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ATMPs in Europe - Do We Have an Access Gap?

Objectives

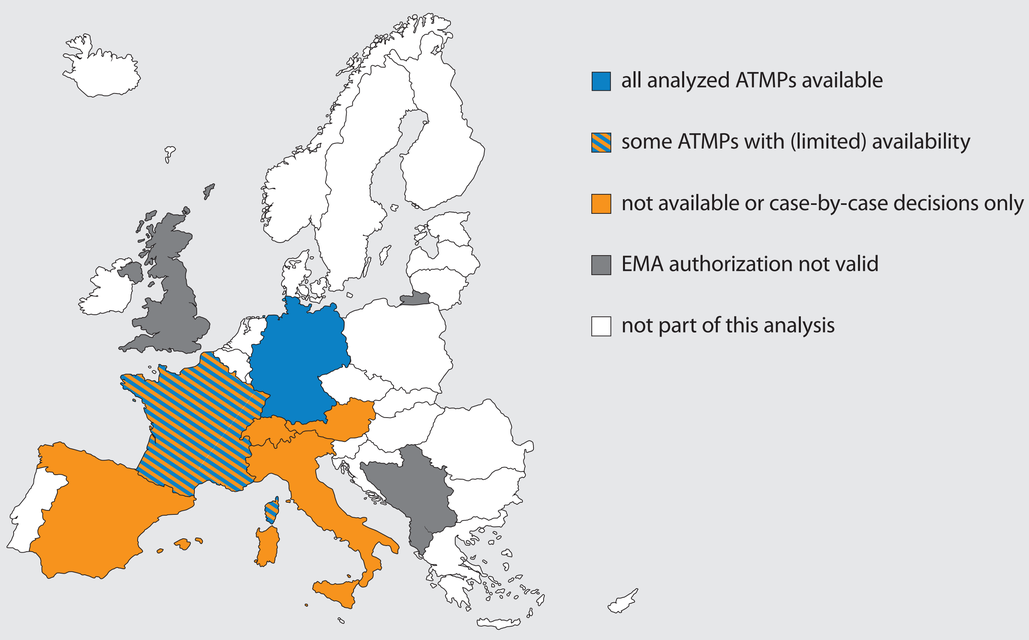
The EU Commission proposes to grant one additional year of market exclusivity for EU-wide product launch of orphan medicinal products (1) and two additional years of regulatory data protection for EU-wide product launch for all new medicinal products (2). With these incentives to pharmaceutical producers, the Commission wants to address the gap in availability and time-to-market of new medicinal products, especially orphan drugs, within the Union. Since most advanced therapy medicinal products (ATMPs) have been granted an orphan designation (3), both proposed incentives would apply to these complex pharmaceuticals. Given their potential for disease modification, ATMPs can provide a good indication as to whether the gap in availability and time-to-market exists.

