Launch sequencing plays a critical role in optimizing the drug market access and revenues. It is critical to achieve market penetration in countries where reimbursement access, healthcare infrastructure, and pricing conditions are ideal for the drug in question. Priorities here can vary significantly according to therapeutic area and secondary/primary care.

The aim of this study was to evaluate how national pricing and reimbursement processes are affecting medicines’ time-to-market (defined as the delay in days between regulatory approval and market launch) and how their evolution over the last 10 years has influenced launch sequences across a sample of 18 developed and emerging markets.

In particular, we were interested to see if the ongoing reforms and austerity measures in critical developed markets such as the United States and Top 5 European markets, coupled with the increasingly attractive demographic and infrastructure developments in emerging markets, is having a tangible shift in prioritization of markets for drug launch.

Clearly, many factors go into launch sequencing strategies that are company-specific – notably where the company has good relationships with local stakeholders and where its higher-level strategies are focused. But we were interested to find overriding trends.

For each market discussed, national pricing and reimbursement processes were studied through primary and secondary research. In each market, these processes were considered from a public versus private sector perspective and from a primary versus secondary-care segment perspective. Meanwhile, to assess evolving launch sequencing trends, time-to-market data were collected in each of the discussed markets for 16 medicines approved for commercialisation between 2000 and 2010.

Our desk research provided extensive data collated from secondary sources including national governmental agencies, national statistics offices, IHS Global Insight Healthcare and Pharmaceutical services (World Markets Healthcare and World Markets Pricing and Reimbursement).

Our primary research consisted of in-depth interviews with key stakeholders, namely policy makers, regulatory affair specialists and industry representatives across 18 key markets as well as 9 interviews with senior industry representatives with extensive experience in planning and executing pharmaceutical launch sequences. Our primary research delved into national opportunities, cross-country market dynamics and corporate strategies.

Medicine launch occurs within weeks of regulatory approval in free-pricing countries and upon completion of pricing and reimbursement negotiations in countries where either the public or both the public and private markets are price-controlled.

Pharmaceutical launch sequences have evolved over the last 10 years, both from a geographic and temporal perspective. Based on our sample of medicines, the time gap between first and second international launch has narrowed from an average of 276 days in 2000 to an average of 57 days in 2010.

Primary-care medicines reach the market faster and in a greater number of countries than secondary-care medicines. Secondary-care medicines remain preferentially commercialised in mature, top-tiers markets unless they meet a medical need in emerging markets.

We examined two case studies in primary and secondary care. In the secondary care setting, the case study demonstrated early launch patterns for the UK, Australia, United States, Denmark and Germany. France saw a major lag of 190 days after the time to market in the UK. In the primary care market, launches in markets such as Mexico, India, Brazil and Russia were broadly comparable with major developed markets such as Germany, France and Spain.

A medicine’s time-to-market varies from country to country and broadly reflects the level of complexity and differentiation of national pricing and reimbursement processes. However, additional factors also come into play, including the level of innovation of the medicine, the national medical need for the medicine, the sector (public versus private) and segment (primary versus secondary care) targeted, and the corporate strategy.

Emerging markets are clearly beginning to play a more critical role in launch sequencing, with markets such as Russia being the first to approve major new drugs such as Gilenya. However, actual launches still occur in priority developed markets in the secondary care settings – the most major advances for emerging markets have been seen in primary care. In drugs approved in 2000, many emerging markets did not even figure in the launch sequence pattern; this has changed significantly in 2010.