Safety Measures

Information provided on the "Dataset download page"

Information about case reports on suspected ADR(reports since fiscal year 2004)

We provide information in CSV format on cases reported by pharmaceutical companies or medical institutions since 2004 in accordance with the Act on Ensuring Quality, efficacy and safety of Pharmaceuticals, Medical Devices, etc. (Act No. 145 of 1960) and cases reported by medical institutions since 2013 in accordance with the Vaccination Act.

Data for each case is provided in a CSV file divided into the following four tables. The dataset can be downloaded all at once or in separate files. Each separate file has a sequential number in its file name.

Please see here for the ER diagram of each table .

(1) Case list table (file name: demoCCYYMM-n)

No.	CSV field name	reference	
		E2B(R3) Data Elements	E2B(R2) data elements
1	Identification number	J2.1	J.4
2	Number of reports	—	J.5
3	sex	D.5	B.1.5
4	age	D.2.2/D.2.3/D.2.2.1	B.1.2.2/B.1.2.3/B.1.2.2.1
5	body weight	D.3	B.1.3
6	height	D.4	B.1.4
7	Reporting Year/Quarter	—	—
8	situation	J2.7.1	J.6
9	Report Type	C.1.3	A.1.4
10	Reporter qualifications	C.2.r.4	A.2.1.4
11	E2B	—	—

Safety Measures
Overview of Measures measures
Collection and organization of information on adverse drug reactions, medical device malfunctions, etc.
Consultation regarding the consideration and implementation of safety Measures(for companies)
Survey and analysis work (epidemiological surveys, etc.)
MID-NET
Information provision work
Pharmaceuticals
Item Basic Information
Alert information
Information on adverse drug reactions etc.
Manuals for management of individual serious adverse drug reactions(for patients and the general public)
Manuals for management of individual serious adverse drug reactions(for medical professionals)
Information about case reports on suspected ADR
Information on case reports of suspected medical device malfunctions of the device components of combination drugs
Generic Drug Quality Information

(2) Drug information table (file name: drugCCYYMM-n)

No.	CSV field name	reference	
		E2B(R3) Data Elements	E2B(R2) data elements
1	Identification number	J2.1	J.4
2	Number of reports	—	J.5
3	Pharmaceutical serial number	—	—
4	Pharmaceutical involvement	G.k.1	B.4.k.1
5	Medicines (Non-proprietary name)	G.k.2.3.r.1	B.4.k.2.2
6	Pharmaceuticals (Brand name)	G.k.2.2	B.4.k.2.1
7	route	G.k.4.r.10.1/G.k.4.r.10.2b	B.4.k.8
8	Day 1 of administration	G.k.4.r.4	B.4.k.12
9	End date of administration	G.k.4.r.5	B.4.k.14
10	Dosage	G.k.4.r.1a	B.4.k.5.1
11	Dosage unit	G.k.4.r.1b	B.4.k.5.2
12	Number of divided doses	Set "1" only if Gk4.r.1 has a dosage	B.4.k.5.3
13	Reason for use	G.k.7.r.1/G.k.7.r.2b	B.4.k.11b
14	Pharmaceutical Treatment	G.k.8	B.4.k.16
15	Relapse after re-administration	G.k.9.i.4	B.4.k.17.1
16	Risk classification, etc. (R3 only)	J2.5.k	—

(3) information on adverse drug reactions Table (file name: reacCCYYMM-n)

No.	CSV field name	reference	
		E2B(R3) Data Elements	E2B(R2) data elements
1	Identification number	J2.1	J.4
2	Number of reports	—	J.5
3	adverse event Serial Number	—	—
4	adverse event	E.i.2.1b	B.2.i.2b
5	Outcome	E.i.7	B.2.i.8
6	Date of onset of adverse event	E.i.4	B.2.i.4b

(4) Primary disease table (file name: hist CCYYMM-n)

No.	CSV field name	reference	
		E2B(R3) Data Elements	E2B(R2) data elements
1	Identification number	J2.1	J.4

