Introduction

Health Technology Assessment (HTA) is increasingly used to assess new medicines in order to inform coverage decision making for efficient allocation of healthcare resources. While there is considerable diversity between HTA organisations and methodologies utilized in HTA assessment in different countries, the HTA agencies are evolving to adopt the best tools and to improve their decision making infrastructures to make high quality decisions. As agency strive to improve their assessment and appraisal process a key element of this is to have quality submissions from companies. The complex environment represents a challenge for the agencies to learn from each other and improve their own process to make better decision, as well as for the industry to adjust their development and submission strategy accordingly.

The Centre for Innovation in Regulatory Science (CIRS) undertakes a series of metrics programmes among HTA agencies and pharmaceutical companies to evaluate both the influence of HTA requirements on development as well as, timelines, procedures and transparency, with the aim to understand and improve the HTA decision making process within companies and agencies.

However one aspect which is critical to good HTA review practices by agencies and good submission practice from companies is to understand just how companies can build quality submission and how agencies can build quality into the HTA process and decision making.

Objectives

- To establish a working definition of “quality” in the HTA context;
- To identify the key features of good-quality dossier for submission in an evolving HTA environment;
- To identify performance indicators to measure the quality of HTA review;
- To recommend key features to be considered for best practice in HTA process and decision making.

Methods

This study was initiated by developing a working definition of quality in the context of HTA; common elements that underpin a quality submission dossier, and a set of key performance indicators of HTA review processes that companies could provide feedback on as markers of either good quality interaction or HTA review.

International experts representing HTA/coverage agencies, academics and pharmaceutical companies were invited to discuss the definition of quality and identified parameters from diverse viewpoints. The key discussion points and recommendations for performance indicators are outlined herein.

Results

Quality of HTA submission

Figure 1: Elements of a good quality dossier

- Robust data supports reimbursement decision and addresses relevant needs such as societal values
- Data must be consistent between tables and text between clinical effectiveness analysis and economic evaluation or budget impact analysis
- Dossier should be a logically structured, well-written compilation using a clear format

Quality of HTA review

Figure 2: Key consideration when preparing a quality submission and areas for which an HTA agency could provide feedback

- How scientific advice was incorporated
- Provide justification for not taking/following scientific advice
- Answer all concerns when expressed

- Specification of overall quality and robustness of evidence
- Subgroup analysis to be supported and the quality of support details
- Address societal needs adequately
- Cost-effectiveness to be well-suited
- Provide justification for quality of life surrogates
- Present patient perspective

- Show where the most benefit will be relevant in the local context
- Explain assumptions made behind dealing with uncertainties
- Be transparent and proactive in addressing the shortcomings

Conclusions

A key outcome of this research was a clear understanding of what could be markers of a “quality” HTA review or submission from the perspectives of both company and agency stakeholders.

These key factors, irrespective of the diversity of HTA agencies, could be used to measure if an agency had a quality review process and companies were submitting a quality dossier.

The next phase of the research will be to develop an instrument to measure the quality of HTA process and submission based on the identified KPIs and to be piloted and validated by key stakeholders.

Bibliography

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Center For Innovation in Regulatory Science

Mission

To maintain a leadership role in identifying and applying scientific principles for the purpose of advancing regulatory and HTA policies and processes in developing and facilitating access to medicinal products

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