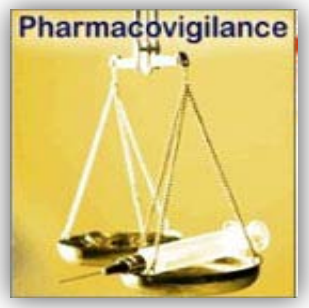
BADAN POM

Pharmacovigilance System and Its Implementation in Indonesia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Therapeutic and Household Healthcare Products

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Jakarta, 13 February 2013

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OUTLINES:

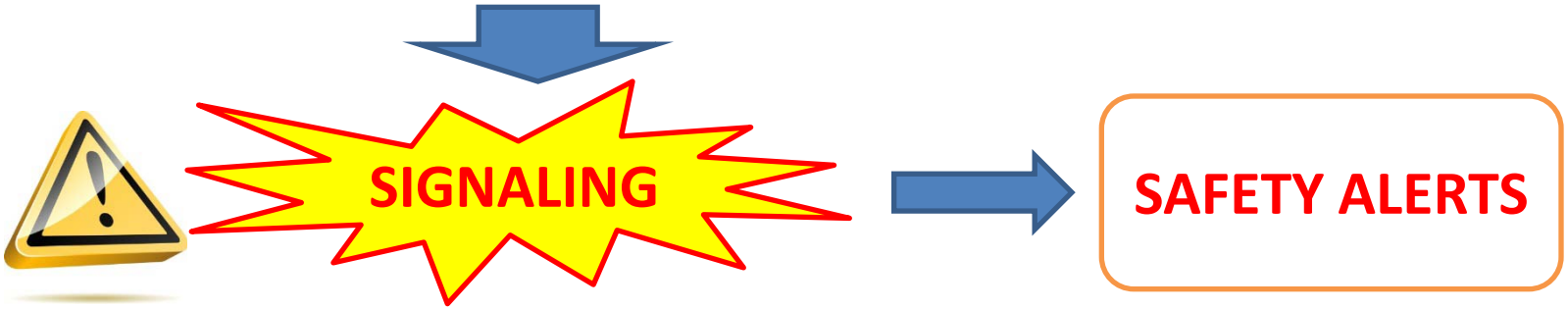
- ✓ Definition of Pharmacovigilance
- ✓ Objectives of Pharmacovigilance
- ✓ History of Pharmacovigilance in Indonesia
- ✓ Pharmacovigilance System
- ✓ ADRs Reporting by Health Care Professional (HCPs)
- ✓ Implementation of Pharmacovigilance by Pharmaceutical Industry or Marketing Authorization Holder
- ✓ Pharmacovigilance Perfomance in 2012

Pharmacovigilance
(WHO Definition)

The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible medicine-related problems

Objectives of *Pharmacovigilance*:

- Early detection of new ADRs (unexpected/never known before)
- Detection of possible drug interactions
- Detection of increasing frequency of expected ADRs
- Identification of risk factors and its mechanism
- Assessment on long term safety
- Study of potential risk group of population (children, elderly, pregnant women)
- Benefit/risk ratio assessment to manage and control the risk
- Provide drug safety profile based on Indonesia Population



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Snapshot and History of Development of ADVERSE DRUG MONITORING/ Pharmacovigilance Activities in Indonesia

1975 - 1978

Piloting project: involving 6 public hospitals

1. GH. Pringadi Medan
2. GH Cipto . JKT
3. GH. Hasan Sadikin Bandung
4. GH. Dr. Sardjito Jogjakarta
5. GH. Dr. Karyadi Semarang
6. GH. Dr. Soetomo Surabaya

1980

- **National Program on Monitoring of ADRs: Voluntary Reporting by HCPs**
- **Advisory Board**

1990

NADFC as a Member of WHO Program for International Drug Monitoring. The collaboration centre for PV: in WHO UMC, Uppsala, Sweden

2004

Establishement of Pharmacovigilance Unit under Directorate of Distribution Control of Therapeutic & Household Healthcare Products

