Key differences between regulatory and HTA decisions.

	Regulatory approval	HTA / Coverage
Legal authority	Typically defined in health legislation with a regulatory authority accountable to their federal government.	Typically defined within the rules and regulations of the healthcare system within which they operate. In certain circumstances, its role and responsibilities are defined in legislation and, as such, the body may be accountable to the government.
Primary role	Marketing authorisation of a product in the relevant jurisdiction on the basis of an assessment of efficacy, safety, quality, and benefit-risk profile. Continuous monitoring of the use of a medicine (pharmacovigilance) under safety aspects.	Recommendations on coverage and/or reimbursement decisions of a product within a particular healthcare system on the basis of assessment of relative effectiveness, costs and in some systems affordability, value for money, priorities and values within the healthcare system.
Decision	Does the product do more good than harm for patients with defined target indication? Should this technology be marketed?	Does product offer useful, appropriate benefits for all, or a select subgroup of, patients in the healthcare system compared to what is the standard of care in the disease area? Are the costs associated with the product affordable and justified by its benefits?
Type of evidence	Safety. Efficacy. Quality.	Safety. Relative effectiveness. Cost effectiveness, and budgetary impact. Social, ethical, legal, organisational impact.

Adapted from: Henshall C, Mardhani-Bayne L, Frønsdal KB, Klemp M. Interactions between health technology assessment, coverage, and regulatory processes: emerging issues, goals, and opportunities. Int J Technol Assess Health Care. 2011 Jul;27(3):253–60. http://www.ncbi.nlm.nih.gov/pubmed/21756413