

Information for fees for marketing authorization via Mutual recognition procedure (MRP) Bulgaria CMS

Fee payable to Bulgarian Drug Agency:

We remind that all bank fees are at the expense of the applicants/MAHs

Article 8 (3) Article 10 (b) Article 10 (a)

For one strength and pharmaceutical form -	4 090,34 EUR
For every other pharmaceutical form -	3 067,76 EUR
For every other strength -	1 022,59 EUR

Article 10 (1) Article 10 (c)

For one strength and pharmaceutical form -	3 067,75 EUR
For every other pharmaceutical form -	2 300,81 EUR
For every other strength -	766,94 EUR

Article 10 (3) Article 10 (4)

For one strength and pharmaceutical form -	4 090,34 EUR
For every other pharmaceutical form -	3 067,76 EUR
For every other strength -	1 022,59 EUR

Line extension Annex I of regulation (EC) № 1234/2008

For one strength and pharmaceutical form -	4 090,34 EUR
For every other pharmaceutical form -	3 067,76 EUR
For every other strength -	1 022,59 EUR

Renewal

50 % fee for marketing authorization

Variations

Type IA -	511,29 EUR
Type IB -	511,29 EUR
Type II -	766,94 EUR