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HPR69

Comparison of Price Trends for Medicines Pre- and Post-Early Access in Key Markets (France, UK, Australia)

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Objectives

Early access programs provide an opportunity and mechanism for investigational medicines to reach patients outside the clinical setting prior to a formal commercial launch. This analysis compares early access schemes of important markets to gain insight into how prices change after exiting an early access scheme and upon entering the traditional pricing and reimbursement system in three key markets (France, the UK, and Australia).

Methods

Markets were selected based on the presence of an early access scheme with a publicly available list of eligible drugs along with relevant prices and entry/exit dates for their time under the scheme. If a brand entered an early access scheme more than once for further indications, the first entry, exit, and respective price change were considered. When early access scheme entry and exit dates were not provided (Australia) then the first price change of the drug and time to first price change were used as a surrogate.

Results

Across the three markets, a total 41 products were assessed as part of their respective early access schemes. The most dramatic price cuts were seen in France, where products received an average 15.9% cut after exiting the early access scheme. In Australia, products saw a lower reduction in price, of 7.20%. A different trend was seen in the UK, were prices increased by 2.9% after early access. As there is no formal state-controlled price setting process in the UK, this allows for additional flexibility even after a drug has left an early access scheme, compared to other countries where the traditional pricing and reimbursement process typically results in certain price control measures.

In France, reimbursed products either fall under a European price guarantee or are priced at or below equivalent treatments during the traditional price and reimbursement process. A similar scenario of downward pricing pressure occurs for Australia, where reimbursed products will either be priced as part of a cost-plus methodology or reference pricing.

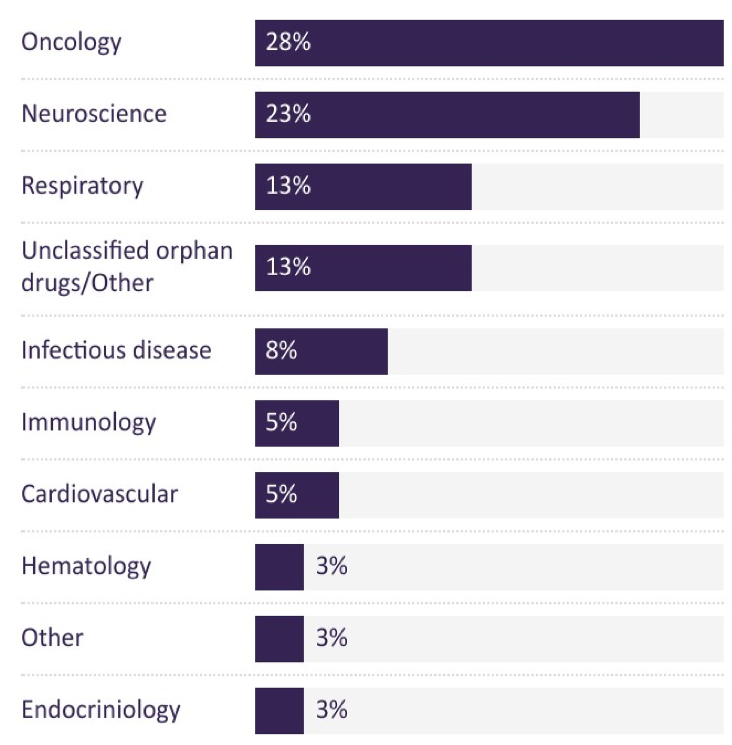
The price a drug receives during early access typically remains fixed until entering the traditional pricing and reimbursement process. The time to this first price change ranged from 6.14 months in the UK to 33.5 months in Australia. In France, early access products were able to maintain their early access price for an average of 20 months before receiving a price cut due to subsequent health technology assessment (HTA) outcomes.

First average price change, and time to price change, for products priced under an early access scheme (France, UK, and Australia)

Country	Average Price Change	Time to Price Change (months)
UK	2.9%	6
France	−15.9%	20
Australia	−7.2%	34

Source: GlobalData

Distribution of medicines under early access programs by therapy area

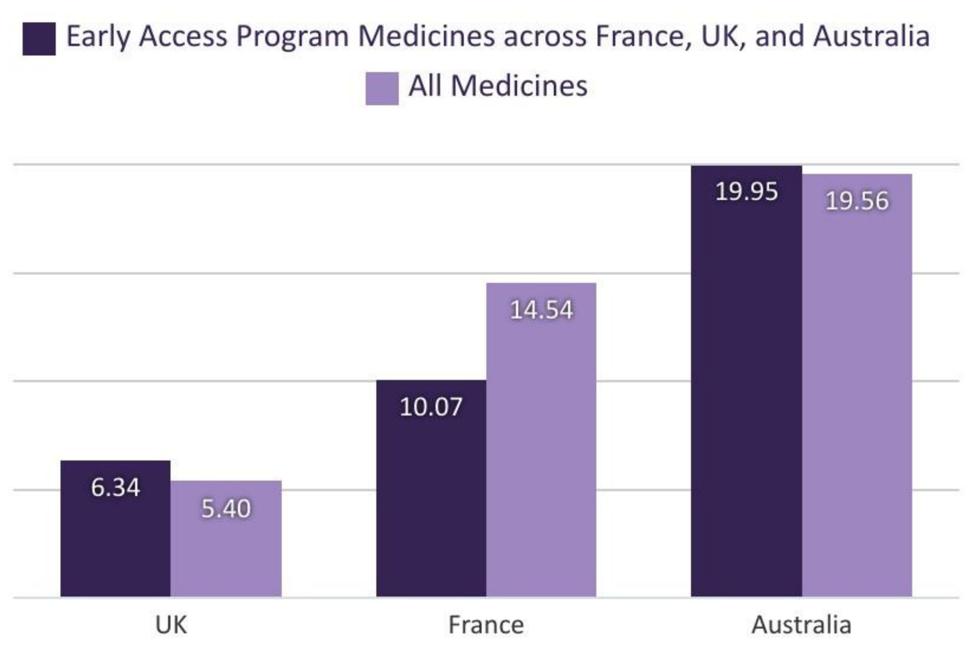


Source: GlobalData

These 41 brands were grouped by therapy area to investigate which indications were most likely to be part of the early access scheme and therefore expect a price change after leaving. The most drugs fell under oncology and neuroscience indications, followed by respiratory.

The average market launch order/sequence of these 41 brands that entered early access schemes was also compared to all medicines. France's ranking in the sequence improved by four places for these products while the UK and Australia saw their ranking move later in the sequence.

Average launch sequence of early access medicines vs. all medicines



Source: GlobalData

Conclusions

Brands that enter the French and Australian markets under early access schemes are likely to see their early access prices reduced within three years while brands in the UK are able to maintain favorable pricing conditions after early access with possible slight price increases. The types of products likely to be included into early access schemes are treatments for oncology and neurological conditions that gain the benefit of reaching patients faster for unmet clinical need while also leveraging more flexible pricing opportunities with possible knock-on effects for international reference pricing (IRP) purposes. This advantage is short-lived across the drug's lifespan, as price cuts in France and Australia are likely to occur after entering the standard price and reimbursement processes of the two countries. Early access schemes aim to improve access to innovative medicines for unmet clinical needs by creating a more favorable market for these drugs. This objective is reflected in the products eligible for early access being more likely to launch in France before other markets as shown in the launch sequence but has less impact on the UK or Australian markets.