# Patient Access Delays for Subsequent Indications of Multi-indication Treatments: An Assessment of Health Technology Assessment Decision Making

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## Conclusion

- **This analysis revealed delays in reimbursement decisions for subsequent new indications when compared with first indication across various HTA bodies.**
- **HAS and IQWiG/G-BA recognised the value of subsequent indications, granting favourable ratings within their benefit assessment framework.**
- **Appraisals did not account for the multi-indication status of medicines.**
- **These findings underscore the unmet need for a revised HTA evaluation framework—one that fully captures the value of multi-indication medicines and ensures timely patient access.**

## Objective

**Quantify the time from marketing authorisation to reimbursement decision for subsequent indications of multi-indication treatments, focusing on assessment duration.**

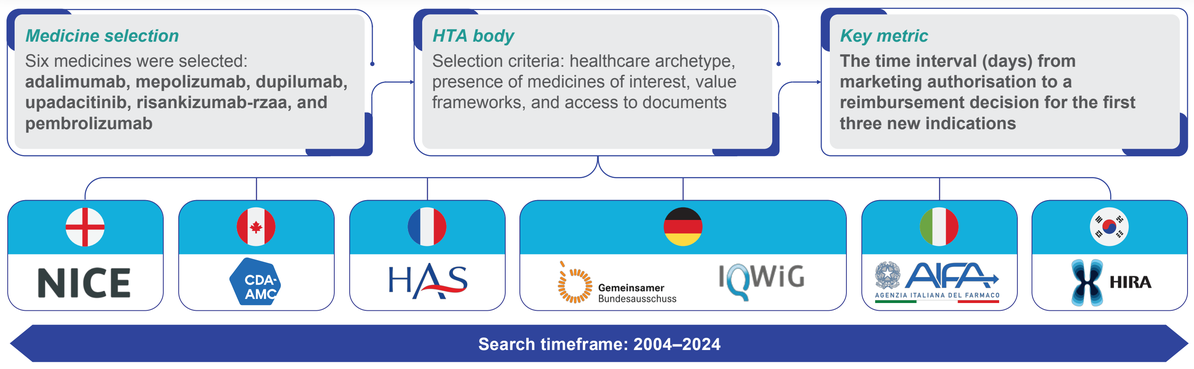
## Background

- In the past 15 years, multiple treatments have received approval for subsequent indications following their initial launch.
- Between 2011 and 2020, the United States Food and Drug Administration approved 124 agents for first indications and 335 supplemental indications, whereas the European Medicines Agency approved 88 and 215, respectively.[1]
- Multi-indication (MI) medicines having subsequent indications offer unique advantages to patients. However, due to complex reimbursement processes involving health technology assessment (HTA) body and/or payers, these treatments may suffer delays in reimbursement approvals for subsequent indications.

## Methods

- A detailed study framework is presented in **Figure 1**.

**Figure 1 . Study framework***




*Data were gathered from above listed HTA body websites,[2-8] and supplemented with additional search when required.[9-11]

AIFA, Agenzia Italiana del Farmaco; CDA, Canada's Drug Agency; G-BA, Gemeinsamen Bundesausschuss; HAS, Haute Autorité de Santé; HIRA, Health Insurance Review and Assessment Service; HTA, health technology assessment; IQWiG, Institute for Quality and Efficiency in Health Care; NICE, National Institute for Health and Care Excellence.

