Incorporated Administrative Agency - Pharmaceuticals and Medical Devices Agency (PMDA)

Midterm Plan (**Provisional Translation*)

**This translation of the original Japanese text is for information purpose only (in the event of inconsistency, the Japanese text shall prevail.*

Authorization No. 0401004 of the Minister, MHLW dated April 1, 2004
Amended: Authorization No. 0331003 of the Minister, MHLW dated March 31, 2005

In order for the Pharmaceuticals and Medical Devices Agency to fulfill the Midterm targets assigned by the Minister of Health, Labour and Welfare, effective April 1, 2004 in accordance with Article 29, Paragraph 1 of the Law on the General Rules of Incorporated Administrative Agency (Law No. 103, 1999), the Pharmaceuticals and Medical Devices Agency Midterm plan shall be developed as stated below, in accordance with Article 30, Paragraph 1 of the same law.

April 1, 2004
Akira Miyajima, Chief Executive
Pharmaceuticals and Medical Devices Agency

No.1 Measures to be taken to achieve targets concerning improvement in the overall operations of the Pharmaceuticals and Medical Devices Agency (hereinafter referred to as "the Agency") and those concerning improvement in the quality in services provided to the public, and other operations.

Measures to be taken to achieve targets concerning operational efficiency as specified under Article 30, Paragraph 2, Item 1 of the General Rules and those to achieve targets concerning the improvement of the quality in services provided to the public and other operations as specified under Paragraph2, Item 2 of the same Article, are as follows:

(1) Efficient and flexible operations management

a.

- Clarify targets and operational responsibilities of each section, and strive to identify problems and improve the areas in question through management of the progress of operations on a daily basis.
- Strengthen the function to develop strategies for overall operations, as well as the system to manage operations --- e.g. risk management, review procedure --- with an aim to build an organization system in which management judgment by the Chief Executive is speedily reflected in operations.
- Establish a deliberative body as a forum in which to exchange views with a wide range of experienced persons to seek their proposals or improvement plans regarding the operational affairs and management system of the Agency. Such views will be used to enhance its efficiency

and to ensure fairness and transparency in operations.

- Establish an efficient system of operations through both a flexible personnel allocation, tailored to situations, and an effective use of external experts.
- In order to ensure thorough risk management of operations, the Agency shall sequentially develop emergency manuals that are tailored to events or emergencies.

b.

- The Agency shall work to limit the number of permanent staff members by utilizing part-time staff members along with standardization of the processes of various areas of operations.

- Various types of documented information shall be in electronic format and incorporated into databases, wherever possible, to allow systematic compilation and storage of such information, and retrieval of information and materials, and analysis, etc.

(2) Expense savings etc., delivered by increased efficiency of operations

a. The Agency shall steadfastly improve its operations and endeavour to increase its efficiency. With curbs on its personnel expenses by reviewing wage levels, and reducing procurement costs, the budget for the Midterm Plan with regard to the general administrative expenses (excluding retirement allowances) shall take into account the following savings upon the completion of the effective period for Midterm Targets:
   ① Approximately 15% of savings in comparison with FY 2003 level
   ② The general administrative expenses due to accrue from FY 2004 in connection with the revisions to laws and systems and other matters shall be saved by approximately 12% in comparison with the FY 2004 level.
   ③ The general expenses due to accrue from FY 2005 in connection with the enforcement of the revised Pharmaceutical Affairs Law in FY 2005 shall be saved by approximately 9% in comparison with the FY 2005 level.

b. By increasing efficiency in operations such as the promotion of computerization, the budget for the Midterm Plan with regard to program expenses (excluding benefit-related expenses, and single-year expenses due to accrue in connection with creation of programs) shall have taken into account the following savings saved at the completion of the effective period for Midterm Targets:
   ① Approximately 5% of savings in comparison with the FY 2003 level
   ② The program expenses due to accrue from FY 2004 in connection with the revisions to laws and systems and other matters shall be saved by approximately 4% in comparison with the FY 2004 level.
   ③ The general expenses due to accrue from FY 2005 in connection with the enforcement of the revised Pharmaceutical Affairs Law in FY 2005 shall be saved by approximately 3% in comparison with the FY 2005 level.

c.

