One size fit all? The impact of EUnetHTA joint clinical assessments on national reimbursement

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Background

- Starting January 2025, all advanced therapy medicinal products (ATMPs) and oncology drugs will be mandated to undergo a joint clinical assessment (JCA) at European level
- JCAs have been previously trialed by EUnetHTA, most recently in Joint Action 3 (JA3)
- This research explores the impact of historic European co-operation, assessing whether drugs evaluated under EUnetHTA JA3 have received faster/divergent outcomes by participating national European health technology assessment (HTA) bodies

Methods

- JA3 JCAs (2016-2021) were identified and the outcome of the associated HTA appraisals from NICE, HAS, SMC, TLV, NCPE, AIFA, ZIN, Medicinradet and AOTM was assessed
- The time period from European Medicines Agency (EMA) market authorization (MA) to the national HTA reimbursement date was calculated, and a two-tailed t-test assessed significance
- JCAs with an overall positive clinical interpretation were selected, and the associated decisions at a national HTA level were compared

Results

- There were 20 EUnetHTA pharmaceutical JCAs in JA3, of which 16 achieved MA
- Overall, of the 16 JCAs with MA, 62 HTA appraisals were identified, 45 (72.6%) of which were positive (including positive with restrictions) and 17 (27.4%) were negative (Figure 1)
- There was no difference in the time to reimbursement if the national HTA agency was involved in the development of the JCA vs. not involved (302.7 vs. 285.9 days, respectively; p=0.749; Figure 2)
- Seven of the 16 JCAs were positive in their interpretation of clinical data. For the seven positive JCAs, 17 associated national HTA appraisals were identified; a positive JCA interpretation generally translated to a positive national reimbursement decision (14/17 were positive) (Figure 3)

Figure 1: National HTA reimbursement decision of the 62 HTA appraisals associated with the 16 JCAs achieving MA

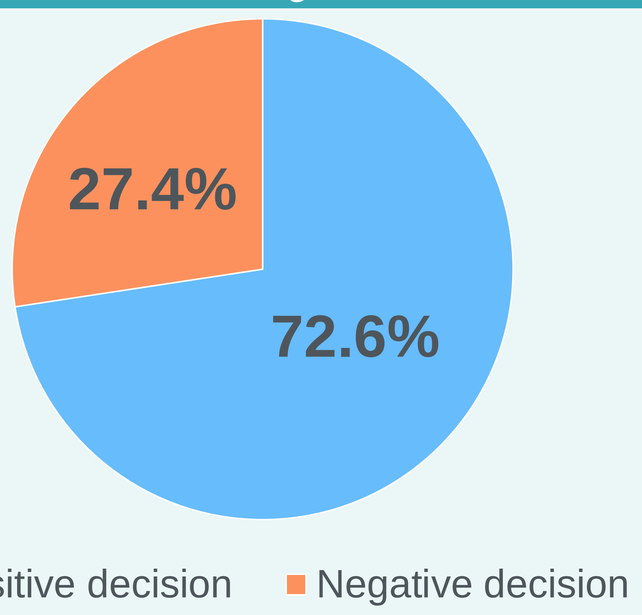
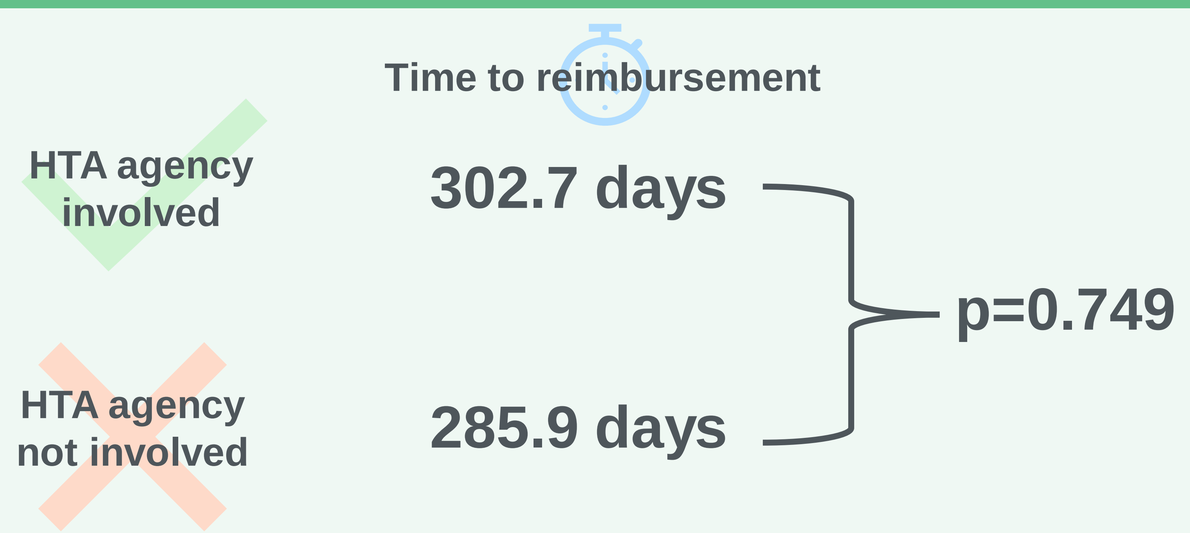


