MARKET ACCESS TRENDS ACROSS THE EU5: 2010 to 2015

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OBJECTIVE AND METHODS

OBJECTIVES:

- To examine potential changes in market access timelines in the EU5 countries between 2010 and 2015.
  - Illustrate any differences between general medicines, oncology and orphan drugs within and across the countries

METHODS:

- New molecular entities, formulations and fixed-dose combinations approved by the EMA (EC centralized approval) between January 2010 and December 2015 were included in the analysis
- For each of the EU5 countries, number of drugs launched each year was calculated along with time to access
- Time comparison for launch of all medicines vs. orphan drugs and oncology drugs was made
  - Timing differences were NOT weighted by the number of products available by country and category

Table 1: Launch date information in the EU5

Country	Launch date information
UK	Product availability/introduction (UKMI/MIMS)
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
Spain	Date of commercialization (Portalfarma)

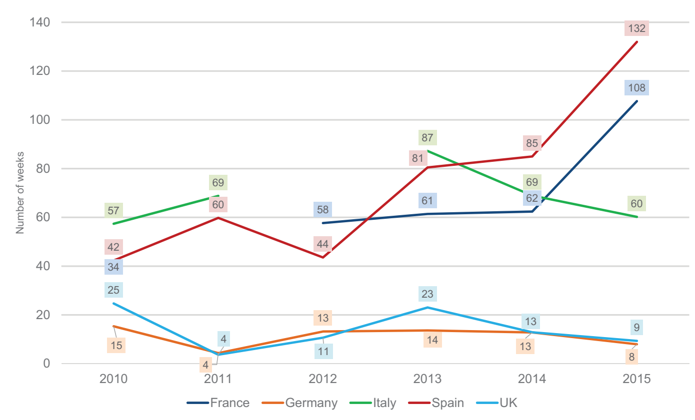
RESULTS

- Germany consistently sees a relatively high number of annual drug launches whereas France and Spain have relatively fewer new drugs (Table 1)
  - Overall 208 drugs launched in Germany whereas only 128 launched in France in the 5 year period (2010-2015)
    - Since AMNOG was implemented in 2011, 16 drugs have been withdrawn from the German market post-launch, primarily due to failure to achieve a successful price negotiation; however number of launches still remain highest in Germany
  - Number of drugs launched in France was particularly low in 2011 (only 10 new drugs launched) likely due to the Mediator scandal (diabetes drug Mediator linked to up to 2,000 deaths)
  - Spain and France have significantly lower number of orphan drug launches compared to Germany (18 in Spain and 27 in France vs. 51 in Germany)
- Examining changes in market access in the past 5 years highlights some interesting trends
  - Time to market has been increasing in Spain since 2012 (from 54 weeks to 83 weeks- Figure 1)
    - This rise is particularly sharp for oncology drugs (from 44 weeks in 2012 to 132 weeks in 2015- Figure 2)
  - In Italy time to market seems to be declining (from 81 weeks in 2013 to 52 weeks in 2015- Figure 1); this decline appears substantial for orphan drugs (from 104 weeks to 57 weeks- Figure 3) and is also consistent for oncology drugs (87 weeks to 60 weeks- Figure 2)
  - Although in general time to market has increased in France, the trend is less clear; in the past year there appears to be a spike in timing for oncology drugs (however only 4 oncology drugs were launched in France in 2015)
  - No significant changes noted in Germany and the UK; however drug withdrawals in Germany and HTA assessments in the UK could change the picture
- Across all EU5 countries, the trends in time to market for oncology products seem to closely follow the trends of all products; on the other hand, more variability is seen in the trends of orphan drugs timelines

Table 2: Number of launches including orphan and oncology drugs by year in the EU5

