Provisional Translation (as of August 2025).

This English document has been prepared for reference purpose only. In the event of inconsistency and discrepancy between the Japanese original and the English translation, the Japanese text shall prevail.

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.

Cataor			User fees	
Catego	ыу	Review	Conformity	Total
Assessment for manufact	uring license of drugs			
	On-site		159,900	159,900
New license	OH-Site		Article 31, Paragraph 1, Item 1 (a)	
New licelise	Document-based		120,400	120,400
	Document-based		Article 31, Paragraph 1, Item 1 (b)	
	On-site		105,200	105,200
Renewal of existing license			Article 31, Paragraph 1, Item 2 (a)	
Tronewar or existing neerise	Document-based		59,700	59,700
	Document-based		Article 31, Paragraph 1, Item 2 (b)	
	On-site		105,200	105,200
Change/addition of classification	OII-site		Article 31, Paragraph 1, Item 3 (a)	
Orlange/addition of classification	Document-based		59,700	59,700
	Document-pased		Article 31, Paragraph 1, Item 3 (b)	
Assessment for foreign manufac	turers' accreditation of drugs			
	On-site		143,900 + overseas travel expenses	143,900 + overseas travel expenses
New accreditation			Article 31, Paragraph 2, Item 1 (a)	
	Document-based		62,600	62,600
	Document-based		Article 31, Paragraph 2, Item 1 (b)	
	On-site		69,700 + overseas travel expenses	69,700 + overseas travel expenses
Renewal of existing accreditation			Article 31, Paragraph 2, Item 2 (a)	
	Document-based		42,900	42,900
	Document-based		Article 31, Paragraph 2, Item 2 (b)	
	On-site		69,700 + overseas travel expenses	69,700 + overseas travel expenses
Change/addition of classification			Article 31, Paragraph 2, Item 3 (a)	
	Document-based		42,900	42,900
	Boodinont based		Article 31, Paragraph 2, Item 3 (b)	

r roddolo moldding	Filaimaceutic		cal Devices.			User fees		(unit: y			
Category					Review	Conformity	Tota	al			
Review for approval of drugs (new approval) First application											
				First application products	36,538,400 Article 32, Paragraph 1, Item 1 (a) (1)	expenses 1)	46,901,700	(+ overseas tra expenses			
		Non-c	orphan drugs	Line extension products	3,784,700	2,590,500 (+ overseas travel expenses *1)	6,375,200	(+ overseas tr expenses			
New dru (No. 1				First application	Article 32, Paragraph 1, Item 1 (a) (3) 30,618,800	(+ aversage travel	35,810,400	(+ overseas tr			
Orp		han drugs	products Line extension	Article 32, Paragraph 1, Item 1 (a) (2) 3,166,400	Article 32, Paragraph 2, Item 1 (b) 1,292,500 (+ overseas travel	4,458,900	(+ overseas t				
			products	Article 32, Paragraph 1, Item 1 (a) (4)	Article 32, Paragraph 2, Item 1 (d)		expense (+ overseas t				
		Non-c	orphan drugs	First application products	17,438,300 Article 32, Paragraph 1, Item 1 (a) (5)	3,891,500 ` expenses *1)	21,329,800	expense			
New dru	ıns	None	orphan arago	Line extension products	1,803,600 Article 32, Paragraph 1, Item 1 (a) (7)	expenses "1)	2,776,700	(+ overseas expense			
(No. 2				First application products	14,354,900	1,947,100 (+ overseas travel expenses *1)	16,302,000	(+ overseas expense			
		Orp	ohan drugs	Line extension	Article 32, Paragraph 1, Item 1 (a) (6) 1,542,200	/ Lavorages travel	2,032,100	(+ overseas expense			
				products	Article 32, Paragraph 1, Item 1 (a) (8) 649,100	Article 32, Paragraph 2, Item 1 (h) 346,700 (+ overseas travel	995,800	(+ overseas			
	Generio	drugs		Subject to inspection	·	Article 32, Paragraph 2, Item 1 (i)		expens			
				Not subject to inspection	649,100 Article 32, Paragraph 1, Item 1 (a) (9)		649,100				
				First application products	1,627,300	expenses i)	1,974,000	(+ overseas expens			
	Switch OTC drugs, etc.		Subject to inspection	Line extension	Article 32, Paragraph 1, Item 1 (a) (10) 1,627,300	Article 32, Paragraph 2, Item 1 (i) 346,700 (+ overseas travel expenses *1)	1,974,000	(+ overseas expens			
		0 1	O 1			products First application	Article 32, Paragraph 1, Item 1 (a) (10) 1,627,300	Article 32, Paragraph 2, Item 1 (i)	1,627,300	•	
				Not subject to inspection	products Line extension	Article 32, Paragraph 1, Item 1 (a) (10) 1,627,300		1,627,300			
						products	Article 32, Paragraph 1, Item 1 (a) (10)				
BTC/OTC drugs				5		One product with several proprietary	First application products	1,505,200 Article 32, Paragraph 1, Item 1 (a) (11)		1,505,200	
			names	Line extension products	1,505,200 Article 32, Paragraph 1, Item 1 (a) (11)		1,505,200				
	Others		Subject		324,200 Article 32, Paragraph 1, Item 1 (a) (12)	expenses 1)	670,900	(+ overseas expens			
			Not subje	ct to inspection	324,200 Article 32, Paragraph 1, Item 1 (a) (12)		324,200				
				h several proprietary names	230,400 Article 32, Paragraph 1, Item 1 (a) (13)		230,400				
			New acti	ve ingredients	4,069,100 Article 32, Paragraph 1, Item 1 (b) (1)		4,069,100				
Qu	asi-drugs		New d	osage, etc.	388,300 Article 32, Paragraph 1, Item 1 (b) (2)		388,300				
			(Others	99,900		99,900				
			New acti	ve ingredients	Article 32, Paragraph 1, Item 1 (b) (9) 6,808,300 Article 32, Paragraph 1, Item 1 (a)		6,808,300				
				One product with several	(14) and (b) (3) 5,237,200		5,237,200				
				proprietary names	Article 32, Paragraph 1, Item 1 (a) (15) and (b) (4) 658,800		658,800				
