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1. INTRODUCTION

The ever-increasing importance of data protection principles in modern economy has undeniably had a significant effect on the pharmaceuticals industry in Croatia, including the areas of clinical trials, pharmacovigilance, and medical research. Considering the importance of the ability to collect and process large volumes of personal data used in clinical trials or medical research and the strict obligations to report adverse reactions under the pharmacovigilance regulations, it is critical for pharmaceutical companies to carefully assess the interplay between general data protection laws and specific regulations governing clinical trials, pharmacovigilance, medicinal products, and medical devices. Furthermore, the processing of personal data relating to data subject's health requires implementation of additional safeguards protecting the special categories of data.

The adoption of the General Data Protection Regulation (Regulation (EU) 2016/679) ('GDPR') has also resulted in the need to implement changes in respect of the processing of personal data by pharmaceutical companies, especially taking into account the GDPR's more aggressive enforcement measures, increased data subjects' rights, and accountability measures.

In Croatia, the pre-GDPR sector-specific legislation (e.g. laws governing clinical trials) contains extensive rules covering data protection issues related to the operations of pharmaceutical companies. However, the GDPR and its implementing regulations have introduced additional requirements, which apply alongside the existing clinical trials legislation, pharmacovigilance, and other legislation applicable to specific activities in the health and pharmaceuticals sector. Examples of such interplay include legislation specific to pharmacovigilance (which is also recognised by the European Data Protection Supervisor ('EDPS') in its Opinion on the Proposal for Regulation amending the Regulation (EC) 726/2004), and the rules governing clinical trials and the GDPR, which have also been addressed by the European Data Protection Board ('EDPB') in 2019. In addition, the marketing activities of pharmaceutical companies, such as marketing of medicinal products to healthcare professionals, regularly include processing of healthcare professionals' personal data and also require consideration of applicable data protection laws.

1.1. Legislation

The Croatian health and pharmaceuticals sector is highly regulated and subject to constant development and change, mostly resulting from Croatia's relatively recent accession to the EU in 2013 and the legislative changes introduced at the EU level.

Key legislation governing the operations in the pharmaceuticals sector and data processing activities related thereto includes: