STATISTICAL TABLES

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

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.

Adverse Health Effect Relief Services

Table 1: Number of Cases on Adverse Health Effect Relief Benefits 1980-2004

Classification / Fiscal year	Number of Claims	Number of Withdrawals	Number of Payments	Number of Non-payments
1980	20 (20)	0 (0)	8 (8)	2 (2)
1981	35 (29)	1 (1)	20 (17)	1 (1)
1982	78 (66)	6 (6)	38 (28)	8 (8)
1983	78 (66)	2 (2)	62 (48)	8 (8)
1984	130 (105)	1 (1)	62 (53)	20 (15)
1985	115 (89)	2 (2)	95 (73)	23 (16)
1986	133 (104)	0 (0)	98 (82)	19 (13)
1987	136 (107)	0 (0)	84 (65)	24 (13)
1988	175 (142)	2 (2)	120 (102)	20 (13)
1989	208 (176)	1 (1)	137 (119)	19 (16)
1990	225 (183)	0 (0)	226 (197)	44 (30)
1991	208 (168)	0 (0)	194 (152)	46 (33)
1992	203 (173)	4 (4)	199 (170)	41 (30)
1993	202 (169)	3 (3)	176 (157)	32 (27)
1994	205 (166)	3 (3)	195 (165)	35 (24)
1995	217 (167)	1 (1)	172 (139)	25 (14)
1996	297 (246)	2 (2)	190 (158)	49 (33)
1997	399 (330)	0 (0)	294 (238)	55 (49)
1998	361 (300)	0 (0)	306 (261)	49 (40)
1999	389 (318)	3 (2)	289 (238)	46 (41)
2000	480 (414)	0 (0)	343 (293)	61 (54)
2001	483 (411)	0 (0)	352 (294)	64 (54)
2002	629 (531)	0 (0)	352 (288)	79 (66)
2003	793 (702)	2 (2)	465 (407)	99 (82)
2004	769 (675)	1 (1)	513 (460)	119 (101)
Total	6,968 (5,857)	34 (33)	4,990 (4,212)	988 (783)

(Note) The number of cases indicates the number of all the claims reported to PMDA. The number includes even multiple claims done by the same claimants for the same reason. The number in the parentheses indicates the number of all the claimants. The number excludes their reclaims done for the same reason.

Table 2: Number of claims and benefit amounts in Adverse Health Effect Relief Services

Fiscal year	Medical expenses				Medical allowance				Disability pension				Pension for raising handicapped children			
	Number of claims	Number of payment	Number of non-payments	Benefit amounts	Number of claims	Number of payments	Number of non-payments	Benefit amounts	Number of claims	Number of payments	Number of non-payments	Benefit amounts	Number of claims	Number of payments	Number of non-payments	Benefit amounts
	(Cases)	(Cases)	(Cases)	(Thousand yen)	(Cases)	(Cases)	(Cases)	(Thousand yen)	(Cases)	(Cases)	(Cases)	(Thousand yen)	(Cases)	(Cases)	(Cases)	(Thousand yen)
1980	17	6	1	292	18	7	1	315	0	0	0	0	0	0	0	0
1981	16	12	1	707	30	17	1	1,308	3	1	0	632	0	0	0	0
1982	26	14	3	1,369	59	28	5	3,647	16	5	3	7,687	0	0	0	0
1983	31	26	2	2,201	61	51	4	7,774	12	4	4	19,094	0	0	0	0
1984	69	28	6	2,947	99	53	13	6,246	22	8	8	33,858	4	0	0	0
1985	69	46	16	6,443	90	72	19	11,891	20	4	9	39,082	0	2	1	1,382
1986	83	61	13	5,937	99	77	12	8,888	17	7	14	53,820	4	1	0	2,647
1987	98	55	11	6,109	122	76	14	10,422	9	9	9	81,209	0	1	1	2,825
1988	107	83	9	9,201	135	105	10	11,924	26	9	2	101,206	6	0	1	2,715
1989	131	90	8	10,890	175	109	12	11,901	20	8	4	105,448	5	2	2	3,506
1990	167	167	17	16,990	185	204	25	22,736	29	10	26	124,128	0	3	5	6,516
1991	148	147	25	15,539	171	167	32	22,631	27	17	15	144,466	2	1	0	5,439
1992	153	149	24	17,156	173	165	26	19,463	21	13	13	167,235	1	2	0	6,326
1993	142	128	16	16,521	166	149	21	16,760	27	11	15	190,711	3	0	1	5,254
1994	155	156	23	18,027	184	177	29	20,055	27	14	17	218,198	1	3	0	6,121
1995	138	122	16	11,775	167	150	18	16,355	36	16	12	245,773	3	0	1	5,666
1996	193	130	25	12,749	239	161	27	19,381	39	18	18	281,838	2	1	2	5,525
1997	283	209	27	24,180	328	252	33	28,114	51	25	23	326,985	7	1	2	3,824
1998	241	226	26	21,456	286	260	28	24,657	36	23	23	385,285	2	2	3	5,647
1999	258	206	20	20,391	327	246	29	26,294	40	11	13	389,353	5	4	0	10,736
2000	321	229	22	21,128	411	305	36	30,496	53	22	19	435,484	3	3	1	11,374
2001	334	252	37	22,541	398	302	48	33,406	35	28	24	483,316	9	4	0	12,226
2002	474	237	54	21,049	533	293	64	30,654	67	24	17	504,134	2	4	0	17,352
2003	640	367	60	34,813	683	408	65	35,388	68	22	27	552,869	9	2	1	16,991
2004	613	448	74	51,722	650	472	80	42,711	73	24	33	592,028	14	4	0	17,810
Total	4,907	3,594	536	372,133	5,789	4,306	652	463,417	774	333	348	5,483,839	82	40	21	149,882

(Note) 1. The number of claims shown in this table indicates one case per payment type, which does not correspond to those in Table 1.

2. Because the figures of the benefit amounts are rounded to the nearest thousand, the sum of the benefit amounts in each fiscal year is not always identical to the total.

Fiscal year	Bereaved family pension				Lump-sum benefit for bereaved family				Funeral expenses				Total			
	Number of claims	Number of payments	Number of non-payments	Benefit amounts	Number of claims	Number of payments	Number of non-payments	Benefit amounts	Number of claims	Number of payments	Number of non-payments	Benefit amounts	Number of claims	Number of payments	Number of non-payments	Benefit amounts
	(Cases)	(Cases)	(Cases)	(Thousand yen)	(Cases)	(Cases)	(Cases)	(Thousand yen)	(Cases)	(Cases)	(Cases)	(Thousand yen)	(Cases)	(Cases)	(Cases)	(Thousand yen)
1980	2	1	1	385	0	0	0	0	2	1	1	85	39	15	4	1,077
1981	4	2	0	2,578	0	0	0	0	4	2	0	182	57	34	2	5,407
1982	13	9	0	16,321	13	6	3	29,514	24	14	3	1,322	151	76	17	59,860
1983	6	7	0	29,232	12	8	2	41,062	18	15	2	1,455	140	111	14	100,818
1984	12	8	1	44,600	16	4	6	20,326	27	12	6	1,107	249	113	40	109,084
1985	12	10	0	66,882	11	12	2	56,916	24	21	2	2,145	226	167	49	184,741
1986	17	16	1	96,026	14	7	2	36,947	30	23	3	2,503	264	192	45	206,768
1987	17	8	5	108,651	15	10	3	49,806	31	17	7	1,937	292	176	50	260,959
1988	18	16	2	150,506	19	16	2	88,679	36	32	4	3,628	347	261	30	367,859
1989	20	21	-1	205,497	23	19	1	100,406	42	39	0	4,561	416	288	26	442,209
1990	19	13	2	229,988	21	18	2	103,777	40	31	4	3,727	461	446	81	507,862
1991	12	15	3	255,044	20	15	6	84,780	31	28	9	3,528	411	390	90	531,427
1992	13	14	5	280,277	20	21	6	123,775	31	33	12	4,261	412	397	86	618,493
1993	13	9	2	274,815	21	24	3	149,044	34	33	4	4,357	406	354	62	657,462
1994	5	8	1	286,863	16	9	2	57,906	21	18	3	2,494	409	385	75	609,664
1995	13	11	0	304,609	15	17	2	114,120	24	25	1	3,617	396	341	50	701,915
1996	14	12	2	286,446	22	12	3	83,301	35	23	5	3,372	544	357	82	692,612
1997	22	11	3	283,497	33	18	6	126,472	53	27	10	4,484	777	543	104	797,556
1998	19	20	3	293,969	42	27	7	190,436	55	45	11	7,535	681	603	101	928,986
1999	17	7	5	266,650	36	30	7	201,100	56	36	7	5,895	739	540	81	920,419
2000	21	11	5	272,662	33	22	15	157,824	49	36	17	6,180	891	628	115	935,148
2001	24	14	5	261,287	50	28	5	201,668	75	44	7	7,742	925	672	126	1,022,185
2002	24	17	7	279,203	44	27	10	195,070	82	48	16	8,522	1,226	650	169	1,055,984
2003	56	32	14	335,829	42	30	12	217,148	98	61	24	11,205	1,596	922	218	1,204,243
2004	54	31	10	412,167	47	19	10	137,041	101	48	20	9,167	1,552	1,046	227	1,262,647
Total	447	323	76	5,043,984	585	399	117	2,567,118	1,023	712	178	105,011	13,607	9,707	1,944	14,185,385

Table 3: Number of claims and benefit cases for Adverse Health Effect Relief Service in each prefecture (dated March 31, 2005)

Prefectures	Number of claims	Number of payments	Prefectures	Number of claims	Number of payments
Hokkaido	366 (303)	267 (223)	Shiga	66 (60)	43 (40)
Aomori	28 (24)	20 (17)	Kyoto	255 (199)	196 (152)
Iwate	38 (32)	23 (19)	Osaka	586 (524)	409 (374)
Miyagi	80 (77)	56 (55)	Hyogo	321 (281)	213 (188)
Akita	50 (44)	39 (35)	Nara	98 (89)	73 (66)
Yamagata	59 (51)	40 (34)	Wakayama	54 (51)	42 (41)
Fukushima	112 (95)	85 (74)	Tottori	22 (18)	13 (11)
Ibaragi	139 (112)	99 (81)	Shimane	42 (32)	29 (22)
Tochigi	73 (66)	54 (50)	Okayama	96 (84)	68 (61)
Gunma	86 (69)	68 (52)	Hiroshima	239 (178)	166 (115)
Saitama	341 (276)	247 (194)	Yamaguchi	103 (84)	76 (60)
Chiba	349 (281)	248 (201)	Tokushima	16 (14)	11 (10)
Tokyo	786 (649)	570 (468)	Kagawa	68 (55)	52 (40)
Kanagawa	504 (436)	362 (321)	Ehime	67 (58)	48 (42)
Niigata	107 (91)	90 (76)	Kochi	42 (35)	26 (25)
Toyama	47 (39)	33 (28)	Fukuoka	225 (186)	152 (125)
Ishikawa	46 (30)	36 (22)	Saga	27 (23)	17 (15)
Fukui	42 (36)	30 (28)	Nagasaki	77 (59)	59 (43)
Yamanashi	44 (38)	36 (31)	Kumamoto	88 (74)	68 (58)
Nagano	98 (91)	70 (67)	Oita	58 (47)	33 (26)
Gifu	136 (122)	99 (90)	Miyazaki	54 (42)	38 (31)
Shizuoka	249 (212)	166 (141)	Kagoshima	93 (77)	63 (53)
Aichi	331 (285)	241 (210)	Okinawa	74 (59)	59 (50)
Mie	84 (67)	55 (45)	Other	2 (2)	2 (2)
			Total	6,968 (5,857)	4,990 (4,212)

(Note) 1. The number of cases indicates the number of all the claims reported to PMDA. The number includes even multiple claims done by the same claimants for the same reason. The number in the parentheses indicates the number of all the claimants. The number excludes their reclaims done for the same reason.
2. "Other" means claims by foreigners, including those claimed after they returned to their countries.