Pest control ager		ıgs for pest		osage, etc.	Article 32, Paragraph 1, Item 1 (a) (16) and (b) (5)		,				
•	control			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)		160,300					
				One product with several	(18) and (b) (7) 100,200		100,200				
		proprietary names	Article 32, Paragraph 1, Item 1 (a) (19) and (b) (8) 66,600		66,600						
		Cosm		Drugo	Article 32, Paragraph 1, Item 1 (c)		37,300				
New applica replacement	ition for char nt of brand n			Orugs	Article 32, Paragraph 1, Item 1 (d) 37,300		37,300				
				ugs/cosmetics	Article 32, Paragraph 1, Item 1 (d)		,				

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

		Categor	y			User fees											
riew for approval of drugs (approval for partial changes to approved matters)					Review	Conformity	Tot	al									
view for approva			approved matters) First application products	15,652,600	3,891,500 (+ overseas travel expenses *1) Article 32, Paragraph 2, Item 2 (a)	19,544,100	(+ overseas expense										
New drugs (No. 1) (No. 2) (non-orphan drugs)		Changes in new indications		Line extension products	1,624,000	// h	2,597,100	(+ overseas expens									
				Subject to inspection	323,000	(+ average travel	518,500	(+ overseas expens									
		Othe	er changes	Not subject to inspection	323,000		323,000	(+ overseasexpen									
						First application products	Article 32, Paragraph 1, Item 2 (a) (3) 12,955,000	1,947,100 (+ overseas travel expenses *1)	14,902,100	(+ oversea expen							
				Changes in	n new indications	Line extension products	1,344,800	· expenses i)	1,834,700	(+ oversea exper							
New drugs (No (orphan o				Subject to inspection	203,700	expenses 1)	377,000	(+ oversea exper									
		Othe	er changes	Not subject to inspection	203,700		203,700	(+ oversea exper									
				First application products	Article 32, Paragraph 1, Item 2 (a) (6) 15,652,600 Article 32, Paragraph 1, Item 2 (a) (7)	3,891,500 (+ overseas travel expenses *1)	19,544,100	(+ oversea exper									
		Changes in	n new indications	Line extension products	1,624,000	expenses ()	2,597,100	(+ oversea exper									
Generic o	drugs	Cha	anges based on g	·	Article 32, Paragraph 1, Item 2 (a) (8) 56,000 Article 32, Paragraph 1, Item 2 (a) (9)	Article 32, Paragraph 2, Item 2 (h)	56,000										
		Othe	er 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	(+ oversea exper									
		Other changes		Not subject to inspection	323,000 Article 32, Paragraph 1, Item 2 (a) (10)		323,000	1									
Prescription	n druge	as and a second		First application products	8,121,100 Article 4, Item 1 of the Supplementary Provisions		8,121,100	(+ oversea exper									
	escription drugs rtility treatment) Changes in new indications		n new indications	Line extension products	851,700 Article 4, Item 2 of the Supplementary Provisions		851,700	(+ oversea exper									
	Switch OTC drugs, etc.	OTC	OTC	OTC								Subject to inspection	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	(+ oversea exper	
						First application products	Not subject to inspection	15,652,600 Article 32, Paragraph 1, Item 2 (a) (11)		15,652,600							
					OTC	OTC	OTC	OTC	OTC	Changes in new		One product with several proprietary names	14,478,400 Article 32, Paragraph 1, Item 2 (a) (12)		14,478,400		
										OTC	witch DTC Line		Subject to inspection	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	(+ oversea exper
												Line extension products	Not subject to inspection One product with	1,332,200 Article 32, Paragraph 1, Item 2 (a) (13) 1,232,300		1,332,200	
								several proprietary names	Article 32, Paragraph 1, Item 2 (a) (14)	(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	1,202,000	(1					
DT0/2=5													Subject to inspection	Article 32, Paragraph 1, Item 2 (a) (15)	Article 32, Paragraph 2, Item 2 (i)	361,200	(+ oversea exper
BTC/OTC drugs		Othe	er changes	Not subject to inspection One product with	165,700 Article 32, Paragraph 1, Item 2 (a) (15) 117,800		165,700 117,800										
				several proprietary names	Article 32, Paragraph 1, Item 2 (a) (16)	(1.20222224201	,	(+ oversea									
				Subject to inspection	Article 32, Paragraph 1, Item 2 (a) (15)	Article 32, Paragraph 2, Item 2 (i)	361,200	exper									
		Other char	nges	Not subject to inspection One product with	165,700 Article 32, Paragraph 1, Item 2 (a) (15) 117,800		165,700 117,800										
				several proprietary names	Article 32, Paragraph 1, Item 2 (a) (16) 44,700	195,500 (+ overseas travel	240,200	(+ oversea									
				Subject to inspection Not subject to	Article 32, Paragraph 1, Item 2 (a) (17) 44,700	Article 32, Paragraph 2, Item 2 (i)	44,700	exper									
	Changes based on guidelines, etc.		guiaelines, etc.	inspection One product with several proprietary	Article 32, Paragraph 1, Item 2 (a) (17) 41,400		41,400										
Quasi-drugs			Article 32, Paragraph 1, Item 2 (a) (18) 55,900		55,900												
		Quasi-(490		Article 32, Paragraph 1, Item 2 (b) (1) 81,200 Article 32, Paragraph 1, Item 2		81,200										
Pest contro	ıl agents/qua	si-drugs for	pest control	One product with	(a) (19) and (b) (2) 50,800		50,800										
			- 4	several proprietary names	Article 32, Paragraph 1, Item 2 (a) (20) and (b) (3) 37,300		37,300										
