IV. STATISTICAL TABLES

Adverse Health Effect Relief Services

Table 1: Number of Cases on Adverse Health Effect Relief Benefits 1980-2005

Classification / Fiscal year	Number of claims	Number of judged cases	Paid	Not paid	Withdrawn
1980	20 (20)	10 (10)	8 (8)	2 (2)	0 (0)
1981	35 (29)	22 (19)	20 (17)	1 (1)	1 (1)
1982	78 (66)	52 (42)	38 (28)	8 (8)	6 (6)
1983	78 (66)	72 (58)	62 (48)	8 (8)	2 (2)
1984	130 (105)	83 (69)	62 (53)	20 (15)	1 (1)
1985	115 (89)	120 (91)	95 (73)	23 (16)	2 (2)
1986	133 (104)	117 (95)	98 (82)	19 (13)	0 (0)
1987	136 (107)	108 (78)	84 (65)	24 (13)	0 (0)
1988	175 (142)	142 (117)	120 (102)	20 (13)	2 (2)
1989	208 (176)	157 (136)	137 (119)	19 (16)	1 (1)
1990	225 (183)	270 (227)	226 (197)	44 (30)	0 (0)
1991	208 (168)	240 (185)	194 (152)	46 (33)	0 (0)
1992	203 (173)	244 (204)	199 (170)	41 (30)	4 (4)
1993	202 (169)	211 (187)	176 (157)	32 (27)	3 (3)
1994	205 (166)	233 (192)	195 (165)	35 (24)	3 (3)
1995	217 (167)	198 (154)	172 (139)	25 (14)	1 (1)
1996	297 (246)	241 (193)	190 (158)	49 (33)	2 (2)
1997	399 (330)	349 (287)	294 (238)	55 (49)	0 (0)
1998	361 (300)	355 (301)	306 (261)	49 (40)	0 (0)
1999	389 (318)	338 (281)	289 (238)	46 (41)	3 (2)
2000	480 (414)	404 (347)	343 (293)	61 (54)	0 (0)
2001	483 (411)	416 (348)	352 (294)	64 (54)	0 (0)
2002	629 (531)	431 (354)	352 (288)	79 (66)	0 (0)
2003	793 (702)	566 (491)	465 (407)	99 (82)	2 (2)
2004	769 (675)	633 (562)	513 (460)	119 (101)	1 (1)
2005	760 (643)	1,035 (906)	836 (745)	195 (157)	4 (4)
Total	7,728 (6,500)	7,047 (5,934)	5,826 (4,957)	1,183 (940)	38 (37)

(Note) The figures in each category indicate the total number of the claimants, and additionally include them as a new one when they made another claim for the same reason to PMDA. The number in the parentheses does not include the same claim who made even another claim for the same reason to PMDA.

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 payments	Number of non payments	Benefit amount	Number of claims	Number of payments	Number of non payments	Benefit amount	Number of claims	Number of payments	Number of non payments	Benefit amount	Number of claims	Number of payments	Number of non payments	Benefit amount
	(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	385,286	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	21,050	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
2005	602	717	115	78,527	659	757	124	70,073	78	33	51	653,143	5	17	4	40,639
Total	5,509	4,311	651	450,661	6,448	5,063	776	533,489	852	366	399	6,136,983	87	57	25	190,520

(Note) 1. In this table, the "Number of claims" indicates the number of applications filed for each benefit type, and is not always identical to the figures 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 amount	Number of claims	Number of payments	Number of non payments	Benefit amount	Number of claims	Number of payments	Number of non payments	Benefit amount	Number of claims	Number of payments	Number of non payments	Benefit amount
	(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	797,557
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	168	1,055,985
2003	56	32	14	335,829	42	30	12	217,148	98	61	24	11,205	1,596	922	203	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
2005	41	44	23	502,468	48	32	28	228,708	84	74	51	14,010	1,517	1,674	396	1,587,567
Total	488	367	99	5,546,453	633	431	145	2,795,826	1,107	786	229	119,021	15,124	11,381	2,324	15,772,953

Table 3: Number of Claims and Benefits for Adverse Health Effect Relief Service in Prefectures

Prefecture	Number of claims	Number of payments	Prefecture	Number of claims	Number of payments
Hokkaido	399 (331)	314 (266)	Shiga	71 (65)	50 (47)
Aomori	30 (26)	24 (21)	Kyoto	275 (215)	225 (176)
Iwate	41 (35)	27 (23)	Osaka	645 (579)	493 (453)
Miyagi	93 (90)	66 (65)	Hyogo	375 (325)	258 (228)
Akita	53 (47)	45 (41)	Nara	105 (96)	86 (79)
Yamagata	66 (56)	46 (40)	Wakayama	59 (56)	48 (47)
Fukushima	117 (100)	97 (84)	Tottori	24 (20)	17 (14)
Ibaragi	149 (120)	117 (96)	Shimane	42 (32)	35 (26)
Tochigi	85 (76)	64 (60)	Okayama	108 (95)	82 (72)
Gunma	93 (73)	73 (57)	Hiroshima	255 (190)	182 (130)
Saitama	370 (302)	290 (230)	Yamaguchi	108 (89)	87 (71)
Chiba	394 (315)	295 (243)	Tokushima	22 (20)	14 (13)
Tokyo	870 (721)	648 (534)	Kagawa	75 (58)	59 (45)
Kanagawa	548 (475)	428 (379)	Ehime	73 (64)	52 (46)
Niigata	119 (103)	94 (80)	Kochi	50 (42)	35 (33)
Toyama	59 (48)	40 (34)	Fuhuoka	248 (207)	176 (149)
Ishikawa	58 (40)	39 (25)	Saga	32 (28)	23 (21)
Fukui	50 (43)	37 (35)	Nagasaki	90 (64)	66 (49)
Yamanashi	50 (43)	44 (37)	Kumamoto	97 (82)	73 (63)
Nagano	110 (100)	82 (77)	Oita	70 (56)	47 (37)
Gifu	146 (131)	111 (102)	Miyazaki	59 (46)	43 (35)
Shizuoka	272 (233)	198 (169)	Kagoshima	113 (96)	74 (64)
Aichi	381 (323)	284 (245)	Okinawa	78 (63)	65 (55)
Mie	98 (78)	71 (59)	Other	3 (3)	2 (2)
			Total	7,728 (6,500)	5,826 (4,957)

(Note)1. The number of cases indicates the number of all the claims reported to PMDA and includes even multiple claims done by the same claimant for the same reason. The number in the parentheses indicates the number of all the claimants and excludes their reclaims done for the same reason.

2. "Other" means claims made by foreigners after they returned to their countries.

Table 4: Yearly trend of diseases (symptoms) caused by adverse reactions

Classification by organ	Diseases caused by adverse reactions	Fiscal year																											Total
		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	2005		
Skin and appendages disorders	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	121	153	226	1,486
Musculo-skeletal 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	29	26	51	331
Central & peripheral nervous system 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	61	72	134	1,056
Autonomic nervous system disorders	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	6	5	9	25
Vision disorders	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	4	11	11	323
Hearing and 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	1	2	4	42
Psychiatric disorders	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	6	9	17	72
Gastrointestinal system 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	18	12	52	292
Liver and biliary system 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	90	122	182	1,025
Metabolic and nutritional 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	7	13	18	54
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	3	3	7	30
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	12	2	8	61
Myo-,endo-,pericardial & valve disorders	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	1	1	0	14
Heart rate and rhythm disorders	Bradycardia etc.	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	11	11
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	10	18	12	95
Respiratory system 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	17	27	70	289
Red blood cell 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	11	10	10	87
White cell & 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	34	28	44	249
Platelet, bleeding & clotting disorders	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	22	25	26	139
Urologic system 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	20	23	34	179
Female reproductive 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	0	2	1	18
Neonatal and infancy disorders	Naonatal asphyxia, etc.	0	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
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	122	97	246	1,255
Application site 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	0	3	1	11
Resistance mechanism disorders	Septis, hacterial 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	24	20	36	129
Total		12	20	40	65	88	111	136	95	157	170	286	209	232	211	220	180	204	290	417	393	387	375	462	619	684	1,211	7,274

(Note) 1: The classification by organ follows the glossary of adverse reactions from the WHO's international monitoring system.

2: Because one person may have multiple adverse reactions, the number is not identical to the number of all the beneficiaries.

Table 5: Yearly Trend of the Number of Pharmaceuticals That Caused Adverse Reactions by Drug Thrapeutic Class

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	2005	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	516	3,445
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	30	304
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	0	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	48	268
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	126	591
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	44	250
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	135	493
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	146	809
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	3	48
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	8	46
Other drugs for indivisual 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	1	10
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	10	83
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	59	236
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	175	613
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	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	34	128
Other drugs based on crude drugs and Chinese medicine	0	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
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	242	1,777
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	117	582
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	33	439
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	2	7
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	39	311
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	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	4	13
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	4	10
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	7	17
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	0	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	6	7
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	1,790	10,601

(Note) The number of causative drugs is not identical to the number of beneficiaries, because some persons suffered adverse reactions caused by multiple drugs.

