

Measuring and Demonstrating the Value and Impact of Policy Shaping

Policy Perceptions Research Report
August 2, 2021



Executive Summary

One of the most common challenges repeatedly voiced by Policy Wisdom's clients is how to translate the successes of the policy function into a meaningful, quantitative value to the business.

To examine the value placed on policy-shaping efforts as one of the strategic approaches to drive market access and business impact, Policy Wisdom conducted in-depth interviews with ten high-level policy executives from eight multinational pharmaceutical companies.

Key findings from the research indicated that, although companies are increasingly recognizing the impact of policy-shaping efforts and giving them a more prominent role, there is still a need for consistent measures that reflect the unique value and broad impact of policy shaping to demonstrate to internal stakeholders that investment in policy-shaping activities can have a desirable impact on the company's business objectives and reputation, and benefit to patients and society.

Utilizing the insights gathered, Policy Wisdom developed a Policy Value Framework and accompanying set of Policy Key Performance Indicators (PKPIs) designed to measure and demonstrate the impact of policy efforts pursued by staff and teams in policy, government affairs, public affairs, or access departments.

Background

As developers of solutions for health policy challenges, Policy Wisdom has worked with more than 60 partners on more than 450 projects covering more than 40 therapeutic areas in 152 countries. Over the last 11 years, we have supported policy leaders at the global, regional, and national levels to align understanding of what health policy is and *isn't* and to build capacity within their teams to engage in policy-shaping activities.

Concurrently, the external environment has rapidly evolved in response to trends in innovation, cost-containment measures, payment models, health system sustainability and, needless to say, the COVID-19 pandemic. This re-shaping of the external environment has expanded the role of strategic policy shaping across all phases of the product lifecycle and amplified its business importance.

Yet, one critical piece of the puzzle has remained elusive for our clients — how to consistently quantify, measure and demonstrate the impact of health policy shaping on business goals.

To better understand why this gap persists, we assessed the perceptions of high-level policy executives on the value their companies place on policy shaping as one of the strategic approaches to drive market access and business impact.

This report and its recommendations can be utilized to support making the case for investment in policy shaping and ensuring that policy has a seat at the corporate decision-making table.

Methodology

Individual telephone interviews were conducted with ten high-level policy executives from eight multinational pharmaceutical companies, who provided a global perspective on the issue. The eight participating companies were:



A ten-question survey was utilized (see Appendix for questionnaire), covering the following topics:

- Making the case for investment in policy shaping
- Role and impact of policy shaping throughout the product lifecycle
- Measures to demonstrate the impact of policy shaping
- Key contributing factors for engaging in policy-shaping
- Value placed on policy shaping as a strategy to deliver market access and business impact
- Value, level of impact to the business and return on investment of regulatory vs health policies
- Preferred timing and level (global/regional/national) to implement policy-shaping activities
- Concepts of broad and sustainable access and their relation to policy shaping
- Company hesitation to invest in policy shaping

Participants were asked to consider their responses in the context of sales, marketing, and policy as the three main business strategies employed within the pharmaceutical industry.

Key Findings

The participants' views were aligned that, although companies are increasingly recognizing the impact of policy-shaping efforts and giving it a more prominent role, a set of clear, consistent measures reflecting the unique value and broad impact of policy shaping is needed to demonstrate to internal stakeholders that investment in policy-shaping activities can have a desirable impact on the company's business objectives, reputation, and patient and societal benefits.

Furthermore, there was consensus that regulatory as well as health policies provide a high return on investment (ROI) for the company. Views on which of these types of policies have the highest ROI were evenly split.

Participants also agreed that policy shaping has a role to play throughout the product lifecycle. However, there is a lack of clear understanding of the opportunities to enhance access through policy shaping during the 'less prominent' stages of the lifecycle. There are additional untapped opportunities to shape policies beyond the 'typical' pre-launch and launch stages during which policy-shaping activities are most often implemented.

The following paragraphs outline the key insights revealed through the research.