Table 4 Transition in the breakdown of different diseases (symptoms) due to adverse reactions

Classification by different organs	Diseases due to adverse reactions	Fiscal year																						
		1980	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
Disorders of appendages of the skin	Disseminated drug eruption, toxic epidermal necrolysis, muco-cutaneo-ocular syndrome, etc	3	3	6	23	18	22	37	23	32	35	69	27	42	60	47	34	40	43	73	73	78	78	120
Musculoskeletal disorders	Femoral capital aseptic necrosis, coxodysfunction, etc	0	0	0	3	2	5	14	4	1	4	32	10	4	7	12	9	7	15	16	28	15	19	18
Central and peripheral nervous disorders	Hypoxic encephalopathia, aseptic cephalomeningitis, etc	2	3	3	3	8	10	11	18	22	14	35	53	50	33	38	23	60	71	85	67	70	48	62
Disorders of autonomic nervous system	Systemic flush, etc	1	0	0	1	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0	0	1	0	0
Visual impairment	Muco-cutaneo-ocular syndrome, visual impairment, optic neuritis, etc	0	2	3	10	14	3	8	4	12	15	35	26	22	19	25	13	4	11	10	11	14	9	27
Auditory vestibular disorders	Sensori-neural hearing loss, etc	0	0	5	2	2	1	5	4	3	2	1	0	1	1	0	3	2	1	1	1	0	0	0
Neurological disorder	Hypersthenia, etc	1	0	0	0	0	1	0	0	2	0	0	1	0	0	2	1	2	0	11	10	0	4	5
Gastrointestinal disorders	Acute hemorrhagic colitis, pseudomembranous colitis, etc	1	3	0	2	6	1	1	5	3	3	20	8	15	11	14	16	7	15	19	17	19	9	15
Hepatobiliary disorders	Drug hepatopathy, intrahepatic cholestasis, etc	1	4	5	3	6	18	10	4	21	29	23	20	7	23	35	20	16	44	62	66	67	80	67
Metabolic disorders	Diabetes, etc	0	0	0	0	0	0	0	0	3	0	0	0	2	0	2	1	0	0	2	0	6	0	0
Endocrine disorders	Adrenal insufficiency, etc	0	0	0	0	0	0	1	0	1	0	0	0	0	0	3	2	1	3	1	0	1	0	4
Cardiovascular disorders	Acute circulatory failure, etc	0	0	1	1	0	2	1	0	0	4	2	1	1	1	0	0	1	2	5	2	7	3	5
Myocardial, endocardiac, pericardial, and cardiovalvular	Myocardial ischemia, etc	0	0	0	0	0	1	1	0	0	1	0	0	0	0	0	0	0	0	1	2	3	3	0
Extracardiac vascular disorders	Cerebral infarction, vasculitis, etc	0	0	0	0	1	1	0	1	0	1	1	3	1	6	1	0	2	2	11	6	4	3	11
Respiratory disorders	Acute respiratory failure, acute respiratory obstruction, etc	1	0	0	1	7	5	6	1	10	4	8	5	6	7	8	8	11	9	20	15	11	16	16
Erythrocytic disorders	Hypoplastic anemia, etc	0	0	1	3	0	3	1	0	4	2	0	5	3	2	0	3	3	1	7	5	4	5	4
Leukocytic and reticuloendotherial disorders	Agranulocytosis, granulocytopenia, etc	0	0	0	1	6	2	3	3	4	5	10	8	9	2	6	3	4	12	9	12	10	15	19
Thrombocytic impairment and coagulopathy	Thrombocytopenia, etc	0	0	0	0	1	3	2	0	2	2	3	3	6	3	3	1	6	3	0	7	8	7	6
Urologic disorders	Renal failure, hemorrhagic cystitis, etc	0	0	1	0	3	4	1	0	3	4	8	3	2	3	4	8	1	3	17	13	9	7	8
Female genital disorders	Ovarian hyperstimulation syndrome, etc	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	2	5	0	2	1	4
General systemic disorders	Drug shock, anaphylactic shock, malignant high fever, etc	2	5	15	12	12	23	32	25	32	39	33	33	56	29	19	30	37	52	57	55	55	66	71
Application disorders	Contact dermatitis, etc	0	0	0	0	0	1	0	0	0	0	3	0	0	0	1	0	0	0	0	1	1	0	0
Dysfunction of defense system	Sepsis, bacterial infection, etc	0	0	0	0	2	5	2	3	2	6	3	3	4	2	0	5	0	1	5	2	2	2	0
Total		12	20	40	65	88	111	136	95	157	170	286	209	232	211	220	180	204	290	417	393	387	375	462

(Note) 1: The classification in different organs follows the glossary of adverse reactions by WHO's international monitoring system.
2. Because one person may have multiple adverse reactions, the number is not identical to the number of persons being paid.

Table 5 Transition in the number of pharmaceuticals causing adverse reactions by different categories of drug actions

Fiscal year / Causative drugs	1980	1981	1982	1983	1984	1985	1986	1987	1988	1989	1990	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	Total
Drugs for central nervous system	2	5	14	43	56	48	50	41	64	90	124	76	98	127	97	71	78	124	163	214	167	232	239	282	424	2,929
Drugs for peripheral nervous system	0	1	1	6	6	14	8	9	10	13	11	6	6	11	9	8	15	16	25	11	18	13	23	14	20	274
Drugs for sensory organs	0	1	0	0	0	0	0	0	0	2	0	0	5	6	2	0	1	6	3	5	10	2	3	0	9	55
Drugs for allergy	0	0	1	1	0	3	5	1	0	3	9	5	3	5	8	4	7	17	21	18	25	31	22	22	9	220
Drugs for circulatory organs	2	0	2	12	2	5	6	3	8	17	10	12	12	18	14	11	7	17	19	40	38	45	41	50	74	465
Drugs for respiratory organs	0	0	2	1	3	6	1	2	8	6	12	2	8	3	7	1	3	6	5	8	24	17	21	27	33	206
Drugs for digestive organs	1	0	2	0	0	3	0	2	2	2	5	4	1	18	14	11	4	22	20	26	25	37	45	45	69	358
Hormone agents	0	0	1	7	2	7	15	5	14	10	55	14	21	21	23	15	21	51	59	50	44	34	44	70	80	663
Drugs for urogenital organs and anus	0	0	1	0	1	1	2	1	1	2	0	2	7	0	0	1	1	1	3	4	3	3	5	4	2	45
Dermatological agents	0	0	0	0	0	0	0	0	3	0	2	1	0	10	3	0	0	2	1	1	0	6	4	2	3	38
Other drugs for individual organs	0	0	0	0	2	0	0	1	0	1	0	0	0	0	0	0	0	0	0	3	0	0	0	0	2	9
Vitamins	0	0	0	1	0	6	4	8	3	6	2	1	4	3	1	4	1	1	6	5	3	4	4	3	3	73
Drugs for blood and body fluids	0	0	3	0	0	4	3	4	2	4	1	3	5	5	3	2	1	10	15	14	10	14	13	31	30	177
Other metabolic drugs	0	3	3	4	3	7	10	3	14	13	15	3	8	7	8	14	9	19	42	29	23	35	47	47	72	438
Crude (Herbal) drugs	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	16	0	0	11	25	0	52
Preparations of Chinese medicine	0	0	0	0	0	0	0	0	0	0	2	0	1	1	1	9	3	2	17	4	6	7	16	10	15	94
Antibiotics	1	6	13	27	24	33	41	28	43	60	69	44	87	57	61	62	42	64	102	74	101	100	94	147	155	1,535
Chemotherapy agents	2	3	2	4	7	6	3	0	10	5	15	14	13	24	17	14	19	25	16	26	30	36	43	61	70	465
Biological preparations	0	0	1	1	1	0	1	1	1	2	23	34	36	12	23	20	35	39	34	23	36	18	20	21	24	406
Drugs for parasites	0	0	0	0	1	0	0	0	0	1	0	1	0	0	0	0	0	0	0	0	0	1	0	0	1	5
In Vivo Diagnostic drugs	1	4	6	2	4	0	10	7	7	6	10	12	8	6	4	6	8	11	16	15	16	24	26	35	28	272
Non-alkaloid narcotics	0	0	0	0	0	0	0	1	0	0	0	1	1	0	0	1	0	1	0	0	0	0	0	0	0	5
Dental drugs	0	0	0	0	0	0	0	0	0	2	1	1	1	0	0	0	0	2	0	0	0	1	0	1	0	9
Nutrient tonics	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	2	0	1	1	0	1	0	0	0	0	6
Drugs for tumors	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	0	2	0	2	2	3	0	10
Radiopharmaceuticals	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1
Other drugs not aimed at treatment	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1	1
Total	9	23	52	109	112	143	159	117	190	245	366	238	325	334	295	256	255	437	568	588	580	662	723	900	1,125	8,811

(Note) Because there are some persons with adverse reactions caused by multiple drugs, the number of causative drugs is not identical to the actual number of persons with benefits.

Table 6: Adverse Drug Reaction Funds from Manufacturers

(at the end of each Fiscal year)

Fiscal year	Pharmaceutical manufacturers and importers		Manufacturers/Importers of pharmacy compounding drugs		Total amounts	Fund rate
	Number of payers	Fund amounts	Number of payers	Fund amounts		
	Companies	M yen	Companies	M yen	M yen	
1979	1,231	74	18,070	18	92	0.02/1,000
1980	1,225	3,745	18,183	18	3,763	1.00/1,000
1981	1,250 (8)	1,275 (3)	18,267	19	1,294	0.3/1,000
1982	1,176 (15)	466 (11)	18,359	19	485	0.1/1,000
1983	1,158 (32)	563 (53)	18,302	19	582	0.1/1,000
1984	1,162 (57)	573 (52)	18,546	19	592	0.1/1,000
1985	1,166 (47)	580 (59)	18,459	19	599	0.1/1,000
1986	1,158 (57)	631 (79)	18,591	19	650	0.1/1,000
1987	1,152 (60)	726 (101)	18,528	19	745	0.1/1,000
1988	1,135 (60)	225 (94)	18,438	19	244	0.02/1,000
1989	1,138 (72)	269 (124)	18,090	18	287	0.02/1,000
1990	1,131 (71)	291 (144)	17,671	18	309	0.02/1,000
1991	1,137 (82)	531 (133)	17,488	18	549	0.05/1,000
1992	1,105 (71)	571 (157)	17,443	18	589	0.05/1,000
1993	1,074 (84)	563 (166)	17,050	17	580	0.05/1,000
1994	1,067 (87)	557 (147)	16,746	17	574	0.05/1,000
1995	1,033 (81)	556 (134)	16,505	17	573	0.05/1,000
1996	1,004 (85)	587 (164)	16,006	16	603	0.05/1,000
1997	963 (85)	581 (168)	13,847	14	595	0.05/1,000
1998	953 (102)	975 (214)	13,455	13	988	0.1/1,000
1999	947 (106)	1,002 (268)	12,988	13	1,015	0.1/1,000
2000	924 (113)	907 (166)	12,193 (1)	12 (0)	919	0.1/1,000
2001	894 (106)	953 (237)	11,794	12	965	0.1/1,000
2002	851 (112)	1,094 (328)	11,436	11	1,105	0.1/1,000
2003	842 (113)	2,596 (292)	11,095	11	2,607	0.3／1,000
2004	834 (115)	2,844 (423)	10,550	11	2,855	0.3／1,000

(Note) 1. The numbers in the parentheses indicate the number of companies with the additional contribution (because their products were causative ones) and the amounts paid by them. The numbers are included in the left side figures.

2. Because the figures of fund amounts and total amounts are rounded to the nearest one million respectively, the sum of the fund amounts is not always identical to the total fund amount.

Table 7: Number of Consultations for Relief Benefits

Fiscal Year	Breakdown										Total of consultations for relief benefits
	On relief benefits	(Breakdown of consultations)						Enquiry on service	Others	Consultations for infectious disease relief benefits	
		Selves	Families	Acquaintances (including lawyers)	Medical professionals	Administration officials	Pharmaceutical companies				
1980	Cases 94	Cases 39	Cases 29	Cases 3	Cases 13	Cases 7	Cases 3	Cases 4	Cases 13	Cases —	Cases 111
1981	139	48	43	6	30	5	7	57	22	—	218
1982	157	51	50	8	35	8	5	158	61	—	376
1983	324	126	82	12	53	26	25	193	100	—	617
1984	414	154	108	23	87	20	22	182	147	—	743
1985	356	121	91	17	96	13	18	126	128	—	610
1986	293	95	47	16	87	12	36	152	140	—	585
1987	358	123	73	23	113	5	21	344	219	—	921
1988	453	167	118	28	104	11	25	1,134	345	—	1,932
1989	333	88	74	22	117	12	20	423	295	—	1,051
1990	488	142	135	22	155	10	24	446	480	—	1,414
1991	440	129	100	26	148	14	23	463	273	—	1,176
1992	372	112	88	32	107	18	15	229	255	—	856
1993	435	161	106	26	115	9	18	287	482	—	1,204
1994	363	106	94	29	109	3	22	407	305	—	1,075
1995	398	117	104	34	113	8	22	545	510	—	1,453
1996	665	320	175	20	130	6	14	1,115	855	—	2,635
1997	534	156	130	25	177	5	41	466	964	—	1,964
1998	979	406	149	58	303	12	51	408	225	—	1,612
1999	853	308	178	20	287	11	49	397	204	—	1,454
2000	991	340	213	45	321	11	61	450	195	—	1,636
2001	1,043	314	279	44	335	11	60	281	89	—	1,413
2002	1,345	391	357	31	442	15	109	369	23	—	1,737
2003	1,559	558	460	39	426	8	68	3,326	453	—	5,338
2004	1,571	488	459	41	502	13	68	1,466	745	129 (38)	3,911 (38)
Total	14,957	5,060	3,742	650	4,405	273	827	13,428	7,528	129 (38)	36,042 (38)

(Note) The numbers in the parentheses are the number of consultations directly made to other offices.

Table 8: Biological Product-derived Infectious Disease Relief Service

Number of relief benefit cases for infectious disease

Classification / Fiscal year	Number of claims	Number of withdrawal	Number of payments	Number of non-payments
2004	5 (4)	0 (0)	2 (1)	0 (0)

(Note) The number of cases indicates the number of all the claims reported to PMDA. The number includes even multiple claims done by the same claimants for the same reason. The number in the parentheses indicates the number of all the claimants. The number excludes their reclaims done for the same reason.

Number of claim cases and payment amounts by types of infectious disease relief benefits

Classification / Fiscal year	Medical expenses				Medical allowances				Disability pensions				Pension for raising handicapped children			
	Number of claims	Number of payments	Number of non-payments	Benefit amounts	Number of claims	Number of payments	Number of non-payments	Benefit amounts	Number of claims	Number of payments	Number of non-payments	Benefit amounts	Number of claims	Number of payments	Number of non-payments	Benefit amounts
	Cases	Cases	Cases	Thousand yen	Cases	Cases	Cases	Thousand yen	Cases	Cases	Cases	Thousand yen	Cases	Cases	Cases	Thousand yen
2004	5	2	0	161	5	2	0	142	0	0	0	0	0	0	0	0

Classification / Fiscal year	Lump sum benefits for bereaved family				Funeral expenses				Total			
	Number of claims	Number of payments	Number of non-payments	Benefit amounts	Number of claims	Number of payments	Number of non-payments	Benefit amounts	Number of claims	Number of payments	Number of non-payments	Benefit amounts
	Cases	Cases	Cases	Thousand yen	Cases	Cases	Cases	Thousand yen	Cases	Cases	Cases	Thousand yen
2004	1	0	0	0	1	0	0	0	12	4	0	302

(Note) 1. The number of claims in this table indicates one case per one relief benefit, but is not identical to the number of relief benefit cases for infectious disease above.
2. The figures of the benefit amounts is rounded to the nearest thousand, and is not always identical to the total amount.

