Provisional Translation (as of August 2025).
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Revised on May 20, 2022

User fees for reviews, etc. of pharmaceuticals, quasi-drugs, and cosmetics based on the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960)

Note) The lower rows in the “User fees” column indicate the applicable articles of the Cabinet Order on Fees related to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices.

(unit: yen)

Category			User fees		
			Review	Conformity	Total
Assessment for manufacturing license of drugs					
New license		On-site		159,900 Article 31, Paragraph 1, Item 1 (a)	159,900
		Document-based		120,400 Article 31, Paragraph 1, Item 1 (b)	120,400
Renewal of existing license		On-site		105,200 Article 31, Paragraph 1, Item 2 (a)	105,200
		Document-based		59,700 Article 31, Paragraph 1, Item 2 (b)	59,700
Change/addition of classification		On-site		105,200 Article 31, Paragraph 1, Item 3 (a)	105,200
		Document-based		59,700 Article 31, Paragraph 1, Item 3 (b)	59,700
Assessment for foreign manufacturers' accreditation of drugs					
New accreditation		On-site		143,900 + overseas travel expenses Article 31, Paragraph 2, Item 1 (a)	143,900 + overseas travel expenses
		Document-based		62,600 Article 31, Paragraph 2, Item 1 (b)	62,600
Renewal of existing accreditation		On-site		69,700 + overseas travel expenses Article 31, Paragraph 2, Item 2 (a)	69,700 + overseas travel expenses
		Document-based		42,900 Article 31, Paragraph 2, Item 2 (b)	42,900
Change/addition of classification		On-site		69,700 + overseas travel expenses Article 31, Paragraph 2, Item 3 (a)	69,700 + overseas travel expenses
		Document-based		42,900 Article 31, Paragraph 2, Item 3 (b)	42,900

Note) The lower rows in the “User fees” column indicate the applicable articles of the Cabinet Order on Fees related to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices.

(unit: yen)

Category				User fees		
				Review	Conformity	Total
Review for approval of drugs (new approval)						
New drugs (No. 1)		Non-orphan drugs	First application products	36,538,400 Article 32, Paragraph 1, Item 1 (a) (1)	10,363,300 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 1 (a)	46,901,700 (+ overseas travel expenses *1)
			Line extension products	3,784,700 Article 32, Paragraph 1, Item 1 (a) (3)	2,590,500 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 1 (c)	6,375,200 (+ overseas travel expenses *1)
		Orphan drugs	First application products	30,618,800 Article 32, Paragraph 1, Item 1 (a) (2)	5,191,600 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 1 (b)	35,810,400 (+ overseas travel expenses *1)
			Line extension products	3,166,400 Article 32, Paragraph 1, Item 1 (a) (4)	1,292,500 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 1 (d)	4,458,900 (+ overseas travel expenses *1)
New drugs (No. 2)		Non-orphan drugs	First application products	17,438,300 Article 32, Paragraph 1, Item 1 (a) (5)	3,891,500 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 1 (e)	21,329,800 (+ overseas travel expenses *1)
			Line extension products	1,803,600 Article 32, Paragraph 1, Item 1 (a) (7)	973,100 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 1 (g)	2,776,700 (+ overseas travel expenses *1)
