Market Access Trends of Pharmaceutical Products in the US, EU4 and UK 2016-2021

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HPR55

Objectives

To examine trends in the time between regulatory approval and standard reimbursed access in the EU4, UK and US between January 2016 and December 2021

Methods

- New molecular entities, formulations and combinations approved by the European Commission (EC) between January 2016 and December 2021, were included in the analysis
  - Availability and commercialization in US were also analysed for the same products (matching sample), to compare EU vs US timelines
  - Cut-off date for data collection was September 30, 2022
- Time comparison for all medicinal products with EC approval vs. orphan and oncology medicinal products was made, including shifts over time
- 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 dates

Country	Launch Date Information in the EU4, UK, and US
France	P&R decision (date published in Journal Officiel)
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 (Portalfarma)
UK	Product available and positive HTA recommendation (NICE/NHS)
US	Medi-Span

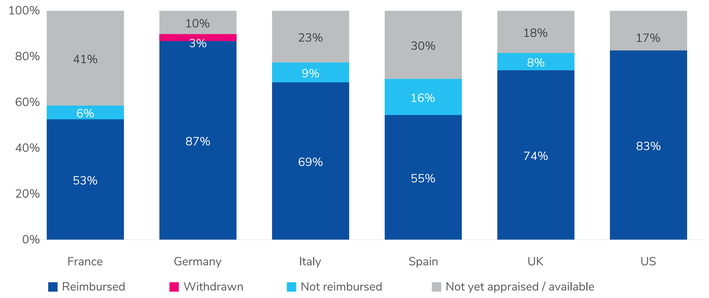
Product Sample

Analysis focuses on 266 new prescription medicinal products, formulations and combinations approved by the EC in the time period January 2016-December 2021 and currently on the market

- Medicinal products excluded from the analysis are prescription medicinal products with marketing authorisation withdrawn in the European Union (n=18), COVID therapies (n=4), non-prescription therapies, generics, biosimilars, hybrid medicinal products and informed consent applications
- Of the 266 medicinal products, following subsets are identified:
  - 118 new active substances
  - 90 medicinal products with orphan drug designation (OD) at launch; of which 11 have lost OD over time
  - 10 medicinal products classified as ATMPs, 9 of which have OD
  - 71 medicinal products approved for oncology indications
  - 34 medicinal products with conditional marketing authorizations, 4 of which have since been converted to full MA
  - 9 authorized under exceptional circumstances
  - 19 authorized under accelerated assessment pathway
    - 11 of which have OD
    - 2 of which with conditional status
    - 2 of which approved under exceptional circumstances

Results: Standard Reimbursed Access Post Regulatory Approval (EC Approvals: January 2016 to December 2021)

Figure 1: Reimbursement status post regulatory approval

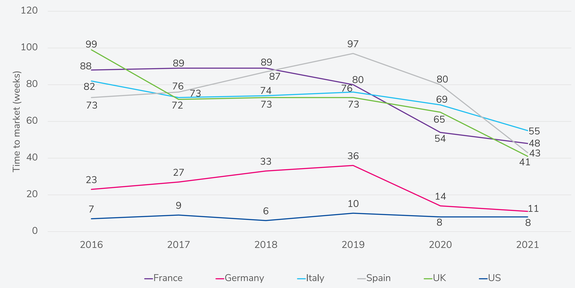


Cut-off date for data collection was September 30, 2022.

Results: Average time to standard reimbursed access from regulatory approval in the US, EU4 and the UK

When looking at individual years, trend toward decrease in average time to market is seen

Figure 2: Average time to reimbursed access from regulatory approval in the US, EU4 and the UK



Cut-off date for data collection was September 30, 2022.

Results: Average Time to Standard Reimbursed Access Post Regulatory Approval (EC Approvals: January 2016 to December 2021)

Number of Weeks to Launch Post Regulatory Approval in US, EU4, and UK for Same EU-Based Sample of 266 Medicinal Products (Jan 2016 – Dec 2021)

Table 2: Average number of weeks to reimbursed access post regulatory approval for all products, oncology and orphan drugs

Country	All Products (n=266)		Oncology (n=71)		Orphan (n=90)^^	
	# of Weeks	% of all EC approved products	# of Weeks	% of all EC approved oncology products	# of Weeks	% of all EC approved orphan products
France	79	53%	77	55%	104	59%
Germany	24	90%*	16	97%	15	92%
Italy	79	69%**	76	73%	79	73%
Spain	83	55%	79	56%	108	48%
UK	70	74%	61	72%	72	64%
US	8	83%	2	94%	5	81%

Of the products not launched in France, ~41% are available through an early access program

*Germany: although 90% (239) of all EC approved medicinal products were launched, at least 8 of them have later been withdrawn post-AMNOG assessment, **Italy: 60 products – approved as Class C-nn – are theoretically available but not reimbursed (not included in the 69%). ^^90 medicinal products had orphan designation (OD) at launch; 11 have lost OD over time, while 79 still have it
Cut-off date for data collection was September 30, 2022.

