



ÚSTAV ŠTÁTNEJ KONTROLY VETERINÁRNYCH BIOPREPARÁTOV A LIEČIV

Institute for State Control of Veterinary Biologicals and Medicaments

TARIFF OF ADMINISTRATIVE AND OTHER FEES

METHODICAL INSTRUCTION No.1/16

Administrative fees are paid for authorisation procedures and others (see below) according to the Act No. 145/1995 Coll. on administrative fees, as amended, according to the Act No. 465/2008 Coll. amending and supplementing the Acts of the Ministry of Finance of the Slovak Republic and according to the Act No. 362/2011 Coll. on Medicines and Medicinal devices, as amended.

Due to the participation of ISCVBM in administrative module, we modify the procedure for submitting of applications for authorisation and other procedures as follows:

1. Fees for authorisation of veterinary medicinal products, renewal and variation

An applicant will send (eAF, by eudralink, e-mail or CD by post ...) a filled and signed electronic application form for marketing authorisation, renewal and variation, and a word form of application for transfer and withdrawal with clearance sale.

An applicant will attach documentation and other particulars (depending on the type of application).

Applications for authorisation procedure should be addressed to the coordinators:

Marta Wagnerová, DVM (MRP, DCP), e-mail: wagnerova@uskvbl.sk

Helena Kimleová, DVM (foreign pharmaceuticals - national authorisation),

e-mail: kimleova@uskvbl.sk

Zuzana Feldmárová, DVM (Czech and Slovak pharmaceuticals and vaccines, foreign vaccines - national authorisation): e-mail: feldmarova@uskvbl.sk

Ms. Jánošíková of the Economics Department will issue an electronic invoice and send it to an e-mail address of the applicant or the payer of administrative fee.

The invoice is unique and is used to pay for the operation that is stated in the invoice. The payment information cannot be used for repeated operation.

The invoice will contain a variable symbol, an account number and a name of the operation.

Payment of the invoice can be done in several ways:

- by transfer to the account indicated in the invoice, including other payment instructions (variable, constant and specific symbol); variable symbol is the necessary data for the application processing,
- or by paying enclosed postal order at the Slovak Post Offices Inc..

It is not necessary to send payment confirmation to the ISCVBM; this information is automatically displayed upon payment of a fee in the central system of the Slovak Post Offices, Inc.

When you make payment by bank transfer it is necessary to specify the correct account number and variable symbol stated in the invoice.

It is necessary to follow strictly the due date specified in the invoice. When you make payment after the due date specified in the invoice, or when you enter an incorrect account number or variable symbol, the fee will be automatically refunded back. Administrative fees will be refunded back by the Slovak Post Offices, Inc.

For re-payment it is necessary to issue a new invoice, for which the client must request by sending an e-mail to: janosikova@uskvbl.sk. If the amount of administrative fee is not paid by the due date stated in the invoice, it will be expired and it is necessary to issue a new invoice for re-payment.

When submitting an application it is necessary to indicate company registration number and the email address of the payer of administrative fee.

2. Fees for other services (which are not administrative ones and maintenance fees) will be paid against an invoice issued by Ms. Jánošíková, janosikova@uskvbl.sk, 00 421/37/6933124, or 00 421/37/6515507.

3. Fees for approval procedures

Fees for issuing an authorisation on the approval, renewal and change to approved veterinary products and devices, have to be paid by e - duty stamps by home - payers.

In the case of a foreign payer Ms. Jánošíková in the Economics Department will issue an electronic invoice and send it to an email address of the payer of administrative fee stated in the application form.

Applications for the approval procedure should to be addressed to: Zuzana Klbiková, e-mail: klbikova@uskvbl.sk

The service will be provided after the payment of funds to the account of the ISCVBM.

The pattern for the payment of an administrative fee is given on page 3.

In Nitra, 1st March, 2016

Use for payments at the



Ministerstvo financií
Slovenskej republiky

NASES
Národná agentúra
pre reguláciu trhu
elektronických služieb



Ústav štátnej kontroly
Payment Instruction - M10-210416-0698
For administrative/court fee payment

Proceeding No.:	1703/2016		
Note:			
Issuance date:	21.04.2016	Expiry date:	06.05.2016

Services to be paid for:

ID	Description	Quantity	Fee	Total
2708	Ústav štátnej kontroly veterinárnych biopreparátov a liečiv - Žiadosť o hybridnú registráciu, to znamená registráciu generickú s údajmi nad rámec zásadnej podobno	1	1659,50	1659,50
Total amount:				1659,50
To be paid:				1659,50

Payers:

#	Name and surname	Address
1		

Use for a bank transfer

Account	0020545788	Bank code:	6500
VS:	2823192303	SS:	0000000000
		CS:	0999
IBAN:	SK8365000000000020545788	SWIFT:	POBNSKBA
EZE:	/VS2823192303/SS0000000000/KS0999		

"NOTICE: Please remember to use the correct variable symbol (VS) at the time of payment. A payment will be returned if the variable symbol is wrong or if the payment instruction has expired."

