

Impact of expedited marketing authorisation on pricing and reimbursement outcomes for drugs in the US and EU-5

Izmirlieva, M¹, Reinaud, F², Ando, G¹

¹IHS Markit, London, United Kingdom, ²IHS Markit, Paris, France

Objectives

A growing number of medicines are approved in the US and EU using at least one expedited pathway, but approval based on more limited clinical data may undermine the ability to achieve successful pricing and reimbursement (P&R) outcomes. This study examines whether expedited-pathway drugs are penalised in terms of price level, length of P&R review and likelihood of being subjected to a risk sharing (RS) scheme.

Methods

Secondary research was conducted to identify products approved for marketing in 2013-2017 under the FDA's Fast Track-designation, Accelerated Review, or Breakthrough Therapy-designation or the EMA's Conditional Approval or Accelerated Assessment procedure. Product launch price, time to pricing, and time to reimbursement were investigated in the US and EU-5, along with the existence of an RS scheme.

Results

A comparison of ex-manufacturer drug prices converted into cost per defined daily dose (DDD) indicates that medicines approved under an expedited pathway are substantially more expensive – as far as list prices are concerned – than those approved for marketing under a standard pathway. Clearly, achieving a higher price for medicines approved under an expedited pathway is not due to the use of an expedited pathway per se. In fact, securing a higher price and being eligible for approval based on an expedited pathway are reflections of the perceived added value that the new product brings compared to existing therapies.

Cost per DDD for branded drugs approved for marketing 2013-2017 in LCU

	US	Germany	UK	France	Italy	Spain
Non-expedited-pathway drugs	277.27	134.30	144.40	79.57	265.35	107.30
Expedited-pathway drugs	1,516.81	447.05	494.01	133.45	454.65	799.45

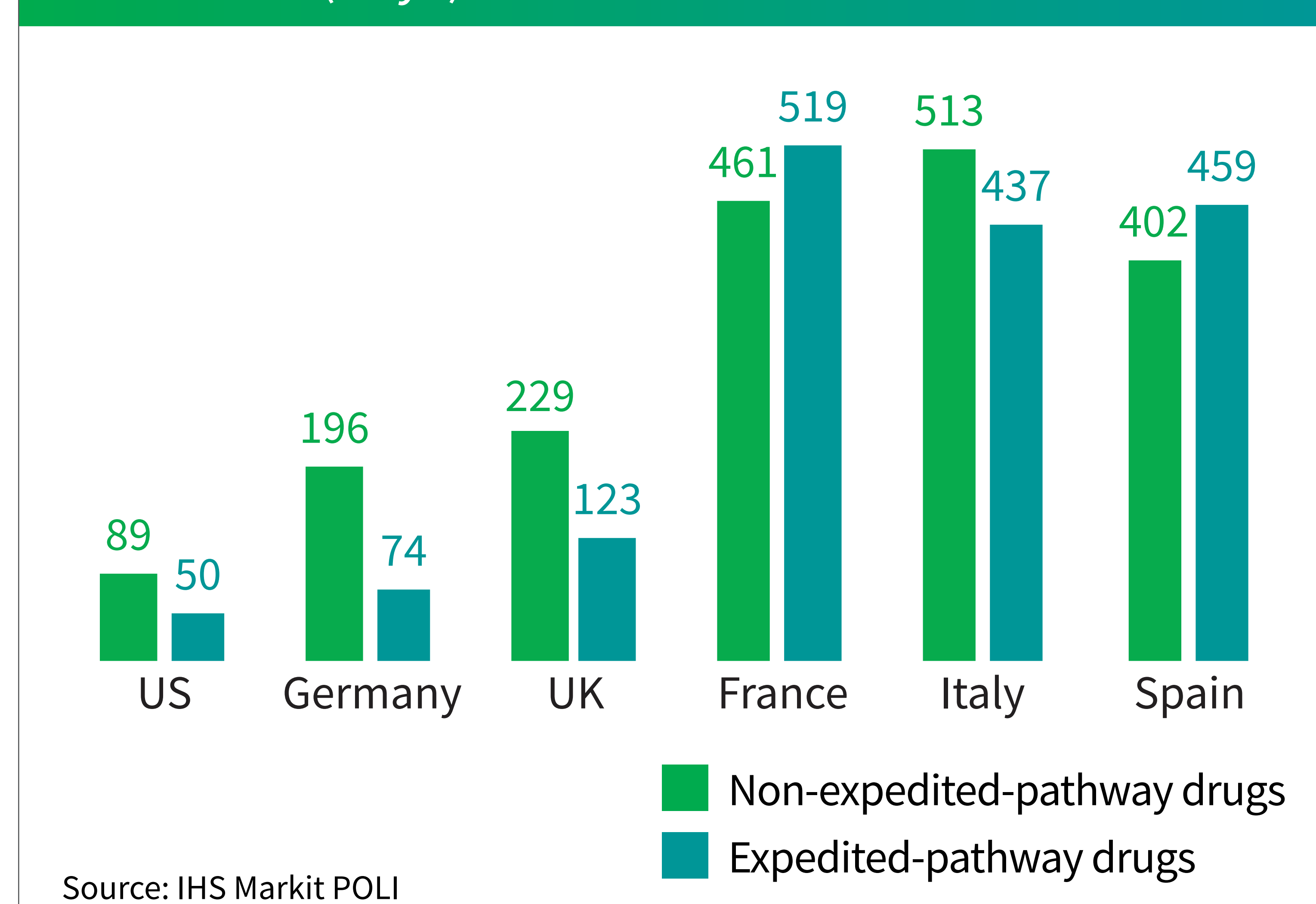
Only medicines for which DDD could be calculated are included in this analysis.