Adverse Health Effect Cases by Type of Infectious Diseases

Fiscal year / Name of infections	2004	Total
Adverse health effect due to virus infection	2	2

Number of Biological Product Caused Infectious Disease

Fiscal year / Type of products	2004	Total
Blood preparations for transfusion	2	2

Infectious Disease Relief Funds from Manufacturers

Fiscal Year	Pharmaceutical manufacturers and importers)		Total amounts	Fund ratio
	Number of payers	Amounts		
	Companies	M yen	M yen	
2004	108	554	554	1/1,000

Table 9: Payment of Healthcare Allowances and Nursing Expenses

(Unit: thousand yen)

Fiscal year	Pharmaceutical companies			Treasury	Total	Number of Beneficiaries at the end of fiscal year
	Healthcare allowances	Nursing expenses	Subtotal	Nursing expenses		
1979-1999	38,297,473	10,943,645	49,241,118	3,844,647	53,085,765	
2000	1,599,072	389,414	1,988,486	159,936	2,148,422	3,062
2001	1,541,965	378,809	1,920,774	153,439	2,074,213	2,941
2002	1,475,029	366,010	1,841,039	143,957	1,984,996	2,816
2003	1,417,469	349,933	1,767,402	134,427	1,901,829	2,713
2004	1,359,056	342,357	1,701,413	127,920	1,829,332	2,598
Total	45,690,064	12,770,168	58,460,231	4,564,326	63,024,557	

Note: The amounts are rounded off and the sum of them is not always identical to the total amounts.

Relief Service for HIV-positive and AIDS Patients

Table 10: Number of Claim Cases and Payment Amounts related to Research and Study Projects

Fiscal year	Number of claims (cases)	Number of approvals (cases)	Number of non-approvals (cases)	Payment amounts (thousand yen)
1993	462	456	6	158,829
1994	99	530 (433)	2	188,434
1995	81	554 (477)	4	251,402
1996	105	605 (503)	2	283,258
1997	113	667 (553)	0	326,823
1998	23	668 (646)	0	344,883
1999	28	680 (652)	1	354,132
2000	10	680 (673)	0	355,974
2001	8	667 (656)	0	357,333
2002	12	673 (661)	0	360,489
2003	6	662 (656)	0	355,343
2004	5	647 (644)	0	348,446
Total	952	7,489 (6,554)	15	3,685,347

(Note) 1. The number in the parenthesis is the number of persons with ongoing approval and is included in the number of approvals.
2. The payment amount is rounded to the nearest 1000 yen.

Relief Service for HIV-positive and AIDS Patients

Table 11 Number of Claim Cases and Payment Amounts related to Healthcare Support Service

Fiscal year	Number of claims (cases)	Number of approvals (cases)	Number of non-approvals (cases)	Payment amounts (thousand yen)
1996	131 (113)	126 (112)	0	169,500
1997	27 (15)	26 (16)	2	219,150
1998	15 (3)	16 (3)	1	215,550
1999	6 (1)	4 (1)	0	225,600
2000	12 (2)	12 (2)	0	226,950
2001	4 (0)	2 (0)	1	225,000
2002	3 (0)	4 (0)	1	221,400
2003	4 (0)	3 (0)	0	212,400
2004	7 (0)	6 (0)	0	210,600
Total	209 (134)	199 (134)	5	1,926,150

(Note) 1. The number in the parenthesis is the number of beneficiaries of the special allowance and is included in the number of claims or payments.

2. The allowance is rounded to the nearest thousand yen.

Table 12: Number of Claims and Benefit Amounts by Types in Relief Services for HIV-positive and AIDS Patients

	Fiscal year	Number of claims	Number of payments	Number of non-payments	Benefit amounts
Medical allowance	1988-1999	247 cases	236 cases	6 cases	25,353 Thousand yen
	2000	2	1	0	145
	2001	0	0	0	0
	2002	0	0	0	0
	2003	0	0	0	0
	2004	0	0	0	0
	Subtotal	249	237	6	25,498
Special allowance	1988-1999	433	364	51	1,639,616
	2000	2	0	0	8,529
	2001	0	0	0	6,397
	2002	0	0	0	6,397
	2003	0	0	0	6,339
	2004	0	0	0	6,319
	Subtotal	435	364	51	1,673,596
Ex gratia for bereaved family	1988-1999	106	101	2	1,208,190
	2000	0	0	0	84,345
	2001	0	0	0	2,416
	2002	0	0	0	2,416
	2003	0	0	0	2,394
	2004	0	0	0	2,387
	Subtotal	106	101	2	1,302,146
Lump-sum benefit for bereaved family	1988-1999	241	237	4	1,562,120
	2000	0	0	0	0
	2001	0	0	0	0
	2002	0	0	0	0
	2003	0	0	0	0
	2004	0	0	0	0
	Subtotal	241	237	4	1,562,120
Funeral expenses	1988-1999	357	349	6	48,479
	2000	0	0	0	0
	2001	0	0	0	0
	2002	0	0	0	0
	2003	0	0	0	0
	2004	0	0	0	0
	Subtotal	357	349	6	48,479
Total	1988-1999	1,384	1,287	69	4,483,757
	2000	4	1	0	93,019
	2001	0	0	0	8,812
	2002	0	0	0	8,812
	2003	0	0	0	8,733
	2004	0	0	0	8,706
	Total	1,388	1,288	69	4,611,840

(Note) 1. The number of claims is expressed as one case per one relief benefit.
2. The benefit amounts are rounded to the nearest thousand yen, and they are not always identical to the subtotal and total.

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Table 13: Number of Consultation Cases for Relief Services

Service / Fiscal year	Research and Study Projects	Healthcare Support Service	Payment Services for Relief	Total
1989.1-1996	889 cases	53 cases	1,601 cases	2,543 cases
1997	236	46	27	309
1998	201	48	24	273
1999	213	40	29	282
2000	178	37	24	239
2001	225	52	4	281
2002	235	45	2	282
2003	170	44	2	216
2004	255	46	5	306
Total	2,602	411	1,718	4,731

Table 14: Number of Applications and Approvals for Drugs (FY1997-FY2004)

(1) Review Operations of Drugs and Others (Unit: cases)

Classification			Number of applications								Number of approvals							
		Fiscal year	1997	1998	1999	2000	2001	2002	2003	2004	1997	1998	1999	2000	2001	2002	2003	2004
Drugs and Others	New drugs	New	86	85	155	129	135	119	99	92	85	142	181	122	166	98	84	57
		Supplemental change	72	83	142	183	256	108	200	272	68	105	92	142	207	148	140	209
		Total	158	168	297	312	391	227	299	364	153	247	273	264	373	246	224	266
	Ethical drugs	New	522	436	472	492	817	554	483	1,057	748	482	434	448	694	492	506	727
		Supplemental change	966	636	1,531	2,917	2,373	1,282	2,583	1,935	757	707	1,093	2,051	2,465	1,339	1,737	2,749
		Total	1,488	1,072	2,003	3,409	3,190	1,836	3,066	2,992	1,505	1,189	1,527	2,499	3,159	1,831	2,243	3,476
	OTC drugs	New	806	770	926	1,124	901	950	1,075	1,365	530	769	801	838	990	970	803	817
		Supplemental change	248	288	300	3,327	2,906	429	1,850	590	191	304	333	487	3,875	1,986	1,131	964
		Total	1,054	1,058	1,226	4,451	3,807	1,379	2,925	1,955	721	1,073	1,134	1,325	4,865	2,956	1,934	1,781
	In vitro diagnostics	New	469	444	420	418	427	248	228	367	445	497	370	347	612	239	173	283
		Supplemental change	284	304	237	250	236	204	202	248	294	301	221	263	261	165	195	219
		Total	753	748	657	668	663	452	430	615	739	798	591	610	873	404	368	502
	Quasi drugs	New	2,154	2,333	2,909	2,721	2,747	2,532	2,396	2,511	2,282	1,991	2,595	2,969	2,352	2,594	2,342	2,372
		Supplemental change	274	292	342	2,293	1,736	513	689	557	286	299	253	389	2,908	1,011	650	600
		Total	2,428	2,625	3,251	5,014	4,483	3,045	3,085	3,068	2,568	2,290	2,848	3,358	5,260	3,605	2,992	2,972
	Cosmetics	New	740	605	510	277	0	0	0	0	678	590	434	521	0	0	0	0
		Supplemental change	147	263	235	141	0	0	0	0	209	190	244	243	0	0	0	0
		Total	887	868	745	418	0	0	0	0	887	780	678	764	0	0	0	0
	Total	New	4,777	4,673	5,392	5,161	5,027	4,403	4,281	5,392	4,768	4,471	4,815	5,245	4,814	4,393	3,908	4,256
		Supplemental change	1,991	1,866	2,787	9,111	7,507	2,536	5,524	3,602	1,805	1,906	2,236	3,575	9,716	4,649	3,853	4,741
		Total	6,768	6,539	8,179	14,272	12,534	6,939	9,805	8,994	6,573	6,377	7,051	8,820	14,530	9,042	7,761	8,997

* The number of applications received was based on data as of the end of March 2005. The number may change due to change of classification after receiving.

Table 15: Number of Applications and Approvals for Medical Devices (FY1997-FY2004)

(Unit: Cases)

Classification \ Fiscal year		Number of applications								Number of approvals							
		1997	1998	1999	2000	2001	2002	2003	2004	1997	1998	1999	2000	2001	2002	2003	2004
New medical devices	New	54	32	62	39	38	39	28	49	53	36	23	19	19	3	10	6
	Supplemental change	25	35	24	25	11	8	4	7	31	19	25	12	19	0	3	2
	Total	79	67	86	64	49	47	32	56	84	55	48	31	38	3	13	8
Improved medical devices	New	-	-	-	96	202	179	154	248	-	-	-	127	106	60	56	75
	Supplemental change	-	-	-	72	56	44	44	73	-	-	-	68	44	24	30	33
	Total	-	-	-	168	258	223	198	321	-	-	-	195	150	84	86	108
Improved medical devices (utilizing materials from humans and animals)	New	-	-	-	0	0	73	2	0	-	-	-	0	0	25	43	0
	Supplemental change	-	-	-	32	204	252	29	4	-	-	-	0	30	3	178	46
	Total	-	-	-	32	204	325	31	4	-	-	-	0	30	28	221	46
Generic medical devices	New	2,053	1,734	1,794	1,392	1,345	1,350	1,475	2,128	1,956	1,485	1,473	1,240	1,266	1,042	1,305	1,426
	Supplemental change	1,907	1,492	1,709	1,254	1,518	1,599	1,851	2,211	1,869	1,539	1,379	1,325	1,396	1,400	1,681	1,721
	Total	3,960	3,226	3,503	2,646	2,863	2,949	3,326	4,339	3,825	3,024	2,852	2,565	2,662	2,442	2,986	3,147
Total	New	2,107	1,766	1,856	1,527	1,585	1,641	1,659	2,425	2,009	1,521	1,496	1,386	1,391	1,130	1,414	1,507
	Supplemental change	1,932	1,527	1,733	1,383	1,789	1,903	1,928	2,295	1,900	1,558	1,404	1,405	1,489	1,427	1,892	1,802
	Total	4,039	3,293	3,589	2,910	3,374	3,544	3,587	4,720	3,909	3,079	2,900	2,791	2,880	2,557	3,306	3,309

* The number of cases received was based on data by the end of March 2005. The number may change due to classification change after receiving.

Table 16: Review Status for generic drugs, etc. in FY 2004

Classification	Number of applications	Withdrawal	Approved	In progress
Generic ethical drugs	(2,966) 5,958	12	3,476	2,470
OCT drugs	(2,622) 4,577	6	1,781	2,790
In vitro diagnostics	(319) 934	2	502	430
Quasi drugs	(1,865) 4,933	23	2,972	1,938
Generic medical devices	(2,127) 6,466	39	3,147	3,280

(Note 1) The number in the parenthesis shows the number of unprocessed cases, which was taken over from PMDEC, as of March 31, 2004, and is included in the number below.

(Note 2) The number of the withdrawals means withdrawals for applications submitted in FY 2004.

