Direct Patient ADR reporting system in Japan

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PMDA’s Philosophy

• We conduct our mission in accordance with the following principles:
  – We pursue the development of medical science while performing our duty with greater transparency based on our mission to protect public health and the lives of our citizens.
  – We will be the bridge between the patients and their wishes for faster access to safer and more effective drugs and medical devices.
PMDA’s Philosophy

– We make science-based judgments on quality, safety, and efficacy of medical products by training personnel to have the latest technical knowledge and wisdom in their field of expertise.

– We play an active role within the international community by promoting international harmonization.

– We conduct services in a way that is trusted by the public based on our experiences from the past.
Summary of the Review of the Drug Regulation for Preventing Recurrence of Drug-induced sufferings (Final recommendation)

The committee on auditing and reviewing hepatitis C cases (associated with specific plasma products) and developing new regulatory structure to prevent relapse of ADR tragedies

YKKKI’s report

 Recommendation of introducing “Direct Patient Reporting System for Adverse Drug Reactions”
To Promote two-way communication with patients and public

We announced that we would accept reports from patients soon at the beginning of the year.
DPRS for ADR (trial phase)
Start from 26 March 2012
Direct Patient Reporting System (DPRS)

Pilot system for direct patient reporting through internet

ADR Reporting form on PMDA website

Submit through internet

Database server

- Patient reports are used as tools for appropriate safety measures. (e.g. Identifying increased incidence of adverse drug reactions by PMDA)

- Following a review of the system based on accumulated reports and questionnaire answers during the pilot period, the system will be launched formally.

- Personal data are protected strictly by being separated from other parts in reports.
Direct Patient Reporting System for Adverse Drug Reactions (DPRS for ADR)

◆ There were a total of 90 reports
  – from 26 March 2012 to 31 May 2012.
◆ Most of these reports involved
  – drugs for ethical use (prescription drugs).
Direct Patient Reporting System for ADR

1. Summary

Initiate the collection of patient reported side effects in the Web system as a trial from the date of **26 March 2012**. Upon start, in the Notice of PMDA Medi-navi delivery, as well as do a press release, medical associations (Japan Medical Association, the Japan Dental Association, Japan Pharmaceutical Association, Japanese Society of Hospital Pharmacists, Japanese Nursing Association, and Clinical Engineering Society, etc.) and industry associations was informed of the start of the DPRS for ADR.

2. Status of the report

(1) 90 reports until May 31, from 26 March 2012

(2) Possible candidate of causal drugs: 120 drugs (117 ethical drugs, 3 OTC drugs)

(3) Timing of ADR reported (59 (66%) cases within 2 years from onset of ADR)

(4) Who is reporter (71 from patient, 19 from family)

(5) 5 cases reported the patient died (Known ADR or possible death due to underlying diseases)
Issues to be considered for DPRS

• How to check and evaluate the report
  – authenticity, seriousness, causability, etc.
• How to access to detailed patient medical record
• How to balance transparency & personal information protection
• How to guide reported patient to ADR relief system
Current concept of Risk Communication

• **2-way** *(interactive)* **communication**
  
  **In-coming info.** (→ Pharmacovigilance)
  - ADR reporting system from Medical professional, company, **patient**
  
  **Out-going info.** (→ Risk minimization)
  - Letter to doctor (yellow, blue, etc.), Patient guide
  - e-mail delivery (**PMDA medi-navi**)
  - Website information (Japanese & English)
Current situation of “PMDA medi-navi”

- 2012/06/04
- 61,415 users
- 96 e-mails delivered (2012/01/01 – 2012/06/06)
Safety Information

PMDA provides the following safety information regarding pharmaceuticals and medical devices.

- **PMDA Risk Communications** *(Drug Risk Information of ongoing evaluation)*
  - Updated
  This webpage contains the most recent Risk Communications from PMDA including early communications or ongoing safety review. The webpage intends to provide the public with easy access to important drug safety information.

- **Safety Information announced by MHLW**
  - Updated
  This section includes safety information (e.g., press release) announced by MHLW regarding pharmaceuticals and medical devices.
  e.g. (Q and A) Resuming vaccination with the pediatric pneumococcal conjugate vaccine and the Hib vaccine (dated March 29, 2011)

- **MHLW Pharmaceuticals and Medical Devices Safety Information (PMDSI)**
  This Pharmaceuticals and Medical Devices Safety Information (PMDSI) is issued based on safety information collected by the Ministry of Health, Labour and Welfare. It is intended to facilitate safer use of pharmaceuticals and medical devices by healthcare providers.

- **PMDA Medical Safety Information**

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**DIA 2012**
Collaborate to Innovate
All the players (include patient) in good harmony

Thank you for your attention