ANNUAL REPORT 2016

NATIONAL CENTRE FOR ADVERSE DRUG REACTIONS MONITORING, NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA)

MALAYSIAN ADVERSE DRUG REACTIONS ADVISORY COMMITTEE (MADRAC)

MADRAC was established in 1987 under the Drug Control Authority (DCA) to perform the function of monitoring safety profiles of drugs registered for use in Malaysia. MADRAC members for the 2016-2018 session comprise of Ministry of Health consultants from various specialties (including two new diciplines added this session: cardiology and oncology), pharmacists, academicians from local universities, and representatives from professional bodies.

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 2016, with 9,136 adverse drug reaction (ADR) reports presented for verification of causality.

Table 1: List of MADRAC Members (Jan- Dec 2016)

No.	Name and Designation
Ex-officio	
1	**Chairman** En. Tan Ann Ling/ Dr. Salmah binti Bahri Director of NPRA
2	**Secretary** Pn. Wan Mohaina binti Wan Mohammad Deputy Director, Centre for Post-Registration of Products and Cosmetic Control, NPRA
3	Pn. Anis Talib/ Datin Dr. Faridah Aryani bt. Md. Yusof Secretary of the Drug Control Authority
Committee Members *(Alternate Members)*	
1	Dr. G.R. Letchuman Ramanathan National Head of Internal Medicine Services Senior Medical Consultant (Endocrinology) Hospital Raja Permaisuri Bainun, Ipoh. *(Datuk Dr. Noel Thomas Ross)*
2	Dato' Dr. Gun Suk Chyn Head of Department and Senior Medical Consultant (Rheumatology) Hospital Tuanku Ja'afar. *(Dato' Dr. Azmillah Rosman)*
3	Dato' Dr. Noor Zalmy Azizan binti Mohd. Ali Azizan Senior Consultant Dermatologist, Hospital Kuala Lumpur. *(Dr. Rohna Ridzwan)*

No.	Name and Designation
4	Dr. Norzila Mohamed Zainudin Senior Consultant Paediatrician, Hospital Kuala Lumpur. *(Dr. Tan Kah Kee)*
5	Dr. Sunita Bavanandan Consultant Nephrologist, Hospital Kuala Lumpur. *(Dr Suryati Yakob)*
5	Dr. Ramli Ali Consultant Psychiatrist, Hospital Kuala Lumpur. *(Dr. Uma Visvalingam)*
6	Dr. Mohd. Sapawi bin Mohamed Consultant Cardiologist, Hospital Raja Perempuan Zainab II. *(Dr. Siti Khairani binti Zainal Abidin)*
7	Dr. Voon Pei Jye Medical Oncologist, Hospital Umum Sarawak. *(Dr. Ibtisam binti Muhamad Nor)*
8	Dr. Rohani Jahis Senior Principal Assistant Director, Vaccine Prevention/ Food & Water Borne Disease Sector Disease Control Division Ministry of Health Malaysia *(Dr. Faridah Kusnin)*
9	Prof. Datin Dr. Zoriah binti Aziz Head of Pharmacy Department, Medical Faculty, Universiti Malaya. *(Dr. Adliah Mhd. Ali)*
10	Pn. Noraini binti Mohamad Ketua Penolong Pengarah Kanan U54, Cawangan Klinikal dan Teknikal, Bahagian Perkhidmatan Farmasi. *(Pn. Rosliza Lajis)*
11	Dr. Thirunavukarasu s/o Rajoo Malaysian Medical Association (MMA) *(Dr. Sivanaesan Letchumanan)*
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) *(En. Lee Min Shen)*

ANALYSIS OF ADR REPORTS

The National Centre received **13,789** ADR reports in 2016 (**Figure 1**). This figure includes Adverse Events Following Immunisation (AEFI) reports received by NPRA. Detailed analysis of the ADR reports received in 2016 is shown in **Figures 2 to 7**.

STRENGTHENING THE PHARMACOVIGILANCE OF VACCINES

The NPRA received 954 Adverse Events Following Immunisation (AEFI) reports in 2016, 656 (68.8%) involving the Human Papilloma Virus (HPV) vaccine. 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.

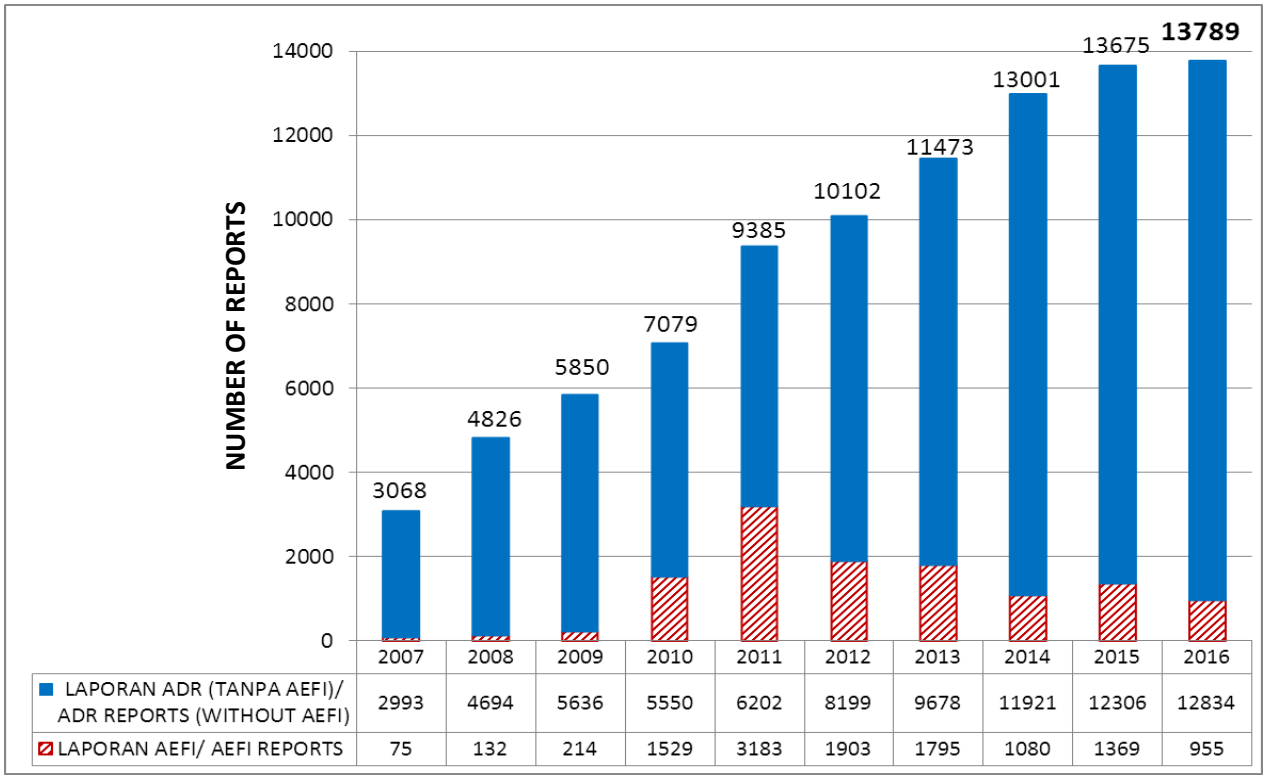
Vaccine Safety Expert Group

The Vaccine Safety Expert Group (JPKV) was established in February 2016. 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.