- By upgrading its current Collection System for Adverse Drug Reaction (ADR) contributions, the Agency shall incorporate into a database information on pharmaceutical manufacturers/importers and their licensed products, specifically with regard to Infectious Disease contributions, as well as contributions for safety measures, which are new activities for the Agency. The Agency shall utilize such computerized information to prevent omission of pharmaceutical manufacturers/importers and declared products. The Agency shall also manage contributions and pursue those pharmaceutical manufacturers/importers with unpaid contributions.
- The Agency shall facilitate checks of the amount of contributions declared by manufacturers/importers by establishing a calculation system to estimate the basic transaction amount per contribution fund.
- In order to increase efficiency in operations, the data shall be accumulated for use in examining contribution ratios for the financial re-calculation..
- The contribution collection ratio for ADR and Infectious Disease shall be no less than 99%.

  *The average collection ratio of ADR Contributions over the past five years is approximately 99%.
- With regard to safety measure contributions, the Agency shall aim to raise the collection ratio to levels similar to those of ADR and infectious disease contributions by the end of the effective period of the Midterm Targets. To this end, the Agency shall work toward the promotion of wide recognition of the system and, at the same time, diligently conduct the management of contributions by pharmaceutical manufacturers and importers.

(3) Improvement of services provided to the public

- The Agency shall improve and strengthen the system to address consultations and complaints received from the general public, etc.
- The Agency shall properly disclose its work and achievements on its website, as well as in its public relations magazines.
- In addition to introducing external audits based on the Incorporated Administrative Agency system, the Agency shall diligently conduct internal operation audits and accounting audits; the results of which shall be disclosed to the public.
- To ensure transparency of its expenditures, the Agency shall also disclose its financial standing, including the use of user fees and contributions.

No.2 Measures to be taken to achieve targets concerning increased improvement in operations of each section of the Agency, and improvement in the quality of services provided to the public and other operations.

1 Adverse Health Effect Relief Services

With regard to Adverse Health Effect Relief Services, the Agency shall work to publicize the Adverse Drug Reaction Relief and Biological Product-derived Infectious Disease Relief System (hereinafter referred to as "the System") to as many people as possible. While managing the System appropriately, the Agency shall take the following measures, in order to provide appropriate and prompt relief service to those people who suffered adverse drug reactions from pharmaceuticals and adverse health effects from biological product-derived infections:

(1) Measures to be taken to achieve targets concerning expansion and review of dissemination of information regarding the System

a. The Agency shall disclose on its website and in other media the instances of benefit payment, operational statistics, and other information by the end of FY 2004.

b.

- The Agency shall improve such items as brochures, application manuals, and the content of the information provided via the website. The Agency shall work to review its methods of disseminating information from the perspective of user-friendliness for the audience of such media.
- The Agency shall make possible the download of applications and other forms from its website by the end of FY 2004.
- While working to further enrich the information posted on its website, the Agency shall increase the number of website visitors by approximately 20% in comparison with the FY 2003 level by the completion of the effective period for the Midterm Targets

(2) Measures to be taken to achieve targets concerning proactive public relations activities toward familiarity with the System

- The Agency shall consider effective public relations for the System, and implement such activities in a proactive manner.
- The Agency shall utilize such media as newspapers to continuously work to familiarize more people with the System.
- The Agency shall endeavour to familiarize medical experts with the System, and gain their understanding.

(3) Measures to be taken to achieve targets concerning expansion of the scale of the consultation office

- The Agency shall assign dedicated regular staff members in its consultation office, to improve the

system dedicated to responding to consultations regarding the use of the System and procedures for ADR or infectious disease benefit claims.

- While improving the system in such manner, the Agency shall increase the annual number of consultations by approximately 20% in comparison with the FY 2003 level by the completion of the effective period for Midterm Targets.

(4) Measures to be taken to achieve targets concerning unified management of information through the database

- The Agency shall upgrade the database of information on ADR relief service for further user-friendliness, particularly on offending agents or on adverse health effects.
- As to the new service of infectious disease relief, the Agency shall establish an efficient system for the new service by utilizing the ADR relief service system.

(5) Measures to be taken to achieve targets concerning expeditious processing of relief applications through fact-finding study and other measures

a. In order to expeditiously process applications for relief benefits, the Agency shall conduct surveys and organize the facts of the matter when applying to the Minister of Health, Labour and Welfare (MHLW) for a judgment on medical and pharmaceutical sciences matters.

b.

- The standard administrative processing time --- from application to judgment as either payable or not payable --- shall be eight months (including the time required for medical and pharmaceutical judgment by MHLW. In addition to conducting surveys and organizing the facts of requests as mentioned in item a above, the Agency, in collaboration with MHLW, shall improve the administrative process for making judgments on payment. The number of cases which can be judged as payable or not payable within the standard administrative process time shall amount to 60% or greater of the total number of requests made.
- However, the period of time in which administrative processing could not be conducted for cases which required medical and pharmaceutical judgment, and thus required additional/supplementary materials and surveys from requestors or medical institutions, shall be excluded from the standard administrative processing time.

(6) Measures to be taken to achieve targets concerning promotion of appropriate communication of information through cross-functional collaboration

The Agency shall seek cross-functional collaboration, in particular, to appropriately provide its postmarketing safety section with instances of benefit payments in the relief services, giving due

consideration to handling sensitive confidential personal information.

(7) Measures to be taken to achieve targets concerning consideration of conducting surveys on adverse health effects, etc.

With regard to a survey on the actual damage and condition of recipients of relief benefits, the Agency shall consider a method of implementing the survey by the end of FY 2004. The survey shall be conducted by the end of FY 2005 based on the result of that consideration.

(8) Measures to be taken to achieve targets concerning appropriate conduct of relief services for SMON (subacute myelo-optico neuropathy) patients and those patients infected with HIV from blood preparations

Upon conducting the relief service for SMON patients and those patients infected with HIV from blood preparations, the Agency shall appropriately conduct the services as described in the commissioned contract, giving due consideration to handling of sensitive confidential personal information.

2 Reviews and Related Operations / Postmarketing Safety Operations

In order that the public can feel assured in the use of pharmaceuticals and medical devices at an international level, the Agency shall ensure that: better pharmaceuticals and medical devices are provided to the medical arena faster and with greater safety; that pharmaceuticals and medical devices are used properly; and that health hazards are prevented or responded to properly and promptly in the event of such occurrences. In order to enable such pharmaceuticals and medical devices to play their part in enhancing the public health for the long term, the Agency shall strengthen its structures for consultation/review and postmarketing safety measures and take the following measures so that both operations organically collaborate:

(1) Measures to be taken to achieve targets concerning faster access to leading-edge pharmaceuticals and medical devices

a.

- The Agency, in addition to conducting dialogue with such partners as academic societies or healthcare professionals, shall implement surveys to grasp the needs of the public and healthcare professionals.
- In order to ensure consistency between clinical trial consultation and reviews, and to accelerate reviews, the Agency shall conduct both operations under one team.

b.

The target review process time for applications submitted on and after April 1st year 2004 shall be as follows:

Note, however, that the review process time includes the review period at MHLW. Therefore, in order to achieve the target for review process time, including the time spent at MHLW, the Agency shall work to increase the efficiency in its operations for an overall acceleration of reviews:

- For new pharmaceuticals, the Agency shall ensure that it attains its performance target of processing 70% of the total NDA (new drug application) reviews within 12 months of review process time throughout the effective period for the Midterm Targets; and 80% by the completion of the effective period of the Midterm Targets.
- The Agency shall attain its performance targets of completing 70% of new medical device application reviews within 12 months of review process time for FY 2004; 80% for FY 2005 and 2006; and 90% for FY 2007 and 2008.
- As to products for priority review specified by the Minister, the Agency shall attain its performance target of completing 50% of priority NDA reviews within 6 months of review process time, and 70% of priority medical device application reviews within 9 months of review process time; both to be achieved by the end of the effective period of the Midterm Targets.

c.

- The Agency shall promote the consistency and harmonization of its practices and requirements with such international standards/guidelines as those for the development of review data which have been agreed among Japan, the US, and the EU ICH Meetings.
- To improve its operations for an efficient review system, the Agency, through its Midterm Targets period, shall take into account international trends, annually monitor the total review time, and reduce backlogs of applications.

d.

