

The Republic of Macedonia  
MINISTRY OF HEALTH  
BUREAU FOR MEDICINES  
Ref. No 15-9360/3  
20.08.2003  
Skopje

The Ministry of Health acting upon the request No 15-9360 of 18.10.2002 filed by INTER-EVROGENEKS for and approval for production and packing auxilliary remedial devices in liquid and solid forms, on the basis of article 93 of the Law on medicines, auxilliary remedial devices and medical helping devices (Official gazette of R.Macedonia No 21/98) and article 10 item 9 of the Law on sanitary and health inspection (Official gazette of R.Macedonia 15/95) and article 202 of the Law on general administrative procedure (Official gazette of SFRY No 47/86) made the following

#### DECISION

It is established that INTER-EVROGENEKS on the basis of the insight related to the premises, equipemnt and human resources completely meets the requirements for the activity of manufacturing and packing of auxilliary remedial devices in fluid pharmaceutical forms (solutions, water extract preparations, drops and tinctures), production and packaging of auxilliary remedial devices in solid pharmaceutical forms (herbal teas, mixtures of tea herbs).

#### Explanation

INTER-EVROGENEKS filed a request Nio 15-9360 of 18.10.2002 with the Ministry of Health for performing the activity of manufacturing and packing of auxilliary remedial devices in liquid and solid pharmaceutical forms.

The Commission of the Ministry of Health made an insight into the proposed premises finding in the minutes No 15-9360/2 of 09.07.2003 that the remarks from the Minutes 15-9360/1 of 14.11.2002 have been completely eliminated. So the Commission found that INTER-EVROGENEKS completely fulfils the requirements for performance of the activity: manufacturing and packing of auxilliary remedial devicies in liquid pharmaceutical forms (solutions, water extract preparations, drops and tinctures), production and packaging of auxilliary remedial devices in solid pharmaceutical forms ( herbal teas, mixtures of tea herbs).

Note: Production of solid pharmaceutical forms: powders, granules, tablets and dragees are excluded till the supply of the necessary equipment.



LEGAL INSTRUCTIONS: Unsatisfactory party may initiate a dispute before the Supreme Court of RM within 30 days from the day of receipt of this decision.

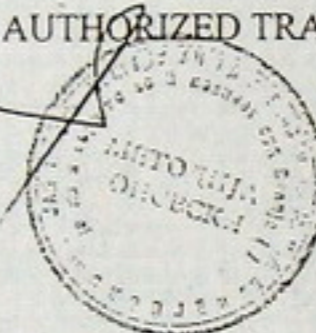
BUREAU FOR MEDICINES  
DIRECTOR  
Prim Spec Romil Sandzakovski, Msc  
(Signed)

MINISTER  
D-r Redzep Seljmani  
(Signed)

A round seal affixed: The Republic of Macedonia, Ministry of Health Skopje

I the undersigned sworn court authorized translator for the English language herein confirm that this document submitted to me in Macedonian has been truly and properly translated into English language and in witness thereof I have hereto set my hand and affixed my official seal.

SWORN COURT AUTHORIZED TRANSLATOR  
Metodija Jonovski



I NOTARY PUBLIC RISTO LIJAKOVSKI SKOPJE- CENTER certify that this translation from Macedonian into English has been made by the authorized translator for the area of the Basic Court Skopje 2 Skopje- Metodija Jonovski from Skopje.

I have established his identity through the signature and his official seal affixed on the translation.

Notary tax in accordance with the Law on court taxes paid in the amount of denars 100,00 and annuled on the copy to be filed.

Notary fee paid in the amount of denars 100,00 according to the Regulations on the notary tariff.

UZP No 4514/2004  
Skopje, 16.08/2004

Notary Public