Vaccine Pharmacovigilance Guidelines

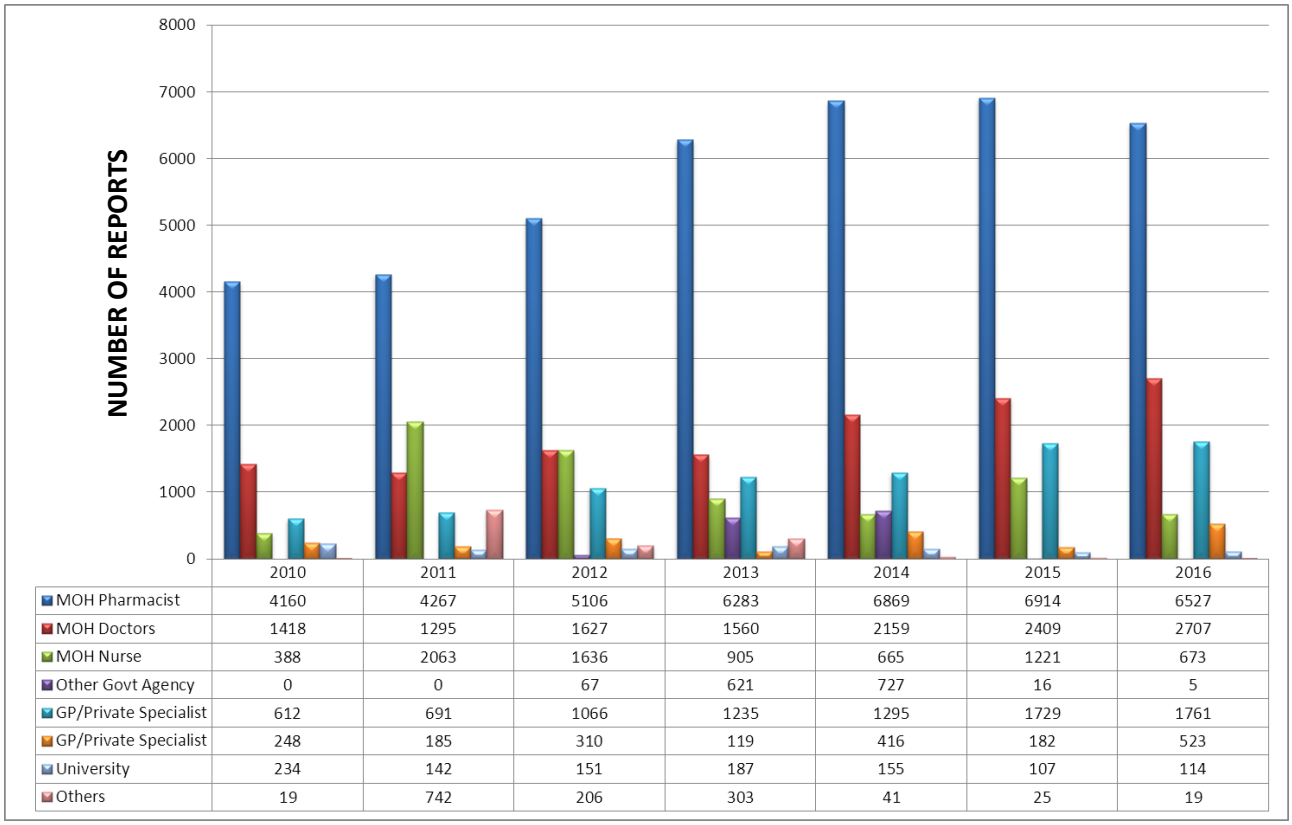
The second edition of the Malaysian Vaccine Pharmacovigilance Guidelines for Healthcare Professionals was released in August 2016. Key updates included revision to the investigation procedures for serious AEFI cases involving MOH and private healthcare facilities. Among the revised procedures were vaccine quarantining, vaccine handling, vaccine quality investigation, patient investigation, and investigation of vaccine storage at the immunisation facility.

Figure 1: Total Number of ADR/AEFI Reports Received in Malaysia (2007-2016)



	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016
LAPORAN ADR (TANPA AEFI)/ ADR REPORTS (WITHOUT AEFI)	2993	4694	5636	5550	6202	8199	9678	11921	12306	12834
LAPORAN AEFI/ AEFI REPORTS	75	132	214	1529	3183	1903	1795	1080	1369	955

Figure 2: ADR/ AEFI Reports by Category of Reporters (2010-2016)



	2010	2011	2012	2013	2014	2015	2016
MOH Pharmacist	4160	4267	5106	6283	6869	6914	6527
MOH Doctors	1418	1295	1627	1560	2159	2409	2707
MOH Nurse	388	2063	1636	905	665	1221	673
Other Govt Agency	0	0	67	621	727	16	5
GP/Private Specialist	612	691	1066	1235	1295	1729	1761
GP/Private Specialist	248	185	310	119	416	182	523
University	234	142	151	187	155	107	114
Others	19	742	206	303	41	25	19

Figure 3: ADR/ AEFI Reports by State from MOH Facilities (2016)

