Pharmaceutical Waste Management in European Union Law

One of the critical sources of active pharmaceutical substances (APIs) in the environment is the improper handling of waste generated from products containing APIs, i.e. primarily medicines. Given the pollution source mentioned above and the numerous demands of the research community of the PiE area (pharmaceuticals in the environment), research was conducted on the issue in the field of legal sciences. The research's objective is to analyse and evaluate the possibility of using legal instruments in dealing with pharmaceutical waste at the European Union (EU) level. The research hypothesis assumes that to undertake effective measures aimed at environmental and health protection, it is necessary to create a legal definition of pharmaceutical waste, together with a specification for the management of pharmaceutical waste in EU law. The research posed the following research questions:

1) What environmental risks do APIs pose?
2) How is waste from medicinal products classified under EU law? Preliminary research shows that there is no legal definition of pharmaceutical waste in EU law, so how should a legal definition of pharmaceutical waste be constructed, and what should it sound like?
3) Which EU competencies and legislation are likely to shape pharmaceutical waste management?
4) How does pharmaceutical waste management fit into the EU waste hierarchy?
5) Which legal institutions and how can they be used in setting up pharmaceutical waste management?

The dissertation consists of an introduction, five chapters and conclusions. The chapters deal with the following issues: environmental pollution by pharmaceutical substances (chapter I), the current status of pharmaceutical waste, their relationship with medical waste and proposition of legal definition (chapter II), regulatory competence and the positioning of pharmaceutical waste legislation in EU law (chapter III), prevention in the management of pharmaceutical waste (chapter IV) and the management of pharmaceutical waste (chapter V).

The research methods used were specific to the field of legal sciences, namely the dogmatic-legal method and the theoretical-legal method. The first method was used to analyse the existing legal regulations relevant to the research topic. Reference was made primarily to EU environmental regulations (Directive 2008/98/EC on waste, OJ L 312 of 22.11.2008) and pharmaceutical law (Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ L 311 of 28.11.2001). The second method made it possible to cite views from the literature and documents. In addition, a meta-analysis of the data was used to gather material in chapter one.

The dissertation first presents the characteristics of environmental pollution by APIs, which must be considered when creating legal regulations. Secondly, it proposes a legal definition of pharmaceutical waste in EU law. Thirdly, it locates the issue of pharmaceutical waste among the sources of EU law, establishes the EU's competencies to regulate the matter and indicates the place for potential new regulations. Fourthly, it discusses and proposes the possibilities of pharmaceutical waste management based on the waste management hierarchy present in EU law.