- The Agency shall establish a system of priority clinical trial consultation to introduce such services/operations as priority consultation and validation of pre-application documents; thereby increasing opportunities to provide guidance and advice at the pre-application stage.
- The Agency shall work to expedite clinical trial consultation procedures through shortening the time from application for clinical trial consultation to face-to-face consultation, or the time before the first face-to-face consultation for a priority clinical trial.

e. For evaluation of such advanced technologies as biotechnology and genomics, the Agency, during the Midterm Targets period, shall effectively use the services of highly knowledgeable external experts; and shall cooperate in developing the government's evaluation guidelines for applied new technology products.

(2) Measures to be taken to achieve targets concerning improvement in reliability of reviews and related operations/postmarketing safety operations

a.

- In order to improve the quality of review and postmarketing safety operations, the Agency shall systematically offer staff members with training opportunities in accordance with the operating targets, and thereby upgrade the skills of its staff members.
- In order to maintain the expertise of staff members, consideration shall be given to not frequently rotating staff members to different fields of operations.
- In order to reinforce the expertise of its internal staff, the Agency shall effectively use external experts with appropriate knowledge.
- To establish a system to improve the quality of its review operations, the Agency shall integrate information on review and postmarketing safety operations. Also, to facilitate Agency operations, an Information Support System shall be established by the end of FY 2006.
- During the Midterm Targets period, the Agency, shall strengthen its ties not only with the regulatory authorities of the US and Europe, but also with those of Asian countries where clinical trials are conducted.

b.

- During the Midterm Targets period, the Agency shall take cooperative action in developing the government's evaluation guidelines for products applying new technologies such as genomics.
- To improve the quality of domestic clinical trials, the Agency shall, during the Midterm Targets period, work to promote appropriate clinical trials by educating health professionals and patients, taking into consideration the results of field audits on clinical trials at medical institutions, etc.

c. To promote transparency, the Agency, in cooperation with MHLW, shall provide the public with timely review reports that include results of priority reviews, and any other information pertaining to its reviews and postmarketing safety operations.

d.

- The Agency shall be aware of the occurrence rate of medical device failures that are not attributable to structural failure but would occur at a certain rate due to the characteristics. By the end of the Midterm Targets period, the Agency shall establish a system in which scientific evaluation of such failures is implemented.
- For high-risk implantable medical devices that require tracking, such as pacemakers, the Agency, by the end of the Midterm Targets period, shall develop a system to collect and evaluate data regarding the operational status of medical devices as well as failure rates over time.

(3) Measures to be taken to achieve targets concerning reinforcement of information management and emergency management

a. Introduction of new method

The Agency shall study the Data Mining Method (such as methods to statistically analyze the ADR information reported by companies or medical institutions, after which ADR cases requiring examination for further details are extracted) to detect ADRs in an early stage or take preventive measures, with the use of information on ADR and other matters collected from multiple companies. The method shall be established by the end of FY 2006 and introduced into postmarketing safety operations by the end of the Midterm Targets period.

Furthermore, the development status of such establishment shall be publicly reported as necessary.

b. Establishment of Sentinel Medical Institution Network

To improve the accuracy of analysis of ADR information, the Agency, in cooperation with its review section and MHLW, shall establish a Sentinel Medical Institution Network that allows intensive collection of information within a certain period of time. Participating medical institutions will be organized by specific therapeutic category, product, and disease. This goal shall be achieved by the end of the Midterm Targets period.

Additionally, the Agency shall provide those medical institutions participating in the Network with information focused on ADRs or on proper use of drugs and devices in specific disease categories. That information will contribute to improvement in medical practices at those medical institutions.

c. Computerization of reports on ADRs, medical device failures, etc.

- The Agency shall ask companies for their cooperation to improve the system to facilitate electronic transmission of information on pharmaceuticals such as ADR/infections, which commenced in October 2003, and raise the electronic transmission percentage to an annual average of 80% or more by the end of the Midterm Targets period.
- MHLW is to develop a system that allows medical institutions, pharmacies and others to report their information on ADRs and infections conveniently via the internet. With the start of this reporting system, the information exchange process between the Agency and MHLW shall be conducted online.

d. Establishment of postmarketing safety system through feedback of information, etc.