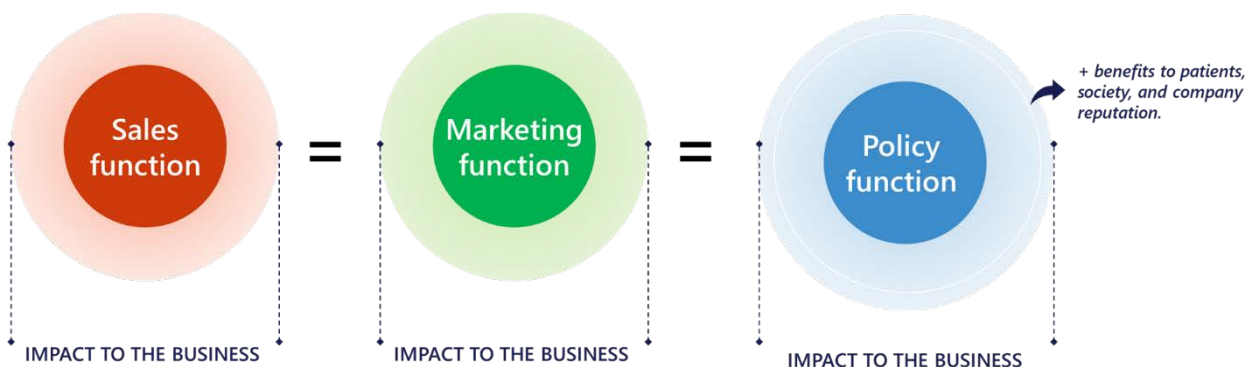
Making the case for investing in policy shaping

The policy function is relatively new compared to sales and marketing; however, it has grown in importance since the early 2000s as a larger percentage of the population is receiving their health care from government sources and the necessary health system evolution requires impactful policy changes.

All participants mentioned that '*achieving broad and sustainable access*' was the basis of efforts to invest in policy-shaping activities. Interviewees agreed that measuring the business impact of policy

shaping in an objective and clear manner, while elusive across the industry, is also essential to gain increased investment in policy shaping.

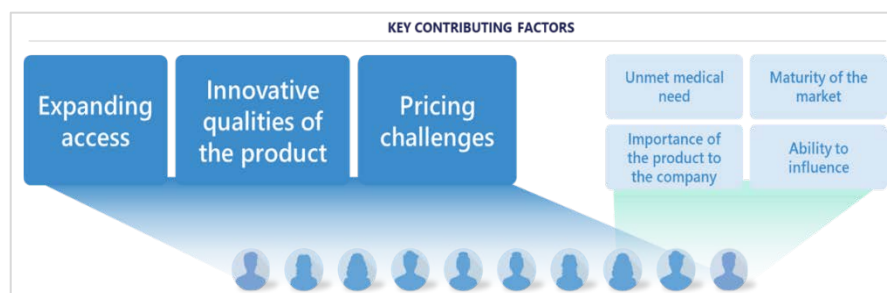
Thus, there is a need for a solution to prove that the policy function delivers the same level of impact as its counterparts — perhaps even on a deeper and broader scale — considering the benefit it brings to patients, society, and company reputation.



Key contributing factors for engaging in policy shaping

There is a general recognition across pharmaceutical companies that engaging in policy shaping is undoubtedly impactful to the business; however, the key factors that drive engagement in policy shaping are not always clear.

The contributing factors that participants mentioned most frequently were expanding access, the innovative qualities of the product, and pricing challenges, and they assigned equal weight to these three factors.



Several additional contributing factors were mentioned:

- Unmet medical need
- Maturity of the market
- Importance of the product to the company

- Ability to influence

Measures utilized to demonstrate the impact of policy shaping

It is not surprising that there are no quantitative and clear measures broadly used by companies to measure the impact of policy shaping efforts.

The research findings demonstrate that the types of methods and metrics used to measure the impact of policy shaping vary across companies. The participants unanimously agreed that demonstrating impact is a challenging topic. They also expressed a desire to measure impact in a more quantitative and standardized way.

Interviewees mentioned examples of measures that companies currently use to demonstrate the impact of their policy-shaping activities: focus groups, surveys, KOL relationships, speaking engagements at congresses and symposia, performance indicators, and country scorecards designed to measure outcomes against priorities.

