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

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. (unit: yen)

Category			User fees		
			Review	Conformity	Total
Assessment for manufacturing license of regenerative medical products					
	New license	On-site		159,900	159,900
				Article 35, Paragraph 1, Item 1 (a)	
		Document-based		120,400	120,400
				Article 35, Paragraph 1, Item 1 (b)	
	Renewal of existing license	On-site		105,200	105,200
				Article 35, Paragraph 1, Item 2 (a)	
		Document-based		59,700	59,700
				Article 35, Paragraph 1, Item 2 (b)	
	Change/addition of classification	On-site		105,200	105,200
				Article 35, Paragraph 1, Item 3 (a)	
		Document-based		59,700	59,700
				Article 35, Paragraph 1, Item 3 (b)	
Assessment for foreign manufacturers' accreditation of regenerative medical products					
	New accreditation	On-site		143,900 + overseas travel expenses	143,900 + overseas travel expenses
				Article 35, Paragraph 2, Item 1 (a)	
		Document-based		62,600	62,600
				Article 35, Paragraph 2, Item 1 (b)	
	Renewal of existing accreditation	On-site		69,700 + overseas travel expenses	69,700 + overseas travel expenses
				Article 35, Paragraph 2, Item 2 (a)	
		Document-based		42,900	42,900
				Article 35, Paragraph 2, Item 2 (b)	
	Change/addition of classification	On-site		69,700 + overseas travel expenses	69,700 + overseas travel expenses
				Article 35, Paragraph 2, Item 3 (a)	
		Document-based		42,900	42,900
				Article 35, Paragraph 2, Item 3 (b)	
Review for approval of regenerative medical products (new approval)					
	New regenerative medical products		18,803,400	1,476,200 (+ overseas travel expenses *1)	20,279,600 (+ overseas travel expenses *1)
			Article 36, Paragraph 1, Item 1 (a)	Article 36, Paragraph 2, Item 1	
	Regenerative medical products in case of new application for approval after the conditional time-limited authorization		9,411,700	1,476,200 (+ overseas travel expenses *1)	10,887,900 (+ overseas travel expenses *1)
			Article 36, Paragraph 1, Item 1 (b)	Article 36, Paragraph 2, Item 1	
	Application for change of brand name		37,300		37,300
			Article 36, Paragraph 1, Item 1 (c)		
Review for approval of regenerative medical products (approval for partial changes to approved matters)					
	Regenerative medical products (changes in new indications)		9,411,700	1,476,200 (+ overseas travel expenses *1)	10,887,900 (+ overseas travel expenses *1)
			Article 36, Paragraph 1, Item 2 (a)	Article 36, Paragraph 2, Item 2 (a)	
	Regenerative medical products (other changes)		2,041,200	65,900 (+ overseas travel expenses *1)	2,107,10 (+ overseas travel expenses *1)
			Article 36, Paragraph 1, Item 2 (b)	Article 36, Paragraph 2, Item 2 (b)	
Review for approval of regenerative medical products (emergency approval)					
At the time of application	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)
			Article 36, Paragraph 1, Item 1 (a)	Article 36, Paragraph 2, Item 3	
At the time of application for change	Approval for partial changes to marketing authorization for new regenerative medical products (changes in indications) (at the time of application)		9,411,700	1,110,000 (+ overseas travel expenses *1)	10,521,700 (+ overseas travel expenses *1)
			Article 36, Paragraph 1, Item 2 (a)	Article 36, Paragraph 2, Item 3	
Review of plan to change approved information on regenerative medical products					
	Regenerative medical products		3,034,700		3,034,700
			Article 38, Paragraph 1		

(*1) 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)