Table 17: Clinical Trial Consultation Achievements

Fiscal year	1999	2000	2001	2002	2003	2004
Number of clinical trial consultations completed	177	241	246	223	269	162
Procedural consultation	—	—	—	—	—	1
Consultation before phase I study	52	78	64	81	81	25
Consultation before phase II study	—	—	—	—	22	52
Consultation after completion of phase II study	53	70	50	42	42	21
Pre-application consultation	35	37	46	34	33	25
Consultation concerning protocol of clinical study for re-evaluation and re-examination	3	0	2	1	0	0
Consultation at the completion of clinical study for re-evaluation and re-examination	0	0	0	0	0	0
Consultation on quality	—	0	1	2	4	2
Consultation on safety	—	2	2	0	6	5
Additional consultation	34	54	81	63	81	31

The numbers of applications for clinical trial consultations received classified by therapeutic categories

Classification of drugs by efficacy	FY1999	FY2000	FY2001	FY2002	FY2003	FY2004
Drugs for central nervous system	20	23	20	26	17	32
Drugs for peripheral nervous system	1	7	8	4	4	4
Antipyretic analgesics	10	8	14	8	2	4
Drugs for sensory organs	9	14	19	18	6	14
Cardiovascular drugs	22	34	29	22	15	22
Drugs for respiratory organs	2	12	9	2	3	4
Drugs for digestive organs	8	8	14	7	10	23
Hormone agents	15	27	20	27	17	17
Drugs for urogenital system and anus	10	19	8	5	7	6
Dermatological agents	6	10	13	7	7	9
Drugs for metabolism	39	51	59	31	33	70
Drugs for tumors	16	25	33	18	17	31
Radiopharmaceuticals	3	4	1	0	2	1
Drugs for allergies	9	13	16	7	11	13
Antibiotics	7	12	1	3	5	5
Chemotherapy agents	3	18	12	10	7	8
Biological preparations	4	13	22	18	12	29
Diagnostic drugs	11	12	7	5	2	2
Others	7	7	7	7	9	12
Total	202	317	312	225	186	306

Examination of Prior Notification of Clinical Trial Plans

Classification \ Fiscal year	Number of notifications						Number of examined cases					
	1999	2000	2001	2002	2003	2004	1999	2000	2001	2002	2003	2004
Examination of Clinical Trial Plans	76	76	69	65	64	76	68	76	62	61	70	67

Examination of export certification

Classification \ Fiscal year	Number of applications						Number of completed cases					
	1999	2000	2001	2002	2003	2004	1999	2000	2001	2002	2003	2004
Examination of export certification	3,717	3,854	2,678	4,197	7,706	6,299	3,637	3,965	2,639	3,397	7,808	10,286

Conformity Document Audit on Review Materials of New Drug Approval

Classification \ Fiscal year	Number of applications (number of items)						Number of completed cases (number of items)					
	1999	2000	2001	2002	2003	2004	1999	2000	2001	2002	2003	2004
New drug 1 (other than orphan)	95	88	95	83	117	66	80	99	61	93	70	60
New drug 1 (orphan)	16	8	6	10	19	14	17	9	6	10	20	7
New drug 2 (subject of equivalence review)	17	32	34	13	24	10	17	23	34	12	14	7
New drug 2 (not subject of equivalence review, orphan)	0	0	2	0	4	2	1	0	0	0	0	2
New drug 2 (change) (subject of equivalence review)	18	18	14	19	38	79	22	16	17	16	11	63
New drug 2 (change) (not subject of equivalence review, orphan)	14	19	22	17	34	31	14	19	14	17	29	14
Ethical drugs (change) (not subject of equivalence review)	30	36	35	42	41	0	22	43	19	41	29	8
Total	190	201	208	184	277	202	173	209	151	189	173	161

Conformity Document Audit on Re-examination Materials/ GPMSP on-site review

Classification \ Fiscal year	Number of applications (number of items)						Number of completed cases (number of items)					
	1999	2000	2001	2002	2003	2004	1999	2000	2001	2002	2003	2004
Document Audit of Materials	173	163	133	78	94	118	92	220	123	132	85	34
GPMSP on-site review	173	163	107	65	75	101	92	220	116	102	66	27
Total	346	326	240	143	169	219	184	440	239	234	151	61

(Note) The number of cases of the completed GPMSP review in 2004 is the number of reported cases after evaluation.

Conformity document audit on generic drugs

Classification \ Fiscal year	Number of applications (number of items)						Number of completed cases (number of items)					
	1999	2000	2001	2002	2003	2004	1999	2000	2001	2002	2003	2004
New	302	389	437	477	401	553	410	401	388	454	402	516
Supplementary change	683	683	784	881	835	646	648	624	741	774	1,023	574
Total	985	1,072	1,221	1,358	1,236	1,199	1,058	1,025	1,129	1,228	1,425	1,090

Conformity document audit on re-evaluation materials

Classification \ Fiscal year	Number of applications (number of items)						Number of completed cases (number of items)					
	1999	2000	2001	2002	2003	2004	1999	2000	2001	2002	2003	2004
Re-evaluation of pharmaceuticals	—	2	–	35	2	0	–	2	–	0	24	0
Re-evaluation of orally administered ethical drugs	145	138	259	320	216	76	145	138	258	234	240	76

GLP review

Classification \ Fiscal year	Number of applications (number of items)						Number of completed cases (number of items)					
	1999	2000	2001	2002	2003	2004	1999	2000	2001	2002	2003	2004
GLP review	26	18	37	39	13	30	37	23	24	40	24	20

GCP review of new pharmaceuticals

Classification \ Fiscal year	Number of applications (number of items)						Number of completed cases (number of items)					
	1999	2000	2001	2002	2003	2004	1999	2000	2001	2002	2003	2004
GCP review of new pharmaceuticals	132	128	127	103	135	116	163	112	103	101	132	68

(Note) The number of completed cases in 2004 is the number of reported cases after evaluation.

GCP on-site review of generic drugs

Classification \ Fiscal year	Number of applications (number of items)						Number of completed cases (number of items)					
	1999	2000	2001	2002	2003	2004	1999	2000	2001	2002	2003	2004
GCP on-site review	9	15	17	18	10	5	9	15	17	17	11	5

Table 18 A list of approved items in 2004 (new drugs)

Category	Date of approval	Brand name (name of company)	Approval/ Supplemental Change	Names of ingredients (Underlined: New active ingredients)	Note
1	April 24, 2004	1 Sandostatin LAR for intramuscular injection 10mg Sandostatin LAR for intramuscular injection 20mg Sandostatin LAR for intramuscular injection 30mg (Nihon Chiba-Geigy K.K.)	Approval Approval Approval	Octreotide Acetate	New form drug with a new administration route administered once every four weeks and which has the following indications: alleviation of various symptoms associated with gastrointestinal hormone-producing tumors and alleviation of excessive secretions of growth hormone and somatomedin-C and other various symptoms in acromegaly and pituitary gigantism
1	July 9, 2004	2 Zione Injection / Lidocaine Zione Injection (Mitsubishi Pharmaceutical Co., Ltd.)	Approval Approval	Aluminum potassium sulfate, tannic acid	A new compound agent for local injection with indications for internal hemorrhoids associated with prolapse and is used for internal hemorrhoid sclerotherapy.
1	October 22, 2004	3 Hepsera Tablet 10 (Glaxo SmithKline K.K.)	Approval	Adefovir pivoxil	A nucleotide analogue of adenosine monophosphate which selectively inhibits HBV DNA polymerase, a new drug containing a new active ingredient with indications for improving hepatic function and levels of viral markers through combined use with lamivudine in chronic hepatitis B and hepatitis B cirrhosis in which abnormality of hepatic function with persistent regrowth of hepatitis B viruses has been confirmed during administration of lamivudine. <Priority assessment>
		Zefix Tablets 100 (Glaxo SmithKline K.K.)	Supplemental Change	Lamivudine	Addition to indications for improving the levels of viral markers and hepatic function in chronic hepatitis B and hepatitis B cirrhosis in which an abnormality of the hepatic function with persistent regrowth of type B hepatitis viruses has been confirmed during administration of this drug combined with adefovir pivoxil. <Priority assessment>

1	October 22, 2004	4 Intron A for injection 300 Intron A for injection 600 Intron A for injection 1000 (Schering Plough K.K.)	Supplemental Change Supplemental Change Supplemental Change	Interferon alfa-2b (Genetical Recombination)	When this drug is combined with ribavirin, the directions and dosage of ribavirin must be changed. <Priority assessment>
		Rebetol capsule 200mg (Schering Plough K.K.)	Supplemental Change	Ribavirin	Addition to indications of combined use with Peginterferon alfa-2b (Genetical recombination) to alleviate viremia in patients with chronic hepatitis C with high blood HCV RNA in serogroup 1. <Priority assessment>
		PegIntron Sterile Powder for Injection 50μg/0.5mL PegIntron Sterile Powder for Injection 100μg/0.5mL PegIntron Sterile Powder for Injection 150μg/0.5mL (Schering Plough K.K.)	Approval Approval Approval	Peginterferon alfa-2b (Genetical recombination)	A drug containing a new active ingredient which enables weekly administration through chemical modification of interferon alfa-2b by polyethylene glycol (PEG) to prolong the drug elimination time in blood and has indications combined with ribavirin to alleviate viremia in patients with chronic hepatitis C with high blood HCV RNA levels for serogroup 1. <Priority assessment>
2	June 22, 2004	5 Flolan for injection 0.5mg Flolan for injection 1.5mg (Glaxo SmithKline K.K.)	Supplemental Change Supplemental Change	Epoprostenol sodium	Addition to indications of pulmonary hypertension associated with specific diseases and a change of the description from "primary pulmonary hypertension" to "pulmonary arterial hypertension" <Orphan drug>
2	October 22, 2004	6 Fenofibrate fine powder Lipidil capsule 67 Lipidil capsule 100 (Grelan Pharmaceutical. Co., Ltd.) Tricor capsule 67mg Tricor capsule 100mg (Taisho Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval Approval	Fenofibrate	Pulverization enables a reduction in the dosage to two thirds of the current dosage for hyperlipidemia (including familial hyperlipidemia).
2	January 19, 2005	7 Crestor 2.5mg Crestor 5mg Crestor 10mg (AstraZeneca K.K.)	Approval Approval Approval	Rosuvastatin calcium	A drug containing a new active ingredient with indications for HMG-CoA reductase inhibition for hypercholestelemia and familial hypercholestelemia.
3	October	8		Tiotropium	A drug containing a new active

	22, 2004	Tiotropium Bromide Hydrate Spiriva Inhalation Capsules 18μg (Nippon Boehringer Ingelheim Co., Ltd.)	Approval Approval	Bromide Hydrate	ingredient with indications for anticholinergic bronchodilation to alleviate various symptoms due to airway obstructive impairment in chronic obstructive pulmonary diseases (chronic bronchitis and emphysema).
3	October 22, 2004	9 P Guard Tablets 20mg P Guard Tablets 30mg P Guard Tablets 60mg P Guard Tablets 120mg (Tanabe Seiyaku Co., Ltd.)	 Approval Approval Approval Approval	Morphine sulfate	A new formulation of opioid drug for daily administration with indications as analgesia for moderate to severe pain in various cancers.
3	October 22, 2004	10 Morphine hydrochloride 10mg Morphine hydrochloride 50mg (Takeda Pharmaceutical Co., Ltd.) Morphine hydrochloride (Sankyo Co., Ltd.) Morphine hydrochloride 10mg Morphine hydrochloride 50mg (Shionogi & Co., Ltd.) Anpec (Dainippon Pharmaceutical. Co., Ltd.) Morphine hydrochloride 10mg Morphine hydrochloride 50mg (Tanabe Seiyaku Co., Ltd.)	 Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change	Morphine hydrochloride	Addition of new routes of administration (epidural and intrathecal administration), besides previous subcutaneous or intravenous administration.
3	January 19, 2005	11 Enbrel 25mg for S.C. Injection (Wyeth K.K..)	Approval	Etanercept (genetic recombination)	A drug containing a new active ingredient, humanized fusion protein having an inhibitory action on the binding of the tumor necrosis factor (TNF) to a TNF

					receptor that has indications for rheumatoid arthritis
3	January 19, 2005	12 Qval 50 Qval 100 (Dainippon Pharmaceutical. Co., Ltd.)	Supplemental Change Supplemental Change	Beclometasone dipropionate	Addition of a pediatric dosage for bronchial asthma
3	January 19, 2005	13 Alesion Dry Syrup 1% (Nippon Boehringe Ingerheim Co., Ltd.)	Approval	Epinastine hydrochloride	A pediatric preparation with indications for allergic rhinitis, urticaria, skin diseases (eczema, dermatitis, skin pruritus)
3	March 4, 2005	14 Epipen injection 0.15mg Epipen injection 0.3mg (Merck Ltd.)	Approval Supplemental Change	Epinephrine	Addition of its pediatric application and indications for adjunctive therapy for anaphylactic reaction induced by food, drug and others.
Anti-infective	April 23, 2004	15 Meropen for intravenous drip infusion 0.25g Meropen for intravenous drip infusion 0.5g (Sumitomo Pharmaceutical. Co., Ltd.)	Supplemental Change Supplemental Change	Meropenem trihydrate	A carbapenem antibacterial agent. Addition of indications for purulent meningitis and dosage for pediatric patients.
Anti-infective	May 21, 2004	16 Zithromac Tablets 250mg (Pfizer Japan Inc.)	Supplemental Change	Azithromycin hydrate	Addition of indications for Chlamydia trachomatis, urethritis and uterine cervicitis and to dosage regimen.
Anti-infective	June 22, 2004	17 Rocephin 0.5g Rocephin 1g Rocephin 1g Bag (Chugai Pharmaceutical. Co., Ltd.)	Supplemental Change Supplemental Change Supplemental Change	Ceftriaxone Sodium	Addition of indications for gonococcus and gonococcal pharyngitis, gonococcal urethritis, gonococcal uterine cervicitis, gonococcal pelvic inflammatory diseases, gonococcal epididymitis, gonococcal proctitis, and to dosage regimen.
Anti-infective	July 9, 2004	18 Gatiflo 0.3% ophthalmic solution (Senju Pharmaceutical. Co., Ltd.)	Approval	Gatifloxacin hydrate	New quinolone antibacterial agent. An ophthalmic solution with indications for blepharitis, hordeolum, dacryocystitis, conjunctivitis, tarsadenitis, keratitis, aseptic therapy for ophthalmologic perioperative period.
Anti-infective	July 9, 2004	19 Tamiflu capsule 75 (Chugai Pharmaceutical. Co., Ltd.)	Supplemental Change	Oseltamivir Phosphate	Addition of indications to prevent influenza A or B viral infections and dosage regimen.
Anti-infective	September 16, 2004	20 Maxipime for	Supplemental	Cefepime dihydrochloride	Addition of indications on febrile neutropenia

		injection 0.5g Maxipime for injection 1g (Bristol Myers K.K.)	Change Supplemental Change		
Anti-infective	October 22, 2004	21 Vancomycin for I.V.Infusion (Eli Lilly Japan K.K.)	Supplemental Change	Vancomycin hydrochloride	Additions of indications for sepsis, pneumonia, and purulent meningitis caused by penicillin-resistant-Streptococcus. <orphan drug>
Anti-infective	February 22, 2005	22 Pasil 300mg Pasil 500mg (Toyama Chemical Co., Ltd.) Pazucross injection 300 Pazucross injection 500 (Mitsubishi Pharmaceutical. Co., Ltd.)	 Supplemental Change Supplemental Change Supplemental Change Supplemental Change	Pazufloxacin mesilate	Addition of indications for legionella infection.
5	April 23, 2004	23 Levitra 5mg Levitra 10mg (Bayer Yakuhin, Ltd.)	 Approval Approval	Vardenafil hydrochloride	A drugs containing a new active ingredient with indications for phosphodiesterase-5 inhibitor in erectile dysfunction
Radioacitve	April 23, 2004	24 Benzodine Injectable (Nihon Medi-Physics Co., Ltd.)	 Approval	Iomazenil (^{123}I)	A drug containing a new active ingredient with indications for detection of epileptic focus in epilepsy by the central benzodiazepine-receptor scintigraphy.
In vivo diagnostic	October 22, 2004	25 Pralmorelin hydrochloride GHRP Kaken 100 (Kaken Pharmaceutical Co., Ltd.)	 Approval Approval	Pralmorelin hydrochloride	A diagnostic agent used for examination of secretory functions of growth hormones.
Oncology drug	May 31, 2004	26 Bleo (Nippon Kayaku Co., Ltd.)	 Supplemental Change	Bleomycin hydrochloride	Addition of indications for germ cell tumors and dosage regimen
		Lastet Inj. (Nippon Kayaku Co., Ltd) VePesid Injection (Bristol Pharmaceuticals Y.K.)	Supplemental Change	Etoposide	

