Current status on Adverse Event Reporting in Japan

Iku Mitta
Safety Reports Management Division, Office of Safety I
PMDA
Abbreviation

ADR: Adverse Drug Reaction
DB: Database
EPPV: Early Post-Marketing Phase Vigilance
HCP: Healthcare Professional
ICSR: Individual Case Safety Report
MAH: Marketing Approval Holder
MHLW: Ministry of Health Labor and Welfare
OTC: over-the-counter
PBRER: Periodic Benefit Risk Evaluation Report
PMD act: Pharmaceuticals and Medical Devices Act
PMDA: Pharmaceuticals and Medical Devices Agency
PMDSI: Pharmaceuticals and Medical Devices Safety Information
PSUR: Periodic Safety Update Reports
Today’s Agenda

1. Introduction of PMDA and Management Division, Office of Safety I

2. Reports from MAH (In the case of Drug ICSR)

3. Reports from HCPs

4. Reports from Patient
1. Introduction of PMDA and Management Division, Office of Safety I
The role of PMDA

Safety Triangle

Comprehensive risk management through the three functions:

- **Securing Safety and Efficacy**
- **Review**: Reduction in risk
- **Three-pillar System Unique to Japan**

- **Safety**: Continuous risk mitigation efforts
- **Japanese citizens**
- **Relief**: Relief measures for health damage caused by adverse drug reactions

6th Joint Conference of Taiwan and Japan on Medical Products Regulation (October 11, 2018)
As of August 1, 2018

6th Joint Conference of Taiwan and Japan on Medical Products Regulation (October 11, 2018)
Safety Offices

Chief Safety Officer

Office of Safety I
- Planning and Management Division
- Safety Reports Management Division
- Risk Communication Division
- Medical Device Safety Division
  - Safety reporting desk, Safety information provision, Survey to medical institutes, Pharmaceutical consultation for consumers etc.

Office of Safety II
- 13 teams
  - Scientific review of safety information

Office of Medical Information and Epidemiology
  - Development of national medical information net work, Epidemiology studies

As of August 1, 2018
Pathway and legal base of ADR Report

Healthcare Professionals (HCPs)
- Drug
- Medical device
- Regenerative medicine
  (Cellular and Tissue-based Products)
- Quasi-drugs, cosmetics

(PMD* Act. Article 68-10, 2)

Marketing Approval Holders (MAHs)
- Drug
- Medical device
- Regenerative medicine
  (Cellular and Tissue-based Products)
- Vaccination

(PMD* Act. Article 68-10, 1)

Patients
- Drug

(Preventive Vaccinations Act. Article 12, 1)

(no legal basis, in trial)
Cycle of Safety Measures

Occurrence of **Adverse Drug Reaction (ADR)**

- Provision of information
- Decision of safety measures
- Data analysis
- Collection of information
- Data analysis

6th Joint Conference of Taiwan and Japan on Medical Products Regulation (October 11, 2018)
Cycle of Safety Measures

Occurrence of **Adverse Drug Reaction (ADR)**

- **Provision of information**
  - Office of Safety I

- **Decision of safety measures**
  - Office of Safety II

- **Data analysis**
  - Office of Safety II

- **Collection of information**
  - Office of Safety I
Data processing flow of ICSR

**HCPs**
- E-mail
- Fax
- Post

**Patients**
- Website

**MAHs**
- Electrical transmission
- Post
- Over-the-counter

*Submission of ICSR files is mandatory*

Create ICSR files by PMDA

Populate ICSR into ADR DB

PMDA`s ADR Database

Office of Safety I

Data Analysis

Office of Safety II

6th Joint Conference of Taiwan and Japan on Medical Products Regulation (October 11, 2018)
2. Reports from MAH
(In the case of Drug ICSR)
Time Schedule of Surveillance Systems

- **Pre-approval**
  - ADR/AE reporting
  - Risk Management Plan

- **Approval**
  - Spontaneous ADR, infection Reporting
  - EPPV
  - Post-market commitment

