PRIME: Does accelerated marketing authorization translate into expedited reimbursement and patient access?

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Introduction

- The EMA Introduced PRIority Medicines (PRIME) to support the development of medicines that can potentially address unmet medical needs
- PRIME medicines may also be eligible for accelerated assessment
- This research examines medicines with PRIME designations that received marketing authorization (MA), and their corresponding reimbursement outcomes in France, Germany and England

Methods

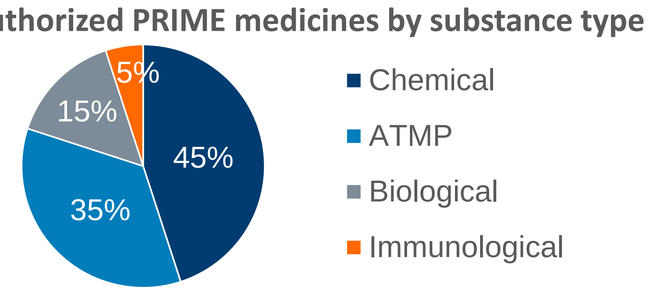
- Medicines previously granted PRIME designations which are now authorized for use in the EU identified from EMA's website, and key information of HAS, G-BA and NICE assessments extracted from their respective websites (as of 13-May-2022)

Results

Overview of PRIME medicines currently authorized for use in the EU

- 20 medicines that had PRIME support are currently authorized for use in the EU, 3 (15%) of which went through accelerated assessment:
  - 11 (55%) received full MA and 9 (45%) received CMA
  - 7 (35%) were ATMPs *(Fig.1)*
  - Mean delay from MA to HTA was 7.4 months (range: 0.4–20.8 months)

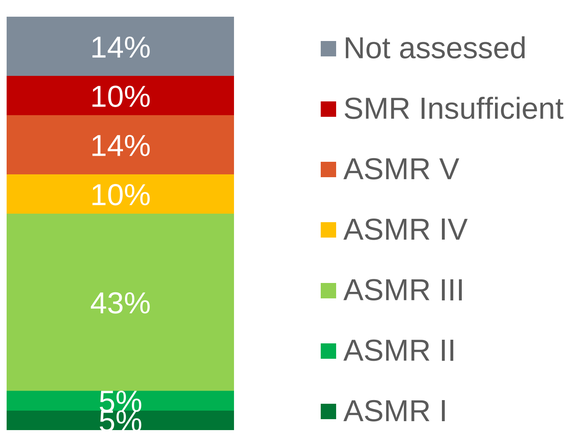
Fig 1: authorized PRIME medicines by substance type



Reimbursement outcomes in France, Germany and England

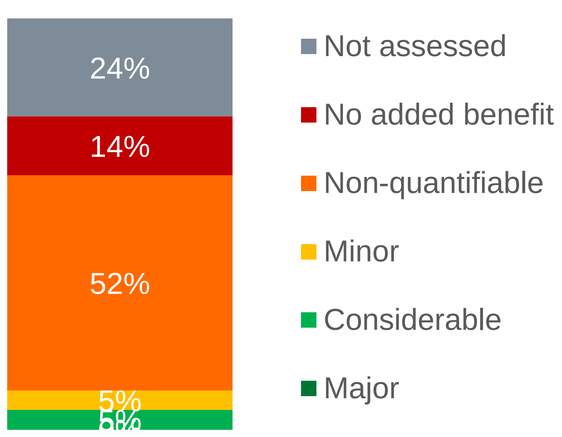
- 9 (45%) were reimbursed to label and 6 (30%) were restricted to subpopulations
- ATMPs received more favourable outcomes (4[57%] reimbursed to label)
- Most ASMR ratings were III (9[43%]), followed by V (3[14%]) and IV (2[10%])
- 2(10%) received SMR Insufficient *(Fig.2)*

Fig 2: HTA outcomes of PRIME medicines in France



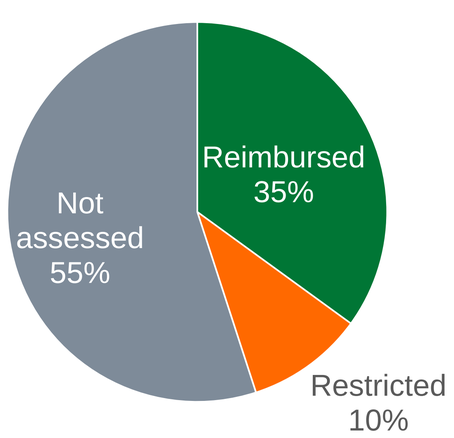
- 11 (52%) obtained a non-quantifiable added benefit, and 3 (14%) received a no added benefit *(Fig.3)*
- % of non-quantifiable added benefit was 78% for medicines with CMA and 71% for ATMPs

Fig 3: G-BA ratings of PRIME medicines in Germany



- 7 (35%) were NICE-recommended with reimbursement to label, 2 (10%) with restrictions and 11 (55%) not assessed *(Fig.4)*
- 67% of medicines assessed by NICE were under the CDF and/or with MA, with a higher proportion for medicines with CMA (75%) and for ATMPs (100%)

Fig 4: HTA outcomes of PRIME medicines in England



Conclusions

- PRIME medicines received mixed HTA outcomes across France, Germany and England, with a considerable delay from MA to HTA
- This emphasizes the importance of pricing and market access strategies to translate regulatory approval into successful reimbursement
- With joint HTA expected to roll out in 2025, there may be opportunities for EMA and the HTA network to collaborate and better support patient access

Abbreviations: ASMR, Amélioration du Service Médical Rendu (Additional Medical Benefit); **ATMPs**, Advanced-Therapy Medicinal Products; **CDF**, Cancer Drugs Fund; **CMA**, Conditional Marketing Authorization; **EMA**, European Medicines Agency; **G-BA**, Gemeinsamer Bundesausschuss (Federal Joint Committee); **HAS**, Haute Autorité de santé (French National Authority for Health); **HTA**, Health Technology Assessment; **MA**, Marketing Authorization; **MAA**, Managed Access Agreement; **NICE**, National Institute for Health and Care Excellence; **PRIME**, PRIority Medicines

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