

Harmonization of HTA methodology and processes

Health Technology Assessment (HTA) is a tool for assessing the clinical, economic, ethical and legal aspects of health care technologies in order to inform decisions about recommendation, reimbursement and coverage.


Implementation of HTA differs across countries, often in important ways, e.g. selection of technologies, scope of assessment, evidence requirements and methods used. Harmonization of HTA is advocated by several players, particularly in the areas of evidence requirements, methodological convergence and information sharing. It is expected that this will result in more timely and efficient assessments. How far harmonization and further coordination of HTA activities will extend is still being explored.

Novartis perspective

Novartis supports HTAs that are based on sound scientific methods and governance standards allowing a timely, balanced and unbiased assessment. We refer to our position on HTA principles on how this should be implemented.

We believe there is potential for harmonization of clinical evidence requirements and assessment methods. Novartis sees limited potential for harmonization of economic evaluations, ethical and legal appraisal, as these require consideration of the local context. We support discussions that will evolve HTA methods and processes to international best practice.

Clinical data for a new technology usually applies across countries. HTAs should explicitly consider and address the degree of generalizability and transferability of findings. Limitations can result e.g. from inherent variability of disease epidemiology, clinical event and complication management, and outcomes across healthcare systems.



The assessment of cost-effectiveness, budget impact and appraisals of technologies for pricing and reimbursement should be done at a national level. The evaluation outcome reflects e.g. different medical practice, healthcare priorities, and choices on what to consider and fund, and is necessarily influenced by national processes and resources.

Any harmonization of HTA methods and processes should aim to improve evidence based healthcare decision making. It should in particular increase the quality and efficiency of HTA, enhance transparency, expand stakeholder involvement and accelerate patient access to valuable new healthcare technologies.

HTA is an evolving discipline and the timely incorporation of progressing state of the art methodology in HTA processes should be ensured.

HTA evidence needs should not supersede marketing authorization requirements or delay the distinct regulatory approval process of a medicine's quality, safety and efficacy.