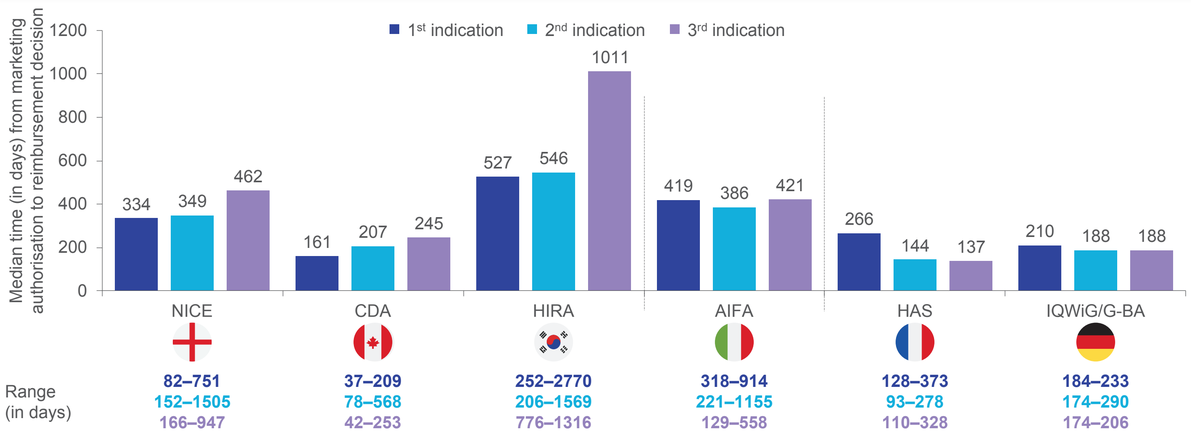
- HTA body websites were searched to gather data for each medicine (as available) including reimbursed indication, dates for submission and decision, reimbursement decision, and evidence submitted for HTA appraisal.

## Results: First three new indications

### Time delays, by HTA body

- In total, 503 assessments (AIFA: 126, HAS: 123, NICE: 75, HIRA: 69, IQWiG/G-BA: 59, and CDA: 51) were analysed.
- Delays in subsequent reimbursement decisions were noted, with NICE, CDA, HIRA, and AIFA requiring longer evaluation periods for the 3rd indication than the 1st indication (**Figure 2**).

**Figure 2. Median time (in days) from marketing authorisation to reimbursement decision, by HTA body and indication**

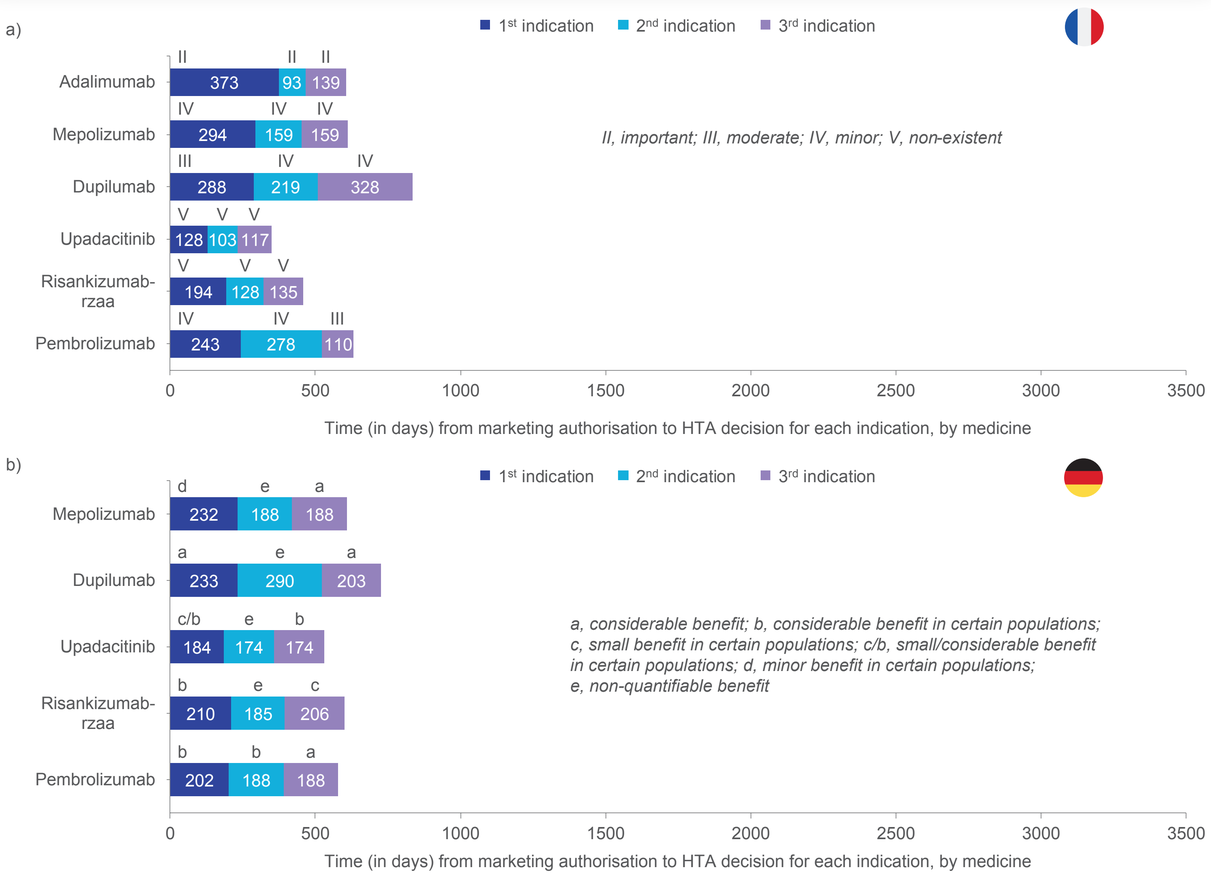



AIFA, Agenzia Italiana del Farmaco; CDA, Canada's Drug Agency; HAS, Haute Autorité de Santé; G-BA, Gemeinsamen Bundesausschuss; HIRA, Health Insurance Review and Assessment Service; HTA, health technology assessment; IQWiG, Institute for Quality and Efficiency in Health Care; NICE, National Institute for Health and Care Excellence.

### Time delays and reimbursement decision, by medicine, indication, and HTA body

- Subsequent indications of 4 of 6 medicines obtained favourable benefit ratings by HAS. Similar results were noted for 4 of 5 medicines assessed by IQWiG/G-BA (**Figure 3**).

