



*8<sup>th</sup>  
meeting on  
medicinal  
biotechnology*

BOOK OF  
ABSTRACTS

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BOOK OF ABSTRACTS OF THE 8<sup>TH</sup> MEETING ON MEDICINAL BIOTECHNOLOGY

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# *Pharmacogenomics and substance use disorders in Portugal: bridging the gap between scientific evidence and drug labelling*

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Background: Substance use represent a major global public health burden requiring pharmacological interventions grounded in robust scientific evidence<sup>(1)</sup>. Pharmacogenomics offers a critical framework for personalised medicine by tailoring therapies to individual genetic profiles an approach particularly relevant in addiction treatment<sup>(2)</sup>. Objectives: To evaluate the degree of alignment between current pharmacogenomic evidence and regulatory documents, namely Summaries of Product Characteristics (SPCs) and Patient Information Leaflets (PILs), for drugs classified under the WHO N07B group and bupropion (N06AX). Methods: A structured review was conducted for drugs spanning ATC subgroups: N07BA (varenicline, cytisinicline, nicotine); N07BB (disulfiram, naltrexone, nalmefene); N07BC (methadone, buprenorphine, buprenorphine/naloxone); and bupropion (N06AX)<sup>(3)</sup>. SPCs and PILs were retrieved from Infomed<sup>(4)</sup>. Pharmacogenomic evidence was systematically sourced

from CPIC guidelines and PharmGKB annotations<sup>(5)</sup>. For each drug, the presence, accuracy, and completeness of pharmacogenomic information in regulatory documents were assessed against these reference databases, with particular focus on clinically actionable gene–drug interactions involving variants such as CYP2D6, ADH1B, ALDH2, and CHRNA5. Results: Genetic variants including CYP2D6, ADH1B, ALDH2, and CHRNA5 are established modulators of drug metabolism and dependence susceptibility across this therapeutic class. Nevertheless, SPCs and PILs for the majority of reviewed drugs contain absent or outdated pharmacogenomic information, with poor alignment to current CPIC and PharmGKB recommendations. Conclusions: Better incorporation of validated genetic data into SPCs and PILs would strengthen clinical decision-making, and support treatment personalisation, in the management of substance use disorders.

**KEYWORDS:** *pharmacogenomics, drugs of abuse, genetic variants*

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