Non-promotional scientific communication: Reducing risk through improved ways of working

Kinapse Consulting, 2012

Advise • Build • Operate

www.kinapse.com
Non-promotional scientific communication between pharmaceutical companies and their customers is vital for product development and commercialisation, and for patient benefit as a whole. Focusing on the issues which most impact R&D and/or Medical Affairs executives, this paper discusses the complexity of non-promotional scientific communication, its benefits and risks, and steps that companies can take to optimise their approach in this area.

We conclude that an optimal approach requires a cross-company attitude of compliance and risk sensitivity, supported by more detailed guidelines and training in areas of highest risk.

External communications can be promotional or non-promotional

Effective communication with external stakeholders is a critical success factor for any major pharmaceutical company, and is a significant and increasingly important role for the majority of its employees. The industry has for some time been moving away from simple one-to-one relationships between sales reps and their assigned physicians to a many-to-many system where multiple company functions need to communicate with multiple external stakeholder groups. This more complex communication network has become difficult to visualise and govern.

An external party with whom a company is communicating is certainly not responsible for (and generally not interested in) whether a communication is promotional or not. However, it is extremely important to make this distinction internally so that execution is aligned with the intent, and thereby compliant with laws and regulations to avoid misuse of a medicine.

Promotion is defined by the World Health Organisation as ‘all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal products’, and may occur only after marketing authorisation is granted. Promotion comes under the accountability of the Commercial department. Promotion is therefore legitimate and is necessary in a competitive commercial environment, but there are good reasons to ensure that promotional and non-promotional activities are clearly separated and subject to specific governance, policies and processes.

Other types of external communication are less simple to define and are often referred to collectively as ‘nonpromotional’ activities. These communications may be scientific and complex such as congress presentations or nonscientific such as press releases for investors and analysts. They may be governed by a variety of functions depending on their nature or purpose, including R&D / Medical Affairs, Government Affairs, External Communications and others.

Non-promotional scientific communication is the focus of this paper.

![Figure 1: Comparing the complexity of promotional and non-promotional communication activities](image-url)
Defining non-promotional scientific communication by its constituent activities

Non-promotional scientific communication with external stakeholders focuses on clinical and scientific matters of mutual interest. These interactions are usually two-way but not always, conference presentations and scientific papers being notable exceptions. These interactions will occur both before and after product launch and are typically the accountability of R&D and/or Medical Affairs.

There are a number of common industry activities that can constitute non-promotional scientific communication; the key activities are listed in Figure 2. An additional complexity is that, as shown in the diagram, some activities can be used for both promotional and non-promotional purposes. The intent must be clearly defined in advance and made transparent to any external parties in these cases.

Figure 2: Key non-promotional scientific communication activities. Dual shaded arrows indicate activities that can be of either promotional or non-promotional nature. This intent must be clearly established and documented in the planning stages of the activity and subsequent actions must be consistent with this intent.
Benefits and risks of non-promotional scientific communication

Non-promotional scientific communication between the pharmaceutical industry and the external medical and scientific community is vital because it:

• Ensures that medicines are developed in an appropriate fashion to meet the needs of patients and physicians.
• Advances scientific understanding of disease, including disease management and treatment outcomes, through peer dialogue.

In simple terms, the primary purpose of these interactions for pharmaceutical companies is to understand what physicians, regulators, payers and patients need. This enables companies to focus on delivering medicines to meet those needs with robust evidence on efficacy, safety, quality and value. It is also valuable to the external community for pharmaceutical companies to share and discuss their data in order to advance scientific understanding and patient care as a whole.

This is not without risk. For pharmaceutical companies, the biggest risk of non-promotional scientific communication is the potential for it to become promotional or for it to be perceived to be promotional. This has happened deliberately through non-compliant pre-launch sales practices in the past, but it may also occur inadvertently. Inappropriate promotion can lead to use of products off-label, risking harm to patients, wasted healthcare spending and injurious consequences to the company’s reputation and revenues.

It is important that these risks are understood and managed appropriately by companies to ensure that they do not become compliance issues.

A comment on digital media

A separate complexity that organisations need to consider in communicating externally is the increasing use and audience expectation of digital media as a vehicle to share scientific material. Digital communication has several advantages: it allows immediate sharing of information, it can be easily updated, it is typically easy to access and use, it can be interactive, and it is an increasingly popular medium with physicians and patients. However, this area must be carefully managed. Thirdparty websites vary greatly in quality and may mix scientific and marketing messages. There is a risk that they simplify scientific messages or do not communicate a balanced picture, with risks to both the message and compliance.

