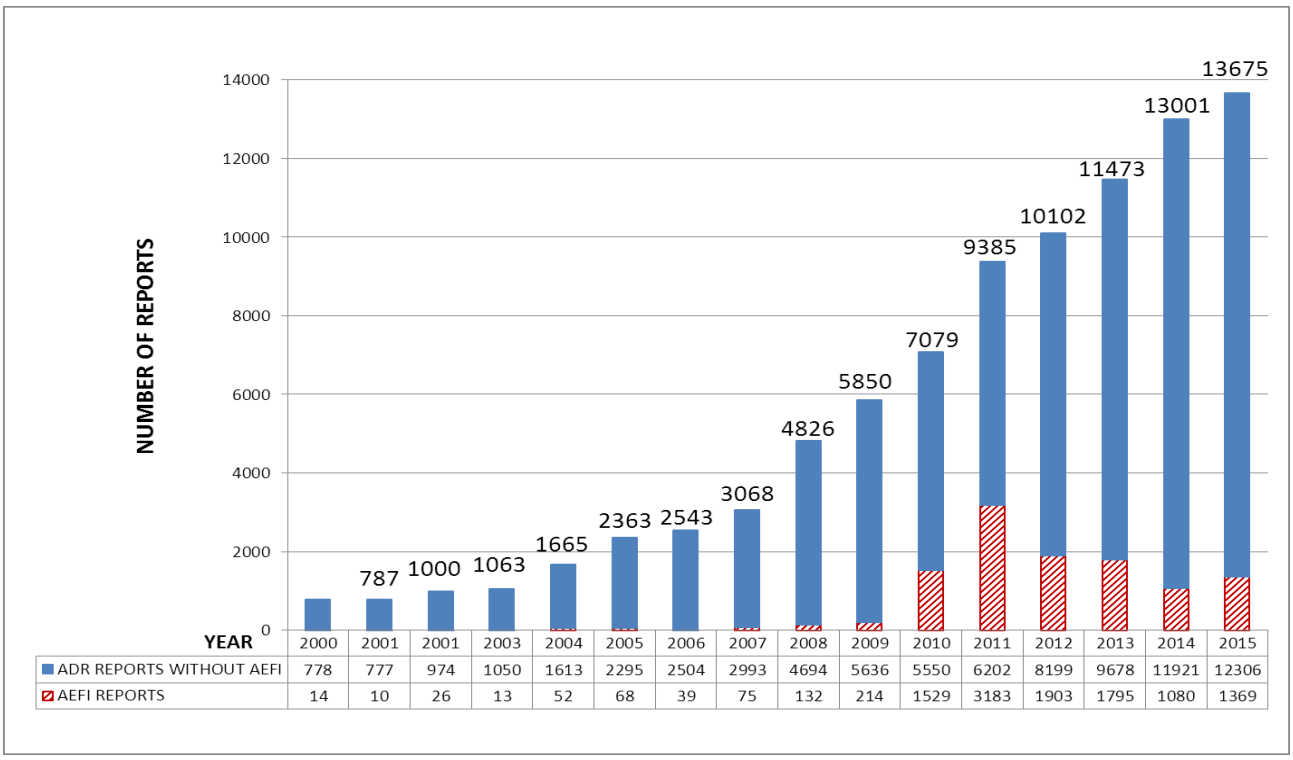
The NPCB will work together with the industry, including local/ generic companies, with the aim of ensuring every company establishes a dedicated and effective PV unit.

Research Collaboration

The National Centre carried out collaboration with local universities for research projects, particularly involving Masters and PhD students.

APPENDIX 1

Figure 1: Total Number of ADR/AEFI Reports Received in Malaysia (2000-2015)



YEAR	2000	2001	2001	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
ADR REPORTS WITHOUT AEFI	778	777	974	1050	1613	2295	2504	2993	4694	5636	5550	6202	8199	9678	11921	12306
AEFI REPORTS	14	10	26	13	52	68	39	75	132	214	1529	3183	1903	1795	1080	1369

Figure 2: Top 20 Low- and Middle-Income Countries in terms of Quantity of Reports Submitted to WHO VigiBase (2010-2015)

