

Price regulation of preparations for medical treatment

Abstract

The present master thesis describes and analyzes the system of medicinal product's pricing regulation in the Czech Republic after the year 1989. The aim is to execute an analysis of the current legal regulation in the context of previous regulation, of particular phases of the process of regulation of medicinal product's prices and to provide a summary of the principles and recommendations as well as to attempt a proposition of future development possibilities. The thesis focuses on Czech legal regulation, decision-making by the judicial bodies, public bodies' activity, as well as on European legislative and jurisdiction. The thesis is divided into five chapters.

The first chapter involves the system of pricing and reimbursement regulation of medicinal products into pharmaceutical legislation.

The second chapter is divided into two sub-chapters. The first presents the current legal regulation of pricing and reimbursement regulation of medicinal products in the context of international legislation, European legislation and European jurisdiction, as well as domestic legislation. The second chapter also considers public bodies – the Ministry of Health of the Czech Republic and the State Institute for Drug Control – and their activity regarding this regulation.

The third chapter is divided into several sub-chapters. The first of them addresses the term pricing regulation on the general economical level. In the next, terms medical product and associated terms are defined. Moreover, there is described the process of introduction of a medicinal product to the market – process of registration and stipulation of price and reimbursement. The third sub-chapter describes the pricing regulation of medicinal products and basic principles of this regulation – official price stipulation in terms of maximal price. In the fourth sub-chapter, there is covered the history of pricing regulation of medicinal products after the year 1989, when the regulation was executed by the regulation activity of the Ministry of Finance up until the year 2007. The fifth sub-chapter analyzes the current system valid since the year 2008, when the prices were established by the normative activity of the State Institute for Drug Control in individual administrative proceedings. At this point, there

are presented Four phases of the process of regulated price stipulation – the price constituent, means of pricing regulation, range of medicinal products that are affected by the regulation, and a procedure in the realms of administrative proceeding on a maximal price stipulation. In the conclusion of the third chapter, approaches to a pricing regulation of medical products in some other European countries are stated.

In the fourth chapter, the thesis focuses on the question of public bodies functioning forms in the field of setting up maximum prices and reimbursement levels, more specifically, it focuses on pricing decision, pricing regulation, individual administrative proceeding and measure of a general scope.

Fifth chapter presents notes on application of subjective public rights of the participants of proceedings on pricing stipulation and reimbursement of medicinal products with regards on Czech jurisdiction.

In the conclusion of the thesis, there is stated that the system of pricing regulation of medicinal products used in the Czech Republic up until the end of the year 2007 was changed with regards to the European law and jurisdiction by the jurisdiction of the Constitutional Court of the Czech Republic. The current legal regulation of setting up the prices is bound by the legislation of the Ministry of Health of the Czech Republic and by the regulations given by the Act on General Health Insurance. The basic method is a pricing reference to the countries of the European Union. The central point of the process are individual administrative proceedings, the central principle is the transparency of the whole process. As a problematic aspect is considered the inappropriate hierarchy of the basic legislation, that stipulates the pricing regulation. It is suggested to unify the legal force of these regulations, shortening of the time periods and a simplification of individual proceedings. We can find here a notification of strengthening of the administrative proceeding participants' position and other findings resulting from the jurisdiction. The thesis concludes that the pricing and reimbursement regulation of medicinal products is settled in the individual administrative proceedings and it is not possible to expect any main change of concept in a near future. The main step that solves the complex problematics should pass an independent act of pricing and reimbursement of medicinal products.

Keywords: administrative law, medicinal products, pricing regulation