SUMMARY OF ANNUAL REPORT
FY 2004

I. OVERVIEW OF PHARMACEUTICAL AND MEDICAL DEVICES AGENCY

- The Pharmaceuticals and Medical Devices Agency (PMDA) was established on April 1, 2004 based on the Law for the Incorporated Administrative Agency-the Pharmaceuticals and Medical Devices Agency. The Agency took over the operations/services of the Pharmaceuticals and Medical Devices Evaluation Center (PMDEC), the Organization for Pharmaceutical Safety and Research (OPSR/Kiko) and a part of the services of the Japan Association for the Advancement of Medical Equipment (JAAME)
- The purpose of the PMDA is to contribute to the improvement of public health through the operation of the following four key services. For your information, the research and development (R&D) promotion service was transferred to the National Institute of Biomedical Innovation (NiBio) on April 2005.

  (1) Adverse Health Effect Relief Services

  - Payment of medical expenses, disability pensions, etc. to the sufferers from adverse drug reactions (ADRs).
  - Payment of healthcare allowances to SMON (subacute myelo-optico-neuropathy) patients and commissioned support for HIV-positive and AIDS patients

  (2) Review and Related Operations

  - Review to approve pharmaceuticals and medical devices, based on the Pharmaceutical Affairs Law (PAL)
  - Guidance and advice concerning clinical trials (CTs)

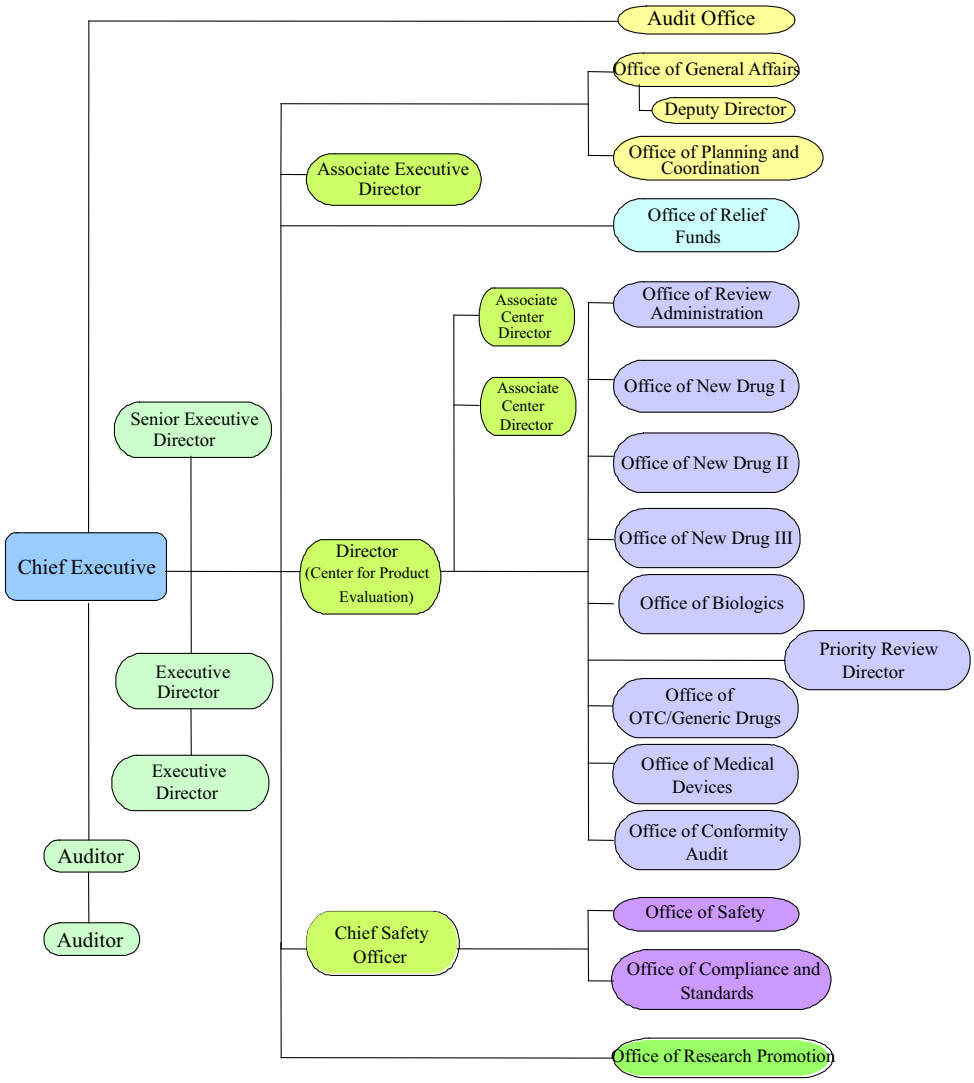
  (3) Post-marketing Safety Operations

  - Collection, analysis and dissemination of information concerning quality, efficacy, and safety of pharmaceuticals and medical devices

  (4) Research and Development Promotion Service

  - Promotion of trials and studies necessary for the development of innovative pharmaceuticals and medical devices

[Structure of the Agency, FY 2004]



II ACHIEVEMENT OF FY 2004

PART 1. IMPROVEMENT IN OVERALL OPERATIONS AND QUALITY IN SERVICE OF PMDA

(1) Efficient and Flexible Operations Management

1. Operation through target management

- The target management system was introduced, and the operation plans for each office were made.

2. Enhancement of operations management system, and top management

- To establish a system that speedily reflects the management judgment of the Chief Executive to the Agency's operation, the "board of directors" (April 2004), the "task force on enforcement of the revised Pharmaceutical Affairs Law" (July 2004) and the "progress management committee of review operations" (January 2005) were established and operated respectively.
- The rules concerning risk management such as internal audits and voluntary internal reporting system were introduced.

3. Establishment of Advisory Council

- The "Advisory Council" that consists of external academic and experienced professionals, with two divisions of relief/review and post-marketing/safety operations and research operations, was established. In addition, the "relief committee" and the "review & post-marketing safety committee" were established under the Advisory Council and held the meetings to consider more specific and technical issues.

4. Development of effective operations management system

- The Review Department is managed based on a team system, and the assigned external experts were employed as an "expert member" of the review teams. (The number of appointed experts was 789 on March 31, 2005.)

5. Standardization of operating procedure (SOP)

- The Standard Operating Procedure (SOP) of the Agency's main operations/services was developed. The Agency made a great effort to employ part-time staff members for the routinely performed operations.

