

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

Fee payable to Bulgarian Drug Agency:

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

For one strength and pharmaceutical form - 8 000 BGN/ 4090,34 EUR

For every other pharmaceutical form - 6 000 BGN/ 3067,75 EUR

For every other strength - 2 000 BGN/ 1022,58 EUR

Article 10 (1) Article 10 (c)

For one strength and pharmaceutical form - 6 000 BGN/ 3067,75 EUR

For every other pharmaceutical form - 4 500 BGN/ / 2300,81 EUR

For every other strength -1 500 BGN/ 766,94 EUR

Article 10 (3) Article 10 (4)

For one strength and pharmaceutical form - 8 000 BGN/ 4090,34 EUR

For every other pharmaceutical form - 6 000 BGN/ 3067,75 EUR

For every other strength - 2 000 BGN/ 1022,58 EUR

Line extension

For one strength and pharmaceutical form - 8 000 BGN/ 4090,34 EUR

For every other pharmaceutical form - 6 000 BGN/ 3067,75 EUR

For every other strength - 2 000 BGN/ 1022,58 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