		Randa Inj. (Nippon Kayaku Co., Ltd) Briplatin injection (Bristol Pharmaceuticals Y.K.) Platosin Injection 10 Platosin Injection 25 Platosin Injection 50 (Pfizer Japan Inc.) CISPLATIN inj. (Maruko Pharmaceutical. Co., Ltd.) Cisplamerck (Merck Hoei Ltd.)	Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change	Cisplatin	
Oncology drug	October 22, 2004	27 Zometa (Nihon Ciba-Geigy K.K.)	Approval	Zoledronic Acid Hydrate	A drug containing a new active ingredient which has a bone-absorption-inhibitory action and has indications for hypercalcemia caused by malignant tumors.
Oncology drug	October 22, 2004	28 Sandostatin 50μg Sandostatin 100μg (Nihon Ciba-Geigy K.K.)	Supplemental Change Supplemental Change	Octreotide Acetate	Addition of indications to alleviate digestive symptoms associated with digestive obstruction in patients with advanced or recurrent cancer.
Oncology drug	October 22, 2004	29 Anhydrous ethanol (Fuso) (Fuso Pharmaceutical Industries, Ltd.) Anhydrous ethanol (Shimizu) (Shimizu Pharmaceutical Co., Ltd.) Anhydrous ethanol (Merck) (Merck Hoei Ltd)	Approval Approval Approval	Anhydrous ethanol	A drug with a new administration route with indications for percutaneous ethanol injection therapy in hepatocellular carcinoma.
Oncology drug	October 22, 2004	30 Trisenox Injection 10mg (Nippon Shinyaku Co., Ltd.)	Approval	Arsenic Trioxide	A drug with a new administration route with indications for relapsed or refractory acute promyelocytic leukemia. <Priority review>
Oncology drug	December 14, 2004	31 TS-1 capsule 20	Supplemental	Tegafur, Gimeracil,	An addition to indications of non-small cell lung cancer to

		TS-1 capsule 25 (Taiho Pharmaceutical Co., Ltd.)	Change Supplemental Change	Oteracil potassium	current indications of gastric cancer, rectal and colonic cancers and head and neck cancers.
Oncology drug	December 14, 2004	32 Ifomide 1g (Shionogi & Co., Ltd.)	Supplemental Change	Ifosfamide	Addition to indications of relapsed or refractory germ cell tumors (testicular tumor, ovarian tumor, extragonadal tumors) and to dosage regimen.
		Exal for Inj. 10mg (Nihon Kayaku Co., Ltd.)	Supplemental Change	Vinblastine sulfate	
Oncology drug	January 19, 2005	33 Aredia 15mg Aredia 30mg (Nihon Ciba-Geigy K.K.)	Supplemental Change Supplemental Change	Pamidronate Disodium	Addition to indications of combined use with chemotherapy, endocrine therapy, or radiotherapy for osteolytic bone metastases of breast cancer. <Combined therapy with anticancer agents>
Oncology drug	February 14, 2005	34 Adriacin injection (Kyowa Hakko Kogyo Co., Ltd.)	Supplemental Change	Doxorubicin hydrochloride	Addition to indications of combined therapy with other anticancer agents in pre- or postoperative chemotherapy for operable cases of breast cancer and to dosage regimen.
Oncology drug	February 14, 2005	35 Adriacin injection (Kyowa Hakko Kogyo Co.,Ltd.)	Supplemental Change	Doxorubicin hydrochloride	Addition to indications of combined therapy with other anticancer agents in postoperative chemotherapy or chemotherapy for metastasis or recurrence of endometrial cancer <Combined therapy with anti-cancer agents>
		Randa Inj. (Nippon Kayaku Co., Ltd) Briplatin injection (Bristol Pharmaceuticals Y.K.) Platosin Injection 10 Platosin Injection 25 Platosin Injection 50 (Pfizer Japan Inc.) CISPLATIN inj. (Maruko Pharmaceutical. Co., Ltd.) Cisplamerck (Merck Hoei Ltd.)	Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change	Cisplatin	
Oncology drug	February 14, 2005	36 Adriacin injection (Kyowa Hakko Kogyo Co.,Ltd.)	Supplemental Change	Doxorubicin hydrochloride	Addition to indications of combined therapy with other anticancer agents for malignant bone tumors and to dosage regimen.

		Randa Inj. (Nippon Kayaku Co., Ltd) Briplatin injection (Bristol Pharmaceuticals Y.K.) Platosin Injection 10 Platosin Injection 25 Platosin Injection 50 (Pfizer Japan Inc.) CISPLATIN inj. (Maruko Pharmaceutical. Co., Ltd.) Cisplamerck (Merck Hoei Ltd.)	Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change Supplemental Change	Cisplatin	<Combined therapy with anticancer agents>
Oncology drug	February 14, 2005	37 Ifomide 1g (Shionogi & Co., Ltd.)	Supplemental Change	Ifosfamide	Addition to indications of combined therapy with other anticancer agents for malignant bone and soft tissue tumors and to dosage regimen. <Combined therapy with anticancer agents>
		Adriacin injection (Kyowa Hakko Kogyo Co.,Ltd.)	Supplemental Change	Doxorubicin hydrochloride	
		Uromitexan 100mg Uromitexan 400mg (Shionogi & Co., Ltd.)	Supplemental Change Supplemental Change	Mesna	In line with the addition to the indications of ifosfamide for malignant bone and soft tissue tumors, an addition to dosage for inhibiting the development of urological impairment associated with administration of said ifosfamide. <Combined therapy with anticancer agents>
Oncology drug	February 14, 2005	38 Ifomide 1g (Shionogi & Co., Ltd.)	Supplemental Change	Ifosfamide	Addition to indications of combined therapy with other anticancer agents on pediatric malignant solid tumors and to dosage regimen. <Combined therapy with anticancer agents>
		Adriacin injection (Kyowa Hakko Kogyo Co.,Ltd.)	Supplemental Change	Doxorubicin hydrochloride	
		VePesid Injection (Bristol Pharmaceuticals Y.K.) Lastet Inj. (Nippon Kayaku Co., Ltd)	Supplemental Change Supplemental Change	Etoposide	

		Uromitexan 100mg Uromitexan 400mg (Shionogi & Co., Ltd.)	Supplemental Change Supplemental Change	Mesna	In line with the addition to the indications of ifofamide for pediatric malignant solid tumors, an addition to dosage for inhibiting the development of urological impairment associated with the administration of said ifosfamide. <Combined therapy with anticancer agents>
Oncology drug	February 14, 2005	39 5-FU injection 250 Kyowa (Kyowa Hakko Kogyo Co., Ltd.)	Supplemental Change	5-Fluorouracil	Addition to indications of combined therapy with anticancer agents for colonic and rectal cancers and to dosage regimen. <Combined therapy with anticancer agents>
		Isovolin injection 25mg (Wyeth K.K.)	Supplemental Change	Levofolinate Calcium	
Oncology drug	February 14, 2005	40 Oncovin for Inj. 1mg (Nihon Kayaku Co., Ltd.)	Supplemental Change	Vincristine Sulfate	Addition to indications of combined therapy with anticancer agents for multiple myeloma and to dosage regimen. <Combined therapy with anticancer agents>
		Adriacin injection (Kyowa Hakko Kogyo Co.,Ltd.)	Supplemental Change	Doxorubicin hydrochloride	
		Decadron Phosphate Injection (Banyu Phamaceutical Co., Ltd.) Orgadrone Injection (Nippon Organon K.K.) Dexart (Fuji Pharma Co., Ltd.)	Supplemental Change Supplemental Change Supplemental Change	Dexamethasone sodium phosphate	
Oncology drug	February 14, 2005	41 5-FU injection 250 Kyowa (Kyowa Hakko Kogyo Co., Ltd.)	Supplemental Change	5-Fluorouracil	Addition to indications of combined therapy with other anticancer agents for head and neck cancers and to dosage regimen. <Combined therapy with anticancer agents>
Oncology drug	February 14, 2005	42 Natulan (Chugai Pharmaceutical Co., Ltd.)	Supplemental Change	Procarbazine hydrochloride	Addition to indications of combined therapy with other anticancer agents for glioma which possesses components of malignant astrocytoma and oligodendroglioma and to dosage regimen. <Combined therapy with anticancer agents>
		Oncovin for Inj. 1mg (Nihon Kayaku Co., Ltd.)	Supplemental Change	Vincristine Sulfate	
Oncology drug	March 18, 2005	43 Elplat for Injection 100mg (Yakult Honsha	Approval	Oxaliplatin	A drug containing a new active ingredient with indications for colonic and rectal cancers. <Priority review>

		Co., Ltd)			
AIDS	November 5, 2004	44 VALIXA Tablets 450mg (Tanabe Seiyaku Co., Ltd.)	Approval	Valganciclovir hydrochloride	A drug containing a new active ingredient, L-valine ester of ganciclovir, with indications for treatment of retinitis caused by cytomegalovirus in patients with acquired immune deficiency syndrome (AIDS) and dosage regimen. <Orphan drug>
AIDS	December 24, 2004	45 Lexiva Tablets 700 (Glaxo Smith Kline K.K.)	Approval	Fosamprenavir Calcium Hydrate	A drug containing a new active ingredient with indications for HIV infection. < Orphan drug >
AIDS	December 24, 2004	46 Epzicom Tablets (Glaxo Smith Kline K.K.)	Approval	Lamivudine, Abacavir Sulfate	A drug containing a new active ingredient with indications for HIV infection. < Orphan drug >
AIDS	December 24, 2004	47 Ziagen Tablets (Glaxo Smith Kline K.K.)	Supplemental Change	Abacavir Sulfate	Addition to dosage regimen of ”daily 600mg, once a day“ to the current ones of ”300mg per dose, twice a day.” < Orphan drug >
AIDS	March 23, 2005	48 Emtriva Capsules 200mg (Japan Tobacco Inc.)	Approval	Emtricitabine	A drug containing a new active ingredient with indications for HIV-1 infection < Orphan drug >
AIDS	March 23, 2005	49 Truvada Tablets (Japan Tobacco Inc.)	Approval	Emtricitabine, Tenofovir disoproxil fumarate	A drug containing a new active ingredient with indications for HIV-1 infection < Orphan drug >

Table 19 A list of approved items in 2004 (new medical devices)

	Date of approval	Brand name (name of company)	Approval/ supplemental change	Generic name	Note
1	September 22, 2004	Kawasumi Potassium adsorption filter (Kawasumi Laboratories, Inc.)	Supplemental Change	Other blood collecting and transfusion device (Potassium adsorption filter)	Cation exchange column used for preventing hyperkalemia by adsorbing and eliminating excessive potassium ions in concentrated human erythrocyte fluid provided for transfusion. (Extension of validity period during re-assessment period)
2	January 12, 2005	Particle radiotherapy facilities (carbon ions / proton type) (Mitsubishi Electric Co.)	Supplemental Change	Other particle accelerator for radiotherapy (Particle radiotherapy facilities)	Equipment for particle radiotherapy with high-energy proton or carbon-ion beam accelerated for treating solid tumors and/or brain tumors. (First kind of apparatus in which carbon-ion beams are added as a beam type.) <Priority review>
3	January 24, 2005	Gelpart (Yamanouchi Pharmaceutical. Co., Ltd.)	Approval	Other surgical and orthopedics operating supplies (multiporous gelatine particles)	First equipment for arterial embolism used for transcatheter arterial embolization in patients with hepatocellular carcinoma.
4	January 24, 2005	MULTI-LINK PIXEL stent (Guidant Japan K.K.)	Approval	Stent	Stent designed for use in small vessels of less than 2.5mm for which coronary stents were not indicated till now. This stent is limited to the treatment of abrupt or threatened abrupt closure with failed interventional therapy of *de novo* and restenotic native coronary artery lesions with reference vessel diameter from 2.25 to

					2.5mm (lesion length, less than 25mm).
5	March 2, 2005	RFA system (Boston Scientific Japan K.K.)	Approval	Electrosurgical unit	RF ablation device which coagulates malignant hepatic tumors through the application of heat generated by radio frequency wave. Compared with devices already approved, the maximum output has been increased to 200W and an electrode with a larger expansion diameter (4cm) has been added.
6	March 25, 2005	JMS Dialysis console GC-110N (JMS Co., Ltd.)	Approval	Hemodialysis equipment	A hemodialysis equipment developed for the purpose of safer dialysis therapy, with the first system to have automated control functions for some processes such as priming of blood circuit and dialyzer, blood removal at initiation of dialysis, rapid fluid replacement during dialysis, and return of blood at the end of dialysis.
7	March 25, 2005	ASD closure set (Japan Lifeline Co Ltd.)	Approval	Vascular prosthesis (device for percutaneous atrial septal defect closure)	This is the first medical device for the percutaneous closure of secundum atrial septal defect by placing the main body (septal occluder) at the defect using the delivery system.
8	March 25, 2005	SynchroMed EL pump (Medtronic Japan Co., Ltd.)	Approval	Other infusion apparatus (Implantable pump)	This pump is indicated for intrathecal infusion of baclofen for severe spasticity of spinal or cerebral origin (limited to the patient for whom conventional therapy was not effective). <Orphan medical device>

Table 20: Number of Reports on ADRs and Medical Device Malfunctions

(1) Drugs

(Unit: Cases)

Sources / Fiscal year	Pharmaceutical companies (Domestic reports)	Pharmaceutical companies (Foreign reports)	Medical Professionals	Total	Research reports
1995	14,288	—	1,859	16,147	689
1996	16,831	—	1,914	18,745	754
1997	17,504	—	3,730	21,234	806
1998	18,466	—	4,882	23,348	861
1999	20,031	—	5,502	25,533	759
2000	22,326	—	5,297	27,623	1,009
2001	22,451	—	4,094	26,545	1,124
2002	24,221	—	4,195	28,416	1,228
2003	28,004	—	5,399	33,403	1,276
2004	25,448	54,423	4,594	84,465	1,311

Note 1: Along with system changes by introducing an online reporting system on October 27, 2003, the additional reports and the withdrawn reports, which were counted as one report respectively, are not included to reports.