Role and impact of policy shaping during the different stages of the product life cycle

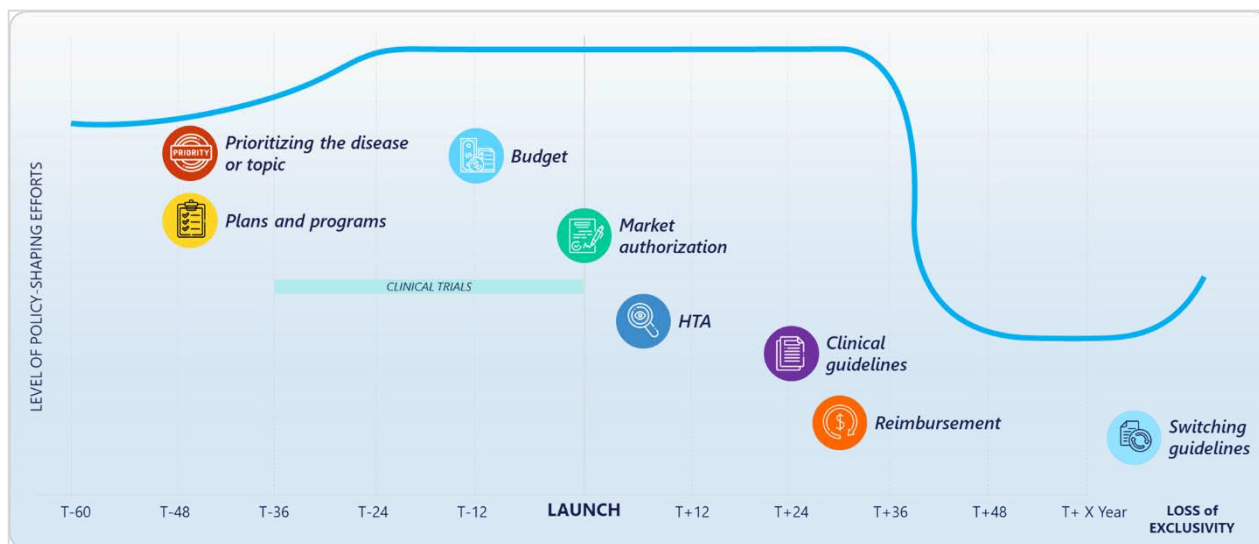
Since policy shaping activities are most often carried out in preparation for the launch of a product or in response to complex issues impacting the industry, companies naturally have a higher degree of experience and comfort when engaging in policy shaping efforts during these times. However, there is a lack of clear understanding of the opportunities to enhance access through policy shaping during the 'less prominent' stages of the lifecycle. This perception was, to a large extent, confirmed by the interviewees.

There was consensus among the interviewees that the role and impact of policy shaping changes throughout the product life cycle and can depend on both internal and external dynamics.

Participants felt that policy shaping has a clearer and more impactful role at three key stages of the product lifecycle:

- at the beginning, when shaping the environment will ultimately allow for commercialization of the product; and
- during launch, when maximizing access to the product; and
- as the product approaches loss of exclusivity.

The role and impact of policy shaping during the middle of the product lifecycle is viewed as less relevant, primarily because there is not as much clarity on what can be done during that period.



