

Applicable Fees for Manufacturing/Wholesaling Authorisations and Inspections

*[The Medicinal Products for Human Use (Fees) Regulations of 2009 (88/2009)
The following fees apply as of 20 February 2009]*

Application Type		Fees for Application Euros (€)
Manufacturing Authorisations (MIA)		
Application N°	Issuance/Renewal of Full Manufacturing Authorisation	
PhS.91 (Φ.Y.91)	Application for the granting/renewal of a full manufacturing authorisation of pharmaceutical products pursuant to Article 40 (3) of the Medicinal Products for Human Use Law 70(I)/2001	4000,00 (plus 256€ for every additional pharmaceutical form)
	Issuance/Renewal of Partial Manufacturing Authorisation (secondary packaging)	
PhS.91 (Φ.Y.91)	Application for the granting/renewal of a partial manufacturing authorisation (secondary packaging) of pharmaceutical products pursuant to Article 40 (3) of the Medicinal Products for Human Use Law 70(I)/2001	1700,00
	Issuance/Renewal of Authorisation for Importation of Pharmaceutical Products from Third Countries	
PhS.91 (Φ.Y.91)	Application for the granting/renewal of manufacturing authorisation for importation of pharmaceutical products from Third Countries pursuant to Article 40 (3) of the Medicinal Products for Human Use Law 70(I)/2001	1700,00
Wholesale Distribution Authorisation (WDA)		
PhS.114 (Φ.Y.114)	Application for the granting of a Wholesale Distribution Authorisation pursuant to Article 83 (3) of the Medicinal Products for Human Use Law 70(I)/2001	1190,00

PhS.114 (Φ.Y.114)	Application for the renewal of a Wholesale Distribution Authorisation pursuant to Article 83 (9) of the Medicinal Products for Human Use Law 70(I)/2001	683,00
INSPECTIONS		Fees for Inspection Euros (€)
MIA Inspections		
PhS.92 (Φ.Y.92)	Application for Inspection under the application of full Manufacturing Authorisation pursuant to Article 40 (3) of the Medicinal Products for Human Use Law 70(I)/2001	205,00
PhS.92 (Φ.Y.92)	Application for Inspection under the application of a Manufacturing Authorisation (partial or importation from Third countries) pursuant to Article 40 (3) of the Medicinal Products for Human Use Law 70(I)/2001	102,00
PhS.92 (Φ.Y.92)	Application for Inspection of a manufacturer of medicinal products overseas (outside Cyprus Republic) – for importing license purposes	854,00 (augmented with all the actual expenses of the inspectors performing the inspection overseas)
WDA Inspections		
PhS.96 (Φ.Y.96)	Application for an Inspection under the application of a Wholesale Distribution Authorisation pursuant to Article 83 (3) of the Medicinal Products for Human Use Law 70(I)/2001	102,00
Other		
PhS.108 (Φ.Y.108)	Application for registration in the Qualified Persons Register pursuant to Article 42 (2) of the Medicinal Products for Human Use Law 70(I)/2001	205,00