Crystallise Insights

Out of order!
Does the geographical sequence of HTA submissions affect acceptance rates?

"Cost-effectiveness analyses for a new technology will always vary by location. But the sheer scale of disagreements between HTA bodies show that factors other than comparative efficacy and safety influence approval rates."
Alison Martin, Director and Head of Reviews

HTAngel tracks HTA decisions globally over time

Since May 2023, Crystallise has been producing a monthly summary of decisions made by 32 Health Technology Assessment (HTA) bodies around the world. In this *Crystallise Insights* issue, we look back over the past year to see if the order in which HTA bodies evaluate submissions for a technology affects the acceptance rate.

"Of the 124 technologies that were assessed for the same indication by 2 or more HTA bodies between May 2023 and May 2024, 59% were approved by some and not approved by others."

Does geography matter?

HTA bodies evaluate the evidence for a new technology to determine whether it is cost-effective or should be reimbursed within the relevant country. Submissions are tailored to the specific country, which vary according to the threshold for determining whether a new technology is cost-effective and the type of economic analysis required for that assessment. However, the underlying evidence supporting a new technology for a specific indication is usually the same.

Between May 2023 and May 2024, 124 pharmacological technologies had assessments published by two to six HTA bodies for the same indication. Across all these assessments, 52% of the decisions were to approve the use or reimbursement of the technology. However, only 27% of technologies were approved by all the HTA bodies that assessed them, 14% were rejected by all, but the majority, 59%, were approved by some and rejected by others (Figure 1).

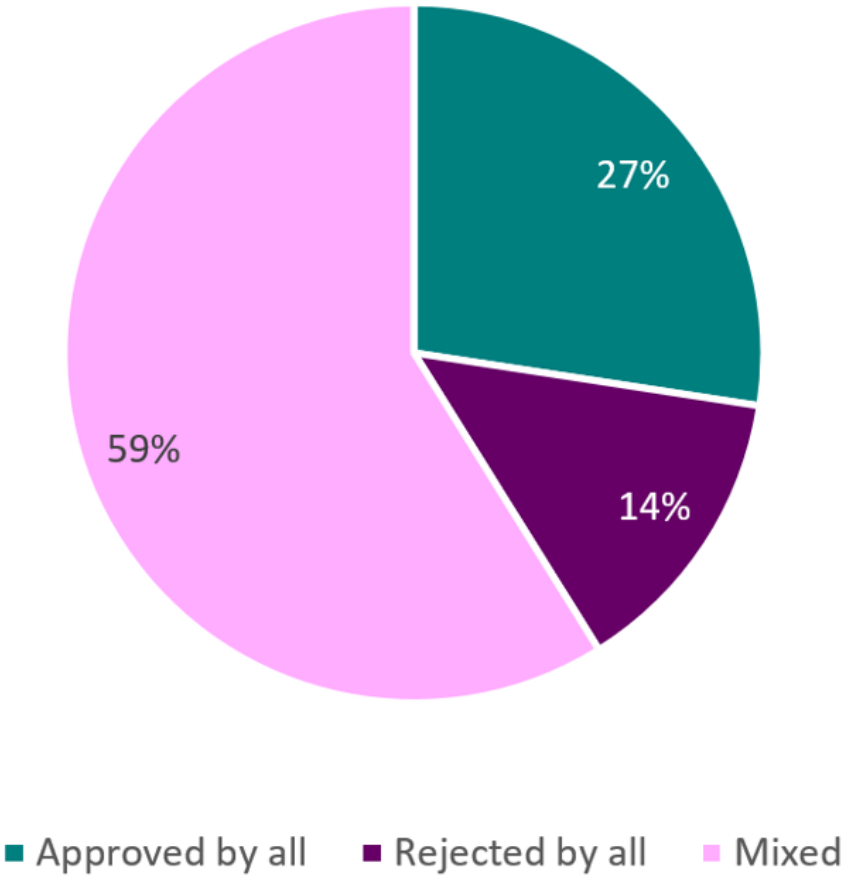

Figure 1 Agreements across HTA bodies for the same technology, May 2023 - May 2024

How do HTA bodies differ in their approval rates?

Of the 10 HTA bodies that made one or more assessments in this comparative analysis, those that conducted the most assessments tended to have the lower approval rates (shown in Table 1 and **Figure 2**). This is partly because the Australian Government Department of Health and Aged Care and the Austrian Institute for Health Technology Assessment seem only to publish approvals, and the All Wales Medicines Strategy Group generally defers to the National Institute for Health and Care Excellence (NICE) in England for its decisions. Where an HTA body made an initial decision not to approve the technology followed by a later review that may or may not have changed that decision, the latest decision has been taken to be their final outcome.

Table 1 Approval rate for HTA organisations in this analysis

Country	Number of decisions published May 2023-May 2024	Approval rate
TGA - Australian Government Department of Health and Aged Care	**16**	**100%**
AIHTA - Austrian Institute for Health Technology Assessment	**8**	**100%**
CONITEC - National Commission for the Incorporation of Technologies in the Unified Health System (Brazil)	**26**	**35%**
NICE - National Institute for Health and Care Excellence (England)	**48**	**63%**
FinCCHTA - Finnish Coordinating Center for Health Technology Assessment, Kansallinen HTA koordinaatioyksikkö	**6**	**83%**
HAS – Haute Autorité de Santé (France)	**63**	**70%**
IQWiG - Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Germany)	**108**	**32%**
Zorginstituut Nederland	**1**	**100%**
SMC - Scottish Medicines consortium	**59**	**69%**
AWMSG - All Wales Medicines Strategy Group	**26**	**0%**