		Cosme			Article 32, Paragraph 1, Item 2 (c)		- ,										

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

	Products including Pharmaceutic	dis and Medical Devices.		User fees					
		Category		Review		Total			
	Daview for engage			Review	Conformity	Tota	ı		
	Review for approv	<mark>val of drugs (emergency appr</mark> I	1		4 224 400 (+ overseas travel		(+ overseas travel		
			First application	36,538,400	4,224,100 (+ overseas travel expenses *1)	40,762,500	expenses *1)		
		Non-orphan drugs	products	Article 32, Paragraph 1, Item 1 (a) (1)	Article 32, Paragraph 2, Item 3 (a)				
		Non-orphan drugs	Line extension products	3,784,700	expenses 1)	5,194,100	(+ overseas travel expenses *1)		
	New drugs		products	Article 32, Paragraph 1, Item 1 (a) (3)	Article 32, Paragraph 2, Item 3 (b)				
	(No. 1)		First application products	30,618,800	4,224,100 (+ overseas travel expenses *1)	34,842,900	(+ overseas travel expenses *1)		
		Orphan drugs	products	Article 32, Paragraph 1, Item 1 (a) (2)	Article 32, Paragraph 2, Item 3 (a)				
Ą		Стр.там. 21.2. 3 2	Line extension products	3,166,400	expenses 1)	4,575,800	(+ overseas travel expenses *1)		
the			products	Article 32, Paragraph 1, Item 1 (a) (4)	Article 32, Paragraph 2, Item 3 (b)				
At the time of application			First application products	17,438,300	4,224,100 (+ overseas travel expenses *1)	21,662,400	(+ overseas travel expenses *1)		
of		Non-orphan drugs	products	Article 32, Paragraph 1, Item 1 (a) (5)	Article 32, Paragraph 2, Item 3 (a)				
app		Orphan drugs	Line extension products	1,803,600	expenses ()	3,213,000	(+ overseas travel expenses *1)		
lica	New drugs		products	Article 32, Paragraph 1, Item 1 (a) (7)	Article 32, Paragraph 2, Item 3 (b)				
tion	(No. 2)		First application products	14,354,900	4,224,100 (+ overseas travel expenses *1)	18,579,000	(+ overseas travel expenses *1)		
			products	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)				
		rugs Switch OTC drugs, etc.	First application products	1,627,300	195,500 (+ overseas travel expenses *1)	1,822,800	(+ overseas travel expenses *1)		
	BTC/OTC drugs		BTC/OTC drugs Switch OTC drugs, etc.	ugs Switch OTC drugs, etc.	products	Article 32, Paragraph 1, Item 1 (a) (10)	Article 32, Paragraph 2, Item 3 (c)		
	210/010 41490		Line extension products	1,627,300	expenses i)	1,822,800	(+ overseas travel expenses *1)		
			products	Article 32, Paragraph 1, Item 1 (a) (10)	Article 32, Paragraph 2, Item 3 (c)				
			First application products	15,652,600	expenses i)	19,876,700	(+ overseas travel expenses *1)		
l ₹		Non-orphan drugs	products	Article 32, Paragraph 1, Item 2 (a) (1)	Article 32, Paragraph 2, Item 3 (a)		,		
At the time of application for change			Line extension products	1,624,000	1,409,400 (+ overseas travel expenses *1)	3,033,400	(+ overseas travel expenses *1)		
me	New drugs		products	Article 32, Paragraph 1, Item 2 (a) (2)	Article 32, Paragraph 2, Item 3 (b)		,		
of a	3		First application products	12,955,000	4,224,100 (+ overseas travel expenses *1)	17,179,100	(+ overseas travel expenses *1)		
힐		Orphan drugs	products	Article 32, Paragraph 1, Item 2 (a) (4)	Article 32, Paragraph 2, Item 3 (a)		,		
catio			Line extension products	1,344,800	1,409,400 (+ overseas travel expenses *1)	2,754,200	(+ overseas travel expenses *1)		
n fo			products	Article 32, Paragraph 1, Item 2 (a) (5)	Article 32, Paragraph 2, Item 3 (b)		,		
or ch			First application products	15,652,600	expenses 1)	15,848,100	(+ overseas travel expenses *1)		
ang	BTC/OTC drugs	Switch OTC drugs, etc.	products	Article 32, Paragraph 1, Item 2 (a) (11)	Article 32, Paragraph 2, Item 3 (c)		,		
ë		3,	Line extension products	1,332,200	195,500 (+ overseas travel expenses *1)	1,527,700	(+ overseas travel expenses *1)		
			products	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

Pharmaceuticals and Medical Devices.						User fees	(unit: yen
		Categor	у		Review	Conformity	Total
	Review of plan to cha	ange appro	ved information o	n drugs			
			First application products		854,100 Article 32-3, Paragraph 1, Item 1 (a)		854,100
		Non-o	rphan drugs	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
	New drugs			First application products	706,900 Article 32-3, Paragraph 1, Item 1 (d)		706,900
		Orp	han drugs	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
			First appli	cation products	854,100 Article 32-3, Paragraph 1, Item 1 (g)		854,100
	Generic drugs		First application products (biological drugs)		1,386,800 Article 32-3, Paragraph 1, Item 1 (h)		1,386,800
				nsion products	323,000 Article 32-3, Paragraph 1, Item 1 (i)		323,000
		First a		cation products	854,100 Article 32-3, Paragraph 1, Item 1 (j)		854,100
	BTC/OTC drugs		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 (I)		323,000
					355,900 Article 32-3, Paragraph 1, Item 2 (a)		355,900
	Quasi-o	drugs		One product with several proprietary names	55,900 Article 32-3, Paragraph 1, Item 2 (b)		55,900
					381,200 Article 32-3, Paragraph 1, Item 1 (m)		381,200
	Pest contro	ol agents		One product with several proprietary	50,800		50,800
				names	Article 32-3, Paragraph 1, Item 1 (n) 381,200		381,200