Table 6: Adverse Drug Reaction Contributions from Marketing Authorization Holders

(at the end of each Fiscal year)

Fiscal year	Marketing authorization holders of drugs		Marketing authorization holders of pharmacy compounding drugs		Total amounts	Funding rate
	Number of payers	Contribution amount	Number of payers	Contribution amount		
	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	833 (115)	2,844 (423)	10,550 (1)	11 (0)	2,855	0.3／1,000
2005	787 (116)	2,923 (425)	9,993	10	2,933	0.3／1,000

(Note) 1. The numbers in parenthesis 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. The figures of contribution amounts and the total are rounded to the nearest one million.

Table 7: Number of Consultations for Relief Benefits

Consultation Detail / Fiscal Year	Consulters of relief benefits related matters							Enquiry on the service	Others	Infectious disease relief related	Total
	Total # of consulters on relief benefits related	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)
2005	1,219	471	357	18	326	11	36	1,705	1,240	143	4,307
Total	16,176	5,531	4,099	668	4,731	284	863	15,133	8,768	272 (38)	40,349 (38)

(Note) The numbers in parenthesis indicate the number of consultations applied to other offices than the consultation office in PMDA and are included in their left figures.

Table 8: Relief Service for Infectious Disease caused by Bio-derived Products

Number of cases of relief benefits paid 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)
2005	5 (4)	0 (0)	3 (3)	3 (3)

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

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

Classification / Fiscal year	Medical expenses				Medical allowances				Disability pension				Pension for raising handicapped children			
	Number of claims	Number of payments	Number of non payments	Benefit amount	Number of claims	Number of payments	Number of non payments	Benefit amount	Number of claims	Number of payments	Number of non payments	Benefit amount	Number of claims	Number of payments	Number of non payments	Benefit amount
	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
2005	5	3	3	475	5	3	3	249	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 amount	Number of claims	Number of payments	Number of non payments	Benefit amount	Number of claims	Number of payments	Number of non payments	Benefit amount
	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
2005	0	0	1	0	0	0	1	0	10	6	8	724

(Note 1) In this table, the number of cases is counted separately by each benefit type. Therefore the numbers of cases are not the same to the above table Number of cases of relief benefits paid for infectious disease.

(Note 2) The figures of the benefit amount is rounded to the nearest thousand, and is not always identical to the total amount.

Health Hazard by type of infectious diseases

Name of infection/ Health Hazard \ Fiscal year	2004	2005	Total
Adverse health effect from virus infection	2	3	5

Number of bio-derived product that caused infectious disease

Type of product \ Fiscal year	2004	2005	Total
Blood preparations for transfusion	2	3	5

Infectious disease relief funds from MAHs

Fiscal year	Marketing authorization holder of Bio-derived product		Funding rate
	Number of payers	Amounts	
	Companies	M yen	
2004	108	554 (－)	1/1,000
2005	105	553 (0)	1/1,000

(Note) 1. The numbers in parenthesis indicate the amounts of additional contribution (because their products were causative ones) and are included in the left figures.

Relief Service for SMON Patients

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
2005	1,305,168	330,086	1,635,254	122,520	1,757,774	2,504
Total	46,995,232	13,100,254	60,095,486	4,686,846	64,782,331	

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 Benefit Amounts related to Research and Study Projects

Fiscal year	Number of claims (cases)	Number of approvals (cases)	Number of non-approvals (cases)	Benefit 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
2005	1	638 （635）	0	341,017
Total	953	8,127 （7,189）	15	3,941,694

(Note) 1. The figures in parentheses show the number of persons who have approvals continuously and are included in the left sidefigures.
2. "Number of approvals" indicates the number of all the approved claimants and excludes their reclaims done for the same reason.
3.The payment amount is rounded to the nearest 1,000 yen.

Relief Service for HIV-positive and AIDS Patients

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

Fiscal year	Number of claims (cases)	Number of payments (cases)	Number of non-payments (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
2005	3 （0）	3 （0）	0	210,300
Total	212 （134）	202 （134）	5	2,136,450

(Note) 1. The figures in the parentheses indicate the number of claimants or beneficiaries of the special allowance and are included in the number of claims or payments.
2. The payments/benefits amount 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
	2005	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
	2005	0	0	0	6,319
	Subtotal	435	364	51	1,679,915
Consolation money 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
	2005	0	0	0	2,387
	Subtotal	106	101	2	1,304,533
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
	2005	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
	2005	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
	2005	0	0	0	8,706
	Total	1,388	1,288	69	4,620,546

(Note) 1. In this table, the number of cases is counted separately by each benefit type.
2. The benefit amounts are rounded to the nearest thousand yen, therefore the total of individual amounts is not always identical to the shown subtotals and tota

Relief Service for HIV-positive and AIDS Patients

Table 13: Number of Consultation for Relief Services

Service / Fiscal year	Research and Study Projects	Healthcare Support Service	Relief Services	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
2005	285	46	8	340
Total	2,887	457	1,726	5,071

Table 14: Number of Applications and Approvals for Drugs (FY1998-FY2005)

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

Classification \ Fiscal year			Number of applications								Number of approvals							
			1998	1999	2000	2001	2002	2003	2004	2005	1998	1999	2000	2001	2002	2003	2004	2005
Drugs and Others	New drugs	New	85	155	129	135	119	99	92	95	142	181	122	166	98	84	57	85
		Supple-mental	83	142	183	256	108	200	272	133	105	92	142	207	148	140	209	195
		Total	168	297	312	391	227	299	364	228	247	273	264	373	246	224	266	280
	Ethical drugs	New	436	472	492	817	554	483	1,057	1,064	482	434	448	694	492	506	727	1,094
		Supple-mental	636	1,531	2,917	2,373	1,282	2,583	1,935	765	707	1,093	2,051	2,465	1,339	1,737	2,749	825
		Total	1,072	2,003	3,409	3,190	1,836	3,066	2,992	1,829	1,189	1,527	2,499	3,159	1,831	2,243	3,476	1,919
	OTC drugs	New	770	926	1,124	901	950	1,075	1,365	925	769	801	838	990	970	803	817	1,034
		Supple-mental	288	300	3,327	2,906	429	1,850	590	206	304	333	487	3,875	1,986	1,131	964	536
		Total	1,058	1,226	4,451	3,807	1,379	2,925	1,955	1,131	1,073	1,134	1,325	4,865	2,956	1,934	1,781	1,570
	In vitro diagnostics	New	444	420	418	427	248	228	367	29	497	370	347	612	239	173	283	163
		Supple-mental	304	237	250	236	204	202	248	40	301	221	263	261	165	195	219	118
		Total	748	657	668	663	452	430	615	69	798	591	610	873	404	368	502	281
	Quasi drugs	New	2,333	2,909	2,721	2,747	2,532	2,396	2,511	1,869	1,991	2,595	2,969	2,352	2,594	2,342	2,372	2,205
		Supple-mental	292	342	2,293	1,736	513	689	557	417	299	253	389	2,908	1,011	650	600	406
		Total	2,625	3,251	5,014	4,483	3,045	3,085	3,068	2,286	2,290	2,848	3,358	5,260	3,605	2,992	2,972	2,611
	Cosmetics	New	605	510	277	0	0	0	0	0	590	434	521	0	0	0	0	0
		Supple-mental	263	235	141	0	0	0	0	0	190	244	243	0	0	0	0	0
		Total	868	745	418	0	0	0	0	0	780	678	764	0	0	0	0	0
	Total	New	4,673	5,392	5,161	5,027	4,403	4,281	5,392	3,982	4,471	4,815	5,245	4,814	4,393	3,908	4,256	4,581
		Supple-mental	1,866	2,787	9,111	7,507	2,536	5,524	3,602	1,561	1,906	2,236	3,575	9,716	4,649	3,853	4,741	2,080
		Total	6,539	8,179	14,272	12,534	6,939	9,805	8,994	5,543	6,377	7,051	8,820	14,530	9,042	7,761	8,997	6,661

* The number of applications received was based on data as of the end of March 2006. The number may change due to change of classification after receiving.