<Feedback to companies>

- In order to contribute to improving the risk management systems of companies, the Agency shall establish a system that enables a company to secure access to information that pertains to its own products, such as ADRs provided by medical institutions or reported by other companies.
- Additionally, the Agency shall conduct the following operations through the Midterm Targets period:

  ① The Agency shall utilize postmarketing information generated from early-phase

postmarketing vigilance or Sentinel medical institutions, to implement consultations for companies on measures to prevent serious ADRs; to detect such ADRs at an early stage; and to prevent such reactions from worsening.

② When companies wish to consult with the Agency upon developing or voluntarily revising the package inserts of their pharmaceuticals/medical devices or patient medication instructions, the Agency shall promptly respond to such consultations.

③ Staff dedicated to review operations, and those dedicated to postmarketing safety, shall jointly deliver advice to companies on their risk management plans concerning their products on the market.

④ The Agency shall analyze improvement or development of products intended for safer use of pharmaceuticals and medical devices in the medical arena. The results shall be used for consultation and review operations.

⑤ For such product improvement or development, the Agency shall implement for companies consultation services based on analyses of "hiyari-hatto" (*near-incidents*) information.

<Feedback to health professionals>

- The Agency shall take the following measures to disseminate information to health professionals:

① The Agency shall disseminate information on ADR and device failure cases, such as those that served as the basis for revisions of package inserts for ethical pharmaceuticals/medical devices.

② The Agency, by the end of FY 2004, shall develop a system in which written instructions for revisions to ethical pharmaceuticals package inserts will be posted on the website within two days of the issuance of the instruction.

③ In addition to providing information such as revisions to ethical pharmaceuticals package inserts on the internet, the Agency, by the end of FY 2006, shall develop a system in which such information would be available via e-mail to those health professionals who wish to receive them.

④ With regard to package inserts information for ethical pharmaceuticals, the Agency shall begin the dissemination of information, prepared by companies, by the end of FY 2006. This shall be based on the results of MHLW's consideration of the modality of a system that would allow access to more detailed information in a hierarchical fashion.

⑤ The Agency shall work to improve the dissemination of information on pharmaceuticals that can be used as instructions for patients.

<Information dissemination to patients>

- In order to ensure safety and security in the use of pharmaceuticals and medical devices, the Agency shall conduct a consultation service for general consumers or patients regarding those products.
- Based on the results of consideration by MHLW, the Agency, by the end of FY 2006, shall launch a service to disseminate to patients on the internet the following information to be prepared by

companies:

・Patient Medication Instructions for ethical pharmaceuticals such as self-injections which patients use at home, or for those pharmaceuticals that may induce serious ADRs and where detection of a patient's subjective symptoms is essential in detecting ADRs at an early stage.

・Self-check charts which list the early signs and other information of known serious ADRs which are relatively likely to develop for the pharmaceuticals described above.

<Improvement of the contents and quality of information for dissemination>

- While giving due consideration to handling confidential personal information, the Agency, in collaboration with the relief and review operations, shall conduct consistent safety evaluations from approval to relief.
- To contribute to the improvement of its information dissemination services, the Agency shall conduct a survey by the end of FY 2006 on the information disseminated to general consumers and health professionals, and analyze the needs and satisfaction level of the audience of that information. The results shall be reflected in improving the operation of information dissemination.

No.3 Budget, Income and Expenditure Plan, and Cash Flow Plan

1 Budget (as per attached Sheet 1)
2 Income and Expenditure Plan (as per attached Sheet 2)
3 Cash Flow Plan (as per attached Sheet 3)

No.4 Limit on short-term borrowing

(1) Limited borrowing amount

2.3 billion yen

(2) Reasons for assuming short-term borrowings

a. Shortage of funds due to delays in the receipt of management grants, subsidies, and commissioning fees, etc.
b. Unexpected retirement allowance expenses
c. Shortage of funds due to the occurrence of unforeseen contingencies

No.5 Plan for transferring or mortgaging important assets

Not applicable.

