Supplementary Material 1. HTA Guidelines in Poland

The first set of HTA Guidelines were introduced in March 2007 and updated in April 2009 and in August 2016. HTA Guidelines are structured in a form of an official AOTMiT document that presents an analytical approach for technology assessment and appraisal in Poland. According to this document, “the purpose of the guidelines is to indicate the principles and acceptable methods of performing Health Technology Assessment to ensure high quality of analyses and reliable results “. As stated on the AOTMiT website: “The agency bases its work on scientific evidence that determine whether the drug is safe and effective for the patient. This information is crucial for making decisions that shape the national health policy. Three elements make up a full assessment: clinical effectiveness analysis, economic analysis and the budget impact analysis”.

The current HTA Guidelines are structured in the following manner:

1. Decision problem analysis following the PICO scheme ie. Population, Intervention, Comparators, Health Outcomes
2. Clinical analysis: data (sources, search strategy, information selection and quality assessment, presentation of included trials and data extraction); data synthesis for effectiveness (qualitative synthesis, meta-analysis, simple and network indirect comparison); safety assessment (purpose, scope of safety analysis); presentation of results; limitations; discussion and final conclusions.
3. Economic analysis: analytical strategy; perspective; time horizon; analytical technique (cost-utility analysis, cost-effectiveness analysis; cost-minimisation analysis; cost-consequences analysis); modelling; health outcomes assessment; cost assessment (cost categories, identification and measurement of used resources, determination of unit costs); discounting; data presentation; presentation of results; sensitivity analysis and result uncertainty assessment; limitations and discussions; final conclusions.
4. Analysis of impact on health care system: budget impact analysis (perspective, time horizon, elements of analysis, data sources, population, compared scenarios, cost analysis, sensitivity analysis, presentation of results, limitations and discussion); ethical, social, legal aspects, impact on the organization of service providing.

In parallel to the guidelines, a 2012 regulation by the Minister of Health determines the manufacturer’s submission template. It specifies the components and data framework of the application within the three main categories: clinical analysis, economic analysis, and budget impact analysis. It also includes guidance for preparing a rationalization analysis if the budget impact analysis demonstrates an increase of reimbursement costs. The rationalization analysis shows scenario(s) for releasing public funds in the amount corresponding to the increase in budget impact.

The clinical analysis builds on the following:

* A description of health problem with epidemiology;
* An overview of existing reimbursed treatments;
* The position of the new drug with regards to existing treatments;
* A systematic review of primary trials and their selection criteria;
* An overview of published systematic reviews.

The economic analysis includes:

* A basic analysis;
* A sensitivity analysis;
* A systematic review of the published economic analyses with regards to comparator technologies for relevant populations.

The budget impact analysis estimates:

* The population size;
* Annual expenditures for the payer, broken down in various categories;
* Additional costs.

It has been noted that HTA Guidelines developed by AOTMiT in 2007 and updated in 2009 and further in 2016 represent significant step toward improved transparency, and even more importantly, toward consistency between the Reimbursement Law of 2011 and HTA Guidelines.