

# TABLE OF CONTENTS

## I. THE PHARMACEUTICALS AND MEDICAL DEVICES AGENCY

PART1. HISTORY AND OBJECTIVE OF THE AGENCY .....	1
PART2. OVERVIEW OF OPERATIONS .....	4
1. Relief Services for Adverse Health Effects .....	4
2. Review Services .....	4
3. Safety Measures .....	5

## II. ACTUAL OPERATION RESULTS FOR FY 2006

PART1. DEVELOPMENT OF 2006 FISCAL YEAR PLAN .....	7
1. Development and Implementation of 2006 Fiscal Year Plan .....	7
2. Evaluation Results of Operational Performance in FY 2005 .....	8
3. Modifications in the Mid-term Plan (Approved on March 30, 2007) .....	10
PART2. IMPROVEMENT IN OVERALL MANAGEMENT OF OPERATIONS AND SERVICE QUALITY OF THE AGENCY .....	13
1. Efficient and Flexible Management of Operations .....	13
1. (1) Operation through Management by Objectives .....	13
1. (2) Reinforcement of Operational Management System and Top Management .....	13
1. (3) Advisory Council Meetings .....	16
1. (4) Approaches for an Efficient Operation System .....	18
1. (5) Standardization of Operating Procedures .....	19
1. (6) Development of Databases .....	19
1. (7) Approaches to Developing the Optimization Plan for Operations and Systems .....	19
2. Cost Control by Increased Efficiency of Operations .....	20
2. (1) Retrenchment of General Administrative Expenses .....	20
2. (2) Cost Control of Project Expenses .....	20
2. (3) Collection and Management of Contributions .....	22
2. (3). 1. Collected contributions for adverse drug reaction fund and shifts in the liability reserve .....	23
2. (3). 2. Collected contributions for relief for infections derived from biological products ..	25
2. (3). 3. Collected contributions for safety measures .....	25
2. (4) Reduction in Personnel Expenses and Overhaul of the Pay System .....	26
3. Improvement of Services to the Public .....	26
3. (1) General Consultation Service .....	26

3. (2) Responses to Consultations, Complaints and Claims of Dissatisfaction from the Private Sector regarding Reviews and Safety Operations .....	27
3. (3) Development of the PMDA Website .....	28
3. (4) National Forum on Pharmaceuticals and Medical Devices .....	28
3. (5) Disclosure Request for Corporate Documents .....	30
3. (6) Auditing and Related Matters .....	32
3. (7) Report on Financial Standing .....	32
 4. Personnel Issues .....	32
4. (1) Review of a Personnel Evaluation System .....	32
4. (2) Systematic Implementation of Staff Training .....	33
4. (3) Appropriate Personnel Allocation .....	34
4. (4) Securing Human Resources through Open Recruitment .....	34
4. (5) Appropriate Personnel Management Based on Work Regulations .....	36
 5. Ensuring Security .....	37
5. (1) Management of Entries and Exits .....	37
5. (2) Security Measures for Information Systems .....	37
 <b>PART3. IMPROVEMENT IN MANAGEMENT OF OPERATIONS AND QUALITY OF SERVICES IN EACH DIVISION .....</b>	<b>39</b>
<b>1 .Relief Fund Services .....</b>	<b>39</b>
1. (1) Expansion and Reconsideration of the Provision of Information .....	39
1. (1). 1. Disclosure of cases of payment of benefits on the Website .....	39
1. (1). 2. Improvement of pamphlets, etc. ....	39
1. (2) Active Implementation of Public Relations Activities .....	40
1. (3) Expansion of the Consultation Service .....	42
1. (4) Uniform Management of Information through Databases .....	43
1. (5) Prompt Processing of Relief Applications .....	43
1. (5). 1. Adverse drug reaction relief services .....	45
1. (5). 2. Infections derived from biological products relief .....	47
1. (6) Promotion of Appropriate Communication of Information through Collaboration between Divisions .....	49
1. (7) Surveys on Actual Status of Effects from Adverse Drug Reactions Caused by Pharmaceuticals (Investigative Researches as a Part of Health and Welfare Services) .....	50
1. (8) Appropriate Implementation of Healthcare Allowances for SMON Patients and HIV Positive Patients Infected through Blood Products .....	50
1. (8). 1. Services for SMON-patients (healthcare allowances) .....	51
1. (8). 2. AIDS-related services (healthcare allowances) .....	51
 2. Reviews and Related Services / Safety Measures .....	53
2. (1) Faster Access to the Latest Pharmaceuticals and Medical Devices .....	53
2. (1). 1. Ensuring the benefits of pharmaceuticals and medical devices for the public and people involved in the medical field .....	53