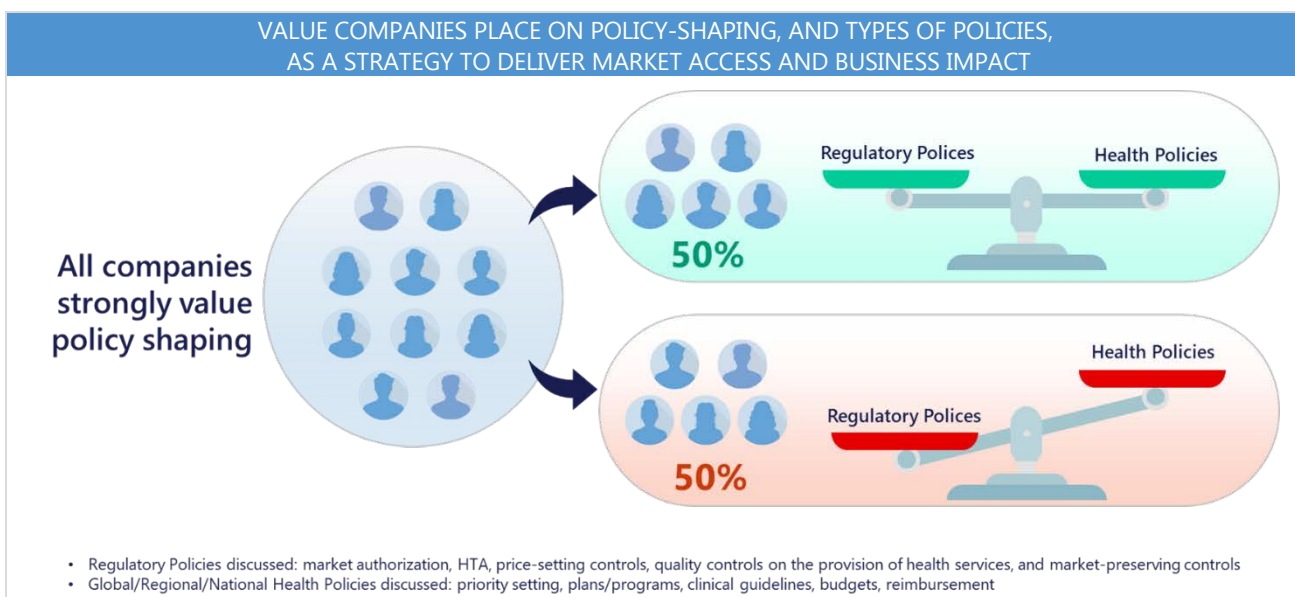
Value companies place on policy-shaping

The value companies place on a particular business strategy or function is reflected in the level of investment and resources dedicated to it which, in turn, impacts the potential for success. Companies need to 'walk the walk' and fully demonstrate their commitment to effectively engage in policy shaping activities.

All participants felt that their respective companies strongly value policy shaping as a strategy to deliver market access and business impact, and that health policies have gained and continue to gain more importance over time. Some participants mentioned that the policy function is not adequately resourced and that this can undermine the full impact that policy has the potential to deliver.

Types of policies most valued to deliver business impact

The respondents' views were divided on which types of policies are more valued — half indicating that regulatory and health policies are equally important and the other half prioritizing regulatory policies over health policies.

