

## **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 lv.

For every other pharmaceutical form - 6 000 lv.

For every other strength - 2 000 lv.

### **Article 10 (1) Article 10 (c)**

For one strength and pharmaceutical form - 6 000 lv.

For every other pharmaceutical form - 4 500 lv.

For every other strength - 1 500 lv.

### **Article 10 (3) Article 10 (4)**

For one strength and pharmaceutical form - 8 000 lv.

For every other pharmaceutical form - 6 000 lv.

For every other strength - 2 000 lv.

### **Line extension**

For one strength and pharmaceutical form - 8 000 lv.

For every other pharmaceutical form - 6 000 lv.

For every other strength - 2 000 lv.

### **Renewal**

50 % fee for marketing authorization

### **Variations**

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

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