Further, companies can be held responsible for the actions of individual employees, even on public sites such as Twitter and Facebook. Very clear employee guidance is therefore required to ensure no discussion of company products or services takes place on personal social media accounts.
The cost of contravention

It is clear now that fines can and should no longer be considered a cost of doing business for the pharmaceutical industry, as some commentators claimed in the past. Between 2009 and 2010, 11 companies were fined a total of over $6 billion by the US government for improper practices. All of the top 5 global companies by income were fined, including Pfizer’s then-record fine of $2.3 billion. Nine of these cases related to inappropriate marketing, most commonly off-label promotion. It should be noted that many of these serious breaches were for historical contraventions that should now not be possible due to changes in procedures including those introduced through adherence to Corporate Integrity Agreements.

Processes alone are not enough

All external communication activities must follow clearly understood processes to ensure robust governance. In some cases, such as approval and distribution of promotional materials, strong processes and SOPs are sufficient. However, non-promotional communications, particularly those of a scientific nature, cannot be governed entirely by process – the understanding and informed judgement of people involved is fundamental. This is primarily due to the dynamic nature of communications, and the consequent impossibility of developing industry-wide definitions and guidelines similar to those that exist for promotion (for example: the term ‘Medical Education’ is often used in some countries for promotional meetings in addition to education focused on improving a physician’s ability to provide high quality patient care). For the same reasons, national laws also do not provide detailed direction on what is legally acceptable in every case.

Additionally, while pre-launch promotion is illegal, there is also risk that non-promotional industry practices will be seen by outside observers to have promotional intent. Fine medical judgement, aided by clear company-wide guiding principles, is required both pre- and post-launch to ensure that approval decisions are consistent across the company and are justifiable to company executives and the outside world. These decisions must be adequately documented to ensure this justification can be given.

It is therefore important for companies to have a strong and consistently understood risk-based policy and to support their decision makers in order to minimise the risks of non-promotional scientific communication.

Optimise the company-wide approach

External communications are increasingly founded on many to many relationships, as multiple functions including Regulatory, Market Access, Medical Affairs and multiple commercial groups need to interface with physicians, patients, policy makers and payers across many countries. This level of complexity adds to the risk of missteps or misunderstandings. This can be particularly challenging at the local level, where in-country Medical Affairs staff often need to broker the flow of information between multiple regional and global company functions and multiple customer groups, while keeping both local regulations and company policies in mind. It is therefore important to build a company-wide mindset, underpinned by clearly understood supporting processes and infrastructure. Again, processes are not enough on their own. Instead, the operating model must be considered in its entirety, as outlined in Figure 3.

In our view, optimising non-promotional scientific communication across an organisation in the long term is a cultural matter, requiring strong leadership from board level. While a company culture takes time to develop and embed, strong organisational and process boundaries can accelerate the process and minimise risk of inappropriate promotion in the short term. Training is a key success factor for implementation; it should focus on ensuring that all key personnel have an understanding of their role with respect to scientific communications, are equipped with the skills to detect and manage risk appropriately and are aware of escalation and support routes available to them.
As an overall principle, we believe that non-promotional communication activities should be the accountability of Medical Affairs. This accountability should be reflected in organisation structure, budgetary control and approval responsibility. For example, Medical Science Liaisons are non-promotional roles that should report to R&D or Medical Affairs and not to Commercial as is sometimes the case. This does not impugn the importance of Commercial groups in communication activities, but reinforces accountabilities and strengthens ownership of nonpromotional and promotional activities. A key strength of the Medical Affairs function is that it is not the re to sell. It is also the best placed function to understand stakeholders and integrate their scientific information needs. In the context of non-promotional activities, Medical Affairs is therefore in an ideal position to:

- Focus on effective external scientific communications.
- Make medical decisions that are demonstrably not driven by commercial imperatives.
- Ensure firewalls exist between promotional and non-promotional activities in terms of processes and individuals’ responsibilities.

These key advantages help ensure that external stakeholders do not perceive activities to be inappropriate promotion.

One caveat to this division of activities is that Medical Affairs and Commercial must still be able to talk to each other. Although not all information can be shared (discussions on off-label topics are an obvious example), customer insights are vital in Medical Affairs and Commercial planning and neither group will hold the complete picture for any customer. It is also important that messages to external customers are consistent and present a ‘single face’ of the company as much as possible. In some cases, we have observed that organisations can become so risk averse that collaboration almost ceases, with detrimental effects for both the company and its customers. Specific interface points in planning processes and in customer management must therefore be established to avoid a blackout in cross-functional collaboration.