No.6 Use of surplus funds

The Agency may apply the surplus of its Review account to the following:

- Financial resources for expenditures pertaining to service improvement
- Financial resources for training to improve the quality of staff members

The residual amount for both the ADR Relief account and the Infectious-disease Relief account shall be arranged as a reserve as in accordance with Article 31, Paragraph 6 of Incorporated Administrative Agency – The Pharmaceuticals and Medical Devices Agency Law (Law No. 192, 2002)

No.7 Other important operational items determined by orders from the competent ministry

Items concerning management operations specified under Article 4 of Ministerial Ordinance regarding operations management, financial affairs, and accounting of Incorporated Administrative Agency – The Pharmaceuticals and Medical Devices Agency (MHLW Ministerial Ordinance No. 55, 2004) shall be as follows:

(1) Items concerning personnel matters

a.

- In order to enhance the quality of its operations and services, the Agency shall provide staff members with training opportunities, in a systematic fashion, in accordance with the operations and services goals, and thereby work to improve the quality and capability of staff members.
- The Agency shall introduce a personnel evaluation system that will lead to an increase in staff motivation. Evaluation and target achievement status of staff members shall be reflected appropriately in remuneration, salary increases and promotions.
- To ensure the professionalism of staff members and the continuity of operations, the Agency shall conduct appropriate personnel placements.

b.

- In order to ensure smooth enforcement of the revised Pharmaceutical Affairs Law in 2005, such as, for example, conducting GMP inspections (see “Regulations for Manufacturing Control and Quality Control of Drugs and Quasi-Drugs” (MHW Ordinance No.16, 1999)) abroad, the Agency shall recruit competent human resources with high levels of expertise, mainly through open recruitment. Recruiting shall be done with due consideration to the impartiality of the Agency.

*Personnel indicators

The number of permanent staff members at the end of the effective period of the Midterm

Targets shall be at a maximum of 109% of the number at the beginning of the period.

(Reference 1)
Number of permanent staff members at the beginning of the period: 317
Number of permanent staff members at the end of the period: 346 (maximum)

(Reference 2)
Total personnel expenses during the period: 16,317 million yen (estimate)

c. In order to avoid any suspicions of inappropriate ties with pharmaceutical and medical device companies and others, the Agency shall place certain restraints on the recruitment and placement of its executives and staff members, as well as on employment of those who leave the Agency, and thereby conduct its personnel management in an appropriate manner.

(2) Ensuring security

- The Agency shall install entrance/exit control devices in its offices for security and confidentiality, and shall have thorough entrance/exit controls in place, day and night, to reinforce its internal control systems.
- The Agency shall ensure the security of information in its information systems.

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Budget Attachment 1

Budget for the Midterm Plan (FY 2004 – 2008)

(Unit: Million yen)

Classification	Amount					
	Account					
	ADR Relief	Infectious-Disease Relief	Review	SMON-Patients Relief	HIVpositive/AIDS Patients Relief	Total
Income						
Grant (for operating expenditures)			3,543			3,543
Governmental Subsidy	989	98				1,087
Commissioned Operation Income			12	8,931	3,692	12,635
Contributions Income	14,478	2,391	4,662			21,531
User-Fee Revenue			33,166			33,166
Non-Operating Income	1,278	56	239	1	1	1,575
Mgmt Income	1,260	55	0	0	0	1,315
Miscellaneous Income	18	1	239	1	1	260
Total	16,746	2,544	41,623	8,932	3,693	73,538
Expenditure						
Operating Expenses	8,247	468	16,759	8,655	3,495	37,624
Administrative Expenses	674	62	9,262	84	49	10,131
Personnel Expenses	1,342	131	14,503	193	148	16,317
Total	10,263	660	40,524	8,932	3,693	64,072

<Note>
The numbers have been rounded off as a rule; therefore, the totals may not coincide with the actual sum.

