OBJECTIVES & METHODS

- Examine the time between regulatory approval and launch/pricing and reimbursement (P&R) approval in the US and EU
  - Identify any differences between general medicines, oncology and orphan drugs
  - Examine changes over time
  - Look for changes in these timelines over a 5-year period (January 2009 to May 2014)
  - Additional analysis of trends for products launched between April 2013 and May 2014
- New molecular entities, formulations and combinations approved by the EMA (EC centralized approval) between January 2009 and May 2014 were included in this analysis. EDA approval dates were reviewed
- Time comparison for general medicines vs. orphan and oncology indications was made excluding orphan drugs
- 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

RESULTS

- Analysis of US and EUS launches of all medications approved by the EMA between January 2009 and May 2014 shows (refer to Figure 1 and Figure 2 below):
  - Average time from FDA approval to US launch was 6 weeks (oncology 4 weeks; orphan drugs 2 weeks) which is much faster than all EU5 countries
  - Spain has the poorest access for orphan drugs; only 24% of orphan medications approved by the EMA in this time period had completed P&R negotiations as of May 2014
  - Look for changes in these timelines over a 5-year period (January 2009 to May 2014)
  - Average time from market in the UK appears short (20 weeks), HTA assessments often mean significant access delays
  - Analysis of US and EU5 launches of all medications approved by the EMA between January 2009 and May 2014 shows (refer to Figure 1 and Figure 2 below):
    - 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
    - New molecular entities, formulations and combinations approved by the EMA (EC centralized approval) between January 2009 and May 2014 were included in this analysis. EDA approval dates were reviewed
    - Time comparison for general medicines vs. orphan and oncology indications was made excluding orphan drugs
    - 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
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    - Timing differences were NOT weighted by the number of products not available by country and category

CONCLUSIONS

- Average time to market in the US is considerably shorter than in the EU5 countries
- Wide disparity exists in the number of EMA approved medications available in each of the EU5 countries and the time to market
  - While ~65% of all medications approved by the EMA are available in Germany, only 45% have completed P&R negotiation in France
  - Dramatic access issues for orphan drugs in Spain are highlighted by the fact that patients only have access to a quarter of medications approved
  - Only one orphan drug has completed P&R in Spain between April 2013 and May 2014, taking 106 weeks to complete the process
- Wide disparity exists in the number of EMA approved medications available in each of the EU5 countries and the time to market
  - While ~65% of all medications approved by the EMA are available in Germany, only 45% have completed P&R negotiation in France
  - While ~85% of all medications approved by the EMA are available in Germany, only 45% have completed P&R negotiation in France
  - Germany analysis includes 8 drugs that were withdrawn from the German market post-launch either after G-BA assessment and/or reimbursement price negotiation with the GKV (Xiapex, Rasilamlo, Trobalt, Livazo, Yellox, Paragon)
  - Time to access for all medications in Spain has increased in the last year when compared to previous years (75 vs. 50 weeks)
  - Patients only have access to a quarter of medications approved in Spain for products launched in the latest year vs. those launched previously
  - Dramatic access issues for orphan drugs in Spain are highlighted by the fact that patients only have access to a quarter of medications approved
  - Only one orphan drug has completed P&R in Spain between April 2013 and May 2014, taking 106 weeks to complete the process
  - Italian average time to complete P&R is 60 weeks, while average time to be listed in Class C, non with rational reimbursement, is only 18 weeks