Regulatory Approval to Patient Access, an Evaluation of EU5 and US National Timing Differences

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OBJECTIVES

- To examine the time between regulatory approval and launch/pricing and reimbursement (P&R) approval 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 5 year period (January 2009 to December 2013)

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
- The European Federation of Pharmaceutical Industries and Associations (EFPIA) presented a report in 2009 that included an analysis of total time delays from marketing authorisation of a new drug to the availability of this drug to patients in Europe
  - For each country, all products with an identified first marketing authorisation date during the period of January 2003 to December 2006 were included
- 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

METHODS

- New molecular entities, formulations and combinations approved by the EMA (EC centralized approval) between January 2009 and December 2013 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
- Drugs with time to market >1000 days were considered outliers and removed from the analysis
- Timing differences were NOT weighted by the number of products not available by country and category

Table 1. Launch date sources

Country	Launch date information
US	Date wholesale acquisition cost was effective
UK	Product availability/introduction
Germany	Product availability/introduction
France	P&R decision (Agrément collectivités/date published in Journal Officiel)
Italy	First P&R Decree publication on Official Gazette
Spain	Date of commercialization

RESULTS

- Time from approval to launch in the US averaged 39 days (17 days for oncology and 14 days for orphan drugs)
- Across the EU5, Germany was fastest while Italy was slowest (16 vs. 66 weeks)
- UK reimbursement decisions by SMC and NICE often lengthen time to access
- No real difference in average time to launch in Germany post AMNOG, however several manufacturers have withdrawn their medications post launch due to failed negotiations
- Pre approval sales programs in France and Italy expedite P&R completion
  - France: 44 weeks for 9 drugs with ATU program
  - Italy: 38 weeks for 9 drugs included in L648 program
- In Spain commercialization of orphan and oncology drugs takes longer than general medications
- Except UK and Spain, P&R timing for orphan drugs is shorter than average time

Table 2. Number of weeks to P&R completion post EMA approval (Jan 2009 to Dec 2013)

Country	All drugs	Oncology	Orphan
US	6 (n=100)	2 (n=29)	2 (n=17)
UK	21 (n=131)	15 (n=32)	27 (n=29)
Germany	16 (n=145)	15 (n=34)	15 (n=26)
France	50 (n=76)	47 (n=18)	47 (n=17)
Italy	66 (n=106)	60 (n=22)	62 (n=20)
Spain	54 (n=85)	59 (n=15)	71 (n=9)

- Note that the time comparisons do not consider disparities in product availability, for example,
  - Between Jan 2009 and Dec 2013 only 76 drugs have completed P&R in France whereas 145 drugs are available and reimbursed in Germany
  - Only 9 orphan drugs have completed P&R in Spain within this time period

Figure 1. Average time to market post regulatory approval (Jan 2009 to Dec 2013)

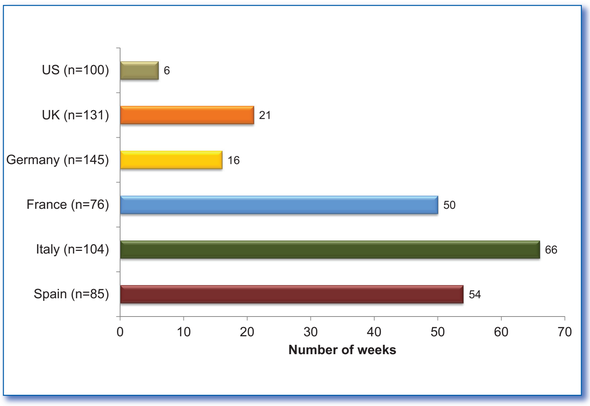
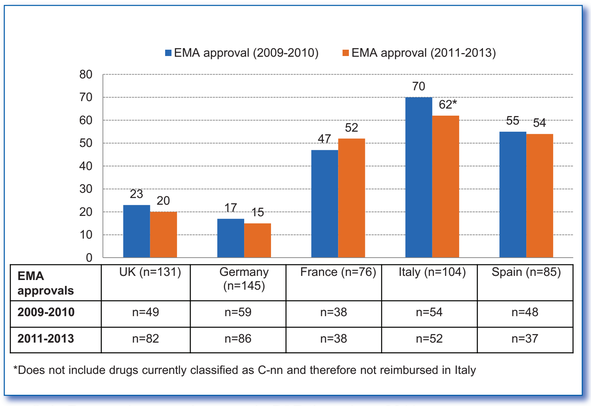


Figure 2. Comparison of time to market: Drugs approved by EMA before and after 2011



EMA approvals	UK (n=131)	Germany (n=145)	France (n=76)	Italy (n=104)	Spain (n=85)
2009-2010	n=49	n=59	n=38	n=54	n=48
2011-2013	n=82	n=86	n=38	n=52	n=37

*Does not include drugs currently classified as C-nn and therefore not reimbursed in Italy

- Only France shows an increase in P&R time since 2011

CONCLUSIONS

- Average time to market in the US is considerably shorter than in the EU5 countries
- In the EU5, the German and UK launches on average were within 4 to 6 months of authorization, while France, Italy and Spain were at, or above one year
- Launch times for orphan and oncology drugs also differ
- Timing disparities – possibly related to country processes and varying financial constraints – can be seen between product types (general vs. oncology vs. orphan) and these disparities may increase over time
- It is important to recognize these differences when analysing market access timelines and their implications on the availability of new drugs to patients

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