## User fees for reviews, etc. of regenerative medical products based on the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No. 145 of 1960)

Note) The applicable articles of the Cabinet Order on Fees related to the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics are shown in the lower rows in the column of user fees.

	Regenerative and Cellular Therapy Products, 0	Gene Therapy Pro	ducts, and Cosmetics are shov		of user fees. (unit: yen)
	Category		Review	User fees Conformity	Total
Ass	essment for manufacturing license of regen	erative medical	IVEAICM	Comorning	i Olai
	products				
		On-site		159,900	159,900
	New license			Article 35, Paragraph 1, Item 1 (a)	
		Document-		120,400	120,400
		based		Article 35, Paragraph 1, Item 1 (b)	
		On-site		105,200	105,200
	Renewal of existing license	OH-Site		Article 35, Paragraph 1, Item 2 (a)	
	Trenewar or existing neerice	Document- based		59,700	59,700
				Article 35, Paragraph 1, Item 2 (b)	
		On-site		105,200	105,200
	Change/addition of classification			Article 35, Paragraph 1, Item 3 (a)	
	Griange/addition or classification	Document-		59,700	59,700
		based		Article 35, Paragraph 1, Item 3 (b)	
	Assessment for foreign manufacturers' acc regenerative medical products	reditation of			
	regenerative medical products			143,900 + overseas travel	143 000 + overseas travel
		On-site		Article 35, Paragraph 2, Item 1 (a)	143,900 expenses
	New accreditation	Document-		62,600	62,600
		based		Article 35, Paragraph 2, Item 1 (b)	1
		On-site		69,700 + overseas travel expenses	69,700 + overseas travel expenses
	Renewal of existing accreditation	On-site		Article 35, Paragraph 2, Item 2 (a)	СХРОПОСО
	ÿ	Document-		42,900	42,900
		based		Article 35, Paragraph 2, Item 2 (b)	+ overseas travel
		On-site		69,700 expenses	69 700
	Change/addition of classification	Decument		Article 35, Paragraph 2, Item 3 (a)	42,900
		Document- based		42,900 Article 35, Paragraph 2, Item 3 (b)	
F	leview for approval of regenerative medical products			, , , , , , , , , , , , , , , , , , , ,	
	(new approval)			/1	/1
	New regenerative medical products		18,803,400	1,476,200 (+ overseas travel expenses *1)	20,279,600 (+ overseas travel expenses *1)
		doto	Article 36, Paragraph 1, Item 1 (a)	· ·	
	Regenerative medical products in case of	new application	9,411,700	1,476,200 (+ overseas travel expenses *1)	10,887,900 (+ overseas travel expenses *1)
	for approval after the conditional time-limite		Article 36, Paragraph 1, Item 1 (b)	•	expenses 1,
			37,300		37,300
	Application for change of brand name		Article 36, Paragraph 1, Item 1 (c)		,
	Review for approval of regenerative medical products				
	(approval for partial changes to approved matters)			/	/
	Regenerative medical products (chan	ges in new	9,411,700	1,476,200 (+ overseas travel expenses *1)	10,887,900 (+ overseas travel expenses *1)
	indications)		Article 36, Paragraph 1, Item 2 (a)	Article 36, Paragraph 2, Item 2 (a)	//
	Regenerative medical products (other changes)		2,041,200	expenses i)	2,107,10 \ expenses *1)
			Article 36, Paragraph 1, Item 2 (b)	Article 36, Paragraph 2, Item 2 (b)	
F	Review for approval of regenerative medion (emergency approval)	cal products			
_	(emergency approvar)			/1 pygrapa tr1	L OVERROOM two
\t th∈ appl	New approval for marketing authorization for regenerative medical products (at the time of application)		18,803,400	1,110,000 (+ overseas travel expenses *1)	19,913,400 + overseas travel expenses *1)
At the time of application					
e of		-	Article 36, Paragraph 1, Item 1 (a)	Article 36, Paragraph 2, Item 3	
ap					
At plica			9,411,700	1,110,000 (+ overseas travel expenses *1)	10,521,700 (+ overseas travel expenses *1)
the t	Approval for partial changes to marketing authorization for new regenerative medical products (changes in indications) (at the time of application)			слрепаса т)	олреноео 1)
At the time of application for change					
of nang			Article 36, Paragraph 1, Item 2 (a)	Article 36, Paragraph 2, Item 3	
Ф	Review of plan to change approved infor	nation on			
	regenerative medical products	nation on			
	Regenerative medical proc	ucts	3,034,700		3,034,700
			Article 38, Paragraph 1	usted in a foreign country (Article	1

<sup>(\*1)</sup> Amount including overseas travel expenses in cases where the inspection is conducted in a foreign country (Article 36, Paragraph 3)

Note) The applicable articles of the Cabinet Order on Fees related to the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics are shown in the lower rows in the column of user fees.