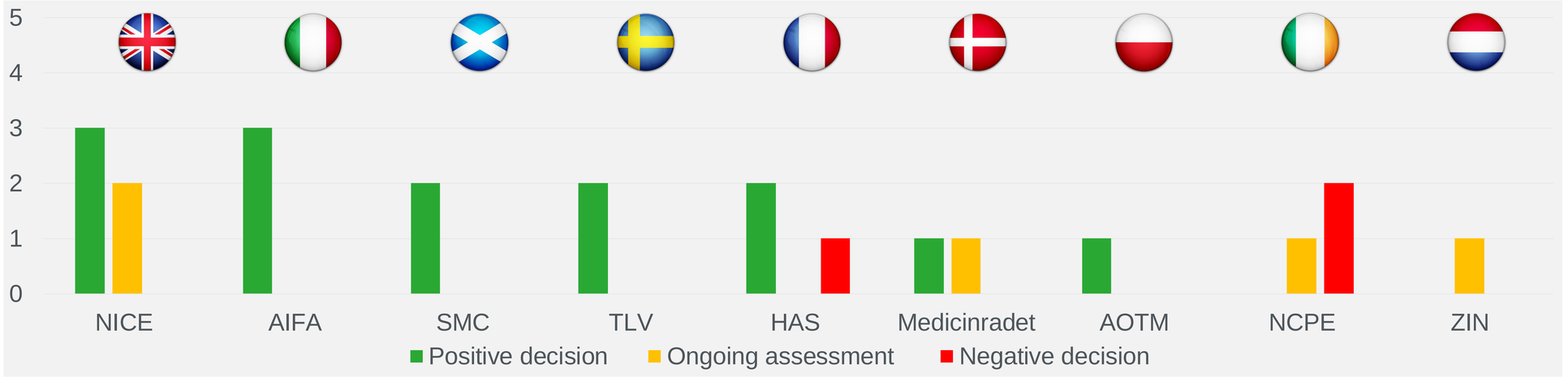
Figure 2: Impact of HTA agency involvement in JCA development on the time to reimbursement



There was **no difference in the time to reimbursement** if the national HTA agency was **involved in the development of the JCA vs. not involved**

7/16 JCAs were positive in their interpretation of clinical data

Figure 3: HTA reimbursement decision at national level of drugs where the EUnetHTA JA3 interpretation of clinical data was positive



Conclusions

- **This research highlights that positive JCAs do not always translate to positive reimbursement decisions at the national level, where reimbursement is dependent on the country-level HTA framework, budget impact and/or cost-effectiveness**
- **It also provides promising results that under the new HTA Regulation, involvement in a JCA may not impact national reimbursement timelines**
- **A limitation of this research is that some HTA agencies have not assessed all drugs with a positive JCA**

Abbreviations

AIFA: Agenzia Italiana del Farmaco; AOTM: Agencja Oceny Technologii Medycznych; ATMP: Advanced therapy medicinal products; DMC: Medicinraadet; EMA: European Medicines Agency; EUnetHTA: European Network for Health Technology Assessment; HAS: Haute Autorité de Santé; HTA: Health Technology Assessment; JA3: Joint action 3; JCA: Joint clinical assessment; MA: Market authorization; NCPE: National Centre for Pharmacoeconomics; NICE: National Institute for Health and Care Excellence; SMC: Scottish Medicine Consortium; TLV: Tandvårds-Läkemedelförmånsverket; ZIN: Zorginstituut Nederlands