	Quasi-drugs for	r pest contr	rol	One product with several	Article 32-3, Paragraph 1, Item 2 (c) 50,800		50,800
		-	- 4:	proprietary names	Article 32-3, Paragraph 1, Item 2 (d) 337,300		337,300
		Cosm	etics		Article 32-3, Paragraph 1, Item 3		,

(u	nit:	ver

	0-1			User fees	
	Category		Review	Conformity	Total
	GMP inspection of drugs				
		In Japan		1,008,700	1,008,700
	Now drugo	п Јарап		Article 32, Paragraph 5, Item 1 (b) (1)	
	New drugs	Oversees		1,272,900	1,272,900
		Overseas		Article 32, Paragraph 5, Item 1 (b) (2)	
₽		In Janan		908,100	908,100
prc	Dialogical drugg/radianharmacauticala etc	In Japan		Article 32, Paragraph 5, Item 1 (a) (1)	
va	Biological drugs/radiopharmaceuticals, etc.	Oversees		1,151,400	1,151,400
Ď.		Overseas		Article 32, Paragraph 5, Item 1 (a) (2)	
ar <u>i</u>		In Japan		632,500	632,500
a c	Starila druga/Starila guasi druga	In Japan		Article 32, Paragraph 5, Item 1 (c) (1)	
ha	Sterile drugs/Sterile quasi-drugs	0		796,700	796,700
nge		Overseas		Article 32, Paragraph 5, Item 1 (c) (2)	
,, (1)		In Inner		459,200	459,200
nd	Others described the second	In Japan		Article 32, Paragraph 5, Item 1 (d) (1)	
ma	Other drugs/quasi-drugs	0		578,500	578,500
Approval, partial change, and manufacture		Overseas		Article 32, Paragraph 5, Item 1 (d) (2)	·
fact				86,800	86,800
iure		In Japan		Article 32, Paragraph 5, Item 2 (a) and	•
ਰੰ	Packaging, labeling, storage, external testing, etc.			Paragraph 6, Item 1 (a)	
r e)	a dokaging, laboling, storage, external testing, etc.	_		115,300	115,300
for export		Overseas		Article 32, Paragraph 5, Item 2 (c) and Paragraph 6, Item 1 (b)	
	Specific storage (manufacturing sites where only registered specific storage takes place)	In Japan		43,400	43,400
				Article 32, Paragraph 5, Item 2 (b)	
		Overseas		57,600	57,600
	otorage takes place)	Overseas		Article 32, Paragraph 5, Item 2 (d)	
		In Janan		1,008,700	1,008,700
	Now drugo	In Japan		Article 32-3, Paragraph 2, Item 1 (b) (1)	
	New drugs	Oversees		1,272,900	1,272,900
		Overseas		Article 32-3, Paragraph 2, Item 1 (b) (2)	
		In Japan		908,100	908,100
	Biological drugs/radiopharmaceuticals, etc.	In Japan		Article 32-3, Paragraph 2, Item 1 (a) (1)	
	Biological drugs/radiopharmaceuticals, etc.	Overseas		1,151,400	1,151,400
		Overseas		Article 32-3, Paragraph 2, Item 1 (a) (2)	
_{ZD}		In Japan		632,500	632,500
Review of	Sterile drugs/Sterile quasi-drugs	Πυαραπ		Article 32-3, Paragraph 2, Item 1 (c) (1)	
e₩	Sterile drugs/Sterile quasi-drugs	Overseas		796,700	796,700
		Overseas		Article 32-3, Paragraph 2, Item 1 (c) (2)	
plan		In Japan		459,200	459,200
n tc	Other drugs/quasi-drugs	πυαραπ		Article 32-3, Paragraph 2, Item 1 (d) (1)	
) 다	Other drugs/quasi-drugs	Overseas		578,500	578,500
to change		Overseas		Article 32-3, Paragraph 2, Item 1 (d) (2)	
ge				86,800	86,800
	Designing labeling stores - system at testing at	In Japan		Article 32-3, Paragraph 2, Item 2 (a) and Paragraph 3, Item 1	
	Packaging, labeling, storage, external testing, etc.			115,300	115,300
		Overseas		Article 32-3, Paragraph 2, Item 2 (c) and Paragraph 3, Item 2	
1				43,400	43,400
	Specific storage	In Japan		Article 32-3, Paragraph 2, Item 2 (b)	10, 100
	(manufacturing sites where only registered specific			57,600	57,600
	storage takes place)	Overseas		Article 32-3, Paragraph 2, Item 2 (d)	0.,000

	Category			Review	User fees Conformity	Total
	GMP inspection	of drugs	Basic fee		866,500	866,500
		In Japan	Additional fee for		Article 32, Paragraph 5, Item 3 (a) (1) 44,000	44,000 multiplied by numb
	Biological		product		Article 32, Paragraph 5, Item 3 (a) (1)	products
	drugs/radiopharmaceuticals, etc.	_	Basic fee —		1,109,800 Article 32, Paragraph 5, Item 3 (a) (2)	1,109,800
		Overseas	Additional fee for product		44,000	44,000 multiplied by numl products
			Basic fee		Article 32, Paragraph 5, Item 3 (a) (2) 615,600	615,600
		In Japan			Article 32, Paragraph 5, Item 3 (b) (1) 17,900	17,900 multiplied by numl
	Sterile drugs/Sterile quasi-drugs		Additional fee for product		Article 32, Paragraph 5, Item 3 (b) (1)	products
٦,	Sterile drugs/Sterile quasi-drugs		Basic fee		779,800 Article 32, Paragraph 5, Item 3 (b) (2)	779,800
Renewal of approval/renewal of manufacture for export		Overseas	Additional fee for		17,900	17,900 multiplied by num products
al of			product		Article 32, Paragraph 5, Item 3 (b) (2) 446.200	446,200
appro		In Japan	Basic fee		Article 32, Paragraph 5, Item 3 (c) (1)	man daine lie and have an annual
oval/r			Additional fee for product		13,700 Article 32, Paragraph 5, Item 3 (c) (1)	13,700 multiplied by numi
enew	Other drugs/quasi-drugs		Basic fee		565,600 Article 32, Paragraph 5, Item 3 (c) (2)	565,600
al of		Overseas	Additional fee for		13,700	13,700 multiplied by numl products
manı			product		Article 32, Paragraph 5, Item 3 (c) (2)	
ıfactu			Basic fee		361,600 Article 32, Paragraph 5, Item 3 (d) (1)	361,600
ire fo		In Japan	Additional for for		and Paragraph 6, Item 2 (a) 9.700	9,700 multiplied by num
r exp	Daakanin u lahalin u atauana		Additional fee for product		Article 32, Paragraph 5, Item 3 (d) (1)	9,700 products
유	Packaging, labeling, storage, external testing, etc.				and Paragraph 6, Item 2 (a) 470,100	470,100