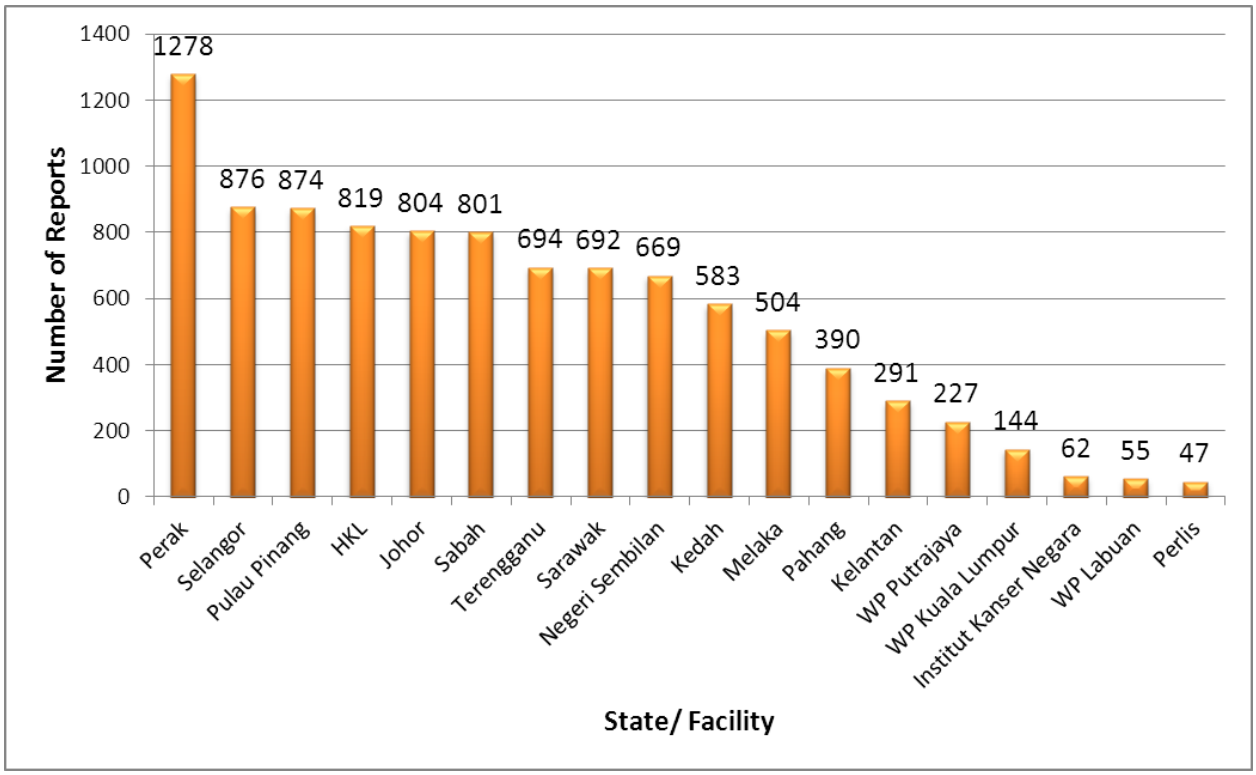


Figure 4: ADR/ AEFI Reports by Patient Age Group (2016)

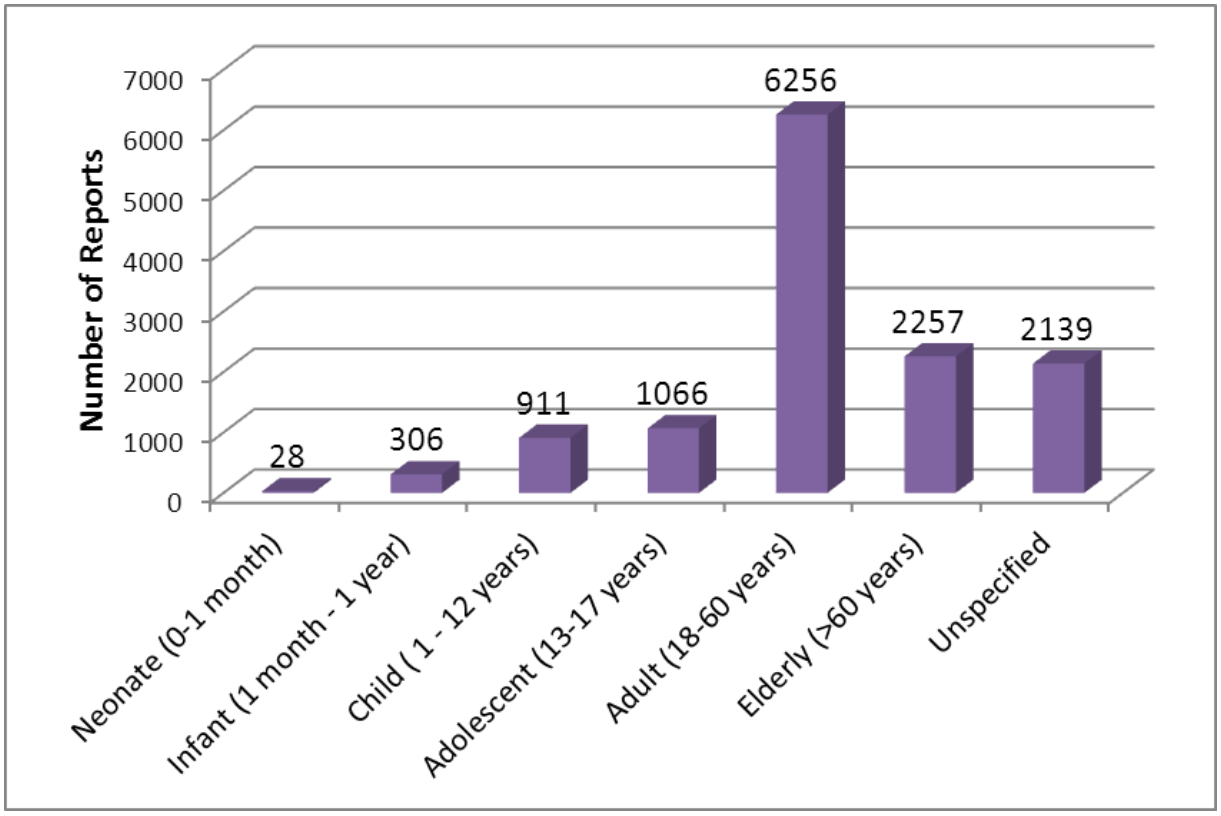


Figure 5: ADR/ AEFI Reports by Patient Gender (2016)

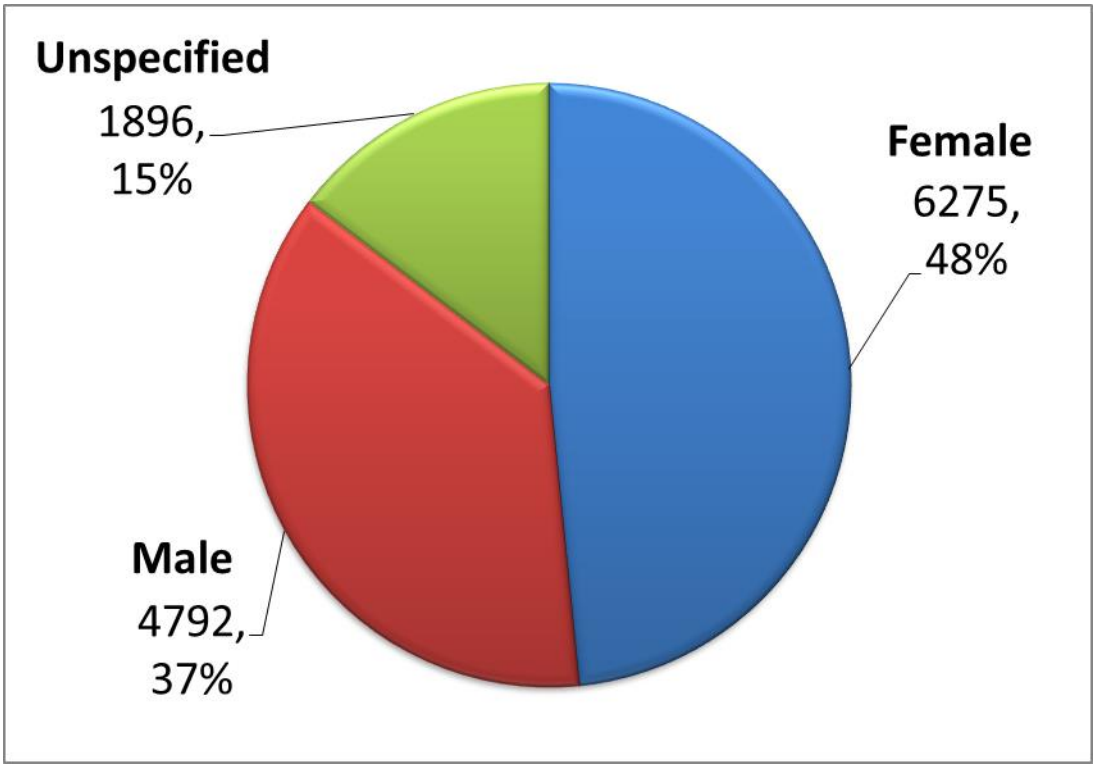


Figure 6: Number of Adverse Drug Reactions by Pharmacological Group (2016)