Note 2: The foreign reports from companies had not been tallied until FY 2003.

(2) Medical Devices

(Unit: Cases)

Sources / Fiscal year	Medical device companies	Medical device companies (Foreign reports)	Medical Professionals	Total	Research reports
1996	119	—	2	121	13
1997	240	—	56	296	17
1998	445	—	76	521	10
1999	555	—	88	643	13
2000	2,749	—	173	2,922	18
2001	8,608	—	166	8,774	21
2002	5,026	—	226	5,252	54
2003	5,013	—	370	5,383	38
2004	11,515	4,210	622	16,347	157

Note : Company reports submitted until FY 2003 include foreign reports.

Table 21 Measures for safety strategies and revision to "precautions on use" related to pharmaceuticals implemented by the Ministry of Health, Labour and Welfare in 2004 – 2004 Designations

Measures for safety strategies implemented by the Ministry of Health, Labour and Welfare in 2004

	Pharmaceuticals	Medical devices
Designated revisions to precautions on use	161	13*
Description of information on "Pharmaceuticals and Medical Devices Safety Information "	38	3

* Including notifications of self-assessment on medical devices.

Revision of "Precautions on Use" related to pharmaceuticals 2004 designations

Date	Names of pharmaceuticals
March 25, 2005	1. Gefitinib
March 23, 2005	1. Tenofovir disoproxil fumarat
February 23, 2005	1. Quetiapine fumarate 2. Raloxifene hydrochloride 3. Trandolapril 4. Tegafur, Gimeracil, Oteracil potassium 5. Streptococcus pyogenes (type 3 group A) Su strain Penicillin-processed freeze-dry powder 6. Anti-human T-lymphocyte immunoglobulin, rabbit
Feburuary 14, 2005	1. Nimustine hydrochloride
February 7, 2005	1. Self testing kit for blood glucose (Glucose dehydrogenase methods that use pyrroloquinoline quinone as a coenzyme.)
January 14, 2005	1. Telithromycin
January 12, 2005	1. Prednisolone (oral medicine) 2. Mizoribine 3. Epirubicin hydrochloride 4. Freeze-dried sulfonated human normal immunoglobulin pH 4-treated human immunoglobulin Polyethylene glycol-treated human normal immunoglobuli Freeze-dried polyethylene glycol-treated human normal immunoglobulin 5. Mefenamic acid 6. Cholestyramine 7. Theophylline (Slow-release oral medicine) (Preparation with pediatric directions and dosage) 8. Betamethasone Betamethasone sodium phosphate (injection solution, enema agent without indications for asthma) Betamethasone acetate, Betamethasone sodium phosphate 9. Betamethaosne sodium phosphate (injection solution with indications for asthma) 10. Cefcapene pivoxil hydrochloride 11. Terbinafine hydrochloride (orally administered agent) 12. Freeze-dried pH 4-treated human immunoglobulin 13. Anti-human thymocyte immunoglobulin, equine 14. Glucagon (gene recombination)) Glucagon 15. Non-prescription drug Anchusan, Shakuyaku-kanzo-to (A preparation containing no less than 1g of kanzo in the maximum combined daily amount (regarding extract, 1g or more converted to original crude drug) 16. Non-prescription drug Anchusan, Shakuyaku-kanzo-to (A preparation containing less than 1g of kanzo in the maximum combined daily amount (regarding extract, 1g or more converted to original crude drug)

Names of pharmaceuticals
1. Phtharal 2. Lisinopril 3. Clofedanol hydrochloride 4. Calcium leucovorin (Calcium folinate) (5mg Tablet, Injection) 5. Tegafur, Gimeracil, Oteracil potassium 6. Mitoxantrone hydrochloride 7. Kami-shoyo-san 8. Non-prescription drug Kami-shoyo-san 9. Sulbactam sodium, Cefoperazone sodium 10. Biapenem
1. Telithromycin 2. Interferon-alfa (NAMALWA) 3. Sodium chloride, potasium chloride, sodium hydrogencarbonate, anhydrous sodium sulfate 4. Magnesium citrate (hypertonic or isotonic preparation) 5. Magnesium citrate (hypertonic preparation) 6. Sevelamer hydrochloride 7. Amitriptyline hydrochloride 8. Mitiglinide calcium hydrate 9. Gabexate mesilate 10. Rituximab (gene recombination) 11.Vancomycin hydrochloride (injection) (Preparation with no indications for sepsis, pneumonia, and purulent meningitis caused by penicillin-resistant Streptococcus pneumoniae (PRSP) with sensitivity to 12. Vancomycin hydrochloride (oral medicine)
1. Dichlorvos spray (using insecticide equipment) 2. Dichlorvos spray (those agents containing 5g or more of dichlorvos per sheet for those without insecticide equipment) 3. Dichlorvos spray (those agents containing less than 5g of dichlorvos per sheet for those without insecticide equipment) 4. Dichlorvos spray (those agents containing less than 5g of dichlorvos per can for those without insecticide equipment)
1. Oxygen Liquid oxygen
1. Blood glucose test kit (Those using glucose dehydrogenase method as a measurement principle, excluding kits using NAD(P) as a coenzyme)
1. Antibiotic preparation for injection, sulphur agent and synthesized antibacterial 2. Antibiotic preparation for suppository and sulphur agent
1. Rabeprazole sodium 2. Paclitaxel 3. Pergolide mesylate 4. Flurbiprofen axetil 5. Flurbiprofen (oral medicine) 6. Bezafibrate 7. Meropenem trihydrate 8. Azithromycin hydrate 9. Gefitinib 10. Pamidronate disodium 11. Atazanavir sulfate 12. Vardenafil hydrochloride hydrate

Names of pharmaceuticals
1. Tacrolimus hydrate (oral medicine, injection) 2. Atazanavir sulfate 3. Cladribine 4. Fosfomycin Sodium (injection) 5. Elental P 6. Monteplase (gene recombination) 7. Iopamidol 8. Iopromide 9. Iomeprol 10. Lornoxicam 11. Beclometasone dipropionate 12. Sevoflurane 13. Mebendazole 14. Aspirin (Enteric tablet) 15. Aspirin, Dialuminate (81mg tablet)
1. Ticlopidine hydrochloride
1. Argatroban 2. Mosapride Citrate 3. Salicylamide, Acetaminophen, Anhydrous caffeine, Promethazine methylene 4. Concentrated glycerin, Fructose 5. Sodium hyaluronate (injection) (A preparation with indications for knee joint pain in chronic articular rheumatism) 6. Abacavir sulfate 7. Flavoxate hydrochloride 8. Pitavastatin calcium 9. Cabergoline 10. Maxacalcitol (external preparation) 11. Edaravon 12. Diaphenylsulfone 13. Micafungin sodium 14. Epalrestat 15. Tizanidine hydrochloride 16. Fluvoxamine maleate 17. Fentanyl citrate
1. Monoethanolamine oleate 2. Melphalan (injection) 3. Tegafur, Gimeracil, Oteracil potassium 4. Clarithromycin 5. Lamivudine (100mg) 6. Melphalan (oral medicine) 7. Milnacipran hydrochloride 8. Dantrolene sodium (oral medicine) 9. Olanzapine 10.Oxycodone hydrochloride 11. Distigmine bromide (oral medicine)
1. Cilostazol (preparation with indications for inhibiting recurrence of cerebral infarction after its onset, excluding cardiogenic cerebral embolism) 2.Cilostazol (preparation without indications for inhibiting recurrence of cerebral infarction after its onset, excluding cardiogenic cerebral embolism)

Date	Names of pharmaceuticals
May 12, 2004	1. Imatinib mesilate 2. Infliximab (gene recombination) 3. Oseltamivir phosphate 4. Tandospirone citrate 5. Donepezil hydrochloride 6. Clomipramine hydrochloride (oral medicine) Imipramine hydrochloride 7. Clomipramine hydrochloride (injection) 8. Fluvoxamine maleate 9. Milnacipran hydrochloride
April 13, 2004	1. Phtharal
April 1, 2004	1. Doxazosin mesylate 2. Flavoxate hydrochloride 3. Clofedanol hydrochloride 4. Risedronate sodium hydrate 5. Vinorelbine tartrate 6. Fluorouracil (injection) 7. Pilsicainide hydrochloride 8. Flecainide acetate 9. Bofu-tsusho-san 10. Non-prescription drug Bofu-tsusho-san 11. Lornoxicam 12. Dobutamine hydrochloride 13. Concentrated glycerin, fructose 14. Praziquantel 15. Rifampicin 16. Mitomycin C 17. Ivermectin 18. Loratadine 19. Rebamipide 20. Linezolid 21. Tranexamic acid (oral medicine) Epsilon-aminocaproic acid Hemocoagulase 22. Tranexamic acid (injection) Aprotinin 23. Irinotecan hydrochloride 24. Mixed preparation of male hormone and follicle hormone (indications for menopausal disorder and osteoporosis) 25. Mixed preparation of male hormone and follicle hormone (Indications for menopausal disorder but not osteoporosis)

Table 22 Revision of "Precautions on Use" related to medical devices: 2004 Designations and notifications on self-assessment 2004 designations

Revised designations on "Precautions on Use" related to medical devices

Notification number	Title
March 31, 2005 No. 0331021 issued by Director of ELD, PFSB, MHLW No. 0331005 issued by Director of SD, PFSB, MHLW Addressed to: The president of Medtronic Japan Co. Ltd	Revised designations on "Precautions on Use" related to Medtronic InSync 8040
February 7, 2005 No. 0207004 issued by Director of SD, PFSB, MHLW Addressed to: Head of the Primary Sanitary Division of each prefecture	Designation on safety measures of simple blood glucose self-measurement apparatus (glucose dehydrogenase method using pyrroloquinoline quinone as a coenzyme)
November 26, 2004 No.1126009 issued by Director of ELD, PFSB, MHLW No. 1126001 issued by Director of SD, PFSB, MHLW Addressed to: Head of the Primary Sanitary Division of each prefecture	Revised designation of "Precautions on Use" related to heaters and humidifiers
July 30, 2004 No. 0730001 issued by Director of ELD, PFSB, MHLW No.0730001 issued by Director of SD, PFSB, MHLW Addressed to: Johnson and Johnson Co. Ltd	Designation on appropriate use of Cypher stent

Notifications on self assessment related to medical devices 2004 designations

Notification number	Title
March 31, 2005 No. 0331007 issued by Director of SD, PFSB, MHLW Addressed to: Chairman of Pacemaker Council, Japan Association of Medical Equipment Industries	Designation on self-assessment of impact of X-ray CT systems etc on implanted heart pacemakers
February 1, 2005 No.0201001 issued by Director of ELD, PFSB, MHLW No.0201001 issued by Director of SD, PFSB, MHLW Addressed to: Head of the Primary Sanitary Division of each prefecture	Designation on self-assessment of urethral stent
January 4, 2005 No.0104001 issued by Director of SD, PFSB, MHLW No.0104002 issued by Director of SD, PFSB, MHLW No.0104003 issued by Director of SD, PFSB, MHLW Addressed to: Head of the Primary Sanitary Division of each prefecture Chairman of Japan Federation of Medical Devices Association Chairman of Japan Medical Devices Manufacturers Association Chairman of Japan Medical Association Chairman of Japan Nursing Association Chairman of Japanese Association of Medical Technologists	Designation on additions to "Precautions on Use" of vacuum blood-collecting tubes
October 7, 2004 No.1007002 issued by Director of DED, PFSB, MHLW No.1007001 issued by Director of SD, PFSB, MHLW Addressed to: Head of the Primary Sanitary Division of each prefecture	Designation on self-assessment of "Precautions on Use" related to catheter sets for blood access placement

* nots ELD : Evaluation and Licensing Division, SD : Safety Division, PFSB : Pharmaceutical and Food Safety Bureau, MHLW : Ministry of Health, Labour and Welfare