Table 15: Number of Applications and Approvals for Medical Devices (FY1998-FY2005)

(Unit: Cases)

Classification \ Fiscal year		Number of applications								Number of approvals							
		1998	1999	2000	2001	2002	2003	2004	2005	1998	1999	2000	2001	2002	2003	2004	2005
New medical devices	New	32	62	39	38	39	28	49	6	36	23	19	19	3	10	6	7
	Supplemental change	35	24	25	11	8	4	7	3	19	25	12	19	0	3	2	4
	Total	67	86	64	49	47	32	56	9	55	48	31	38	3	13	8	11
Without approval standard/ with clinical study	New	-	-	-	-	-	-	-	13	-	-	-	-	-	-	-	0
	Supplemental change	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-	0
	Total	-	-	-	-	-	-	-	14	-	-	-	-	-	-	-	0
Without approval standard/ without clinical study	New	-	-	-	-	-	-	-	113	-	-	-	-	-	-	-	11
	Supplemental change	-	-	-	-	-	-	-	100	-	-	-	-	-	-	-	5
	Total	-	-	-	-	-	-	-	213	-	-	-	-	-	-	-	16
With approval standard/ without clinical study	New	-	-	-	-	-	-	-	28	-	-	-	-	-	-	-	2
	Supplemental change	-	-	-	-	-	-	-	33	-	-	-	-	-	-	-	1
	Total	-	-	-	-	-	-	-	61	-	-	-	-	-	-	-	3
Without approval standard/ without certification standard	New	-	-	-	-	-	-	-	42	-	-	-	-	-	-	-	0
	Supplemental change	-	-	-	-	-	-	-	30	-	-	-	-	-	-	-	1
	Total	-	-	-	-	-	-	-	72	-	-	-	-	-	-	-	1
Improved medical devices	New	-	-	96	202	179	154	248	-	-	-	127	106	60	56	75	137
	Supplemental change	-	-	72	56	44	44	73	-	-	-	68	44	24	30	33	47
	Total	-	-	168	258	223	198	321	-	-	-	195	150	84	86	108	184
Improved medical devices (utilizing materials from humans and animals	New	-	-	0	0	73	2	0	-	-	-	0	0	25	43	0	0
	Supplemental change	-	-	32	204	252	29	4	-	-	-	0	30	3	178	46	79
	Total	-	-	32	204	325	31	4	-	-	-	0	30	28	221	46	79
Generic medical devices	New	1,734	1,794	1,392	1,345	1,350	1,475	2,128	-	1,485	1,473	1,240	1,266	1,042	1,305	1,426	747
	Supplemental change	1,492	1,709	1,254	1,518	1,599	1,851	2,211	-	1,539	1,379	1,325	1,396	1,400	1,681	1,721	786
	Total	3,226	3,503	2,646	2,863	2,949	3,326	4,339	-	3,024	2,852	2,565	2,662	2,442	2,986	3,147	1,533
Total	New	1,766	1,856	1,527	1,585	1,641	1,659	2,425	202	1,521	1,496	1,386	1,391	1,130	1,414	1,507	904
	Supplemental change	1,527	1,733	1,383	1,789	1,903	1,928	2,295	167	1,558	1,404	1,405	1,489	1,427	1,892	1,802	923
	Total	3,293	3,589	2,910	3,374	3,544	3,587	4,720	369	3,079	2,900	2,791	2,880	2,557	3,306	3,309	1, 827

* The number of cases received was based on data by the end of March 2006. The number may change due to classification change after receiving.

Table 16: Review Status for generic drugs, etc. in FY 2005

Classification	Number of applications*	Withdrawn	Approved	In progress
Generic ethical drugs	4,299 (1,829)	221	1,919	2,159
OCT drugs	3,921 (1,131)	144	1,570	2,207
In vitro diagnostics	499 (69)	34	281	184
Quasi drugs	4,224 (2,286)	118	2,611	1,495
Generic medical devices	3,281 (0)	258	1,533	1,490

Note: The cases in the Withdrawn column include those whose classification had been changed during the reviewing period.

*The parenthesized numbers represent applications made in FY 2005 and are included in the figures above them.

Table 17: Clinical Trial Consultation Achievements (FY1999-FY2005)

Fiscal year	1999	2000	2001	2002	2003	2004	2005
Number of clinical trial consultations completed (cases for which fee payment completed)	177	241	246	223	269	162	215
Procedural consultation	—	—	—	—	—	1	2
Pre-Phase I Consultation	52	78	64	81	81	25	42
Pre-first period Pre-Phase II Consultation	—	—	—	—	22	3	2
Pre-latter period Post-Phase II Consultation						49	47
Post-Phase II Consultation	53	70	50	42	42	21	33
Pre-NDA consultation	35	37	46	34	33	25	41
Consultation about CT Plan for Re-evaluation and Re-examination	3	0	2	1	0	0	2
Post-CT Consultation for Re-evaluation and Re-examination	0	0	0	0	0	0	0
Consultation about quality	—	0	1	2	4	2	5
Consultation about safety	—	2	2	0	6	5	5
Additional consultation	34	54	81	63	81	31	31
Consultation about Bioequivalence testing etc.	—	—	—	—	—	0	3
Conformity Criteria Compliance Consultation	—	—	—	—	—	0	2

Note: Only the cases for which fee payment have been completed are counted. Consultations are classified according to the classification criteria of FY 2005. Withdrawn cases are included.

Investigation on Notified CT Protocol

Classification \ Fiscal year	Number of notifications						Number of examined cases					
	2000	2001	2002	2003	2004	2005	2000	2001	2002	2003	2004	2005
Investigation on Notified CT Protocol	76	69	65	64	76	112	76	62	61	70	67	109

Review and Confirmation of Exporting Lisence Application

Classification \ Fiscal year	Number of applied items						Number of completed items					
	2000	2001	2002	2003	2004	2005	2000	2001	2002	2003	2004	2005
Review and Confirmation of Exporting Lisence Application	3,854	2,678	4,197	7,706	10,952	12,245	3,965	2,639	3.397	7,808	10,286	11,320

Conformity Audit for Application Materials for New Drug Approval

Classification \ Fiscal year	Number of applied items						Number of completed items					
	2000	2001	2002	2003	2004	2005	2000	2001	2002	2003	2004	2005
New drug 1 (other than orphan)	88	95	83	117	66	60	99	61	93	70	60	53
New drug 1 (orphan)	8	6	10	19	14	6	9	6	10	20	7	10
New drug 2 (subject of equivalence review)	32	34	13	24	10	13	23	34	12	14	7	7
New drug 2 (not subject of equivalence review, orphan)	0	2	0	4	2	0	0	0	0	0	2	0
New drug 2 (supplemental applications) (subject of equivalence review)	18	14	19	38	79	65	16	17	16	11	63	40
New drug 2 (supplemental applications) (not subject of equivalence review, orphan)	19	22	17	34	31	12	19	14	17	29	14	25
Ethical drugs (supplemental applications) (not subject of equivalence review)	36	35	42	41	-	-	43	19	41	29	8	-
Total	201	208	184	277	202	156	209	151	189	173	161	135

Conformity Audit of Application Materials for Re-examination and On-site GPMSP/GPSP Review

Classification \ Fiscal year	Number of applied items						Number of completed items					
	2000	2001	2002	2003	2004	2005	2000	2001	2002	2003	2004	2005
Conformity Audit of Application Materials for Re-examination	163	133	78	94	118	116	220	123	132	85	34	96
On-site GPMSP/GPSP review	163	107	65	75	101	96	220	116	102	66	27	82
Total	326	240	143	169	219	212	440	239	234	151	61	178

Note: The number of cases of completed GPMSP/GPSP review in and after 2004 represents the notified cases after evaluation.

Conformity Audit for Generic Drugs

Classification \ Fiscal year	Number of applications						Number of completed cases					
	2000	2001	2002	2003	2004	2005	2000	2001	2002	2003	2004	2005
New	389	437	477	401	553	434	401	388	454	402	516	483
Supplementary change	683	784	881	835	646	350	624	741	774	1,023	574	458
Total	1,072	1,221	1,358	1,236	1,199	784	1,025	1,129	1,228	1,425	1,090	941

Conformity Audit of Application Materials for Re-evaluation

Classification \ Fiscal year	Number of applied items						Number of completed items					
	2000	2001	2002	2003	2004	2005	2000	2001	2002	2003	2004	2005
Reliability Audit for Re-evaluation of pharmaceuticals	2	-	35	2	0	0	2	-	0	24	0	0
Reliability Audit for Re-evaluation of orally administered ethical drugs	138	259	320	216	76	206	138	258	234	240	76	206

GLP Review

Classification \ Fiscal year	Number of applied items						Number of completed items					
	2000	2001	2002	2003	2004	2005	2000	2001	2002	2003	2004	2005
GLP review	18	37	39	13	30	38	23	24	40	24	20	37

GCP Review of New Pharmaceuticals

Classification \ Fiscal year	Number of applied items						Number of completed items					
	2000	2001	2002	2003	2004	2005	2000	2001	2002	2003	2004	2005
On-site GPMSP/GPSP review	128	127	103	135	116	133	112	103	101	132	68	120

Note: The number of completed cases in and after 2004 represents the notified cases after evaluation.