		Orphan drugs	First application products	14,354,900 Article 32, Paragraph 1, Item 1 (a) (6)	1,947,100 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 1 (f)	16,302,000 (+ overseas travel expenses *1)
			Line extension products	1,542,200 Article 32, Paragraph 1, Item 1 (a) (8)	489,900 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 1 (h)	2,032,100 (+ overseas travel expenses *1)
Generic drugs			Subject to inspection	649,100 Article 32, Paragraph 1, Item 1 (a) (9)	346,700 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 1 (i)	995,800 (+ overseas travel expenses *1)
			Not subject to inspection	649,100 Article 32, Paragraph 1, Item 1 (a) (9)		649,100
BTC/OTC drugs	Switch OTC drugs, etc.	Subject to inspection	First application products	1,627,300 Article 32, Paragraph 1, Item 1 (a) (10)	346,700 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 1 (i)	1,974,000 (+ overseas travel expenses *1)
			Line extension products	1,627,300 Article 32, Paragraph 1, Item 1 (a) (10)	346,700 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 1 (i)	1,974,000 (+ overseas travel expenses *1)
		Not subject to inspection	First application products	1,627,300 Article 32, Paragraph 1, Item 1 (a) (10)		1,627,300
			Line extension products	1,627,300 Article 32, Paragraph 1, Item 1 (a) (10)		1,627,300
		One product with several proprietary names	First application products	1,505,200 Article 32, Paragraph 1, Item 1 (a) (11)		1,505,200
			Line extension products	1,505,200 Article 32, Paragraph 1, Item 1 (a) (11)		1,505,200
	Others	Subject to inspection		324,200 Article 32, Paragraph 1, Item 1 (a) (12)	346,700 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 1 (i)	670,900 (+ overseas travel expenses *1)
		Not subject to inspection		324,200 Article 32, Paragraph 1, Item 1 (a) (12)		324,200
		One product with several proprietary names		230,400 Article 32, Paragraph 1, Item 1 (a) (13)		230,400
Quasi-drugs		New active ingredients		4,069,100 Article 32, Paragraph 1, Item 1 (b) (1)		4,069,100
		New dosage, etc.		388,300 Article 32, Paragraph 1, Item 1 (b) (2)		388,300
		Others		99,900 Article 32, Paragraph 1, Item 1 (b) (9)		99,900
Pest control agents/quasi-drugs for pest control		New active ingredients		6,808,300 Article 32, Paragraph 1, Item 1 (a) (14) and (b) (3)		6,808,300
			One product with several proprietary names	5,237,200 Article 32, Paragraph 1, Item 1 (a) (15) and (b) (4)		5,237,200
		New dosage, etc.		658,800 Article 32, Paragraph 1, Item 1 (a) (16) and (b) (5)		658,800
			One product with several proprietary names	411,800 Article 32, Paragraph 1, Item 1 (a) (17) and (b) (6)		411,800
		Others		160,300 Article 32, Paragraph 1, Item 1 (a) (18) and (b) (7)		160,300
			One product with several proprietary names	100,200 Article 32, Paragraph 1, Item 1 (a) (19) and (b) (8)		100,200
Cosmetics				66,600 Article 32, Paragraph 1, Item 1 (c)		66,600
New application for change or replacement of brand name		Drugs		37,300 Article 32, Paragraph 1, Item 1 (d)		37,300
		Quasi-drugs/cosmetics		37,300 Article 32, Paragraph 1, Item 1 (d)		37,300

