Health technology assessment (HTA) outcomes can make, or break, a product’s fate; depending on the HTA body’s remit, outcome decisions can affect a technology’s reimbursement status or position within a clinical pathway, and/or directly influence the price negotiation process. With such high stakes riding on HTA results, a timely, evidence-based and country-specific approach must be adopted. As an expert agency that partners with pharmaceutical, device and diagnostics companies to deliver effective market access strategies, Hayward Medical Communications reports on how industry can avoid the ‘snakes’ by climbing strategic ‘ladders’ to achieve HTA success.

**Pre-launch considerations**

- In the early stages of a product’s lifecycle, industry can often become absorbed with clinical development activities and assume an island status. Consequently, companies are at risk of becoming isolated and disengaged from early external HTA stakeholders, such as horizon scanning bodies. The Horizon Scanning Research & Intelligence Centre (HSRIC) advises that: ‘Companies need to factor in early discussions with horizon scanning organisations as part of their clinical development plans to ensure their drugs are scheduled into assessment and commissioning cycles. Failure to do so may result in delays to market access.’
  
  **Senior analyst, HSRIC**

- Industry should be encouraged to engage with horizon scanning bodies to stimulate an early, positive dialogue. An independent pharmaceutical adviser explains that: ‘Bids for the introduction of new medicines are informed by horizon scanning bodies, such as UKMi, who help the NHS plan up to two years (or more) ahead.’
  
  **Independent pharmaceutical adviser**

- ‘The materials sent from global rarely meet my country-specific requirements’ – sound familiar? A disconnect between global and in-country affiliates can result in data silos, the creation of global tools that are unfit for purpose and resource inefficiencies, all of which can harm downstream HTA submissions.

- Eighteen to 24 months before a product’s launch is the ideal time to develop a global launch strategy that engages in-country business unit leaders. By sourcing data from pricing and reimbursement market research, an informed launch sequence strategy, price corridor and country-specific tactics can be created.

- All too often, industry stockpiles key evidence as ‘data on file’, which can create gaps in the published literature and a reliance on HTA bodies to accept data classed as commercially confidential. A lack of transparency and access to key data can stifle the review process and increases the risk of rejection of submissions by HTA bodies. A research fellow experienced in conducting systematic reviews for HTAs tells us that: ‘For new drugs or new indications, evidence may understandably be limited; however, in cases where evidence is available, it is often of...’

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**A disconnect between global and in-country affiliates**

**‘Our Company is an island’ mentality**

**Early engagement with horizon scanning bodies**

**Development of an integrated global launch strategy**

**Hoarding data**
variable quality (eg, reporting bias, publication bias). Incomplete, inaccurate, or delayed reporting of medical research may not help decision-making; as such, complete, accurate, balanced and timely peer-reviewed research should therefore be a priority.’ Research fellow, University of Exeter Medical School

- It is critical to combine publication planning, expert medical writing and editorial expertise to produce opportune publication plans. Through timely mapping of peer-reviewed journal and conference targets, a product’s value proposition can be published to create an accessible and robust evidence base, which HTA bodies, and customers, can use to inform decision-making.

**Developing your HTA submission**

- As internal budgets become stretched and timelines get busy, there can be a tendency for industry HTA teams to cut corners and adopt a ‘one size fits all’ strategy. A lack of consideration for country-specific data, financial flows and healthcare structures can leave HTA submissions open to heavy criticism and rejection. The director of a leading health economics institute explains that:

  ‘Every market is different, with different needs. Trying to force the UK-based QALY approach onto decision-makers in, say, France will likely cause confusion and will take focus away from the benefits that the local decision-makers want to see.’ Director, York Health Economics Consortium

- HTA submissions must be populated with market-relevant data; for example, a submission to the Scottish Medicines Consortium (SMC) relies on cost and resource use data being derived from sources such as the Information Services Division Scotland. Industry should derive country-specific data from the literature, through the use of formal consensus methods (eg, Delphi methodology) and/or real-world data capture.

- ‘We can just copy and paste from the regulatory submission, right?’ Wrong. A ‘copy and paste’ approach is likely to result in an inconsistent, error-prone and unclear submission that lacks a strong value proposition. Insight from a former SMC reviewer tells us that: ‘Licensing and HTA agencies have different remits ... for example, licensing prioritises a measurable effect on a marker of disease, whereas HTA emphasises gains in patient quality of life and length of life. These can be very different and even when they are similar, a different story needs to be told about the data.’ Former SMC reviewer

- The empowerment of a dedicated HTA submission team that benefits from market access consultancy, editorial and research specialist input is advised. Through a mixture of de novo writing, quality control checks and the provision of HTA body-specific insight, submissions with a clear and evidence-based value proposition are developed.

**Making the most of your positive HTA outcome**

- After the HTA hurdle has been cleared, complacency can set in. Industry can rely on the positive recommendation to ‘do its work’ and fail to maximise HTA success at a regional or local level.

- Targeted communication activities can be used to maximise a positive national HTA outcome and, importantly, how it may impact healthcare provision. The adaptation of HTA outcomes to create regional and local-level materials is critical to meet the needs of local customers.

**Complacency in the face of a positive HTA outcome**

- Need advice on how to navigate your way to a positive HTA? For further information, please contact Sarah Strachan at sarah.strachan@hayward.co.uk or on 01638 723560.

* To be considered as the individual’s opinion and not that of the quoted affiliation

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