"What is the value and return on investment for our company to maintain a regulatory policy function?"

In June 2019, the Centre for Innovation in Regulatory Science (CIRS) held an Executive Colloquium in Rockville, MD, USA that brought together representatives from multinational pharmaceutical companies to gauge their experiences and plans with regards to measuring the value and return on investment of a regulatory policy function to the broader organisation.

BACKGROUND

Regulatory professionals collaborate with internal and external partners to develop policy positions and engage with policymakers and health authorities to develop approaches to advance innovation through regulatory science. Indeed, through discussions with its member pharmaceutical companies, a question has emerged that many regulatory policy professionals get challenged with "What is the value and return on investment for our company to maintain a regulatory policy function?".

The challenge of measuring value in an organisation is not new, nevertheless some of the measures that have been developed tend to be financial and short-term in nature. The question that remains is how to capture an organisation's less tangible assets such as advocacy, strategy and knowledge, which are pertinent to those working in a regulatory policy organisation. From the point of view of those who conduct this work, the answer may seem straightforward, but there appears to be a need to identify and more clearly communicate this to senior management as well as to illustrate the short- and long-term impact of policy activities and deliverables.

Recognising the importance of this question, CIRS organised an Executive Colloquium with the following objectives:

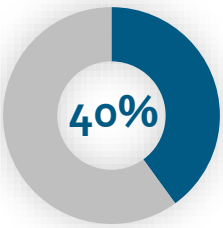
- Discuss the evolving role of Regulatory policy company professionals, the challenges and opportunities
- Identify indicators regulatory policy functions have in place to demonstrate their value to the organisation
- Discuss additional metrics that could be used to continue demonstrating the growing importance and the return on investment of such functions in the future.

KEY POINTS – POLICY GROUP CHARACTERISTICS

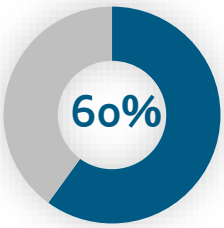
As part of the June 2019 Colloquium held in Rockville, MD, USA, CIRS undertook a short survey across participants (Regulatory Policy/Intelligence functions at Senior Manager/Director/VP level) from the following 10 companies: Abbvie, Amgen, AstraZeneca, Bayer, Leo, Merck, J&J, Sanofi, Pfizer, Vertex.

***6- 20 individuals was the size range of Regulatory Policy Groups**, and these were most-commonly organised as part of a global Regulatory Affairs (RA) organisation, jointly with Regulatory Intelligence.*

The objectives and goals of the regulatory policy group are set at the global level as part of the overall RA scorecard, but taking into consideration regional as well as commercial/business priorities.



***Only 40% participants responded that their policy group had a formal set of indicators** in place to demonstrate the value of the policy function to the organisation.*



The goal setting is primarily done annually with the team and approved by leadership. **60% companies provide a periodic report** (mainly quarterly or half yearly) to Senior Leadership against the goals.

There was divergence across participants as well as an indication that there is room for improvement in terms of the perception of Senior Leadership on the value of the policy role to the organisation. Average perception score was 3.8 out of 5 (range 3-5)*.

* 1=senior management has no clue how my Policy organisation contributes to the efficiency and effectiveness of my Company AND 5=senior management understands and highly values the role my Policy organisation plays for my Company.

KEY POINTS - EXAMPLES OF ORGANISATIONAL INDICATORS

Meeting participants suggested and discussed short and long-term impact indicators to demonstrate the value of a policy function to the company:

Suggested indicators to demonstrate the value of a policy function

Outputs/activities of the policy group

- # of comments to health authorities on topics and guidances and regulations – provided and accepted/integrated
- # of publications as well as citations, quotes, downloads and invitations to present research
- Monthly reports, conference/meeting summaries

Supporting financial goals of the organisation (ROI)

- Decrease in regulatory hurdles to derail a development program – potential to reduce attrition and development costs

Enabling changes to the external environment

- # of representatives on trade association working groups
- # of meetings with health authorities and their feedback
- Implementation of changes by health authorities
- Case studies, media coverage based on input/changes

Supporting internal company activities

- Degree of application of disseminated knowledge e.g. use in meetings
- Input on R&D development plan
- # of questions received by policy group from internal project teams
- # of advice updates given to organisation on business priorities
- Relating to regulatory intelligence – tracking queries
- Scorecard feedback from reg function and the wider organisation

KEY POINTS – MUTUALLY SUPPORTIVE ENVIRONMENT

Finally, as the role of the policy organisation is to foster and maintain a mutually supportive environment (for companies, agencies and patients), the company representatives also discussed how this could be addressed at the product level but also by supporting different organisations, where similar indicators could apply

- **Industry-wide initiatives** – meeting participants discussed the importance of groups such as PhRMA and BIO, which maintain good engagement and representation across companies, as well as linkages with major regulatory agencies such as the FDA. The challenges highlighted were the capabilities and efficiency of such organisations to deliver change.

- **Change agents –** in this case, organisations such as Transcelerate as well as patient groups such as Friends of Cancer Research are recognized for a good level of engagement as well as focused interest, noting though that participation in such activities can be resource intensive on the sponsor, and particularly for therapy-area specific patient groups, the focus may be narrow.

CONCLUSION

Regulatory policy groups across companies differ in size and structure, but face a common challenge of demonstrating their value to the wider organisation. Participants at a recent CIRS Executive Colloquium described possible indicators that could be used to achieve this based on the group's activities and deliverables. Although establishing whether a deliverable from a regulatory policy group impacted on a financial measure or enabled some wider business objective is difficult, one proposed way to assess this impact may be with a "customer" survey to obtain feedback both from the regulatory organisation as well as the wider company. Such a survey could evaluate the various indicators of relevance, efficiency, effectiveness, impact and sustainability of the policy group and could be used to improve deliverables and shape future offerings of policy groups.

In addition, participants discussed the importance of setting expected change *goals* and communicating those across the organisation as well as demonstrating the *outcomes* against those and conveying them, for example through specific case studies. There is also a need to better emphasise the transferability of policy knowledge and successes across therapeutic areas and therefore demonstrate its wide value to the company.

REFERENCES

The following two publications were sent to the participants as a pre-read: 1. SCRIP Regulatory Affairs. (2015). Measuring the value of a pharmaceutical company's regulatory intelligence function. UK: Informa UK Ltd.
2. Weyrauch, V. (2012). Toolkit N°3: Design/Establishing the pillars of M&E strategy. In: How to monitor and evaluate policy influence? Buenos Aires: CIPPEC.

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