Time to HTA Assessment Completion by HTA Agency Archetype: Five-Year Review for 20 European Countries

Izmirlieva M
GlobalData, London, United Kingdom

Objectives

Countries using health technology assessment (HTA) differ in the way HTA is conducted. HTA agencies can be broadly split into different archetypes and one interesting research question is whether the time required to complete an HTA is affected by the agency archetype. The objective of this study is to examine the time elapsed between marketing authorization and 1) first HTA decision and 2) first positive HTA decision for each of the four agency archetypes selected for inclusion in this review: advisory arm's-length, advisory integrated, regulatory (i.e., issuing binding decisions) arm's-length, and regulatory integrated.

Methods

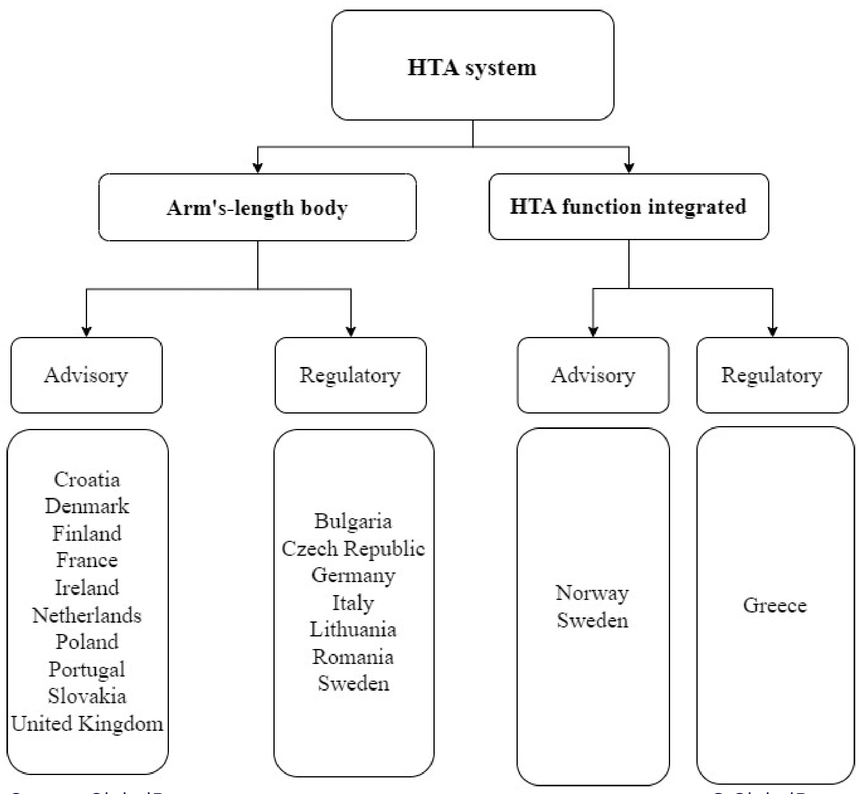
Twenty national-level European HTA agencies were categorized under the four archetypes. All final HTA decisions issued by these agencies in the 20 countries between January 1, 2018, and December 31, 2022, were extracted from the GlobalData POLI database and reviewed. The average time, in days, between marketing authorization and first HTA decision, as well as the average time in days between marketing authorization and first positive HTA decision, were calculated and compared for each of the four agency archetypes.

Results

Different approaches have been used to classify HTA agencies into an archetype, but for the purposes of this review, the four archetypes were defined based on organizational characteristics of the HTA body and the impact of its assessments. The HTA archetypes classification from a Fontrier et al paper(1) was adapted to exclude subnational-level HTA entities and those HTA entities with a coordination function only. The United Kingdom's National Institute for Health and Care Excellence (NICE) was treated as a national-level body and included in the analysis because its Multiple Technology Appraisals (MTAs) apply to all parts of the UK.

Notably, Fontrier et al classify NICE as advisory, but its role goes beyond the advisory function. While NICE describes itself as providing merely guidance, there is a legal requirement that the National Health Service (NHS) should start funding medicines within three months of a positive NICE guidance. To accommodate the two different possible archetype classifications for NICE, alternative analyses were performed – one in which NICE is classified as a regulatory entity and another one in which NICE is classified as an advisory HTA body – to assess how this would affect the average scores for the four agency archetypes. The HTA entity selection was cross-referenced with available HTA data from the GlobalData POLI database to arrive at the final list of countries with an HTA agency included in this analysis.

HTA entities by country included in this analysis



Source: GlobalData

The results indicate that the longest time between marketing authorization and first HTA decision was for the regulatory integrated archetype (1,238 days), followed by the advisory integrated HTA archetype (782.5 days). Advisory arm's-length and regulatory arm's-length agencies had a similar time to first HTA of 675.8 days and 674.8 days, respectively. The latter two swap places in the ranking if NICE is reclassified as advisory instead of regulatory. If the time to first positive HTA decision is examined instead, regulatory integrated agencies required the longest time, on average, to publish a positive HTA decision of 1,244 days, followed by 813 days for advisory integrated agencies, 748.9 days for regulatory arm's-length agencies and 737.7 days for advisory arm's-length agencies. The ranking order is maintained if NICE is reclassified as advisory instead of regulatory archetype agency.

Length of HTA review by HTA archetype (average number of days across all countries with the same HTA archetype)

	With NICE classified as regulatory		With NICE classified as advisory	
HTA archetype	**Time to first HTA**	**Time to first positive HTA**	**Time to first HTA**	**Time to first positive HTA**
Advisory arm's-length	675.8	737.7	656.5	712.4
Advisory integrated	782.5	813.0	782.5	813.0
Regulatory arm's-length	674.8	748.9	702.1	786.6
Regulatory integrated	1,238.0	1,244.0	1,238.0	1,244.0

Source: GlobalData

Conclusions

Countries with arm's-length agencies of both regulatory and advisory function were found to produce HTA reviews faster. They are also more likely to issue the first positive HTA decision faster compared to integrated agencies. The finding of a very long review time for the regulatory integrated HTA archetype should be treated with caution as there was a single national-level HTA agency in this archetype.

(1) Fontrier, AM., Visintin, E. & Kanavos, P. Similarities and Differences in Health Technology Assessment Systems and Implications for Coverage Decisions: Evidence from 32 Countries. *PharmacoEconomics Open 6, 315–328 (2022).* https://doi.org/10.1007/s41669-021-00311-5.