(*1) Amount including overseas travel expenses (Article 32, Paragraph 3) in cases where the inspection is conducted in a foreign country

Note) The lower rows in the “User fees” column indicate the applicable articles of the Cabinet Order on Fees related to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices.

(unit: yen)

Category				User fees		
				Review	Conformity	Total
Review for approval of drugs (approval for partial changes to approved matters)						
New drugs (No. 1) (No. 2) (non-orphan drugs)		Changes in new indications	First application products	15,652,600 Article 32, Paragraph 1, Item 2 (a) (1)	3,891,500 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 2 (a)	19,544,100 (+ overseas travel expenses *1)
			Line extension products	1,624,000 Article 32, Paragraph 1, Item 2 (a) (2)	973,100 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 2 (b)	2,597,100 (+ overseas travel expenses *1)
		Other changes	Subject to inspection	323,000 Article 32, Paragraph 1, Item 2 (a) (3)	195,500 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 2 (c)	518,500 (+ overseas travel expenses *1)
			Not subject to inspection	323,000 Article 32, Paragraph 1, Item 2 (a) (3)		323,000 (+ overseas travel expenses *1)
New drugs (No. 1) (No. 2) (orphan drugs)		Changes in new indications	First application products	12,955,000 Article 32, Paragraph 1, Item 2 (a) (4)	1,947,100 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 2 (d)	14,902,100 (+ overseas travel expenses *1)
			Line extension products	1,344,800 Article 32, Paragraph 1, Item 2 (a) (5)	489,900 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 2 (e)	1,834,700 (+ overseas travel expenses *1)
		Other changes	Subject to inspection	203,700 Article 32, Paragraph 1, Item 2 (a) (6)	173,300 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 2 (f)	377,000 (+ overseas travel expenses *1)
			Not subject to inspection	203,700 Article 32, Paragraph 1, Item 2 (a) (6)		203,700 (+ overseas travel expenses *1)
Generic drugs		Changes in new indications	First application products	15,652,600 Article 32, Paragraph 1, Item 2 (a) (7)	3,891,500 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 2 (g)	19,544,100 (+ overseas travel expenses *1)
			Line extension products	1,624,000 Article 32, Paragraph 1, Item 2 (a) (8)	973,100 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 2 (h)	2,597,100 (+ overseas travel expenses *1)
		Changes based on guidelines, etc.		56,000 Article 32, Paragraph 1, Item 2 (a) (9)		56,000
		Other changes	Subject to inspection	323,000 Article 32, Paragraph 1, Item 2 (a) (10)	195,500 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 2 (i)	518,500 (+ overseas travel expenses *1)
			Not subject to inspection	323,000 Article 32, Paragraph 1, Item 2 (a) (10)		323,000
Prescription drugs (fertility treatment)		Changes in new indications	First application products	8,121,100 Article 4, Item 1 of the Supplementary Provisions		8,121,100 (+ overseas travel expenses *1)
			Line extension products	851,700 Article 4, Item 2 of the Supplementary Provisions		851,700 (+ overseas travel expenses *1)
BTC/OTC drugs	Switch OTC drugs, etc.	Changes in new indications	First application products	15,652,600 Article 32, Paragraph 1, Item 2 (a) (11)	195,500 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 2 (i)	15,848,100 (+ overseas travel expenses *1)
				15,652,600 Article 32, Paragraph 1, Item 2 (a) (11)		15,652,600
				14,478,400 Article 32, Paragraph 1, Item 2 (a) (12)		14,478,400
			Line extension products	1,332,200 Article 32, Paragraph 1, Item 2 (a) (13)	195,500 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 2 (i)	1,527,700 (+ overseas travel expenses *1)
				1,332,200 Article 32, Paragraph 1, Item 2 (a) (13)		1,332,200
				1,232,300 Article 32, Paragraph 1, Item 2 (a) (14)		1,232,300
		Other changes	Subject to inspection	165,700 Article 32, Paragraph 1, Item 2 (a) (15)	195,500 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 2 (i)	361,200 (+ overseas travel expenses *1)
			Not subject to inspection	165,700 Article 32, Paragraph 1, Item 2 (a) (15)		165,700
			One product with several proprietary names	117,800 Article 32, Paragraph 1, Item 2 (a) (16)		117,800
	Changes based on guidelines, etc.		Subject to inspection	165,700 Article 32, Paragraph 1, Item 2 (a) (15)	195,500 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 2 (i)	361,200 (+ overseas travel expenses *1)
			Not subject to inspection	165,700 Article 32, Paragraph 1, Item 2 (a) (15)		165,700
			One product with several proprietary names	117,800 Article 32, Paragraph 1, Item 2 (a) (16)		117,800
		Changes based on guidelines, etc.	Subject to inspection	44,700 Article 32, Paragraph 1, Item 2 (a) (17)	195,500 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 2 (i)	240,200 (+ overseas travel expenses *1)
			Not subject to inspection	44,700 Article 32, Paragraph 1, Item 2 (a) (17)		44,700
			One product with several proprietary names	41,400 Article 32, Paragraph 1, Item 2 (a) (18)		41,400
Quasi-drugs				55,900 Article 32, Paragraph 1, Item 2 (b) (1)		55,900
Pest control agents/quasi-drugs for pest control				81,200 Article 32, Paragraph 1, Item 2 (a) (19) and (b) (2)		81,200
			One product with several proprietary names	50,800 Article 32, Paragraph 1, Item 2 (a) (20) and (b) (3)		50,800
Cosmetics				37,300 Article 32, Paragraph 1, Item 2 (c)		37,300

(*1) Amount including overseas travel expenses (Article 32, Paragraph 3) in cases where the inspection is conducted in a foreign country

Note) The lower rows in the “User fees” column indicate the applicable articles of the Cabinet Order on Fees related to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices.

(unit: yen)

