

Information for fees for marketing authorization via Decentralized procedure (DCP) 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 -	5 112,92 EUR
For every other pharmaceutical form -	3 834,69 EUR
For every other strength -	1 278,23 EUR

Article 10 (1) Article 10 (c)

For one strength and pharmaceutical form -	3 579,04 EUR
For every other pharmaceutical form -	2 684,28 EUR
For every other strength -	894,76 EUR

Article 10 (3) Article 10 (4)

For one strength and pharmaceutical form -	5 112,92 EUR
For every other pharmaceutical form -	3 834,69 EUR
For every other strength -	1 278,23 EUR

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

For one strength and pharmaceutical form -	4 601,63 EUR
For every other pharmaceutical form -	3 451,22 EUR
For every other strength -	1 150,41 EUR.

Renewal

50 % fee for marketing authorization

Variations

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