			Basic fee		Article 32, Paragraph 5, Item 3 (d) (3) and Paragraph 6, Item 2 (b)	
		Overseas	Additional fee for		9,700	9,700 multiplied by num products
			product		Article 32, Paragraph 5, Item 3 (d) (3) and Paragraph 6, Item 2 (b)	
	Specific storage (manufacturing sites where only registered specific storage takes place)		Basic fee —		180,800 Article 32, Paragraph 5, Item 3 (d) (2)	180,800
		In Japan	Additional fee for		9,700	9,700 multiplied by number products
			product		Article 32, Paragraph 5, Item 3 (d) (2) 235.000	235,000
		Overseas	Basic fee		Article 32, Paragraph 5, Item 3 (d) (4)	0.700 multiplied by num
			Additional fee for product		9,700 Article 32, Paragraph 5, Item 3 (d) (4)	9,700 multiplied by numi products
			Basic fee —		1,165,200 Article 32-2, Paragraph 1, Item 1	1,165,200
<u>s</u>			Additional fee for		44,000	44,000 multiplied by num
Issuance	Biological drugs/radiopharmace	euticals, etc.	product		Article 32-2, Paragraph 1, Item 1	multiplied by num
ce of			Additional fees for manufacturing and		10,000	10,000 marketing authorize holders
certif			sales		Article 32-2, Paragraph 1, Item 1 818,700	818,700
icatio			Basic fee		Article 32-2, Paragraph 1, Item 2	multiplied by pure
on of	Sterile drugs/Sterile quasi	-drugs	Additional fee for product		17,900 Article 32-2, Paragraph 1, Item 2	17,900 products
confo	3 4240.	44401 41490			10,000	multiplied by numl 10,000 marketing authoriz
rmity			manufacturing and sales		Article 32-2, Paragraph 1, Item 2	holders
(exa			Basic fee —		593,800 Article 32-2, Paragraph 1, Item 3	593,800
of certification of conformity (examination of conformity regarding type of manufacturing)			Additional fee for		13,700	13,700 multiplied by number products
tion o	Other drugs/quasi-dru	gs	product		Article 32-2, Paragraph 1, Item 3	multiplied by num
f con			Additional fees for manufacturing and		10,000	10,000 marketing authoriz
formi			sales		Article 32-2, Paragraph 1, Item 3 493,600	493,600
ty reg			Basic fee		Article 32-2, Paragraph 1, Item 4	10.10
yardir	Packaging, labeling, sto	rage	Additional fee for product		9,700 Article 32-2, Paragraph 1, Item 4	9,700 multiplied by number products
ng typ	0.0.	-	Additional fees for		10,000	multiplied by numl
e of r			manufacturing and sales		Article 32-2, Paragraph 1, Item 4	holders
nanu			Basic fee		246,800 Article 32-2, Paragraph 1, Item 5	246,800
factu	Specific storage		Additional fee for		9,700	9,700 multiplied by number products
ring)	(manufacturing sites where only reg storage takes place)		product		Article 32-2, Paragraph 1, Item 5	multiplied by num
	j , 133,		Additional fees for manufacturing and		10,000	10,000 marketing authori: holders
	<u> </u>		sales		Article 32-2, Paragraph 1, Item 5 230,000	230,000
Ad	ditional fees for on-site inspection	In	Japan		Article 32, Paragraph 7, Item 1; Article 32-2, Paragraph 2, Item 1;	
	(per day)	Ov	/erseas		200,000 + overseas travel expenses	200,000 + overseas travel expenses
						i

						User fees			
Category					Review	Conformity	Tot	al	
GLF	P inspection of					3,258,300	3,258,300		
			In Japan				Article 32, Paragraph 4, Item 1 (a)		
GLP		0,	/erseas			3,606,200 + overseas travel expenses	3,606,200	+ overseas tr expenses	
			/erseas			Article 32, Paragraph 4, Item 1 (b)		охроносо	
GCP inspection of drugs					4.000.000	4.000.000			
		First on all set		n Japan		4,302,300 Article 32, Paragraph 4, Item 2 (a) (1)	4,302,300		
		First applicat products				4,758,500 + overseas travel expenses	4,758,500	+ overseas tr	
	New	·	0	Overseas		Article 32, Paragraph 4, Item 2 (a) (2)	.,. 00,000	expenses	
	application		l,	n Japan		1,138,600	1,138,600		
		Line extensi		П Јарап		Article 32, Paragraph 4, Item 2 (a) (3)			
		products	0	Overseas		1,187,700 + overseas travel expenses	1,187,700	expenses	
GCP for new drugs						Article 32, Paragraph 4, Item 2 (a) (4) 4,302,300	4,302,300		
		First applicat		n Japan		4,302,300 Article 32, Paragraph 4, Item 2 (b) (1)	4,302,300		
		products				4,758,500 + overseas travel expenses	4,758,500	+ overseas tra	
	Partial		0	Overseas		Article 32, Paragraph 4, Item 2 (b) (2)		expenses	
	change		lı	n Japan		1,138,600	1,138,600		
		Line extensi				Article 32, Paragraph 4, Item 2 (b) (3)		+ overseas tra	
		products	0	Overseas		1,187,700 + overseas travel expenses		expenses	
						Article 32, Paragraph 4, Item 2 (b) (4) 696,700	696,700		
				n Japan		Article 32, Paragraph 4, Item 2 (a) (5)	223,100		
		New applicat	_	Overseas		1,026,200 + overseas travel expenses	1,026,200	+ overseas tra expenses	
GCP for generic dru	ıas					Article 32, Paragraph 4, Item 2 (a) (6)		•	
CC. 101 gonono dia	J-		lı	n Japan		696,700 Article 32, Paragraph 4, Item 2 (b) (5)	696,700		
		Partial chan	ge			1,026,200 + overseas travel expenses		+ overseas tr	
			0	Overseas		expenses Article 32, Paragraph 4, Item 2 (b) (6)	1,020,200	expenses	
			1.			696,700	696,700		
				n Japan		Article 32, Paragraph 4, Item 2 (a) (5)			
		New application		Overseas		1,026,200 + overseas travel expenses	1,026,200	+ overseas tra expenses	
GCP for BTC/OTC dr	ruas					Article 32, Paragraph 4, Item 2 (a) (6)			
	Ü		lı	n Japan		696,700 Article 32, Paragraph 4, Item 2 (b) (5)	696,700		
		Partial change				1,026,200 + overseas travel expenses		+ overseas tra	