6. Unified management of information through database

(2) Cost Reduction by Increasing Operational Efficiency

1. Reduction of general management expenses and program expenses

- The Agency conducted expense reduction efficiently according to the Midterm Plan Budget, and the regular salary increase of its staff was cancelled.

2. Collection and management of contributions

- A new contribution management system was established, in which the infectious disease contributions and the safety measure contributions were integrated into the existing collection system of the adverse drug reaction contributions.
- The Agency executed various measures for the more efficient collection of contributions.

[Midterm Plan]
The collection rate of the contribution for adverse drug reactions (ADR) and infectious diseases shall be no less than 99%.
The Agency shall aim to raise the contribution collection rate to the same levels as those of ADR and infectious disease contributions by the end of the effective period of the Midterm Targets.

[2004 Results of Each Contribution Collection]

Adverse drug reaction contributions	99.0%	(The number of paid cases 11,383 / The number of subject cases 11,495)
Infection disease contributions	100.0%	(The number of paid cases 108 / The number of subject cases 108)
Safety measure contributions	93.4%	(The number of paid cases 13,617 / The number of subject cases 14,587)

(3) Improvements in Services to Public

1. General consultation service

- In order to reinforce the consultation system that properly deal with complaints from general consumers, the Agency launched general consultation service in February 2005. (The number of actual consultations was 219.)

2. Handling complaints from companies regarding reviews and post-marketing safety operations

- In September 2004, the Agency started a service to have the office director in charge hold a face-to-face interview when there is an inquiry from applicants regarding review progress of their new pharmaceutical, new medical devices and improved medical device.
- In March 2005, when complaints from applicants about the review and post-marketing

safety operations occur, the office director in charge directly conduct an investigation and provide a response to the applicants within 15 working days.

(4) Personnel Matters

1. Implementation of systematic training

- The “training committee” was established in April 2004, and the committee developed a basic policy on training and training programs based on the staff's need.
- The Agency carried out long-term overseas training, dispatch of staff to Japanese and foreign universities and to foreign pharmaceutical regulatory agencies as well as orientation, training in internal and external institutions.

2. Securing human resources through open recruitment

- The Agency created an employment plan and reconsidered the employment conditions/benefits for each of its job categories in searching for competent persons in the understaffed fields. The opportunity of open recruitment for regular staff was announced 8 times including the advertisements prior to the foundation of the Agency.

  [Employment Situation]

  1) Technical staff (Through 5 times of public advertisement)

  The number of the employed: 21

  (32 persons as of April 1, 2005/ 15 persons planned to be employed subsequently)

  2) Administrative staff (Through 3 times of public advertisement)

  The number of the employed: 11 (4 persons as of April 1, 2005)

- Regarding the job categories that is difficult to secure necessary staff members, the Agency reconsider the employment restriction and temporarily alleviated it in its work regulations on hiring employees for the field of GMP review and biometrics from private companies.

[The Number of Permanent Staff Members in the Agency]

	April 1, 2004	April 1, 2005	Targeted (in Midterm plan) Start of FY 2004	Targeted (in Midterm plan) End of FY 2008
Agency total (including executives)	256	291	317	346
Review Department	154	178	–	–
Safety Department	29	43	–	–

3. Appropriate personnel management based on employment rules

- The following rules were enacted:

  (i) The employment restriction of the persons with his/her career background in pharmaceutical industry and the restriction of the Agency's staff to join a pharmaceutical company after their leaving the Agency

  (ii) The code of conduct

(5) Ensuring security

- A control system for entering and leaving the office was introduced, and information security rules were enacted.

PART 2. IMPROVEMENT IN OPERATIONS OF EACH DEPARTMENT IN QUALITY OF SERVICES

1. ADVERSE HEALTH EFFECT RELIEF SERVICES

(1) Expeditious Processing of Relief Applications

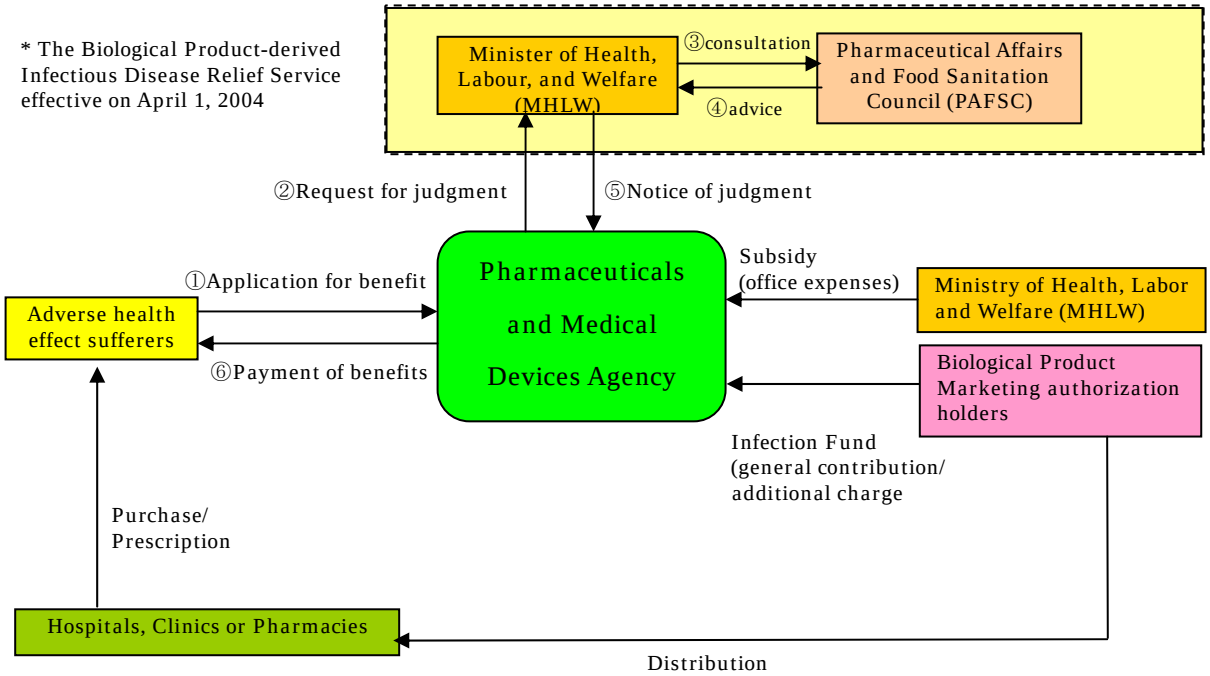
- In response to a great increase and speedy process of relief benefits applications, the Agency considered the increase of the staff number of the office of relief fund and the reform of its organizational structure. Also the Agency introduced a council consisting of "expert members" for its review operation along with the coming shift of the "drug committee" of the Ministry of Health, Labor and Welfare (MHLW) to a dual-committee system (in 2005).

