

## **Fees for marketing authorization via national procedure**

Fee payable to Bulgarian Drug Agency:

We remind that all bank fees are at the expense of the applicants/MAHs

**Article 27 (1) NATIONAL LAW or Article 8 (3) Dir. 2001/83/EC**

**Article 30 (1) NATIONAL LAW or Article 10 (a) Dir. 2001/83/EC**

**Article 30 (2) NATIONAL LAW or Article 10 (b) Dir. 2001/83/EC**

**Article 31 (1) NATIONAL LAW or Article 10 (b) Dir. 2001/83/EC**

For one strength and pharmaceutical form - 7 669,38 EUR

For every other pharmaceutical form - 5 752,04 EUR

For every other strength - 1 917,35 EUR

**Article 28 NATIONAL LAW or Article 10 (1) Dir. 2001/83/EC**

**Article 32 NATIONAL LAW or Article 10 (c) Dir. 2001/83/EC**

For one strength and pharmaceutical form - 3 834,69 EUR

For every other pharmaceutical form - 2 876,02 EUR

For every other strength - 958,67 EUR

**Article 29 (1) NATIONAL LAW or Article 10 (3) Dir. 2001/83/EC**

**Article 29 (2) NATIONAL LAW or Article 10 (4) Dir. 2001/83/EC**

For one strength and pharmaceutical form - 7 669,38 EUR

For every other pharmaceutical form - 5 752,04 EUR

For every other strength - 1 917,35 EUR

**Article 66 NATIONAL LAW or LINE EXTENSION - Annex I of  
Regulations EC № 1234/2008**

For one strength and pharmaceutical form - 3 579,04 EUR

For every other pharmaceutical form - 2 684,28 EUR

For every other strength - 894,76 EUR

### **Renewal**

50 % of fee for marketing authorization

### **Variation**

Type IA - 255,65 EUR

Type IB - 511,29 EUR

Type II - 766,94 EUR