MARKET ACCESS TRENDS ACROSS THE EU5 & US: 2009 to 2016- AN UPDATE

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Objective

- To examine the time between regulatory approval and launch/pricing and reimbursement (P&R) approval (as defined in Table 1) in the EU5
  - Illustrate any differences between all medicines with EC approval , oncology and orphan drugs within and across the countries
- To examine potential changes in market access timelines in the EU5 countries between 2009 and 2016.

Methods

- New molecular entities, formulations and combinations approved by the EMA (EC centralized approval) between January 2009 and December 2016 were included in the analysis
  - Commercialization timelines in US were also analysed for the same products (comparable sample)
  - Cut off date for data collection was May 19, 2017
- Time comparison for all medicines with EC approval vs. orphan and oncology medications was made including shifts over time
- Timing differences were NOT weighted by the number of products available by country and category
- Sources for launch date information provided in Table 1

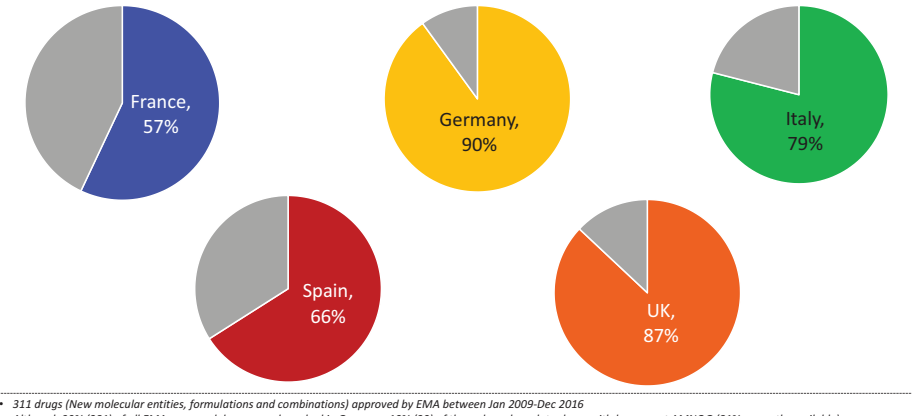
Table 1: Launch date information in US and EU5

Country	Launch date information
US	MediSpan
UK	Product introduction (MIMS/NHS SPS/NHS DMD)- Launch date does not consider HTA decisions
Germany	Product availability/introduction (ABDATA)
France	P&R decision (Agrément collectivités/date published in Journal Officiel)
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)

RESULTS

- Overall time to market is quickest in the US at ~7 weeks
  - US time to market is even shorter for oncology drugs (5.3 weeks) and orphan drugs (2.4 weeks)
- Across the EU5 Germany has the fastest access (17 weeks), Italy is the slowest (72 weeks)
  - Although the time to launch in the UK is only 23 weeks, reimbursement is dependent upon decision of national HTA bodies which could considerably extend timelines
- 90% of all EMA approved drugs between 2009 and 2016 launched in Germany whereas only 57% launched in France
  - 10% of drugs (30 products) launched in Germany post AMNOG have been subsequently withdrawn from the German market (81% currently available)
  - Spain has the poorest access for orphan drugs; only 39% of orphan medications approved by the EMA in this time period had completed P&R procedures in Spain
  - Comparing time to market for all medicines with EC approval vs. orphan and oncology indications highlights that oncology drugs launch faster in Germany
  - Time to market for orphan drugs is significantly higher in Spain/Italy compared to all other drugs
  - 8 drugs approved under Class C-nn in Italy
- Analysing trends over time (from 2010 to 2016) demonstrates:
  - Consistently fewer annual drug launches in France with similar numbers observed in Italy/Spain and Germany/UK
  - Increasing time to market in all countries, especially in France (46 weeks in 2010 to 74 weeks in 2016)

Figure 1: Percent of EMA approved medications (January 2009 to December 2016) available in the EU5

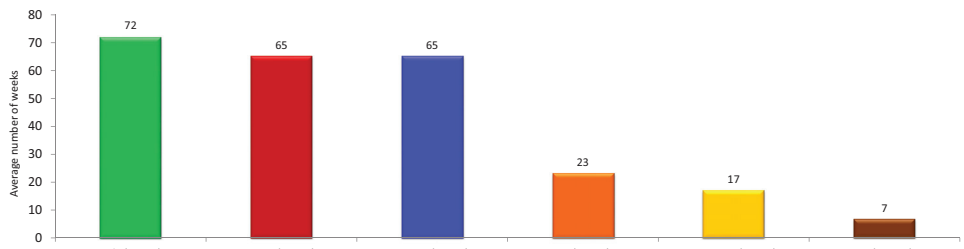


- *311 drugs (New molecular entities, formulations and combinations) approved by EMA between Jan 2009-Dec 2016*
- *Although 90% (281) of all EMA approved drugs were launched in Germany, 10% (30) of these drugs have later been withdrawn post AMNOG (81% currently available)*
- *8 drugs approved as Class C-nn, that are theoretically available in Italy (not included in the 79%)*

