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HTA League Of Nations – Which Bodies Were Most Likely To Approve Submissions And For What Disease Areas?

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Introduction

Obtaining approval by Health Technology Assessment (HTA) bodies is crucial for market access for a new product, but approval rates vary by location.

Objective

We aimed to compare approval rates internationally for each major disease area, to guide manufacturers in their decisions about where to seek approval.

Method

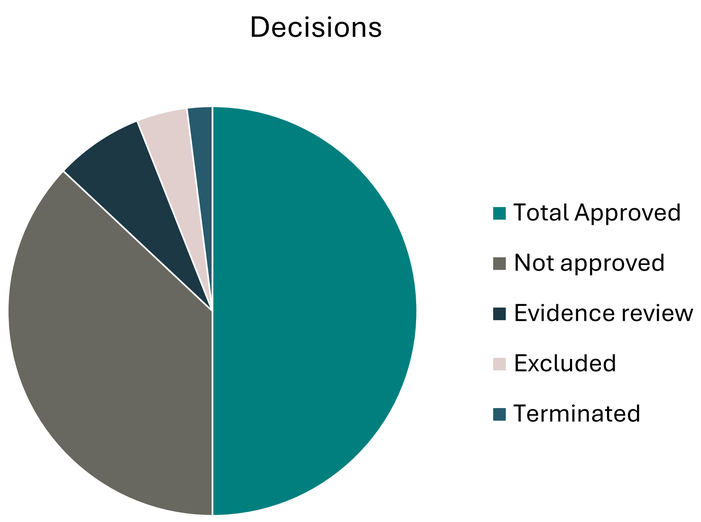
We assessed all decisions published by 24 HTA bodies internationally from May 2023 to April 2025 using data from the HTAngel newsletter (https://www.crystallise.com/htangel/). Details of the HTA body and country, technology assessed, and disease were evaluated.

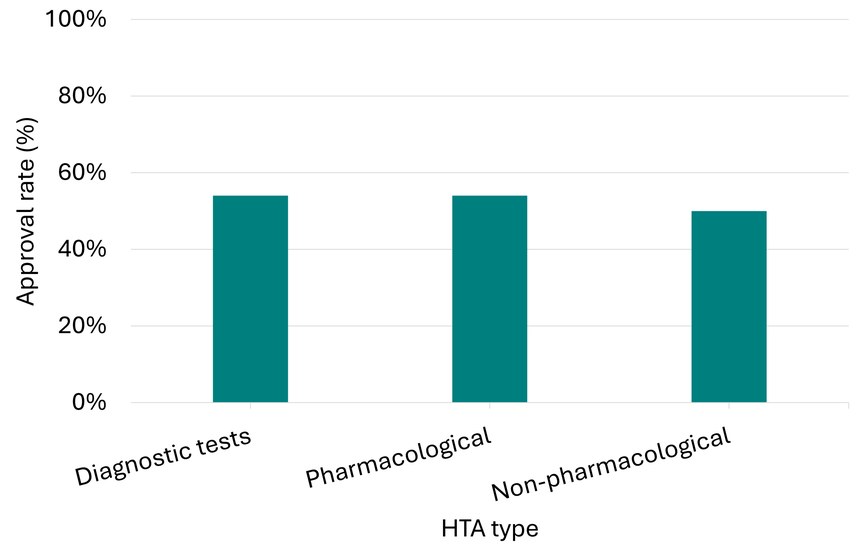
Results

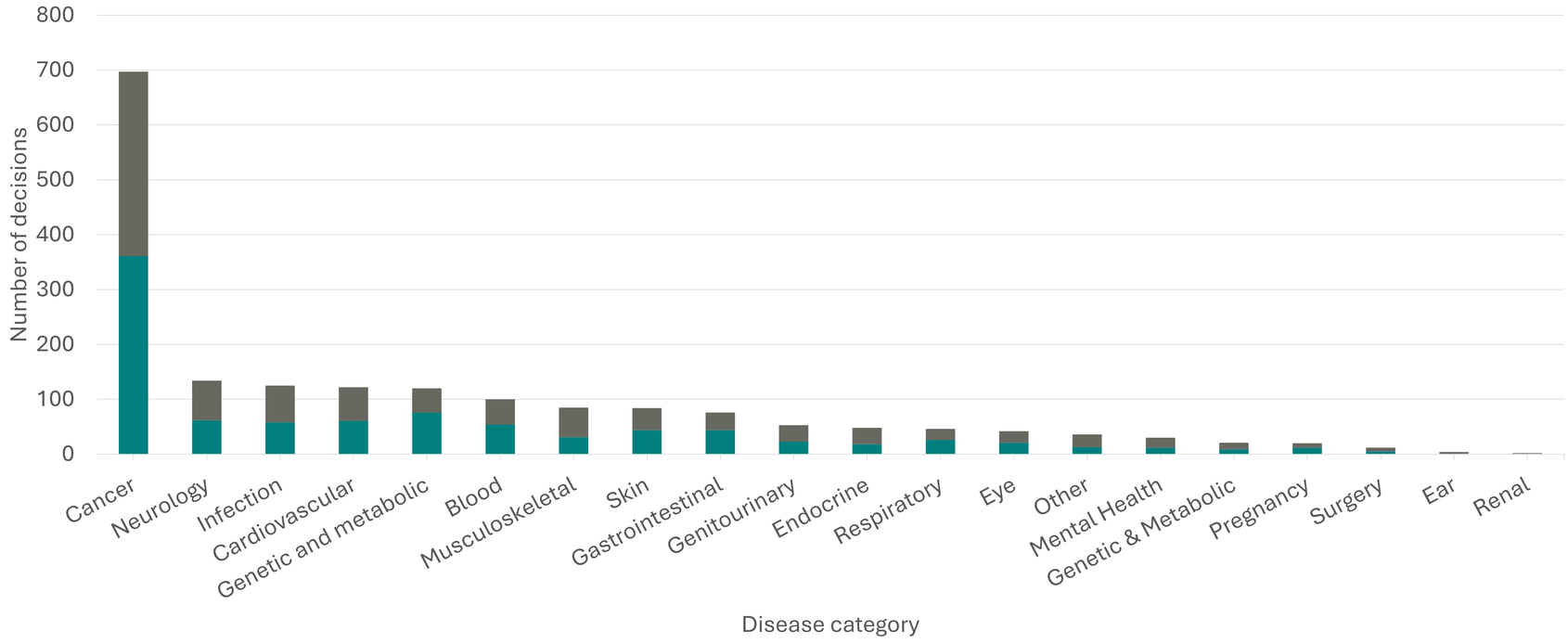
Of the total of 1,838 decisions, 50% were approvals, 37% not approved, 4% excluded and 2% terminated, with 7% of publications being general evidence reviews. Approval rates were slightly higher for diagnostic technologies (54% of 116 decisions) and pharmacological interventions (54% of 1,398 decisions) than non-pharmacological technologies (50% of 202 decisions).