Source: IHS Markit PharmOnline International (POLI)

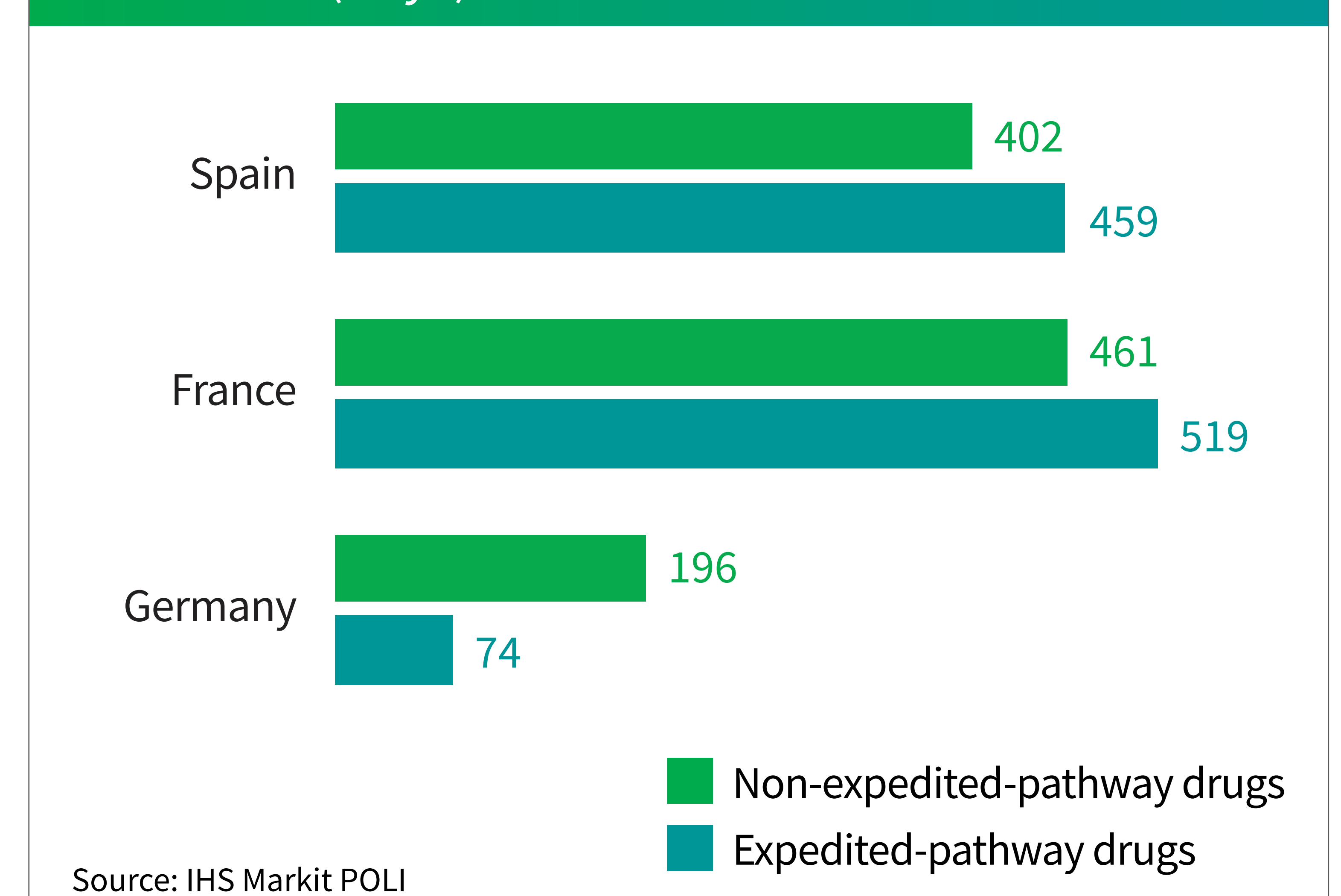
Expedited approval is linked to faster time to pricing. On average, compared to standard-review drugs, expedited-pathway drugs launched 39 days faster in the US, 122 days faster in Germany, 106 days faster in the UK and 76 days faster in Italy, but did not launch faster in France and Spain.

