

| Country | Fees for Marketing Authorisation Applications   | Fees for Variations   | Payment Schedule   |
|---------|---|---|--|
| Greece  | <p><b>National/ Mutual Recognition (CMS)/ Decentralised (CMS) Procedures:</b></p> <p><u>1) Complete application</u></p> <p>a) New or known active substance (first pharmaceutical form &amp; strength): 20.000 €</p> <p>b) Application based on bibliographic references plus studies conducted by the applicant (first pharmaceutical form &amp; strength): 20.000 €</p> <p>c) Application based on well established use (first pharmaceutical form &amp; strength): 18.000 €</p> <p>d) Additional strength or pharmaceutical form submitted simultaneously with the first authorisation application: 5.000 €</p> <p><u>2) Abridged application</u></p> <p>a) Applications with reference to the original product: 20.000 €</p> <p>b) Generic application requiring bioequivalence study: 14.000 €</p> <p>c) Generic application not requiring bioequivalence study: 9.000 €</p> <p>d) Informed consent applications: 5.000 €</p> <p>e) Additional strength or pharmaceutical form submitted simultaneously with the first authorisation application: 3.000 €</p> <p><u>3) Combination of known active substances: 20.000 €</u></p> <p><u>4) Line extension (new pharmaceutical form, strength): 10.000 €</u></p> <p><u>5) Application for renewal: 5.000 €</u></p> <p><b>Mutual Recognition (RMS)/ Decentralised (RMS) Procedures:</b></p> <p><u>1) Complete application: 40.000 €</u></p> <p><u>2) Abridged application: 30.000 €</u></p> <p>Informed consent applications: 10.000 €</p> <p><u>3) Line extension (new pharmaceutical form, strength): 10.000 €</u></p> <p><u>4) Application for renewal: 7.000 €</u></p> | <p><b>National/ Mutual Recognition (CMS)/ Decentralised (CMS) Procedures:</b></p> <p>a) Type IA: 500 €</p> <p>b) Type IB: 1.000 €</p> <p>c) Type II “new indication” 5.000 €</p> <p>d) Type II “quality &amp; security issues”: 2.000 €</p> <p><b>Mutual Recognition (RMS)/ Decentralised (RMS) Procedures:</b></p> <p>a) Type IA: 1.000 €</p> <p>b) Type IB: 2.000 €</p> <p>c) Type II “new indication”: 10.000 €</p> <p>d) Type II “quality &amp; security issues”: 3.000 €</p> | <p>A copy of the payment receipt should accompany the file of the application.</p> |