Company strategy and culture

What cross-company values should all externally-facing employees hold and work towards?

- Will there be one way of working globally, or regional differences based on local practice?
- Is everything that we do in the interests of patients, in line with our mission?
- How do we want to be perceived by our external customers - meeting regulations only, or proactively take an industry-leading position?

<table>
<thead>
<tr>
<th>Processes</th>
<th>Organisation Architecture</th>
<th>Information Architecture</th>
<th>HR &amp; Performance</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Are processes for approval of non-promotional activities clearly defined?</td>
<td>• Are accountabilities and budget holders appropriate?</td>
<td>• Do we have the required tools e.g. to store documents, approvals?</td>
<td>• Do we have the required resources and staff competencies?</td>
</tr>
<tr>
<td>• Are vendors and alliance partners aware of our approach?</td>
<td>• Are individual roles and responsibilities appropriate and clear in each region?</td>
<td>• Are system firewalls in place that separate non-promotional and promotional processes?</td>
<td>• Do we have appropriate training?</td>
</tr>
<tr>
<td>• How is customer feedback captured and used for continuous improvement?</td>
<td>• Are reference groups available to advise on complex issues?</td>
<td></td>
<td>• Do we reward success in non-promotional activities?</td>
</tr>
</tbody>
</table>

Figure 3: Key operating model considerations for non-promotional scientific communication
### Address the high-risk activities

Given current perceptions of the pharmaceutical industry, particularly in the public and media, there is always a risk that industry activities will be seen to have promotional intent. It is incumbent on companies to ensure they not only do the right thing, but are seen to be doing the right thing.

In order to see where risks of perceived promotion lie and to mitigate against them it is necessary to consider the drivers of risk, such as the audience, timing and communicator. Example considerations include:

- **Product status**: Communication on new indications for a licensed product carries a higher risk of perceived off-label promotion than work on an entirely new product.
- **Timing**: The peri-launch period is higher risk than Phase II, as a much larger volume of data will be shared at this time, many more questions will be asked by external stakeholders and there is a strong commercial incentive to promote the product to maximise launch success.
- **Communicator on behalf of the company**: Sales reps are higher risk than MSLs, who are arguably in turn higher risk than an external investigator.

Particularly where risks are greatest, company guidelines and strong processes can reduce the risk that external communication activities are perceived to be promotional. For example, a company may choose to not conduct company-sponsored symposia in a therapy area related to a new indication prior to launch, in case this is seen to be encouraging off-label discussion.

Internal communications should also be considered as part of a culture of risk sensitivity and appropriate communication. These communications, including emails, should be written with the consideration that they might one day need to be shared with the outside world as proof of intent.

### Develop tools for successful risk-based management

Non-promotional scientific communication is both a key governance issue and a key commercial success factor for pharmaceutical companies. It has relevance to a company’s scientific credibility, innovation, product development and commercialisation, and external customer relationships.

We believe that there are four key tools that companies must design and implement effectively in order to manage their non-promotional scientific communications in the best possible way:

- An agreed and communicated understanding of non-promotional scientific communication including definitions of its constituent activities.
- Company guidelines on non-promotional scientific communication, including global and regional standards and avenues for gaining advice and escalating issues.
- Clear roles and responsibilities with respect to non-promotional scientific communication activities, including accountability of Medical Affairs and involvement of Commercial groups.
- Training for global, regional and local staff to clarify guidance and establish clear expectations and ensure consistency of approach within the organisation.
About Kinapse

Kinapse provides consulting and outsourcing services to life sciences organisations. Our mission statement is: ‘Collaborating with our clients to innovate for exceptional results’. Kinapse clients include many of the world’s leading pharmaceutical, biotechnology, medical device and specialty pharmaceutical companies, government organisations and life sciences service providers. Our key advantages are:

- Focus on the life sciences industries
- Deep industry experience and technical acumen
- Successful history of project delivery and repeat business

Authors: Neil Croft and Matthew McLoughlin

Neil is a Manager at Kinapse Consulting. He has a special interest in organisation and process improvement in Medical Affairs and Clinical Development.

Matthew is a Vice President at Kinapse Consulting, and works extensively with Medical Affairs organisations in global pharmaceutical companies.

For more information contact Neil Croft at: neil.croft@kinapse.com