

Information about the payment regarding to registration process in Slovak republic

1. The applicant / MAH should submit the application form for registration, renewal or variation at the State Institute for Drug Control in order to getting the reference number for the application which will be the Variable symbol for the wire transfer. After wire transfer of payment, the applicant / MAH should submit the confirmation form of payment which is attached (Attachment 1).
2. The confirmation should have following information:
 - Name of the medicinal product
 - Pharmaceutical form
 - Applicant / Marketing Authorisation Holder
 - in MRP: the number of MRP

3. Fees payable to

The bank account (payment from foreign countries):

• **IBAN: SK348180000007000133673**
 • **SWIFT (BIC): SUBASKBX**

• **BANK: Všeobecná úverová banka, a. s.**
Mlynské Nivy 1
829 90 Bratislava

The bank account (domestic payment):

7000133673/8180

Constant symbol: 0558

Variable symbol: application number (SIDC reference number)

4. The specific fees:

Slovak Republic	Fees (SKK) per product (per strength)
<u>SIDC as RMS/CMS</u>	
MRP (Mutual Recognition Procedure)	
New application – Full dossier Know substance Well established substance Extension Generic application Fixed combination	60.000 SKK

DCP (Decentralised Procedure)	
New application – Full dossier Know substance Well established substance Extension Generic application Fixed combination	75.000 SKK
Variations (MRP, DCP)	
Type 1A	Free of charge
Type 1B	Free of charge
Type II. Variation	20.000 SKK
Renewal (MRP, DCP)	50.000 SKK
Transfer of a MAH (MRP, DCP)	10.000 SKK
<u>National Procedures</u>	
New application – Full dossier Know substance Extension Generic application Fixed combination	75.000 SKK
New application – Well established substance	5.000 SKK
Variations	
Type 1A	Free of charge
Type 1B	Free of charge
Type II. Variation	20.000 SKK
Renewal	50.000 SKK
Transfer of a MAH	10.000 SKK
<u>Homeopathic MP</u>	
New application	5.000 SKK
Variations	2.000 SKK
Renewal	4.000 SKK

Confirmation form of payment

National Marketing Authorization	<input type="checkbox"/> 75.000,-	Renewal of MA	<input type="checkbox"/> 50.000,-
NMA – Well established substance	<input type="checkbox"/> 5.000,-	Notification – type 1A	<input type="checkbox"/> free of charge
DCP procedure	<input type="checkbox"/> 75.000,-	Notification – type 1B	<input type="checkbox"/> free of charge
MRP procedure	<input type="checkbox"/> 60.000,-	Variation – type II.	<input type="checkbox"/> 20.000,-
		Transfer	<input type="checkbox"/> 10.000,-

Name of the medicinal product: _

Pharmaceutical form: _ _

Registration number (by renewal or variation): _ / _ / - _

Applicant / Marketing Authorisation Holder:

_ _

Reference number:

2107/□□□□

(This is the Variable symbol for the wire transfer)

Stamp and signature:

SIDC confirms the payment under the Variable symbol:

2107/□□□□

Payment :Sk

Stamp and signature:

SIDC confirms receipt of the dossier on date:

□□. □□. 2007