Category				User fees		
				Review	Conformity	Total
GCTP inspection for regenerative medical products						
At the time of approval, partial change, and manufacture for export	Other than manufacturing sites where only packaging, labeling, and storage are performed		In Japan		1,008,700 Article 36, Paragraph 5, Item 1 (a)	1,008,700
			Overseas		1,272,900 Article 36, Paragraph 5, Item 1 (b)	1,272,900
	Packaging, labeling, storage		In Japan		86,800 Article 36, Paragraph 5, Item 2 (a)	86,800
			Overseas		115,300 Article 36, Paragraph 5, Item 2 (b)	115,300
	Testing institutions		In Japan		86,800 Article 36, Paragraph 6, Item 1 (a)	86,800
			Overseas		115,300 Article 36, Paragraph 6, Item 1 (b)	115,300
At the time of review of plan to change	Other than manufacturing sites where only packaging, labeling, and storage are performed		In Japan		1,008,700 Article 38, Paragraph 2, Item 1 (a)	1,008,700
			Overseas		1,272,900 Article 38, Paragraph 2, Item 1 (b)	1,272,900
	Packaging, labeling, storage		In Japan		86,800 Article 38, Paragraph 2, Item 2 (a)	86,800
			Overseas		115,300 Article 38, Paragraph 2, Item 2 (b)	115,300
	Testing institutions		In Japan		86,800 Article 38, Paragraph 3, Item 1	86,800
			Overseas		115,300 Article 36, Paragraph 3, Item 2	115,300
At the time of renewal of approval/renewal of manufacture for export	Other than manufacturing sites where only packaging, labeling, and storage are performed	In Japan	Basic fee		866,500 Article 36, Paragraph 5, Item 3 (a) (1)	866,500
			Additional fee for product		44,000 Article 36, Paragraph 5, Item 3 (a) (1)	44,000 x number of items
		Overseas	Basic fee		1,109,800 Article 36, Paragraph 5, Item 3 (a) (2)	1,109,800
			Additional fee for product		44,000 Article 36, Paragraph 5, Item 3 (a) (2)	44,000 x number of items
	Packaging, labeling, storage	In Japan	Basic fee		361,600 Article 36, Paragraph 5, Item 3 (b) (1)	361,600
			Additional fee for product		9,700 Article 36, Paragraph 5, Item 3 (b) (1)	9,700 x number of items
		Overseas	Basic fee		470,100 Article 36, Paragraph 5, Item 3 (b) (2)	470,100
			Additional fee for product		9,700 Article 36, Paragraph 5, Item 3 (b) (2)	9,700 x number of items
	Testing institutions	In Japan	Basic fee		361,600 Article 36, Paragraph 6, Item 2 (a)	361,600
			Additional fee for product		9,700 Article 36, Paragraph 6, Item 2 (a)	9,700 x number of items
		Overseas	Basic fee		470,100 Article 36, Paragraph 6, Item 2 (b)	470,100
			Additional fee for product		9,700 Article 36, Paragraph 6, Item 2 (b)	9,700 x number of items
At the time of issuance of certification of conformity (examination of conformity regarding type of manufacturing)	Other than manufacturing sites where only packaging, labeling, and storage are performed		Basic fee		1,165,200 Article 37, Paragraph 1, Item 1	1,165,200
			Additional fee for product		44,000 Article 37, Paragraph 1, Item 1	44,000 x number of items
			Additional fee for manufacturing and sales		10,000 Article 37, Paragraph 1, Item 1	10,000 x number of marketing authorization holders
	Packaging, labeling, storage		Basic fee		493,600 Article 37, Paragraph 1, Item 2	493,600
			Additional fee for product		9,700 Article 37, Paragraph 1, Item 2	9,700 x number of items
			Additional fee for manufacturing and sales		10,000 Article 37, Paragraph 1, Item 2	10,000 x number of marketing authorization holders
Additional fee for on-site inspection (per day)		In Japan			230,000 Article 36, Paragraph 7, Item 1; Article 37, Paragraph 2, Item 1; Article 38, Paragraph 4, Item 1	230,000
		Overseas			200,000 + overseas travel expenses Article 36, Paragraph 7, Item 2 (a) (b); Article 37, Paragraph 2, Item 2 (a) (b); Article 38, Paragraph 4, Item 2 (a) (b)	200,000 + overseas travel expenses
Issuance and reissuance of certification of conformity					11,000 Article 37, Paragraph 4	11,000

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Category			User fees		
			Review	Conformity	Total
GLP inspection for regenerative medical products					
	GLP	In Japan		3,665,600	3,665,600
				Article 36, Paragraph 4, Item 1 (a)	
		Overseas		4,057,000 + overseas travel expenses	4,057,000 + overseas travel expenses
				Article 36, Paragraph 4, Item 1 (b)	
GCP inspection for regenerative medical products					
	GCP	In Japan		1,128,900	1,128,900
				Article 36, Paragraph 4, Item 2 (a)	
		Overseas		1,632,300 + overseas travel expenses	1,632,300 + overseas travel expenses
				Article 36, Paragraph 4, Item 2 (b)	
GPSP inspection for regenerative medical products					
	GPSP (in case of new application for approval after the conditional time-limited authorization)	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)	
Regenerative medical products (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 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)	

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