Category				User fees		
				Review	Conformity	Total
Review for approval of drugs (emergency approval)						
At the time of application	New drugs (No. 1)	Non-orphan drugs	First application products	36,538,400	4,224,100 (+ overseas travel expenses *1)	40,762,500 (+ overseas travel expenses *1)
				Article 32, Paragraph 1, Item 1 (a) (1)	Article 32, Paragraph 2, Item 3 (a)	
			Line extension products	3,784,700	1,409,400 (+ overseas travel expenses *1)	5,194,100 (+ overseas travel expenses *1)
				Article 32, Paragraph 1, Item 1 (a) (3)	Article 32, Paragraph 2, Item 3 (b)	
		Orphan drugs	First application products	30,618,800	4,224,100 (+ overseas travel expenses *1)	34,842,900 (+ overseas travel expenses *1)
				Article 32, Paragraph 1, Item 1 (a) (2)	Article 32, Paragraph 2, Item 3 (a)	
			Line extension products	3,166,400	1,409,400 (+ overseas travel expenses *1)	4,575,800 (+ overseas travel expenses *1)
				Article 32, Paragraph 1, Item 1 (a) (4)	Article 32, Paragraph 2, Item 3 (b)	
	New drugs (No. 2)	Non-orphan drugs	First application products	17,438,300	4,224,100 (+ overseas travel expenses *1)	21,662,400 (+ overseas travel expenses *1)
				Article 32, Paragraph 1, Item 1 (a) (5)	Article 32, Paragraph 2, Item 3 (a)	
			Line extension products	1,803,600	1,409,400 (+ overseas travel expenses *1)	3,213,000 (+ overseas travel expenses *1)
				Article 32, Paragraph 1, Item 1 (a) (7)	Article 32, Paragraph 2, Item 3 (b)	
		Orphan drugs	First application products	14,354,900	4,224,100 (+ overseas travel expenses *1)	18,579,000 (+ overseas travel expenses *1)
				Article 32, Paragraph 1, Item 1 (a) (6)	Article 32, Paragraph 2, Item 3 (a)	
			Line extension products	1,542,200	1,409,400 (+ overseas travel expenses *1)	2,951,600 (+ overseas travel expenses *1)
				Article 32, Paragraph 1, Item 1 (a) (8)	Article 32, Paragraph 2, Item 3 (b)	
	BTC/OTC drugs	Switch OTC drugs, etc.	First application products	1,627,300	195,500 (+ overseas travel expenses *1)	1,822,800 (+ overseas travel expenses *1)
				Article 32, Paragraph 1, Item 1 (a) (10)	Article 32, Paragraph 2, Item 3 (c)	
			Line extension products	1,627,300	195,500 (+ overseas travel expenses *1)	1,822,800 (+ overseas travel expenses *1)
				Article 32, Paragraph 1, Item 1 (a) (10)	Article 32, Paragraph 2, Item 3 (c)	
At the time of application for change	New drugs	Non-orphan drugs	First application products	15,652,600	4,224,100 (+ overseas travel expenses *1)	19,876,700 (+ overseas travel expenses *1)
				Article 32, Paragraph 1, Item 2 (a) (1)	Article 32, Paragraph 2, Item 3 (a)	
			Line extension products	1,624,000	1,409,400 (+ overseas travel expenses *1)	3,033,400 (+ overseas travel expenses *1)
				Article 32, Paragraph 1, Item 2 (a) (2)	Article 32, Paragraph 2, Item 3 (b)	
		Orphan drugs	First application products	12,955,000	4,224,100 (+ overseas travel expenses *1)	17,179,100 (+ overseas travel expenses *1)
				Article 32, Paragraph 1, Item 2 (a) (4)	Article 32, Paragraph 2, Item 3 (a)	
			Line extension products	1,344,800	1,409,400 (+ overseas travel expenses *1)	2,754,200 (+ overseas travel expenses *1)
				Article 32, Paragraph 1, Item 2 (a) (5)	Article 32, Paragraph 2, Item 3 (b)	
	BTC/OTC drugs	Switch OTC drugs, etc.	First application products	15,652,600	195,500 (+ overseas travel expenses *1)	15,848,100 (+ overseas travel expenses *1)
				Article 32, Paragraph 1, Item 2 (a) (11)	Article 32, Paragraph 2, Item 3 (c)	
			Line extension products	1,332,200	195,500 (+ overseas travel expenses *1)	1,527,700 (+ overseas travel expenses *1)
				Article 32, Paragraph 1, Item 2 (a) (13)	Article 32, Paragraph 2, Item 3 (c)	

(*1) Amount including overseas travel expenses (Article 32, Paragraph 3) in cases where the inspection is conducted in a foreign country

Note) The lower rows in the “User fees” column indicate the applicable articles of the Cabinet Order on Fees related to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices.