EZE reference should be used if it is a payment from a foreign account.

Use for payment in a post office of

POŠTOVÝ POUKAZ EKONOMICKÝ PODACÍ LÍSTOK Pláťte iba na pošte PODACIE ČÍSLO		PODACIE ZNAKY OKR. PEČ. POD. ČIS.		POŠTOVÝ POUKAZ EKONOMICKÝ SUMA =1659 50 K. SPRAC. 3 K. SL. 90 K. PROD. 38 SLOVOM jedentisícšest'stopäťdesiatdeväť EUR 50 cent (centy uvedte čiarkou)	
VÝPLATNÉ V HOTOVOSTI KÓD SLUŽBY 90 KÓD PROD. 38		ČÍSLO ÚČTU IBAN SK83 6500 0000 0000 2054 5788		VARIABILNÝ SYMBOLO 2823192303 KONŠT. SYMBOLO 0999	
SUMA =1659 50 cent		ADRESÁT Slovenská pošta, a.s. Partizánska cesta 9 97599 Banská Bystrica		ODOSIELATEĽ	
ČÍSLO ÚČTU IBAN SK83 6500 0000 0000 2054 5788		ŠPECIFICKÝ SYMBOLO 0000000000		REFERENČNÉ ČÍSLO 0000000000	
VARIABILNÝ SYMBOLO 2823192303		ŠPECIFICKÝ SYMBOLO 0000000000		SPRÁVA PRE ADRESÁTA 999714625719992823192303	
ADRESÁT Slovenská pošta, a.s. Partizánska cesta 9 97599 Banská Bystrica		ADRESÁT Slovenská pošta, a.s. Partizánska cesta 9 97599 Banská Bystrica		ADRESÁT Slovenská pošta, a.s. Partizánska cesta 9 97599 Banská Bystrica	
ODOSIELATEĽ		ODOSIELATEĽ		ODOSIELATEĽ	
Slovenská pošta, a. s., Partizánska cesta 9, 975 09 Banská Bystrica 1 Zap. v OR OS Banská Bystrica, v odd. Sa, v. č. 603/3 IČO: 36631124, IČ DPH: SK202187369		Slovenská pošta, a. s., Partizánska cesta 9, 975 09 Banská Bystrica 1 Zap. v OR OS Banská Bystrica, v odd. Sa, v. č. 603/3 IČO: 36631124, IČ DPH: SK202187369		Slovenská pošta, a. s., Partizánska cesta 9, 975 09 Banská Bystrica 1 Zap. v OR OS Banská Bystrica, v odd. Sa, v. č. 603/3 IČO: 36631124, IČ DPH: SK202187369	
389042823192303001659509		389042823192303001659509		389042823192303001659509	

Application for administrative fee refund

Application Ref. no. / File ID:		
Type of application:		
Name of the veterinary medicinal product in case of MA application:		
Specification of the content of the application:		
Name of the applicant:		
Address of the applicant:	Street, P.O. BOX:	City, ZIP Code, country:
Contact person:		
Address of the contact person:		Telephone:
The amount paid in €:		Date of payment:
Reference number of the application:		
Applicant's bank name:		Address:
Account number/bank code:		IBAN:
Swift address:		
Rationale for the requested refund:		
Source reference where the statement could be checked :		

 Date
 signature

 Applicant's bank name and
 Stamp

Do not complete – for the ISCVBM 's internal use

- Administrative fee refund is not in compliance with the § 10 of the Act on Administrative fees:

- Paid administrative fee, which is not mentioned in the price list or was paid by a person who is not a payer or administrative fee overpayment

I agree/disagree with refund of the amounts of:€

Date

Name and signature of section manager

Decision under the ref. No issued on, the ISCVBM decided on

a) completely refund of the administrative fee

b) partially refund of the administrative fee in an amount

c) refusal of the application for the administrative fee refund

Date
 economical section

Name and signature of an

manager

Tariff of administrative fees - authorisation of the veterinary medicinal products