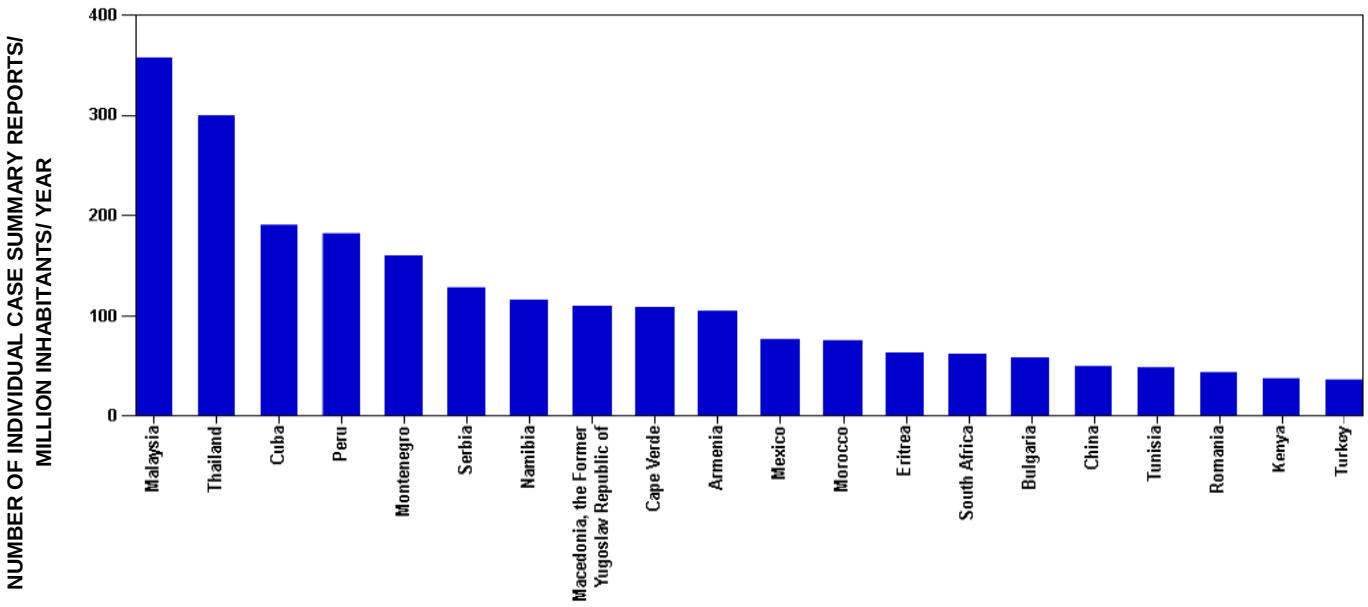
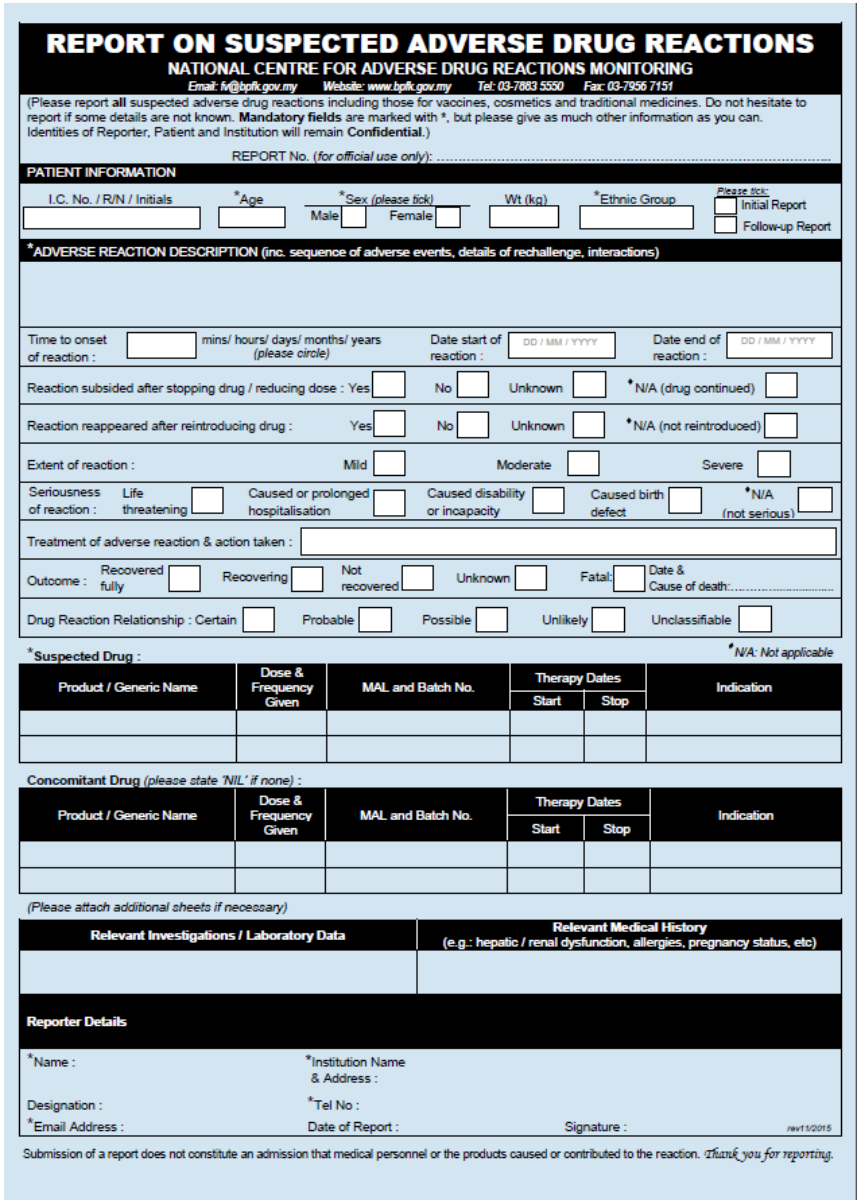


