

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

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

For one strength and pharmaceutical form - 15 000 BGN
For every other pharmaceutical form - 11 250 BGN
For every other strength - 3 750 BGN

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

For one strength and pharmaceutical form - 7 500 BGN
For every other pharmaceutical form - 5 625 BGN
For every other strength - 1 875 BGN

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

For one strength and pharmaceutical form - 15 000 BGN
For every other pharmaceutical form - 11 250 BGN
For every other strength - 3 750 BGN

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

For one strength and pharmaceutical form - 7 000 BGN
For every other pharmaceutical form - 5 250 BGN
For every other strength - 1 750 BGN

Renewal

50 % of fee for marketing authorization

Variation

Type I A - 500 BGN
Type I Б - 1000 BGN
Type II - 1500 BGN

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