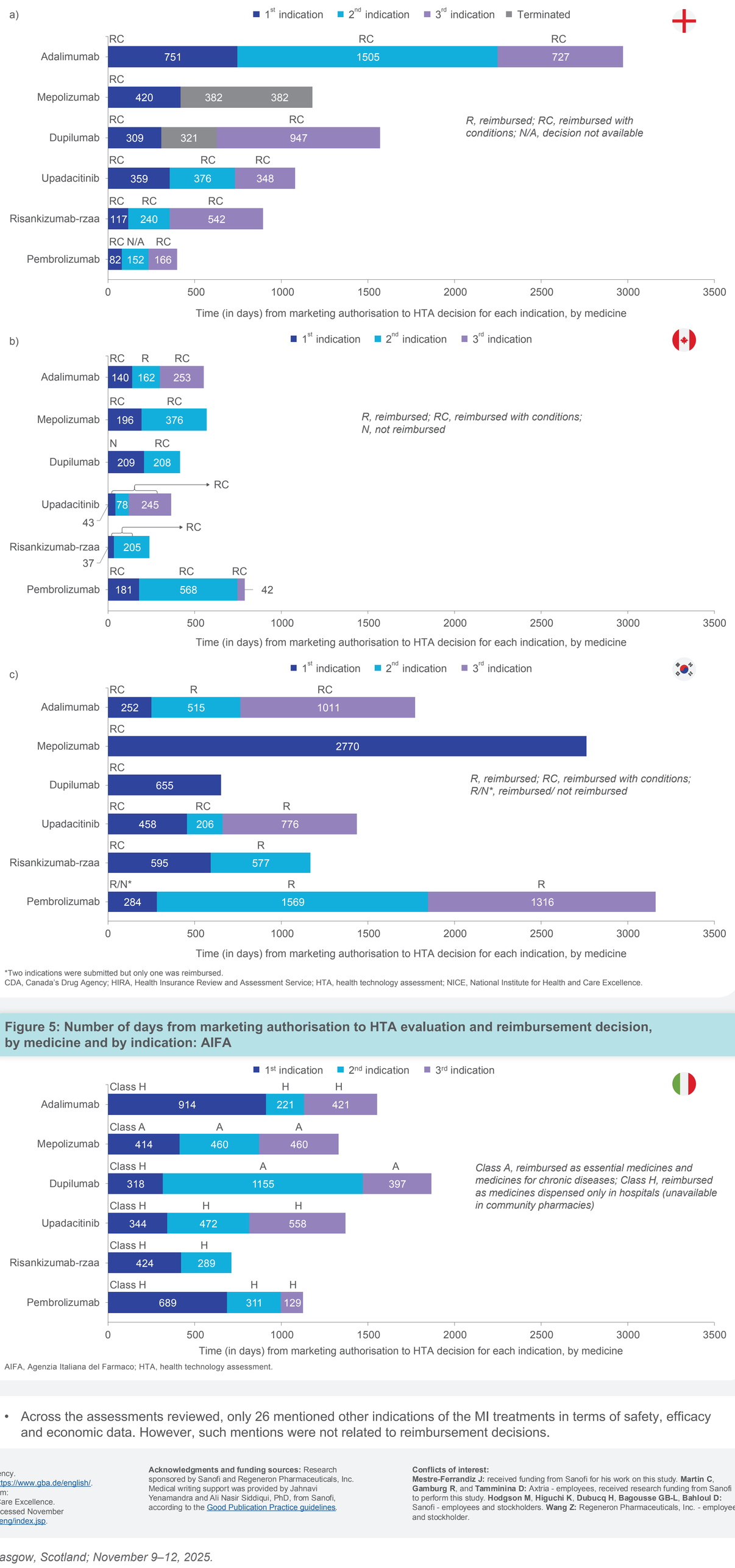
**Figure 3. Number of days from marketing authorisation to HTA evaluation, and rating, by medicine and by indication: a) HAS* and b) IQWiG/G-BA¶**




*HAS provides ASMR ratings on a scale of I-V. ¶Adalimumab assessment was not publicly available with IQWiG/G-BA.
ASMR, improvement in actual benefit; G-BA, Gemeinsamen Bundesausschuss; HAS, Haute Autorité de Santé; HTA, health technology assessment; IQWiG, Institute for Quality and Efficiency in Health Care.

- Most subsequent indications reviewed by NICE (8 of 12), CDA (8 of 9), and HIRA (2 of 7) obtained restricted reimbursement (**Figure 4**).
- The appraisal was terminated for 3 of 12 subsequent indications (across medicines) submitted to NICE (**Figure 4**).
- Subsequent indications of only 2 of 6 medicines (mepolizumab and dupilumab) achieved a Class A reimbursement by AIFA (**Figure 5**).

**Figure 4: Number of days from marketing authorisation to HTA evaluation and reimbursement decision, by medicine and by indication: a) NICE, b) CDA, and c) HIRA**




*Two indications were submitted but only one was reimbursed.
CDA, Canada's Drug Agency; HIRA, Health Insurance Review and Assessment Service; HTA, health technology assessment; NICE, National Institute for Health and Care Excellence.

**Figure 5: Number of days from marketing authorisation to HTA evaluation and reimbursement decision, by medicine and by indication: AIFA**




AIFA, Agenzia Italiana del Farmaco; HTA, health technology assessment.

- Across the assessments reviewed, only 26 mentioned other indications of the MI treatments in terms of safety, efficacy and economic data. However, such mentions were not related to reimbursement decisions.

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