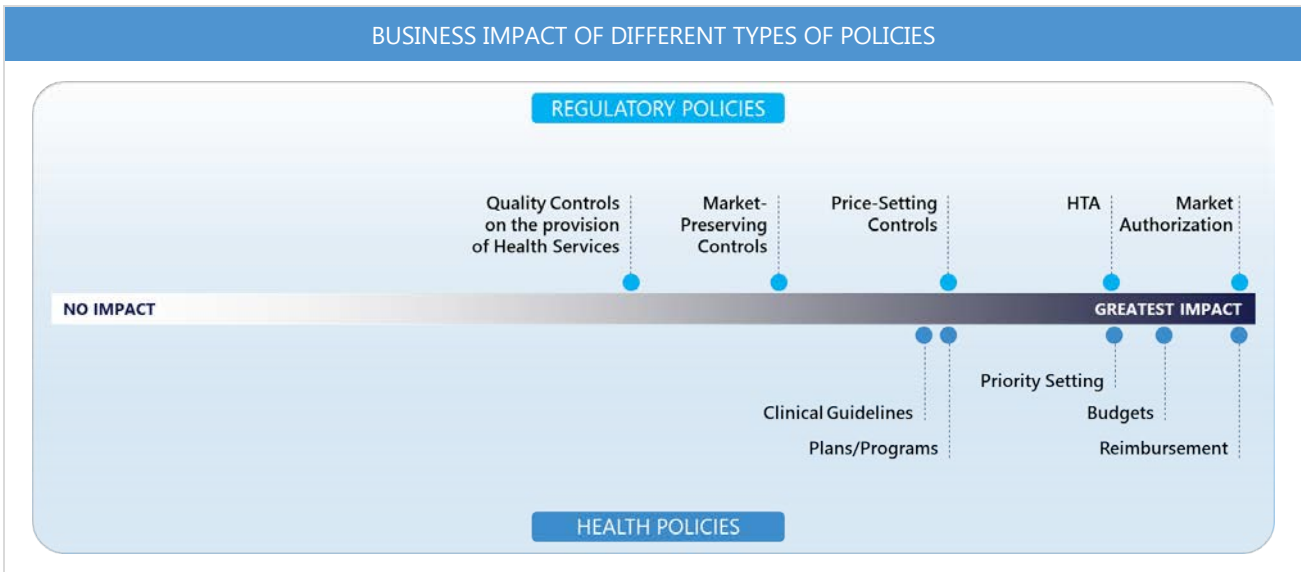


Business impact and return on investment of policy shaping

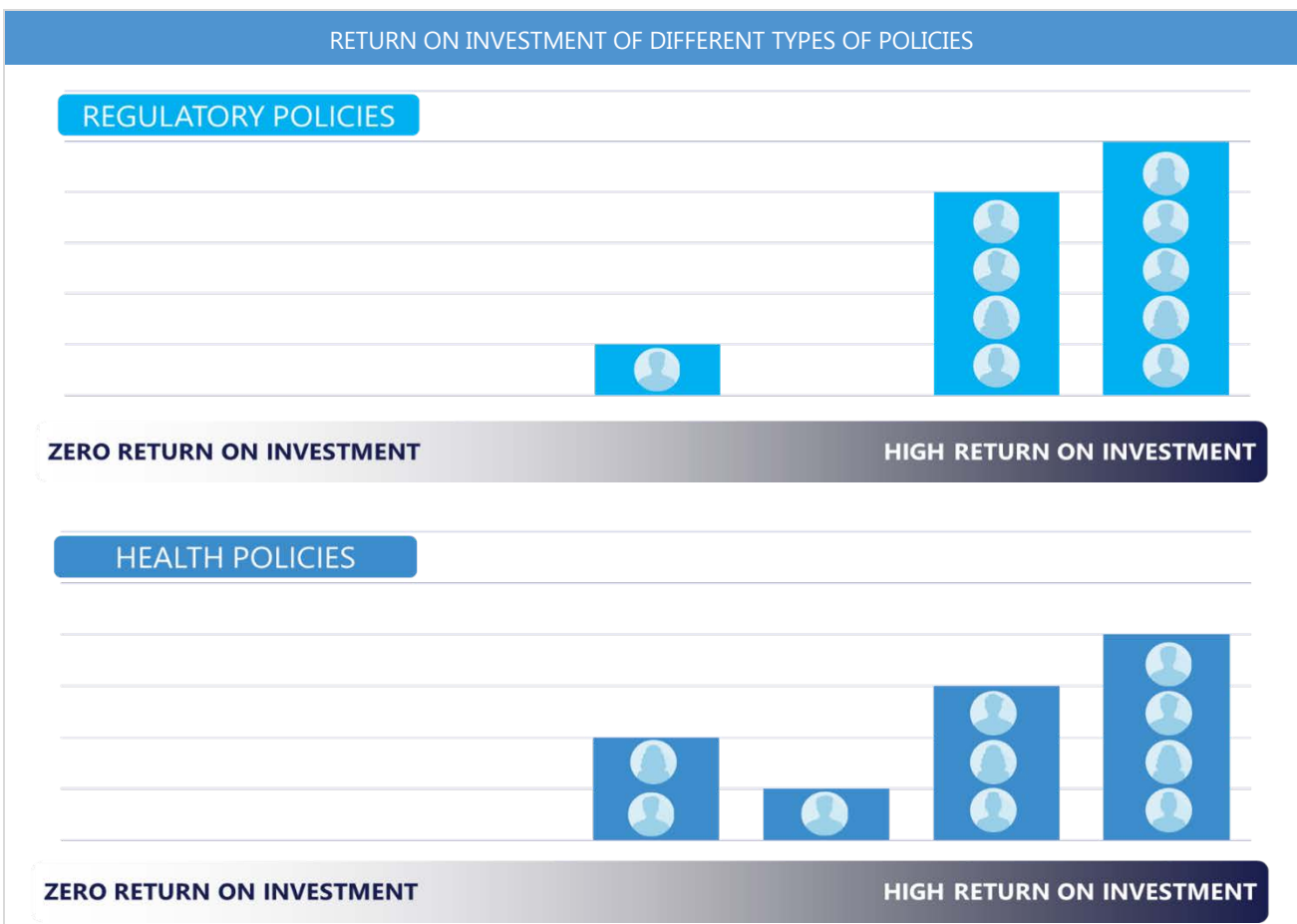
Return on investment is an essential method to assess where resources are assigned if one wants to run a successful business. Functions such as sales and marketing that are able to show a very quick return on investment are given recognition and a greater level of resources. Policy often does not receive the same credit and recognition as other functions not only because it delivers longer-term results, but also because, thus far, its value has been very difficult to demonstrate.

It's not surprising to see that the policies considered to have the greatest impact are those that overcome the biggest barriers: market authorization and reimbursement.