GCP Review of Generic Drugs

Classification \ Fiscal year	Number of applied items						Number of completed items					
	2000	2001	2002	2003	2004	2005	2000	2001	2002	2003	2004	2005
GCP review	15	17	18	10	5	13	15	17	17	11	5	11

Table-18. A List of Approved Articles in 2005 (New Drugs)

Category	Date of Approval	Trade Name (Name of Company)	Approval/ Partial change	Name of Ingredient (underlined: new active ingredient)	Notes
1	11-Apr-05	1 Actemra Liquid Concentrate Actemra for Intravenous Infusion 200 (Chugai Pharmaceutical Co., Ltd.)	Approval Approval	Tocilizumab (genetical recombination	Drugs containing a new active ingredient indicated for improving various symptoms and laboratory findings associated with Castleman's disease for which lymphadenectomy is not indicated. **[Orphan drug]**
1	16-Sep-05	2 Zefix Tablets 100 (GlaxoSmithKline K.K.)	Partial	Lamivudine	A new indication for "improving viral markers in patients with hepatitis B cirrhosis complicated by proliferation of hepatitis B virus and with abnormal hepatic function to be confirmed" in monotherapy **[Priority review]**
1	11-Oct-05	3 Propecia Tablets-1mg Propecia Tablets-0.2mg (Banyu Pharmaceutical Co., Ltd.)	Approval	Finasteride	Drugs containing a new active ingredient used for delaying progression of male pattern alopecia in men.
1	11-Oct-05	4 Seibule Tablets 25mg Seibule Tablets 50mg Seibule Tablets 75mg (Sanwa Kagaku Kenkyusho Co., Ltd.)	Approval Approval Approval	Miglitol	Drugs containing a new active ingredient, an α-glucosidase inhibitor, indicated for improving postprandial hyperglycemia in patients with type 2 diabetes.
1	22-Dec-05	5 PegIntron Sterile Powder for Injection (50μg/0.5 mL) PegIntron Sterile Powder for Injection (100μg/0.5 mL) PegIntron Sterile Powder for Injection (150μg/0.5 mL) (Schering-plough K.K.)	Partial	Peginterferon alfa-2b (genetical recombination)	A new indication for either case of chronic hepatitis C mentioned below in combined therapy (1) Patients with high blood levels of HCV-RNA except serogroup 1
		Rebetol Capsule 200 (Schering-plough K.K.)	Partial	Ribavirin	(2) Patients with no response to monotherapy with interferon preparation, or patients relapsing after monotherapy with interferon preparation **[Priority review]**
2	11-Apr-05	6 Tracleer Tablets 62.5 mg (Actelion Japan)	Approval	Bosentan hydrate	A drug containing a new active ingredient, the endothelin-receptor antagonist, indicated for pulmonary arterial hypertension **[Orphan drug]**
2	25-Jul-05	7 Cleactor Injection 400,000 Cleactor Injection 800,000 Cleactor Injection 1,600,000 (Eisai Co., Ltd.)	Partial Partial Partial	Monteplase (genetical recombination)	A new indication for "lysis of pulmonary artery thrombosis caused by acute pulmonary embolism in the presence of hemodynamic instability" **[Orphan drug]**
2	11-Oct-05	8 Activacin for Injection 6,000,000 Activacin for Injection 12,000,000 Activacin for Injection 24,000,000 (Kyowa Hakko Kogyo Co., Ltd.) Grutopa for Injection 6,000,000 Grutopa for Injection 12,000,000 Grutopa for Injection 24,000,00 (Mitsubishi Pharma Corporation)	Partial Partial Partial Partial Partial Partial	Alteplase (genetical recombination)	A new indication for improving dysfunction caused by acute ischemic cerebrovascular diseases **[Priority review]**
2	11-Oct-05	9 Blopress Tablets 2 Blopress Tablets 4 Blopress Tablets 8 (Takeda Pharmaceutical Company Limited)	Partial Partial Partial	candesartan cilexetil	A new indication for chronic heart failure, extended from use as an angiotensin-converting enzyme inhibitor
2	31-Oct-05	10 Bayaspirin 100mg Aspirin "Bayer" (Bayer Yakuhin, Ltd.)	Partial Approval	Aspirin	A new indication for "Kawasaki disease" **[Notification of off label use]**
2	31-Oct-05	11 Bufferin 81 mg Tablets (Lion Corporation)	Partial	Aspirin dialminate	A new indication for "Kawasaki disease" **[Notification of off label use]**
		Nitogis Tablets 81 mg (Shiono Chemical Co.,Ltd.)	Partial		
		Bassamin Tablets 81 mg (Taiyo Yakuhin Co., Ltd.)	Partial		
		Famoter 81mg Tablets (Tsuruhara Pharmaceutical Co., Ltd.)	Partial		
		Asphanate Tablets 81 mg (Nakakita Yakuhin Co., Ltd.)	Partial		
		Aspirin "Metal" (Nakakita Yakuhin Co., Ltd.)	Partial	Aspirin	
		aspirin "Yoshida" (Yoshida Pharmaceutical Co., Ltd.)	Partial		
		Aspirin "Hoei" (Merck Hoei Ltd.)	Partial		
2	23-Jan-06	12 Clopidogrel sulfate (Sanofi-Synthelabo Daiichi K.K..)	Approval	Clopidogrel sulfate	Drugs containing a new active ingredient indicated for preventing recurrences of ischemic cerebrovascular diseases (except cardiogenic cerebral infarction) **[Prompt review]**
		Plavix Tablets 25 mg Plavix Tablets 75 mg （Daiichi Pharmaceutical Co.,Ltd.）	Approval Approval		
3	11-Apr-05	13 Gabalon 0.005% 1 mL Gabalon 0.05% 20 mL Gabalon 0.2% 5 mL (Daiichi Pharmaceutical Co.,Ltd.)	Approval Approval Approval	Baclofen	Drugs with a new route of intrathecal infusion indicated for the treatment of severe spasticity resulting from cerebrospinal diseases **[Orphan drug]**

Category	Date of Approval	Trade Name (Name of Company)	Approval/ Partial change	Name of Ingredient (underlined: new active ingredient)	Notes
3	25-Jul-05	14 Salagen Tablets 5 mg (Kissei Pharmaceutical Co., Ltd.)	Approval	Pilocarpine hydrochloride	Drug with a new route of oral administration indicated for the treatment of symptoms of dry mouth caused by radiotherapy for head and neck cancer
3	30-Sep-05	15 Pacif Capsules 30 mg Pacif Capsules 60 mg Pacif Capsules120 mg (Takeda Pharmaceutical Company Limited)	Approval Approval Approval	Morphine hydrochloride	Drugs with a new formulation, a sustained-release preparation containing morphine hydrochloride given once a day
3	11-Oct-05	16 Luvox Tablets 25 Luvox Tablets 50 (Solvay Seiyaku K.K.) Depromel Tablets 25 Depromel Tablets 50 (Meiji Seika Kaisha, Ltd.)	Partial Partial Partial Partial	Fluvoxamine maleate	A new indication for the treatment of "social anxiety disorder"
3	23-Jan-06	17 Aripiprazole Abilify Tablets 3 mg Abilify Tablets 6 mg Abilify Powder 1% (Otsuka Pharmaceutical Co., Ltd.)	Approval Approval Approval Approval	Aripiprazole	Drugs containing a new active ingredient indicated for schizophrenia, with partial agonist activity at D2 receptor
3	23-Jan-06	18 Paxil Tablets 10 mg Paxil Tablets 20 mg （GlaxoSmithKline K.K.）	Partial Partial	Paroxetine hydrochloride hydrate	A new indication for the treatment of "obsessive compulsive disorder"
4	11-Apr-05	19 Luliconazole (Nihon Nohyaku Co., Ltd.) Lulicon Cream 1% Lulicon Solution1% (Pola Kasei Kogyo KK)	Approval Approval Approval	Luliconazole	Drugs containing a new active ingredient, an imidazole anti-fungal agent
4	11-Apr-05	20 Vfend Tablets 50 mg Vfend Tablets 200 mg Vfend for Intravenous Use 200 mg (Pfizer Japan Inc.)	Approval Approval Approval	Voriconazole	Drugs containing a new active ingredient, a triazole anti-fungal agent
4	25-Jul-05	21 Finibax for Intravenous Infusion 0.25 g Finbax for Intradermal Test (Shionogi & Co., Ltd.)	Approval Approval	Doripenem hydrate	Drugs containing a new active ingredient, a carbapenem antimicrobial agent
4	11-Oct-05	22 Augmentin ES Dry Syrups for Children (GlaxoSmithKline K.K.)	Approval	Clavulante potasium · amoxicillin	A combination prescription drug with a new composition ratio
4	11-Oct-05	23 Avelox Tablets 400 mg (Bayer Yakuhin, Ltd.)	Approval	Moxifloxacin Hydrochloride	A drug containing a new active ingredient, a new quinolone antimicrobial agent
4	14-Oct-05	24 Synagis Intramuscular 50 mg Synagis Intramuscular 100 mg (Abbott Japan Co., Ltd.)	Partial Partial	Palivizumab (genetical recombination)	Drugs with a new indication for preventing serious lower respiratory tract disease caused by RS virus infections in newborns, infants and children under 24 months of age with haemodynamically significant congenital heart disease **[Priority review drug]**
4	23-Jan-06	25 Ozex Ophthalmic Solution 0.3% （Toyama Chemical Co., Ltd.） Tosuflo Ophthalmic Solution 0.3% （Nidek Co., Ltd.）	Approval Approval	Tosufloxacin tosilate	Drugs with a new route of administration (eye drops) indicated for the treatment of blepharitis, dacryoadenitis, hordeolum, conjunctivitis, inflammation of the tarsal glands, inflammation of the cornea (including corneal ulcer), and aseptic treatment during ophthalmic surgery.
4	17-Feb-06	26 Relenza （GlaxoSmithKline K.K.）	Partial	Zanamivir hydrate	A new pediatric dosage regimen indicated for the treatment of influenza virus infection
4	23-Feb-06	27 Gatiflo Tablets 100 mg （Kyorin Pharmaceutical Co., Ltd.）	Partial	Gatifloxacin	A new indication for the treatment of genus Legionella infection **[Notification of off label use]**
4	23-Feb-06	28 Clarith Tablets 200 Clarith Tablets 50 for Pediatric Clarith Dry Syrup for Pediatric (Taisho Pharmaceutical Co., Ltd.) Klaricid Tablets 200 mg Klaricid Tablets 50 mg for Pediatric Klaricid Dry Syrups for Pediatric （Abbott Japan Co., Ltd.）	Partial Partial Partial Partial Partial Partial	Clarithromycin	A new indication for the treatment of genus Legionella infection **[Notification of off label use]**
4	23-Feb-06	29 Ciproxan-I.V.200 Ciproxan-I.V.300 Ciproxan 100 Ciproxan 200 （Bayer Yakuhin, Ltd.）	Partial Partial Partial Partial	Ciprofloxacin Ciprofloxacin hydrochloride	A new indication for the treatment of genus Legionella infection **[Notification of off label use]**
4	23-Feb-06	30 Cravit Tablets Cravit Fine Granules （Daiichi Pharmaceutical Co., Ltd）	Partial Partial	Levofloxacin	A new indication for the treatment of genus Legionella infection **[Notification of off label use]**
5	11-Apr-05	31 Follistim Injection 75 Follistim Injection 150 (Organon-Japan)	Approval Approval	Follitropin beta (genetical recombination)	Drugs containing a new active ingredient, a human follicle-stimulating hormone (genetical recombination), indicated for "regularly stimulating the ovary to develop multiple follicles in
5	23-Jan-06	32 Gonalef 75 (Subcutaneous) Gonalef 150 (Subcutaneous) (Serono Japan Co., Ltd.)	Approval Approval	follitropin alfa （genetical recombination）	Drugs containing a new active ingredient indicated for induction of spermatogenesis in male hypogonadotrophic hypogonadism in combination with human chorionic gonadotropin **[Orphan drug]**
5	23-Jan-06	33 Profasi 5000 (Injection) (Serono Japan Co., Ltd.)	Partial	Chorionic Gonadotrophin	A new indication and a new route of subcutaneous administration for induction of spermatogenesis in male hypogonadotrophic hypogonadism in combination with follitropin alpha **[Prompt review drug]**

