

## **Abstract**

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Title of Thesis: The referral procedure as a tool for influence the regulatory status of medicinal product in EU.

The referral procedure is very important possibility how the medical agencies in EU can influence the regulatory status of a medical product – change, suspend or revoke the registration.

Our first aim was to describe the referral procedures defined in „The rules governing medicinal products in the European Union“ – reasons for initiation, course and possible outcomes.

One chapter deals with procedures concerning risk of venous and arterial thromboembolism in users of combined hormonal contraceptive.

Our second aim was to observe the number of procedures during 2005-2014. We were interested in reason for initiation and outcomes of some procedures. We observed an increase in the number of procedures which are initiated from safety reasons on the basis of pharmacovigilance data.