

## 1. Purpose of the project

Biosimilar medicinal products are medicinal products produced using substances derived from biological material. They are one of the most important innovations. They triggered revolution in many fields of medicine. They are used to treat rare and severe diseases such as cancer, heart attack, stroke, multiple sclerosis, diabetes, rheumatoid arthritis, autoimmune diseases, and their prevention. The market of biosimilar medicinal products, being an important factor of development of modern standard of health, is growing faster than other segments of the pharmaceutical market.

At the same time they have a more complex structure than chemical drugs that are so far dominant in the treatments. This results in a significant differences in the process of their manufacturing, marketing authorization, pharmacovigilance and acceptability of substitution. These differences may require an enactment of specific legal rules. These rules must ensure patient safety and optimal distribution of biosimilar medicinal products in the pharmaceutical industry and in the health care system.

The aim of the project is first to propose (if this is justified) a unified legal model for biosimilar medicinal products, with a particular focus on patent law, conflict of laws rules, marketing, principles of access to biosimilar agents and their financing, precise differentiation between biological medicinal products and biosimilars, including insurance issues and unified model of biosimilar products names.

## 2. What tests will be carried out in the project?

The applicant is going, based on the analysis of legal regulations (Polish, European and from the US), EU documents (strategies, action plans and other guidelines directional EU) and studies of expert groups, to: 1) reconstruct the current model concerning biosimilar products, 2) identify the legal means of access to medicines, which determine how access should be implemented on the basis of new mechanisms of financing and insurance, 3) to analyse the current legal model concerning biosimilar drugs in comparative perspective and – with this perspective – to propose the introduction of a new legal model, 4) indicate in which areas the proposed unified model for regulation of biosimilar products could gradually replace current solutions.

The project is part of the European debate on the future of the law for biosimilar drugs by identifying opportunities to create a model of legal regulation that protect patients in terms of access to modern therapies. No such studies were carried out in relation to the Polish law. The results will be very important, relating to an important aspect of the functioning of the pharmaceutical law, patent and in the field of insurance.

## 3. Reasons for the research topics

The applicant and his tutor have been conducting research relating to pharmaceutical law (including the issues of patent law, marketing and reimbursement of medicinal products) for many years. The research on the biosimilar products is inspired by the observation of legislative changes taking place in these areas in recent years in the field of new drug therapies.