<i>a. Implementation structure for clinical trial consultations and reviews</i>	53
<i>b. Comprehension of the needs of public and healthcare professionals</i>	59
2. (1). 2. Efforts for efficient and prompt reviews	60
<i>a. Approval reviews for new drugs</i>	60
<i>b. Approval reviews for new medical devices</i>	64
<i>c. Document conformity audit of application materials, GLP conformity audits, GCP conformity audits and GPMSP conformity audits</i>	68
<i>d. Approval reviews for generic drugs, over-the-counter (OTC) drugs and quasi-drugs</i>	69
2. (1). 3. Improvement of clinical trial consultations	72
<i>a. Conducting priority clinical trial consultations</i>	72
<i>b. Acceleration of clinical trial consultations for pharmaceuticals</i>	73
2. (1). 4. Promotion of international harmonization	75
<i>a. Approaches towards international harmonization such as through the ICH</i>	75
<i>b. Efforts to introduce the total review time</i>	77
2. (2) Improvement in Reliability of Operations	78
2. (2). 1. Planned recruitment of staff with advanced expertise and systematic provision of training opportunities	78
2. (2). 2. Development of a GMP/QMS audit system	78
2. (2). 3. Use of external experts	82
2. (2). 4. System development for more efficient review services	82
2. (2). 5. Reinforcement of partnerships with foreign regulatory authorities	83
2. (2). 6. APEC network symposium	83
2. (2). 7. Evaluation of the advanced technologies, such as biotechnology and genomics; cooperation in developing national guidelines	84
2. (2). 8. Promotion of appropriate clinical trials	85
2. (2). 9. Prompt provision of information such as review reports	85
2. (3) Enhancement of Safety Measures (Reinforcement of Information Management and Risk Management System)	86
2. (3). 1. Basic direction of safety measures	86
2. (3). 2. Introduction of a new method (review of the data mining method)	89
2. (3). 3. Building a sentinel medical institution network	91
2. (3). 4. Review of the system for comprehending and evaluating medical device malfunctions	93
2. (3). 5. Proper implementation of surveys for reports on adverse reaction and medical device malfunctions	95
2. (3). 6. Digitization of adverse reaction reports and reports on medical device malfunctions	97
2. (3). 7. Establishment of post-marketing safety system based on feedback of information	98
<i>a. Feedback to the private sector</i>	98
<i>b. Feedback to healthcare professionals</i>	99
<i>c. Provision of information to general consumers and patients</i>	102

### III. SUPPLEMENTARY INFORMATION

Table 1. FY2006 List of approved items: new drugs .....	111
Table 2. FY 2006 List of approved items: new medical devices .....	118
Table 3. Safety measures implemented by MHLW / FY 2006 .....	120
Table 4. Revisions to PRECAUTIONS in package insert for pharmaceuticals, instructed by MHLW / FY 2006 .....	121
Table 5. Revisions to PRECAUTIONS and instruction for self-inspection for medical devices / FY2006 .....	126
Table 6. FY2006 Pharmaceuticals and Medical Devices Safety Information (No.224-234) .....	127
Table 7. User fee list of review and audit for ethical drugs, quasi drugs and cosmetics (effected on April 1, 2005) .....	130
Table 8. User fee list for medical devices (effected on April 1,2005) .....	134
Table 9. User fees under the Article 3 of the administrative instruction of business and service documents range of reviewing and other services of the Independent Administrative Agency, Pharmaceutical and Medical Devices Agency .....	137
Table 10.Comparison of former and revised user fees (revision implemented on April 1,2007) .....	138
Reference 1. Interim Report of the Clinical Trial Issues Review Committee [Summary] (September, 2006) .....	141
Reference 2. Proposal from the Council for Science and Technology Policy “Institutional reform for promoting science and technology and passing on the benefits to the society” (excerpt) (December 25, 2006) .....	146