The Influence of the National Institute for Health and Care Excellence on Other Health Technology Appraisal Markets

HTA349

Dominic Cameron, Andy Boateng, Sarah Campbell-Hill, Hannah Harrington*, Grace Lambert

Takeda UK Ltd, London, UK, Costello Medical, London, UK

Objectives

The National Institute for Health and Care Excellence (NICE) conducts health technology appraisals (HTAs) and makes recommendations on the use of treatments in NHS England and Wales. This study assessed the influence of NICE on other HTA bodies in terms of methodological approach and reimbursement decisions.

Methods

1. Targeted Literature Review

A targeted literature review (TLR) of electronic databases and congresses was conducted on 20th October 2022 to identify publications reporting the influence of NICE recommendations or HTA methodologies on HTAs in other markets.

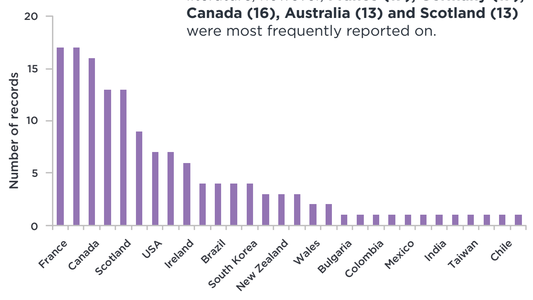
38 records were included in the review

Methodological requirements, guidance and standards	Both	Reimbursement decisions
12	10	16

Of the records which discussed methodological guidance:

- **11** reported on **clinical evidence requirements** (e.g. clinical study design, RWE, and generation of comparative evidence).
- **4** reported on **SLR requirements.**
- **14** commented on the requirements for **economic modelling** by NICE and other HTA bodies.

A range of markets were identified in the literature, however, **France (17), Germany (17), Canada (16), Australia (13) and Scotland (13)** were most frequently reported on.



Abbreviations: HTA: health technology assessment; NICE: National Institute of Health and Care Excellence; RWE: real-world evidence; SLR: systematic literature review; TLR: targeted literature review.

2. Internal Takeda Survey

To supplement the TLR, a survey was conducted with 24 employees responsible for HTA submissions across 21 countries and 6 continents within Takeda, a global biopharmaceutical company.

The survey focused on three main areas:

(1) The **alignment** between NICE guidelines and **methodological requirements,** and those from other HTA bodies.

(2) The influence of **reimbursement decisions** made by NICE on the reimbursement decisions made by other HTA bodies.

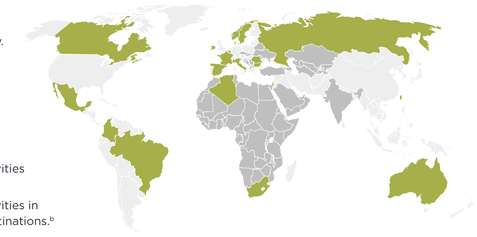
(3) The **efficiency** of developing HTA submissions for other HTA bodies, if developed before or after the development of a NICE submission.

Survey Respondents

- A range of markets responded to the survey.
- 20 respondents were responsible for access activities in a single country.
- Four respondents were responsible for access activities in multiple countries or regional/global remit.

Key:

- Respondents responsible for access activities in a single country.[a]
- Respondents responsible for access activities in multiple countries or regional/global destinations.[b]



Footnote: [a]The respondent who was responsible for access activities in South Africa was also responsible for access activities in Sub-Saharan Africa. [b]The respondent who was responsible for activities in Eastern Europe (Eastern Europe includes Albania, Bosnia and Herzegovina, Bulgaria, Croatia, Estonia, Hungary, Kosovo, Latvia, Lithuania, Montenegro, North Macedonia, Romania, Serbia and Slovenia & Czech Republic) has not been highlighted on the map as the individual countries were not specified. Abbreviations: HTA: health technology assessment; NICE: National Institute for Health and Care Excellence; TLR: targeted literature review.

