Decision making in NICE, SMC and NCPE; Assessing time from regulatory approval to HTA Decision Outcome

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01. Introduction

Improving access to new medicines has become a crucial issue for healthcare payers globally. This is particularly relevant in the current environment of increasing complexity of new technologies, rising costs of new medicines and the significant budgetary constraints faced by health systems.

Reimbursement timelines have also become a significant concern, with Ireland falling behind many European countries in terms of speed of access to new medicines, including the UK.

Health Technology Assessments (HTA) on new medicines are conducted in Ireland and the UK, as outlined below.

- Ireland: National Centre for Pharmacoeconomics (NCPE);
- England, Wales and Northern Ireland (NI): National Institute for Health & Care Excellence (NICE);
- Scotland: Scottish Medicines Consortium (SMC).

There are several differences between the assessment process on new medicines for these three agencies including :

1. The NCPE process has a unique, preliminary and mandatory Rapid Review (RR) assessment stage. RR assessments can be submitted once a positive Committee for Medicinal Products for Human Use (CHMP) opinion is received. The outcome of RR assessments determines the requirement for an HTA. Therefore, some new medicines in Ireland do not undergo a full HTA assessment.
2. NICE assessments on new medicines can commence pre-regulatory approval.
3. As of 2021, regulatory approval for new medicines in the UK is completed through the Medicines and Healthcare products Regulatory Agency (MHRA), rather than the European Medicines Agency (EMA).

This research aims to evaluate the variations in time from market authorisation (MA) to the publication of the HTA outcome across the three assessment agencies in Ireland and the UK. to assess whether companies submit a HTA in all three jurisdictions over a similar timeline.

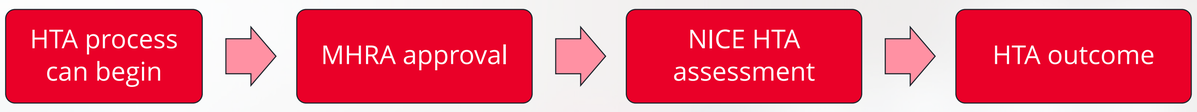
02. HTA Processes

Figures 1–3 provide a brief overview of the key differences in the HTA processes between the three agencies in the UK and Ireland.

Figure 1: Brief overview of NCPE HTA process

In Ireland, a RR can be submitted once a CHMP positive opinion is received. Following the RR outcome, a HTA may or may not be required. For medicines which undergo a full HTA, the NCPE aims to complete assessments within 90 days (utilising a stop-clock) approach.

Figure 2: Brief overview of NICE HTA process



In England and Wales, the HTA process can begin pre-MHRA approval. The main clinical and cost effectiveness evidence can be submitted at this point. Topic selection occurs approximately 2 years before the guidance publication. A NICE group discusses which topics should be prioritised and what route should follow, including Technology Appraisal vs Highly Specialised Technology Appraisal.

Figure 3: Brief overview of SMC HTA process

In Scotland, following CHMP positive opinion or MHRA approval, the SMC will seek confirmation of the HTA submission date from the company.

03. Methods

A centralised database was created in Excel® using regulatory approval data and HTA outcomes from publicly available sources including the NCPE, SMC, NICE, EMA, and MHRA websites.

A total of 47 medicines that were submitted to each of the three agencies for a full HTA were identified between 2022 and 2024. These medicines were selected to assess the time to HTA outcome from MA for the relevant indication.

For NICE and SMC, where the MA predates the MHRA conversion (where centrally authorised products were converted to UK authorised products with a new MA number given on the 1st January 2021), the EMA authorisation date is utilised. Table 1 below provides an overview of sources and extracted data utilised in the analysis.

Table 1: Overview of sources and extracted data

Source	NCPE Website	NICE website	SMC website	EMA website	MHRA website
Extracted data points	Date of HTA outcome	Date of HTA outcome	Date of HTA outcome	Date of regulatory approval for relevant indication	Date of regulatory approval for relevant indication

Analysis Plan

To gain insight regarding the variation between time to HTA outcome from regulatory approval, the following information was calculated for each new medicine/indication:

- Time to HTA outcome from regulatory approval within each agency
- The average time to HTA outcome within each agency

Subsequently, timelines were further analysed to assess:

- The overall average time to HTA outcome from regulatory approval
- The proportion of assessments in each agency that fall under the average
- The variation between time to HTA outcome across the three agencies.

04. Results

The overall average time to HTA assessment outcome from regulatory approval across all three jurisdictions for assessment outcomes between 2022 and 2024 was **547.68 days (1.50 years).**

Results for the 47 HTA assessments identified across all three agencies with HTA outcomes between 2022 and 2024 are detailed in Table 2, below.

Table 2: Average time to HTA outcome from regulatory approval

NCPE	NICE	SMC
771.74 days (~2.11 years)	437.51 days (~1.20 years)	433.79 days (~1.19 years)

The average time to HTA outcome from MA date for NICE and SMC is relatively aligned at **437.51 days (1.20 years)** and **433.79 days (1.19 years),** respectively.

