

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 lv.

For every other pharmaceutical form - 7 500 lv.

For every other strength - 2 500 lv.

Article 10 (1) Article 10 (c)

For one strength and pharmaceutical form - 7 000 lv.

For every other pharmaceutical form - 5 250 lv.

For every other strength - 1 750 lv.

Article 10 (3) Article 10 (4)

For one strength and pharmaceutical form - 10 000 lv.

For every other pharmaceutical form - 7 500 lv.

For every other strength - 2 500 lv.

Line extension

For one strength and pharmaceutical form - 9 000 lv.

For every other pharmaceutical form - 6 750 lv.

For every other strength - 2 250 lv.

Renewal

50 % fee for marketing authorization

Variations

Type I A-1000lv. Type I Б-1000lv. Type II-1500lv.

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