

<<Quasi-drug>>

		Fee (tax excluded)	Note
Pre-Application	Pre-check of ingredients of product	JPY30,000 per item	* Check of ingredients referred by Standards of Quasi-drug Ingredients and so on.
	Support for pre-application consultations by PMDA	JPY50,000 per time	*Consultation fee will be paid to PMDA separately (actual cost and expenses:JPY22,600 per request) *May be needed several times depends on the case.
Application	Support for application of accreditation of foreign Quasi-drug manufactures	JPY150,000 on a per-request basis	*Fee for application will be paid to PMDA separately (actual cost and expenses:JPY152,600 per request).
	Arrangement of standard test by inspection body	Actual costs and expenses	
	Support for application for approval of item (*Compliance review is required for GMP complied items)	(1) Phase I - JPY500,000 (2) Phase II - JPY250,000 (3) Phase III - JPY250,000 Total JPY1,000,000- per item + fee of compliance review	* Fee of application for approval paid to PMDA will be depends on classification. For updated info, please refer website of PMDA.
	Notification of succession of marketing approval of Quasi-drug	Request to partner company (it will be quoted separately)	
	Notification of minor change of Quasi-drug/Application for partial changes	Request to partner company (it will be quoted separately)	
Importing/Post-marketing	Entrustment fee of quasi-drug products	1st year :JPY600,000 From 2nd year on:JPY300,000	* In case of succession of marketing approval, separate consultation is required.
	Handling fee (product labelling, customs clearance, quality control)	Basic:JPY20,000 per item/month	*Depending on requested work, additional fee may apply.
	Handling fee for market release	5% of cost price based on invoice *May be negotiable during contract renewal depending on annual amount of import	

※Regarding expenses such as warehouse operation fee, storage fee, transportation fee, customs clearance fee and import consumption tax, actual costs and expenses will be charged.

※Regarding expenses such as safety management after market release and recall will be charged separately.