

Pharmacogenetic information in drug labels: large heterogeneity

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Background Pharmacogenetics (PGx) is a key issue in personalized medicine. Drug labels provide structured information to advice health care professionals for safe and effective drug use. Currently, no distinct section is providing PGx information.

Purpose The aim of this project is to explore PGx information in drug labels of drugs registered in Switzerland and to provide an overview of a) wordings used for PGx relevant information and b) instructions about PGx management.

Method In this ongoing project all Swiss drug labels (> 4000 German texts) are screened for PGx relevant information concerning drug metabolism. The search is performed with natural language processing provided by AmiKoWeb (<https://amiko.oddb.org/>). The search strategy (25 word stems, e.g. Pharmakogenetik combined with the Boolean operator ?OR?) was developed by exploring the drug labels and discussing in an interdisciplinary team. The output of the search consists in a table, displaying drug name, section, corresponding sentence, and link to the drug label. These identified drug labels will be evaluated according to wording and section of PGx relevant information, and precision of the instructions concerning PGx testing.

Findings Results will be available at the time of the conference. Two manually searched cases illustrate the predominating heterogeneity: For statins, the PGx description differs widely. The drug labels for Simvastatin, Rosuvastatin and Pitavastatin, held a clear explanation towards the SLCO1B1 polymorphism in the pharmacokinetics section, however all with another subtitle. The other statins lack of any PGx information. It remains unclear, whether no information exists or whether there is nothing to be considered. For Codeine, available in a large variety of registered pharmaceutical products, the PGx description varies from one product to the other. While in the contraindication section, wording is almost consistent, in the pharmacokinetics section, very different wordings appear. E.g., the drug label of Benylin® (20 mg Codeine per dose) gives a detailed explanation including poor and ultrarapid metabolizers, the drug label of Makatussin® (10.6 mg Codeine per dose) only mentions poor metabolizers and Pectocalmine® (20 mg Codeine per dose) does not mention the genetic polymorphism. No drug label provides recommendations in the dosing/application section.

Conclusion PGx information in drugs registered in Switzerland varies in wording and in the section the information is presented. Furthermore, precision of instructions is heterogeneous. A similar picture is expected to be present in other countries. Standardization and consistency of information about PGx is needed to advice health care professionals in personalizing drug therapies and tailoring pharmaceutical care.