  [* The increase of the staff numbers engaging in the AHE relief services and the structural reform: The number of staff changed from 18 to 27. Establishment of the relief application review division.]

[Midterm Plan]

The standard administrative processing time (SAPT) is to be within 8 months; the number of judged cases, as payable or not payable, within the standard administrative processing time shall amount to 60% or greater of the total number of requests.

【Adverse Drug Reaction Relief System】



【Number of Applications for ADR Relief】

Fiscal Year	FY 2002	FY 2003	FY 2004
Number of applications	629	793	769
Number of judged cases	431	566	633
Number of cases withdrawn	0	2	1
Number of cases in progress*	593	820	956
Accomplishment rate ** of SAPT	46.6%	17.6%	14.5%
Processing time (Median)	8.3 months	10.6 months	12.4 months

* The number of cases in progress increased because the number of applications from FY 2002 to 2003 dramatically increased; as a result, the accomplishment rate of SAPT declined.

【Number of Applications for Infectious Disease Relief】

Number of applications: 5, Number of cases judged: 2 (Accomplishment rate**: 100%)

* The number of cases in progress indicates the number at the end of each fiscal year.

**The accomplishment rate of SAPT is the percentage of the cases judged within 8 months out of the total number of cases judged in the fiscal year.

(2) Unified Management of Information through the Database

- The database of information on adverse health effect (AHE) relief service was upgraded, and the time-clock management, statistical analysis and search functions of the Agency were reinforced.

(3) Promotion of Appropriate Information Transmission through Cross-functional collaboration

- The information about the relief benefit payment cases was provided appropriately for the post-marketing safety department.

(4) Fact-finding Surveys on Adverse Drug Reactions (ADR)

- The “Study Group for the Fact-finding Survey on Adverse Drug Reactions” was started in October 2004, and the subjects and the items of the survey questionnaire were reviewed.

(5) Expansion of Consultation Service

- The Agency arranged regular staff members specially for the consultation service and enhanced the service to meet the increasing number of consultation requests from 9:00 a.m.

to 17:30 p.m. without lunch break.

The numbers of consultations and web accesses, by the end of the effective Midterm Target period of FY 2008, is expected to be 20% increase of those of FY 2003. On the other hand, the 5% increase is expected in the 2004 fiscal year plan.

Fiscal Year	FY 2002	FY 2003	FY 2004	Annual Growth rate of FY 2004 to FY 2003
# of consultations	1,737	5,338	3,873	down 27%
# of web accesses	--	35,726	41,947	up 17%

* The decline in the number of consultations in FY 2004 is probably due to the Agency's advertisements including its website address in the newspapers and others. The public can obtain information on consultation service via internet. The number of inquiries about the service via the phone decreased sharply while the number of web accesses increased.

(6) Expansion and Review of Information Dissemination

1. The eligible and ineligible cases judged for relief benefits in the period from April to June 2004 were posted on the Agency's website.
2. The Agency improved the pamphlets and application manuals, and the application form is now available by downloading from its website.

(7) Proactive Public Relations

- The advertisement of the Agency was actively conducted in the newspapers, journals, and on Yakutais, small paper bags containing prescribed drugs that is given in hospital or pharmacy.

(8) Appropriate Conduct of Relief Services for SMON (subacute myelo-optico-neuropathy), HIV-positive and AIDS patients infected by blood preparations

- In particular, personal information was sensitively handled, and appropriate services were carried out based on the contract of commissioned operations/services.

2. REVIEWS AND RELATED OPERATIONS, AND POST-MARKETING SAFERY OPERATIONS

(1) Faster Access to Innovative Pharmaceuticals and Medical Devices

1. Ensuring benefits of pharmaceuticals and medical devices for public and healthcare professionals

a. Clinical trial (CT) consultations and reviews

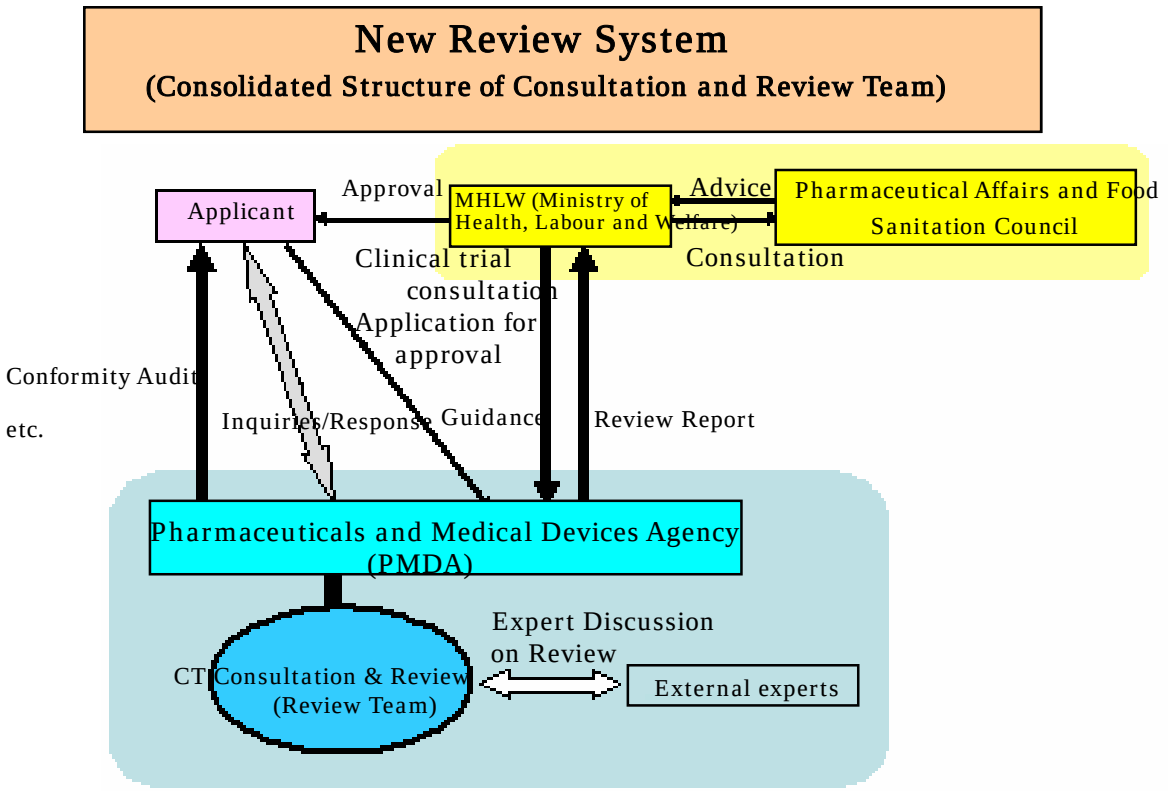
- With the launch of PMDA, the Agency was to strengthen its system in the following direction to improve the review system.