BADAN POM

Snapshot and History of Development of ADVERSE DRUG MONITORING/ Pharmacovigilance Activities in Indonesia

2008 → 2010 → 2011 → 2012 - 2014

Strengthening Legal Framework on PV

MoH Decree No. 1010/Menkes/Per/XI/2008 on Drug Registration , Article No. 22

MoH Decree No. 1799/Menkes/Per/XII/2010 on Pharmaceutical Industry, Article No. 9: Mandatory for Pharmaceutical Industry to perform PV

Head of NADFC Regulation No. HK.03.1.23.12.11.10690 of 2011 on PV Implementation for Pharmaceutical Industry and its coresponding Technical Guidelines

1. Strengthening Risk Management Program approaches
2. Linking NRA with Public Health Program:
   a. EPI for AEFI Surveillance
   b. ATM Drugs
3. Development of dedicated subsite for PV Activities, incl. e- ADRs reporting
4. Networking with relevant stakeholders to promote PV activities
5. Workshop on PV: improve HCPs roles and responsibility to involve in ADRs reporting

PHARMACOVIGILANCE SYSTEM

VOLUNTARY → **Health Care Professionals (HCPs)**

- ✓ Hospitals / Public Healthcare centre
- ✓ General Practices / Private
- ✓ Pharmacist in Pharmacy
- ✓ Other HCPs

Spontaneous Reporting: Yellow Form

MANDATORY → **Pharmaceutical Industry (PI) / Marketing Authorization Holders (MAHs)**

- Spontaneous Reporting: CIOMS Form instead of Yellow Form
- PSUR (for certain conditions)
- Scientific Publication and Study Reports
- Regulatory Action in Other country

HCPs: AEs/ADRs REPORTING

SPONTANEOUS VOLUNTARY REPORTING

Passive Surveillance

***Spontaneous Voluntary Reporting is unsolicited AEs/ADRs* report by HCPs, based on clinical practice experiences, which does not derive from a study**