Category	Date of Approval	Trade Name (Name of Company)	Approval/ Partial change	Name of Ingredient (underlined: new active ingredient)	Notes
5	23-Jan-06	34 Magsent Injection 100mL （Toa Pharmaceuticals Co., Ltd.）	Approval	magnesium sulfate /glucose	A new indication and new dosage for relaxing the uterus muscles and suppressing preterm labour **[Notification of off label]**
5	23-Jan-06	35 Silodosin "SFL" （Shiono Finesse, Ltd.） Urief Capsules 2mg Urief Capsules 4mg （Kissei Pharmaceutical Co., Ltd.）	Approval Approval Approval	<u>Silodoshin</u>	Drugs containing a new active ingredient indicated for the treatment of urination disorder associated with prostatic hypertrophy
5	3-Mar-06	36 Amigrand Intravenous Infusion （Terumo Corporation） Paresafe for IV. Infusion （Ajinomoto Medica Co., Ltd.)	Approval Approval		A combination prescription drugs containing thiamine hydrochloride combined with peripheral parenteral nutrition
5	3-Mar-06	37 Bfluid for I.V. Infusion （Otsuka Pharmaceutical Factory, Inc.)	Approval		A combination prescription drug containing thiamine hydrochloride combined with peripheral parenteral nutrition
6	11-Apr-05	38 Prograf Capsules 0.5 mg Prograf Capsules 1 mg (Astellas Pharma Inc.)	Partial Partial	Tacrolimus hydrate	A new indication for the treatment of articular rheumatism (only where conventional treatments are inadequate)
6	11-Oct-05	39 Papilock Mini Ophthalmic Solution 0.1% (Santen Pharmaceutical Co., Ltd.)	Approval	Ciclosporin	Eye drops indicated for the treatment of spring catarrh (where treatment with anti-allergic agents is inadequate) **[Orphan drug]**
6	22-Dec-05	40 Voltaren (Novartis Pharma K.K.) Sorelmon Tablets. (Towa Pharmaceutical Co., Ltd.) Volmagen Tablets (Taisho Pharm. Ind. Ltd.) Adefuronic (Taiyo Yakuhin Co., Ltd.) Blesin Tablets (Sawai Pharmaceutical Co., Ltd.)	Partial Partial Partial Partial Partial	Diclofenac Sodium	A new indication for the treatment of “toothache”, the format of the indication for "rheumatoid arthritis" was coordinated. **[Notification of off label use]**
6	22-Dec-05	41 Loxonin Tablets, Loxonin Fine Granules (Sankyo Co., Ltd.) Ollox Oral Solution 60 mg (Teikoku Medix Co., Ltd.) Lobu Tablets (Ohara Pharmaceutical Co., Ltd.) LoxipainTablets 60 mg (Kyowa Pharmaceutical) Threenofen Tablets (Asuka Pharmaceutical Co., Ltd.) Loxoprofen Sodium Tablets "Kunihiro" 60 mg (Kokando Pharmaceutical Co., Ltds) Cobalokinin Tablets (Kobayashi Kako Co., Ltd.) Letrac Tablets 60 mg (Sanwa Kagaku Kenkyusho Co., Ltd.) Loxomarin Tablets (Taisho Pharm. Ind. Ltd.) Roseol Tablets, Roseol Fine Granules (Tatsumi Kagaku Co., Ltd.) Lokiflan Tablets, Lokiflan Fine Granuales (Choseido Pharmaceutical Co., Ltd.) Tsurumerin Tablets (Tsuruhara Pharmaceutical Co., Ltd.) Confatanin Tablets (Towa Pharmaceutical Co., Ltd.) Lorfenamin Tablets, Lorfenamin Fine Granules (Nichi-Iko Pharmaceutical Co., Ltd.) Loxot Tablets (Nissin Pharmaceutical Co., Ltd.) Kentan Tablets, Kentan Fine Granules (Medisa Shinyaku Inc.) Unastin Tablets (Merck Hoei Ltd.) Ringereaze Tablets (Yoshindo Inc.) Rokifen Tablets 60 mg (Ryukakusan Co., Ltd.) Syllable Tablets (Taiyo Yakuhin Co., Ltd.) Loxipronal Tablets (Kotobuki Pharmaceutical Co., Ltd.)	Partial Partial	Sodium loxoprofen	A new indication for the treatment of “toothache”, the format of the indication for "rheumatoid arthritis" was coordinated. **[Notification of off label use]**

Category	Date of Approval	Trade Name (Name of Company)	Approval/ Partial change	Name of Ingredient (underlined: new active ingredient)	Notes
6	23-Jan-06	42 Loxonin Pap 100mg (Lead Chemical Co., Ltd.)	Approval	Loxoprofen Sodium	A drug with a new route of administration indicated for the treatment of osteoarthritis, myalgia, post-traumatic swelling/pain and anti-inflammatory/analgesic effects on these symptoms
Radiopharma-ceuticals	25-Jul-05	43 FDGscan Injectable (Nihon Mediphysics Co., Ltd.) FDGscan-MP Injectable (The Medical & Pharmacological Research Center Foundation)	Approval Approval	fludeoxyglucose (F18)	Drugs containing a new active ingredient used for making a diagnosis of malignant tumors accompanied by accelerated glucose metabolism, ischemic heart diseases or epilepsy
In vivo diagnostics	11-Apr-05	44 Adenoscan Injection 60mg Adenoscan Injection 90mg (Daiichi Suntory Pharma Co., Ltd.)	Approval Approval	adenosine	Drugs containing a new active ingredient used for load induction to make a diagnosis of heart disease based on myocardial perfusion scintigraphy in patients unable to tolerate sufficient exercise load
In vivo diagnostics	11-Oct-05	45 Inulin (Kanto Kagaku) Inulead Injection (Fujiyakuhin Co., Ltd.)	Approval Approval	Inulin	Drugs containing a new active ingredient used for renal function tests based on measurement of glomerular filtration rate
Oncology drugs	11-Apr-05	46 Tamibarotene "Toko" Amnolake Tablet 2 mg (Toko Pharmaceutical Industrial Co., Ltd.)	Approval Approval	tamibarotene	Drugs containing a new active ingredient indicated for the treatment of acute promyelocytic leukemia **[Orphan drug]**
Oncology drugs	31-May-05	47 Navelbine Injection 10 Navelbine Injection 40 (Kyowahakko Co., Ltd.)	Partial Partial	Vinorelbine ditartrate	A new indication for the treatment of inoperable or recurrent breast cancer, in addition to the current indication for lung cancer
Oncology drugs	31-May-05	48 Taxol Injection (Bristol Seiyaku KK)	Partial	Paclitaxel	A new indication for the treatment of cancer of the uterus body, in addition to the current indications for ovarian cancer, non-small-cell lung cancer, breast cancer and stomach cancer
Oncology drugs	25-Jul-05	49 Mylotarg Injection 5 mg (Wyeth K.K.)	Approval	Gemtuzumab Ozogamicin (Genetical Recombination)	A drug containing a new active ingredient indicated for the treatment of relapsing or intractable CD33 positive acute myeloid **[Orphan drug]**
Oncology drugs	18-Aug-05	50 Taxotere Injection (Aventis Pharma Ltd.)	Partial	Docetaxel hydrate	A new indication for the treatment of "cancer of the uterus body", in addition to the current indications for ovarian cancer, non-small-cell lung cancer, breast cancer, stomach cancer, head and neck carcinoma, and esophageal carcinoma
Oncology drugs	18-Aug-05	51 Leuplin SR For Injection Kit 11.25 (Takeda Pharmaceutical Company Limited)	Partial	leuprorelin acetate	A new indication for the treatment of "premenopausal breast cancer", in addition to the current indication for prostatic cancer
Oncology drugs	15-Sep-05	52 Endoxan Injection 100 mg Endoxan Injection 500 mg (Shionogi & Co., Ltd.)	Partial Partial	Cyclophosphamide	A new indication and a new dosage regimen in combination with other anti-cancer agents for the treatment of breast cancer **[Combination chemotherapy with anti-cancer drgs]**
Oncology drugs	15-Sep-05	53 Farmorubicin Injection Farmorubicin RTU Inj (Pfizer Japan Inc.) Epirubicin Hydrochloride Injection 10 mg "Merck" Epirubicin Hydrochloride Injection 50 mg "Merck" (Merck Hoei Ltd.)	Partial Partial Partial Partial	Epirubicin hydrochloride	A new indication and a new dosage regimen in combination with other anti-cancer agents for the treatment of breast cancer **[Combination chemotherapy with anti-cancer drgs]**
		Endoxan Injection 100 mg Endoxan Injection 500 mg (Shionogi & Co., Ltd.)	Partial Partial	Cyclophosphamide	
Oncology drugs	15-Sep-05	54 Randa Injection (Nippon Kayaku Co., Ltd.) Briplatin Injection (Bristol Seiyaku KK) Platosin Injection 10 Platosin Injection 25 Platosin Injection 50 (Pfizer Japan Inc.) Cisplatin Injection "Maruko" (Maruko Pharmaceutical Co., Ltd.) Cisplamerck Injection 0.05% (Merck Hoei Ltd.)	Partial Partial Partial Partial Partial Partial Partial	Cisplatin	A new indication and a new dosage regimen in combination with other anti-cancer agents for the treatment of malignant lymphoma **[Combination chemotherapy with anti-cancer drgs]**
		Solu-Medrol 40 Solu-Medrol 125 Solu-Medrol 500 (Pfizer Japan Inc.) Decacort 125 Decacort 500 (Sawai Pharmaceutical Co., Ltd.) Sol-melcort Injection 40 Sol-melcort Injection 125 Sol-melcort Injection 500 (Fuji Pharma Co., Ltd.) Pridol for Injection 40 Pridol for Injection 125 Pridol for Injection 500 (Sankyo Yell Yakuhin Co., Ltd.)	Partial Partial Partial Partial Partial Partial Partial Partial Partial Partial Partial	Methylprednisolone sodium succinate	