  i) The previously separated, three review-related organizations were integrated for the purpose of increasing consistency and obtaining greater efficiency.

  ii) The number of staff members, including reviewers, is greatly increased by about 100 by the end of the effective Midterm Targets period.

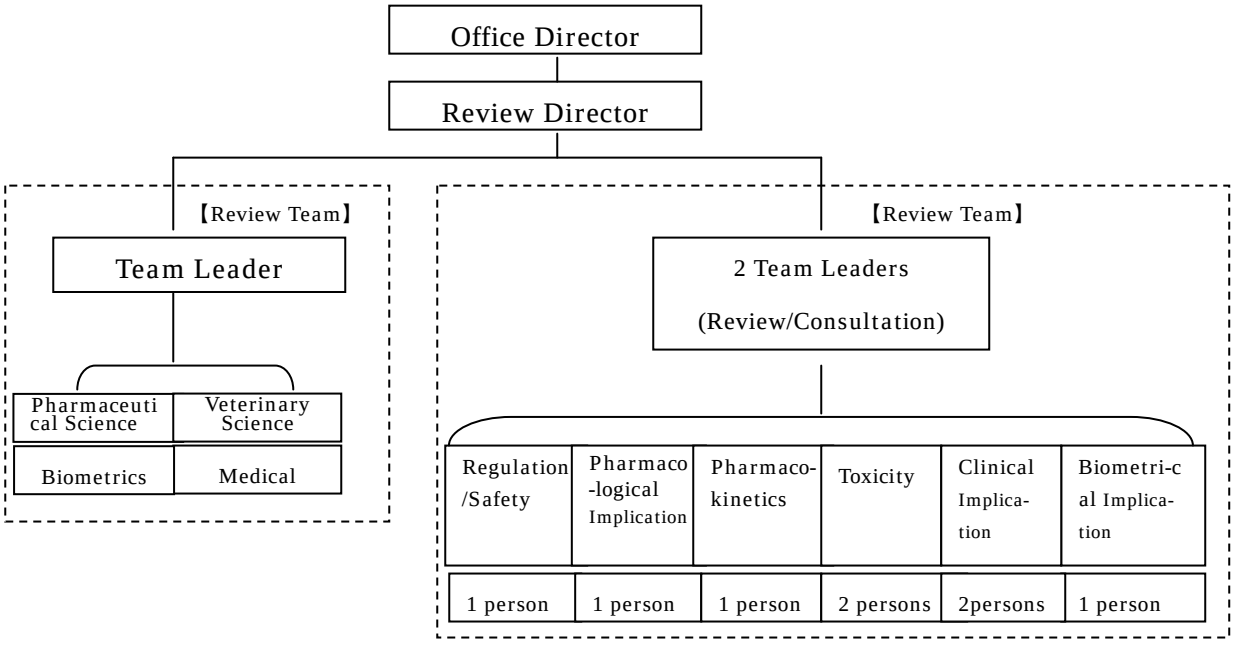
  iii) A single team conducts the whole review process from CT consultation to review with consistency and coordination.

  iv) Review of biological/biotechnology-derived products and the review function of medical devices are to be reinforced.



【Structure of Review Teams】 In the case of review of new pharmaceuticals

【**Structure of Review Team**】※In the case of new drug application (NDA)



(Note)

- In review for new pharmaceuticals, the Agency assigned dedicated offices and teams (12 teams in total in FY 2004). Each of the team undertakes review for pharmaceuticals belonging to one therapeutic category.
- For clinical trial consultations, the review director, a reviewer in charge and a deputy reviewer draft instructions and advice for face-to-face and clinical trial consultations, and each review team discusses and conducts consultations/interviews with applicants in accordance with the draft and develops consultation records.

[Number of Consultations and Reviews on New Drugs in FY 2004]

○ Clinical trial consultations and related matters — pre-application consultation: 287 cases; clinical trial consultation: 193 cases

○Review and related matters — Expert Discussion: 192 cases
(Document review: 127 cases, Face-to-face reviews: 65 cases)
Reviewed in the Drug Committee of PFSC: 38 cases,
Reported to the Drug Committee: 14 cases

2. Measures for effective and prompt reviews

[Midterm Plan]

For approval review applications submitted on and after April 1, 2004:

○ In the case of new drugs, the Agency shall attain its performance target, completing 70% of the total new drug application (NDA) reviews within 12 months, through FY 2004 to 2007.

○ In the case of new medical devices, the Agency shall attain its performance target, completing 70% of the total new medical device application (NDA) reviews within 12 months, for FY2004. The Agency shall attain its performance target, completing 80% of the total new medical device application (NDA) reviews within 12 months, for FY2005 and FY 2006.

○ In FY 2008, at the end of the Midterm Targets period

The Agency shall attain its performance target, completing 80% of the total new drug application (NDA) reviews within 12 months. (For priority review specified by MHLW, 50% of the total NDA review within 6 months)

And 90% of the total new medical device application reviews within 12 months (in and after FY 2007) (for priority review specified by MHLW, 70% of the total new medical device application reviews within 9 months)

* The review process time indicates the total processing time combining the period for the item(s) to be reviewed by the Agency and the following period for the item(s) to be approved by MHLW.

a. Approval review for new pharmaceuticals

- The "procedure of new drug application review" and the "standard operating procedures (SOP)" were established.
- The "progress management committee of review operations" was established in January 2005. The committee held a meeting at the end of month and examined the progress of review operations.