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Income and Expenditure Plan Attachment 2

Income and Expenditure Plan for the Midterm Plan (FY2004 – 2008)

(Unit: Million yen)

Classification	Amount					
	Account					
	ADR Relief	Infectious-Disease Relief	Review	SMON-Patients Relief	HIV Positive/AIDS Patients Relief	Total
Expenditures	80,394	1,965	38,523	8,932	3,693	133,507
Ordinary Expenses	80,394	1,965	38,523	8,932	3,693	133,507
Relief Benefits	7,488	266				7,754
Health and Welfare Operating Expenses	83					83
Review Operating Cost			11,581			11,581
Safety Measures Operating Cost			3,242			3,242
Benefits(Healthcare Allowance, etc.)				8,594		8,594
Benefits (Special Allowance, etc.)					1,417	1,417
Reseach and Study Operating Cost					1,983	1,983
Administrative Expenses	1,451	257	9,233	150	144	11,235
Personnel Expenses	1,231	131	14,376	187	146	16,071
Depreciation Expenses	14		86	0	0	100
Provision for Liability Reserve	70,116	1,305				71,421
Non-operating Expenses	8	4	5			17
Income	83,436	3,406	38,537	8,932	3,693	138,004
Ordinary Income	83,436	3,406	38,537	8,932	3,693	138,004
Income from Contributions	14,478	2,391	4,662			21,531
Governmental Subsidy	989	98				1,087
User-Fee Income			30,077			30,077
Commissioned Operation Income			12	8,931	3,692	12,635
Reversal of Asset Offset Subsidies	5		7			12
Reversal of Asset Offset Grants			1			1
Grant for Operating Expenditures			3,538			3,538
Reversal of Liability Reserve	66,598	862				67,460
Non-operating Income	1,365	56	240	1	1	1,663
Net Income (△Net Loss)	3,042	1,441	15	0	0	4,498
Reversal of Appropriated Surplus	0	0	0	0	0	0
Gross Income (△Gross Loss)	3,042	1,441	15	0	0	4,498

<Note 1>

The grant (for operating expeditures) is assumed to be the resource for retirement allowance for those staff members that pertain to the operation addressed by the grant under the Review Account.

However, this excludes the amount that has been arranged by grant (for operating expenditures) as a retirement allowance equivalent to one's tenure, as indicated under Article 8, Paragraph 2 of supplementary provision.

<Note 2>

The numbers have been rounded off as a rule; therefore, the totals may not coincide with the actual sum.

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Cash Flows Plan Attachment 3

Cash Flows Plan for the Midterm Plan (FY2004 – 2008)

(Unit: Million Yen)

Classification	Amount					
	Account					
	ADR Relief	Infectious-Disease Relief	Review	SMON-Patients Relief	HIV Positive/AIDS Patients Relief	Total
Cash Outflows						
Cash Outflows from Operating Activities	10,152	659	40,472	8,926	3,692	63,901
Relief Benefits	7,488	266				7,754
Health and Welfare Operating Expenses	83					83
Benefits (Healthcare Allowance, etc.)				8,594		8,594
Benefits (Special Allowance, etc.)					1,417	1,417
Reseach & Study Operating Expenses					1,983	1,983
Administrative Expenses	1,340	257	9,262	144	143	11,146
Personnel Expenses	1,231	131	14,451	187	146	16,146
Refund	4	4				8
Miscellaneous	3		5			8
Cash Outflows from Investing Activities	5,869					5,869
Cash Outflows from Financial Activities	18		51	1	1	71
Amount carried fwd to the next Midterm Period	26,251	5,612	9,639	227	732	42,461
Total	42,292	6,272	50,163	9,156	4,424	112,307
Cash Inflows						
Cash Inflows from Operating Activities	15,485	2,489	41,623	8,932	3,693	72,222
Relief Benefits	14,478	2,391	4,662			21,531
Grant			3,543			3,543
Government Subsidy	989	98				1,087
User-Fee Income			33,166			33,166
Commissioned Operation Income			12	8,931	3,692	12,635
Miscellaneous Income	18	1	239	1	1	260
Cash Inflows from Investing Activities	1,259	55				1,314
Cash Inflows from Financial Activities	4,934		51	1	1	4,987
Amount brought fwd at the beginning of a period (during the Midterm Plan period)	20,612	3,728	8,489	222	730	33,781
Total	42,292	6,272	50,163	9,156	4,424	112,307

<Note>

The figures have been rounded off as a rule; therefore, the totals may not coincide with the actual sum.