Figure 3: Amended ADR Reporting Form for Healthcare Professionals



REPORT ON SUSPECTED ADVERSE DRUG REACTIONS

NATIONAL CENTRE FOR ADVERSE DRUG REACTIONS MONITORING

Email: fv@bpfk.gov.my Website: www.bpfk.gov.my Tel: 03-7883 5550 Fax: 03-7956 7151

(Please report **all** suspected adverse drug reactions including those for vaccines, cosmetics and traditional medicines. Do not hesitate to report if some details are not known. **Mandatory fields** are marked with *, but please give as much other information as you can. Identities of Reporter, Patient and Institution will remain **Confidential**.)

REPORT No. (*for official use only*): .....

PATIENT INFORMATION

I.C. No. / R/N / Initials | *Age | *Sex (please tick) Male ☐ Female ☐ | Wt (kg) | *Ethnic Group | Please tick: ☐ Initial Report ☐ Follow-up Report

***ADVERSE REACTION DESCRIPTION (inc. sequence of adverse events, details of rechallenge, interactions)**

Time to onset of reaction : ____ mins/ hours/ days/ months/ years (*please circle*) | Date start of reaction : DD / MM / YYYY | Date end of reaction : DD / MM / YYYY

Reaction subsided after stopping drug / reducing dose : Yes ☐ No ☐ Unknown ☐ *N/A (drug continued) ☐

Reaction reappeared after reintroducing drug : Yes ☐ No ☐ Unknown ☐ *N/A (not reintroduced) ☐

Extent of reaction : Mild ☐ Moderate ☐ Severe ☐

Seriousness of reaction : Life threatening ☐ Caused or prolonged hospitalisation ☐ Caused disability or incapacity ☐ Caused birth defect ☐ *N/A (not serious) ☐

Treatment of adverse reaction & action taken :

Outcome : Recovered fully ☐ Recovering ☐ Not recovered ☐ Unknown ☐ Fatal ☐ Date & Cause of death:.....

Drug Reaction Relationship : Certain ☐ Probable ☐ Possible ☐ Unlikely ☐ Unclassifiable ☐

***Suspected Drug :** *N/A: Not applicable

Product / Generic Name	Dose & Frequency Given	MAL and Batch No.	Therapy Dates Start	Therapy Dates Stop	Indication

Concomitant Drug (*please state 'NIL' if none*) :

Product / Generic Name	Dose & Frequency Given	MAL and Batch No.	Therapy Dates Start	Therapy Dates Stop	Indication

(Please attach additional sheets if necessary)

Relevant Investigations / Laboratory Data	Relevant Medical History (e.g.: hepatic / renal dysfunction, allergies, pregnancy status, etc)

Reporter Details

*Name : | *Institution Name & Address :

Designation : | *Tel No :

*Email Address : | Date of Report : | Signature :

rev11/2015

Submission of a report does not constitute an admission that medical personnel or the products caused or contributed to the reaction. *Thank you for reporting.*

ADR Reporting Guide

Before submitting your ADR report, do check if you have inserted the following information.

