Horizon Scanning and Early Assessment of Health Technologies for the Treatment of Orphan Diseases

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By
Victoria Nazarkina, • Alla Nemchenko, • Illya Podolsky, • Kostyantyn Kosyachenko, • Mykhailo Babenko, • Tetiana Koba, •

1. Professor, Department of Organization and Economics of Pharmacy, National University of Pharmacy, Kharkiv, Ukraine
2. Professor, Department of Organization and Economics of Pharmacy, National University of Pharmacy, Kharkiv, Ukraine
3. Professor, Department of Medicinal Chemistry, National University of Pharmacy, Kharkiv, Ukraine
4. Professor, Head of Department of Organization and Economy of Pharmacy, Bogomolets National Medical University, Kyiv, Ukraine
5. Director, State Expert Center of the Ministry of Health of Ukraine, Kyiv, Ukraine
6. Postgraduate student, National University of Pharmacy, Kharkiv, Ukraine

Abstract

The theoretical foundations and regulatory framework of the processes of the formation of an effective health technology assessment (HTA) system at the early stages of the life cycle of medicines are analyzed in the article. Particular attention is paid to horizon scanning (HS) and early assessment of expensive innovative drugs utilized for treating rare diseases. In order to inform policymakers, purchasers, and providers (to prioritize MT research, financial, and operational planning) or facilitate early access (by facilitating controlled dissemination of MTs), Horizon Scanning Systems, also known as “early warning and information systems,” seek to identify, filter, and prioritize new and innovative medical technologies (MTs) with significant foreseeable impacts on health, costs, society, and the healthcare system. Public and private organizations (governments, payers, healthcare systems, venture capitalists, and developers of MTs) around the world have long used formal and informal HS programs. The HS method enables proactive planning and decision-making on the use and payment of novel medications based on first evaluations of their clinical efficacy and financial impact. It is of utmost importance for rare diseases that have significant unfulfilled medical needs. Based on the review of scientific publications, analytical reports, and data from the official websites of regulatory authorities and HTA agencies, it was found that an effective system of HS, early assessments, dialogue, and managed access allows for early identification of innovative MTs that will potentially have a significant impact on healthcare. It allows us to prepare in advance for the implementation of such MTs and to rationally use limited resources and distribute risks.

Keywords: health technology assessment, horizon scanning, early dialogue, innovative medical technologies, medicines, rare (orphan) diseases

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