Results: January 2016 – December 2021 Analysis

- US is quickest in terms of time to access for all products (8 weeks) as well as oncology (2 weeks) and orphan (5 weeks) sub-sets
- In Europe there are substantial differences based on trends analysis over time. Majority (90%) of approved therapies are launched in Germany while fewest have completed pricing and reimbursement negotiations in France (53%) (Table 2, Figure 1, Figure 2)
  - Germany: Procedures result in a short time from regulatory to pricing and reimbursement approval (24 weeks) because price listing precedes negotiations, however, 3% of the reimbursed products have subsequently been withdrawn
  - France, Italy and Spain: Procedures require a local filing and negotiation before entering the market, the gap between regulatory and pricing approval is longer (79 to 83 weeks), and the number of products completing the process varies
  - UK: 84% went through a NICE assessment in England, which on average takes 66 weeks, vs. 16% that have regional reimbursement variation due to the lack of national assessment (NICE has reviewed all oncology and 98% of orphan therapies)
    - 3 therapies included in our analysis have been approved by the MHRA prior to the EC (1 to 5 months earlier than EC approval)
    - Access date is completion of NICE HTA versus date at which product is first available in the UK

Results: January 2016 – December 2021 Analysis (Continued)

- Some differences are also noted for time to reimbursed access across therapy areas (Table 2)
  - Oncology therapies' time to access tends to be faster in all countries
  - Orphan drugs' time to access is considerably longer in France and Spain
    - France: 41% of orphan products that have not completed standard P&R procedures are available to patients through early access programs, while this is not the case in Spain

Results: Average Time to Standard Reimbursed Access Post Regulatory Approval – 2016 to 2018 and 2019 to 2021 Approval Subsets

Table 3: Average time to reimbursed access differences for all/oncology and orphan drugs: Subset selected 2016 to 2018 and 2019 to 2021

Country	All products (n=266)		Oncology products (n=71)		Orphan products (n=90)[1]	
	EC approval 2016-2018 (n=134)	EC approval 2019-2021 (n=132)	EC approval 2016-2018 (n=37)	EC approval 2019-2021 (n=34)	EC approval 2016-2018 (n=47)	EC approval 2019-2021 (n=43)
France	89 (69%)	60 (36%)	80 (76%)	69 (32%*)	112 (79%)	82 (35%*)
Germany	28 (95%)	19 (85%)	15 (97%)	11 (97%)	20 (94%)	10 (91%)
Italy	82 (84%)	73 (53%)	79 (84%)	70 (62%)	82 (83%)	75 (63%)
Spain	84 (75%)	82 (33%)	79 (81%)	79 (29%)	107 (68%)	111 (26%)
UK	79 (86%)	59 (68%)	72 (81%)	46 (62%)	97 (74%)	51 (53%)
US	6 (84%)	11 (81%)	2 (89%)	1 (100%)	5 (83%)	4 (79%)

[1]90 medicinal products had orphan designation (OD) at launch; 11 have lost OD over time, while 79 maintain status
Cut-off date for data collection was Sep 2022; Data was gathered from official national HTA agencies and P&R bodies

*Note: 57% orphan and 30% oncology therapies *(approved 2019 to 2021)* that have not completed standard P&R procedures in France are available to patients through an early access program

Results – Cohort Analysis: 2016 to 2018 and 2019 to 2021

- A lower percentage of approved drugs were launched in most European countries in the more recent cohort due to the time lag built into completing local procedures. US and German access procedures do not have similar lags and timing remains stable
  - Lag in timing of reimbursed access in France and Spain can especially be seen in Table 3
- Between the two time cohorts, time to access declines in France, Spain, UK and Italy, but in every case, this is offset by a smaller percentage of drugs being launched in the more recent cohort
  - This apparent decline might be a "false positive" while additional products complete the process
- A review of the status of therapies not approved in France reveals a trend towards several oncology therapies being assigned SMR insufficient in more recent years
  - While only 3 oncology therapies were assigned SMR insufficient in the first cohort (2016 to 2018), 8 were assigned SMR insufficient in the second (2019 to 2021)

Conclusions

- Healthcare system procedures consistently determine time to access, however there is some variability in recent trends based on local initiatives (e.g., France using early access programs)
  - US continues to have considerably shorter time to access than Europe
  - Analysis of market access trends across the EU4 and the UK shows that Germany continues to have the broadest and fastest access
  - In France, Italy and Spain although time to access appears to have shortened, this is attributed to the lag in time to market and fewer number of launches rather than a trend toward faster negotiations. UK's HTA procedures lead to a similar lag time
- In the UK, despite European Commission Decision Reliance Procedure being extended by 12 months to apply until 31st December 2023, we observed few therapies with faster approval by the MHRA relative to the EC
  - This trend should be monitored and tracked as the UK aims to boosts its appeal to life science companies by speeding up approval with the implementation of international recognition framework from 1 January 2024
- Changing rules in these markets (e.g., German reforms) continue to shape the time it takes to achieve access post regulatory approval. Continuing to monitor these trends and the factors shaping them is critical to understanding how market access is evolving

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