Cut off date for data collection was May 19, 2017

RESULTS (cont'd)

Figure 2: Average time to launch post regulatory approval in US and EU5 for same sample of products (January 2009 to December 2016)



	Italy (n=246)	Spain (n=204)	France (n=177)	UK (n=270)	Germany (n=281)	US (n= 240)
Min. weeks	12	11	1	0	0	0
Max. weeks	249	328	212	168	185	189
# Not yet launched	65*	107	134	41	30	n/a

- **Including 8 drugs approved as Class C-nn, that are theoretically available*
- *Outliers include: Sovaldi French launch in ~ 1 week and Exviera / Viekirax Spanish launch in ~11 weeks*

Cut off date for data collection was May 19, 2017

Table 2: Number of weeks to launch post regulatory approval in US and EU5 for same sample of products (January 2009 to December 2016)

Country	All drugs (n=311)		Oncology (n=69)		Orphan (n=70)	
	# of Weeks	*% of all EMA approved drugs*	*# of Weeks*	*% of all EMA approved oncology drugs*	*# of Weeks*	*% of all EMA approved orphan drugs*
France	65	57%	67	64%	67	51%
Germany	17	90%*	9	99%	18	94%
Italy	72	79% ^	72	75%	86	70%
Spain	65	66%	77	68%	100	39%
UK	23	87%	14	99%	28	87%
US	7	n/a	5.3	n/a	2.4	n/a

- *311 drugs (New molecular entities, formulations and combinations) approved by EMA between Jan 2009-Dec 2016*
- ** Although 90% (281) of all EMA approved drugs were launched in Germany, 10% (30) of these drugs have later been withdrawn post AMNOG (81% currently available)*
- *^ 8 drugs approved as Class C-nn, that are theoretically available in Italy (not included in the 79%)*

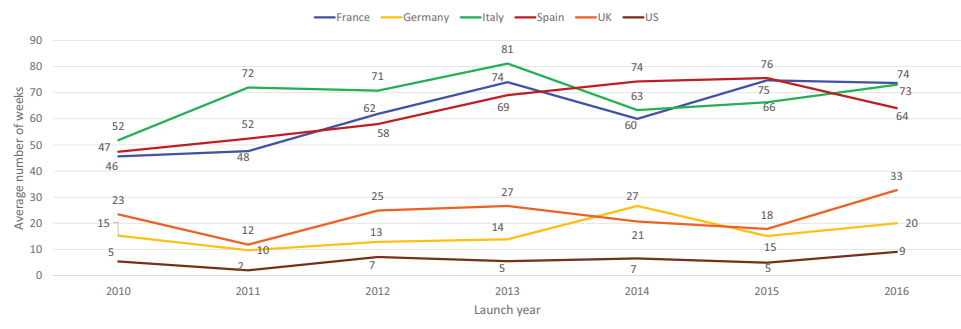
Cut off date for data collection was May 19, 2017

Table 3: Number of weeks to launch post regulatory approval in US and EU5 for same sample of products from 2010 to 2016

Number of drugs launched	2010	2011	2012	2013	2014	2015	2016	Total
France	21	10	26	21	27	26	32	**163**
Germany	25	28	29	26	54	46	43	**251**
Italy	24	27	11	36	37	41	42	**218**
Spain	21	25	11	23	32	41	40	**193**
UK	22	25	29	27	53	39	46	**241**
US*	19	20	20	36	48	44	20	**207**

While different systems have various review criteria and timelines, over the 7 years covered:
- *France consistently sees fewer annual drug launches*
- *Similar numbers observed in Italy/Spain and Germany/UK*
- **Number of drugs actually launched in the US is higher than the numbers in the table given the above analysis only includes drugs also approved by the EMA*

Figure 3: All drugs- Time to launch post regulatory approval in US and EU5 for same sample of products from 2010 to 2016



Cut off date for data collection was May 19, 2017

CONCLUSIONS

- US time between approval and launch is considerably shorter than in any EU5 country and this has been the case for the entire 7 years of data covered
- Wide disparity exists in the number of EMA approved medications commercially available in each of the EU5 countries as well as time to market
  - While ~90% of all medications approved by the EMA are available in Germany, only 57% have completed P&R negotiation in France
  - 30 drugs have been withdrawn in Germany post launch likely due to failure in price negotiations (10% of all drugs launched since implementation of AMNOG)
  - Dramatic access issues for orphan drugs in Spain are highlighted by the fact only 39% of medications approved by the EMA are available
- Market access trend analyses across the EU5 suggests a modest increase in time to market (for products being actually launched) in all countries which may be due to additional data requirements (e.g. pharmacoeconomic dossiers in France), increasing number of resubmissions and budget pressures
- It is important to recognize variation in ability to launch and timing disparities when analysing market access timelines and their implications on the availability of new drugs to patients
- Limitation of the study is that timing differences were NOT weighted by the number of products available by country and category, which could be significant - this should be explored in future work