

Comparative Analysis of Reimbursement Decisions for Advanced Oncology Combination Therapies in Japan and England

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Introduction

- **Combination therapies (CTs)** are increasingly used in oncology with proven clinical efficacy.
 - However, their high costs place financial pressure on health systems and pose **challenges for health technology assessment (HTA)**, including cost-effectiveness and ownership issues.^{1,2}
 - **England** has introduced reforms to address these CT-related challenges.
 - **Japan and England differ in their reimbursement and HTA frameworks**, leading to variation in access to cancer medicines.^{3,4}
- These access differences may be particularly pronounced for CTs.

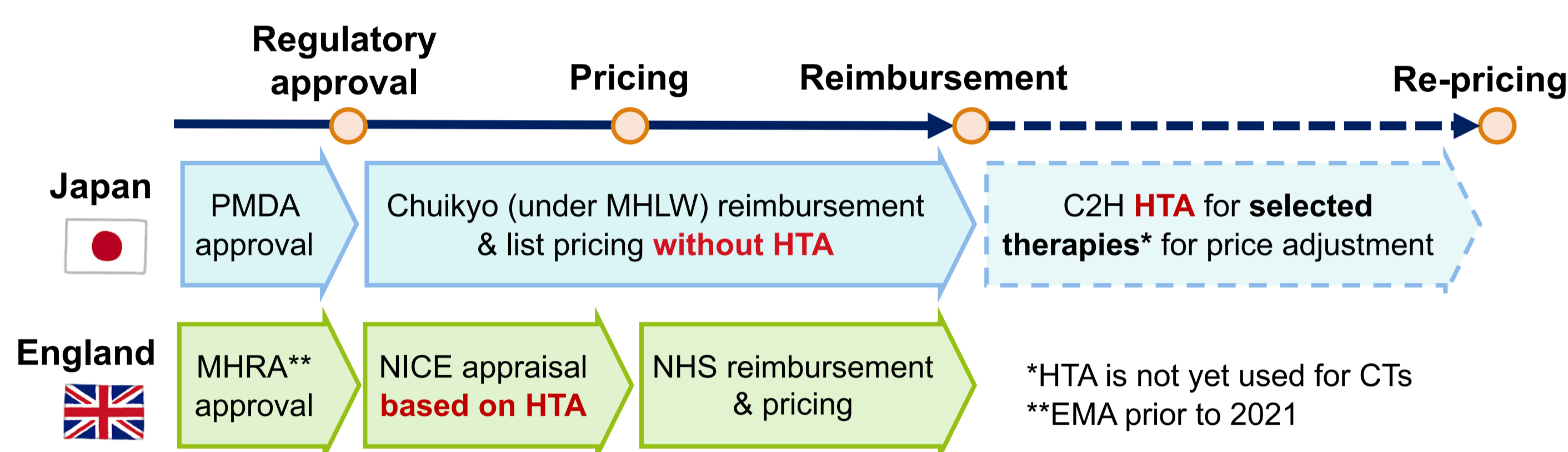


Figure 1. Comparison of reimbursement and HTA processes in Japan and England

Japan: Reimbursement directly follows marketing authorisation.

England: HTA by the National Institute for Health and Care Excellence (NICE) informs reimbursement and pricing.

Objective

To examine how system-level differences in reimbursement and HTA between Japan and England influence access to CTs, and to explore policy implications for Japan's evolving HTA system informed by England's experience.

Method

Descriptive two-part analysis

Data sources: Regulatory and HTA reports (2015–2024)

– Japan: PMDA

– England: MHRA, EMA, NICE

CT definition: Combination of ≥ 2 molecular targeted agents and/or immune checkpoint inhibitors for solid tumours

Part 1: Cross-Country comparison of reimbursement (Japan vs. England)

- Availability (reimbursement status)
- Timelines (approval – reimbursement)
- Affordability (list prices)

Part 2: NICE HTA appraisal analysis (England only)

- Recommendation outcomes
- Appraisal timelines
- Manufacturer structure (Single vs. multi-company products)

Results

Part 1: Cross-Country comparison of reimbursement

- **37 CTs** were identified (PMDA approved or NICE appraised).
- **Japan reimbursed 32 (86%) vs. 23 (62%) in England** ($p = 0.018$).
- Among 20 CTs reimbursed in both countries, reimbursement indications were narrower in England for **55% vs. 10%** in Japan.



Figure 2. Comparison of reimbursement status for CTs in Japan and England, 2015–2024

The Venn diagram illustrates the overlap of CTs approved by PMDA (Japan) and appraised by NICE (England); the inner circle indicates the subset of CTs recommended by NICE.