(unit: yen)

Category				User fees		
				Review	Conformity	Total
Review of plan to change approved information on drugs						
New drugs	Non-orphan drugs		First application products	854,100 Article 32-3, Paragraph 1, Item 1 (a)		854,100
			First application products (biological drugs)	1,386,800 Article 32-3, Paragraph 1, Item 1 (b)		1,386,800
			Line extension products	323,000 Article 32-3, Paragraph 1, Item 1 (c)		323,000
	Orphan drugs		First application products	706,900 Article 32-3, Paragraph 1, Item 1 (d)		706,900
			First application products (biological drugs)	1,147,700 Article 32-3, Paragraph 1, Item 1 (e)		1,147,700
			Line extension products	323,000 Article 32-3, Paragraph 1, Item 1 (f)		323,000
Generic drugs			First application products	854,100 Article 32-3, Paragraph 1, Item 1 (g)		854,100
			First application products (biological drugs)	1,386,800 Article 32-3, Paragraph 1, Item 1 (h)		1,386,800
			Line extension products	323,000 Article 32-3, Paragraph 1, Item 1 (i)		323,000
BTC/OTC drugs			First application products	854,100 Article 32-3, Paragraph 1, Item 1 (j)		854,100
			Line extension products	323,000 Article 32-3, Paragraph 1, Item 1 (k)		323,000
			One product with several proprietary names	323,000 Article 32-3, Paragraph 1, Item 1 (l)		323,000
Quasi-drugs				355,900 Article 32-3, Paragraph 1, Item 2 (a)		355,900
			One product with several proprietary names	55,900 Article 32-3, Paragraph 1, Item 2 (b)		55,900
Pest control agents				381,200 Article 32-3, Paragraph 1, Item 1 (m)		381,200
			One product with several proprietary names	50,800 Article 32-3, Paragraph 1, Item 1 (n)		50,800
Quasi-drugs for pest control				381,200 Article 32-3, Paragraph 1, Item 2 (c)		381,200
			One product with several proprietary names	50,800 Article 32-3, Paragraph 1, Item 2 (d)		50,800
Cosmetics				337,300 Article 32-3, Paragraph 1, Item 3		337,300

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(unit: yen)

Category				User fees		
				Review	Conformity	Total
GMP inspection of drugs						
Approval, partial change, and manufacture for export		New drugs	In Japan		1,008,700 Article 32, Paragraph 5, Item 1 (b) (1)	1,008,700
			Overseas		1,272,900 Article 32, Paragraph 5, Item 1 (b) (2)	1,272,900
		Biological drugs/radiopharmaceuticals, etc.	In Japan		908,100 Article 32, Paragraph 5, Item 1 (a) (1)	908,100
			Overseas		1,151,400 Article 32, Paragraph 5, Item 1 (a) (2)	1,151,400
		Sterile drugs/Sterile quasi-drugs	In Japan		632,500 Article 32, Paragraph 5, Item 1 (c) (1)	632,500
			Overseas		796,700 Article 32, Paragraph 5, Item 1 (c) (2)	796,700
		Other drugs/quasi-drugs	In Japan		459,200 Article 32, Paragraph 5, Item 1 (d) (1)	459,200
			Overseas		578,500 Article 32, Paragraph 5, Item 1 (d) (2)	578,500
		Packaging, labeling, storage, external testing, etc.	In Japan		86,800 Article 32, Paragraph 5, Item 2 (a) and Paragraph 6, Item 1 (a)	86,800
			Overseas		115,300 Article 32, Paragraph 5, Item 2 (c) and Paragraph 6, Item 1 (b)	115,300
		Specific storage (manufacturing sites where only registered specific storage takes place)	In Japan		43,400 Article 32, Paragraph 5, Item 2 (b)	43,400
			Overseas		57,600 Article 32, Paragraph 5, Item 2 (d)	57,600
	Review of plan to change	New drugs	In Japan		1,008,700 Article 32-3, Paragraph 2, Item 1 (b) (1)	1,008,700
			Overseas		1,272,900 Article 32-3, Paragraph 2, Item 1 (b) (2)	1,272,900
		Biological drugs/radiopharmaceuticals, etc.	In Japan		908,100 Article 32-3, Paragraph 2, Item 1 (a) (1)	908,100
			Overseas		1,151,400 Article 32-3, Paragraph 2, Item 1 (a) (2)	1,151,400
		Sterile drugs/Sterile quasi-drugs	In Japan		632,500 Article 32-3, Paragraph 2, Item 1 (c) (1)	632,500
			Overseas		796,700 Article 32-3, Paragraph 2, Item 1 (c) (2)	796,700
		Other drugs/quasi-drugs	In Japan		459,200 Article 32-3, Paragraph 2, Item 1 (d) (1)	459,200
			Overseas		578,500 Article 32-3, Paragraph 2, Item 1 (d) (2)	578,500
		Packaging, labeling, storage, external testing, etc.	In Japan		86,800 Article 32-3, Paragraph 2, Item 2 (a) and Paragraph 3, Item 1	86,800
			Overseas		115,300 Article 32-3, Paragraph 2, Item 2 (c) and Paragraph 3, Item 2	115,300
		Specific storage (manufacturing sites where only registered specific storage takes place)	In Japan		43,400 Article 32-3, Paragraph 2, Item 2 (b)	43,400
			Overseas		57,600 Article 32-3, Paragraph 2, Item 2 (d)	57,600

