



PREZES

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

Grzegorz Cessak

**COMMUNICATION of the
PRESIDENT OF THE OFFICE FOR REGISTRATION OF MEDICINAL
PRODUCTS, MEDICAL DEVICES AND BIOCIDAL PRODUCTS
of 8 July 2015**

**regarding the Regulation of the Minister of Health of 16 June 2015
on the method of setting and payment of 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 16 June 2015 **on the method of setting and payment of medicinal product marketing authorization fees** has been published on 08.07.2015 in the Journal of Laws, position 958 (<http://dziennikustaw.gov.pl/DU/2015/958>)

According to the Regulation's §16 it will come into force within 14 days from the publication date 23.07.2015.

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, with exclusion of 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 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