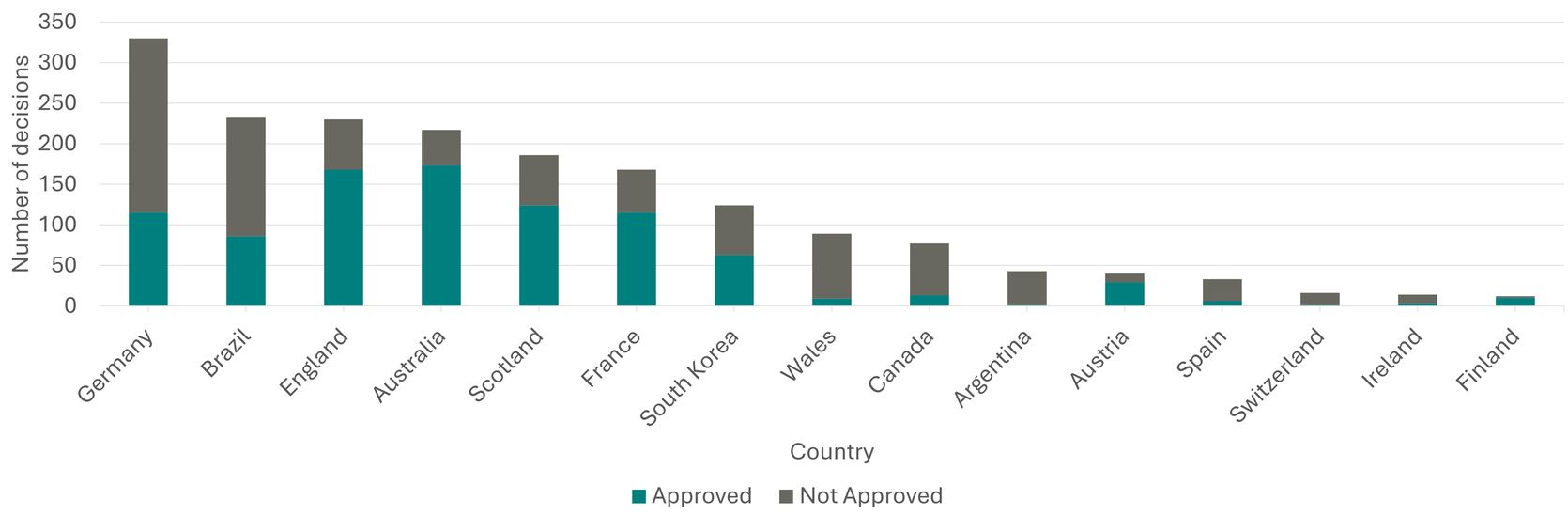
Submissions were most likely to be for cancer (38% of all decisions), followed by genetic/ metabolic disorders (8%), neurology, cardiovascular and infection (7% each). Approval rates were highest for genetic and metabolic disorders (63% approved), pregnancy (60%), gastrointestinal (58%), respiratory (57%), blood (54%), skin and cancer (52% each), and lowest for technologies for musculoskeletal and neurological (34% each) and ear disorders (25%).

Of countries publishing ≥10 decisions over the 2 years, the highest acceptance rates were in Finland (FINCCHTA, 83% of 12 decisions), Australia (PBAC/TGA, 80% of 217 decisions), England (NICE, 73% of 230 decisions), Austria (AIHTA, 73% of 40 decisions), France (HAS, 69% of 168 decisions), Scotland (SMC, 67% of 186 decisions) and South Korea (NECA, 51% of 124 decisions).









Conclusion

No clear association was seen between number of decisions and approval rate by country or disease area. Unlike some other HTA bodies, IQWiG in Germany publishes initial rejections and subsequent approvals separately, accounting for its low 35% approval rate across 330 decisions.

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