HIGH-COST ANTICANCER DRUGS: CLINICAL BENEFIT OR FINANCIAL BURDEN FOR THE HEALTHCARE SYSTEM?

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Relevance: the growing number of innovative but expensive anticancer drugs imposes a significant burden on healthcare systems. Many of these medicines are approved under accelerated procedures with a limited evidence base and often fail to demonstrate a clinically meaningful additional effect, raising doubts about the rationality of their use.

Objective of the study: to conduct a market analysis of anticancer drugs approved by the European Medicines Agency between 1995 and 2020, focusing on the assessment of their proven clinical effectiveness, comparison with market costs, and determination of payback periods.

Materials and methods: a review of anticancer drugs approved during the specified period was carried out, with analysis of the level of evidence for their clinical benefit and the timelines for recouping research and development costs. Additionally, examples of rational use of high-cost drugs were considered (in particular, the SONIA study on HR+/HER2– breast cancer).

Results: the analysis showed that a significant proportion of new anticancer drugs approved by the European Medicines Agency between 1995 and 2020 did not demonstrate a substantial additional clinical benefit compared to existing standards of therapy. This was especially characteristic of molecules registered under accelerated or conditional approval procedures: their effectiveness was often confirmed on the basis of surrogate endpoints (e.g., tumor shrinkage or disease progression) rather than survival data or improvement in quality of life. From an economic perspective, more than 90% of such drugs recoup development costs within 8 years, with a median payback period of only 3–4 years, reflecting the high profitability of this market segment. However, this does not always correspond to proportional patient benefit. An example is the SONIA study (Sequential versus Optimal strategy of treatment with New generation aromatase Inhibitors in Advanced breast cancer), which demonstrated that optimizing the timing of expensive drug use (e.g., deferring their administration to later lines of therapy) can result in significant cost savings without worsening clinical outcomes.

Conclusions: there is a gap between regulatory approval procedures and the actual clinical benefit for patients. Policies are needed to encourage the development of genuinely meaningful medicines and the more rational use of high-cost drugs. Otherwise, healthcare systems risk being overwhelmed by the financial burden of anticancer drugs without proven additional benefit.