Methods

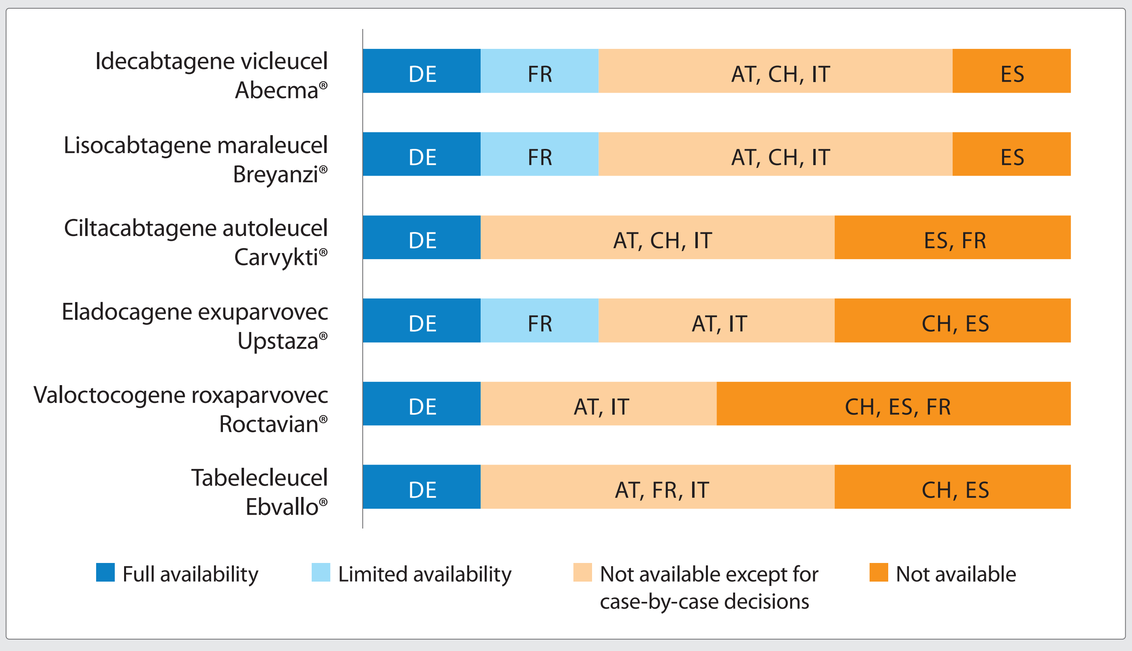
- We identified all ATMPs approved by EMA in 2021 and 2022, excluding medicinal products with withdrawn marketing authorization (3).
- For each of the identified ATMPs, we analyzed availability, launch date if applicable, and reimbursement status in Austria, France, Germany, Italy and Spain.
- For comparison, we additionally recorded marketing authorization and reimbursement status in Switzerland.
- We used reimbursement by national payers as a proxy for availability, classifying reimbursement via Early Access Programs (EAP) as 'Limited availability' and reimbursement limited to individual cases as 'Not available except for case-by-case decisions'.
- The results include information as of 31/05/2023.

Results

- 6 ATMPs have received EMA approval in 2021 and 2022. Availability and reimbursement status differed within countries.
- For Austria, it can be assumed that for the majority of ATMPs formal requests for hospital listing (LKF-MEL System) have been submitted (4-6). Until they will become effective, availability is limited to case-by-case decisions in hospitals.
- Three out of six ATMPs are available in France via EAP with preliminary prices determined by the manufacturer and one ATMP is available via compassionate use authorization (case-by-case basis). Mean duration until approval of EAP after EMA authorization was five months. EAP for Carvykti® was stopped by the manufacturer on 23/05/2023 (7).
- In Germany, all six ATMPs were commercially available and reimbursed as of 31/05/2023 (8). Mean duration until product launch with general reimbursement after EMA authorization was four months. As of 01/08/2023, however, Upstaza® is no longer marketed in Germany.
- In Italy, none of the six ATMPs are currently marketed nor reimbursed, with price negotiations still ongoing except for Abecma® which was recently negotiated in C class (not reimbursed) but not yet marketed (9). Early access assessments before reimbursement by the Italian Medicines Agency are evaluated on a case-by-case basis following specific requests.
- None of the six ATMPs are marketed nor reimbursed in Spain. While four out of six ATMPs are currently in the national HTA process, national HTA for Upstaza® has already been completed with price negotiation ongoing, and Breyanzi® has not been authorized by the national authority yet (10).
- For comparison: Approval for pharmaceuticals in Switzerland is the responsibility of the national authority. Three of the ATMPs are already approved and included in the list of additional charges for hospitals with prior special approval of the insurer (case-by-case basis) (11-12). None of the three remaining ATMPs are officially reimbursed nor authorized (yet), a marketing authorization application for Ebvallo® has been submitted (11).



ATMP availability and reimbursement per country as of 31/05/2023[a)]



ATMP availability and reimbursement per medicinal product as of 31/05/2023
Medicinal products sorted by EMA authorization date

[a)] EMA authorization not valid in Switzerland, included in this analysis for comparison only

Conclusions

- Despite not all EU countries included in this analysis, our results clearly show that accessibility to ATMPs differs among European countries.
- Further research could clarify whether this access gap is due to the particularities of national pricing and reimbursement processes or the special characteristics of ATMPs.
- It remains to be seen whether the proposed incentives for EU-wide market launch will contribute to closing the current access gap.

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