P.PORTO

ESCOLA SUPERIOR DE SAÚDE

8th meeting on medicinal biotechnology

BOOK OF ABSTRACTS

MAY 29TH, 2026
SCHOOL OF HEALTH
POLYTECHNIC OF PORTO

8th meeting on medicinal biotechnology

BOOK OF ABSTRACTS OF THE 8TH MEETING ON MEDICINAL BIOTECHNOLOGY

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ISBN: 978-989-9226-20-3
DOI: HTTPS://DOI.ORG/10.26537/ED.P.PORTO.251

May, 2026

Evaluation of the Concordance of Pharmacogenomic Information in the RCM and FI with the International Recommendations of CPIC and PharmGKB

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Introduction: Pharmacogenomics plays an increasing role in optimizing antiviral therapy, allowing the choice and dosage of drugs to be tailored to the patient's genetic profile. However, the integration of this information into regulatory documents, such as the Summary of Product Characteristics (SmPC) and the Patient Information Leaflet (PIL), remains inconsistent.

Objective: To evaluate the degree of concordance between the pharmacogenomic information presented in the SmPC and PIL of antiviral drugs with the international recommendations of the Clinical Pharmacogenetics Implementation Consortium (CPIC) and the evidence levels reported in PharmGKB.

Methods: An analysis was conducted on a set of 146 marketed antiviral drugs, assessing the presence of pharmacogenomic recommendations in their respective SmPCs and PILs. These data were compared with CPIC guidelines and the pharmacogenomic evidence levels assigned by PharmGKB.

Results: Only 14 out of the 146 drugs analysed presented recommendations based on CPIC. Regarding PharmGKB evidence levels, most active substances exhibited level 3. Complete agreement with CPIC guidelines was observed in only 2 SmPCs, while other 5 did not consider any genetic polymorphisms. The remaining documents contained incomplete or partially aligned pharmacogenomic information relative to international recommendations.

Conclusion: The results show that, with the exception of abacavir, there is a discrepancy between the available pharmacogenomic evidence and its integration into the SmPCs of antiviral medicines. This misalignment reinforces the need for more comprehensive studies and effective harmonization between international guidelines and the content of SmPCs, promoting the adoption of personalized medicine.

KEYWORDS: *pharmacogenomics; antiviral; cpic; smpcs; abacavir; atazanavir; efavirenz*