Medical Devices
regenerative medical product
in vitro diagnostics
quasi-drugs and cosmetics(warning information)
Medical Safety Information
PMDA medi-navi My Drug List Creation Service
Collaboration with patient groups
Consultation desk for patients and the general public regarding medicines and medical devices
Collection of contributions to safety measures
Symposiums and Workshops
Public Comment

2	Number of reports	—	J.5
3	Original disease serial number	—	—
4	Primary disease, etc.	D.7.1.r.1b	B.1.7.1a.2

Notes - About downloading -

- The csv file is updated with all data for the target period each time. Please note that it does not include differential data from the previous publication.
- Image Verification We use an image verification system to prevent unauthorized access. Please enter the same characters as shown in the image verification system, and then click the download button.

Notes - About the data content -

- The content of each item in the provided CSV file, with the exception of the evaluation column, is information reported by pharmaceutical companies to the Pharmaceuticals and Medical Devices Agency (PMDA)(PMDA). Please be aware that the PMDA has not individually evaluated the relationship between drugs and adverse drug reactions/ adverse event.
- Although the Ministry of Health, Labour and Welfare requests that cases of suspected adverse drug reactions be widely reported, this does not mean that each report is made after it has been determined that there is a causal relationship between the drug or related medical procedure and the symptoms or abnormal findings listed in the adverse drug reactions column.
- The number of reported cases for each drug varies depending on the number of patients administered the drug and the drug's characteristics. Furthermore, even for drugs with the same Active ingredients(Non-proprietary name), the number of reported cases for each product varies depending on the number of patients administered and the availability of information from each product's marketing authorization holder. For these reasons, the number of reported cases or cases contained in the CSV file cannot be used to simply evaluate or compare the safety of drugs.
- The same case may be reported by multiple reporters. In such cases, duplicate cases will be listed in the CSV file. For example, if information obtained from literature does not specify the Brand name, but only the Non-proprietary name name is known, the marketing authorization holder that marketing and sells the drug under that Non-proprietary name must report it as their own product. If there are multiple applicable marketing authorization holder, the same case may be reported multiple times by each marketing authorization holder. Please also understand that the published CSV file includes cases reported as their own product even though the Brand name is unknown, as in this example.
- Cases of claims for adverse drug adverse drug reactions relief benefits are published on the "Information on decisions regarding adverse drug reactions relief benefits" page, so they are not included in the CSV file. Also, cases that are identical to those included in the CSV file may be posted twice as cases of claims for adverse drug adverse drug reactions relief benefits.
- Only available Brand name will be displayed.
- To standardize terminology, disease names will be displayed using preferred terms (preferred terms) listed in the Japanese version of the ICH International Medical Dictionary for Clinical Practice (MedDRA/J).
- As a new reporting format has been accepted since FY2016, reports for the first quarter and year of 2016 onwards will be in both the old reporting format (hereafter referred to as R2) and the new reporting format (hereafter referred to as R3). The "Case List Table" will indicate which reporting format is used.
- If any additional information or corrections are reported regarding the CSV files that have already been released, the relevant information will be updated.
- The CSV file contains cases that PMDA received from pharmaceutical companies or medical institutions within the four months prior to publication. For example, the file published in August 2016 contains adverse drug reactions reports received up to April 2016.

Contact Information

Pharmaceuticals and Medical Devices Agency (PMDA)(PMDA) Office of Informatics and Management for Safety Risk Communication Promotion Division (Email: fukusayou-database[at]pmda.go.jp)
(Note) To Measures spam, please replace [at] with a half-width @ symbol when sending.

<Notes>
(1) Please note that we are unable to response to inquiries regarding additional information regarding the reported cases due to privacy and other issues.
(2) Notification to PMDA before publication as prescribed in Article 4-7 of the Terms of Use

- Please send notifications by email to the Risk Communication Promotion Division , Office of Informatics and Management for Safety, PMDA, as listed above.

- Please attach documents that clearly explain the contents of your announcement to your email.

(Note) The purpose of this notice is not to determine whether or not the product can be used, but to determine whether or not safety Measures and investigations are necessary based on the information received.

Do you understand the above?

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