3. Internal Takeda Interviews

Structured interviews were conducted with Takeda market access leads to gain deeper insights into 14 countries. These countries were selected based on the findings from the TLR or survey:

- Brazil, CONITEC
- Spain, AETS, and Portugal, Infarmed[b]
- France, HAS
- China, NHSA
- Taiwan, NHIA
- Denmark, DMC
- United States, ICER[a]
- Norway, NoMA
- Ireland, NCPE
- Japan, C2H
- Canada, CADTH
- Sweden, TLV
- South Korea, HIRA

Footnote: [a]Findings from the United States are not summarised due to limited relevance of HTA in the US and as limited influence of NICE was identified. [b]Spain and Portugal were covered in one interview. Discussions from the interview with Spain/Portugal are assumed to apply to both countries. Abbreviations: AETS: Agencia de Evaluacion de Tecnologias Sanitarias; CADTH: Canadian Agency for Drugs and Technologies in Health; CONITEC: National Committee for Health Technology Incorporation; C2H: Centre for Outcomes Research and Economic Evaluation for Health; DMC: Danish Medicines Consortium; HAS: French National Authority for Health; HIRA: Health Insurance Review and Assessment; ICER: Institute for Clinical and Economic Review; NCPE: National Centre for Pharmacoeconomics; NHIA: National Health Insurance Administration; NHSA: National Healthcare Security Administration; NoMA: Norwegian Medicines Agency; PBAC: Pharmaceuticals Benefits Advisory Committee; TLR: targeted literature review; TLV: Swedish Dental and Pharmaceutical Benefits Agency.

4. Analysis of HTA Processes and Methods Guides

The HTA processes and methods guides of four countries and ISPOR[a] were analysed and compared to NICE:

- The methods review focused on guidelines including clinical evidence, use of clinical expert opinion, economic evaluations and RWE.

Canada, CADTH

Including guidelines on:
- Economic evaluations.
- Clinical evidence.
- Real-world evidence.

Brazil, CONITEC

Including guidelines on:
- Economic evaluations.
- Systematic reviews and meta-analysis.

Norway, NoMA

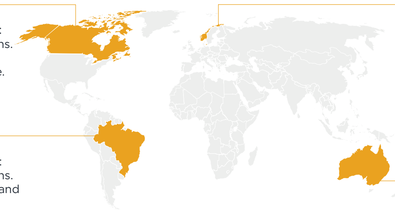
Including guidelines on:
- Overall HTA submissions.

ISPOR

Including guidelines on:
- Economic evaluations.
- Indirect treatment comparisons.
- Real-world evidence.

Australia, PBAC

Including guidelines on:
- Overall HTA submissions.



Footnote: [a]For ISPOR, four specific guidelines were extracted which focused on clinical evidence synthesis, economic modelling, and RWE. ISPOR guidelines have a global influence so are not indicated on the map. Abbreviations: CADTH: Canadian Agency for Drugs and Technologies in Health; CONITEC: National Committee for Technology Incorporation; HTA: health technology assessment; ISPOR: The Professional Society for Health Economics Research; NICE: National Institute for Health and Care Excellence; NoMA: Norwegian Medicines Agency; PBAC: Pharmaceuticals Benefits Advisory Committee; RWE: real-world evidence.

Results

1. Targeted Literature Review

Methodological requirements, guidance and standards

Based on the literature identified, when all evaluated elements of an HTA submission were considered, Canada and Australia were most consistently aligned with the NICE requirements.

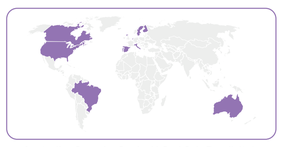
Clinical Evidence

Australia and **Canada**

SLRs

Australia, France, Ireland and Scotland

Economic Modelling

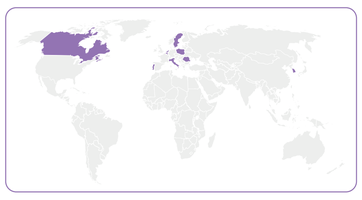


Australia, Canada, Spain (AQuASa), Brazil, Italy (CRUFa), Finland, United States, South Korea, Ireland, Portugal, Scotland, Sweden and The Netherlands

Reimbursement decisions

Six records identified that reimbursement decisions made by NICE do influence reimbursement decisions made by other countries.

