Abstract

Clinical trials of medicinal products is increasingly important area of pharmaceutical law. Number of clinical trials and amount of financial resources is constantly rising and therefore the rules and principles of the clinical trials itself are being clarified overtime.

This diploma thesis aims to provide an overview of the basic aspects of clinical trials of medicinal products for human use from a legal point of view. The author focuses in particular on the national legislation of clinical trials, which is complemented by the legislation of the European Union and important sources of the international law. Author is more closely analysing the particular procedures performed within the clinical trials, especially from the point of view of the administrative law. Particular attention is paid to the ethical review of the clinical trials, their particular aspects and the overall concept.

The thesis is divided into twelve chapters. In the introduction, the author focuses on the development of the clinical trials and mentions the crucial moments that contributed to the formulation of the basic rules of the clinical trials.

The following chapter focuses on the sources of law. Firstly, sources of international law are described, where more general sources and specific sources of law of medicinal products research are analysed. Further, an overview of the European legislation and national legislation is provided. National legislation is hierarchically organized from statutory legislation to subordinate legislation. The nature of the instructions of the State Institute for Drug Control is further analysed.

The next chapter contains the definitions of the basic terms that are essential for a comprehensive understanding of the given issue. Emphasis is placed on explaining the term of clinical trials itself and defining medicinal products. Particular subjects involved in the clinical trials are also described. The thesis continues with a chapter devoted to particular organizations and bodies and their characteristics.

Key chapters of the thesis are dedicated to the clinical trial procedure. First, preclinical testing prior to the clinical trial is described. The following is a chapter dealing with conditions for beginning of clinical trial. Ethical review committee and its opinion is being analysed in more details because of its unclear nature. The guarantees of independence of ethical review are also discussed. The individual phases of the clinical trial and the possibilities of its termination are described too.

The eleventh chapter deals with changes concerning Regulation (EU) No. 536/2014 and its implications for national legislation.

In conclusion, the main findings of the thesis are summarized and the current legislation as well as the changes that will occur in connection with the new legal regulation are evaluated.

Key words: clinical trial, medicinal product, ethical review