The policies that promote a more positive environment and facilitate implementation and uptake are ranked higher than the policies that only tangentially impact the product.



When looking at the ROI by type of policy, we see that regulatory policies were reported to provide a slightly higher return than health policies, but both are considered to have significant impact to the business.



Company hesitation to invest in policy-shaping activities

Hesitation to invest in policy-shaping activities stems from the typical business mindset where results can be presented at the end of each year. Clearly, the policy strategy does not fit within that mindset since it is a medium-term strategy. Therefore, policy measurements need to account for the milestones that demonstrate advances in achieving the desired policy goals.

Furthermore, respondents saw the opportunity to demonstrate that policy shaping can go beyond sales and marketing in terms of building relationships that can be beneficial when faced with crises that can negatively affect company or industry reputation.

Timing of policy shaping activities

Timing of policy-shaping efforts is critical. If started too early, we risk inconsistency in government commitment. If started too late, there is a risk that corresponding programs and budgets may not yet be in place at the time of launch.



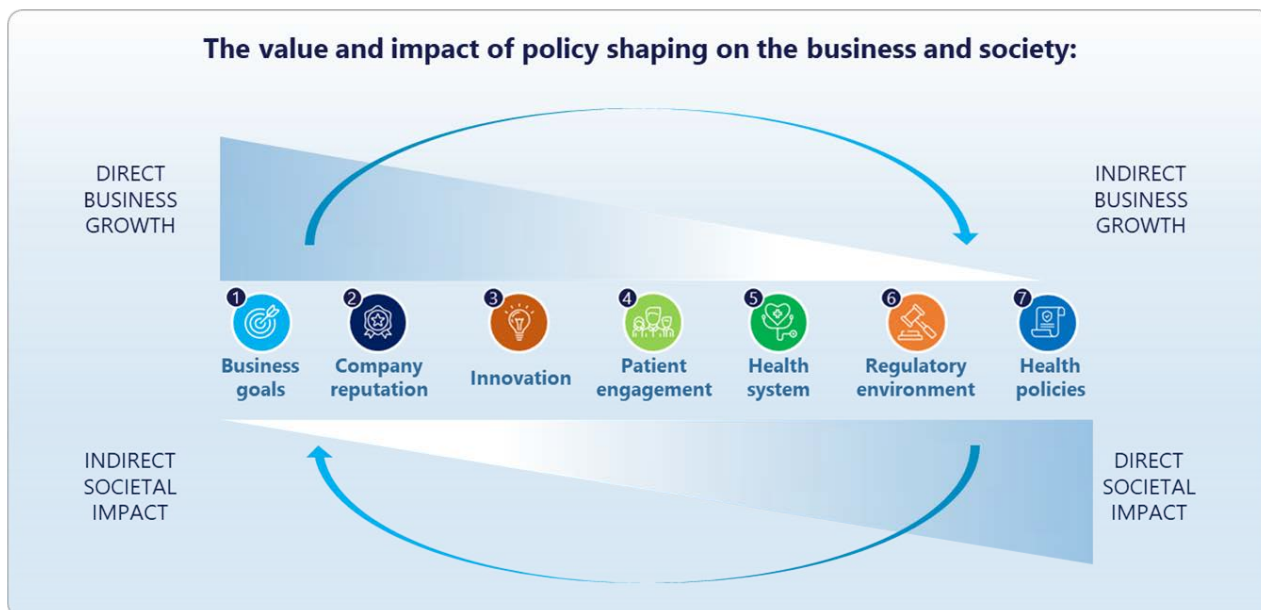
There was alignment among participants that health policy and regulatory policy shaping activities should start 24-30 and 24 months prior to launch, respectively.

Recommendations

The results of our policy perceptions research demonstrate a great need for a methodological, quantitative approach to measuring the value that policy shaping brings to the business. Put simply: the c-suite does not know how to best measure or value the work that the policy function executes on a daily, monthly, or yearly basis.

Policy Wisdom’s health policy experts have developed a value framework for policy shaping efforts and an accompanying set of KPIs specifically designed to measure the impact of those efforts — we call these ‘Policy Key Performance Indicators’ (PKPIs).

The value framework for policy shaping is rooted in the concept that policy shaping efforts can be organized into seven categories and plotted across the continuum from business to society. The efforts carried out within these categories influence each other and impact both the business and society in direct or indirect ways, depending on where they lie on the continuum.