Category	Date of Approval		Trade Name (Name of Company)	Approval/ Partial change	Name of Ingredient (underlined: new active ingredient)	Notes
Oncology drugs	15-Sep-05	55	Randa Injection (Nippon Kayaku Co., Ltd.)	Partial	Cisplatin	A new indication and a new dosage regimen in combination with other anti-cancer agents for the treatment of malignant solid tumors of childhood **[Combination chemotherapy with anti-cancer drgs]**
			Briplatin Injection (Bristol Seiyaku KK)	Partial		
			Platosin Injection 10	Partial		
			Platosin Injection 25	Partial		
			Platosin Injection 50 (Pfizer Japan Inc.)	Partial		
			Cisplatin Injection "Maruko" (Maruko Pharmaceutical Co., Ltd.)	Partial		
			Cisplamerck Injection 0.05% (Merck Hoei Ltd.)	Partial		
			Paraplatin For Injection 150 mg	Partial	Carboplatin	
			Paraplatin Injection (Bristol Seiyaku KK)	Partial		
			Carbomerck for Injection 1% (Merck Hoei Ltd.)	Partial		
			Carboplatin Injection 1% (Nippon Hexal Corporation)	Partial		
			Cosmegen (Banyu Pharmaceutical Co., Ltd.)	Partial	Actinomycin D	
Oncology drugs	15-Sep-05	56	Decadron Tablets (Banyu Pharmaceutical Co., Ltd.)	Partial	Dexamethasone	A new indication and a new dosage regimen for the treatment of gastrointestinal (nausea, vomiting) symptoms associated with administration of antitumor agents **[Combination chemotherapy with anti-cancer drgs]**
			Dexamethasone Tablets 0.5 mg "Taiyo" (Taiyo Yakuhin Co., Ltd)	Partial		
			Decadron Phosphate Injection	Partial	Dexamethasone Sodium Phosphate	
			Orgadrone Injection (Banyu Pharmaceutical Co., Ltd.)	Partial		
			Dexart Injection (Fuji Pharma Co., Ltd.)	Partial		
Oncology drugs	14-Nov-05	57	TS-1 Capsule 20	Partial	Tegafur/Gimeracil/Oteracil potassium	A new indication for the treatment of “inoperable or recurrent breast cancer”
			TS-1 Capsule 25 (Taiho Pharmaceutical Co., Ltd.)	Partial		
Oncology drugs	23-Jan-06	58	Femara	Approval	Letrozole	Drugs containing a new active ingredient indicated for the treatment of post-menopausal breast cancer
			Femara 2.5 mg Tablet （Nihon Ciba-Geigy K.K.. ）	Approval		
Biological products	25-Jul-05	59	Mearubik (The Research Foundation for Microbial Diseases of Osaka University)	Approval	Freeze-dried live attenuated measles and rubella combined	A combination of two vaccines used for prevention against measles and rubella
Biological products	14-Oct-05	60	Freeze-Dried Live Attenuated Measles and Rubella Combined Vaccine "Takeda" (Takeda Pharmaceutical Company Limited)	Approval	Freeze-dried live attenuated measles and rubella combined	A combination of two vaccines used for prevention against measles and rubella

Table-19. A List of Approved Articles in 2005 (New Medical Devices)

Category	Date of Approval	Trade Name (Name of Company)	Approva /Partial	Classification Japanese Accepted Name	Notes
4	6-Jul-05	1 Contak CD, and another trade name (Guidant Japan KK)	Approva	Other cardioverter defibrillator and related equipment (implantable biventricular pacing pulse generator with a cardioverter defibrillation)	The first chest-implantable pulse generator capable of providing CRT equipped with cardioverter defibrillative functions . CRT (Cardiac Resynchronization Therapy : Therapy to relieve symptoms associated with cardiac failure. Provides biventricular electrical stimulation over long hours to synchronize the ventricular contractions.)
4	6-Jul-05	2 Contak CRTD, and another trade name (Guidant Japan KK)	Approva	Other cardioverter defibrillator and related equipment (implantable biventricular pacing pulse generator with a cardioverter defibrillation)	Same as above
4	6-Jul-05	3 Easytrack Lead, and another trade name (Guidant Japan KK)	Approva	Other heart pacemaker (iImplantable cardioverter defibrillator/pacemaker lead)	The first OTW(Over The Wire) type lead (used with CONTAK CD, etc., a chest implantable pulse generator for CRT)
4	6-Jul-05	4 Easytrack CS, and another trade name (Guidant Japan KK)	Approva	Other heart pacemaker (implantable cardioverter defibrillator/pacemaker lead)	Same as above
4	6-Jul-05	5 Attain OTW Lead (Medtronic Japan Co., Ltd.)	Approva	Lead for an implantable heart pacemaker	The first OTW (over the wire) type lead to be used with an implantable cardiac pacemaker with a port for a left ventricular lead
4	20-Jul-05	6 Medtronic InSync 8040 (Medtronic Japan Co., Ltd.)	Partial	Lead for an Implantable heart pacemaker	Addition of OTW type lead (Attain OTW lead) to list of leads usable with implantable heart pacemaker for CRT [Partial change during re-examination period]
4	15-Nov-05	7 Medtronic InSync ICD (Medtronic Japan Co., Ltd.)	Approva	Other cardioverter defibrillator and related equipment (implantable biventricular pacing pulse generator with a cardioverter defibrillation)	The first chest-implantable pulse generator capable of providing CRT equipped with cardioverter defibrillative functions . CRT (Cardiac Resynchronization Therapy : Therapy to relieve symptoms associated with cardiac failure. Provides biventricular electrical stimulation over long hours to synchronize the ventricular contractions.)
4	15-Nov-05	8 Attain Lead (Medtronic Japan Co., Ltd.)	Partial	Lead for an Implantable heart pacemaker	Medtronic InSync ICD is added to list of devices usable with this lead [Partial change during the re-examination period]
5	8-Dec-05	9 Cool-tip RF System (Tyco Healthcare)	Approva l	Electric surgical instrument	A device with a new indication for coagulating hepatic tumor by high-frequency current of the radio-frequency waves (480 kHz). Since the attached electrode is of the straight needle type with beveled tip, the intermittent high-frequency electrification as well as the internal electrode cooling mechanism are adopted in order to prevent an increase in temperature at the tip. [Prompt review]
5	9-Dec-05	10 Cool-tip RF System (Valleylab, a division of Tyco Healthcare Group LP)	Partial	Electric surgical instrument for treatment	Electric surgical instrument on high-frequency current of radio-frequency waves (480 kHz), the indication of which was changed to "for coagulating hepatic tumor" [Prompt review]
6	1-Mar-06	11 Super Fixsorb 30, and another trade (TAKIRON Co., LTD.)	Partial	absorbable osteosynthesis device	Addition of shapes (product with medium size, larger core diameter), dye (marker) and packaging materials to absorbable osteosynthesis devices (major ingredients: poly lactic acid, hydroxyapatite) [Partial change in the approved items during the re-examination period]

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
2005	24,751	65,316	3,992	94,059	971

Note1: 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.