- **Post-marketing**
  - Periodic Safety Reports
    - use-results surveys
    - specified use-results surveys
    - post-marketing clinical study
    - PSUR, PBRER
  - Re-examination
  - 6 months
  - 6-10 years

Re-evaluation If necessary

6th Joint Conference of Taiwan and Japan on Medical Products Regulation (October 11, 2018)
## Standards of ADR Reporting by MAH

<table>
<thead>
<tr>
<th>Type</th>
<th>Domestic</th>
<th>Foreign</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unexpected</td>
<td>15 days</td>
<td>15 days</td>
</tr>
<tr>
<td>Expected</td>
<td>15 days (death)</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>30 days*</td>
<td>-</td>
</tr>
<tr>
<td>Non-serious</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unexpected</td>
<td>Annual Cumulative</td>
<td>-</td>
</tr>
<tr>
<td>Expected</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Unexpected ADR occurrence trends</td>
<td>15 days</td>
<td>15 days</td>
</tr>
<tr>
<td>Case indicating health hazard by change of ADR occurrence trends</td>
<td>15 days</td>
<td>15 days</td>
</tr>
</tbody>
</table>

* Except for death cases and
  - ADRs by new drugs (new ingredients) within 2 years after approval
  - ADRs detected through EPPV
Flow chart of ADRs reporting system from MAHs

- HCPs
  - Provide information
  - Investigation
- MAHs
  - ADR reports
- PMDA Database
  - Data accumulation
- Information sharing
- PMDA
- MHLW

6th Joint Conference of Taiwan and Japan on Medical Products Regulation (October 11, 2018)
Numbers of ADR Reports

<table>
<thead>
<tr>
<th>Year</th>
<th>from MAH (Japanese case)</th>
<th>from MAH (Foreign case)</th>
<th>from HCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY2013</td>
<td>38,427</td>
<td>266,539</td>
<td>4,520</td>
</tr>
<tr>
<td>FY2014</td>
<td>49,276</td>
<td>300,216</td>
<td>6,180</td>
</tr>
<tr>
<td>FY2015</td>
<td>51,065</td>
<td>345,193</td>
<td>6,129</td>
</tr>
<tr>
<td>FY2016</td>
<td>55,817</td>
<td>393,825</td>
<td>6,047</td>
</tr>
<tr>
<td>FY2017</td>
<td>60,972</td>
<td>425,297</td>
<td>7,624</td>
</tr>
</tbody>
</table>

6th Joint Conference of Taiwan and Japan on Medical Products Regulation (October 11, 2018)
Rate of electronic submission in 2017 (Drug, Quasi-drug and cosmetics Reports)

99%

Electronic submission  FD, CD or Paper


6th Joint Conference of Taiwan and Japan on Medical Products Regulation (October 11, 2018)
ICH guidelines for ICSR

ICH E2B (R2):
Data Elements for Transmission of Individual Case Safety Reports (ICSR)

ICH M2:
Electronic Transmission of Individual Case Safety Reports Message Specification

Start of E2B(R3) implementation in Japan

- ICH E2B (R3) Step 4: 2012/11
- Start of implementation: 2016/4/1
- Transitional period: until 2019/3/31
  - Parallel implementation of R2 and R3
- Complete conversion to R3: starting 2019/4/1
Major discussion points concerning conversion to R3

- Issuance of a notice regarding R3 implementation (including revisions of existing notifications, etc.)
  - Review of Japan-only items (J items) to be added to ICH E2B data items

- Determine whether the reporting companies can comply (R3 remodeling, schedule)

- Determine system vendors availability (R3 remodeling, schedule)
  - Establish a working group (MHLW, PMDA, industry) and consider

- Determine whether R2 and R3 will be applied together or R2 will be integrated into R3
  - Based on opinions from industry at the above working group, determine whether R3 compliance is possible for all reporting companies