AEs/ADRs *SPONTANEOUS VOLUNTARY REPORTING*

Advantages **:**

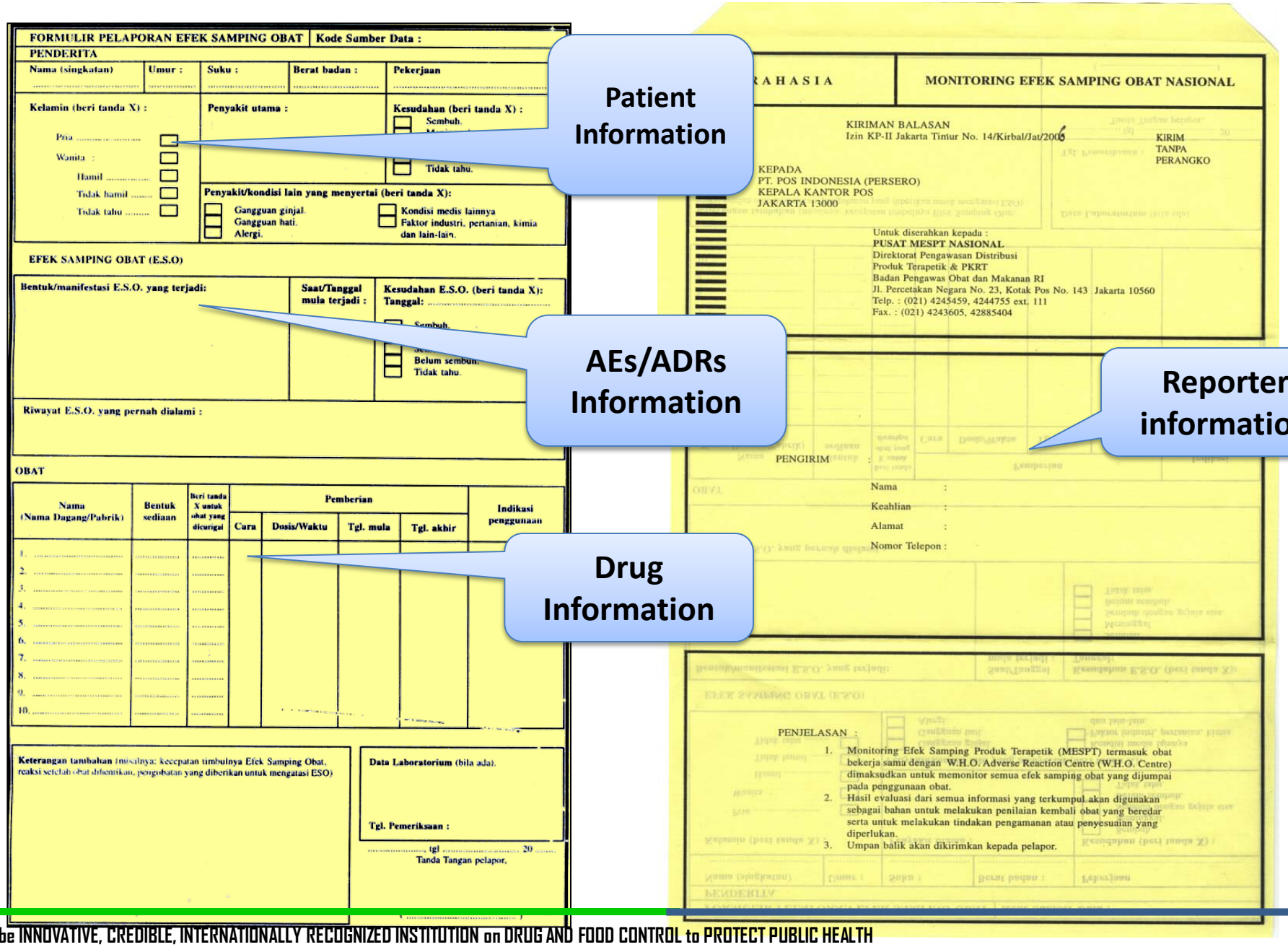
- ❑ Involving wider population incl. Children, elderly, pregnant women, breast feeding women.
- ❑ In- and out-patients
- ❑ Can be applied to all drugs
- ❑ May detect very rare ADRs
- ❑ Detect drug interaction
- ❑ Evaluation of drug use in bigger population
- ❑ No intervention to the reporters
- ❑ Possible to conduct individual assessment of patient
- ❑ Can compare ADRs profiles between drugs within the same therapeutic class
- ❑ Simple, easy and cheap

Limitations **:**

- ❑ Under reporting
- ❑ Number of patients exposure is unknown
- ❑ Can not calculate incidence
- ❑ Incomplete or insufficient information
- ❑ Difficult to detect delayed reactions
- ❑ No Control group
- ❑ Difficult to analysing prescribing rate due to differences in quantities and doses prescribed
- ❑ Biases

UNDER REPORTING: Phenomenon of Ice Berg

REPORTING FORM for HCPs (Yellow Form)



FORMULIR PELAPORAN EFEK SAMPING OBAT | Kode Sumber Data :

PENDERITA

Nama (singkatan) | Umur : | Suku : | Berat badan : | Pekerjaan

Kelamin (beri tanda X) : Pria / Wanita / Hamil / Tidak hamil / Tidak tahu

Penyakit utama :

Kesudahan (beri tanda X) : Sembuh. / Tidak tahu.

Penyakit/kondisi lain yang menyertai (beri tanda X):
Gangguan ginjal. Gangguan hati. Alergi. Kondisi medis lainnya Faktor industri, pertanian, kimia dan lain-lain.

EFEK SAMPING OBAT (E.S.O)

Bentuk/manifestasi E.S.O. yang terjadi:

Saat/Tanggal mula terjadi :

Kesudahan E.S.O. (beri tanda X): Tanggal: Sembuh. Belum sembuh. Tidak tahu.

Riwayat E.S.O. yang pernah dialami :

OBAT

Nama (Nama Dagang/Pabrik)	Bentuk sediaan	Beri tanda X untuk obat yang dicurigai	Pemberian: Cara	Dosis/Waktu	Tgl. mula	Tgl. akhir	Indikasi penggunaan
1.							
2.							
3.							
4.							
5.							
6.							
7.							
8.							
9.							
10.							

