

GNMA10: Policy and public affairs for life science companies

Strategic policy and public affairs activity can shape the environment for your company or product. It will address potential challenges or developments that may have an impact on patient access and make a case to government and policymakers across the UK and Europe on the most critical issues facing life science companies. It is particularly important for small and mid-sized life sciences companies to engage to ensure their voices are heard. A deep understanding of the policy and public affairs environment combined with established relationships with stakeholders and decision-makers ensures opportunities are created and optimised, threats mitigated and minimised and patient access to innovative technologies is accelerated.

A policy and public affairs activity programme can include thought leadership; strategic engagement and planning; identifying the key stakeholders and prioritising the most influential and relevant; understanding the policy landscape and stakeholder environment; developing accessible, audience-specific messaging and materials; supporting engagement through drafting briefings and follow-up; ongoing monitoring of parliamentary, policy and stakeholder developments; research and evidence generation and collaborative policy development.

The policy environment

The UK health policy environment is undergoing a significant period of change, with further developments on the horizon such as senior staff changes at the National Institute of Health and Care Excellence (NICE) and NHS England and NHS Improvement (NHS&I), the passage of the Health and Care Bill, the establishment of the Innovative Medicines Fund and implementation of the new NICE programme manual, Life Sciences Vision, Innovation Strategy, and the UK Rare Disease Action Plans. These policy changes sit within a landscape of recovery from the COVID-19 pandemic, continued economic pressures, affordability challenges and a government focused on maximising opportunities in a post-EU environment.

Identifying key stakeholders

Individual parliamentarians and policymakers are highly influential. Each nation has its own processes, ambitions, and priorities and as such, identifying networks, nation specific stakeholders and their influence is critical for consistent engagement. Stakeholder mapping is a useful tool to prioritise outreach. Ranking stakeholders by their influence and interest creates a hierarchy of priority and helps focus engagement on the most influential stakeholders. When engaging and targeting stakeholders, it is imperative to maintain good relationships and build trust and goodwill to promote your policy objectives. The development of effective messaging materials can support constructive discussions with key policymakers and parliamentarians to help raise awareness of your challenge and ensure the discussion is fruitful. Ongoing strategic advice can be provided to implement an engagement strategy that is fit for purpose and provide ongoing advice on new opportunities, post-engagement follow up and recommendations on maintaining long-term relationships.

Policy analysis

Environmental and situational analysis maps the current landscape for hooks in existing or new policies that could support messaging and leverage engagement opportunities. Multiple sources are reviewed to identify the key policy and stakeholder dynamics affecting the market, including patient pathways, commissioning routes, policy landscape and trends, therapy area developments, review of parliamentary activity and patient group activities. These developments are assessed in the context of the technology and therapy area to keep abreast of relevant discussions and themes that align with your brand and corporate objectives. High-level recommendations are made to support activity in the health policy environment.

Opportunities and barriers

Further policy analysis can be conducted using a Political, Economic, Social and Technological (PEST) analysis. PEST analyses can support future strategic planning by identifying opportunities and threats that can be planned for and carefully managed to mitigate against external risks and optimise opportunities. It can also highlight macro-level scanning to gather evidence which can be used to test existing strategies and ensure future strategic plans are fit for purpose, whilst maintaining an objective view of the environment.

The role of coalition in driving policy change

Collaborating with stakeholders, where there are areas of alignment, can accelerate policy change and help move the discussion beyond a particular product or disease area and strengthens the message. A coalition can highlight systematic issues and avoids duplication as stakeholders can lend their support to overarching messages outside any specific engagement they might be undertaking individually. Whilst participating in coalition groups, close dialogue should be maintained with other stakeholders that are campaigning on similar issues to ensure alignment. In 2019, a report *Access to Medicines: A Case for Change* was published following work undertaken through a MAP-led collaboration. A Steering Group was formed, consisting of seven life science companies with an interest in access to innovative treatments for rare conditions and who shared concerns regarding the 'gap' between the Single Technology Appraisal (STA) and Highly Specialised Technology (HST) programmes and its impact on patient access. Treatments for rare conditions referred to NICE's STA programme faced significant barriers which hindered timely access to new treatments. The report and subsequent engagement led to:

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- One national and six pharmaceutical sector items of news coverage, including priority placement on major pharmaceutical news websites
- Eight mentions in Parliament, through questions, debates, Select Committee sessions and All-Party Parliamentary Group (APPG) meetings including active reference to our report by NICE's then Chief Executive, Sir Andrew Dillon and NHS England's Director of Specialised Commissioning, John Stewart
- At least eight references to our report in independent stakeholder documents, including consultation submissions, briefing documents, website pages and reports
- Meetings or teleconferences with 12 key stakeholders and decision-makers about the report, with 13 health charities, and eight Parliamentarians participating in a collaborative event in Parliament
- Recognition that there should be flexibilities in for orphan medicines assessed via the STA programme to address the uncertainties which are inherent when assessing treatments for rare conditions

The collaborative approach was successful in driving policy change, and helped to re-set the narrative on orphan medicines, alongside a greater focus on orphan medicines from leading industry groups such as the Association of British Pharmaceutical Industry (ABPI).

Conclusion

In the context of the ever-changing health policy environment, an effective policy and public affairs programme is essential to address potential challenges or developments that may have an impact on patient access now or in the future.

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