How can regulatory policy functions in pharmaceutical companies measure their value and impact?

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BACKGROUND

Regulatory policy professionals collaborate with internal and external partners to engage with stakeholders to develop approaches to advance innovation through regulatory science. Indeed, through discussions with 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?”

Recognising the importance of this question, a meeting was organised by CIRS in June 2019 and a short survey undertaken to identify and describe common metrics that can be considered by regulatory policy groups to demonstrate what value their activities and deliverables add to a pharmaceutical company's business.

OBJECTIVES

- Appraise the evolving role of regulatory policy company professionals
- Identify short- and long-term indicators that regulatory policy functions have in place to demonstrate their value to the wider organisation
- Propose what additional indicators could be used in the future.

METHOD

Discussions from a meeting held in June 2019 in Rockville, USA with ten major international pharmaceutical companies were analysed, as well as results from a survey undertaken across the meeting participants (Regulatory Policy/Intelligence functions at Manager/Director/VP level).

RESULTS

The following findings were identified from across the ten pharmaceutical companies

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.

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.

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.

There was divergence 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.

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

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 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

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

Suggested indicators to demonstrate the value of a policy function

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. Here, similar indicators could apply and this could be done at the product level within each company but also by supporting different organisations– industry-wide initiatives or other change agents like patient groups.

CONCLUSION

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.