Keterangan tambahan (misalnya: kecepatan timbulnya Efek Samping Obat, reaksi setelah obat dihentikan, pengobatan yang diberikan untuk mengatasi ESO)

Data Laboratorium (bila ada).

Tgl. Pemeriksaan :

..... tgl ..... 20 .....
Tanda Tangan pelapor,

R A H A S I A

MONITORING EFEK SAMPING OBAT NASIONAL

KIRIMAN BALASAN
Izin KP-II Jakarta Timur No. 14/Kirbal/Jat/2006

KIRIM TANPA PERANGKO

KEPADA
PT. POS INDONESIA (PERSERO)
KEPALA KANTOR POS
JAKARTA 13000

Untuk diserahkan kepada :
PUSAT MESPT NASIONAL
Direktorat Pengawasan Distribusi
Produk Terapetik & PKRT
Badan Pengawas Obat dan Makanan RI
Jl. Percetakan Negara No. 23, Kotak Pos No. 143 Jakarta 10560
Telp. : (021) 4245459, 4244755 ext. 111
Fax. : (021) 4243605, 42885404

PENGIRIM :

Nama :

Keahlian :

Alamat :

Nomor Telepon :

PENJELASAN :

1. Monitoring Efek Samping Produk Terapetik (MESPT) termasuk obat bekerja sama dengan W.H.O. Adverse Reaction Centre (W.H.O. Centre) dimaksudkan untuk memonitor semua efek samping obat yang dijumpai pada penggunaan obat.
2. Hasil evaluasi dari semua informasi yang terkumpul akan digunakan sebagai bahan untuk melakukan penilaian kembali obat yang beredar serta untuk melakukan tindakan pengamanan atau penyesuaian yang diperlukan.
3. Umpan balik akan dikirimkan kepada pelapor.

Patient Information

AEs/ADRs Information

Reporter information

Drug Information

Implementation of PV by PI/MAH

PI/MAH

MANDATORY TO PERFORM PV
AND REPORT TO AUTHORITY

NADFC

NEW REGULATION

- ✓ **MoH Regulation No. 1799/Menkes/Per/XII/2010 on Pharmaceutical Industry, Article No. 9**
- ✓ **Head of NADFC Regulation No. HK.03.1.23.12.11.10690 of 2011 on Implementation of Pharmacovigilance for Pharmaceutical Industry (Enacted in 5 January 2012)**

AIMS:

GENERAL:
TO ENSURE DRUG SAFETY AFTER ITS MARKETING, AND TO ENSURE PATIENT SAFETY AS DRUG END USER.

SPECIFIC:
TO STRENGTHEN THE DIRECTION OF AND TO HAVE BETTER STRUCTURED PV SYSTEM IN INDONESIA, WITH OPTIMALIZATION OF THE ROLES AND RESPONSIBILITIES OF PI/MAH TO ENSURE THE SAFETY OF THEIR PRODUCTS

WHAT SHOULD BE PREPARED BY PHARMACEUTICAL INDUSTRY/MAH TO INITIATE PV SYSTEM

ORGANIZATION:
A DESIGNATION UNIT SPECIFIC FOR PV FUNCTION
(NOT NECESSARILY A NEW UNIT, BUT THIS FUNCTION MAY BE ATTACHED TO AVAILABLE UNIT WITH ADDITIONAL FUNCTION OF PV)

PV RESPONSIBLE PERSON/PIC

ESTABLISHMENT OF MONITORING SYSTEM FOR CAPTURING AEs/ADRs FROM HCPs by i.e.:

- DEVELOP SOPS
- DEVELOP PV CARD/FORM/INFORMATION CONTACT/STANDARD QUESTIONER
- TRAIN ALL STAFF INCL MEDREP OR PEOPLE IN THE FRONT ROW
- PROMOTE PV to HCPs to SENSITIZE THEM to REPORT

