

P.45 PHARMACEUTICAL PROFILING OF FENTANYL USE IN PORTUGAL: CONSUMPTION PATTERNS AND ABUSE DETERRENCE GAPS[†]

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Fentanyl is a synthetic opioid widely used in severe pain management due to its high potency and rapid action. However, its pharmacokinetic profile and formulation characteristics make it highly prone to misuse and diversion. Globally, fentanyl-related morbidity and mortality have risen dramatically, prompting calls for regulatory vigilance and harm-reduction strategies. In Portugal, although fentanyl has been primarily prescribed for legitimate medical use, recent trends show a significant increase in its outpatient use, raising concerns over misuse, improper disposal, and associated environmental and veterinary risks. This study aims to characterize fentanyl consumption trends in Portugal, examine the distribution of dosage forms, and evaluate the potential for abuse based on formulation properties. A retrospective analysis was conducted using sales data for all outpatient opioid analgesics dispensed in Portuguese community pharmacies between 2015 and 2022. Data were obtained from the National Pharmacies Association (ANF) and cross-referenced with the Infarmed database. Variables included year, dosage form, brand vs. generic status, and total number of doses. Each fentanyl formulation was assessed for abuse potential based on pharmacokinetic properties, route of administration, and presence or absence of abuse-deterrent features. Descriptive statistics were applied to identify consumption trends and correlate them with misuse liability. Fentanyl ranked as the fourth most dispensed opioid in Portugal, following tramadol, tapentadol, and buprenorphine. Over the study period outpatient fentanyl consumption increased by approximately 90%, both in packages and total doses dispensed. The annual average increase was 22,468 packages/year, highlighting a strong and consistent upward trend. Transdermal patches and sublingual tablets dominated the market, representing 58–60% and 27–36% of fentanyl doses sold, respectively. The use of sublingual tablets increased by over 30%, while oral transmucosal lozenges saw a steep decline from 11.7% in 2015 to 2.8% in 2022, possibly due to safety concerns. Buccal films and nasal sprays, introduced more recently, remained marginal, accounting for less than 1% of total consumption by 2022. Generic products saw increasing market penetration, particularly in transdermal forms, supporting policy efforts to promote cost-effective prescribing. However, none of the fentanyl formulations available in Portugal include recognized abuse-deterrent formulations (ADFs). Formulation analysis showed that rapid-onset and short-duration products (e.g., sublingual tablets, buccal films, nasal sprays) present high misuse potential, especially in outpatient settings. Although transdermal patches contain large drug loads, their slow onset and partial tamper resistance (e.g., matrix systems) confer a relatively lower risk of misuse under prescribed use. The marked rise in fentanyl use—particularly of high-risk formulations—underlines the urgent need for regulatory and pharmaceutical interventions. The absence of ADFs, combined with increased outpatient prescribing, reveals a significant vulnerability in Portugal's current opioid strategy. Recommended actions include integrating ADFs into formularies, enhancing prescription monitoring, and implementing targeted education on safe use and disposal. Furthermore, improper disposal and veterinary use, although limited, pose risks to animal and environmental health. A One Health approach to opioid stewardship that integrates human, animal, and environmental health perspectives and contemplates cross-sectoral collaboration is essential to mitigate these interconnected risks and ensure the sustainable and responsible use of fentanyl.

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