NATIONAL MARKETING AUTHORIZATION

No.	Type of application	Cover in €
1.	Application for an independent marketing authorisation supported by full experimental or bibliographic data – veterinary medicinal products intended for more than two target animal species	2489,50
2.	Application for an independent marketing authorisation supported by full experimental or bibliographic data – veterinary medicinal products intended for less than two target animal species	1991,50
3.	Application for a generic marketing authorisation and a marketing authorisation with the consent of a different marketing authorisation holder (informed consent)	1327,50
4.	Application for a hybrid marketing authorisation, i. e. generic marketing authorisation with data beyond the scope of essential similarity	1659,50
5.	Application for a marketing authorisation of another strength or pharmaceutical form - extension of the marketing authorisation – veterinary medicinal product intended for more than two target animal species	995,50
6.	Application for a marketing authorisation of another strength or pharmaceutical form - extension of the marketing authorisation - veterinary medicinal product intended for less than two target animal species	663,50
7.	Application for renewal of a marketing authorisation of a veterinary medicinal product excluding veterinary homeopathic medicinal products	995,50
8.	Application for variation to a marketing authorisation of a veterinary medicinal product - Type IA and IB	99,50
9.	Application for variation to a marketing authorisation of a veterinary medicinal product - Type II	663,50
10.	Shortening of the withdrawal period after an amendment to the maximum residue limit issued by the Official Journal of the European Commission	663,50
11.	Application for transfer of a marketing authorisation of a veterinary medicinal product	165,50
12.	Application for withdrawal of a marketing authorisation of a veterinary medicinal product with further requirements	66,00
13.	Application for withdrawal of a marketing authorisation without further requirements	Free of charge
14.	Application for a marketing authorisation of a veterinary homeopathic medicinal product – simplified procedure	497,50
15.	Application for a marketing authorisation of another strength(s) or pharmaceutical form of a veterinary homeopathic medicinal product – extension of a marketing authorisation	165,50

MUTUAL RECOGNITION PROCEDURE and DECENTRALISED PROCEDURE

(MRP and DCP)

No.	Type of application	Cover in €
1.	Application for recognition of a marketing authorisation for a veterinary medicinal product - marketing authorisation granted by a competent authority of another Member state (CMS)	1659,50
2.	Application for recognition of a marketing authorisation for a veterinary medicinal product with reference to a scientific bibliography granted by a competent authority of another Member state (CMS)	1327,50
3.	Application for recognition of a marketing authorisation for a homeopathic veterinary medicinal product - simplified procedure granted by a competent authority of another Member state (CMS)	663,50
4.	Application for recognition of a marketing authorisation for a veterinary medicinal product with an informed consent of the marketing authorisation holder, application for a marketing authorisation for a veterinary medicinal product (line extension) (CMS)	995,50
5.	Application for mutual recognition procedure of a veterinary medicinal product if the Slovak Republic is a reference member state (RMS)	2655,50
6.	Application for recognition of a marketing authorisation for a veterinary medicinal product via decentralised procedure if the Slovak Republic is a reference member state (RMS)	4979,00
7.	Application for mutual recognition procedure of a veterinary medicinal product with reference to a scientific bibliography if the Slovak Republic is a reference member state (RMS)	1991,50
8.	Application for mutual recognition procedure of a veterinary homeopathic medicinal product via simplified procedure if the Slovak Republic is a reference member state (RMS)	995,50
9.	Application for mutual recognition procedure of a veterinary medicinal product with consent of the marketing authorisation holder (line extension) if the Slovak Republic is a reference member state (RMS)	1327,50
10.	Application for variation to a marketing authorisation of a veterinary medicinal product via mutual recognition procedure in a reference member state (Type IA and IB) (RMS)	99,50
11.	Application for variation to a marketing authorisation of a veterinary medicinal product via mutual recognition and decentralised procedure granted by a competent authority of another member state (Type IA and IB)	99,50
12.	Application for variation to a marketing authorisation of a veterinary medicinal product Type II via mutual recognition granted by a competent authority of another member state (CMS)	497,50
13.	Application for variation to a marketing authorisation of a veterinary medicinal product Type II via decentralised procedure	995,50
14.	Application for renewal of a marketing authorisation of a veterinary medicinal product authorised via decentralised or mutual recognition procedure	995,50
15.	Application for transfer of a veterinary medicinal product authorised via decentralised or mutual recognition procedure	165,50

Notes:

- 1) Application for withdrawal of marketing authorisation of a veterinary medicinal product without further requirements is free of charge.
- 2) Change in the marketing authorisation conditioned by the European Commission Regulation is free of charge.

Item 152:

(Act No. 145/1995 effective since 1st October 2012)

Type of decision	Cover in €
j) Issue of a decision on the approval of a veterinary preparation and veterinary medical device	99,50
k) Issue of a decision to a variation or renewal of a veterinary preparation or veterinary medicinal device	16,50

OTHER OPERATION ACCORDING TARIFF OF ADMINISTRATIVE FEES**Item 152:**

(Act No. 145/1995 effective since 1st October 2012)

Type of application	Cover in €
l) Application for granting an approval of a clinical trial of a veterinary medicinal product	16,50

Type of application	Cover in €
m) Application for granting an import and use of not authorised medicinal product, including autogenous vaccines	16,50

Type of application	Cover in €
g) 10 Application for granting a parallel import of a veterinary medicinal product	16,50

Date of revision: 1th March 2016