Note2: 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
2005	6,222	5,012	445	12,152	37

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 2005

Measures for safety strategies implemented by the Ministry of Health, Labour and Welfare in 2005

	Pharmaceuticals	Medical devices
Designated revisions to precautions on use	251	7
Description of information on "Pharmaceuticals and Medical Devices Safety Information"	31	7

* Including notifications of self-assesment on medical devices.

Revision of "Precaution on use" related to pharmaceuticals
Designations in FY 2005

Date	Name of pharmaceuticals
April 1, 2005	1 .Torasemide 2 .Candesartan cilexetil Telmisartan Valsartan Losartan potassium 3 .Ceftriaxone sodium (CTRX) 4 .Japanese encephalitis vaccine 5 .Difteria Pertussis Tetanus vaccine (DPT) 6 .Fradiomycin sulfate (FRM)・Methyl predonisolone Betamethasone sodium phosphate・Fradiomycin sulfate (FRM)[Eye Oint ment (EO)] 7. Olmesartan medoxomil 8. Infliximab (recombinant) 9. Tribenoside 10.Iodoform 11.Betamethasone valerate・Fradiomysin sulfate (FRM) 12.Azathioprine (AZP) 13.Saikokeishikankyo-to- 14.(O.T.C.) Saikokeishikankyo-to- 15.Sammotsuo-gonto- 16.(O.T.C.) Sammotsuo-gonto- 17.Bo-i o-gonto- 18.(O.T.C.) Bo-i o-gonto- 19.Rikkunshito- 20.(O.T.C) Rikkunshito- (Medicine manufacturing which the maximum mixture amo unt on 1 day contains by equal to or more than 1 g (converting to the primordial medicine, extract drug will be equal to or more than 1 g) as the licorice) 21.(O.T.C) Rikkunshito- (Medicine manufacturing which the maximum mixture amo unt on 1 day does not contains by equal to or more than 1 g (converti ng to the primordial medicine, extract drug will be equal to or more

	than 1 g) as the licorice) 22.Peginterferon alfa-2a (genetical recombination) 23.Fentanyl citrate

Date	Name of pharmaceuticals
May 11, 2005	1 .Donepezil hydrochloride 2 .Alprostadil Alprotadil alfadex (PEG_1) (20μg injection) 3 .Leuprorelin acetate 4 .Lopinavir・Ritonavir 5 .Cabergoline 6 .Nifekalant hydrochloride 7 .Pitavastatin calcium 8 .Limaprost alfadex 9 .Dextromethorphan hydrobromide Dextromethorphan hydrobromide・Cresol potassium sulfonic acid 10.Vardenafil hydrochloride hydrate 11.Zoledronic acid hydrate 12.Ramatroban 13.Tosufloxacin tosilate (TFLX) 14.Atazanavir sulfate (ATV) 15.Avacavir sulfate (ABC) Amprenavir Indinavir sulfate ethanolate (IDV) Efavirenz (EFV) Sanilvudine (d4T) Zalcitabine (ddC) Didanosine (ddI) Zidovudine (AZT) Delavirdine mesilate Nevirapine (NVP) Nelfinavir Mesilate (NFV) Ritonavir 16.Saquinavir (SQV) Saquinavir mesilate 17.Zidovudine・Lamivudine (AZT/3TC) 18.Fosamprenavir calcium hydrade 19.Lamivudine(3TC) (150mg、300mg) 20.Lamivudine・avacavir sulfate (3TC/ABC)

Date	Name of pharmaceuticals
June 15, 2005	1 .Etodolac 2 .Omeprazole Omeprasole sodium 3 .Gemcitabine hydrochloride 4 .Ethionamide 5 .Tiaprofenic acid 6 .Loxoprofen sodium 7 .Paroxetine hydrochoride 8 .Fluticasone propionate [nose drops] 9 .Alacepril Imidapril hydrochloride Enalapril maleate Captopril Quinapril hydrochloride Temocapril hydrochloride Delapril hydrochloride Trandolapril Benazepril hydrochloride Perindopril erbumine Lisinopril 10.Cilazapril 11.Salmeterol xinefoate 12.Fluticasone propionate [inhalant] 13.Lac-B Lac-B fine grain 14.Thiamazole (MMI) 15.Estoladiol preparation（Medicine which has the effect of the climacteric-disorder） Estriol preparation（Medicine which has the effect of the climacteric-dis order） Androgen・estrogen mixed preparation 16.conjugated estrogens 17.Camostat mesilate 18.Methotrexate (MTX)（Medicine which has the effect of the arthrit is rheumatoides） 19.Capeciabine 20.Docetaxel hydrate (DOC/TXT) 21.Cisplatin (CDDP/DDP) [hepatic artery infusion] 22.Salazosulfapyridine

Date	Name of pharmaceuticals
July 20, 2005	1 .Sodium valprorate (VPA) 2 .Pranoprofen [oral administration] 3 .Hochu-ekkito- 4 .Carbamazepine (CBZ) 5 .Tizanidine hydrochloride 6 .Colestimide 7 .Bufexamac 8 .(O.T.C.) Formulations containing bufexamac 9 .Polidocanol 10.Metformin hydrochloride 11.Syo-seiryu-to- 12.(O.T.C.) Syo-seiryu-to- 13.(O.T.C) Hotyu-ekkito- 14.Ciprofloxacin Ciprofloxacin hydrochloride (CPFX) 15.Oseltamivir phosphate 16.nicotine
August 24, 2005	1 .O.T.C. Formyulations containing Zedoary rhizome・Japanese Kelp powder 2 .Paroxetine hydrochloride 3 .Pimozide 4 .Fluvoxamine maleate 5 .Norethisterone 6 .Norethisterone・Mestranol Norethisterone・ethinylestradiol 7 .Aluminium potassium sulfate・Tannic acid 8 .Pioglitazone hydrochloride 9 .Bucillamine 10.Fentanyl

Date	Name of pharmaceuticals
August 24, 2005	1 .(O.T.C.) Deet
September 15, 2005	1 .Cytarabine (Ara-C) (Medicine for high dose therapy) 2 .Dexamethasone [oral agent] (Medicine which does'nt have effect on digestive organ symptom which accompanies anti-malignant tumor drug administration) Dexamethasone acetate Dexamethasone sodium phosphate [injection] (Medicine which does'nt have the effect on lymphoma malignum) 3 .Dexamethasone palmitate 4 .Dexamethasone sodium metasulufobenzoate [injection] 5 .Dexamethasone sodium phosphosphate [injection] (Medicine which have the effect on lymphoma malignum)
September 28, 2005	1 .Fludarbine phosphate 2 .Barium sulfate (Excluding medicine for CT) 3 .Bepridil hydrochloride 4 .Ritodrine hydrochloride [oral agent] 5 .Ritodrine hydrochloride [injection] 6 .Elental Elental P Enterued Twinline 7 .Pneumococcal vaccine (Medicine which have the effect on lymphoma malignum)
October 17, 2005	1 .Sodium prasterone sulfate[injection] 2 .Sodium prasterone sulfate [ovule]

Date	Name of pharmaceuticals
November 2, 2005	1 .Sevofrane 2 .Phenitoin (PHT) Phenitoin sodium 3 .Phenitoin・phenobarbital Phenitoin・phenoberbital・caffeine sodium benzoate 4 .Amiodarone hydrochloride 5 .Carboplatin 6 .Whole human blood Synthetic blood Fresh frozen human plazma Human platelet concentrate Human concentrated red cells Frothen-thawed human red cells Washed human red blood cells suspension Human leucocyte poor red blood cell suspension 7 .Zopiclone 8 .Chlorpromazine hydrochoride Chlorpromazine hibenzate Chlorpromazine phenolphthalinate 9 .Chlorpromazine hydrochoride・Promethazine hydrochoride・Phenobarbital 10.Levomepromazine hydrochoride Levomepromazine maleate 11.Spironolactone 12.(O.T.C.) Formulations containing famotidine 13.Aminoleban EN 14.Sarpogrelate hydrochoride 15.Levofolinate calcium (l-LV) 16.Tegafur gimeracil oteracil potassium mixure 17.Minocycline hydrochloride (MINO) [oral agent, injection] 18.Linezolid (LZD) 19.Terbinafine hydrochloride [oral agent]

Date	Name of pharmaceuticals
December 2, 2005	1 .Ibuprofen 2 .Zaltoprofen 3 .Chlorpromazine Hydrochoride Chlorpromazine・Promethazine hydrochoride・Phenobaebital Chlorpromazine hibenzate Chlorpromazine Phenolohthalinate 4 .Levomepromazime hydrochoride Levomepromazine maleate 5 .Glimepiride 6 .Arsenic trioxide 7 .Cefcapene pivoxil hydrochloride(CFPN-PI)（subtle granule for infants） Cefditoren pivoxil (subtle granule for infants) Cefeteram pivoxil(subtle granule for infants) 8 .Living Calmette-Guelin Bacillus（BCG）・connote strain
December 14, 2005	1 .Amino phylline [oral agent] Choline theophylline 2 .Amino phylline [injection] 3 .amino phylline [suppositories] 4 .Theophylline [oral sustained release form] （Medicine which has the dosage and administration for infants） 5 .Theophylline[oral sustained release form] （Medicine which does’nt have the dosage and administration for infants） 6 .Theophylline [injection]

