

How will UK's new 'Budget Impact Test' Impact Product Launch Planning?

Within the UK pharmaceutical world, the latest buzzword is 'Budget Impact Test'.

Not a practical joke, on April 1st, NHS England has introduced the 'Budget Impact Test', which will determine if the financial impact of a newly introduced medicine exceeds £20million, in any of the first 3 years. What does this mean?

Under the current system, drugs approved as cost effective by NICE are made available by the NHS within 90 days. Under the 'Budget Impact Test', any treatment assumed to cost the NHS more than £20m a year in the first 3 years, NHS England could ask NICE to extend the 90 days to negotiate lower cost of treatment, and phase-in the treatment, making it available only to a limited number of patients.

In fact, NHS can delay access of new pharmaceuticals by as much as 3 years.

What are the consequences for the pharmaceutical industry?

A recent poll by the Association of the British Pharmaceutical Industry suggests that drug firms are expected to prioritize launching medicines in European countries other than the UK¹.

Furthermore, nine out of 10 believe that the changes will mean a decline in patient access to medicines. According to the ABPI, for every 100 patients in Germany, France and Spain prescribed new drugs in the first year, only 17 patients in the UK currently have access.

Currently there are widely conflicting views by NICE, NHS on the one hand, and industry and patient groups on the other, on the impact of the new regulation on the access situation of new medicines.

Even today, the UK is already lagging in "time to access" - it takes 27.6 months in England reach a decision on patient access to rare disease medications, compared to 19.5 months in France, 18.6 months in Italy and almost immediate access in Germany².

If the scenarios expressed by the British Pharmaceutical Industry proof correct, the situation could be even worse in England in the near future – with significant implications for the launch timelines and market penetration expectations pharma companies need to take into account in the UK.

¹ Association of the British Pharmaceutical Industry, News Release, 5/2017

² Office of Health Economics, 'Comparing Access to Orphan Medicinal Products (OMPs) in the United Kingdom and other European countries', 2017