In summary, using this value framework and the seven categories required for business growth and societal impact, the Policy Key Performance Indicators can measure the impact of policy efforts pursued by staff and teams in policy, government affairs, public affairs, or access departments. Furthermore, these seven categories can help companies strategically plan their policy shaping work and develop the strategies in which they will engage.

The PKPIs can be weighted to reflect business objectives, implemented as part of performance review processes, used to demonstrate the true value of strategic policy efforts, and even to support requests for policy-related resources. Additionally, Policy Wisdom can customize the PKPIs to appropriately reflect the broader business and non-business-related objectives of the company.

1 Business Goals
1. Increase in number of doses sold to the government after country makes a given TA a priority
2. Increase in sales after inclusion of drug in clinical guidelines
3. Increase in market share after clinical guidelines inclusion
4. Revenue growth after clinical guidelines inclusion
5. Increase in government sales after government reimbursement is granted
6. Increase in market share after reimbursement granted
7. Revenue growth after reimbursement granted
8. Reduction in time (months) to get market authorization if policy shaping activities were performed
9. Closeness to price expectations if HTA policy shaping was performed
10. Improve gross profit margin after larger government purchases
11. Time (days) between inclusion in clinical guidelines and reimbursement authorization as compared to time for reimbursement without clinical guidelines inclusion
12. Inclusion in national essential medicines list when aligned with company strategy
13. Reduction in cost per unit produced after policies reflected larger government purchases

2 Company Reputation
14. Net policy promoter score (NPPS) ¹
15. Access to Medicines Index improvement over prior year
16. Share of Voice among policymakers ²
17. Unprompted brand recall among policy makers ³
18. Contract intent ⁴
19. Brand Equity after active engagement in policy shaping efforts and partnerships ⁵
20. Policy Sentiment Analysis ⁶
21. Increase in public-private partnerships with the intention of improving the health system
22. Calls or requests from policy makers to get the company opinion on a given issue (trusted partner)
23. Invitations to speak or contribute to government sponsored/driven policy events

3 Innovation
24. Company research for new products is aligned with health needs
25. Company able to increase number of drugs in portfolio that are publicly reimbursed through evidence of additional value/benefits of innovation
26. Company influences the establishment of a country strategy for innovation
27. Company performs systematic engagement of stakeholders on the issue of innovation
28. Company stimulates the availability of dedicated financial resources to evaluate and adopt innovations
29. Company proposes IP policies conducive to innovation
30. Company proposes increased focus on value-based healthcare and outcomes-based payment
31. Company proposes flexible and innovative pricing schemes
32. Company reverses trend of external reference pricing and price controls
33. Company has and shares with stakeholders its transparency requirements in clinical trials data
34. Company proposes using evidence to prioritize purchasing decisions and price
35. Company engages in efforts to ensure purchase commitments and volume guarantees
36. Company proposes patient-driven regulatory framework
37. Company uses and share reliable methods for measuring the value of innovation to the health system
38. Company ensures equitable access to medicines where they are needed

¹ How likely is a policy maker to define your company as a partner for improved health to his/her fellow policy makers?

² Social listening of policy issues among policy makers and influencers

³ The first pharmaceutical brand that comes to mind as a partner to strengthen policies that generate health equity among policy makers.

⁴ Based on the policy work with government, how are government contracts for your products increasing/improving?

⁵ Brand Strength = (Contract Intent + NPPS) x 100

⁶ Percentage of company social media posts addressing policy issues in relation of all company posts.