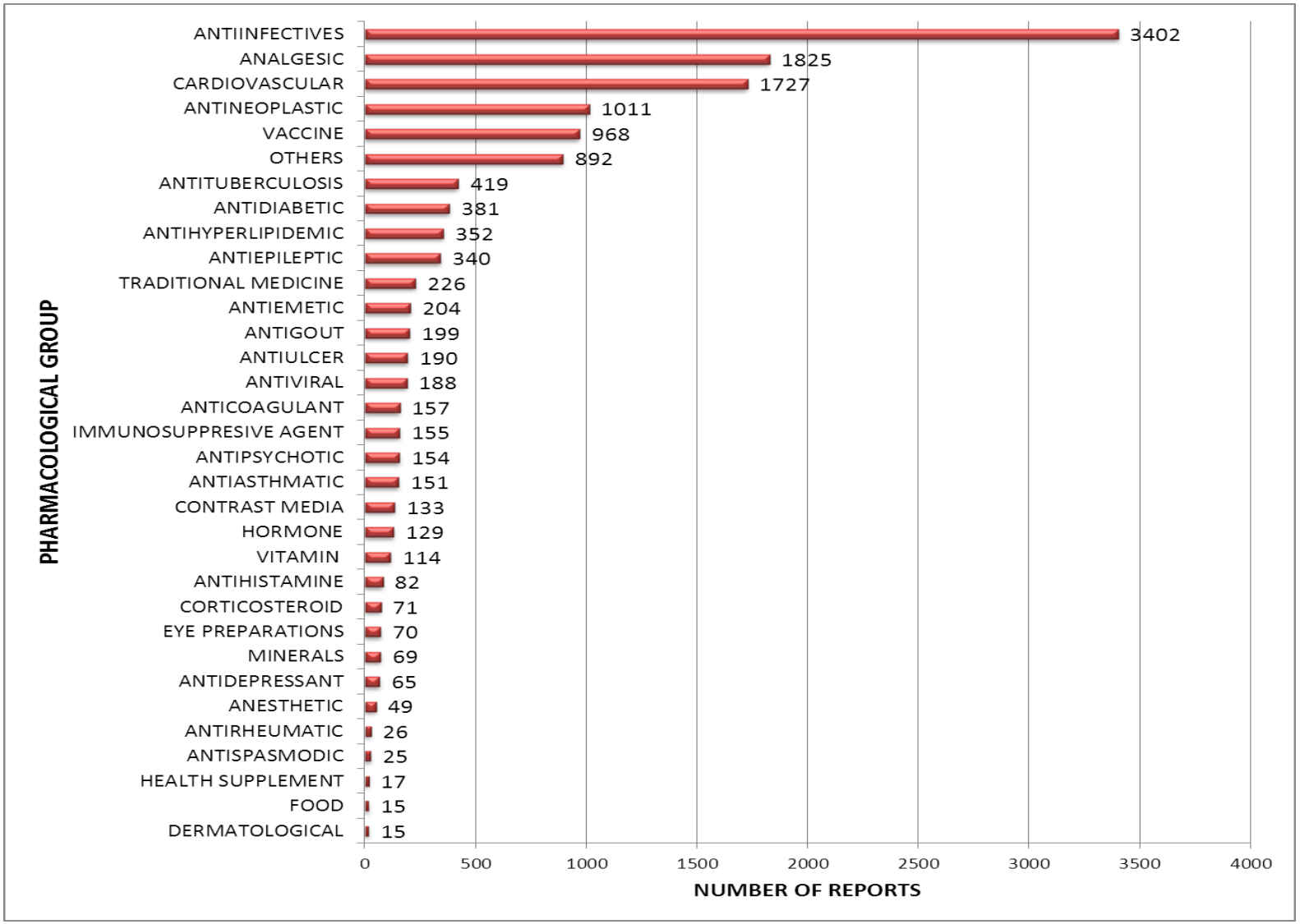
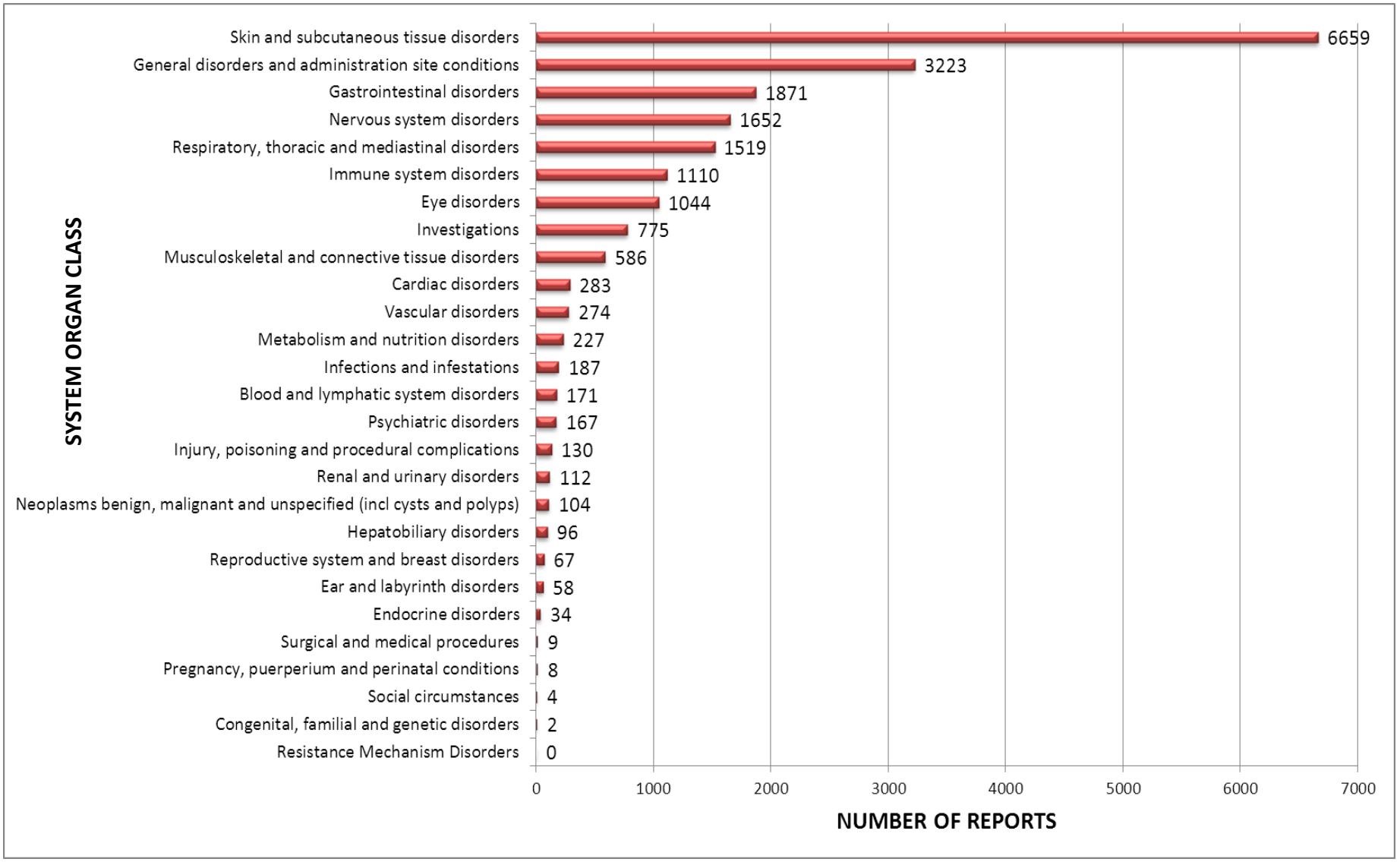