- Review of R3 reporting tools and reporting procedures (EDI, uploading to dedicated website, mailing paper reports and electronic media)
  - We decided to enhance the R3 reporting tool and reporting process such that SMEs without a side effect reporting system can easily comply with R3
Related notifications for R3 implementation

a. ICH E2B(R3) Implementation Guide (IG)  
   (Notification for translated IG issued by MHLW)

b. Q&As for ICH E2B(R3) IG  
   (Notification for translated Q&As issued by MHLW)

c. Reporting Form  
   (Notification issued by MHLW)

d. MHLW IG  
   (Notification issued by MHLW)

e. Q&As for MHLW IG  
   (Notification issued by MHLW)

f. PMDA User Guide  
   (Notification issued by PMDA)

g. Supplemental Information
Timeline for E2B(R3) implementation

- Working group was formed from 4Q/2012
  - Members: MHLW, PMDA and Industries
  - Work Items:
    - Draft implementation guides (IG), user guide (UG) and Q&As - MHLW/PMDA
    - Review these documents – Industries
    - Test E2B(R3) reporting using PMDA provided tools to evaluate feasibility of the IG/UG and the tool – Industries
    - Develop E2B(R3) reporting user manual (generally called “green book” ) – Industries

- E2B(R3) Complete enforcement April 1, 2019

4Q/2012
- WG formed

2013 to 2014
- Develop IG/UG and Q&A, and revise

3Q/4Q 2015
- Test

1Q 2016
- Issue revised IG/UG

April 1, 2016
- E2B(R3) start

6th Joint Conference of Taiwan and Japan on Medical Products Regulation (October 11, 2018)
Coordination with industry re: R3 implementation

- Version 1 of R3 implementation will be announced 3 years prior to the start of implementation in consideration of the preparatory period for R3 correspondence by companies and system vendors
  - Subsequently, multiple notice revisions will be carried out before R3 implementation
- Publish a beta version of the R3 reporting tool developed by PMDA and provide opportunities for reporting companies to test
  - Provide comments from participating companies to PMDA
- Representatives from industry associations will participating in the Working group and provide industry opinions as working groups
- Industry members of the working groups will survey participating companies and accumulate industry opinions as necessary
- Industry associations will set up R3 briefing sessions for participating companies, MHLW, PMDA, and industry representatives will explained the contents of R3
  - Main briefing session will be described in the next slide
Presentations of E2B(R3) implementation

- Major presentations
  - **A full-day seminar (July 2011):** Introduction of ICH E2B(R3) IG
  - **ICH symposium in Japan (December 2012):** Report of achieving Step 4 and explanation of the ICH E2B(R3) IG package
  - **A half-day seminar (September 2013):** Introduction of MHLW/PMDA IG/UG
  - **A half-day seminar (May 2015):** Introduction of revised MHLW/PMDA IG/UG
  - **A half-day seminar (July 2016):** Summary of E2B(R3) implementation
## Advantages of R3 over R2

<table>
<thead>
<tr>
<th></th>
<th>R2</th>
<th>R3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Report format</td>
<td>SGML</td>
<td>XML (HL7 format)</td>
</tr>
<tr>
<td></td>
<td>The following 2 SGML files:</td>
<td>1 XML file also including J items</td>
</tr>
<tr>
<td></td>
<td>• ICH items (ICSR)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• J items</td>
<td></td>
</tr>
<tr>
<td>Characteristics</td>
<td>No versatility (static nature of</td>
<td>High versatility of information</td>
</tr>
<tr>
<td></td>
<td>information)</td>
<td></td>
</tr>
<tr>
<td>Character code used</td>
<td>s-JIS</td>
<td>All possible if UTF8</td>
</tr>
<tr>
<td>File attachments</td>
<td>Submitted via postal mail or in-</td>
<td>All electronic attachments can be</td>
</tr>
<tr>
<td></td>
<td>person submission</td>
<td>encoded as XML</td>
</tr>
<tr>
<td>Batch reporting?</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Reporting method</td>
<td>Electronic reporting, CD reporting,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>paper reporting</td>
<td></td>
</tr>
<tr>
<td>Electronic submission</td>
<td>AS1</td>
<td>AS1, AS2, Web site</td>
</tr>
<tr>
<td>protocol</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Batch reporting is a reporting method in which multiple individual case reports, etc. are submitted as a single report.
R2 and R3 electronic reporting methods