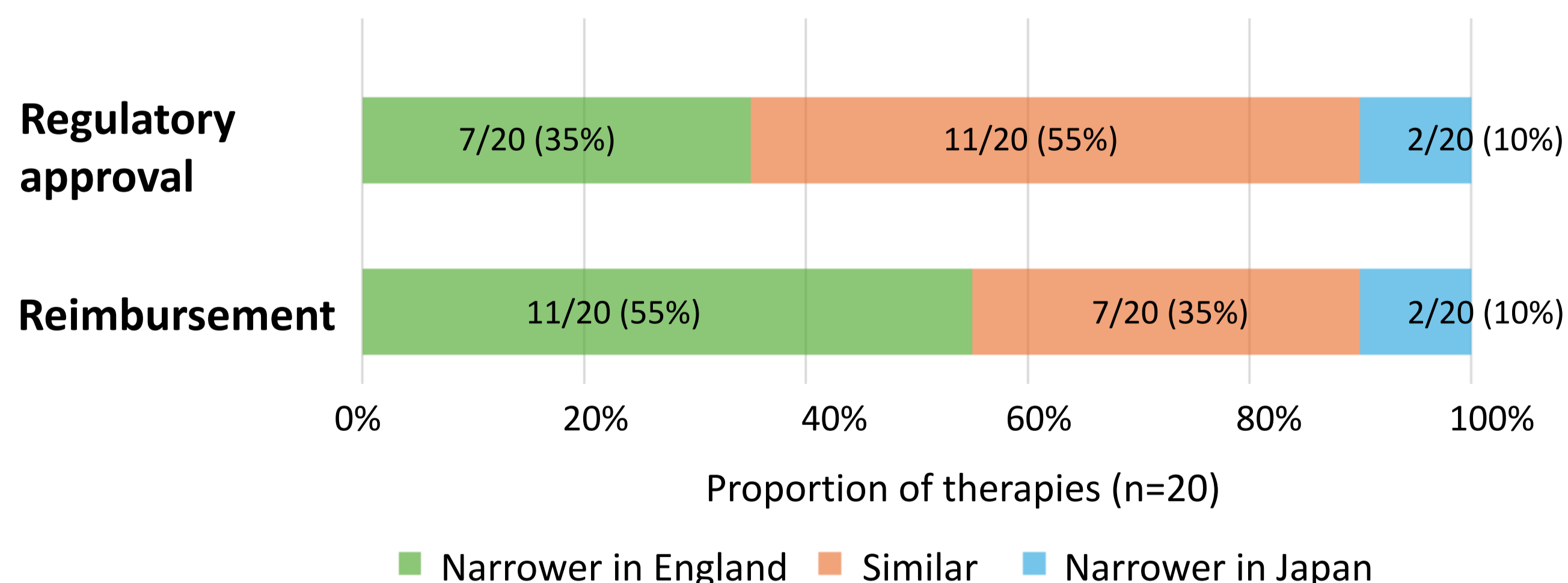


Figure 3. Comparison of indication scope for CTs reimbursed in Japan and England (n=20)

Stacked bar charts compare the indication scope of 20 CTs reimbursed in Japan and England at regulatory approval and reimbursement, showing the proportions with narrower indications in England, similar, or narrower in Japan.

Discussion & Conclusion

- Japan ensures broader and faster reimbursement for oncology CTs compared to England, reflecting its integrated approval–reimbursement system.
- The NICE experience illustrates that CTs are vulnerable to cost-effectiveness concerns and coordination delays between manufacturers. Recent reforms in England, such as indication-specific pricing and cross-company negotiations, are expected to mitigate these CT-related challenges.
- For Japan, it is crucial to maintain rapid access through post-reimbursement HTA while gradually expanding its scope, strengthening pricing adjustments, and developing HTA capacity. Learning from England's indication-specific pricing and cross-company negotiations may help address future HTA challenges for CTs.

References

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- **Regulatory approvals** were faster in **England** (median 80 days), whereas **reimbursement** occurred faster in **Japan** (median 194 days). **NICE HTA assessments** required a median of **314 days**.
- Japan's list prices were lower (median **61%** of England's; IQR 57–88%).