Figure 7: Number of Adverse Drug Reactions by System Organ Class (2016)



MALAYSIAN PHARMACOVIGILANCE GUIDELINES (SECOND EDITION)

In September 2016, NPRA published the Malaysian Pharmacovigilance Guidelines (2nd edition) to align with current international requirements in adverse drug reaction (ADR) reporting and safety monitoring of medicinal products.

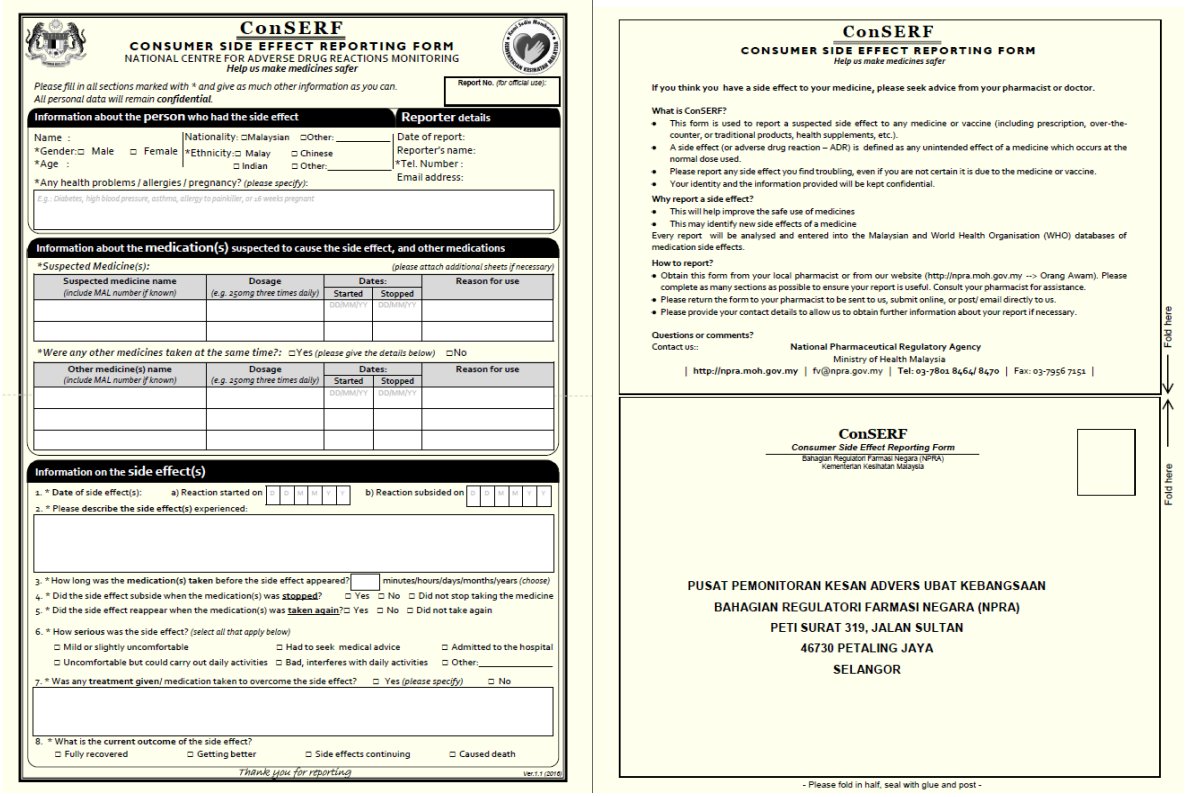
This guidance document has been updated since its first publication in 2002, to include detailed information on ADR reporting for healthcare professionals and product registration holders (PRHs), as well as the responsibilities of PRHs in drug safety monitoring.

CONSUMER SIDE EFFECT REPORTING FORM (ConSERF)

To increase consumer empowerment, a new form for direct consumer ADR reporting (known as the Consumer Side Effect Reporting Form – ConSERF) was released in October 2016 to ensure the Malaysian ADR database captures more complete coverage of types of ADRs and products, including traditional products and health supplements. This form is available for download on the NPRA website, along with guidance for reporters.

Figure 8: New Consumer Side Effect Reporting Form – ConSERF

(a) English version



ConSERF

CONSUMER SIDE EFFECT REPORTING FORM

NATIONAL CENTRE FOR ADVERSE DRUG REACTIONS MONITORING

Help us make medicines safer

*Please fill in all sections marked with * and give as much other information as you can.*
All personal data will remain confidential.

Report No. *(for official use)*:

Information about the person who had the side effect

Name :
*Gender: ☐ Male ☐ Female
*Age :
Nationality: ☐Malaysian ☐Other: _____
*Ethnicity: ☐ Malay ☐ Chinese ☐ Indian ☐ Other: _____
*Any health problems / allergies / pregnancy? *(please specify)*:
E.g.: Diabetes, high blood pressure, asthma, allergy to painkiller, or ≥6 weeks pregnant

Reporter details

Date of report:
Reporter's name:
*Tel. Number :
Email address:

Information about the medication(s) suspected to cause the side effect, and other medications

Suspected Medicine(s): *(please attach additional sheets if necessary)*

Suspected medicine name (include MAL number if known)	Dosage (e.g. 250mg three times daily)	Dates: Started	Dates: Stopped	Reason for use
		DD/MM/YY	DD/MM/YY	

*Were any other medicines taken at the same time?: ☐Yes *(please give the details below)* ☐No

Other medicine(s) name (include MAL number if known)	Dosage (e.g. 250mg three times daily)	Dates: Started	Dates: Stopped	Reason for use
		DD/MM/YY	DD/MM/YY	

Information on the side effect(s)