- **R3 adds 2 new methods of reporting**
- In addition to the AS1 format reporting using EDI tools used up to now, R3 adds AS2 format reporting as well as functionality allowing uploading from company ADE websites (GW)

<table>
<thead>
<tr>
<th>Submission protocol</th>
<th>R2</th>
<th>R3</th>
<th>Digital signature</th>
<th>File size</th>
<th>Path</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>AS1</td>
<td>○</td>
<td>○</td>
<td>Required</td>
<td>10MB</td>
<td>EDI</td>
<td>SMTP</td>
</tr>
<tr>
<td>AS2</td>
<td>×</td>
<td>○</td>
<td>Required</td>
<td>50MB</td>
<td>EDI</td>
<td>Sent via https protocol</td>
</tr>
<tr>
<td>GW</td>
<td>×</td>
<td>○</td>
<td>Required</td>
<td>100MB</td>
<td>WEB</td>
<td>Uploaded from company ADE website</td>
</tr>
<tr>
<td>紙</td>
<td>○</td>
<td>○</td>
<td>Not Required</td>
<td>100MB</td>
<td>Postal mail or in-person submission</td>
<td>Paper+CD, etc.</td>
</tr>
<tr>
<td>CD等</td>
<td>○</td>
<td>○</td>
<td>Not Required</td>
<td>100MB</td>
<td>Postal mail or in-person submission</td>
<td>Paper+CD, etc.</td>
</tr>
</tbody>
</table>
- Users must apply to begin use
- Applicants will be issued an administrator ID by PMDA
On the upload screen, users can select the appropriate report files and submit their report:

- Report files must be signed/encrypted in order to ensure validity
- Users will use a specialized digital signature/encryption tool provided by PMDA
- Users can check the status of report processing and data check results on the list of received reports screen
- Users can also check reports submitted by methods other than the reporting website
Possible to review report error details on the report information screen
## Reporting format (E2B R3)

### 別紙様式第Ⅰ

<table>
<thead>
<tr>
<th>項目</th>
<th>内容</th>
</tr>
</thead>
<tbody>
<tr>
<td>販売名/製薬成分記号</td>
<td>有効成分名</td>
</tr>
<tr>
<td>世界に限定された症例報告者</td>
<td>第一送信者</td>
</tr>
<tr>
<td>安全性報告識別子</td>
<td>送信者の種類</td>
</tr>
<tr>
<td>過去に報告された症例</td>
<td>過去の送信の情報源及び症例識別子</td>
</tr>
</tbody>
</table>

### 管理情報

<table>
<thead>
<tr>
<th>項目</th>
<th>内容</th>
</tr>
</thead>
<tbody>
<tr>
<td>緊急報告の基準を満たすか</td>
<td>報告の種類</td>
</tr>
<tr>
<td>第一報告日</td>
<td>最新報告日</td>
</tr>
<tr>
<td>報告起算日</td>
<td>報告起算日に関するコメント</td>
</tr>
<tr>
<td>完了/未完了区分</td>
<td>未完了に対するコメント</td>
</tr>
<tr>
<td>報告対象外</td>
<td>理由</td>
</tr>
<tr>
<td>報告の破棄/修正</td>
<td>理由</td>
</tr>
</tbody>
</table>

### 備考

上記薬品/薬剤に関する副作用/感染症症例を別紙のとおり報告します。

年 月 日

住所：(法人にあっては、主たる施設の所在地)