Notification number	Title
September 29, 2004 Administrative notification Director of SD, PFSB, MHLW Addressed to: Japan Medical Devices Manufacturers Association Japan Analytical Instruments Manufacturers Association	Designation on self-assessment of blood glucose measurement apparatus using glucose dehydrogenase (GDH) method
September 24, 2004 No.0924006 issued by Director of ELD, PFSB, MHLW No.0924004 issued by Director of SD, PFSB, MHLW Addressed to: Head of Primary Sanitary Division of each prefecture	Designation on self-assessment of electric surgical devices with bipolar electrodes
September 24, 2004 No.0924003 issued by Director of ELD, PFSB, MHLW No.0924001 issued by Director of SD, PFSB, MHLW Addressed to: Head of Primary Sanitary Division of each prefecture No.0924002 issued by Director of ELD, PFSB, MHLW No.0924002 issued by Director of SD, PFSB, MHLW Addressed to: Chairman of Japan Federation of Medical Devices Association Chief director of Japan Association of Medical Equipment Industries Chairman of Medical Electronics Business Committee, Japan Electronics and Information Technology Industries Association Chairman of Medical Equipment subcommittee, American Chamber of Commerce in Japan Chairman of Medical Equipment Committee, European Business Council No.0924005 issued by Director of ELD, PFSB, MHLW No.0924003 issued by Director of SD, PFSB, MHLW Addressed to: Chairman of Japan Medical Association Chairman of Japan Hospital Association Chairman of All Japan Hospital Association Chairman of Association of Japanese Healthcare Corporations Chairman of Japan Association for Clinical Engineering Technologists	Designation on self-assessment of concomitant use of electric surgical devices and puncture needle guides
September 10, 2004 No.0910001 issued by Director of ELD, PFSB, MHLW No.0910001 issued by Director of SD, PFSB, MHLW Addressed to: Head of Primary Sanitary Division of each prefecture	Designation on self-assessment of "Precautions on Use" related to self-blood collection set
September 6, 2004 No.0906001 issued by Director of ELD, PFSB, MHLW No.0906001 issued by Director of SD, PFSB, MHLW Addressed to: Head of Primary Sanitary Division of each prefecture	Designation on self-assessment of ignition by carbon dioxide absorbents

* Notes ELD : Evaluation and Licensing Division, SD : Safety Division, PFSB : Pharmaceutical and Food Safety Bureau, MHLW : Ministry of Health, Labour and Welfare

Table 23 Safety information of pharmaceuticals and devices in FY2004 (No.200-211)

Date	No.	Contents
March 31, 2005	211	1. Information about important adverse reactions 1 Raloxifene hydrochloride 2 Quetiapine fumarate 3 Self testing kit for blood glucose (glucose dehydrogenase methods that use pyrrolo-quinoline quinone as a coenzyme) 2. Revision of precautions on use (No.164) Trandolapril and others (4 cases)
February 24, 2005	210	1. Interstitial pneumonia caused by leflunomide 2. Information about important adverse reactions 1 Epirubicin hydrochloride 2 Freeze-dried sulfonated human normal immunoglobulin, pH 4-treated human immunoglobulin, Polyethylene glycol-treated human normal immunoglobulin, Freeze-dried polyethylene glycol-treated human normal 3. Telithromycin 4. Prednisolone (oral medicine) 5 mizoribine 3. Revision of precautions on use (No.163) Mefenamic acid and others (11 cases)
January 27, 2005	209	1. Information about important adverse reactions 1 Phtharal 2. Revision of precautions on use (No.162) Lisinopril and others (8 cases)
December 21, 2004	208	1 Information about important adverse reactions 1 Interferon-alfa (NAMALWA) 2 Telithromycin 2. Revision of precautions on use (No.161) Amitriptyline hydrochloride and others (13 cases)
November 25, 2004	207	1. Information about important adverse reactions 1 Paclitaxel 2 Rabeprazole sodium 2. Revision of precautions on use (No.160) Flurbiprofen (oral medicine) and others (13 cases)
October 28, 2004	206	1. Safety measures for antibiotic injection induced shock 2. Investigation report (special investigation) on a prospective study of Iressa tablet 250 3. Safety measures for blood glucose testing kit
September 30, 2004	205	1. 2003 Report on adverse reactions of influenza vaccines 2. Post marketing safety measures for ticlopidine hydrochloride preparation and Cypher stent 3. Information about important adverse reactions 1 Tacrolimus hydrate (oral medicine, injection) 4. Revision of precautions on use (No.159) Sevoflurane and others (14 cases)

Date	No.	Contents
August 26, 2004	204	1. Information about important adverse reactions 1 Argatroban 2 Mosapride citrate 3 Salicylamide, acetaminophen, Anhydrous caffeine, promethazine methylenedisalicylate 4 Concentrated glycerin, Fructose 2. Revision of precautions on use (No.158) Cabergoline and others (12 cases)
July 29, 2004	203	1. Serious skin disorders due to pharmaceuticals 2. Influence on medical devices by radio waves from burglar prevention 3. Information about important adverse reactions 1 Monoethanolamine oleate 2 Clarithromycin 3 Tegafur, Gimeracil, Oteracil potassium 4 Melphalan (injection) 4. Revision of precautions on use (No.157) Milnacipran hydrochloride and others (6 cases)
June 24, 2004	202	1. Safety measures for pharmaceuticals with a high risk of being taken by 2. Information about important adverse reactions 1 Infliximab (gene recombination) 2 Imatinib mesilate 3 Oseltamivir phosphate 3. Revision of precautions on use (No.156) Tandospirone citrate and others (5 cases)
May 27, 2004	201	1. Information about important adverse reactions 1 Clofedanol hydrochloride 2 Flavoxate hydrochloride 3 Vinorelbine tartrate 4 Phtharal 5 Fluorouracil (injection) 6 Doxazosin mesylate 7 Risedronate sodium hydrate 2. Revision of precautions on use (No.155) Lornoxicam and others (18 cases)
April 22, 2004	200	1. Prevention of excessive dosage associated with the use of Optipen Pro 1 (injector for insulin self injection) 2. Crude drugs and preparations with names that are so similar that when imported mistakenly, adverse reactions may become a problem. 3. Change of homepage address due to establishment of PMDA. 4. Damage to health due to health foods and non-approved or non-licensed pharmaceuticals

Table 24: User Fee Lists

User Fee List of Review and Audit for Ethical Drugs, Quasi Drugs and Cosmetics (Effected on April 1, 2005)

Note: The lower row in User fee column indicates the articles on user fees to MHLW in the Cabinet Ordinance on Fees related to the Pharmaceutica (Unit: yen)

Classification			User Fee		
			Review	Compliance Review (Audit)	Total
Reviews (Audits) for Manufacturing License of Drugs					
New License		On-site Review		148,100	148,100
				Article 16 (1) 1 – a	
		Document Review		111,500	111,500
				Article 16 (1) 1 – b	
Change/Addition of Classification		On-site Review		97,400	97,400
				Article 16 (1) 2 – a	
		Document Review		55,300	55,300
				Article 16 (1) 2 – b	
Renewal of Existing License		On-site Review		97,400	97,400
				Article 16 (1) 3 – a	
		Document Review		55,300	55,300
				Article 16 (1) 3 – b	
Reviews (Audits) for Foreign Manufacturers Accreditation of Drugs					
New Accreditation		On-site Review		133,300 + travel expences	133,300 + travel expences
				Article 16 (2) 1 – a	
		Document Review		58,100	58,100
				Article 16 (2) 1 – b	
Change/Addition of Classification		On-site Review		64,600 + travel expences	64,600 + travel expences
				Article 16 (2) 2 – a	
		Document Review		39,700	39,700
				Article 16 (2) 2 – b	
Renewal of Existing Accreditation		On-site Review		64,600 + travel expences	64,600 + travel expences
				Article 16 (2) 3 – a	
		Document Review		39,700	39,700
				Article 16 (2) 3 – b	
Drug Reviews (New applications)					
New drug 1 (non-orphan drugs)		First application items	9,841,500	6,559,600	16,401,100
			Article 17 (1) 1 – a (1)	Article 17 (2) 1 – a	
		Applications with different dosage etc.	2,464,000	1,639,800	4,103,800
			Article 17 (1) 1 – a (3)	Article 17 (2) 1 – c	
New drug 1 (orphan drugs)		First application items	8,251,700	3,286,000	11,537,700
			Article 17 (1) 1 – a (2)	Article 17 (2) 1 – b	
		Applications with different dosage etc.	2,061,500	818,100	2,879,600
			Article 17 (1) 1 – a (4)	Article 17 (2) 1 – d	
New drug 2 (non-orphan drugs)		First application items	4,699,000	2,463,200	7,162,200
			Article 17 (1) 1 – a (5)	Article 17 (2) 1 – e	
		Applications with different dosage etc.	1,174,300	615,900	1,790,200
			Article 17 (1) 1 – a (6)	Article 17 (2) 1 – f	
New drug 2 (orphan drugs)		First application items	3,876,000	1,232,500	5,108,500
			Article 17 (1) 1 – a (7)	Article 17 (2) 1 – g	
		Applications with different dosage etc.	1,004,100	310,100	1,314,200
			Article 17 (1) 1 – a (8)	Article 17 (2) 1 – h	
Generic Ethical Drugs (With compliance audit)			412,100	214,000	626,100
			Article 17 (1) 1 – a (9)	Article 17 (2) 1 – i	
OTC (over-the-counter) drugs			110,300		110,300
			Article 17 (1) 1 – a (10)		
In vitro diagnostics (without standard for approval)			584,100		584,100
			Article 17 (1) 1 – a (13)		
In vitro diagnostics (with standard for approval)		Basic	282,900		282,900
			Article 17 (1) 1 – a (12)		
		Addition of series	60,300		60,300
			Article 17 (1) 1 – a (11)		
Quasi drugs / cosmetics			63,500		63,500
			Article 17 (1) 1 – b, c		
New application of change or replacement of brand name			35,600		35,600
			Article 17 (1) 1 – e		

Classification				User fee		
				Review	Review (Audit)	Total
Drug Reviews (Approval of partial changes to approved matters (supplementary))						
New drug 1 (other than orphan)	Changes to indications	First application items		4,215,500	2,463,200	6,678,700
				Article 17 (1) 2 – a (1)	Article 17 (2) 2 – a	
		Applications with different dosage etc.		1,057,400	615,900	1,673,300
				Article 17 (1) 2 – a (2)	Article 17 (2) 2 – b	
	Other			205,100	120,700	325,800
				Article 17 (1) 2 – a (3)	Article 17 (2) 2 – c	
New drug 1 (orphan)	Changes to indications	First application items		3,487,100	1,232,500	4,719,600
				Article 17 (1) 2 – a (4)	Article 17 (2) 2 – d	
		Applications with different dosage etc.		875,600	310,100	1,185,700
				Article 17 (1) 2 – a (5)	Article 17 (2) 2 – e	
	Other			132,700	109,800	242,500
				Article 17 (1) 2 – a (6)	Article 17 (2) 2 – f	
New drug 2 (other than orphan)	Changes to indications	First application items		4,215,500	2,463,200	6,678,700
				Article 17 (1) 2 – a (1)	Article 17 (2) 2 – a	
		Applications with different dosage etc.		1,057,400	615,900	1,673,300
				Article 17 (1) 2 – a (2)	Article 17 (2) 2 – b	
	Other			205,100	120,700	325,800
				Article 17 (1) 2 – a (3)	Article 17 (2) 2 – c	
New drug 2 (orphan)	Changes to indications	First application items		3,487,100	1,232,500	4,719,600
				Article 17 (1) 2 – a (4)	Article 17 (2) 2 – d	
		Applications with different dosage etc.		875,600	310,100	1,185,700
				Article 17 (1) 2 – a (5)	Article 17 (2) 2 – e	
	Other			132,700	109,800	242,500
				Article 17 (1) 2 – a (6)	Article 17 (2) 2 – f	
Generic drugs (with compliance audit)	Changes to indications	First application items		4,215,500	2,463,200	6,678,700
				Article 17 (1) 2 – a (1)	Article 17 (2) 2 – a	
		Applications with different dosage etc.		1,057,400	615,900	1,673,300
				Article 17 (1) 2 – a (2)	Article 17 (2) 2 – b	
	Other			205,100	120,700	325,800
				Article 17 (1) 2 – a (3)	Article 17 (2) 2 – c	
OTC drugs				56,400		56,400
				Article 17 (1) 2 – a (7)		
In vitro diagnostics (without standard for approval)				295,800		295,800
				Article 17 (1) 2 – a (10)		
In vitro diagnostics (with standard for approval)			Basic	143,500		143,500
				Article 17 (1) 2 – a (9)		
			Addition of series	31,900		31,900
				Article 17 (1) 2 – a (8)		
Quasi drugs and cosmetics				35,600		35,600
				Article 17 (1) 2 – b, c		