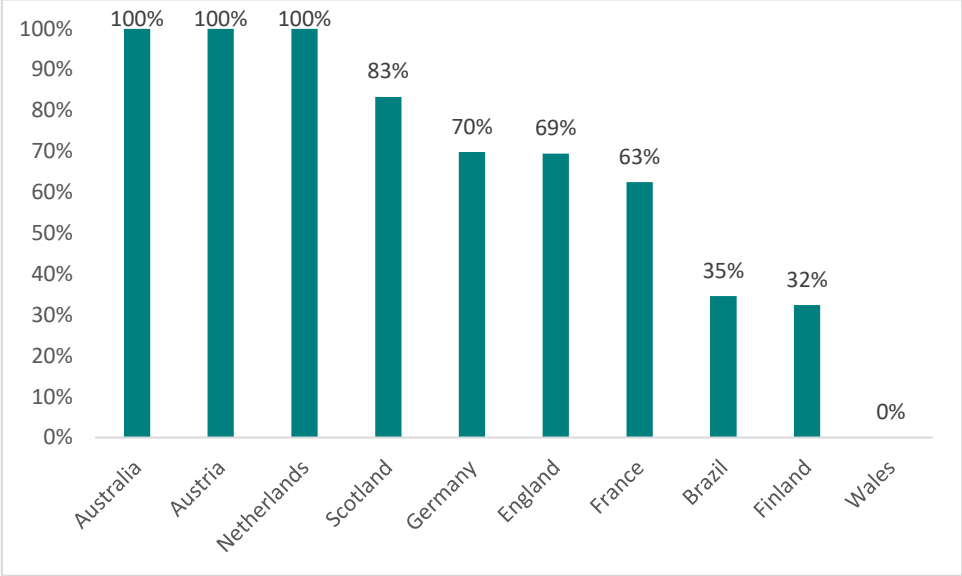

Figure 2 Approval rates for HTA decisions in this analysis

How often do specific HTA bodies agree with each other?

"HAS in France, IQWiG in Germany and NICE in England disagree with each other's decisions around half the time."

We took the decisions published between May 2023 and May 2024 for the same technology and indication from the four HTA bodies that produced the most decisions in that time: Haute Autorité de Santé (HAS) in France, Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG) in Germany, NICE in England and Scottish Medicines Consortium (SMC) in Scotland.

During the period of our analysis, 30 technologies had assessments published for the same indication by both HAS and IQWiG. Both bodies came to the same decision 53% of the time, but disagreed with each other's decision for 47% of submissions.

HAS and NICE both assessed 13 technologies, with a 46% agreement, while NICE and IQWiG both assessed 15 technologies, agreeing on only 40% of decisions. In contrast, both NICE in England and SMC in Scotland published assessments on the same 16 technologies. They came to the same decision in 81% of assessments.

So, does the order in which HTA bodies make their decisions affect the approval rate?

"In general, IQWiG, HAS and SMC are more likely to approve a technology that had already been assessed by another HTA body than if they are making the first decision. NICE is a bit less predictable."

Comparing decisions published by HAS, IQWiG, NICE and SMC between May 2023 and May 2024, we determined which one published its decision first, and what the decisions were.

Although numbers were small and we did not calculate statistical significance, there is a suggestion that IQWiG and HAS are all more likely to approve a technology if they reach their decisions after the other HTA body or NICE had published their decisions. The SMC was more likely to approve a technology if it reported after NICE published its decision. However, NICE was less predictable, being more likely to approve a technology if it had previously been assessed by IQWiG, but less likely to approve technologies that had already been assessed by HAS or SMC.

Germany vs France

	% approved by IQWiG	% approved by HAS
IQWiG reported first	45% (5/11)	64% (7/11)
HAS reported first	63% (12/19)	53% (10/19)

Germany vs England

	% approved by IQWiG	% approved by NICE
IQWiG reported first	38% (3/8)	63% (5/8)
NICE reported first	43% (3/7)	57% (4/7)

France vs England

	% approved by NICE	% approved by HAS
NICE reported first	50% (3/6)	100% (6/6)
HAS reported first	43% (3/7)	43% (3/7)

England vs Scotland

	% approved by NICE	% approved by SMC
NICE reported first	64% (7/11)	64% (7/11)
SMC reported first	60% (3/5)	40% (2/5)

What does this mean for planning your HTA submission timetable?

The overall success rate is around 50%, and the randomness of the results must seem at times as though they were based on the toss of a coin. And, although approval rates vary somewhat depending on the order in which the different HTA bodies reach their judgements, the differences were not large for each HTA body, making it difficult to predict what the decision is likely to be based on the results from previous assessments.

There were almost twice as many occasions when a technology was initially rejected by the first HTA body in our analysis and then approved by a different HTA body (28% of technologies) than the number that were approved by the first HTA body and then not approved by the second body (16% of technologies). This suggests that the situation is less like the Eurovision song contest, where certain countries will always vote against the decision of a rival, and more like the football Euros, where a team regroups after a stressful first half and (maybe) comes back with a more refined strategy for the following session. It seems likely that the manufacturer, at least in some cases, is able to adapt an unsuccessful submission to position their technology more favourably for the next HTA body, regardless of which body did the first and then the second assessment.

It is difficult to draw too many conclusions from this analysis – it's a snapshot of the past 13 months, so doesn't account for decisions made before May 2023; the number of decisions analysed is small and the difference between approval rates may not be statistically significant. But it does suggest that, unless you are very confident of initial success, it might be worth testing the waters in a less important market, then adapting later submissions based on that initial response.

Crystallise's insights & expertise

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