1. * **Date** of side effect(s): a) Reaction started on D D M M Y Y b) Reaction subsided on D D M M Y Y
2. * Please **describe the side effect(s)** experienced:
3. * How long was the **medication(s) taken** before the side effect appeared? _____ minutes/hours/days/months/years *(choose)*
4. * Did the side effect subside when the medication(s) was **stopped**? ☐ Yes ☐ No ☐ Did not stop taking the medicine
5. * Did the side effect reappear when the medication(s) was **taken again**? ☐ Yes ☐ No ☐ Did not take again
6. * How **serious** was the side effect? *(select all that apply below)*
   ☐ Mild or slightly uncomfortable ☐ Had to seek medical advice ☐ Admitted to the hospital
   ☐ Uncomfortable but could carry out daily activities ☐ Bad, interferes with daily activities ☐ Other: _____
7. * Was any **treatment given**/ medication taken to overcome the side effect? ☐ Yes *(please specify)* ☐ No
8. * What is the **current outcome** of the side effect?
   ☐ Fully recovered ☐ Getting better ☐ Side effects continuing ☐ Caused death

Thank you for reporting

Ver.1.1 (2016)

ConSERF

CONSUMER SIDE EFFECT REPORTING FORM

Help us make medicines safer

If you think you have a side effect to your medicine, please seek advice from your pharmacist or doctor.

What is ConSERF?
- This form is used to report a suspected side effect to any medicine or vaccine (including prescription, over-the-counter, or traditional products, health supplements, etc.).
- A side effect (or adverse drug reaction – ADR) is defined as any unintended effect of a medicine which occurs at the normal dose used.
- Please report any side effect you find troubling, even if you are not certain it is due to the medicine or vaccine.
- Your identity and the information provided will be kept confidential.

Why report a side effect?
- This will help improve the safe use of medicines
- This may identify new side effects of a medicine

Every report will be analysed and entered into the Malaysian and World Health Organisation (WHO) databases of medication side effects.

How to report?
- Obtain this form from your local pharmacist or from our website (http://npra.moh.gov.my --> Orang Awam). Please complete as many sections as possible to ensure your report is useful. Consult your pharmacist for assistance.
- Please return the form to your pharmacist to be sent to us, submit online, or post/ email directly to us.
- Please provide your contact details to allow us to obtain further information about your report if necessary.

Questions or comments?
Contact us::

National Pharmaceutical Regulatory Agency
Ministry of Health Malaysia
| http://npra.moh.gov.my | fv@npra.gov.my | Tel: 03-7801 8464/ 8470 | Fax: 03-7956 7151 |

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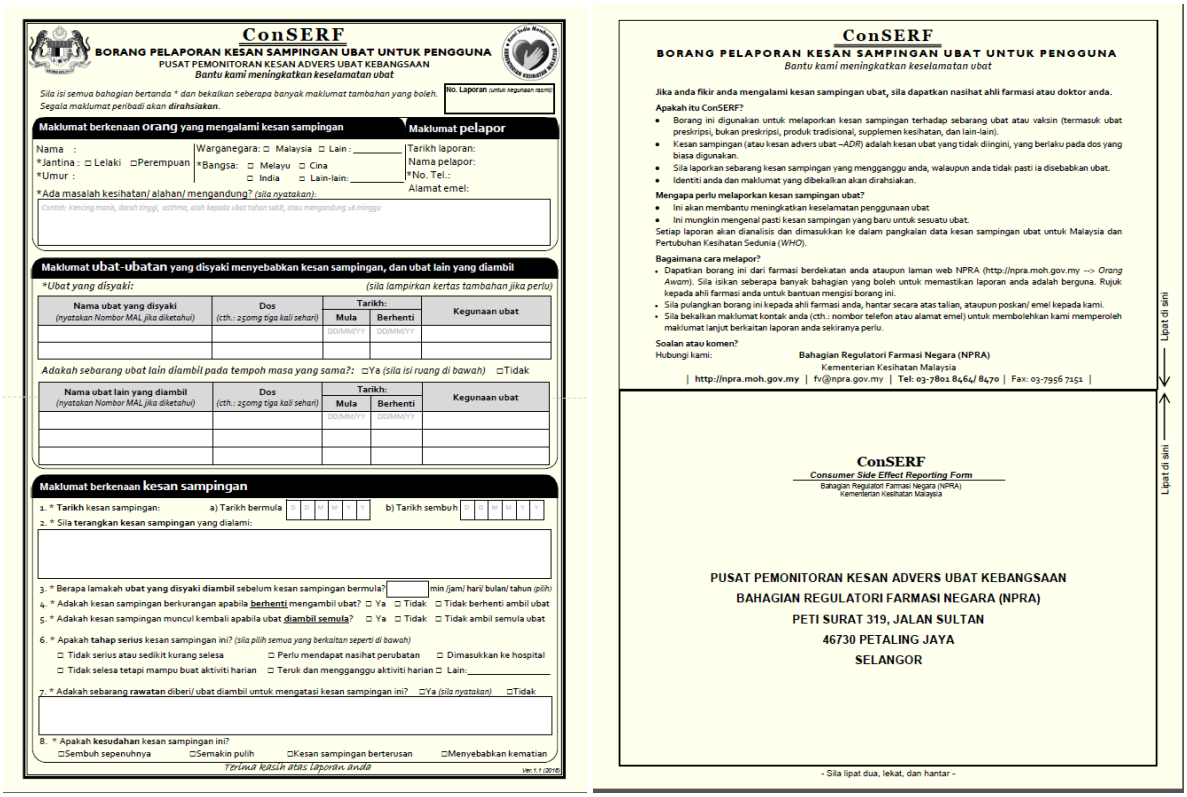
ConSERF
Consumer Side Effect Reporting Form
Bahagian Regulatori Farmasi Negara (NPRA)
Kementerian Kesihatan Malaysia

PUSAT PEMONITORAN KESAN ADVERS UBAT KEBANGSAAN
BAHAGIAN REGULATORI FARMASI NEGARA (NPRA)
PETI SURAT 319, JALAN SULTAN
46730 PETALING JAYA
SELANGOR

Fold here

- Please fold in half, seal with glue and post -

(b) *Bahasa Melayu* version



ConSERF

BORANG PELAPORAN KESAN SAMPINGAN UBAT UNTUK PENGGUNA

PUSAT PEMONITORAN KESAN ADVERS UBAT KEBANGSAAN

Bantu kami meningkatkan keselamatan ubat

*Sila isi semua bahagian bertanda * dan bekalkan seberapa banyak maklumat tambahan yang boleh.*
*Segala maklumat peribadi akan **dirahsiakan**.*

No. Laporan (untuk kegunaan rasmi)

Maklumat berkenaan orang yang mengalami kesan sampingan | **Maklumat pelapor**

Nama :
*Jantina : ☐ Lelaki ☐Perempuan
*Umur :
Warganegara: ☐ Malaysia ☐ Lain : _____
*Bangsa: ☐ Melayu ☐ Cina ☐ India ☐ Lain-lain: _____
*Ada masalah kesihatan/ alahan/ mengandung? *(sila nyatakan)*:
Contoh: kencing manis, darah tinggi, asthma, alah kepada ubat tahan sakit, atau mengandung 16 minggu