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(unit: yen)

Category					User fees		
					Review	Conformity	Total
GMP inspection of drugs							
Renewal of approval/renewal of manufacture for export		Biological drugs/radiopharmaceuticals, etc.	In Japan	Basic fee		866,500 Article 32, Paragraph 5, Item 3 (a) (1)	866,500
				Additional fee for product		44,000 Article 32, Paragraph 5, Item 3 (a) (1)	44,000 multiplied by number of products
			Overseas	Basic fee		1,109,800 Article 32, Paragraph 5, Item 3 (a) (2)	1,109,800
				Additional fee for product		44,000 Article 32, Paragraph 5, Item 3 (a) (2)	44,000 multiplied by number of products
		Sterile drugs/Sterile quasi-drugs	In Japan	Basic fee		615,600 Article 32, Paragraph 5, Item 3 (b) (1)	615,600
				Additional fee for product		17,900 Article 32, Paragraph 5, Item 3 (b) (1)	17,900 multiplied by number of products
			Overseas	Basic fee		779,800 Article 32, Paragraph 5, Item 3 (b) (2)	779,800
				Additional fee for product		17,900 Article 32, Paragraph 5, Item 3 (b) (2)	17,900 multiplied by number of products
		Other drugs/quasi-drugs	In Japan	Basic fee		446,200 Article 32, Paragraph 5, Item 3 (c) (1)	446,200
				Additional fee for product		13,700 Article 32, Paragraph 5, Item 3 (c) (1)	13,700 multiplied by number of products
			Overseas	Basic fee		565,600 Article 32, Paragraph 5, Item 3 (c) (2)	565,600
				Additional fee for product		13,700 Article 32, Paragraph 5, Item 3 (c) (2)	13,700 multiplied by number of products
		Packaging, labeling, storage, external testing, etc.	In Japan	Basic fee		361,600 Article 32, Paragraph 5, Item 3 (d) (1) and Paragraph 6, Item 2 (a)	361,600
				Additional fee for product		9,700 Article 32, Paragraph 5, Item 3 (d) (1) and Paragraph 6, Item 2 (a)	9,700 multiplied by number of products
			Overseas	Basic fee		470,100 Article 32, Paragraph 5, Item 3 (d) (3) and Paragraph 6, Item 2 (b)	470,100
				Additional fee for product		9,700 Article 32, Paragraph 5, Item 3 (d) (3) and Paragraph 6, Item 2 (b)	9,700 multiplied by number of products
		Specific storage (manufacturing sites where only registered specific storage takes place)	In Japan	Basic fee		180,800 Article 32, Paragraph 5, Item 3 (d) (2)	180,800
				Additional fee for product		9,700 Article 32, Paragraph 5, Item 3 (d) (2)	9,700 multiplied by number of products
			Overseas	Basic fee		235,000 Article 32, Paragraph 5, Item 3 (d) (4)	235,000
				Additional fee for product		9,700 Article 32, Paragraph 5, Item 3 (d) (4)	9,700 multiplied by number of products
Issuance of certification of conformity (examination of conformity regarding type of manufacturing)		Biological drugs/radiopharmaceuticals, etc.		Basic fee		1,165,200 Article 32-2, Paragraph 1, Item 1	1,165,200
				Additional fee for product		44,000 Article 32-2, Paragraph 1, Item 1	44,000 multiplied by number of products
				Additional fees for manufacturing and sales		10,000 Article 32-2, Paragraph 1, Item 1	10,000 multiplied by number of marketing authorization holders
		Sterile drugs/Sterile quasi-drugs		Basic fee		818,700 Article 32-2, Paragraph 1, Item 2	818,700
				Additional fee for product		17,900 Article 32-2, Paragraph 1, Item 2	17,900 multiplied by number of products
				Additional fees for manufacturing and sales		10,000 Article 32-2, Paragraph 1, Item 2	10,000 multiplied by number of marketing authorization holders
		Other drugs/quasi-drugs		Basic fee		593,800 Article 32-2, Paragraph 1, Item 3	593,800
				Additional fee for product		13,700 Article 32-2, Paragraph 1, Item 3	13,700 multiplied by number of products
				Additional fees for manufacturing and sales		10,000 Article 32-2, Paragraph 1, Item 3	10,000 multiplied by number of marketing authorization holders
		Packaging, labeling, storage		Basic fee		493,600 Article 32-2, Paragraph 1, Item 4	493,600
				Additional fee for product		9,700 Article 32-2, Paragraph 1, Item 4	9,700 multiplied by number of products
				Additional fees for manufacturing and sales		10,000 Article 32-2, Paragraph 1, Item 4	10,000 multiplied by number of marketing authorization holders
		Specific storage (manufacturing sites where only registered specific storage takes place)		Basic fee		246,800 Article 32-2, Paragraph 1, Item 5	246,800
				Additional fee for product		9,700 Article 32-2, Paragraph 1, Item 5	9,700 multiplied by number of products
				Additional fees for manufacturing and sales		10,000 Article 32-2, Paragraph 1, Item 5	10,000 multiplied by number of marketing authorization holders
Additional fees for on-site inspection (per day)			In Japan			230,000 Article 32, Paragraph 7, Item 1; Article 32-2, Paragraph 2, Item 1; and Article 33-3, Paragraph 4, Item 1	230,000
			Overseas			200,000 + overseas travel expenses Article 32, Paragraph 7, Item 2 (a) (b); Article 32-2, Paragraph 2, Item 2 (a) (b); and Article 33-3, Paragraph 4, Item 2 (a) (b)	200,000 + overseas travel expenses
Issuance and reissuance of certification of conformity						11,000 Article 32-2, Paragraph 4	11,000