				Overseas		Article 32, Paragraph 4, Item 2 (b) (6)	1,020,200	expenses	
Interim evaluation	of drugs wit	th conditional app	roval						
			First app		4,987,400	4,224,100 (+ overseas travel expenses *3)	9,211,500	(+ oversea: expen	
	Non-o	rphan drugs	prod	ucts	Article 32, Paragraph 9, Item 1 (a)	Article 32, Paragraph 9, Item 2 (a)		·	
		rten erpnan arage		tension	498,700	1,409,400 (+ overseas travel expenses *3)	1,908,100	(+ oversea expen	
Review/inspection of interim evaluation	<u> </u>		prod		Article 32, Paragraph 9, Item 1 (c)	Article 32, Paragraph 9, Item 2 (b)		(+ oversea	
GvaluatiOH				plication lucts	4,127,800	4,224,100 (+ overseas travel expenses *3)	8,351,900	(+ oversea expen	
	Orpl	han drugs	Prod						
	Ī				Article 32, Paragraph 9, Item 1 (b)	Article 32, Paragraph 9, Item 2 (a)	4.000 150	(+ oversea	
			Line ext		412,700	1,409,400 (+ overseas travel expenses *3)	1,822,100		
	<u> </u>	Γ	prod			1,409,400 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 2 (b)			
		In			412,700	1,409,400 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 2 (b) 3,258,300 Article 32, Paragraph 9, Item 3 (a) (1)	1,822,100	expen	
GLP of interim evalua	ation		prod Japan		412,700	1,409,400 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 2 (b) 3,258,300		expen	
GLP of interim evalua	ation		prod		412,700	1,409,400 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 2 (b) 3,258,300 Article 32, Paragraph 9, Item 3 (a) (1) 3,606,200 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (a) (2)	3,258,300	expen	
GLP of interim evalua	ation	Ov	Japan /erseas		412,700	1,409,400 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 2 (b) 3,258,300 Article 32, Paragraph 9, Item 3 (a) (1) 3,606,200 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (a) (2) 3,465,200	3,258,300	expen	
GLP of interim evalua	ation	Ov First applicat	Japan /erseas	lucts	412,700	1,409,400 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 2 (b) 3,258,300 Article 32, Paragraph 9, Item 3 (a) (1) 3,606,200 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (a) (2) 3,465,200 Article 32, Paragraph 9, Item 3 (b) (1) 3,806,000 (+ overseas travel)	3,258,300 3,606,200 3,465,200	(+ oversea expen	
		Ov	Japan /erseas	lucts	412,700	1,409,400 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 2 (b) 3,258,300 Article 32, Paragraph 9, Item 3 (a) (1) 3,606,200 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (a) (2) 3,465,200 Article 32, Paragraph 9, Item 3 (b) (1) 3,806,900 (+ overseas travel expenses *3)	3,258,300	(+ oversea expen	
GLP of interim evalua		Ov First applicat	Japan /erseas ion O	n Japan Overseas	412,700	1,409,400 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 2 (b) 3,258,300 Article 32, Paragraph 9, Item 3 (a) (1) 3,606,200 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (a) (2) 3,465,200 Article 32, Paragraph 9, Item 3 (b) (1) 3,806,900 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (3) Article 32, Paragraph 9, Item 3 (b) (3) 1,188,900	3,258,300 3,606,200 3,465,200	(+ oversea expen	
		First applicat products Line extensi	Japan verseas liion U	lucts n Japan	412,700	1,409,400 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 2 (b) 3,258,300 Article 32, Paragraph 9, Item 3 (a) (1) 3,606,200 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (a) (2) 3,465,200 Article 32, Paragraph 9, Item 3 (b) (1) 3,806,900 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (3) 1,188,900 Article 32, Paragraph 9, Item 3 (b) (2)	3,258,300 3,606,200 3,465,200 3,806,900 1,188,900	(+ oversea expen	
		Ov First applicat products	Japan /erseas tion	n Japan Overseas	412,700	1,409,400 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 2 (b) 3,258,300 Article 32, Paragraph 9, Item 3 (a) (1) 3,606,200 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (a) (2) 3,465,200 Article 32, Paragraph 9, Item 3 (b) (1) 3,806,900 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (3) 1,188,900 Article 32, Paragraph 9, Item 3 (b) (2) 1,220,000 (+ overseas travel expenses *3)	3,258,300 3,606,200 3,465,200 3,806,900	(+ oversea expen	
GPSP of interim evalu	uation	First applicat products Line extensi products	Japan verseas lition O II O O	in Japan Overseas n Japan	412,700	1,409,400 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 2 (b) 3,258,300 Article 32, Paragraph 9, Item 3 (a) (1) 3,606,200 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (a) (2) 3,465,200 Article 32, Paragraph 9, Item 3 (b) (1) 3,806,900 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (3) 1,188,900 Article 32, Paragraph 9, Item 3 (b) (2) 4,220,000 (+ overseas travel expenses *3)	3,258,300 3,606,200 3,465,200 3,806,900 1,188,900	(+ oversea exper	
GPSP of interim evalu	uation	First applicat products Line extensi	yerseas ion O O al)	n Japan Overseas n Japan Overseas	412,700	1,409,400 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 2 (b) 3,258,300 Article 32, Paragraph 9, Item 3 (a) (1) 3,606,200 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (a) (2) 3,465,200 Article 32, Paragraph 9, Item 3 (b) (1) 3,806,900 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (3) 1,188,900 Article 32, Paragraph 9, Item 3 (b) (2) 1,220,000 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (2) 1,220,000 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (4)	3,258,300 3,606,200 3,465,200 3,806,900 1,188,900 1,220,000	(+ oversea expen	