Expedited-pathway drugs took nearly two months longer to secure reimbursement in France and in Spain compared to standard-review drugs. In Germany, they completed the reimbursement process in less than half the time required for standard-review medicines.

Time to pricing for branded drugs approved in 2013-17 (days)



Time to reimbursement for branded drugs approved in 2013-17 (days)



Approval of a medicine using an expedited pathway would be expected to increase the likelihood that such a medicine would be funded under an RS scheme considering approval was based on limited data. As of March 2018, only 3% of the expedited-pathway medicines were subject to an RS in the US, but accounted for 18.4% of all RS agreements in the country. The three medicines subjected to an RS scheme in the US were Viekira Pak (ombitasvir, paritaprevir, ritonavir, dasabuvir), Harvoni (ledipasvir and sofosbuvir), and Entresto (sacubitril and valsartan). Interestingly, 71% of the RS deals for these drugs in the US were performance-based, with only two discount-based RS deals. In the EU, 43% of expedited-review drugs were subject to RS in at least one EU country. As of March 2018, Harvoni was subject to the highest number of RS deals in Europe, including risk shares in Croatia, France, Greece, Italy, Poland, Portugal, and Spain, as well as three separate deals with different counties in Sweden.

Conclusions

Expedited-review drugs are not penalised in terms of list price and reach the market quicker than their standard-review counterparts. However, the P&R review in countries conducting a full assessment before granting a price takes longer than for standard-review drugs, and the likelihood of an RS scheme is relatively high for expedited-review medicines.

Overall, securing approval under an expedited marketing authorisation pathway appears to be well worth it on average, but pharmaceutical companies need to be prepared for a slightly longer P&R review in some markets and for pressure to provide discounts on the list price or enter an outcomes-based arrangement to reduce the risk to payors. However, managing to secure additional clinical data between the marketing authorisation filing and the start of the P&R review or HTA review would help companies minimise the likelihood of unfavourable RS schemes, while also reaping the benefits of early market access.