(Results of overall NDA reviews)

- The Agency attained its performance target, completing 100% of the total new drug application (NDA) reviews within 12 months (17/17 cases).
- The achievement rate was 65% in the total NDAs including those submitted before April 1, 2004 were included (32/49 cases).

[Number of Approved NDAs]

	2002*	FY2003	FY2004
No. of approvals & review process time (Median)	52 (10.8 months)	51 (11.3 months)	49 (8.6 months) [65%]* *

*) The data of 2002 is based on a calendar year.

**) The percentage in bracket indicates the rate of the number of applications processed within 12 months of review process time and includes those filed before April 2004, which is excluded from

the Midterm Targets.

[Results of New Drug Review in FY 2004]

	Number of cases*	Withdrawn	Approved	In Progress
Applied before April 2004	140	12	41**	87
Applied on and after April 1, 2004	89	4	17	68
Total	229	16	58	155

*) The number shows the number of review reports both reviewed at and reported to the Drug Committee of PFSC.

**) The number includes the 9 approved applications which were reported to and discussed in the Executive Committee of PFSC.

(Results of priority NDA reviews)

- The Agency accomplished 100% of its performance target, completing the total 16 priority NDA reviews filed in and after April 2004 within 6 months, which was targeted in the Midterm Plan and the 2004 fiscal year plan.
- The achievement rate was 86%, including those submitted before April 1, 2004. (19 out of the total 22 applications)

b. Review of new medical devices

- The “procedure of new medical device application review” and the “standard operating procedure” were created.
- Review progress was checked monthly by the “progress management committee of review operations”.

(Results of new medical device application reviews)

- For the new medical devices applications submitted on and after April 1, 2004, the Agency approved 100% of the application (1/1case) within 12 months, which was targeted in the Midterm Plan and the fiscal year plan of 2004.
- The achievement rate of the total new medical device approval reviews was 50% including their applications submitted before March 31, 2004. (4/8 applications)

[Number of Approved New Medical Devices]

	FY 2002	FY 2003	FY 2004
Number. of approvals & review process time (median)	3 (2.9 months)	13 (8.9 months)	8 (12.7 months) [50%]*

*) The percentage in bracket indicates the rate of the number of applications processed within 12 months of review process time, but includes those filed before April 2004, which are out of the Midterm Targets.

[Results of New Medical Device Reviews in FY 2004]

	Number of cases*	Withdrawals	Approvals	In Progress
Applications submitted before April 1, 2004	132	38	8**	86
Applications submitted on and after April 1, 2004	56	2	1	53
Total	188	40	9	139

*) The number indicates the number of the applications for new medical devices.

**) The number includes one case/application approved as an improved medical device.

c. Compliance review of application materials

- The Agency reviewed of the site, documents and data included in new drugs and medical devices approval review applications to determine if the studies, which are a basis of the review materials, were implemented according to the appropriate guidelines such as GLP and GCP, and if the application materials were prepared in accordance with the reliability criteria.

[The Number of Compliance Reviews: FY 2004]

Compliance document review	GLP review	GCP review	GPMSP review
161	20	73	27

(Note): The numbers of GCP and GPMSP reviews in FY 2004 is the number of notifications after evaluation.

d. Approval review for generic drugs, over-the-counter (OTC) drugs and quasi-drugs

- During FY 2004, as to achievement rate of the targeted standard administrative processing time for generic drugs applied on and after April 1, 2004, the Agency processed 100% of the total 1,468 applications for generic drugs within 12 months (1,468/1,468), 83% of the total applications for over-the-counter drugs within 10 months (224/270), and 89% of the total applications for quasi-drugs within 6 months (1,277/1,431).

[FY 2004 Plan]

The standard administrative processing time (October 1, 1985 [notification on the standard administrative processing time])

Generic drugs: 12 months OTC drugs: 10 months Quasi-drugs: 6 months

3. Reinforcement of clinical trial consultation system

a. Establishment of priority consultation system

- As for clinical trial consultations for drugs, the Agency received priority consultation applications of 9 ingredients during FY 2004, and designated 7 ingredients out of the 9 for prioritized subjects, and conducted priority consultations for them.

* The Agency received no application for priority consultations for medical devices.

b. Acceleration of clinical trial consultations for pharmaceuticals

- In FY 2004, the Agency are to complete 45% of face-to-face advice within 60 working days from the application, to complete 10% of CT consultation record less than 30 working days waiting period after face-to-face advice and to conduct 50% of the first face-to-face advice for priority CT consultations within 30 working days.
- However, for CT consultation for pharmaceuticals, the Agency conducted face-to-face advice within 60 working days from the application for 57 cases/applications (29.5%: 57/193), completed the CT consultation record less than 30 working days waiting period after face-to-face advice for 19 cases/applications (9.8%: 19/193), and conducted the first face-to-face advice for priority CT consultation for 2 cases/applications (40%: 2/5). These results were lower than the targeted level of FY 2004.
- As a consequence that the clinical trial consultation and the approval review were integrated, the Agency considers the expectation and demand for clinical trial consultation significantly increased. In addition, the appointments for CT consultations were full for more than next 6 months, so the Agency suspended accepting reservation for consultation in March 2005, and addressed a new method to accept applications. (The Agency has just issued a notification on the improvement of clinical trial consultations for new drugs as a provisional measure on April 26, 2005, and planned to resume receiving applications for consultations to be conducted after October 2005 according to the new method from July.)

[Annual Changes on the Number of CT consultations]

	FY 2002	FY 2003	FY 2004
Number of CT consultation applications	246	185	334
Number of conducted CT consultations	225	206	193

4. Promotion of international harmonization

- The Agency actively attended ICH Steering Committee Meetings and Expert Working Groups in order to achieve compatibility and harmonization of the international standards.

- The median of total review process time from application to approval for 49 new pharmaceuticals approved in FY 2004 was 411.0 days (13.7 months).

(2) Improvement in Reliability of Operations

1. Planned recruitment of staff with high levels of expertise and systematic provision of opportunities for training

2. Development of GMP review system

- The Agency conducted 70 GMP on-site reviews in FY 2004.
- The Office of Compliance and Standard was reinforced by increasing its staff members because the scope of GMP review subject would be expanded to overseas manufacturing facilities in FY 2005. (from 6 staff members on April 1, 2004 to 18 staff members on April 1, 2005)

3. Effective use of external experts

4. Establishment of information support system

- The Agency developed the information system that can be shared by the Review Department and the Post-marketing Safety Operation Department in line with the enactment of the revised Pharmaceutical Affairs Law in April 2005.