氏名：(法人にあっては、名称及び代表者の氏名)
J data elements

- Most of data elements in ICSR are harmonized in ICH E2B
- Still require some regional data elements due to different regulations
- J data elements for E2B(R3) reports are updated from E2B(R2) reports

<table>
<thead>
<tr>
<th>Data Element Number</th>
<th>Data Element Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>J2.1a</td>
<td>Local Identifier (Type of Report)</td>
</tr>
<tr>
<td>J2.1b</td>
<td>Local Identifier (number)</td>
</tr>
<tr>
<td>J2.2.1</td>
<td>Initial Date of Reporting Obligation</td>
</tr>
<tr>
<td>J2.2.2</td>
<td>Comments on Initial Date of Reporting Obligation</td>
</tr>
<tr>
<td>J2.3</td>
<td>Flag for Immediate Reports</td>
</tr>
<tr>
<td>J2.4.k</td>
<td>Status of Drugs</td>
</tr>
</tbody>
</table>

...  ...  ...
<table>
<thead>
<tr>
<th>Year/month</th>
<th>Event</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nov 22nd 2028</td>
<td>Event 1</td>
<td>Details 1</td>
</tr>
<tr>
<td>Mar 30th 2029</td>
<td>Event 2</td>
<td>Details 2</td>
</tr>
<tr>
<td>May 31st 2029</td>
<td>Event 3</td>
<td>Details 3</td>
</tr>
</tbody>
</table>

Notifications regarding ADR reports
**PMDA website for MAHs 2/5**

**Information page regarding ADR reports (E2B(R3))**

**Information from PMDA**
- Reception time
- Additional information for reporting via postal or Over-the-counter etc...

| 部品後 | | | |
|---|---|---|
| 受付時間について | sishango_uketsuke.pdf | ※2016/4/1 更新 |
| 副作用等報告について | | |
| 提出方法 | sishango_teishutsu.pdf | ※2017/4/3 更新 |
| CD等のラベル | sishango_CD_label.pdf | ※2016/4/1 更新 |
| 報告書の提出 | sishango_chorui.pdf | ※2016/4/1 更新 |
| エラー後の提出方法 | sishango_error.pdf | ※2017/4/3 更新 |

---

6th Joint Conference of Taiwan and Japan on Medical Products Regulation (October 11, 2018)
Information page regarding ADR reports (E2B(R3))

<table>
<thead>
<tr>
<th>Checklist Item</th>
<th>Description</th>
<th>Date Updated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Elements List</td>
<td>data_elements_lists_v3.1.3.zip</td>
<td>2017/8/15</td>
</tr>
<tr>
<td>Check Rules</td>
<td>checkrules_v3.1.4.zip</td>
<td>2017/12/22</td>
</tr>
<tr>
<td>UCUM Code Check</td>
<td>UCUM.Code.Check.pdf</td>
<td>2016/4/1</td>
</tr>
<tr>
<td>UCUM Overview</td>
<td><a href="http://unitsofmeasure.org/ucum.html">http://unitsofmeasure.org/ucum.html</a></td>
<td>2017/4/3 (AppendicesのD. Example Unit TermsにUCUMコード例「unit term」列が掲載されています)</td>
</tr>
<tr>
<td>Reference Instances</td>
<td>ReferenceInstances_v3.2.zip</td>
<td>2018/7/2</td>
</tr>
<tr>
<td>ICH Bi-lingual Code List</td>
<td>ICH_Bilingual_Code_Lists_v2.9.zip</td>
<td>2017/8/15</td>
</tr>
</tbody>
</table>
### Information page regarding ADR reports (E2B(R3))

