REGULATORY APPROVAL TO PATIENT ACCESS, AN EVALUATION OF EU5 AND US NATIONAL TIMING DIFFERENCES: AN UPDATE (2009-2015)

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OBJECTIVE AND METHODS

- To examine the time between regulatory approval and launch/pricing and reimbursement (P&R) approval (as defined in Table 1) in the EU5 and US
  - Illustrate any differences between general medicines, oncology and orphan drugs within and across the countries
  - Look for changes in these timelines over a 6 year period (January 2009 to December 2015)
- New molecular entities, formulations and combinations approved by the EMA (EC centralized approval) between January 2009 and December 2015 were included in the analysis. FDA approval dates were retrieved.
- Time comparison for general medicines vs. orphan and oncology indications was made including shifts over time
- Timing differences were NOT weighted by the number of products not available by country and category

Table 1: Launch date information in the US and EU5

Country	Launch date information
US	Date wholesale acquisition cost was effective
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)

INTRODUCTION

- Increasing divergence between regulatory and P&R approval and a dearth of literature on time to market access in recent times makes this topic both a relevant and interesting issue for analysis
- Since 2006 the regulatory and reimbursement landscape has changed dramatically
- Trials sufficient to gain regulatory approval are now in a vast number of cases not seen as adequate for reimbursement by national authorities
- MME presented a review of time to market access for new molecular entities, formulations and combinations approved by the EMA (between January 2009 and May 2014) at ISPOR Amsterdam in November 2014
- This poster includes EC centralized approvals from January 2009 to December 2015

RESULTS

- Analysis of all EMA approved medications between January 2009 and December 2015 shows:
  - Across the EU5, Germany was the fastest to market (15 weeks) whereas average time to market in Italy was over a year after regulatory approval (64 weeks)
  - Although time to market in the UK appears short (20 weeks), HTA assessments often mean much longer reimbursement timelines and therefore significant access delays
  - Average time from FDA approval to US launch was 5 weeks (oncology 4 weeks; orphan drugs 2 weeks)
  - ~80% of all EMA approved medications in this time period were available in Germany, whereas only 45% had completed P&R negotiations in France
    - 72% of medications that had completed P&R in France were available across the EU5 and 83% were available in at least 3 of the other markets (in most cases the medication had not completed P&R in Spain but was available in Italy, Germany and the UK)
  - Spain has the poorest access for orphan drugs; only 28% of orphan medications approved by the EMA in this time period had completed P&R negotiations in Spain as of December 2015

Figure 1: Average time to launch post regulatory approval (January 2009 to December 2015)

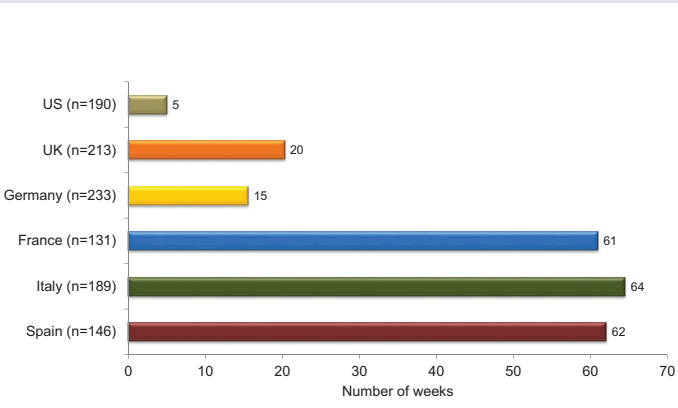

Figure 2: Percent of EMA approved medications (January 2009 to December 2015) available in the EU5

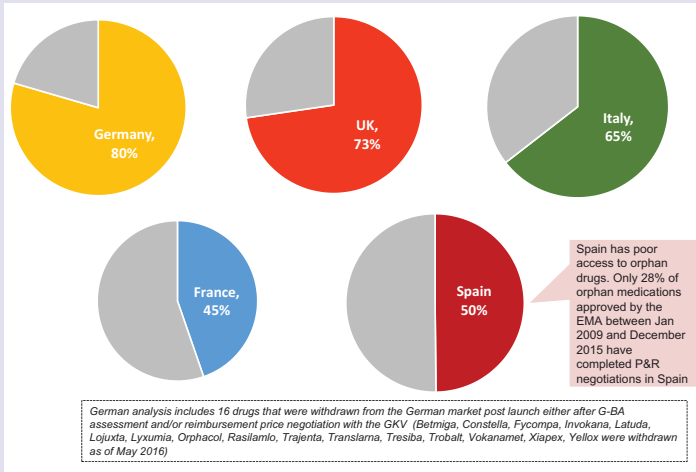

Table 2: Number of weeks to launch post EMA approval (January 2009 to December 2015)

Country	All drugs	Oncology	Orphan
US	5 (n=190)	4 (n=42)	2 (n=33)
UK	20 (n=213)	14 (n=53)	27 (n=47)
Germany	15 (n=233)	11 (n=55)	18 (n=53)
France	61 (n=131)	62 (n=33)	58 (n=28)
Italy	64 (n=189)	70 (n=41)	72 (n=32)
Spain	62 (n=146)	83 (n=35)	93 (n=18)

CONCLUSIONS

- Average time to launch in the US is considerably shorter than in the EU5 countries
- Wide disparity exists in the number of EMA approved medications commercially available in each of the EU5 countries and the time to market
  - While ~80% of all medications approved by the EMA are available in Germany, only 45% have completed P&R negotiation in France
    - 16 drugs were withdrawn in Germany post launch likely due to failure in price negotiations
  - Dramatic access issues for orphan drugs in Spain are highlighted by the fact that patients only have access to 28% of medications approved by the EMA
  - In the EU5, the German and UK launches on average were within 4 to 6 months of authorization, while France, Italy and Spain are >1 year
- 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
- While overall timelines remain consistent with previous analysis, variability can be seen in the analysis of shorter periods (see poster "**MARKET ACCESS TRENDS ACROSS THE EU5: 2010 to 2015**" for details)