5. Strengthening of partnership with foreign regulatory authorities

- The cooperation with the regulatory authorities in the U.S., Europe, and other Asian countries was promoted.

6. Evaluation of such advanced technologies as biotechnology and genomics / cooperation in developing the national guidelines

- The Agency assisted the development of the national evaluation and guidelines for new products applying the cutting-edge technologies such as biotechnology and genomics.

7. Promotion of appropriate clinical trials

- The Agency summarized the information/explanations about clinical trial, which were supervised by MHLW and the system operated under the Pharmaceutical Affairs Law, summarized. The summary was posted on the website of the Agency.

- The Agency provided pharmacists and nurses of medical institutions with a training for Clinical Research Coordinators– the training was composed of lectures in September 2004 and practical training from October 2004 to February 2005.

8. Timely provision of information including review reports

(Review reports on new drugs)

- The Agency confirmed the publicly disclosed 35 review reports and 16 summaries of the application materials.

(Review reports on new medical devices)

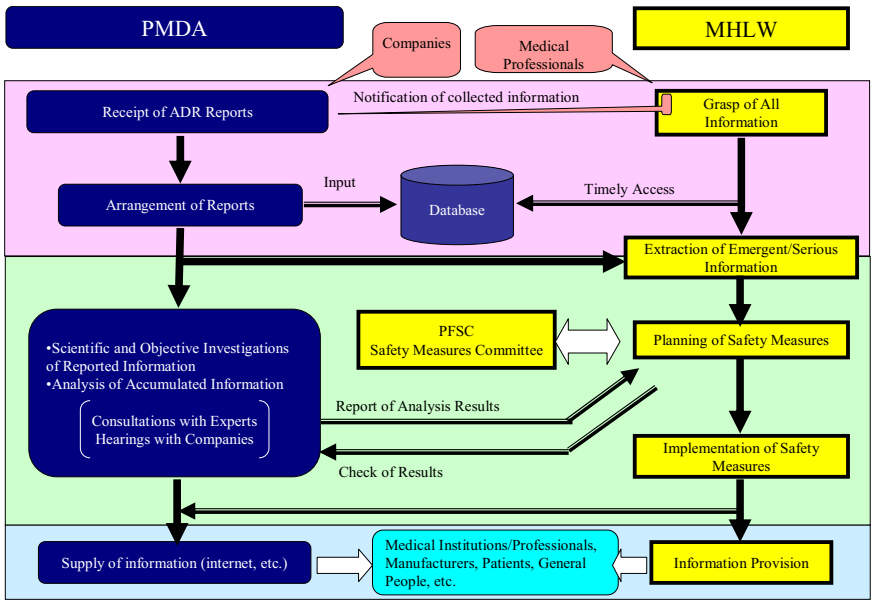
- The Agency also plans to disclose review reports on new medical devices according to the disclosing procedure to be specified in the notification of MHLW.

(3) Reinforcement of Post-Marketing Safety Measures

1. Basic direction of safety measures

- The Agency shall aim to significantly reinforce the safety measures so that review and post-marketing safety operations function as an inseparable pair.
- The number of ADRs reported in a year reached about 30,000 in Japan and about 80,000, when including overseas reports. This information will be evaluated and analyzed more scientifically by using computer technology and statistical techniques to predict risks and take preventive measures.
- As the problems in the past are often caused by improper use of drugs or medical devices, the Agency provided the information for appropriate use of drugs widely.
- As mentioned earlier, the Agency aims to take proactive safety measures by predicting and preventing risks through scientific evaluation and analysis in the cooperation with MHLW.

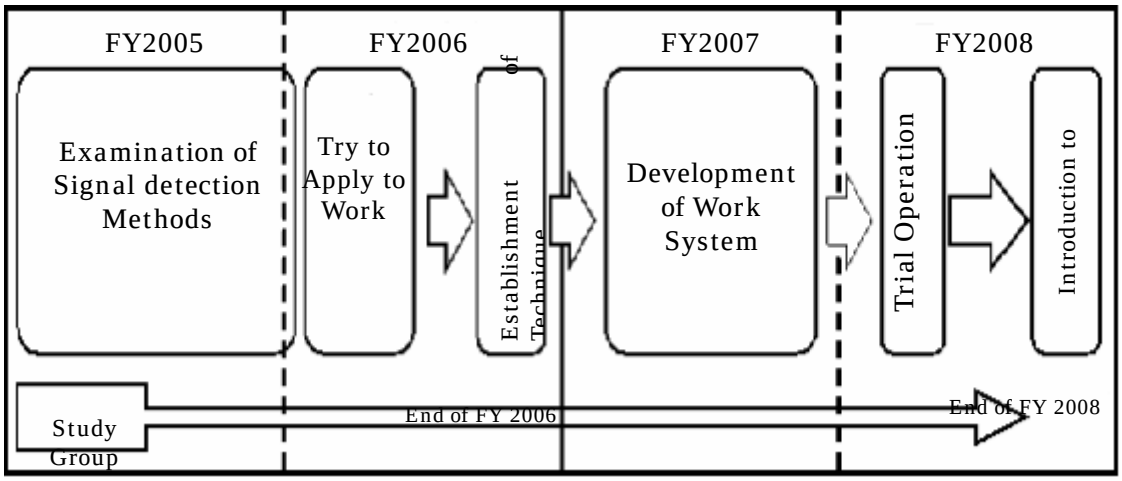
New safety measures (Prediction / prevention)