GPSP of interim evalu	uation	First applicat products Line extensi products mergency approv	Japan /erseas ion O O Tal)	in Japan Overseas n Japan	412,700	1,409,400 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 2 (b) 3,258,300 Article 32, Paragraph 9, Item 3 (a) (1) 3,606,200 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (a) (2) 3,465,200 Article 32, Paragraph 9, Item 3 (b) (1) 3,806,900 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (3) 1,188,900 Article 32, Paragraph 9, Item 3 (b) (2) 1,220,000 (+ overseas travel expenses *3)	3,258,300 3,606,200 3,465,200 3,806,900 1,188,900	(+ oversea exper	
GPSP of interim evalu	uation	First applicat products Line extensi products	prod Japan verseas ion O II O al) Iiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiii	n Japan Overseas n Japan Overseas n Japan	412,700	1,409,400 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 2 (b) 3,258,300 Article 32, Paragraph 9, Item 3 (a) (1) 3,606,200 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (a) (2) 3,465,200 Article 32, Paragraph 9, Item 3 (b) (1) 3,806,900 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (3) 1,188,900 Article 32, Paragraph 9, Item 3 (b) (2) 1,220,000 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (2) 1,220,000 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (4) 3,465,200 Article 32, Paragraph 4, Item 2 (c) (1)	3,258,300 3,606,200 3,465,200 3,806,900 1,188,900 1,220,000 3,465,200	(+ oversea exper	
GPSP of interim evalu	nation	First applicat products Line extensi products mergency approv First applicat	prod Japan verseas ion O II O al) Iiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiii	n Japan Overseas n Japan Overseas	412,700	1,409,400 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 2 (b) 3,258,300 Article 32, Paragraph 9, Item 3 (a) (1) 3,606,200 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (a) (2) 3,465,200 Article 32, Paragraph 9, Item 3 (b) (1) 3,806,900 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (3) 1,188,900 Article 32, Paragraph 9, Item 3 (b) (2) 1,220,000 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (4) 3,465,200 Article 32, Paragraph 4, Item 2 (c) (1) 3,806,900 (+ overseas travel expenses travel expenses *3) Article 32, Paragraph 4, Item 2 (c) (2)	3,258,300 3,606,200 3,465,200 3,806,900 1,188,900 1,220,000 3,465,200	(+ oversea exper	
GPSP of interim evalu	nation	First applicat products Line extensi products mergency approv First applicat	prod Japan /erseas ion O on II O al) ion O on on	n Japan Overseas n Japan Overseas n Japan	412,700	1,409,400 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 2 (b) 3,258,300 Article 32, Paragraph 9, Item 3 (a) (1) 3,606,200 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (a) (2) 3,465,200 Article 32, Paragraph 9, Item 3 (b) (1) 3,806,900 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (3) 1,188,900 Article 32, Paragraph 9, Item 3 (b) (2) 1,220,000 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (4) 3,465,200 Article 32, Paragraph 4, Item 2 (c) (1) 3,806,900 + overseas travel expenses Article 32, Paragraph 4, Item 2 (c) (2) 1,188,900	3,258,300 3,606,200 3,465,200 3,806,900 1,188,900 1,220,000 3,465,200	(+ oversea exper	
GPSP of interim evalue GCP inspection GPSP for emergency appro	nation	First applicat products Line extensi products mergency approv First applicat products	prod Japan verseas ion O al) II O III O III O III O III III O III II III	n Japan Overseas n Japan Overseas n Japan Overseas	412,700	1,409,400 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 2 (b) 3,258,300 Article 32, Paragraph 9, Item 3 (a) (1) 3,606,200 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (a) (2) 3,465,200 Article 32, Paragraph 9, Item 3 (b) (1) 3,806,900 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (3) 1,188,900 Article 32, Paragraph 9, Item 3 (b) (2) 1,220,000 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (4) 3,465,200 Article 32, Paragraph 4, Item 2 (c) (1) 3,806,900 + overseas travel expenses Article 32, Paragraph 4, Item 2 (c) (2) 1,188,900 Article 32, Paragraph 4, Item 2 (c) (3)	3,258,300 3,606,200 3,465,200 3,806,900 1,188,900 1,220,000 3,465,200 3,806,900 1,188,900	(+ oversea expen (+ oversea expen (+ oversea expen + overseas trexpenses	
GPSP of interim evalue GCP inspection GPSP for emergency appro	nation	First applicat products Line extensi products mergency approv First applicat products	prod Japan verseas lition O on lition	n Japan Overseas n Japan Overseas n Japan Overseas	412,700	1,409,400 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 2 (b) 3,258,300 Article 32, Paragraph 9, Item 3 (a) (1) 3,606,200 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (a) (2) 3,465,200 Article 32, Paragraph 9, Item 3 (b) (1) 3,806,900 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (3) 1,188,900 Article 32, Paragraph 9, Item 3 (b) (2) 1,220,000 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (4) 3,465,200 Article 32, Paragraph 4, Item 2 (c) (1) 3,806,900 + overseas travel expenses Article 32, Paragraph 4, Item 2 (c) (2) 1,188,900 Article 32, Paragraph 4, Item 2 (c) (3) Article 32, Paragraph 4, Item 2 (c) (3) 1,220,000 + overseas travel expenses	3,258,300 3,606,200 3,465,200 3,806,900 1,188,900 1,220,000 3,465,200 3,806,900 1,188,900	(+ oversea exper	