PHARMACOVIGILANCE REPORTS BY PI/MAH

1. SPONTANEOUS ADRs/ADRs
2. PSUR (PERIODIC SAFETY UPDATE REPORTS)
3. POST-MARKET SAFETY STUDY
4. SCIENTIFIC PUBLICATION/JOURNALS
5. ACTIONS BY MAH IN OTHER COUNTRIES
6. ACTION BY DRUG REGULATORY AUTHORITY IN OTHER COUNTRIES
7. RISK MANAGEMENT PLAN

Spontaneous AEs/ADRs TIMELINE for PI/MAH Reporting

Report Type	Description	Time line
SUL	Serious Unexpected Local	15 calendar days
SUF	Serious Unexpected Foreign	15 calendar days
SEL	Serious Expected Local	15 calendar days
Non SUL	Non Serious Unexpected Local	6 monthly
Non SEL	Non Serious Expected Local	No need to report
Non SUF	Non Serious Unexpected Foreign	No need to report

Criteria of Serious Adverse Event for Spontaneous Reports

A serious adverse event (experience) or reaction is any untoward medical occurrence that at any dose:

- results in death
- is life threatening
- requires inpatient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability/incapacity or
- is a congenital anomaly/birth defect or
- other medical condition considered serious

AEs/ADRs REPORTING FORMAT FOR PI/MAH

Local Version

Lampiran-2

...an Farmakovigilans Bagi Industri Farmasi

...ONTAN KEJADIAN TIDAK DIINGINKAN (KTD) OLEH INDUSTRI FARMASI — RAHASIA

Informasi Pasien

Nama/Inisial Pasien: _____ No. Pelaporan: _____

Usia : _____ Berat Badan: _____ Jenis Kelamin: □ Laki-laki □ Wanita

Pekerjaan : _____

Informasi Manifestasi KTD

Tanggal mula: ___/___/___ (dd,mm,yy) Kesudahan KTD:

Deskripsi KTD: Tanggal___/___/___(dd,mm,yy)

□ Sembuh
□ Meninggal
□ Belum sembuh
□ Sembuh dg gejala sisa
□ Tidak diketahui

Apakah KTD berkurang/sembuh setelah obat dihentikan? □ Ya □ Tidak □Tidak ada informasi

Apakah KTD timbul kembali setelah obat diberikan kembali? □ Ya □ Tidak □Tidak ada informasi

Obat yang dicurigai menimbulkan KTD	Dosis	Frekuensi	Rute	Tgl mula	Tgl berhenti	Indikasi penggunaan obat
1.						
2.						
3.						
4.						
5.						
6.						
Obat lain (termasuk suplemen dan obat tradisional yang diminum pada waktu bersamaan atau 3 bulan sebelumnya)						
1.						
2.						

Informasi lain yang relevan (misal penyakit lain yang menyertai, diagnosis, alergi, kehamilan, pemeriksaan lab, dsb):

Informasi Pelapor

Nama : _____ Tanda tangan: _____

Profesi: _____ Tanggal Pelaporan: ___/___/___

No. Tlp: _____ Alamat E-mail: _____

Nama IF : _____

Alamat : _____

No. Kontrol IF: _____

CIOMS Form

CIOMS FORM

SUSPECT ADVERSE REACTION REPOR...

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last)	1a.COUNTRY	2. DATE OF BIRTH Day	Month	Year	2a. AGE Years	3. SEX	4-6 REACTION ONSET Day	Month	Year

7+13 DESCRIBE REACTION(S) (including relevant test/ lab data)

8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION

- ☐ PATIENT DIED
- ☐ INVOLVED OR PROLONGED INPATIENT HOSPITALISATION
- ☐ INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY
- ☐ LIFE THREATENING
- ☐ CONGENITAL ABNORMALITY/ BIRTH DEFECT
- ☐ IMPORTANT MEDICAL EVENT

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)

20. DID REACTION ABATE AFTER STOPPING DRUG? ☐ YES ☐ NO ☐ NA

15. DAILY DOSE(S)

16. ROUTE(S) OF ADMINISTRATION

21. DID REACTION REAPPEAR AFTER REINTRODUCTION? ☐ YES ☐ NO ☐ NA

17. INDICATION(S) FOR USE

18. THERAPY DATES (from/to)

19. THERAPY DURATION

III. CONCOMITANT DRGUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATE OF ADMINISTRATION (exclude those used to treat reaction)

23. OTHER RELEVANT HISTORY (e.g. diagnoses, allergies, pregnancy with last menstrual period, etc.)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER

24b. MFR CONTROL NO.