Note) The lower rows in the “User fees” column indicate the applicable articles of the Cabinet Order on Fees related to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices.

(unit: yen)

Category				User fees		
				Review	Conformity	Total
GLP inspection of drugs						
GLP			In Japan		3,258,300 Article 32, Paragraph 4, Item 1 (a)	3,258,300
			Overseas		3,606,200 + overseas travel expenses Article 32, Paragraph 4, Item 1 (b)	3,606,200 + overseas travel expenses
GCP inspection of drugs						
GCP for new drugs	New application	First application products	In Japan		4,302,300 Article 32, Paragraph 4, Item 2 (a) (1)	4,302,300
			Overseas		4,758,500 + overseas travel expenses Article 32, Paragraph 4, Item 2 (a) (2)	4,758,500 + overseas travel expenses
		Line extension products	In Japan		1,138,600 Article 32, Paragraph 4, Item 2 (a) (3)	1,138,600
			Overseas		1,187,700 + overseas travel expenses Article 32, Paragraph 4, Item 2 (a) (4)	1,187,700 + overseas travel expenses
	Partial change	First application products	In Japan		4,302,300 Article 32, Paragraph 4, Item 2 (b) (1)	4,302,300
			Overseas		4,758,500 + overseas travel expenses Article 32, Paragraph 4, Item 2 (b) (2)	4,758,500 + overseas travel expenses
		Line extension products	In Japan		1,138,600 Article 32, Paragraph 4, Item 2 (b) (3)	1,138,600
			Overseas		1,187,700 + overseas travel expenses Article 32, Paragraph 4, Item 2 (b) (4)	1,187,700 + overseas travel expenses
GCP for generic drugs	New application		In Japan		696,700 Article 32, Paragraph 4, Item 2 (a) (5)	696,700
			Overseas		1,026,200 + overseas travel expenses Article 32, Paragraph 4, Item 2 (a) (6)	1,026,200 + overseas travel expenses
	Partial change		In Japan		696,700 Article 32, Paragraph 4, Item 2 (b) (5)	696,700
			Overseas		1,026,200 + overseas travel expenses Article 32, Paragraph 4, Item 2 (b) (6)	1,026,200 + overseas travel expenses
GCP for BTC/OTC drugs	New application		In Japan		696,700 Article 32, Paragraph 4, Item 2 (a) (5)	696,700
			Overseas		1,026,200 + overseas travel expenses Article 32, Paragraph 4, Item 2 (a) (6)	1,026,200 + overseas travel expenses
	Partial change		In Japan		696,700 Article 32, Paragraph 4, Item 2 (b) (5)	696,700
			Overseas		1,026,200 + overseas travel expenses Article 32, Paragraph 4, Item 2 (b) (6)	1,026,200 + overseas travel expenses
Interim evaluation of drugs with conditional approval						
Review/inspection of interim evaluation	Non-orphan drugs	First application products		4,987,400 Article 32, Paragraph 9, Item 1 (a)	4,224,100 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 2 (a)	9,211,500 (+ overseas travel expenses *3)
		Line extension products		498,700 Article 32, Paragraph 9, Item 1 (c)	1,409,400 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 2 (b)	1,908,100 (+ overseas travel expenses *3)
	Orphan drugs	First application products		4,127,800 Article 32, Paragraph 9, Item 1 (b)	4,224,100 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 2 (a)	8,351,900 (+ overseas travel expenses *3)
		Line extension products		412,700 Article 32, Paragraph 9, Item 1 (d)	1,409,400 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 2 (b)	1,822,100 (+ overseas travel expenses *3)
GLP of interim evaluation			In Japan		3,258,300 Article 32, Paragraph 9, Item 3 (a) (1)	3,258,300
			Overseas		3,606,200 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (a) (2)	3,606,200 (+ overseas travel expenses *3)
GPSP of interim evaluation		First application products	In Japan		3,465,200 Article 32, Paragraph 9, Item 3 (b) (1)	3,465,200
			Overseas		3,806,900 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (3)	3,806,900 (+ overseas travel expenses *3)
		Line extension products	In Japan		1,188,900 Article 32, Paragraph 9, Item 3 (b) (2)	1,188,900
			Overseas		1,220,000 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (4)	1,220,000 (+ overseas travel expenses *3)
GCP inspection of drugs (emergency approval)						
GPSP for emergency approval of new drugs		First application products	In Japan		3,465,200 Article 32, Paragraph 4, Item 2 (c) (1)	3,465,200
			Overseas		3,806,900 + overseas travel expenses Article 32, Paragraph 4, Item 2 (c) (2)	3,806,900 + overseas travel expenses
		Line extension products	In Japan		1,188,900 Article 32, Paragraph 4, Item 2 (c) (3)	1,188,900
			Overseas		1,220,000 + overseas travel expenses Article 32, Paragraph 4, Item 2 (c) (4)	1,220,000 + overseas travel expenses
Other GPSP for emergency approval of new drugs			In Japan		696,700 Article 32, Paragraph 4, Item 2 (c) (5)	696,700
			Overseas		1,026,200 + overseas travel expenses Article 32, Paragraph 4, Item 2 (c) (6)	1,026,200 + overseas travel expenses