Countries identified as being most influenced by NICE



- **Belgium, Canada, Italy, Poland, Portugal, Romania, South Korea, Sweden and The Netherlands** were identified as being influenced by NICE reimbursement decisions.
- In additional analyses, **Canada** was identified as having a high proportion of decisions similar to NICE if made after the NICE decision. This aligned with other findings from the literature.

2. Internal Takeda Survey

Overall, findings from the survey demonstrated that:

- Several markets aligned with NICE methods; such as, alignment with NICE on economic modelling was observed for almost all countries and many countries stated that there was alignment with NICE on SLRs.
- Negative reimbursement decisions from NICE had a greater influence than positive reimbursement decisions.

Reimbursement Decisions

Results indicate that reimbursement decisions in **Brazil, Bulgaria, Croatia, Israel, Middle Eastern countries, Romania, Russia, South Africa, Spain, Taiwan and Turkey** are potentially influenced by both positive and negative reimbursement decisions made by NICE.

Methods

Results indicate that **Ireland and Sweden** have similar guidelines and requirements across all elements of the HTA evidence package when compared with NICE (clinical evidence, SLRs, HRQoL data and economic modelling).

Abbreviations: HRQoL: health-related quality of life; HTA: health technology assessment; NICE: National Institute for Health and Care Excellence; SLR: systematic literature review.

3. Internal Takeda Interviews

Methodological requirements, guidance and standards

Almost all interviewees commented that the NICE guidelines and guidelines for HTA in their market are **generally aligned**

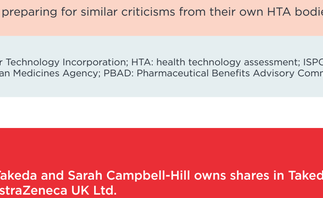
- A particularly high degree of alignment was identified for **Canada, Denmark, Norway, Sweden and Ireland.**

- Where guidelines exist, the majority of aspects aligned.
- At least one element of the evidence package was identified as aligned.

Reimbursement decisions

Almost **all interviewees** stated that NICE reimbursement decisions have **some degree of impact** on their market

- Many interviewees highlighted that a **positive NICE decision** is **beneficial to some extent;** a positive reimbursement decision by NICE would typically be viewed as a 'good thing'.
- **Negative NICE decisions** were identified as making a submission in other markets **more challenging** and subject to **increased scrutiny.**



Although beneficial, a positive NICE decision was identified as not guaranteeing reimbursement across all markets interviewed.

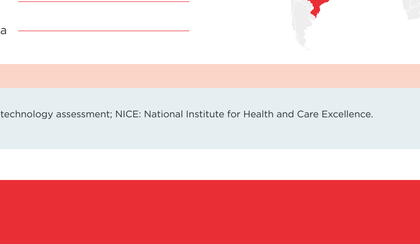
Of the countries interviewed:

- Japan and Taiwan were identified as being directly influenced by NICE reimbursement decisions.
- NICE decisions have some degree of impact, but a direct influence was not identified for numerous markets.
- Australia, France and Norway were identified as not being influenced by NICE reimbursement decisions.

Abbreviations: HTA: health technology assessment; NICE: National Institute of Health and Care Excellence.

4. Analysis of HTA Processes and Methods Guides

Where guidelines existed, **CONITEC, CADTH, PBAC, NoMA and ISPOR** requirements covering clinical evidence, evidence synthesis, use of clinical expert opinion, economic evaluations and RWE were **generally aligned with NICE;** with NoMA, CONITEC and CADTH **making explicit reference to NICE guidelines within their guidelines.**



NICE guidelines tended to be **more detailed** than others included in the review, which limited the ability to observe potential alignment in some areas. This was particularly evident when analysing **CONITEC** guidelines, and when reviewing RWE recommendations.

The **greatest difference in requirements** between NICE and other markets **related to economic evaluations.** Key differences **related to country-specific inputs** (such as discount rates, costs and preference weights used to derive utility values) rather than more substantial changes to the modelling, such as analysis type and model structure.