#### 3. 副作用等報告ツール等

<table>
<thead>
<tr>
<th>ICSRファイル作成ツール</th>
<th>インストーラあり版</th>
<th>ICSR_creationtool_installer_v3.1.9.zip</th>
<th>2018/7/2 更新</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>インストーラなし版</td>
<td>ICSR_creationtool_EXE_v3.1.9.zip</td>
<td>2018/7/2 更新</td>
</tr>
<tr>
<td></td>
<td>マニュアル等</td>
<td>ICSR_creationtool_annex_v3.1.2.zip</td>
<td>2017/6/12 更新</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>RG署名・暗号化ツール</th>
<th>インストーラあり版</th>
<th>RG_JCSR_signaturetool_installer_v3.0.0.zip</th>
<th>2016/4/1 更新</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>インストーラなし版</td>
<td>RG_JCSR_signaturetool_exe_v3.0.0.zip</td>
<td>2016/4/1 更新</td>
</tr>
<tr>
<td></td>
<td>マニュアル等</td>
<td>RG_JCSR_signaturetool_annex_v3.0.0.zip</td>
<td>2016/4/1 更新</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>未知・非重篤副作用定期報告書作成ツール</th>
<th>Read Meファイル（必ずお読みください）</th>
<th>ReadMe.txt</th>
<th>2016/10/17 更新</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>未知・非重篤副作用定期報告書作成ツール</td>
<td>nitihiTool.jsm</td>
<td>2016/10/17 更新</td>
</tr>
<tr>
<td></td>
<td>入力例</td>
<td>nitihiRexlsx</td>
<td>2008/11/27 更新</td>
</tr>
</tbody>
</table>
Free tools for ADR reports submission

Tool for creating ICSR files

Preview in report format
4. 各種様式

| 副作用等報告様式（別紙様式第1〜第6） | 0031Youshi2.pdf | ※2018/4/1 更新 |
| 市販後治療局長通知における別紙様式第1〜第6とE2B項目との対応表 | P3_youshi_taisu.pdf | ※2018/4/11 更新 |
| 未知非重篤副作用定期報告様式（別紙様式第7） | youshi7.doc | ※2018/4/1 更新 |
| 別紙1 承認等登録票 | 1_shoukei.doc | ※2017/4/3 更新 |
| 別紙2 送信者識別子申込票 | 2_sender_b2.docx | ※2017/4/3 更新 |
| 別紙3 副作用等報告企業および担当者の登録票 | 3_kigyou_tantousha.docx | ※2017/4/3 更新 |
| 別紙4 副作用等報告送付整理票 | 4_seinhyou.docx | ※2017/5/31 更新 |
| 別紙5 電子の報告事前確認書 | 5_ijenkakunido.docx | ※2017/4/3 更新 |
| 別紙6 電子の報告必要事項確認票 | 6_hisyoujiikoudo.docx | ※2017/4/3 更新 |
| 別紙7 接続確認申込書 | 7_settsuko_test.doc | ※2017/4/3 更新 |
| 別紙8 PMDA ICSR受付サイト利用申込書 | 8_uketsuke_she2.docx | ※2017/4/3 更新 |
| 別紙9 暫定コード登録票 | 9_zantei_code.docx | ※2017/4/3 更新 |
| 別紙10 体外診断用医薬品等報告用コード申請票 | 10_taikei_drug_code2.docx | ※2017/4/3 更新 |
| 別紙11 医薬部外品・化粧品製品コード申請票 | 11_quasi_drug_code.docx | ※2017/4/3 更新 |
| 別紙12 接続テスト結果報告書 | 12_test_report2.docx | ※2017/4/3 更新 |
3. Reports from HCPs
ADRs Reporting from HCPs

● Reporting is a duty of all HCPs.
  – Reports are submitted directly to PMDA in accordance with the PMD act.

● Information to be reported
  – Information (cases) regarding the onset of ADRs, infections or malfunctions resulting from the use of drugs or medical devices for which reporting is deemed necessary from the point of view of preventing the occurrence or spread of hazards in public health

● Reporting deadline is not defined
Flow chart of ADRs reporting system from HCPs

Medical institutions

Pharmaceutical companies

Information sharing

Detailed information

Investigation

ADR reports

MHLW

PMDA database

Data accumulation

Provide information

Information sharing

PMDA

6th Joint Conference of Taiwan and Japan on Medical Products Regulation (October 11, 2018)
Shifts in domestic drug-related side effect reports

- **1967**: MAH reporting begins as specified by ministerial ordinance.
- **1980**: MAH reporting becomes mandatory.
- **1997**: Infectious disease reporting becomes mandatory.
- **2003**: Medical institution reporting becomes mandatory.