GPSP of interim evalue GCP inspection GPSP for emergency appro	nation	First applicat products Line extensi products mergency approv First applicat products	prod Japan verseas ion O II O II O III O III O III O O	n Japan Overseas n Japan Overseas n Japan Overseas n Japan Overseas	412,700	1,409,400 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 2 (b) 3,258,300 Article 32, Paragraph 9, Item 3 (a) (1) 3,606,200 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (a) (2) 3,465,200 Article 32, Paragraph 9, Item 3 (b) (1) 3,806,900 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (3) 1,188,900 Article 32, Paragraph 9, Item 3 (b) (2) 1,220,000 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (4) 3,465,200 Article 32, Paragraph 4, Item 2 (c) (1) 3,806,900 + overseas travel expenses Article 32, Paragraph 4, Item 2 (c) (3) 1,220,000 + overseas travel expenses Article 32, Paragraph 4, Item 2 (c) (3) 1,220,000 + overseas travel expenses Article 32, Paragraph 4, Item 2 (c) (4)	3,258,300 3,606,200 3,465,200 3,806,900 1,188,900 1,220,000 3,465,200 3,806,900 1,188,900 1,220,000	(+ oversea expen (+ oversea expen + overseas trexpenses	
GPSP of interim evalue GCP inspection GPSP for emergency approdugs	n of drugs (er	First applicat products Line extensi products mergency approv First applicat products Line extensi products	prod Japan verseas ion O II O II O III O III O O III O O	n Japan Overseas In Japan Overseas In Japan Overseas In Japan Overseas In Japan	412,700	1,409,400 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 2 (b) 3,258,300 Article 32, Paragraph 9, Item 3 (a) (1) 3,606,200 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (a) (2) 3,465,200 Article 32, Paragraph 9, Item 3 (b) (1) 3,806,900 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (3) 1,188,900 Article 32, Paragraph 9, Item 3 (b) (2) 1,220,000 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (4) 3,465,200 Article 32, Paragraph 4, Item 2 (c) (1) 3,806,900 + overseas travel expenses Article 32, Paragraph 4, Item 2 (c) (2) 1,188,900 Article 32, Paragraph 4, Item 2 (c) (3) Article 32, Paragraph 4, Item 2 (c) (3) 1,220,000 + overseas travel expenses	3,258,300 3,606,200 3,465,200 3,806,900 1,188,900 1,220,000 3,465,200 3,806,900 1,188,900	(+ overseas expenses) (+ overseas expenses) + overseas transporter expenses	
GPSP of interim evalue GCP inspection GPSP for emergency appro-	n of drugs (er	First applicat products Line extensi products mergency approv First applicat products Line extensi products	prod Japan verseas ion O on II O on II on on	n Japan Overseas n Japan Overseas n Japan Overseas n Japan Overseas	412,700	1,409,400 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 2 (b) 3,258,300 Article 32, Paragraph 9, Item 3 (a) (1) 3,606,200 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (a) (2) 3,465,200 Article 32, Paragraph 9, Item 3 (b) (1) 3,806,900 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (3) 1,188,900 Article 32, Paragraph 9, Item 3 (b) (2) 1,220,000 (+ overseas travel expenses *3) Article 32, Paragraph 9, Item 3 (b) (4) 3,465,200 Article 32, Paragraph 4, Item 2 (c) (1) 3,806,900 + overseas travel expenses Article 32, Paragraph 4, Item 2 (c) (2) 1,188,900 Article 32, Paragraph 4, Item 2 (c) (3) 1,220,000 + overseas travel expenses Article 32, Paragraph 4, Item 2 (c) (3) 1,220,000 + overseas travel expenses Article 32, Paragraph 4, Item 2 (c) (4) 696,700	3,258,300 3,606,200 3,465,200 3,806,900 1,188,900 1,220,000 3,806,900 1,188,900 1,220,000 1,188,900 1,220,000	+ overseas tra	

1 Todacis including Friannaceuticals and Medic						(unit. yen)
Categor	v			User fees		
Categor	у		Review	Conformity	Tota	al
Re-examination of drugs						
	First application	products	1,238,700	4,224,100 (+ overseas travel expenses *4)	5,462,800	(+ overseas travel expenses *4)
Paviow/inapaction of re examination		'	Article 32, Paragraph 12, Item 1	Article 32, Paragraph 13, Item 1 (a)		
Review/inspection of re-examination	Line extension p	roducts	417,000	1,409,400 (+ overseas travel expenses *4)	1,826,400	(+ overseas travel expenses *4)
	Eme extension products		Article 32, Paragraph 12, Item 2	Article 32, Paragraph 13, Item 1 (b)		
	GLP for re-examination Overseas			3,258,300	3,258,300	
				Article 32, Paragraph 13, Item 2 (a) (1)		
GLP for re-examination				3,606,200 (+ overseas travel expenses *4)	3,606,200	(+ overseas travel expenses *4)
				Article 32, Paragraph 13, Item 2 (a) (2)		
		In Japan		3,465,200	3,465,200	
	First application			Article 32, Paragraph 13, Item 2 (b) (1)		
	products	Overseas		3,806,900 (+ overseas travel expenses *4)	3,806,900	(+ overseas travel expenses *4)
GPSP for re-examination				Article 32, Paragraph 13, Item 2 (b) (2)		
GFSF 101 Te-examiliation		In Japan		1,188,900	1,188,900	
	Line extension	пт зарап		Article 32, Paragraph 13, Item 2 (b) (3)		
	products	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