24c. DATE RECEIVED BY MANUFACTURER

24d. REPORT SOURCE ☐ STUDY ☐ LITERATURE ☐ HEALTH PROFESSIONAL

DATE OF THIS REPORT

25a. REPORT TYPE ☐ INITIAL ☐ FOLLOW UP

NI- No Information available at this time UNK- Information unknown *= Item completed on continuation page(s)

Reporting Criteria for Other PV Reports

PSUR (Periodic Safety Update Reports)

- *Drug with New Chemical Entity* (NCE) include similar biotherapeutic product.
- Other Drugs, upon request by NADFC

Postmarketing Safety Study

- If required as conditional approval of the products to perform post-marketing study
- Any drugs which have been marketed and required risk management based on benefit risk assessment an/or expert recommendation, and upon request by NADFC.

Regulatory Action by Drug Regulatory Authorities and or MAH in Other Countries

Pharmaceutical Industries must report all information on regulatory action from other country related to safety aspect such as suspension or withdrawal marketing authorizations, recall drugs from the market by other regulatory authorities or voluntary action by MAH.

Risk Management Plan

Upon request by NADFC

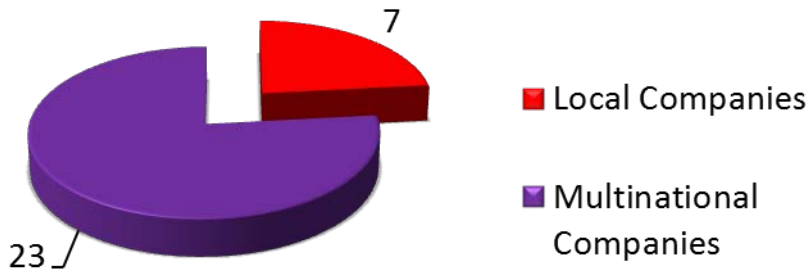
PV PERFORMANCE IN 2012

- **AEs/ADRs Reports total received in 2012**:

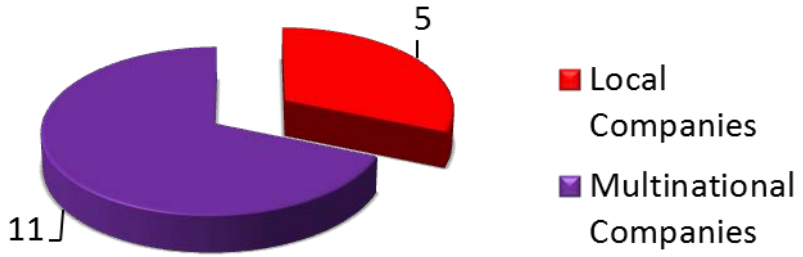
  - HCPs reports: 201 reports

  - PI/MAH reports: 169 (local reports); 38 (AEFI reports); 18.080 (foreign reports)

Total PI/MAH reported AEs/ADRs: 30 PI/MAH



Total PI/MAH reported PSUR/RMP: 16 PI/MAH



Pusat Farmakovigilans:

Direktorat Pengawasan Distribusi Produk Terapetik dan PKRT

Badan Pengawas Obat dan Makanan

Republik Indonesia

Informasi Kontak:
Alamat : Jl. Percetakan Negara No. 23, Jakarta Pusat, 10560
E-mail : pv-center@pom.go.id
No. Fax : +62-21-4288345
No. Tlp :+62-21-4244755 Ext. 111; 4244691 Ext.1072

Terima kasih
THANK YOU
ARIGATO GOZAIMAS