Tarikh laporan:
Nama pelapor:
*No. Tel.:
Alamat emel:

Maklumat ubat-ubatan yang disyaki menyebabkan kesan sampingan, dan ubat lain yang diambil

**Ubat yang disyaki:* *(sila lampirkan kertas tambahan jika perlu)*

Nama ubat yang disyaki *(nyatakan Nombor MAL jika diketahui)*	Dos *(cth.: 25omg tiga kali sehari)*	Tarikh: Mula	Tarikh: Berhenti	Kegunaan ubat
		DD/MM/YY	DD/MM/YY	

Adakah sebarang ubat lain diambil pada tempoh masa yang sama?: ☐Ya *(sila isi ruang di bawah)* ☐Tidak

Nama ubat lain yang diambil *(nyatakan Nombor MAL jika diketahui)*	Dos *(cth.: 25omg tiga kali sehari)*	Tarikh: Mula	Tarikh: Berhenti	Kegunaan ubat
		DD/MM/YY	DD/MM/YY	

Maklumat berkenaan kesan sampingan

1. * **Tarikh** kesan sampingan: a) Tarikh bermula D D M M Y Y b) Tarikh sembuh D D M M Y Y
2. * Sila **terangkan kesan sampingan** yang dialami:
3. * **Berapa lamakah ubat yang disyaki diambil** sebelum kesan sampingan bermula? _____ min /jam/ hari/ bulan/ tahun *(pilih)*
4. * Adakah kesan sampingan berkurangan apabila **berhenti** mengambil ubat? ☐ Ya ☐ Tidak ☐ Tidak berhenti ambil ubat
5. * Adakah kesan sampingan muncul kembali apabila ubat **diambil semula**? ☐ Ya ☐ Tidak ☐ Tidak ambil semula ubat
6. * Apakah **tahap serius** kesan sampingan ini? *(sila pilih semua yang berkaitan seperti di bawah)*
   ☐ Tidak serius atau sedikit kurang selesa ☐ Perlu mendapat nasihat perubatan ☐ Dimasukkan ke hospital
   ☐ Tidak selesa tetapi mampu buat aktiviti harian ☐ Teruk dan mengganggu aktiviti harian ☐ Lain: _____
7. * Adakah sebarang **rawatan** diberi/ ubat diambil untuk mengatasi kesan sampingan ini? ☐Ya *(sila nyatakan)* ☐Tidak
8. * Apakah **kesudahan** kesan sampingan ini?
   ☐Sembuh sepenuhnya ☐Semakin pulih ☐Kesan sampingan berterusan ☐Menyebabkan kematian

Terima kasih atas laporan anda

ver.1.1 (2015)

ConSERF

BORANG PELAPORAN KESAN SAMPINGAN UBAT UNTUK PENGGUNA

Bantu kami meningkatkan keselamatan ubat

Jika anda fikir anda mengalami kesan sampingan ubat, sila dapatkan nasihat ahli farmasi atau doktor anda.

Apakah itu ConSERF?

- Borang ini digunakan untuk melaporkan kesan sampingan terhadap sebarang ubat atau vaksin (termasuk ubat preskripsi, bukan preskripsi, produk tradisional, supplemen kesihatan, dan lain-lain).
- Kesan sampingan (atau kesan advers ubat –*ADR*) adalah kesan ubat yang tidak diingini, yang berlaku pada dos yang biasa digunakan.
- Sila laporkan sebarang kesan sampingan yang mengganggu anda, walaupun anda tidak pasti ia disebabkan ubat.
- Identiti anda dan maklumat yang dibekalkan akan dirahsiakan.

Mengapa perlu melaporkan kesan sampingan ubat?

- Ini akan membantu meningkatkan keselamatan penggunaan ubat
- Ini mungkin mengenal pasti kesan sampingan yang baru untuk sesuatu ubat.

Setiap laporan akan dianalisis dan dimasukkan ke dalam pangkalan data kesan sampingan ubat untuk Malaysia dan Pertubuhan Kesihatan Sedunia (*WHO*).

Bagaimana cara melapor?

- Dapatkan borang ini dari farmasi berdekatan anda ataupun laman web NPRA (http://npra.moh.gov.my --> *Orang Awam*). Sila isikan seberapa banyak bahagian yang boleh untuk memastikan laporan anda adalah berguna. Rujuk kepada ahli farmasi anda untuk bantuan mengisi borang ini.
- Sila pulangkan borang ini kepada ahli farmasi anda, hantar secara atas talian, ataupun poskan/ emel kepada kami.
- Sila belalikan maklumat kontak anda (cth.: nombor telefon atau alamat emel) untuk membolehkan kami memperoleh maklumat lanjut berkaitan laporan anda sekiranya perlu.

Soalan atau komen?

Hubungi kami: **Bahagian Regulatori Farmasi Negara (NPRA)**
Kementerian Kesihatan Malaysia
| **http://npra.moh.gov.my** | **fv@npra.gov.my** | **Tel: 03-7801 8464/ 8470** | Fax: 03-7956 7151 |

Lipat di sini

Lipat di sini

ConSERF
Consumer Side Effect Reporting Form
Bahagian Regulatori Farmasi Negara (NPRA)
Kementerian Kesihatan Malaysia

PUSAT PEMONITORAN KESAN ADVERS UBAT KEBANGSAAN
BAHAGIAN REGULATORI FARMASI NEGARA (NPRA)
PETI SURAT 319, JALAN SULTAN
46730 PETALING JAYA
SELANGOR

- Sila lipat dua, lekat, dan hantar -

CPD POINTS FOR ADR REPORTING BY PHARMACISTS

As part of the effort to increase the quantity and quality of ADR reports in particular from private sector healthcare professionals, beginning January 2016, pharmacists are eligible to claim Continuing Professional Development (CPD) points for the submission of quality ADR reports.

The Pharmacy Board Malaysia has agreed to award one (1) CPD point under category A4 for every ADR report submitted to the NPRA which fulfills certain mandatory criteria [Ref: KKM-55/BPF/101/001/01 JLD 29 (20) and KKM.600-16/1/6(57)].

MONITORING DRUG SAFETY ISSUES

In 2016, a total of 130 drug safety issue alerts were identified, mostly through the screening of reference regulatory agency alerts which is carried out daily. Following review, 25 issues were presented at MADRAC meetings to determine the appropriate risk minimisation measures [**Table 1**]. The majority of these issues resulted in updates to the package insert safety information, such as tightening of indications or additional contraindications. Regulatory actions for nine (9) 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 336 products.

