

Fees for marketing authorization via national procedure

Fee payable to Bulgarian Drug Agency:

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

Article 27 (1) NATIONAL LAW or Article 8 (3) Dir. 2001/83/EC
Article 30 (1) NATIONAL LAW or Article 10 (a) Dir. 2001/83/EC
Article 30 (2) NATIONAL LAW or Article 10 (b) Dir. 2001/83/EC
Article 31 (1) NATIONAL LAW or Article 10 (b) Dir. 2001/83/EC

For one strength and pharmaceutical form -	7 669,38 EUR
For every other pharmaceutical form -	5 752,04 EUR
For every other strength -	1 917,35 EUR

Article 28 NATIONAL LAW or Article 10 (1) Dir. 2001/83/EC
Article 32 NATIONAL LAW or Article 10 (c) Dir. 2001/83/EC

For one strength and pharmaceutical form -	3 834,69 EUR
For every other pharmaceutical form -	2 876,02 EUR
For every other strength -	958,67 EUR

Article 29 (1) NATIONAL LAW or Article 10 (3) Dir. 2001/83/EC
Article 29 (2) NATIONAL LAW or Article 10 (4) Dir. 2001/83/EC

For one strength and pharmaceutical form -	7 669,38 EUR
For every other pharmaceutical form -	5 752,04 EUR
For every other strength -	1 917,35 EUR

Article 66 NATIONAL LAW or LINE EXTENSION - Annex I of Regulations EC № 1234/2008

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

Renewal

50 % of fee for marketing authorization

Variation

Type IA -	255,65 EUR
Type IB -	511,29 EUR
Type II -	766,94 EUR