Since carer perspective is not commonly accepted in HTA, NICE was the only agency with relevant guidance on this topic. INESSS required the societal perspective as standard, while the PBAC and Pharmac explicitly excluded it. CADTH may consider carer perspective in some circumstances, whereas the SMC guidance was ambiguous.
Conclusions: While there is good alignment on most topics, there are several areas where agencies would need to resolve divergences in preferred methodology if joint assessments are going to be carried out in the future. All relevant stakeholders should be part of this process, including patient groups and industry.

PD204 Comparison Of Reimbursement Systems In France Denmark, Norway, And The United Kingdom - Possibilities Of Implementation In Poland

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Introduction: Reimbursement schemes should be regularly updated to maintain a trade-off between costs for the system and access to medicines. The aim of this study was to review reimbursement systems in several European countries in terms of solutions that could have a positive impact on the health technology assessment (HTA) and reimbursement processes in Poland (e.g., increasing patient access to medicines while maintaining payers' spending).
Methods: Secondary publications and the websites of key institutions responsible for drug policy (the Ministry of Health, HTA agencies, and payers) in selected European countries were searched to find unique solutions that could have a positive impact on drug policies in Poland. The keywords used were "drug reimbursement" and "HTA". A more specific search was conducted as needed.
Results: The following solutions considered worthy of further consideration:

- central organization of tenders for hospital drugs and conducting price negotiations with regional financial responsibility;
- determining the maximum annual copayment per patient for reimbursed drugs;
- complementary private health insurance that reduces patient copayments;
- creating a separate path for hybrid drugs in the HTA and pricing processes;
- increasing the number of consultations with the market authorization holder, clinical experts, and the public during drug evaluation; and
- not accounting for the costs of lost productivity during HTA due to the discrimination of seniors and children.

Conclusions: Minor changes in the HTA process, such as increasing the role of consultations, as well as major systemic changes (e.g., introducing complementary private insurance, creating a separate path for hybrid drugs, and introducing a maximum annual copayment for reimbursed drugs) could improve patients' access to drugs. Implementing these solutions requires significant adaptation of the local legal framework.

PD205 "Medical Fund" – A Novel Approach To Granting Individuals Access To Cutting-Edge Therapies

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Introduction: Access to innovative and expensive medicines is a significant challenge for Poland's healthcare system. These therapies often do not meet the reimbursement criterion that is currently set at three times the gross domestic product per capita. Nevertheless, there are ongoing efforts to identify funds that can cover the cost of innovative and expensive medicines.
Methods: A new legal act established the Medical Fund, which is an addition to the regular National Health Fund. The Medical Fund finances medical technologies recognized by the Polish healthcare system as highly innovative or of high clinical value. Lists of such therapies are prepared by the health technology assessment agency, in consultation with clinical experts, and then approved by the Ministry of Health. Simplified marketing authorization applications based on a budget impact analysis, a more straightforward assessment process, and a separate budget may allow patients to access these therapies faster.
Results: Since January 2022, ten highly innovative therapies have been funded for patients with conditions such as spinal muscular atrophy, acute hepatic porphyria, and primary hyperoxaluria. The reimbursement decisions were issued for a two-year period, during which data on treatment efficacy were collected. If the data collected after two years is insufficient to assess the treatment's efficacy, the decision can be extended without an additional procedure for another two years. After two or four years, the marketing authorization holder must submit a reimbursement application based on a full health technology assessment report. Risk-sharing schemes based on clinical outcomes are mandatory.
Conclusions: The Medical Fund has granted early access to modern therapies. The decision to continue funding for a particular drug depends on whether registry results confirm data from experimental studies.

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