Date	Name of pharmaceuticals
January 13, 2006	1. Paroxetine hydrochloride 2. Amitriptyline hydrochoride 3. Amoxapine 4. Imipramine hydrochoride Clomipramine hydrochoride [oral agent] 5. Clomipramine hydrochoride [injection] 6. Setiptilinemalate Dosulepin hydrochoride Trimipramina malate Lofepramine hydrochloride 7. Trazodone hydrochloride 8. Nortriptyline hydrochoride 9. Fluvoxamine maleate 10. Maprotiline hydrochoride 11. Mianserin hydrochloride 12. Milnacipran hydrochloride 13. Riluzole 14. Indapamide 15. (O.T.C.) Ephedra・Glycyrriza・Apricot kernel・Kanbo-i・Coicis semen Ephedra・Apricot kernel・Coicis semen・Glycyrriza・Sinomenium stem・Animal bile 16. (O.T.C.) Formulation containing Theophylline, Aminophylline（Medicine which has the dosage and administration for infants）
January 27, 2006	1. Paroxetine hydrochloride 2. Pemoline
February 17, 2006	1. Selegiline hydrochloride 2. Lornoxicam 3. Ceftazime (CAZ) 4. Albendazole 5. (O.T.C.) Bacitracin・Fladiomycin sulfate・Hydrocortizone acetate

Date	Name of pharmaceuticals
March 24, 2006	1. Aspirin [excluding enteric coated tablet] （Medicine which has the effect for Kawasaki disease） 2. Aspirin [excluding enteric coated tablet] （Medicine which does'nt have the effect for Kawasaki disease Aspirin・Ascorbic acid Aspirin・Dialuminate（330ｍｇ） 3. Tiqizium Bromide 4. Triamcinolone acetanide [injection] 5. Dalteparin sodium Parnaparin sodium Reviparin sodium 6. Heparin calcium Heparin sodium [injection] （medicine which does'nt have the effect of the prevention of the blood clotting in the endovenous custody route） 7. Heparin sodium [injection] （medicine which have the effect of the prevention of the blood clotting in the endovenous custody route） 8. Aspirin [enteric coated tablet] Aspirin・dialuminate（81ｍｇ） 9. Norchorestenol iodomethyl [^{131}I] 10. (O.T.C.) Mecobalamin・folic acid・d-α-tocopherol acetate・Fursultiamine hydrochloride・Pyridoxine hydrochloride 11. Piperidolate hydrochoride 12. Eptazocine hydrobromide 13. Isosorbide dinitrate(ISDN) [patch] Nitroglycerin [ointment, patch] 14. Salometerol xinafoate 15. Elgometrine maleate [oral agent] 16. Elgometrine maleate [injection] 17. Diclofenac sodium [dermatologic agent] 18. Calcipotriol

*Detailed information is available at our Information Website

Table-22: Revision of the "Precautions on Use" in relation to medical devices in 2005

Revisions ordered by MHLW and notification of self-assessment

Revision of the "Precautions on Use" in relation to medical devices in 2005

Date	Heading
22-Aug-05	Orders of revision of the Precautions in relation to magnetic resonance imaging appliances
25-Nov-05	Orders of revision of the Precautions in relation to interactions between X-ray computed tomography and implantable cardiac pacemakers
25-Nov.05	Appeal for attention to the use of implantable cardiac pacemakers (THERA series) made by Medtronic Inc.
02-Dec-05	Revision of the Precautions in relation to electronic surgical instruments used with radio-frequency ablation (RFA)
3-Mar-06	Handling of the puncture device for blood collection (with a needle of non-disposable type)
31-Mar-06	Orders of revision of the Precautions in relation to interactions between so-called "smart key system" and implantable cardiac pacemakers
31-Mar-06	Dissemination of information in relation to interactions between so-called "smart key system" and an implantable cardiac pacemaker [Request]

Detailed information is available at our Information Website

"Notification of self-assessment" in relation to medical devices in 2005

Revisions ordered by MHLW in 2005

Date	Heading
26-Oct-05	Request for cooperation to survey and test motor vehicles with a wireless key system
26-Oct-05	Self-inspections, etc. of the effects of radio waves on implantable cardiac pacemakers and others

Detailed information is available at our Information Website

Table-23: Pharmaceuticals and medical devices safety information (N0. 212-223) in 2005

Date	No.	Contents
27-Apr-05	212	1. Results of investigations in the expert meeting on gefitinib 2. An outline of self-inspection notifications issued from April 2004 to February 2005 3. Request for cooperation in early post-marketing surveillance
26-May-05	213	1. Effects of X-ray computed tomography on implantable cardiac pacemakers (Medtronic InSync 8040) 2. Information on clinically significant adverse reactions, etc. 1. Candesartan cilexetil, telmisartan, valsartan, losartan potassium 2. Ceftriaxone sodium 3. Adsorbed diphtheria-purified pertussis-tetanus combined vaccine 4. Torasemide 5. Japanese encephalitis vaccine 3. Revision of the Precautions (165) Fradiomycin sulfate/methylprednisolone betamethasone sodium phosphate/fradiomycin sulfate (eye ointment) and others (19 preparations) 4. A list of drugs subject to early post-marketing surveillance
23-Jun-05	214	1. Information on clinically significant adverse reactions 1. Alprostadil, alprostadil alfadex (Injection 20 μg) 2. Donepezil hydrochloride 3. Leuprorelin acetate 4. Lopinavir/ritonavir 2. Revision of the Precautions (166) Cabergoline and others (15 preparations) 3. A list of drugs subject to early post-marketing surveillance
27-Jul-05	215	1. Information on clinically significant adverse reactions 1. Ethionamide 2. Etodolac 3. Gemcitabine hydrochloride 4. Omeprazole, omeprazole sodium 2. Revision of the Precautions (167) Tiaprofenic acid and others (15 preparations) 3. A list of drugs subject to early post-marketing surveillance
25-Aug-05 (continued on the following page)		1. Serious health damage attributed to the use of bone cement 2. Effects of the terminals of cellular phones equipped with a new system or RFID instrument on implantable medical devices (cardiac pacemaker and defibrillator) 3. Information on clinically significant adverse reactions 1. Sodium valproate

Date	No.	Contents
25-Aug-05 (continued from the previous page)	216	2. Pranoprofen (oral preparation) 3. Hochuekkito extract 4. Revision of the Precautions (168) Carbamazepine and others (12 preparations) 5. A list of drugs subject to early post-marketing surveillance
29-Sep-05	217	1. Reports, etc. on adverse reactions caused by influenza vaccine in 2004 2. Information on clinically significant adverse reactions 1. Preparations containing gajutu powder /laminaria powder 3. Revision of the Precautions (169) Paroxetine hydrochloride hydrate and others (9 preparations) 4. A list of drugs subject to early post-marketing surveillance
27-Oct-05	218	1. Results of the post marketing safety measures for Cypher stent in combination with ticlopidine hydrochloride preparations 2. Serious skin damage caused by pharmaceuticals 3. A list of drugs subject to early post-marketing surveillance
24-Nov-05	219	1. Information on clinically significant adverse reactions 1. Barium sulfate (except preparations used for CT) 2. Fludarabine phosphate 2. Revision of the Precautions (170) Bepridil hydrochloride and others (11 revisions) 3. A list of drugs subject to early post-marketing surveillance (reference materials) A view of pharmacogenomics
22-Dec-05	220	1. Information on clinically significant adverse reactions 1. Amiodarone hydrochloride 2. Carboplatin 3. Sevoflurane 4.Whole blood, blood for exchange transfusion, fresh frozen plasma, concentrated platelets, concentrated red blood cells, frozen thawed concentrated red blood cells, washed red blood cell suspension, leukocyte poor red cell suspension 5.Phenytoin, phenytoin sodium, phenytoin/phenobarbital, phenytoin/phenobarbital/caffeine and sodium benzoate 2. Revision of the Precaution (171) Zopiclone and others (12 preparations) 3. A list of drugs subject to early post-marketing surveillance

Date	No.	Contents
26-Jun-06	221	1. Proper use of theophylline for children with bronchial asthma 2. Effects of X-ray computed tomography on implantable cardiac pacemakers 3. Revision of the Precaution (172) (1) Ibuprofen and others (13 preparations) (2) Electric surgery instruments used with radio-frequency ablation 4. A list of drugs subject to early post-marketing surveillance
23-Feb-06	222	1. Pharmaceutical guide for patients 2. Revision of the Precaution (173) Amoxapine and others (16 preparations) 3. A list of drugs subject to early post-marketing surveillance
23-Mar-06	223	1. Information on clinically significant adverse reactions 1. Selegiline hydrochloride 2. Revision of the Precautions (174) Lornoxicam and others (3 preparations) 3. A list of drugs subject to early post-marketing surveillance

Detailed information is available at our Information Website

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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