 Patient Engagement	 Health Systems	 Policy and Regulatory Environment	 Health Policies
39. Share of Voice among patient organizations ⁷	47. Increased funding for health after policy shaping efforts	56. Reduction in time (months) to get market authorization if policy shaping activities were performed	65. Priority setting—TA or issue becoming a priority after policy shaping efforts
40. Unprompted brand recall among patient organizations ⁸	48. Increased funding for a therapeutic category after policy shaping efforts	57. Success in accelerated pathway based on company strategy	66. Priority Setting—Increased funding for a therapeutic category after policy shaping efforts
41. Ranking of company reputation for providing positive patient experiences ⁹	49. Improvements in health care quality after policy shaping efforts	58. Increase opportunities for stakeholders, including industry, to present their views during the HTA process	67. Priority Setting—Increase in access to preventive care after therapeutic category is made a priority
42. Patient organizations' policy shaping actions aligned with company position	50. Improvements in access after policy shaping efforts	59. Once opportunities are available, company views presented and influencing final result of HTA	68. Priority Setting—Increase in access to diagnostic tests after therapeutic category is made a priority
43. Increased inclusion of patient voice on company decisions	51. Increased patient engagement across the continuum of care	60. Closeness to desired indications if HTA policy shaping was performed	69. Priority Setting—Increase in access to population screening after therapeutic category is made a priority
44. Integration of patient perspectives in key company processes	52. Integrated patient care pathways	61. Closeness to price expectations if HTA policy shaping was performed	70. Priority Setting—Increase in access to treatment after therapeutic category is made a priority
45. Increase opportunities for stakeholders, including patient perspectives, to present their views during the HTA process	53. Reduction of wait lists after policy shaping efforts	62. Calls or requests from regulators to get the company opinion on a given issue (trusted partner)	71. Priority Setting—Increase in access to cure after therapeutic category is made a priority
46. Company engages in Patient Assistance Programs and Access Solutions	54. Improvement in geographical access after policy shaping efforts	63. Interchangeability/ substitution of drugs prevented.	72. Plans/programs—Inclusion or raised profile of the TA/issue in national plans after policy shaping activities
	55. Improvements in equity after policy shaping efforts	64. Unfavorable regulatory barriers addressed and/or negative regulations prevented.	73. Plans/programs—Creation or expansion of programs to address the TA after policy shaping activities
			74. Clinical guidelines—Inclusion of specific drugs/treatments in clinical guidelines after policy shaping activities
			75. Budgets—increase in budgets for treatments after policy shaping efforts
			76. Budgets—increase in budgets for treatments after inclusion in clinical guidelines
			77. Budgets –increase in sales of drugs after expanded budget
			78. Reimbursement -- Market share after reimbursement granted
			79. Reimbursement -- Sales growth from pre to post reimbursement authorization
			80. ROI of policy shaping activities ¹⁰
			81. Increase in the number of private insurance companies adopting public health system policies (ie. clinical guidelines, reimbursement, etc)
			82. Reimbursement continues after drug loses exclusivity with minimal price erosion
			83. Switching policies evolve to recognize the benefits of continuity of treatment and patient trust in treatment

⁷ Social listening of policy issues among patient organizations.

⁸ The first pharmaceutical brand that comes to mind as a partner to strengthen policies that generate health equity among patient organizations.

⁹ PATIENTVIEW-PRESS-RELEASE-The-Corporate-Reputation-of-Pharma-in-2020-during-the-Covid-Pandemic-Global-edition.pdf (patient-view.com)

¹⁰ Net Income attributable to policy shaping efforts/Cost of policy shaping efforts.

Appendix

Interview Questionnaire

1. When considering the three overarching strategic approaches -- sales, marketing, and policy -- how do you 'make the case' for investing in policy shaping?
2. Do you think that the role and impact of policy shaping is similar during the different stages of the product life cycle? If not, can you elaborate on the differences?
3. How do you demonstrate the impact of policy shaping? Which measures do you use?
- 3a. What are the key contributing factors for engaging in policy-shaping (i.e., maturity of market, innovative qualities of the product, degree of reimbursement for the disease)?
4. How strongly do you feel that the company values policy shaping as a strategy to deliver market access and business impact?
5. Do you feel that the company values one category of policy over the other (i.e., regulatory policies over health policies or vice versa)?
6. Which of these policies do you feel have greater business impact?
 - Regulatory Policies*
 - Market authorization
 - HTA
 - Price-setting controls
 - Quality controls on the provision of health services
 - Market-preserving controls
 - Global/Regional/National Health Policies*
 - Priority setting
 - Plans/programs
 - Clinical guidelines
 - Budgets
 - Reimbursement
7. If we take a closer look at the policies that you ranked as having the greatest business impact, can you specify the preferred timing for initiating policy-shaping activities and at which level (global/regional/national) these activities should be performed?
8. In your experience, when it comes to shaping the policy landscape for optimal business impact, have you found investment in regulatory or health policy-shaping activities to have a greater return on investment?
9. Do you ever use the concepts of broad and sustainable access to explain the value of policy-shaping activities?
10. Does your company have any hesitations regarding investing in policy-shaping activities? If yes, why do you think that is?