Time to Access Trends of Pharmaceutical Products in EU4 and UK (2019-2021)

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Objective

Examine trends, drivers and rationale of manufacturers whose products achieved faster than usual times between regulatory approval and standard reimbursed access in the EU4 and UK

Methods

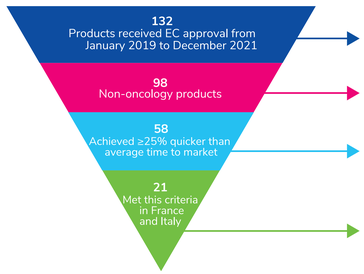
- New molecular entities, formulations and combinations approved by the European Commission (EC) between January 2019 and December 2021, were included in the analysis
  - Cut-off date for data collection was September 30, 2022
- Data was gathered from official national HTA agencies and P&R bodies; sources for launch date information provided in Table below

Table 1: Sources for launch or reimbursement dates and pricing information

Country	Launch Date Information in the EU4 and UK
France	P&R decision (pricing information and date published in Journal Officiel) HTA decisions (HAS)
Germany	Product availability/introduction (ABDATA)
Italy	First P&R Decree publication on Official Gazette • Analysis of launch date does not consider initial approval in Class C-nn
Spain	Date of commercialization (BotPlus)
UK	Product available and positive HTA recommendation (NICE/NHS)

- Analysis focuses on 21 products that achieved ≥25% quicker than average time to market in France and Italy

Figure 1: Product Sample



Excluded products withdrawn in the EU (n=4), COVID therapies (n=4), non-prescription therapies, generics, biosimilars, hybrid medicinal products and informed consent applications

Oncology products were excluded due to many countries' availability of alternative funding pathways

Products that achieved ≥25% quicker than average time to market in at least 1 country within EU4 & UK were considered

France and Italy were chosen as countries of focus based on their similarities and differences in driving factors for fast time to market in a preliminary assessment; Criteria for inclusion:

- Extended time to reimbursed access (>6 months)
- Drivers for quicker time to market apart from competition were identified

Analysis

Table 2: Time to market differences by country

Country	Average time to market (# of weeks)	25% faster time to market (in weeks)	Products that achieved ≥25% faster time to market	50% faster time to market (in weeks)	Products that achieved ≥50% faster time to market
France	62	46.5	16	31	5
Italy	66	49.5	09	33	0
Germany	23	17.3	51	11.5	46
UK	64	48	17	32	10
Spain	85	63.8	12	42.5	5

Note: Time to market is the average number of weeks to reimbursed access post regulatory approval

Results

Table 3: Sample of 21 products achieved ≥25% faster than average time to market in France and Italy compared to EU4 & UK