---

The SMON and thalidomide drug-related disasters occurred prior to this point.

Japan's adverse event reporting system has 50-year anniversary.

Medical inst. reporting has been practiced for 20 years.
Comparison of the numbers of ADE reports, infectious disease reports, industry reports, and medical institution reports

Approx. 1/10 industry reports are medical institution reports
Numbers and percentages of reports by medical facility type (drugs)
Numbers of domestic ADE/infectious disease reports from medical institutions

No. of reports by medical facility type* (percentage of reports submitted annually by each type of facility)

<table>
<thead>
<tr>
<th>medical facility type</th>
<th>FY2012</th>
<th>FY2013</th>
<th>FY2014</th>
<th>FY2015</th>
<th>FY2016</th>
<th>FY2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospitals</td>
<td>2670(80.8%)</td>
<td>3455(85.0%)</td>
<td>4213(88.1%)</td>
<td>4293(87.8%)</td>
<td>4392(88.6%)</td>
<td>4785(72.4%)</td>
</tr>
<tr>
<td>Clinics</td>
<td>147(4.4%)</td>
<td>162(4.0%)</td>
<td>148(3.1%)</td>
<td>127(2.6%)</td>
<td>91(1.8%)</td>
<td>84(1.3%)</td>
</tr>
<tr>
<td>Pharmacies</td>
<td>457(13.8%)</td>
<td>432(10.6%)</td>
<td>398(8.3%)</td>
<td>458(9.4%)</td>
<td>465(9.4%)</td>
<td>1721(26.1%)</td>
</tr>
<tr>
<td>Dental clinics</td>
<td>22(0.7%)</td>
<td>12(0.3%)</td>
<td>16(0.3%)</td>
<td>8(0.2%)</td>
<td>5(0.1%)</td>
<td>10(0.2%)</td>
</tr>
<tr>
<td>Number of reports</td>
<td>3304</td>
<td>4067</td>
<td>4782</td>
<td>4891</td>
<td>4956</td>
<td>6606</td>
</tr>
</tbody>
</table>

Approx. 70% are hospitals

Sharp increase in reports from pharmacies
Numbers and percentages of reports by job category (drugs)
Numbers of domestic ADE/infectious disease reports from medical institutions

<table>
<thead>
<tr>
<th>No. of reports by job category (%)</th>
<th>FY2012</th>
<th>FY2013</th>
<th>FY2014</th>
<th>FY2015</th>
<th>FY2016</th>
<th>FY2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists</td>
<td>1816(55.1%)</td>
<td>2337(57.5%)</td>
<td>3206(67.0%)</td>
<td>3417(69.9%)</td>
<td>3598(72.6%)</td>
<td>5128(77.6%)</td>
</tr>
<tr>
<td>Medical doctors</td>
<td>1049(31.8%)</td>
<td>1215(29.9%)</td>
<td>1140(23.8%)</td>
<td>1045(21.4%)</td>
<td>881(17.8%)</td>
<td>924(14.0%)</td>
</tr>
<tr>
<td>Dentists</td>
<td>36(1.1%)</td>
<td>17(0.4%)</td>
<td>39(0.8%)</td>
<td>24(0.5%)</td>
<td>21(0.4%)</td>
<td>16(0.2%)</td>
</tr>
<tr>
<td>Nurses</td>
<td>56(1.7%)</td>
<td>57(1.4%)</td>
<td>40(0.8%)</td>
<td>39(0.8%)</td>
<td>71(1.4%)</td>
<td>52(0.8%)</td>
</tr>
<tr>
<td>Other</td>
<td>341(10.3%)</td>
<td>438(10.8%)</td>
<td>357(7.5%)</td>
<td>365(7.5%)</td>
<td>385(7.8%)</td>
<td>486(7.4%)</td>
</tr>
</tbody>
</table>