**Please try to fill every section in the ADR form overleaf, stating 'none / nil' if applicable. A complete report is a useful report.*

NO.	IMPORTANT POINTS TO NOTE
1	**Definitions:** **(i) Time to onset of reaction**: time interval between first dose (initiation) of the drug until first sign of the ADR. **(ii) Initial report:** First submission of report to NPCB of a particular patient involving a particular ADR. **(iii) Follow-up report:** Submission of further reports related to the same case to inform of additional information not mentioned previously or which occurred after the initial report. Please mention the date of initial report for reference.
2	Please specify any previous history of **allergy** (including drugs, food, etc.).
3	Include information on any **concomitant medications** or **underlying illnesses**? *(Please state 'nil' if none)* • Date started and stopped for each medication • Please state 'cont' for any medication still continued after the ADR
4	Please state the specific **indication** of the suspected drug (e.g.: '*pneumonia due to S. Pneumoniae*' - not 'infection' or 'antibiotic').
5	If the ADR reappeared after reintroducing drug (**rechallenge**), please describe the rechallenge fully (dose given, timing, brand used, etc.) under section 'Adverse Reaction Description'.
6	Please specify if any **treatment** was given for the ADR, or if the suspected drug was stopped, what **alternative drug** was started and how the patient responded.
7	Please include the latest / current **outcome** of the patient *(e.g. recovered fully, not recovered)*. • If possible, follow-up the patient periodically until the final outcome is known. • A follow-up report may be sent in to update on the final outcome of the patient.
8	**Skin reactions**: Please describe the specific type and location of the skin reaction. *(Use the Cutaneous ADR form and guide available on **www.bpfk.gov.my**)*
9	Do keep your own record of details enabling you to **contact** the patient or trace the case notes later on if necessary *(e.g. IC number, patient name and phone number)*.

*Please refer to our website for additional guidance on ADR Reporting, or contact us at **fv@bpfk.gov.my** if you have any queries.*

Lipat di sini

Lipat di sini

Laporan Kesan Advers Ubat

Biro Pengawalan Farmaseutikal Kebangsaan (BPFK)
Kementerian Kesihatan Malaysia

BAYARAN POS DIJELASKAN OLEH BPFK

NO STAMP REQUIRED

SAMPUL LIPAT JAWAPAN PERNIAGAAN

NO. PERMIT SEL 0259

PUSAT PEMONITORAN KESAN ADVERS UBAT KEBANGSAAN

BIRO PENGAWALAN FARMASEUTIKAL KEBANGSAAN

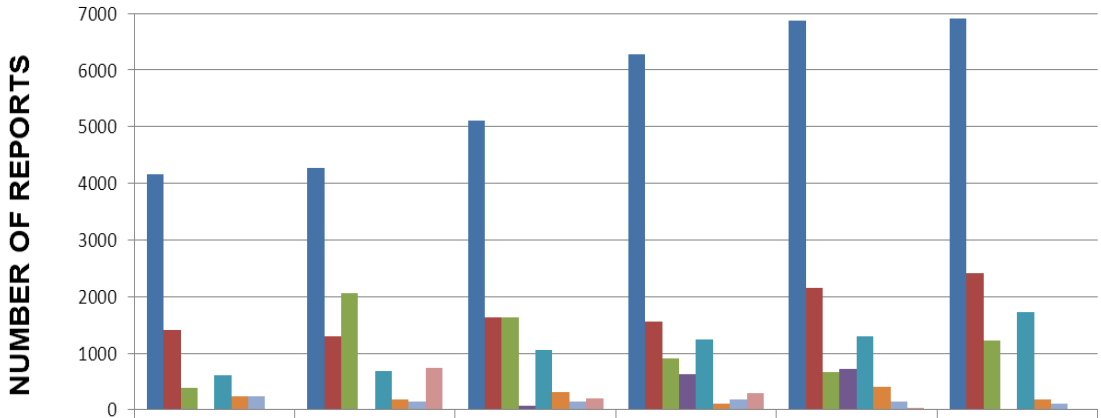
PETI SURAT 319, JALAN SULTAN

46730 PETALING JAYA

SELANGOR

- Sila lipat dua, lekat, dan hantar. Tekan beberapa saat dan pastikan pelekatan adalah memuaskan -

Figure 4: ADR/ AEFI Reports by Category of Reporters (2010-2015)



	2010	2011	2012	2013	2014	2015
MOH Pharmacist	4160	4267	5106	6283	6869	6914
MOH Doctors	1418	1295	1627	1560	2159	2409
MOH Nurse	388	2063	1636	905	665	1221
Other Govt Agency	0	0	67	621	727	16
Product Registration Holder	612	691	1066	1235	1295	1729
GP/Private Specialist	248	185	310	119	416	182
University	234	142	151	187	155	107
Others	19	742	206	303	41	25