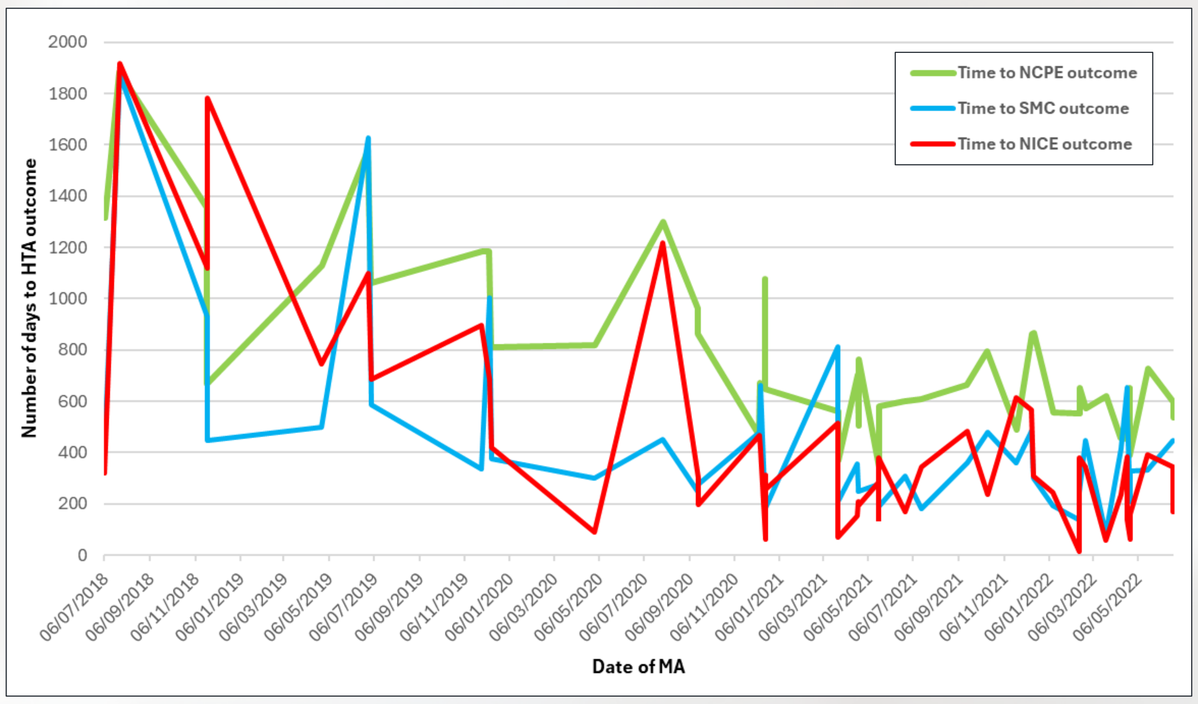
The average time to HTA outcome from regulatory approval is significantly longer for NCPE submissions at **771.74 days (2.11 years)**.

Of the 47 medicines/indications analysed, only **9 (19.15%)** of NCPE assessments fell under the overall average time to HTA outcome from regulatory approval of 547.68 days (1.50 years). In contrast, the majority of NICE (36; 76.60%) and SMC (38; 80.85%) assessments fell under this average. This signals that reimbursement for medicines in Ireland may be longer, in comparison to the other two jurisdictions**.**

Trends over time

Figure 4 below details the trend in time to HTA assessment outcome from marketing authorisation date across the three agencies.

Figure 4: Time to HTA assessment outcome from marketing authorisation date



As expected, there is a downward trend in the number of days to HTA assessment outcome from regulatory approval, over time. Medicines with a marketing authorisation in in 2018 and 2019 generally saw a greater time to HTA assessment outcome than those authorised for use from 2020 onwards.

Although there are several variations in the trends over time between the three jurisdictions, these results are relatively aligned with those of the average time to HTA outcome depicted in Table 2, particularly for medicines/indications authorised for use from 2020 onwards.

The shortest time to HTA outcome from marketing authorisation for this sample (n=47) was **13 days (NICE**). The longest time to HTA outcome from marketing authorisation was **1917 days (NICE)**. It should be noted that although NICE holds the longest time to HTA outcome for this sample, this medicine/indication had a similar time to HTA outcome for SMC (1873 days) and NCPE (1882). This timeline could be down to a particularly complex assessment or related to delays at the pharmaceutical company rather than the processes of HTA assessment in NICE.

05. Conclusions and Recommendations

Overall, there are several differences between the HTA assessment processes of NCPE, NICE and SMC, which could affect variation in the time to HTA outcomes between the agencies.

For medicines/indications with a HTA assessment across all three jurisdictions between 2022 and 2024, the average time to outcome from regulatory approval was **547.68 days (1.50 years).**

The average time to HTA outcome for NCPE assessments was significantly higher than that of NICE and SMC **(2.11 years** versus **1.20 years** and **1.19 years**).

Furthermore, when the proportion of assessments for each agency that fall below the overall average are considered, the trends are similar, as the proportion of NCPE assessments falling below the average **(19.15%)** is significantly less than that of NICE **(76.60%)** and SMC **(80.85%).**

As expected, a downward trend can be seen overtime in the number of days it takes for a medicine/indication to reach HTA outcome from regulatory approval, over time. Further analysis should include increasing the sample size.

It is important to reduce the variation in time to HTA outcomes between the agencies across UK and Ireland, and subsequently the average time to reimbursement, to ensure patients across these countries have equal access to treatment in a timely manner. The current variation between NCPE and NICE and SMC could be due to variation on local country HTA processes. It is also linked to pharmaceutical companies' decisions on when to make the submissions to each jurisdiction. It should be noted that the NCPE assessments not requiring a full HTA are excluded from this analysis.

Overall, across the three agencies, there are several processes that may be viewed as positive when considering overall time to reimbursement/decision making, including the NCPE RR, the ability to commence the HTA process ahead of MA in NICE, and the confirmation of submission date at SMC.

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