TARIFF for marketing authorizations, collected by Bulgarian Food Safety Agency

Art. 41. (1) A Marketing authorization of a veterinary medicinal products according to the type of procedure the following fees are collected for a pharmaceutical form of one active substance concentration:

BGN

1	2	3
1.	Under the national procedure	3500,00
2.	MRP, when the Republic of Bulgaria is a reference member state	20 000,00
3.	MRP, when the Republic of Bulgaria is the concerned member state	4500,00
4.	Decentralized procedure, when the Republic of Bulgaria is a reference member state	20 000,00
5.	Decentralized procedure where Bulgaria is the Concerned member state	4500,00

(2) For each different pharmaceutical form which is submitted simultaneously with the initial application for a Marketing authorization, the fee is 40 per cent of the under par. 1.

(3) For each different concentration of the active substance which is submitted simultaneously with the initial application for a Marketing authorization, the fee is 25 per cent of the under par. 1.

(4) To obtain a Marketing authorization of homeopathic veterinary medicinal products according to the type of procedure the following fees are collected:

BGN

1	2	3
1.	Under a national procedure:	
	a) from one single source:	2000,00
	b) up to 5 sources	3500,00
	c) more than 5 sources	4500,00
2.	MRP, when the Republic of Bulgaria is a reference member state:	
	a) from one single source:	4000,00
	b) up to 5 sources	6000,00
	c) more than 5 sources	8000,00
3.	MRP, when the Republic of Bulgaria is interested member state:	
	a) from one single source:	2000,00
	b) up to 5 sources	3500,00
	c) more than 5 sources	4500,00
4.	Decentralized procedure, when the Republic of Bulgaria is a reference member state:	
	a) from one single source:	4000,00
	b) up to 5 sources	6000,00
	c) more than 5 sources	8000,00
5.	Decentralized procedure where Bulgaria is Concerned member state:	
	a) from one single source:	2000,00

	b) up to 5 sources	3500,00
	c) more than 5 sources	4500,00

(5) Deleted

(6) Approving the variations to a Marketing authorization of veterinary medicinal products according to the type of variations the following fees are collected:

1	2	3
1.	For Type I:	
1.1.	Under a national procedure: a) type 1 A b) type 1B	 200,00 400,00
1.2.	On Mutual Recognition Procedure:	
	a) when the Republic of Bulgaria is a reference member state - Type 1 A - Type 1 B	 200,00 400,00
	b) where Bulgaria is Concerned member state - Type 1 A - Type 1 B	 200,00 400,00
1.3.	In decentralized procedure:	
	a) when the Republic of Bulgaria is a reference member state Type 1 A Type 1B	 200,00 400,00
	b) where Bulgaria is concerned member member state - Type 1 A - Type 1 B	 200,00 400,00
2.	For Type II:	
2.1.	Under a national procedure	1500,00
2.2.	On mutual recognition procedure:	
	a) when the Republic of Bulgaria is a reference member state	5000,00
	b) where Bulgaria is concerned member member state	1500,00
2.3.	In decentralized procedure:	
	a) when the Republic of Bulgaria is a reference member state	5000,00
	b) where Bulgaria is concerned member member state	1500,00
3.	For transferring of a Marketing authorization	400,00

(7) When an application for approval of variations grouped according to the type of variations the following fees are collected:

1. Type IA variations in one Holder of Marketing authorization:

a) national procedure - fee under par. 6, item 1.1 for major variation plus 50 per cent of it for each subsequent variation;

b) decentralized procedure and mutual recognition procedure - fee under par. 6, paragraphs 1.2 and 1.3 of the major variation plus 50 per cent of it for each subsequent variation;

2 . Type IA variations in more than one Marketing authorization held by the same holder shall be paid for each variation and for each authorization:

a) under a national procedure - fee under par. 6 , item 1.1 for major variation plus 50 per cent of it for each subsequent variation;

b) decentralized procedure and mutual recognition procedure - fee under par. 6 , paragraphs 1.2 and 1.3 for major variation plus 50 per cent of it for each subsequent variation;

3 . Variations in the type IB a Marketing authorization:

a) national procedure - fee under par. 6, item 1.1 for major variation plus 50 per cent of it for each subsequent variation;

b) decentralized procedure and mutual recognition procedure - fee under par. 6, paragraphs 1.2 and 1.3 of the major variation plus 50 per cent of it for each subsequent variation;

5 . Variations in a type II Marketing authorization holder:

a) national procedure - fee under par. 6, item 2.1 for major variation plus 50 per cent of it for each subsequent variation type II;

b) decentralized procedure and mutual recognition procedure - fee under par. 6 items 2.2 and 2.3 for the major variation plus 50 percent of it for each subsequent variation type II;

5 . For Type IA and Type IB in a Marketing authorization:

a) national procedure - fee under par. 6, item 1.1 for major variation plus 50 per cent of it for each subsequent variation;

b) decentralized procedure and mutual recognition procedure - fee under par. 6 , paragraphs 1.2 and 1.3 of the major variation plus 50 per cent of it for each subsequent variation;

8 . For Type II and Type IA and / or IB in a Marketing authorization holder:

a) national procedure - fee under par. 6, item 2.1 for the basic type II variation plus 50 per cent of it for each subsequent variation type II and the full fee under par. 6, item 1.1 for each variation type I;

b) decentralized procedure and mutual recognition procedure - fee under par. 6 items 2.2 and 2.3 for the initial type II variation plus 50 per cent of it for each subsequent variation type II and the full fee under par. 6 t 1.2 and 1.3 for each variation type I;

7. grouping of the first 9 variations the fees covered items 1 - 9 and the subsequent after the ninth - 50 percent of them.

(8) No fees are payable upon cancellation of the animal trials or in reducing the number of animals involved in trials intended for quality control.

(9) To renew a Marketing authorization of the veterinary medicinal product, the fee is 50 per cent under par. 1, item 1-5.

(10) Deleted.

(11) Deleted.

Art. 42. (1) For assessing the documentation for extension of the Marketing authorization of the product according to the type of procedure the following fees are collected - for one pharmaceutical form and one concentration of the active substance:

BGN

1	2	3
1.	Under the national procedure	2000,00
2.	By MRP	3000,00
3.	Decentralized procedure	3000,00

For any clarification and further information please contact: icvp@itp.bg