Figure 5: ADR/ AEFI Reports by State from MOH Facilities (2015)

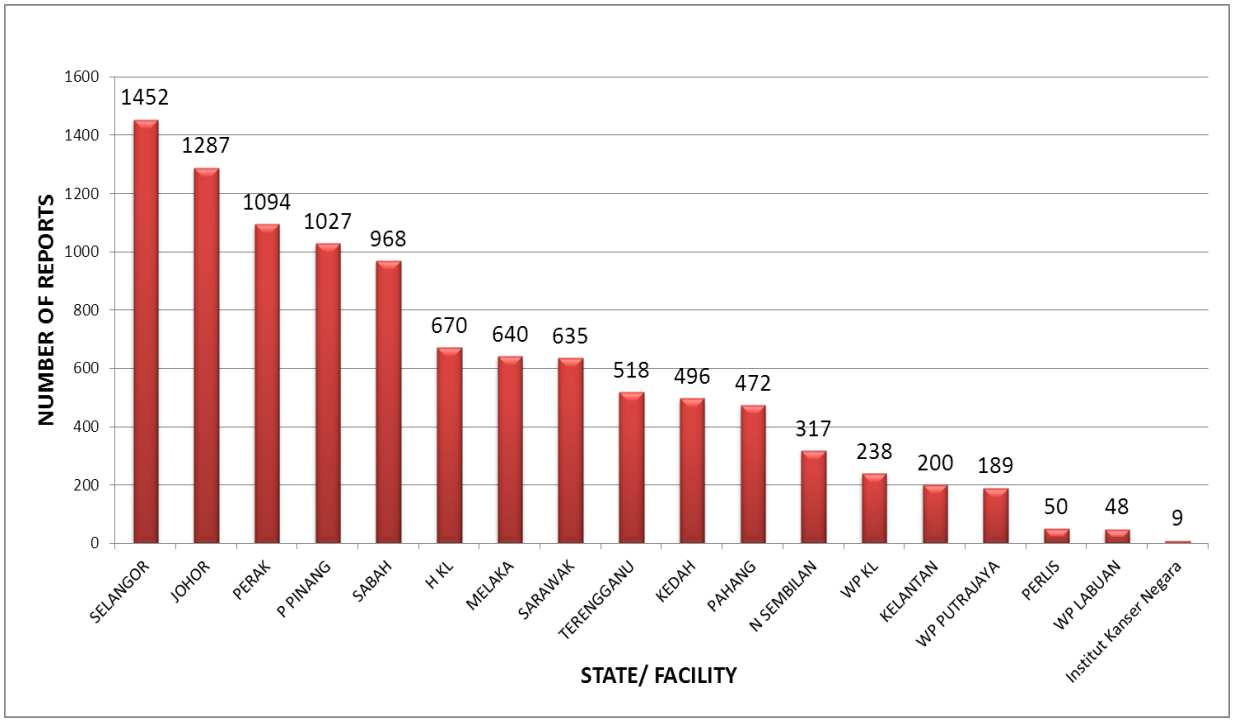


Figure 6: ADR/ AEFI Reports by Age Group of Patient (2015)

