

Information for fees for marketing authorization via Decentralise procedure (DCP)

Fee payable to Bulgarian Drug Agency:

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

For one strength and pharmaceutical form - 10 000 BGN/ 5112,92 EUR

For every other pharmaceutical form - 7 500 BGN/ 3834,69 EUR

For every other strength - 2 500 BGN/ 1278,23 EUR

Article 10 (1) Article 10 (c)

For one strength and pharmaceutical form - 7 000 BGN/ 3579,04 EUR

For every other pharmaceutical form - 5 250 BGN/ 2684,28 EUR

For every other strength -1 750 BGN/ 894,76 EUR

Article 10 (3) Article 10 (4)

For one strength and pharmaceutical form - 10 000 BGN/ 5112,92 EUR

For every other pharmaceutical form - 7 500 BGN/ 3834,69 EUR

For every other strength - 2 500 BGN/ 1278,23 EUR

Line extension

For one strength and pharmaceutical form - 9 000 BGN/ 4601,63 EUR

For every other pharmaceutical form - 6 750 BGN/ 3451,22 EUR

For every other strength - 2 250 BGN/ 1150,41 EUR

Renewal

50 % fee for marketing authorization

Variations

Type I A-1000 BGN/ 511,29 EUR

Type I B-1000 BGN/ 511,29 EUR

Type II-1500 BGN/ 766,94 EUR

ALL not finalized procedures till 17.12.2007 must be paid in accordance by new government decree № 296/04.12.2007.