Marcin Lewandowski

Leki generyczne: uwarunkowania kliniczno-ekonomiczno-prawne i postawy środowiska medycznego w Polsce

Generic medicines: clinical, economic, legal determinants, and attitudes of healthcare professionals in Poland

Rozprawa doktorska
w dziedzinie nauk medycznych i nauk o zdrowiu
w dyscyplinie nauki o zdrowiu
przedkładana Radzie Dyscypliny Nauk o Zdrowiu
Warszawskiego Uniwersytetu Medycznego

Promotor: Dr hab. n. med. i n. o zdr. Adam Kobayashi, prof. UKSW
Promotor pomocniczy: Dr hab. n. med. i n. o zdr. Piotr Merks

Warszawa, 2025

Summary

Contemporary pharmacotherapy is based on two complementary pillars: innovative (originator) medicines and their generic counterparts - pharmaceutical products that contain the same active substance in an identical dose and pharmaceutical form. The marketing authorization of a generic medicine requires compliance with the same standards of quality, stability and safety as the reference product, and demonstration of bioequivalence. Nevertheless, the perception of generics remains ambivalent: doubts about their clinical efficacy and safety are voiced by both patients and healthcare professionals, particularly with regard to complex formulations and medicines with a narrow therapeutic index. Physicians' and pharmacists' attitudes shape medicine policy and public acceptance of these products and are therefore crucial for the rational use of generics. Although data describing attitudes in other countries are available, comprehensive analyses of how generics are perceived by physicians and pharmacists in Poland are lacking.

For this reason, the aim of the present doctoral thesis was to provide a comprehensive summary of the clinical, economic and social aspects related to the use of originator and generic products, and to evaluate the attitudes of physicians and pharmacists in Poland toward these two categories of medicines.

The thesis comprises a narrative literature review and two survey studies addressed to physicians and pharmacists. In the literature review, documents issued by governmental bodies and regulatory authorities (national and international) were analyzed alongside peer-reviewed scientific publications from medical and pharmaceutical journals. Sources included systematic reviews, cross-sectional questionnaire studies, real-world data analyses employing big-data methods, and multicenter cohort investigations. The survey studies employed structured questionnaires consisting of two parts: a general section (six demographic and professional items) and a detailed section assessing attitudes and practices related to the use of generic medicines.

The literature review provided a synthetic account of regulatory frameworks, clinical evidence and economic considerations pertaining to generic medicines. It emphasized that adherence to quality standards and confirmed bioequivalence form the foundation for marketing authorization of generics, and that coexistence of innovative and generic products is both feasible and desirable. The review concluded that achieving a sustainable balance

between supporting pharmaceutical innovation and ensuring universal, equitable access to therapy should remain a principal objective of health policy.

Survey results revealed heterogeneous attitudes among physicians: while a substantial proportion of respondents considered generics to be therapeutically equivalent to originator products, a significant subgroup - particularly older physicians and those with longer professional tenure - expressed concerns regarding clinical efficacy, patient safety and therapeutic outcomes.

Among pharmacists, the prevailing view was that generics are clinically equivalent and contribute positively to the functioning of the healthcare system; cost remained the primary determinant of recommendation. Notable differences were observed by practice setting: in community pharmacies greater emphasis was placed on cost considerations alongside high ratings for generics' efficacy and safety, whereas in hospital pharmacies therapeutic efficacy was more frequently cited as the principal selection criterion. It was also shown that professionals who less frequently recommended generics tended to be older and more experienced. Concerns about generics' efficacy were more commonly reported by women, hospital pharmacists and specialist pharmacists.

In summary, this body of work highlights the multidimensional nature of attitudes toward generic medicines and indicates that formal regulatory compliance (quality, stability, bioequivalence), while necessary, is insufficient to secure full acceptance of generics in clinical practice. To optimize the use of generic medicines, implementation of targeted measures is suggested, including educational initiatives directed at physicians and pharmacists - particularly groups with greater reservations (e.g. senior specialists, hospital pharmacists) - and the standardization and dissemination of information materials for patients and healthcare personnel describing the generic approval process, bioequivalence criteria and relevant clinical evidence. In the long-term perspective, building trust in generic medicines among healthcare professionals may contribute to reduced healthcare costs and improved access to therapy without compromising quality of care.