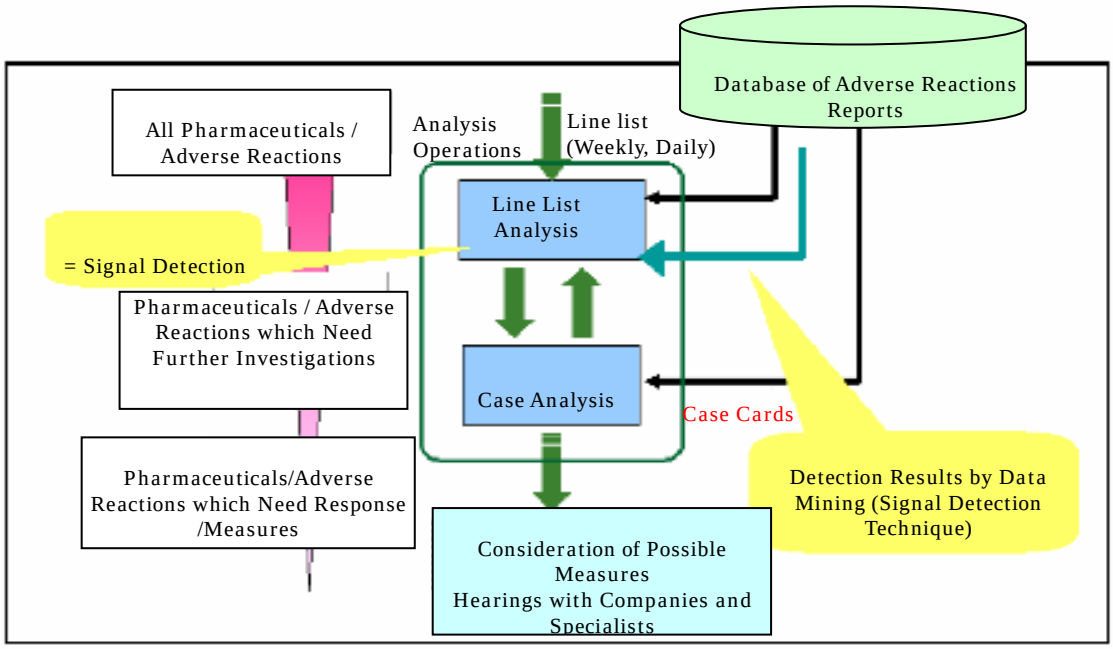
2. Introduction of new method (Study to introduce the Data Mining Technique)

- By the end of the Midterm Plan period, the Agency shall introduce the data mining technique that extracts the events that frequently concur as highly correlative events from a large amount of data accumulated in a database. The purpose of the introduction is to find relevancy among multiple adverse reaction information, to study techniques for the detection and analyses of new safety information and to take preventive measures for possible adverse reactions.
- In FY 2004, the Agency recognizes the data mining method is to detect combinations/signals of drugs and ADRs with “likely causality” from the database of ADR reports, and it defines the policy that the retrieved signals shall be evaluated by clinical and other experts and utilized for taking appropriate preventive measures.
- By the end of FY 2005 and 2006, the Agency shall establish the advanced method that can detect signals concerning concomitant drugs and patients’ demographic characteristics (age and sex, etc.). By the end of Midterm Target period of FY 2008, the Agency shall introduce the method into the post-marketing safety operations.

Schedule of Introduction of Data Mining Technique to Operations (Plan)

