Abstract

The issue of legislative and ethical requirements on research of innovative medicines became more intense in connection to the expansion of the pharmaceutical industry in last few decades.

This master thesis aims to complexly describe and analyse theoretical bases of current legislative regulating the process of clinical trials of medicinal products for human use in the Czech Republic, as well as to take a closer look to the issue of ethical review administered by specialized ethical review committees. The author also deals with some specific responsibilities of the committees from the perspective of administrative law, especially focusing on aspects of legal nature of the positive opinions, which are one of the conditions for commencement of a clinical trial.

The thesis is divided into nine chapters and the introductory chapter is focused on the general outline of the issue of clinical trials of medicines for human use in the Czech Republic.

The aim of the second chapter is to define the basic concepts stated in the Czech medicinal products act, which are specific for this area of pharmaceutical law. The next chapter analyses the relevant competencies of individual state authorities over the clinical studies.

The fourth chapter contains the list of sources of law, whereas a particular emphasis is placed on distinction of binding and nonbinding documents and evolution of domestic law having its roots in the law of the European Union.

The next chapter describes the process of clinical trial and points outs its specifics, which are essential for deeper understanding of content and meaning of the current legal instruments according to the medicinal products act.

The sixth chapter deals with the most important conditions for commencement of a clinical trial, concerning the informed consent of involved patients, the authorization of the State Institute for Drug Control and the opinion of the ethical review committee, whereas a substantial part of the chapter contents the analysis of ambiguous legal nature of the opinion. The process and the termination of the research is encompassed in the following chapter.

The eighth chapter summarizes and evaluates the impact of the latest amendment of the medicinal products act, which modifies the current system of ethical committees within the scope of the clinical trials of medicines.

The conclusion recapitulates the main aims and results of the recent legal research, whilst the question of additional potential amendments of the medicinal products act is raised.

Key words:
Pharmaceutical law, clinical trial, clinical study, ethical review committee