	Drug Name	Therapeutic Area(s)	MAH	EU Orphan	Percent quicker than average relative to each individual country				
					France	Italy	Spain	UK	Germany
Achieved fast TTM in FR & IT	Dolutegravir + Lamivudine	HIV Infections	ViiV Healthcare B.V.	N	41%	29%	69%	N/A	81%
	Glycerol phenylbutyrate	Excessive daytime sleepiness	Bioprojet Pharma	N	32%	40%	N/A	58%	62%
	Elexacaftor + Tezacaftor + Ivacaftor	Cystic Fibrosis	Vertex Pharmaceuticals (Ireland)	Y	27%	31%	22%	N/A	84%
	Filgotinib	Rheumatoid Arthritis	Gilead Sciences Ireland UC	N	45%	25%	32%	66%	87%
Achieved fast TTM in FR	Ponesimod	Multiple Sclerosis, Relapsing	Janssen-Cilag International N.V.	N	42%	21%	31%	42%	83%
	Upadacitinib	Rheumatoid Arthritis	AbbVie Deutschland GmbH & Co. KG	N	54%	22%	41%	20%	71%
	Ofatumumab	Multiple Sclerosis, Relapsing	Novartis Ireland Ltd	N	63%	19%	N/A	88%	1%
	Formoterol + Glycopyrronium + Budesonide	COPD	AstraZeneca AB	N	45%	14%	30%	N/A	49%
	Indacaterol + Mometasone furoate	Asthma	Novartis Europharm Limited	N	60%	-13%	8%	N/A	80%
	Abrocitinib	Dermatitis, Atopic	Pfizer Europe MA EEIG	N	47%	N/A	N/A	47%	77%
	Lysin + Arginine	Radiation Injuries	Advanced Accelerator Applications	N	38%	-55%	-19%	N/A	-473%
	Insulin lispro-aabc	Diabetes Mellitus	Eli Lilly Nederland B.V.	N	44%	-76%	-29%	N/A	0%
	Imipenem + Cilastatin + Relebactam	Gram-Negative Bacterial Infections	Merck Sharp & Dohme B.V	N	94%	-82%	N/A	N/A	-203%
	Fostemsavir	HIV Infections	ViiV Healthcare B.V.	N	38%	-5%	N/A	N/A	65%
	Risankizumab-rzaa	Psoriasis	AbbVie Deutschland GmbH & Co. KG	N	36%	-6%	43%	74%	78%
	Diroximel fumarate	Multiple Sclerosis, Relapsing	Biogen Netherlands B.V.	N	59%	N/A	67%	54%	71%
Achieved fast TTM in IT	Pegcetacoplan	Hemoglobinuria, Paroxysmal	Swedish Orphan Biovitrum AB (publ)	Y	AAP*	47%	N/A	81%	32%
	Risdiplam	Spinal Muscular Atrophy	Roche Registration GmbH	Y	12%	31%	N/A	41%	78%
	Onasemnogene abeparvovec	Spinal Muscular Atrophy	Novartis Gene Therapies EU Limited	Y	AAP*	35%	6%	7%	73%
	Givosiran	Porphyrias, Hepatic	Alnylam Netherlands B.V.	Y	-30%	30%	8%	-41%	73%
	Brolucizumab-dbll	Wet Macular Degeneration	Novartis Europharm Limited	N	N/A	30%	-36%	-108%	81%

*AAP = early access authorization; Manufacturers that have products with AAP in France may not feel the need to achieve fast time to standard reimbursement
TTM = Time to Market

≥25% quicker ≥50% quicker

- As a baseline, we need to consider the differences in average time to market to understand what 25% quicker means for each country (see Table 2)
- The 21 products fell into three cohorts for faster than usual time to market in both France and Italy or just one of the two countries (see Table 3)
  - Drivers of quick access emerged such as:
    1. **Competitive categories (e.g., RA, MS) exhibited quicker time to market in both France and Italy**
       - This was likely due to the existing known list and net price benchmarks setting the stage
         - Manufacturers that chose to price products in these competitive spaces in a similar strata to their benchmarks likely had an expedited negotiation process
         - E.g., Dovato, Jyseleca, Ozawade, Kaftrio/Trikafta all launched at ex-factory prices very similar to their comparator(s)[1]
       - Our analysis focused on France and Italy product prices and comparators, but faster access in these cases was often evident in Germany, UK, and Spain
    2. **In France, products with Added Therapeutic Value of no improvement (ASMR V) often achieved faster access as limited pricing flexibility and manufacturers' willingness to negotiate helped achieve quicker access**
       - ~70% of the products that achieved faster time to market in France only had an ASMR V rating
    3. **In Italy, some orphan therapies made it to market quicker likely due to a special pathway allowing the submission of clinical data prior to regulatory approval**
       - Orphan therapies including Aspaveli, Evrysdi, and Givlaari submitted their clinical evidence packages between 25 and 46 days prior to regulatory approval, giving them an early advantage on the negotiation process compared to non-orphan therapies

[1]Comparators within HTA assessment were chosen based on the most recent launch prior to the product

Conclusions

- Manufacturers' knowledge, agile tactics, and willingness to negotiate directly impacts time to market
- Various underlying factors drive these differences by country including competition, HTA outcomes, early evidence submissions, and availability of alternative pathways
- Other factors that were not explored but may be drivers of fast time to market include:
  - Robustness of clinical trial data
  - 2nd time submissions
  - Portfolio evaluations
  - Willingness to settle on net price relative to other countries

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