

Towards sustainable risk-sharing solutions (standard framework agreement) for entry of new innovative medicines

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| Background | <ul style="list-style-type: none"> ● Limited Health care funding and short term (1 year) budgeting - have been main drivers for introducing a standard risk-sharing or financial co-participation framework agreement by the MoH and its adoption by pharmaceutical industry; ● Form positive side agreement has fostered access to many new, effective innovative treatments that otherwise would not be possible due to the limited HC budget (25 agreements in y2018); ● However standard framework agreement is very unbalanced towards industry: <ul style="list-style-type: none"> - Cost of overspending the assigned budget should be 100% covered by pharma company (including cost of wholesaler and pharmacy mark-ups and VAT) - Agreement is of unlimited duration, with exit penalty fee as much as 12month of total spend for given medicine; - No legal provision to guarantee actions from the payer side in case of substantial increase in treated patient numbers with respective excessive budget overspend; ● Neighboring countries Lithuania and Estonia have similar risk-sharing agreement framework with incorporated risk management solutions for both sides: <ul style="list-style-type: none"> - In Lithuania payback for pharma companies is a fraction of overspend, proportionately distributed between pharma companies and payers; - In Estonia – agreement is for one year, in case of potential overspend pharma company notifies payer; imminent negotiations are scheduled with agreement amendments; if no agreement reached- no exit penalty for pharma company. |
| Proposal | <p>To create new framework for risk sharing agreements that would balance risk more evenly and would incorporate legal provisions to protect pharma companies from financial hardship due to unpredictable and excessive financial liabilities.</p> |
| Project: execution | <ul style="list-style-type: none"> ● State institutions to get acquainted with industry prepared framework agreement amendment proposals (October 2019); ● State institutions to prepare they own vision/agreement amendment proposals (October-November 2019); ● Mediated/moderated workshop with aim to establish for both parties acceptable solution (November 2019); ● Detailed preparation of legal framework agreement in line with pre-agreed solution (December 2019); ● Validation of the agreement by both parties (December 2019); ● Implementation of the new framework agreement (from January 2020). |
| Potential stakeholders | <p>State institutions Ministry of Health National Health Service Pharma industry NGO Legal experts Mediator/moderator to facilitate discussions and help to reach agreement</p> |