(unit: yen)

Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmeti					User fees	f user fees. (unit: yen)
Category				Review	Conformity	Total
GCT	P inspection for rege	nerative medic	al products			1 2 2211
At the			In Japan		1,008,700	1,008,700
	Other than manufa where only packaging		пт зарап		Article 36, Paragraph 5, Item 1 (a)	
ime	storage are pe		Overseas		1,272,900	1,272,900
of a			Overseas		Article 36, Paragraph 5, Item 1 (b)	
ppro			In Japan		86,800	86,800
oval, ture	Packaging, labeling, storage		· ·		Article 36, Paragraph 5, Item 2 (a)	445.200
par for e			Overseas		115,300 Article 36, Paragraph 5, Item 2 (b)	115,300
tial o					86,800	86,800
time of approval, partial change, manufacture for export			In Japan		Article 36, Paragraph 6, Item 1 (a)	00,000
					115,300	115,300
and			Overseas		Article 36, Paragraph 6, Item 1 (b)	
Α.	Other than manufacturing sites where only packaging, labeling, and storage are performed		In Japan		1,008,700	1,008,700
At the			пт зарап		Article 38, Paragraph 2, Item 1 (a)	
the time			Overseas		1,272,900	1,272,900
ie of			_		Article 38, Paragraph 2, Item 1 (b)	00.000
rev			In Japan		86,800	86,800
iew	Packaging, labelir	ng, storage	-		Article 38, Paragraph 2, Item 2 (a) 115,300	115,300
of pl			Overseas		Article 38, Paragraph 2, Item 2 (b)	113,300
of review of plan to change					86,800	86,800
o ch	<b>+</b>	4:	In Japan		Article 38, Paragraph 3, Item 1	,
ang	Testing instit	utions	Overseas		115,300	115,300
O			Overseas		Article 36, Paragraph 3, Item 2	
≥			Basic fee		866,500	866,500
At the	Other than	In Japan			Article 36, Paragraph 5, Item 3 (a) (1)	
eti	manufacturing sites	iii oapaii	Additional fee		44,000	44,000 x number of item
time	where only		for product		Article 36, Paragraph 5, Item 3 (a) (1)	4 400 000
of ren	packaging, labeling, and storage are		Basic fee		1,109,800 Article 36, Paragraph 5, Item 3 (a) (2)	1,109,800
ene	performed	Overseas	Additional fee		44,000	44,000 x number of item
iewal	'		for product		Article 36, Paragraph 5, Item 3 (a) (2)	44,000 x number of item
of					361.600	361,600
			Basic fee		Article 36, Paragraph 5, Item 3 (b) (1)	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
approval/renewal of		In Japan	Additional fee		9,700	9,700 x number of items
val/	Packaging, labeling, storage		for product		Article 36, Paragraph 5, Item 3 (b) (1)	
ren			Basic fee		470,100	470,100
ewa		Overseas			Article 36, Paragraph 5, Item 3 (b) (2)	
9 0			Additional fee		9,700	9,700 x number of item
			for product		Article 36, Paragraph 5, Item 3 (b) (2) 361,600	361,600
ant	Testing institutions	In Japan	Basic fee		Article 36, Paragraph 6, Item 2 (a)	301,000
ıfac			Additional fee		9,700	9,700 x number of item
manufacture			for product		Article 36, Paragraph 6, Item 2 (a)	5,100 K Hambor of Roll
			,		470,100	470,100
for export		Overses	Basic fee		Article 36, Paragraph 6, Item 2 (b)	·
φ̈́		Overseas	Additional fee		9,700	9,700 x number of iter
ᅲ			for product		Article 36, Paragraph 6, Item 2 (b)	
Ąŧŧ	Other than manufacturing sites where only packaging, labeling, and storage are performed		Basic fee		1,165,200	1,165,200
At the time of issuance of certification of conformity (examination of conformity regarding type of manufacturing)					Article 37, Paragraph 1, Item 1	44.000
ne o			Additional fee for product		44,000	44,000 x number of item
f issu			Additional fee for		Article 37, Paragraph 1, Item 1	10 000 X number of market
Jance of col			manufacturing		10,000	10,000 x number of market authorization holder
e of c nforn ufact			and sales		Article 37, Paragraph 1, Item 1	400.000
ertifi nity r	Packaging, labeling, storage		Basic fee		493,600	493,600
catio egar			Additional fee		Article 37, Paragraph 1, Item 2 9,700	9,700 x number of item
n of ding			for product		Article 37, Paragraph 1, Item 2	ə, r oo x number or item
confc type			Additional fee for		10,000	10,000 x number of marketin
of			manufacturing		, , , , , , , , , , , , , , , , , , ,	authorization holders
_ <	<u> </u>		and sales		Article 37, Paragraph 1, Item 2	220 000
٨٨٥	inspection		apan		230,000 Article 36, Paragraph 7, Item 1; Article 37,	230,000
Auc					Paragraph 2, Item 1; Article 38, Paragraph 4, Item 1	+ aversees travel
			rseas		200,000 expenses	200,000 + overseas travel expenses
370,000					Article 36, Paragraph 7, Item 2 (a) (b); Article 37, Paragraph 2, Item 2 (a) (b); Article 38, Paragraph 4, Item 2 (a) (b)	
	Issuance and reissuance of certification of conformity			<u> </u>	11,000	11,000
led	suance and reissuance	e of certification	of conformity		Article 37, Paragraph 4	11,000

