

Fees for marketing authorization via national procedure
All fees should be paid to Bulgarian Drug Agency:

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

For one strength and pharmaceutical form - 15 000 BGN/ 7669,38 EUR
For every other pharmaceutical form -11 250 BGN/ 5752,03 EUR
For every other strength - 3 750 BGN/1917,34 EUR

Article 28 NATIONA LAW or Article 10 (1) Dir. 2001/83/EO Article 32
NATIONA LAW or Article 10 (c) Dir. 2001/83/EO

For one strength and pharmaceutical form - 7 500 BGN / 3834,69 EUR
For every other pharmaceutical form - 5 625 BGN/ 2876,02 EUR
For every other strength - 1 875 BGN/ 958,67 EUR

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

For one strength and pharmaceutical form - 15 000 BGN/ 7669,38 EUR
For every other pharmaceutical form - 11 250 BGN/ 5752,03 EUR
For every other strength - 3 750 BGN/ 1917,34 EUR

Article 66 NATIONA LAW or Line extension EO № 1084/2003

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

Renewal

50 % of fee for marketing authorization

Variation

Type I A	- 500 BGN/ 255,65 EUR
Type I Б	-1000 BGN/ 511,29 EUR
Type II	-1500 BGN/ 894,76 EUR