Nearly 80% of reports were from pharmacists, more than twice the number of such reports submitted in 2013.
Reporting parties and Reporting Periods

● Reporting parties
People who open pharmacies, people who open hospitals or clinics, physicians, dentists, pharmacists, registered retailers, other persons engaged in healthcare-related activities hospitals, etc., persons in the business of handling of pharmaceuticals, medical equipment, or regenerative medicine products, etc.

● Reporting periods
Although no specific reporting period has been established, prompt submission of required reports is desirable from the perspective of the mitigation and prevention of hazards and risks to the public health.

Who needs to report, and by when should reports be submitted?
Reporting of drug safety information


Patient information

Adverse event-related information

Drug use status-related information

Reporter information

Reporter opinions

Clinical test values

6th Joint Conference of Taiwan and Japan on Medical Products Regulation (October 11, 2018)
4. Reports from Patient
A project for receiving ADR reports from patients on trial basis via Internet
(Implemented by Mar 2019)

You can report from PMDA Web Page

Send reports via internet

Database server

◎ Reports are used for the purpose of carrying forward safety measures for drugs such as identifying trends in occurrence of adverse reactions to drugs.

◎ Based on reports and questionnaire results collected during the trial period, PMDA intends to revise the reporting system and then formally start receiving reports.

◎ Personal information is stored separately from reports.
患者の皆様からの副作用報告

オンラインで医薬品による副作用報告をすることができます。
PMDAでは、厚生労働省の医薬品の副作用報告に係る事項等に関する指導方針を公表しており、医薬品責任者等には、適切な副作用報告を求めています。

副作用報告を行った場合は、適切な処置を講じた場合等を報告する必要があり、また、医薬品の副作用に関する情報は、医薬品の製造販売責任者等に提供されている場合があります。さらに、医薬品の副作用報告に関するQ&AのQ&Aを観てください。

ご報告前にお読みいただきたいこと

- 現在、報告が疑わしい状況がある方は、まず、医薬機関にご相談ください。
- 報告いただいた副作用の確認のため、医薬品の副作用に係る医薬品療法に関する家庭の医薬品療法に関する医薬品療法に関する指導方針を公表しております。医薬品の副作用報告に関するQ&AのQ&Aをご覧ください。
- 医薬品の副作用報告に関する情報提供に関する記載の注意を含む情報を含む医薬品の副作用報告に関する情報提供に関する記載の注意を含む情報を含む。
- 医薬品の副作用報告に関する情報提供に関する記載の注意を含む情報を含む。
- 医薬品の副作用報告に関する情報提供に関する記載の注意を含む情報を含む。

2. 情報の取り扱いについて

- 報告いただいた情報は、セキュリティに十分配慮し、PMDAにおいて、厳重に保管し、安全対策の目的以外には使用しません。
- 報告いただいた情報は、個人情報及び、PMDAから厚生労働省及び当該医薬品を供給する製造販売責任者等に提供し、保険設備の管理の一環として公表されることがありますので、ご了承ください。
- 報告いただいた情報は、個人情報及び、PMDAから厚生労働省及び当該医薬品を供給する製造販売責任者等に提供し、保険設備の管理の一環として公表されることがあり、法令に基づき情報開示請求があった場合は、個人情報及び、PMDAから厚生労働省及び当該医薬品を供給する製造販売責任者等に提供し、保険設備の管理の一環として公表されることがありますので、ご了承ください。
- 報告いただくためには、E-mailアドレスが必要です。
- 報告いただく際には、プライバシーポリシーをご覧いただき、同意の上、報告してください。
Images of ADR reports from patients
Thank you for your attention!!