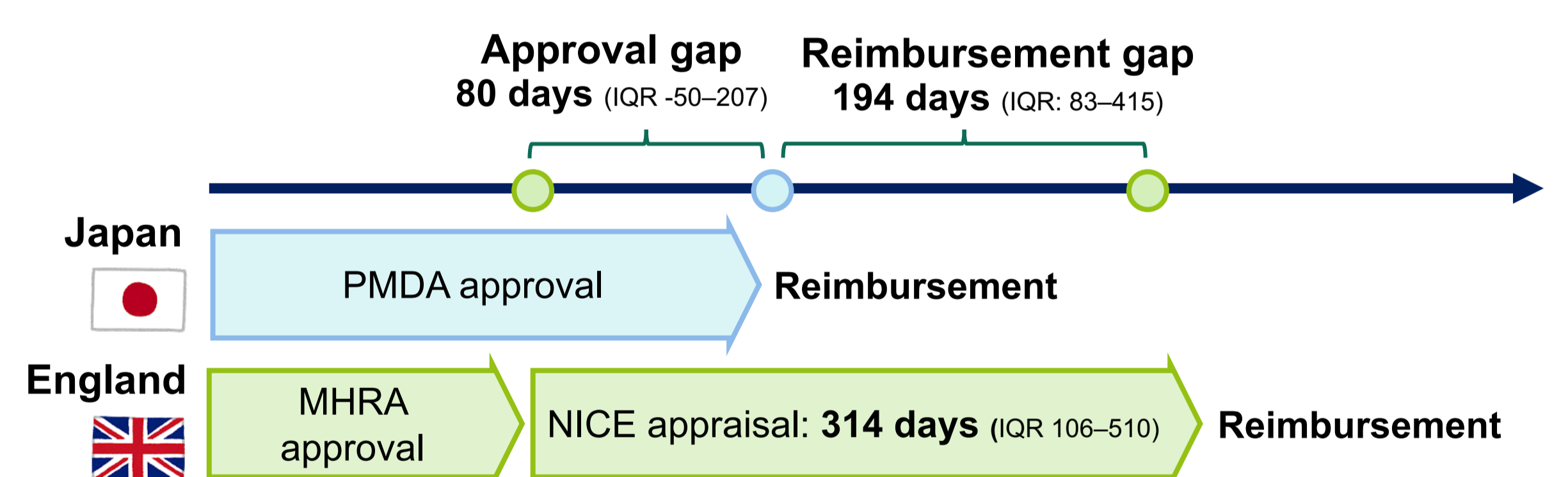


Figure 4. Comparison of approval and reimbursement timelines in Japan and England

This timeline compares the median time required for regulatory approval and the subsequent reimbursement in Japan and England.

Part 2: NICE HTA appraisal analysis

- Among **27 CTs** appraised by NICE, **23 (85%)** received positive recommendations, all with **commercial arrangements**.
- Non-recommendations were primarily due to poor cost-effectiveness and uncertainty in the evidence.
- Appraisal for **multi-manufacturer products** took longer than for single-manufacturer products (median **420 vs. 124 days**, $p = 0.067$).

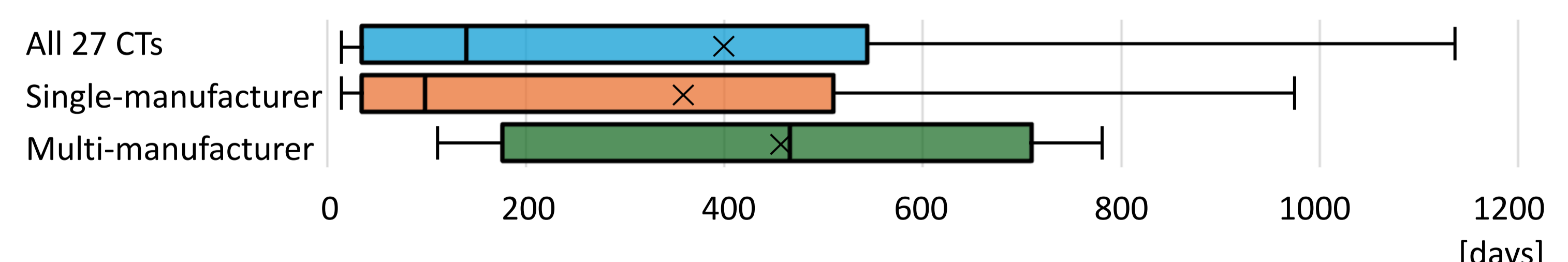


Figure 5. Duration from MHRA approval to NICE appraisals by manufacturer type

Box plots illustrate the distribution of time (in days) from regulatory approval to NICE recommendation for CTs, stratified by single-manufacturer and multi-manufacturer products.