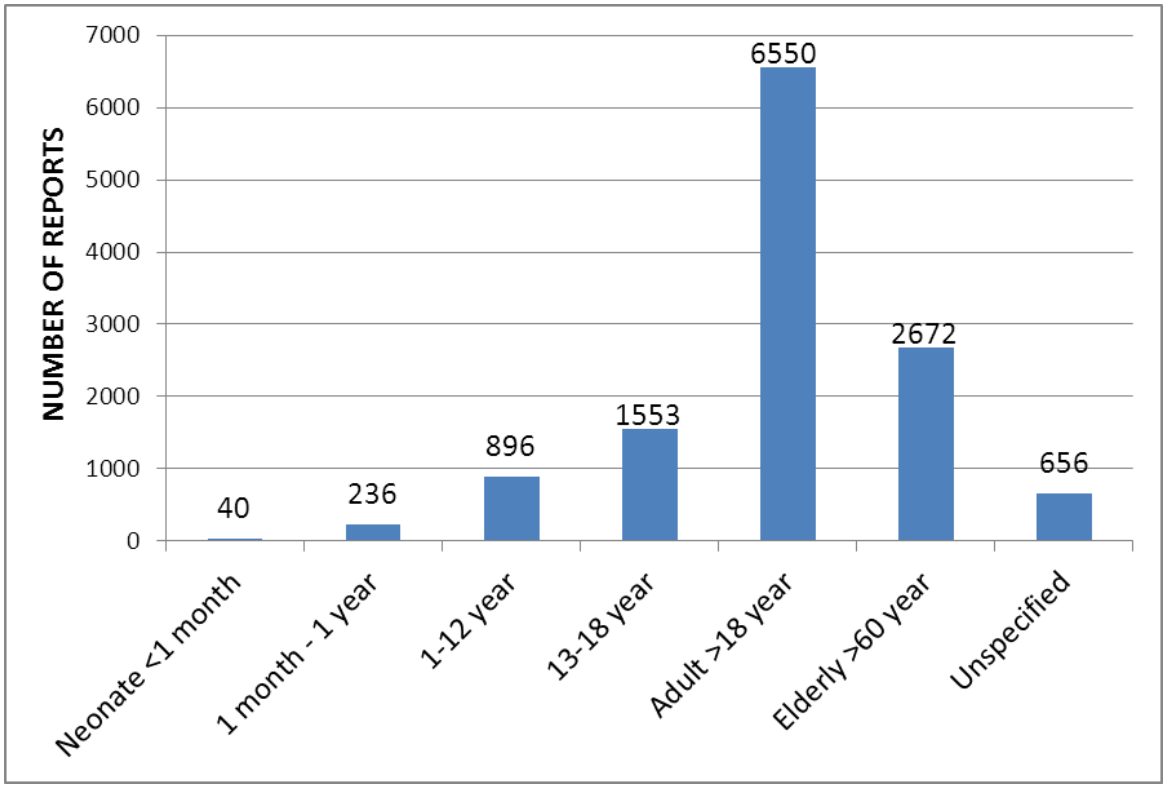


Figure 7: ADR/ AEFI Reports by Patient Race (2015)

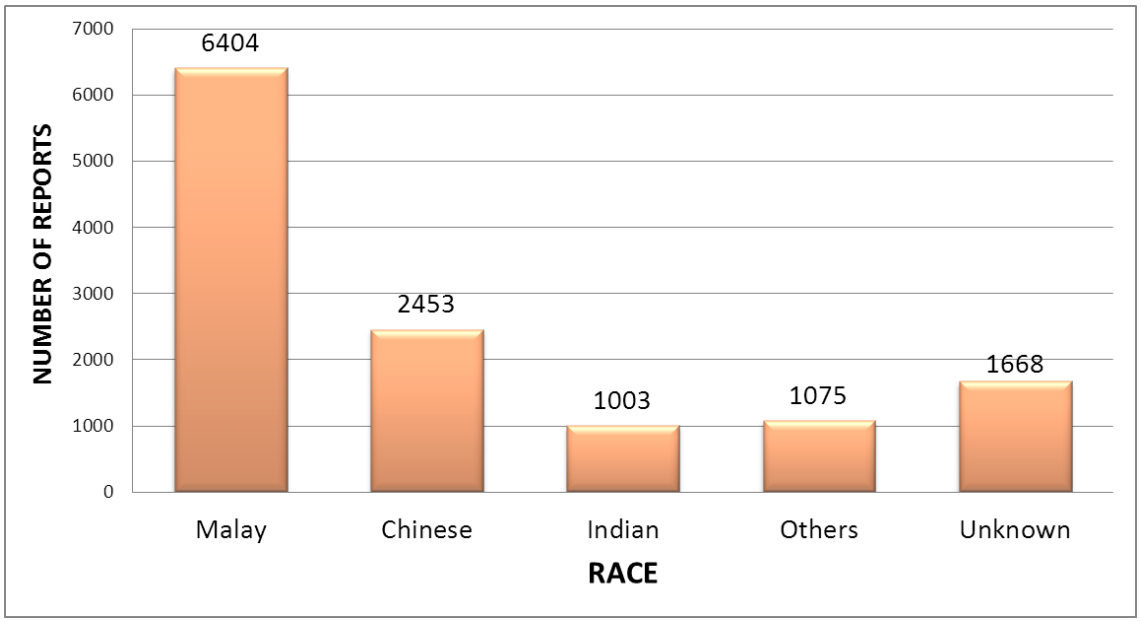


Figure 8: ADR/ AEFI Reports by Patient Gender (2015)