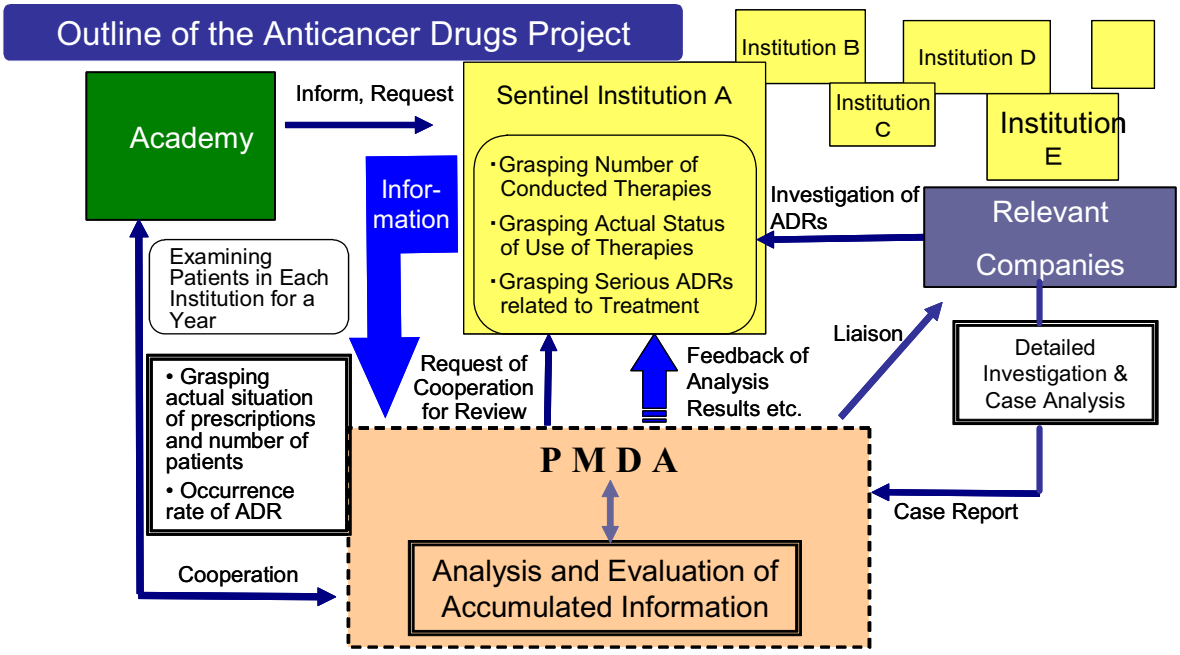


Application of data mining technique to safety measure operations



3. Establishment of sentinel medical institution network

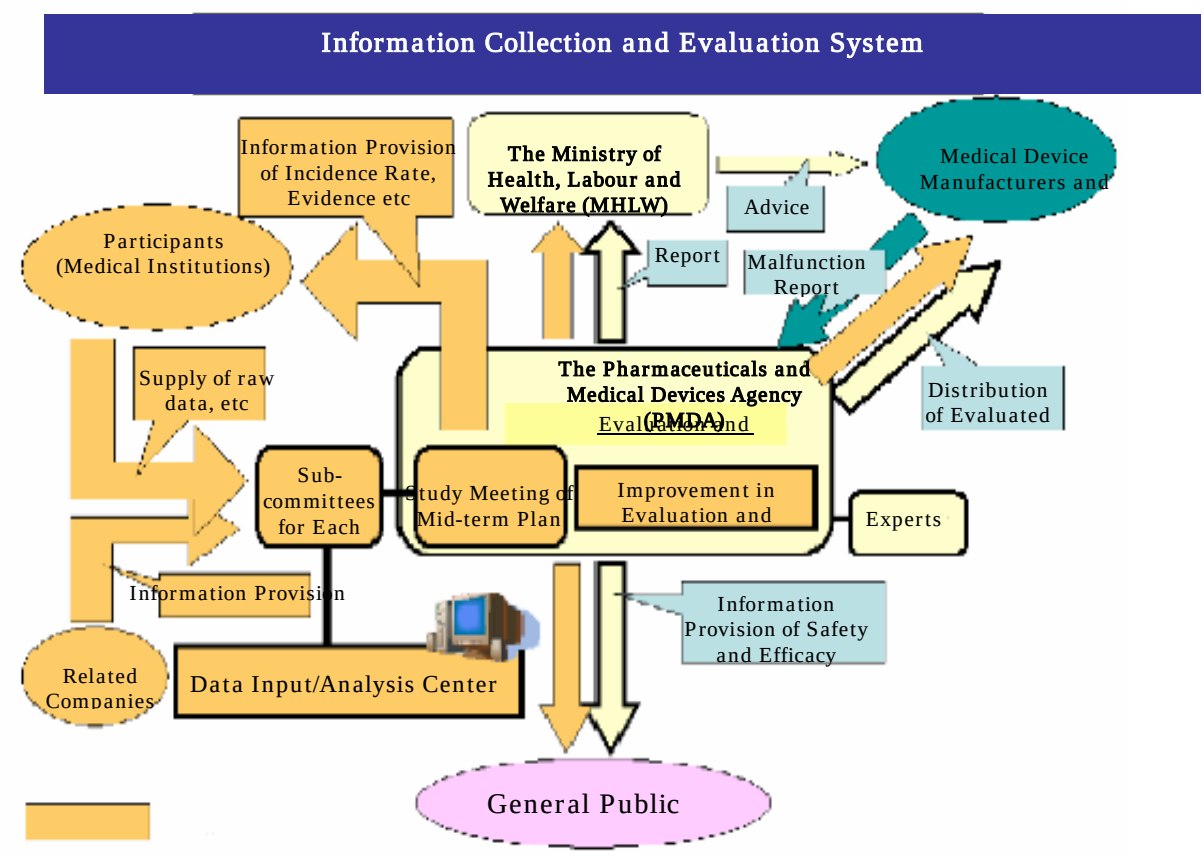
- During the Midterm Plan period, the Agency planned to establish a Sentinel Medical Institution Network as a new system to focus its post-marketing safety measures. The network aims to collect information intensively within a certain period of time from the medical institutions organized by specific therapeutic category, product and disease in cooperation with the review department to improve the accuracy of analysis of ADR information.
- In FY 2004, the Agency decided to conduct a fact-finding survey to investigate the actual conditions of use of 22 anti-cancer combination therapies. The investigation committee of MHLW discussed anti-cancer combination therapies. The Agency has proceeded with the preparation in cooperation with MHLW by holding briefings for medical institutions to participate in the survey and negotiating with relevant academic societies and pharmaceutical industries.



4. Study on the system for information gathering and review on medical device malfunctions

- The Agency shall be aware of the certain level of occurrence rate of medical device malfunctions that are not attributable to structural defects but due to their characteristics, and establish a system in which scientific evaluation on such malfunctions is conducted. The Agency held a committee composed of healthcare professionals and scholars in which coronary stent and implantable drug infusion instrument were chosen as subjects for the pilot study.
- The Agency cooperated with MHLW to study the establishment of the system to collect and evaluate data regarding the operational status of medical devices as well as malfunction rates over time for high-risk implantable medical devices that require tracking*. such as implantable pacemakers.

  * Medical device tracking is intended to ensure that malfunctions of certain devices can locate the uses of those devices. The manufacturers store and manage the information on the use of designated devices.



New Review System

5. Proper examination of reports on ADRs and medical device malfunction

- The Agency conducted the following measures in order to appropriately collect, arrange and examine the reports on ADRs and medical device malfunctions submitted by companies and medical institutions :

  1) Raised online reporting rate by asking the companies that had not get reported online for their cooperation and reduced the workload associated with data receipt and input.

  2) Clarified the method of applying for consultations and other matters to be consulted upon by posting application forms concerning consultation operations on its website.

  3) Held the weekly liaison meetings with MHLW on drugs and medical devices.

6. Computerization of reports on ADRs and medical device malfunctions

- The Agency established the system and asked companies for their cooperation to improve electronic data reporting on the information of ADRs and infections in order to ensure 60% of the electronic reporting rate targeted in FY 2004. The Agency achieved 69.1% of the electronic reporting rate in FY 2004 by promoting the system to major companies which had not yet introduced the system.

7. Establishment of post-marketing safety system through Information feedback

a. Feedback to companies

- The Agency is to establish a system that enables a company to secure access to information that pertains to its own products, such as ADR reports provided by medical institutions or reported by other companies, and started considering the development of the system.
- In order to contribute to improve safety measures of companies, the Agency started the consultation for companies concerning preventive measures of serious ADRs, revision of package inserts, the post-marketing risk management plan and so on.

b. Feedback to healthcare professionals

- The Agency took the following measures to disseminate safety information on drugs and medical devices to healthcare professionals and the public:

1) The Agency disseminated information on cases which led to the revision of package inserts of ethical drugs. The Agency had discussions to expand the information dissemination on new drugs. The Agency made an effort to post instruction for package inserts revision of ethical drugs issued by MHLW on its website.

2) For information on revisions of ethical drugs' package inserts, the Agency now makes it possible to post 11,706 package inserts on its website at the end of FY 2004. The Agency also completed the development of a system in which such information would be available via e-mail to healthcare professionals who seek to receive them.

3) In order to develop a system that allows accessing the shared information on attached documents of medical devices via internet, the Agency cooperated to develop the system in a pilot study conducted by MHLW.

c. Information provision to general consumers and patients

- The Agency recruited another two new counselors who worked for the previous Agency (Kiko/OPSR).
- In order to start consultation service on medical devices, the Agency employed new counselors.
- For ethical drugs such as self-injection drugs which patients use at home, or for those drugs that may induce serious ADRs and where detection of patients' subjective symptoms is essential in detecting ADRs at an early stage, the Agency cooperated with MHLW to

develop patient-instruction documents of the designated drugs.

d. Improvement of the contents and quality of disseminating information

- In order to facilitate cooperation of the departments between Post-marketing Safety and Relief and between Post-marketing Safety and Review, the Agency made an effort that enables the departments to share the information taking the protection of personal information into consideration.