Note) The applicable articles of the Cabinet Order on Fees related to the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics are shown in the lower rows in the column of user fees.

(unit: yen)

Category			User fees User fees			
			Review	Conformity	Total	
	GLP inspection for regen	erative medical products				
		In Japan		3,665,600	3,665,600	
				Article 36, Paragraph 4, Item 1 (a)		
	GLP	Overseas		4,057,000 + overseas travel expenses	4,057,000 + overseas travel expenses	
				Article 36, Paragraph 4, Item 1 (b)		
	GCP inspection for regen	erative medical products				
		In Japan		1,128,900	1,128,900	
	000			Article 36, Paragraph 4, Item 2 (a)		
	GCP	Overseas		1,632,300 + overseas travel expenses	1,632,300 + overseas travel expenses	
				Article 36, Paragraph 4, Item 2 (b)		
	GPSP inspection for reger	nerative medical products				
	GPSP	In Japan		1,085,900	1,085,900	
	(in case of new application	пі зарап		Article 36, Paragraph 4, Item 3 (a)		
	for approval after the conditional time-limited authorization)	Overseas		1,686,600 + overseas travel expenses	1,686,600 + overseas travel expenses	
				Article 36, Paragraph 4, Item 3 (b)		
	Regenerative medical produ	ucts (emergency approval)				
	GPSP (in case of new application- for approval after the emergency approval)	In Japan		1,085,900	1,085,900	
				Article 36, Paragraph 4, Item 3 (a)		
		Overseas		1,686,600 + overseas travel expenses	1,686,600 + overseas travel expenses	
				Article 36, Paragraph 4, Item 3 (b)		
	Re-examination of regenerative medical products					
	Review/inspection	on of re-examination	871,500	1,110,000 (+ overseas travel expenses *2)	1,981,500 (+ overseas travel expenses *2)	
			Article 36, Paragraph 10	Article 36, Paragraph 11, Item 1		
	GLP for re-examination	In Japan		3,665,600	3,665,600	
				Article 36, Paragraph 11, Item 2 (a) (1)		
		Overseas		4,057,000 (+ overseas travel expenses *2)	4,057,000 (+ overseas travel expenses *2)	
				Article 36, Paragraph 11, Item 2 (a) (2)		
	GPSP for re-examination	In Japan		1,085,900	1,085,900	
				Article 36, Paragraph 11, Item 2 (b) (1)		
		Overseas		1,686,600 (+ overseas travel expenses *2)	1,686,600 (+ overseas travel expenses *2)	
				Article 36, Paragraph 11, Item 2 (b) (2)		

<sup>(\*2)</sup> Amount including overseas travel expenses in cases where the inspection is conducted in a foreign country (Article 36, Paragraph 12)