Abbreviations: HTA: health technology assessment; CONITEC: National Committee for Health Technology Incorporation; CADTH: Canadian Agency for Drugs and Technologies in Health; PBAC: Pharmaceuticals Benefits Advisory Committee; NoMA: Norwegian Medicines Agency; ISPOR: The Professional Society for Health Economics Research; NICE: National Institute of Health and Care Excellence.

Additional considerations

- Based on the identified themes, many interviewees suggested that there were important efficiency gains when the NICE submission occurred prior to a submission in other markets.

Learning from the NICE Evaluation

- Learning from the challenges and uncertainties raised allows important efficiency gains.
- This was highlighted by almost all interviewees, with explicit mention from **Australia, Brazil, Denmark, France, Ireland, South Korea, Brazil** and **Norway.**

Submission Development

- Some interviewees noted that there are efficiency gains internally when their submission is developed after the NICE submission, due to adaptation of UK materials such as the submission dossier and SLRs.
- This was the case for **Canada, Denmark, Norway, South Korea, Taiwan, Brazil** and **Ireland.**

Cost-Effectiveness Model Development

- In particular, adaptation of the Global/NICE cost-effectiveness model (rather than de novo model development) was identified as a key source of efficiency gains.
- However, almost all interviewees noted that some local adaptation of the Global/NICE cost-effectiveness model is required.

Conclusion

Methodological Requirements

- Findings from the TLR, survey and interviews suggest general alignment between NICE methods, guidelines and requirements and those from other markets.
  - This was validated by the analysis of methods guides for PBAC, CADTH, CONITEC, NoMA and ISPOR.
- The greatest divergences from NICE guidelines were observed for economic evaluations. However, these differences mostly related to the requirement for country-specific inputs, rather than substantial modelling changes.

Reimbursement Decisions

- Findings on reimbursement decisions were nuanced and varied; many markets suggested a degree of impact of decisions made by NICE, but ultimately other HTA bodies are autonomous.
- Negative decisions made by NICE were generally identified as more influential than positive decisions.
  - This was largely due to uncertainties and challenges raised during the NICE evaluation being transparent and likely to be raised by other HTA bodies.
  - However, reviewing the NICE evaluation of these challenges offers an important learning opportunity for other markets.

NICE submissions also provide opportunities for other markets to experience **efficiency gains** when preparing their HTA submissions through:

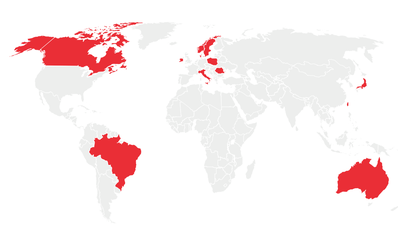
- The adaptation of materials from the NICE submission, such as economic models.
- Learning from the challenges and criticisms raised during the NICE submission, and preparing for similar criticisms from their own HTA bodies.

Abbreviations: CADTH: Canadian Agency for Drugs and Technologies in Health; CONITEC: National Committee for Technology Incorporation; HTA: health technology assessment; ISPOR: International Society for Pharmacoeconomic Outcomes Research; NICE: National Institute for Health and Care Excellence; NoMA: Norwegian Medicines Agency; PBAD: Pharmaceutical Benefits Advisory Committee; TLR: targeted literature review.

Across all stages of this research, **NICE was identified as influencing other HTA bodies.** However, the extent of this influence, and specific countries identified as influenced, varied between project stages, and it was not possible to quantify the influence that NICE has globally.

Markets identified as being most **influenced by NICE,** in terms of reimbursement decisions and alignment of methods, were:

- Canada
- Ireland
- Italy
- Romania
- Poland
- Brazil
- Australia



The markets identified as being most influenced by NICE **span the globe,** highlighting the geographical extent of NICE's influence.

- Sweden
- Norway
- Denmark
- Japan
- Taiwan

Abbreviations: HTA: health technology assessment; NICE: National Institute for Health and Care Excellence.

Dominic Cameron BSc, Andy Boateng MSc, and Sarah Campbell-Hill DPhil are employees of Takeda and Sarah Campbell-Hill owns shares in Takeda. Grace Lambert is an employee of Costello Medical.
*Hannah Harrington is a former employee of Costello Medical and is currently employed by AstraZeneca UK Ltd.
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