Abstract

Title: Ageing of the population and use of low-dose drug regimens in older patients (ii.)

Author: Jana Koleníková

Tutor: Assoc. Prof. Daniela Fialová, PharmD, Ph.D.

University: Charles University

Faculty: Faculty of Pharmacy in Hradec Králové

Department: Department of Social and Clinical Pharmacy

Introduction: Proportion of seniors in the population is increasing worldwide, therefore rational pharmacotherapy in older adults is more emphasized. The drug pharmacokinetics and pharmacodynamics change in older age due to physiological and pathological changes, but also due to frequent polymorbidity and polypharmacotherapy. The use of certain medicines is therefore considered risky in seniors. For this reason, explicit expert criteria of medications potentially inappropriate in the aged (so called PIMs) have been created in many countries. Considering the fact that seniors were usually not included in randomized controlled trials, information about specific dosing in older adults for many medications is not stated in Summary of Product Characteristics (SmPCs) which provide basic information on effective and safe administration of medicines. The aim of the diploma thesis was to clarify whether in case of PIMs specific information about geriatric dosing is stated in SmPCs, or at least general warnings that these medications are potentially inappropriate in older persons.

Methods: For evaluation of SmPCs, which was conducted from winter 2020 to spring 2021, the list of 327 PIMs was used, including PIMs published until 2019 in 21 explicit expert criteria. We searched SmPC of drug products that were approved for clinical use in the Czech Republic and were currently marketed. Due to a wide range of these medicinal products, the work was limited only to monocomponent medicinal products in a solid single-dose oral drug form. In evaluated SmPC we searched for information on geriatric dosing. For information search we used Database of registered drug products, administered by the State Institute for Drug Control of the Czech Republic. Quantitative research was amended for so called “content analysis” which enabled to quantify

obtained results. By this content analysis were analyzed items divided into 7 cathegories. For statistical processing of results, we used basic descriptive statistics.

Results: We analyzed 381 SmPC of medicinal products containing 121 PIMs. For 29 (24 %) PIMs we found at least some information on geriatric dosing in SmPCs, in 16 (13 %) PIMs there were recommendations to use lower doses in seniors in the SmPCs (not specified numerically) and in 9 (7 %) of PIMs it was recommended to use these medications with caution in seniors. In 23 (19 %) of PIMs, the SmPCs reported same doses as in the middle-aged population and no information on geriatric dosing was available for 20 (17 %) of PIMs in analyzed SmPCs. There was a recommendation to be careful in administering PIMs to older adults (but without a dose change) in 9 (7 %) PIMs. For 17 (14 %) PIMs there was a different information available in evaluated SmPC and for remaining 7 (6 %) PIMs it was not possible to match information to any above stated categories.

Conclusion: In evaluated SmPCs containing PIMs for only 24 % of PIMs there were clarified geriatric doses. In SmPC of 36 % PIMs, there was no information about dosage change in older patients, neither general information about caution in administration of PIMs to seniors. Insufficient specification of dosing for high-risk medications in the aged in SmPCs makes rational pharmacotherapy in geriatric patients more complicated.

Keywords: geriatrics, rational pharmacotherapy, Potentially Inappropriate Medications, geriatric dosing, Summary of Product Characteristics

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