HTA390

Conditional Marketing Authorization: *How do Outcomes in France, Germany, and England/Wales Compare?*

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INTRODUCTION

- The European Medicines Agency (EMA) and Medicines and Healthcare products Regulatory Agency (MHRA) can grant a Conditional Marketing Authorization (CMA) for medicines that treat severe diseases based on less comprehensive clinical data than usual, pending the collection of more comprehensive data post-authorization
- This research describes how the number of CMAs have evolved over time and evaluates their conversion to successful reimbursement

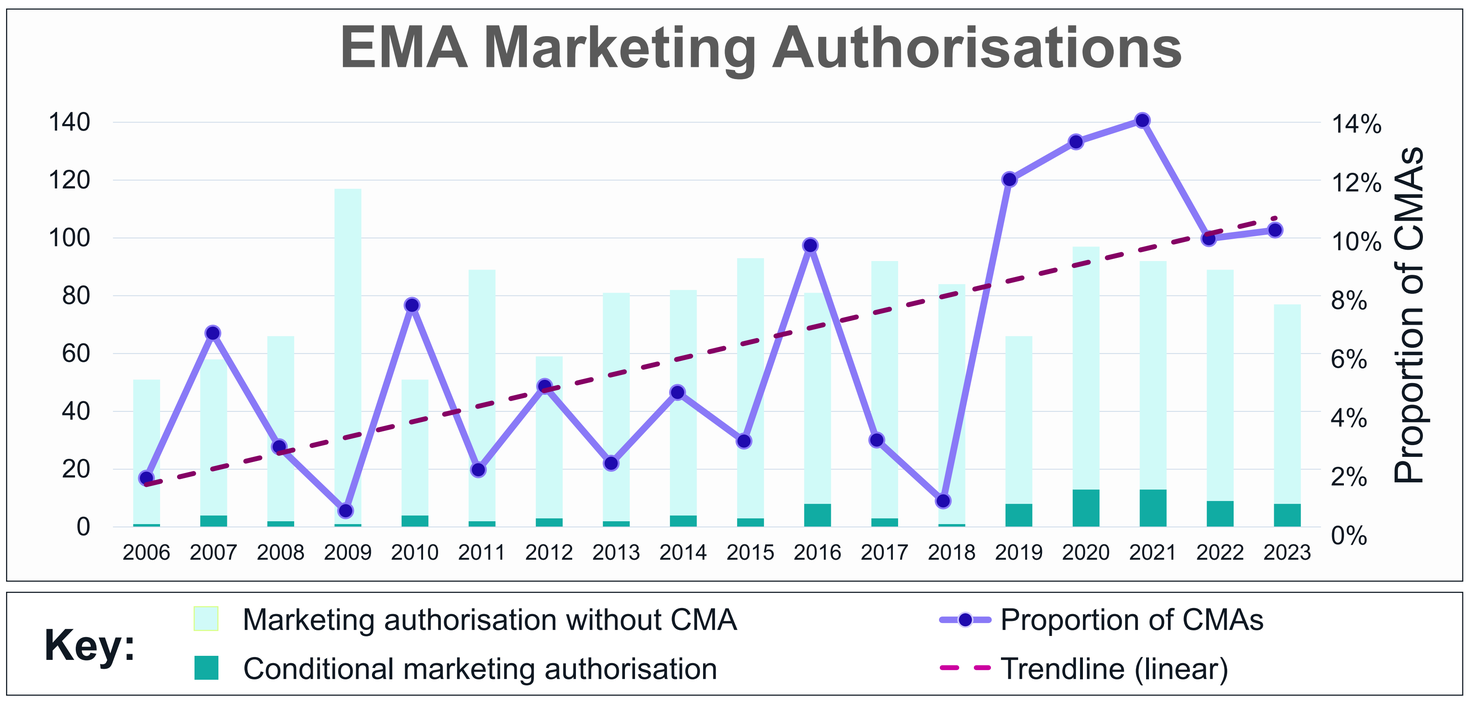
METHODS

- All publicly-available EMA CMAs were identified (01-Jan-2006 to 31-Dec-2023) and cross-checked with MHRA CMAs (01-Jan-2021 to 31-Dec-2023) to identify a list of all products with conditional marketing authorisation at launch; 2 products had received a CMA from the EMA but not the MHRA so were excluded from the England/Wales analysis
- Referencing products with marketing authorization after 2018, NICE, G-BA, and HAS evaluations from the past 6.5 years (01-Jan-2018 to 29-Jun-2024) were extracted