Year	Drugs	2010	2011	2012	2013	2014	2015	2010:2015
France	All	23	9	27	22	26	21	**128**
	Orphan	5	1	6	5	5	5	**27**
	Oncology	6	-	5	10	8	4	**33**
Germany	All	26	29	30	27	53	43	**208**
	Orphan	7	4	8	3	17	12	**51**
	Oncology	5	6	10	12	8	9	**50**
Italy	All	25	30	13	38	38	46	**190**
	Orphan	2	6	2	5	10	7	**32**
	Oncology	5	6	-	10	13	7	**41**
Spain	All	23	26	12	25	36	21	**143**
	Orphan	2	4	1	1	5	5	**18**
	Oncology	5	5	2	6	9	8	**35**
UK	All	17	23	26	30	28	54	**196**
	Orphan	7	2	8	7	12	9	**45**
	Oncology	4	6	5	8	11	10	**49**

Figure 2: Oncology drugs- Time to launch in EU5 countries between January 2010 and December 2015



Time to market not graphed for France in 2011 and Italy in 2012 due to lack of oncology product launches during those periods in the respective markets

Figure 1: All drugs- Time to launch in EU5 countries between January 2010 and December 2015

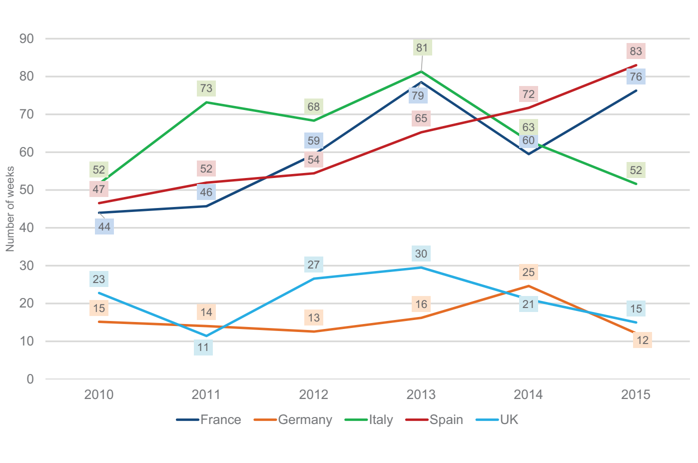
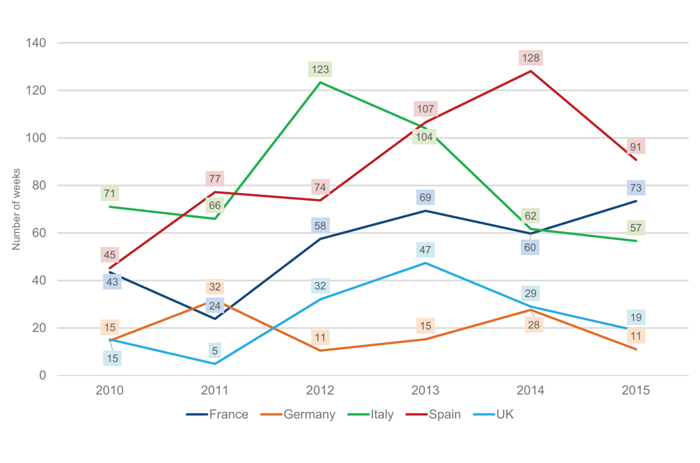


Figure 3: Orphan drugs- Time to launch in EU5 countries between January 2010 and December 2015



CONCLUSIONS

- Analysis of developments in time to launch over the past 5 years presents interesting insights
- Germany consistently sees a relatively high number of drug launches on an annual basis whereas France and Spain have relatively fewer new drugs
- This is especially true for orphan drugs
- While Spain and, to some extent, France have seen an increase in overall time to launch, the opposite is true for Italy
- Although no apparent changes seen in Germany, other factors (e.g. product withdrawals) are very important beyond launch
- In the UK, while orphan/oncology meds reach the market faster, they do not necessarily enjoy expedited reimbursement and funding
- At least for some countries – in particular, Spain – timing disparities are possibly related to economic conditions, reflected in a tightening of requirements for P&R completion of new drugs