Table 1: Drug Safety Issues Discussed by MADRAC

		MADRAC Recommendation/ Resulting Action				
No.	**Product name (active ingredient) & Safety Issue**	**DCA Directive**	**PI Update**	**DHPC**	**Publication of article**	**Further review**
1	Fusafungine: Revocation of marketing authorisations for fusafungine sprays in the European Union (EU) due to the Risk of Serious Allergic Reactions including Anaphylaxis			/	/	
2	Xgeva® and Prolia® (denosumab): Clinically Significant Cases of Hypercalcaemia after Cessation of Treatment with Denosumab in Pediatric Patients		/	/	/	
3	Mycophenolate (mycophenolate mofetil and mycophenolic acid): Risk of teratogenic effects	/	/		/	
4	Saxagliptin and Alogliptin: Risk of Heart Failure					/
5	BCR-ABL Tyrosine Kinase Inhibitors: Risk of hepatitis B virus (HBV) reactivation		/	/	/	
6	Febuxostat: Potential Risk of Heart Failure					/
7	Viekirax® (ombitasvir/ paritaprevir/ ritonavir) and Exviera® (dasabuvir): Not recommended in Child-Pugh B Patients		/	/	/	
8	Xalkori® (crizotinib): Inclusion of a new warning regarding cardiac failure		/	/	/	
9	Bisphosphonates (alendronate, clodronate, ibandronic acid, pamidronate, risedronate, zoledronic acid): Risk of Osteonecrosis of the External Auditory Canal		/	/	/	
10	Olanzapine: Risk of Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS)	/	/		/	

		MADRAC Recommendation/ Resulting Action				
No.	**Product name (active ingredient) & Safety Issue**	**DCA Directive**	**PI Update**	**DHPC**	**Publication of article**	**Further review**
11	Interferon alfa and beta: Risk of pulmonary arterial hypertension	/	/		/	
12	Sodium Valproate: Risk of abnormal pregnancy outcomes	/	/		/	
13	Minyak Cajeput (*melaleuca leucodendran*) – topical dosage form: Risk of causing breathing problems/ shortness of breath	/	/		/	
14	Carbamazepine: Information on the importance of genetic screening for new patients to reduce the risk of serious cutaneous adverse events	***/***				
15	Infliximab: Risk of Cervical Cancer				/	
16	Adempas® (riociguat): New contraindication in patients with pulmonary hypertension associated with idiopathic interstitial pneumonia (PH-IIP)		/	/	/	
17	Tarceva® (erlotinib): First-line maintanence indication now restricted to treatment of patients whose tumours harbor an EGFR-activating mutation		/	/	/	
18	Invokana® (canagliflozin): *Risk of lower limb amputation (primarily of the toe)*		/	/	/	
19	Codeine: Update of package inserts with safety information on the risk of respiratory depression	/	/		/	
20	Warfarin: Risk of calciphylaxis	/	/		/	
21	Gabapentin: Risk of serious breathing problems *(respiratory depression)*					/

		MADRAC Recommendation/ Resulting Action				
No.	**Product name (active ingredient) & Safety Issue**	**DCA Directive**	**PI Update**	**DHPC**	**Publication of article**	**Further review**
22	Enbrel® (etanercept): Potential harm to the developing babies of mothers treated with Enbrel®					/
23	Miconazole (oral gel & injection): Risk of severe bleeding following co-administration of miconazole and warfarin					/
24	Implanon NXT® (etonogestrel): Implants have been found rarely in the vasculature and lung. An update on possible risks and complications regarding insertion, localization, removal and migration.			/	/	
25	Zaltrap® (aflibercept): Risk of osteonecrosis of the jaw					/

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 2016, a total of 222 PBRERs/ PSURs involving 173 products were assessed, resulting in implementation of package insert changes for 23 products (13.3%) to ensure that they contain the latest safety information.

Risk management plans (RMPs) are also submitted by product registration holders to NPRA when there is any concern about a risk affecting the benefit-risk balance of a product. In 2016, a total of 40 RMPs involving 26 registered products were received and reviewed.

CONSUMER MEDICATION INFORMATION LEAFLETS (RiMUPs)

Since April 2011, the submission of Consumer Medication Information Leaflets (or Risalah Maklumat Ubat untuk Pengguna- RiMUP) is compulsory for products which are self-administered by consumers. RiMUPs for almost 1,300 registered products are currently available on the NPRA website for consumers and healthcare professionals to view and print out.

In the year 2016, a total of 3,426 RiMUPs of registered products were reviewed, with 451 (13.2%) approved and uploaded on the NPRA website for use by consumers or healthcare professionals. The remaining RiMUPs are still under evaluation. The necessary steps will be taken to ensure more RiMUPs are available for use by all parties mentioned above.

DRUG SAFETY COMMUNICATION

Effective communication is essential in pharmacovigilance, to ensure the timely and transparent sharing of medicine safety information. The NPRA released three (3) issues of the MADRAC Bulletin in 2016, as well as seven (7) issues of Reaksi Drug Safety News.

Two television interviews with RTM and TV AL-Hijrah were conducted in November 2016, aiming to increase public awareness on medication safety.

An electronic mailing list of healthcare professionals will be maintained in the continuous effort to ensure wider and prompt dissemination of safety information. This mailing list currently consists of more than 2,000 contacts. Further information may be obtained from the NPRA website, or by emailing queries to **fv@npra.gov.my**.

Besides the publications, a total of 12 Direct Healthcare Professional Communications (DHPCs) were approved by the NPRA for distribution in 2016. These were issued by the product registration holders to highlight important changes in the prescribing information, safety profile or use of a product.

IMPROVING THE QUALITY OF ADR REPORTS

Further measures are being taken to increase the quality of ADR reports in Malaysia.

With the new Pharmacovigilance system and database, as well as continuous training for reporters, it is hoped that more complete reports will be received.

Over the past five years, NPRA has conducted training sessions all across Malaysia on ADR report analysis and causality assessment. In 2016, training was held in Sarawak and Terengganu, involving 80 pharmacists. Such training is in-line with the future plan for causality assessment to be done at reporter institution level, for verification by the NPRA.

Besides the causality assessment training mentioned above, there were 23 training programmes conducted or presentations delivered, which involved more than 1000 MOH staff, 247 private sector healthcare professionals, and 46 international participants. These sessions aimed to increase awareness on the importance of reporting, improve the quality of ADR/ AEFI reporting, and train reporters to assess causality.

TOWARDS IMPLEMENTATION OF PHARMACOVIGILANCE INSPECTION

The NPRA is heading towards conducting pharmacovigilance (PV) inspection in Malaysia. PV inspection is conducted by health regulatory authorities on product registration holders to determine compliance with regulatory PV obligations.

In the effort to establish a competent PV Inspectorate, NPRA PV Section staff were given an overview on this topic in August 2016 by an Expert Inspector of Good Pharmacovigilance Practice from the United Kingdom (UK) Medicines and Healthcare Products Regulatory Agency (MHRA). The PV staff received further training in November 2016, from representatives of the UK MHRA PV Information & Signal Management Unit, in a two-day course coordinated by the World Health Organisation (WHO).

The next stage will be for selected staff to attend fellowship training as observers of a PV inspection in the UK, scheduled in mid-2017. The Malaysian PV Guidelines will then be updated with requirements for the PV System Master File and PV Inspection. Actual

implementation of PV Inspection in Malaysia will be carried out in stages, targeted to begin in 2018.

RESEARCH COLLABORATION

In 2016, a total of 11 students from local universities collaborated with the NPRA for research projects, including two (2) Masters and two (2) PhD students.