



**PREZES**

**Urzędu Rejestracji Produktów Leczniczych,  
Wyrobnów Medycznych i Produktów Biobójczych**

*Grzegorz Cessak*

**COMMUNICATION of the  
PRESIDENT OF THE OFFICE FOR REGISTRATION OF MEDICINAL  
PRODUCTS, MEDICAL DEVICES AND BIOCIDAL PRODUCTS  
of 21 July 2015**

**regarding the Regulation of the Minister of Health of 8 July 2015  
on the method of setting and payment of veterinary medicinal product marketing  
authorization fees**

On behalf of The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, I hereby kindly inform that the Regulation of the Minister of Health of 8 July 2015 **on the method of setting and payment of veterinary medicinal product marketing authorization fees** has been published on 15.07.2015 in the Journal of Laws, position 988 (<http://dziennikustaw.gov.pl/du/2015/988>).

According to the Regulation's § 16 it will come into force within 14 days from the publication date 30.07.2015.

Additionally I would like to inform you that pursuant to § 14 of the Regulation on setting and payment of fees described in Article 36 (1) and (2) of the Act for veterinary medicinal products, previous regulations still apply to procedures launched and unfinished that was submitted before the date of the Regulation coming into force.

The Regulation is in line with guidelines set by the legal delegation in Article 36a of the Act of 6 September 2001 – Pharmaceutical Law,

The Regulation repeal setting of fees based on a percentage ratio to the base rate, which is the minimum work salary (currently the fees have been quantified). It also unified fee calculation rules for group applications for veterinary medicinal products authorized not only in European, but also national procedures. The fee for applications for minor type IA variations has been lowered.

To simplify setting of fees for marketing authorisation holders, please find attached a table presenting changes to the base rate.

President of the Office  
for Registration of Medicinal Products,  
Medical Devices and Biocidal Products

/-/ Grzegorz Cessak