Classification					User fee		
					Review	Review (Audit)	Total
GMP review (audit) of drugs							
	Approval, Partial Change and Manufacture for Export	New pharmaceuticals		Domestic		739,800	739,800
						Article 17 (4) 1 – b (1)	
				Overseas		933,500 + travel expences	933,500 + travel expences
						Article 17 (4) 1 – b (2)	
		Bio-derived pharmaceuticals/Radiopharmaceuticals		Domestic		666,100	666,100
						Article 17 (4) 1 – a (1)	
				Overseas		844,400 + travel expences	844,400 + travel expences
						Article 17 (4) 1 – a (2)	
		Sterilized pharmaceuticals/sterilized quasi-drugs		Domestic		201,300	201,300
						Article 17 (4) 1 – c (1)	
				Overseas		229,800 + travel expences	229,800 + travel expences
						Article 17 (4) 1 – c (2)	
		Pharmaceuticals and quasi-drugs other than the above		Domestic		141,200	141,200
						Article 17 (4) 1 – d (1)	
				Overseas		155,400 + travel expences	155,400 + travel expences
						Article 17 (4) 1 – d (2)	
		Package, labeling, storage, external testing etc.		Domestic		63,800	63,800
						Article 17 (4) 2– a, Article 17 (5) 1– a	
				Overseas		84,800 + travel expences	84,800 + travel expences
						Article 17 (4) 2– b, Article 17 (5) 1– b	
	Renewal of the above	Bio-derived pharmaceuticals/Radio-pharmaceuticals	Basic	Domestic		436,000	436,000
						Article 17 (4) 3– a(1)	
				Overseas		554,200 + travel expences	554,200 + travel expences
						Article 17 (4) 3– a (2)	
			Addition of items	Domestic		30,500	30,500
						Article 17 (4) 3– a (1)	
				Overseas		30,500	30,500
						Article 17 (4) 3– a (2)	
		Sterilized pharmaceuticals/ sterilized quasi-drugs	Basic	Domestic		380,000	380,000
						Article 17 (4) 3– b (1)	
				Overseas		480,000 + travel expences	480,000 + travel expences
						Article 17 (4) 3– b (2)	
			Addition of items	Domestic		12,400	12,400
						Article 17 (4) 3– b (1)	
				Overseas		12,400	12,400
						Article 17 (4) 3– b (2)	
		Pharmaceuticals and quasi-drugs other than the above	Basic	Domestic		336,500	336,500
						Article 17 (4) 3– c (1)	
				Overseas		409,400 + travel expences	409,400 + travel expences
						Article 17 (4) 3– c (2)	
			Addition of items	Domestic		9,600	9,600
						Article 17 (4) 3– c (1)	
				Overseas		9,600	9,600
						Article 17 (4) 3– c (2)	
		Package, labeling, storage, external testing etc.	Basic	Domestic		258,500	258,500
						Article 17 (4) 3– d (1), Article 17 (5) 2– a	
				Overseas		338,100 + travel expences	338,100 + travel expences
						Article 17 (4) 3– d (2), Article 17 (5) 2– b	
			Addition of items	Domestic		6,700	6,700
						Article 17 (4) 3– d (1), Article 17 (5) 2– a	
				Overseas		6,700	6,700
						Article 17 (4) 3– d (2), Article 17 (5) 2– b	

Classification				User fee		
				Review	Review (Audit)	Total
GLP review (audit) of drugs						
	GLP	Domestic			2,062,400	2,062,400
					Article 17 (3) 1– a, Article 17 (9) 2– a (1)	
		Overseas			2,282,600 + travel expences	2,282,600 + travel expences
					Article 17 (3) 1– b, Article 17 (9) 2– a (2)	
GCP review (audit) of drugs						
	New GCP	First application item	Domestic		2,723,200	2,723,200
					Article 17 (3) 2– a	
			Overseas		3,011,900 + travel expences	3,011,900 + travel expences
					Article 17 (3) 2– b	
		Applications with different dosage etc.	Domestic		720,800	720,800
					Article 17 (3) 2– c	
			Overseas		751,800 + travel expences	751,800 + travel expences
					Article 17 (3) 2– d	
	GCP review on generic drugs		Domestic		645,200	645,200
					Article 17 (3) 2– e	
			Overseas		950,200 + travel expences	950,200 + travel expences
					Article 17 (3) 2– f	
Pharmaceutical re-examination						
	Confirmation / examination	First application item		806,600	2,673,700	3,480,300
				Article 17 (8) 1– a	Article 17 (9) 1– a	
		Application with different dosage etc.		271,500	892,100	1,163,600
				Article 17 (8) 1– b	Article 17 (9) 1– b	
	GPSP	First application item	Domestic		2,193,300	2,193,300
					Article 17 (9) 2– b (1)	
			Overseas		2,409,600 + travel expences	2,409,600 + travel expences
					Article 17 (9) 2– b (2)	
		Application with different dosage etc.	Domestic		752,600	752,600
					Article 17 (9) 2– b (3)	
			Overseas		772,300 + travel expences	772,300 + travel expences
					Article 17 (9) 2– b (4)	

A list of user fees of medical devices (Enforced on April 1, 2005)

Note: The lower row in User fee column indicates the articles on user fees to MHLW in the Cabinet Ordinance on Fees related to the Pharmaceutica

(Unit: yen)

Classification			Service fees		
			Assessment	Compliance	Total
Review (Audit) for Manufacturing License of Medical Devices					
	New License	On-site Review		148,100	148,100
				Article 16 (1) 1– a	
		Document Review		111,500	111,500
				Article 16 (1) 1– b	
	Change / addition of classification	On-site Review		97,400	97,400
				Article 16 (1) 2– a	
		Document Review		55,300	55,300
				Article 16 (1) 2– b	
	Renewal of Existing License	On-site Review		97,400	97,400
				Article 16 (1) 3– a	
		Document Review		55,300	55,300
				Article 16 (1) 3– b	
Review (Audit) for Foreign Manufacturing Accreditation of Medical Devices					
	New Accreditation	On-site Review		133,300 + travel expences	133,300 + travel expences
				Article 16 (2) 1– a	
		Document Review		58,100	58,100
				Article 16 (2) 1– b	
	Change / addition of classification	On-site Review		64,600 + travel expences	64,600 + travel expences
				Article 16 (2) 2– a	
		Document Review		39,700	39,700
				Article 16 (2) 2– b	
	Renewal of Existing Accreditation	On-site Review		64,600 + travel expences	64,600 + travel expences
				Article 16 (2) 3– a	
		Document Review		39,700	39,700
				Article 16 (2) 3– b	
Review of medical devices (new application)					
	Approval of medical devices (without approval standard / with clinical data)		3,077,000	664,500	3,741,500
			Article 17 (1) 1– d (1)	Article 17 (2) 1– j	
	Approval of medical devices (without approval standard / without clinical data)		1,164,300	68,500	1,232,800
			Article 17 (1) 1– d (3)	Article 17 (2) 1– l	
	Approval of specially controlled medical devices (with approval standard / without clinical data)		282,900	68,500	351,400
			Article 17 (1) 1– d (2)	Article 17 (2) 1– k	
	Approval of controlled medical devices (with certification standard / without clinical data)		282,900		282,900
			Article 17 (1) 1– d (2)		
	Change of brand name		35,600		35,600
			Article 17 (1) 1– e		
Review of medical devices (Approval of partial changes to approved matters (supplementary))					
	Approval of medical devices (without approval standard / with clinical data)		1,538,000	664,500	2,202,500
			Article 17 (1) 2– d (1)	Article 17 (2) 2– g	
	Approval of medical devices (without approval standard / without clinical data)		584,100	37,100	621,200
			Article 17 (1) 2– d (3)	Article 17 (2) 2– i	
	Approval of specially controlled medical devices (with approval standard / without clinical data)		143,500	37,100	180,600
			Article 17 (1) 2– d (2)	Article 17 (2) 2– h	
	Approval of controlled medical devices (with certification standard / without clinical data)		143,500		143,500
			Article 17 (1) 2– d (2)		

Classification					User fee		
					Review	Review (Audit)	Total
GMP review (audit) of medical devices							
	Approval, Partial Change and Manufacture for Export	New medical devices		Domestic		739,800	739,800
						Article 17 (4) 1– b (1)	
				Overseas		933,500 + travel expences	933,500 + travel expences
						Article 17 (4) 1– b (2)	
		Bio-derived medical devices, specially controlled medical devices (class IV), etc		Domestic		666,100	666,100
						Article 17 (4) 1– a (1)	
				Overseas		844,400 + travel expences	844,400 + travel expences
						Article 17 (4) 1– a (2)	
		Sterilized medical devices		Domestic		201,300	201,300
						Article 17 (4) 1– c (1)	
				Overseas		229,800 + travel expences	229,800 + travel expences
						Article 17 (4) 1– c (2)	
		Medical devices other than the above		Domestic		141,200	141,200
						Article 17 (4) 1– d (1)	
				Overseas		155,400 + travel expences	155,400 + travel expences
						Article 17 (4) 1– d (2)	
		Package, labeling, storage, external testing etc.		Domestic		63,800	63,800
						Article 17 (4) 2 –a, Article 17 (5) 1– a	
				Overseas		84,800 + travel expences	84,800 + travel expences
						Article 17 (4) 2 –b, Article 17 (5) 1 – b	
	Renewal of the above	Bio-derived medical devices, specially controlled medical devices (class IV), etc	Basic	Domestic		436,000	436,000
						Article 17 (4) 3– a (1)	
				Overseas		554,200 + travel expences	554,200 + travel expences
						Article 17 (4) 3– a (2)	
			Addition of items	Domestic		30,500	30,500
						Article 17 (4) 3– a (1)	
				Overseas		30,500	30,500
						Article 17 (4) 3– a (2)	
		Sterilized medical devices	Basic	Domestic		380,000	380,000
						Article 17 (4) 3– b (1)	
				Overseas		480,000 + travel expences	480,000 + travel expences
						Article 17 (4) 3– b (2)	
			Addition of items	Domestic		12,400	12,400
						Article 17 (4) 3– b (1)	
				Overseas		12,400	12,400
						Article 17 (4) 3– b (2)	
		Medical devices other than the above	Basic	Domestic		336,500	336,500
						Article 17 (4) 3– c (1)	
				Overseas		409,400 + travel expences	409,400 + travel expences
						Article 17 (4) 3– c (2)	
			Addition of items	Domestic		9,600	9,600
						Article 17 (4) 3– c (1)	
				Overseas		9,600	9,600
						Article 17 (4) 3– c (2)	
		Package, labeling, storage, external testing etc.	Basic	Domestic		258,500	258,500
						Article 17 (4) 3 –d (1), Article 17 (5) 2 – a	
				Overseas		338,100 + travel expences	338,100 + travel expences
						Article 17 (4) 3 –d (2), Article 17 (5) 2 – b	
			Addition of items	Domestic		6,700	6,700
						Article 17 (4) 3 –d (1), Article 17 (5) 2 – a	
				Overseas		6,700	6,700
						Article 17 (4) 3 –d (2), Article 17 (5) 2 – b	

Classification			User fees		
			Review	Review (Audit)	Total
GLP Review (audit) of medical devices					
	GLP	Domestic		2,062,400	2,062,400
				Article 17 (3) 1 –a, Article 17 (9) 2 – a (1)	
		Overseas		2,282,600 + travel expences	2,282,600 + travel expences
				Article 17 (3) 1 –b, Article 17 (9) 2 – a (2)	
GCP Review (audit) of medical devices					
	GCP	Domestic		635,300	635,300
				Article 17 (3) 3– a	
		Overseas		918,400 + travel expences	918,400 + travel expences
				Article 17 (3) 3– b	
Re-examination of medical devices					
	New medical devices		502,600	624,600	1,127,200
			Article 17 (8) 2 – a	Article 17 (9) 1 – c	
	Medical devices other than new ones		51,600		51,600
			Article 17 (8) 2– b		
	GPSP	Domestic		610,700	610,700
				Article 17 (9) 2– b (5)	
		Overseas		949,000 + travel expences	949,000 + travel expences
				Article 17 (9) 2– b (6)	

A list of other user fees (Enforced on April 1, 2005)

(Unit: yen)

Classification			User fees	Timing of Payment
Face to face consultations				
Clinical trial consultations	Pharmaceuticals	Reliability standard compliance consultation for pharmaceuticals	2,875,500 yen per consultation	Payment by the date of application after arrangement of the date of the face to face consultation
		Procedural consultation for pharmaceuticals	139,800 yen per consultation	
		Biological equivalence testing etc. for pharmaceuticals	556,000 yen per consultation	
		Quality consultation for pharmaceuticals	1,478,300 yen per consultation	
		Safety consultation for pharmaceuticals	1,782,800 yen per consultation	
		Consultation before initiation of phase I study for pharmaceuticals	2,341,400 yen per consultation	
		Consultation before initiation of the first stage of phase II study for pharmaceuticals	845,500 yen per consultation	
		Consultation before initiation of the second stage of phase II study for pharmaceuticals	1,673,300 yen per consultation	
		Consultation after completion of phase II study for pharmaceuticals	3,320,600 yen per consultation	
		Pre application consultation for pharmaceuticals	3,319,400 yen per consultation	
		Additional consultation for pharmaceuticals	1,478,300 yen per consultation	
		Consultation concerning protocol of clinical study for reevaluation and re-examination of pharmaceuticals	3,320,600 yen per consultation	
		Consultation at the completion of clinical study for reevaluation and re-examination of pharmaceuticals	3,319,400 yen per consultation	
		Pre application consultation of new OTC drugs	445,100 yen per consultation	
	Devices and in vitro diagnostics	Pre clinical trial/ application consultation of medical devices or in vitro diagnostics	1,594,700 yen per consultation	
		Reliability standard compliance consultation of medical devices or in vitro diagnostics	650,300 yen per consultation	
Simple consultations		Generic drugs	21,000 yen per consultation	
		OTC drugs	21,000 yen per consultation	
		Quasi-drugs	21,000 yen per consultation	
		Medical devices or in vitro diagnostics	34,300 yen per consultation	
		Writing of application materials	21,000 yen per consultation	
		MF (Master file)	21,000 yen per consultation	
Review of designation of priority face to face consultation				
Review of designation of priority face to face consultation on drugs			818,800 yen per application	Request to the agency after advance payment
Review of designation of priority face to face consultation on medical devices or in vitro diagnostics			818,800 yen per application	
Safety testing review (GLP on-site review)				
All study items (pharmaceuticals and medical devices)			3,023,800 yen per facility	Request to the agency after advance payment
All study items (pharmaceuticals or medical devices)		Domestic	2,062,400 yen per facility	
		Overseas	2,282,600 yen + travel expenses per facility	
Limitation of study items			995,200 yen per facility	
Additional compliance accreditation			932,600 yen per facility	
Examination of certification on drugs				
Certification of medical preparations			15,100 yen per item	Request to the agency after advance payment
Other certifications			8,400 yen per matter of one item	
Use of document storage room				
			3,000 yen per day / room	Pay invoice sent from the agency after the end of use period

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