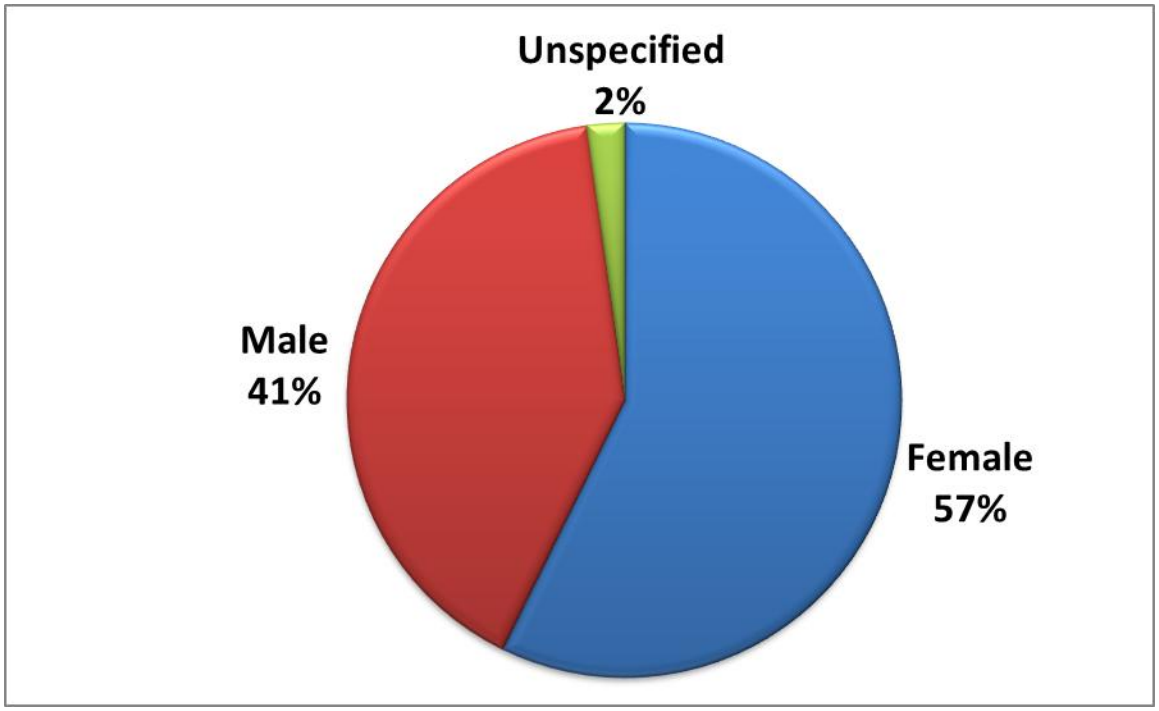


Figure 9: ADR/ AEFI Reports by Product Category (2015)

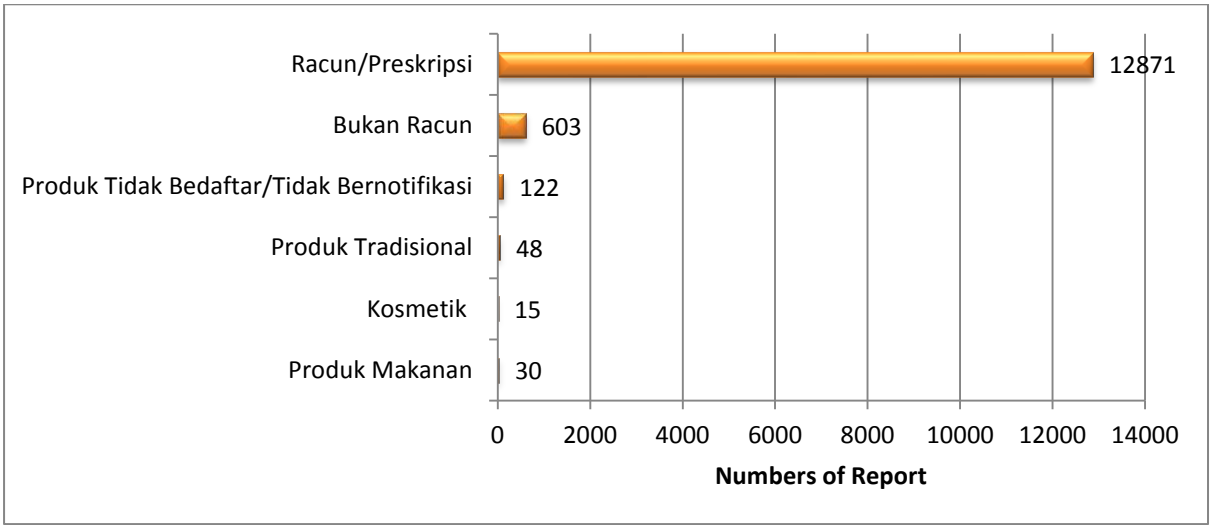


Figure 10: Number of Adverse Drug Reactions by Pharmacological Group (2015)