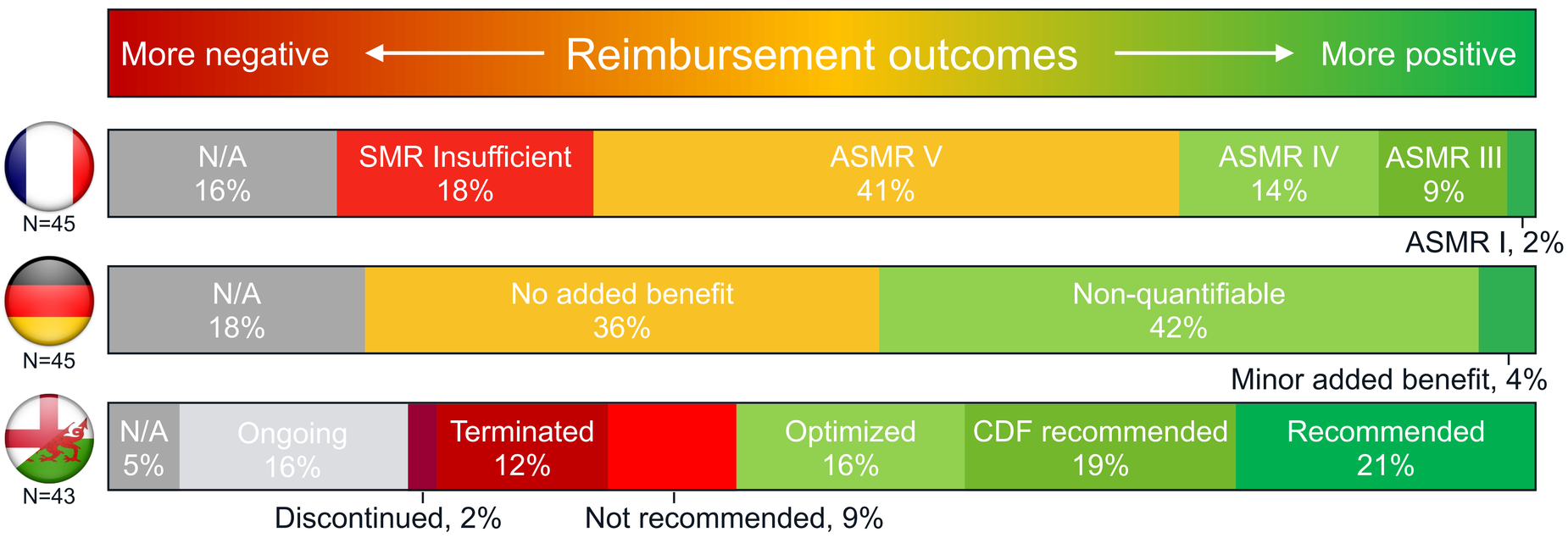
RESULTS

CMAs represent 6.2% of all EMA authorizations since 2006; however, there is a clear trend towards these becoming more common:

CMAs represented >10% of all EMA approvals every year since 2019, but <10% every year beforehand



HTA outcomes (at launch) of conditionally-approved products / indications



Common payer concerns

- × Trial design weaknesses, incl. absence of active comparison
- × Lack of patient-relevant outcomes
- × Immature or non-significant OS data (where applicable)
- × Uncertainties in long-term benefit
- × Significant safety concerns

CONCLUSIONS

- CMAs are becoming an increasingly common route to market for new medicines
- However, many therapies that received a CMA were either unable to achieve successful reimbursement, received conditional reimbursement (e.g., via the CDF in England/Wales), or faced reimbursement outcomes with price constraints (e.g., No added benefit in Germany or ASMR V in France)
- This emphasizes how manufacturers need to carefully assess the trade-offs and risks before leveraging expedited regulatory pathways, risking delaying access to patients

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