Note) The lower rows in the “User fees” column indicate the applicable articles of the Cabinet Order on Fees related to the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices.

(unit: yen)

Category				User fees		
				Review	Conformity	Total
Re-examination of drugs						
	Review/inspection of re-examination	First application products		1,238,700	4,224,100 (+ overseas travel expenses *4)	5,462,800 (+ overseas travel expenses *4)
				Article 32, Paragraph 12, Item 1	Article 32, Paragraph 13, Item 1 (a)	
		Line extension products		417,000	1,409,400 (+ overseas travel expenses *4)	1,826,400 (+ overseas travel expenses *4)
				Article 32, Paragraph 12, Item 2	Article 32, Paragraph 13, Item 1 (b)	
	GLP for re-examination	In Japan			3,258,300	3,258,300
					Article 32, Paragraph 13, Item 2 (a) (1)	
		Overseas			3,606,200 (+ overseas travel expenses *4)	3,606,200 (+ overseas travel expenses *4)
					Article 32, Paragraph 13, Item 2 (a) (2)	
	GPSP for re-examination	First application products	In Japan		3,465,200	3,465,200
					Article 32, Paragraph 13, Item 2 (b) (1)	
			Overseas		3,806,900 (+ overseas travel expenses *4)	3,806,900 (+ overseas travel expenses *4)
					Article 32, Paragraph 13, Item 2 (b) (2)	
		Line extension products	In Japan		1,188,900	1,188,900
					Article 32, Paragraph 13, Item 2 (b) (3)	
			Overseas		1,220,000 (+ overseas travel expenses *4)	1,220,000 (+ overseas travel expenses *4)
					Article 32, Paragraph 13, Item 2 (b) (4)	

(*3) Amount including overseas travel expenses (Article 32, Paragraph 10) in cases where the inspection is conducted in a foreign country
(*4) Amount including overseas travel expenses (Article 32, Paragraph 14) in cases where the inspection is conducted in a foreign country