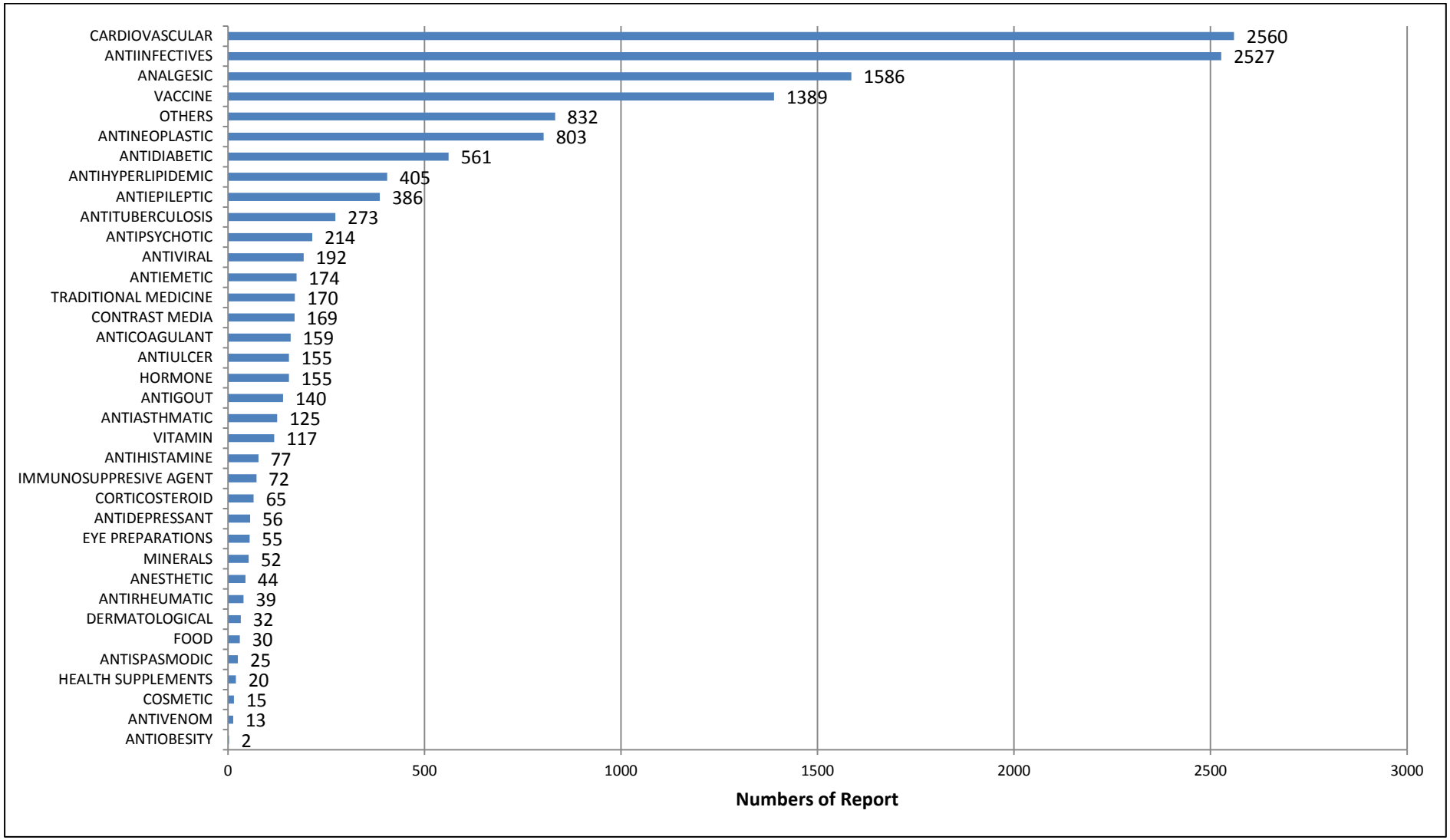


Figure 11: Number of Adverse Drug Reactions by System Organ Class (2015)