

## **Section 3 (i)**

## **Stakeholders**

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**It takes years to build trust and a good reputation/image, and seconds to ruin it**

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The communication of information plays a strategic role within the medicines regulatory environment. Effective communication supports the development of positive relationships with the stakeholder community and can also be utilised to influence attitudes and behaviours within the wider environment.

This document focuses exclusively on the stakeholder community and the considerations when developing communication strategies for this grouping.

In order to develop an effective communication strategy we must examine the 'stakeholder' under a number of headings:

- **Who are our stakeholders?**
- **Why do we need to communicate with them?**
- **What do we wish to communicate with our stakeholder(s)?**
- **When should we communicate?**
- **What are the best mechanisms for effective communication?**
- **Challenges to effective communication?**

### **1. Who are our stakeholders?**

A stakeholder may be defined as an individual or group that can influence, or be influenced by the agency's actions.

The principal stakeholder groupings for a medicines regulatory agency are the general public, health care professionals, the pharmaceutical industry, national government, other regulators within the EU/EMEA/EC, other non-EU regulators, media together with colleagues (internal communication)

Stakeholder analysis is an important element in the establishment of a communications strategy. In order to communicate effectively we need to clearly identify what we want to say, whom we wish to convey the information to and what action we wish to result from the communication. As medicines regulators we are required to present information that is accurate, meaningful and actionable to a very varied audience – and this is the issue that presents the greatest challenge to the regulatory agency(s).

In order to develop a comprehensive strategy it is important to acknowledge the differences between the various stakeholders and ensure that communication is appropriate to the grouping(s) involved in the communication.

Different stakeholders require different considerations:-

**Pharmaceutical industry**

- Timing
- Confidentiality
- Commercial Sensitivity
- Stock Market

**Patient groups**

- Language, clarity, concise, non-sensational, non-trivial
- Relevant to audience
- Timing
- Actions clearly defined
- Contacts provided
- Follow-up by NCA/regulatory agency

**General public**

- Language, clarity, concise, non-sensational, non-trivial
- Timing
- Actions clearly defined
- Contacts provided

**Health care professionals**

- Target accurately identified
- Timely access
- Clear recommendations for action;
- Contacts provided
- Follow-up by NCA/regulatory agency

**Other regulators within the EU/EMEA/EC**

- Confidentiality assured
- Pre-publication discussion
- Agreed timeline for discussion; agreement and action
- Co-ordinated response
- HCP documentation coordinated and agreed

**Other non-EU regulators**

- Confidentiality agreements
- Information sharing pre-action

**National government**

- Accurate information
- Meaningful language
- Contextual; background information

**Media**

- Effective media relations are an essential aspect of the communications activities of any organisation dealing with issues of social or political interest, especially in high-profile areas such as

public health. It is important to acknowledge the importance of relationships with the media and identifying the most appropriate methods of harnessing the power of the media to support the message being conveyed by the regulator. An organisation with an active media relations policy aligned with its communications strategy can at least hope to derive some benefits rather than simply ignoring or underestimating the power of the media.

#### **Colleagues (internal communication)**

- Confidentiality
- Relevant colleagues involved in pre-action discussion
- CHMP;CVMP;COMP; MRCG; PHVP involvement
- Clear understanding of issue
- Consistent message from the organisation
- Circulation/notification of information

## **2. Why do we need to communicate?**

Protection of public health is the basis for all communication with stakeholders. Whether the information being conveyed is pertinent to the urgent recall of a faulty product or the sharing of new prescribing information – both situations are grounded in the regulators key function as a protector of public health.

Information and effective communication can assist in the development of a good relationship between the regulatory network and its environment, and may also assist in influencing the wider environment by informing and changing attitudes in the various target groups. The HMA has a particular role in strengthening the profile of the regulatory agencies group as a legitimate source of quality information.

Other important reasons to communicate include the development of trust, social responsibility, market transparency and professional ethics all of which support the overall goal of protecting public health.

Changes in society and technology have brought about new mechanisms to access information on medicines and medical treatment. Society is generally more informed on health matters and the consumer has become more active in treatment and medication planning. This concept of concordance is a growing concept in the world of medical treatment and will result in a greater demand for quality information.

It is appropriate therefore that the regulatory agencies responsible for the licensing and safety monitoring of medicinal products be actively involved in the dissemination of information with regard to medicines. The principle of ‘trust’ should be established and stakeholders should feel confident that the regulator is the appropriate source of up-to-date, quality information.

Establishing trust and confidence is not a trivial concept. The regulatory network must be proactive in its approach to stakeholder management and communication. The first step to this approach is the establishment of an appropriate strategy.

New legislation focussing on improved access and transparency is also a key driver to developing policies in this area. The regulatory framework must now embrace a wider stakeholder grouping than heretofore. Many bodies within the regulatory network will be required to review their existing arrangements with a view to introducing a more holistic method of communicating with interested parties. Agencies will be required to replace

traditional views of ‘need to know’ basis with a more open and transparent approach. This approach must recognise the right of individuals/organisations to accurate, meaningful and helpful information in respect of medication or treatment.

The combined effect of these changes brings new challenges to the business of medicines regulation. Changes are not limited to dealings outside the regulatory network. Good communication plays a vital role in the licensing and post-licensing activities of the entire regulatory community. Information sharing across the regulatory community has become the lifeblood of decision-making and the resulting communication with the wider stakeholder grouping.

It is essential that a framework for effective communication between the regulatory parties is designed and adopted by all parties within the community. This framework would form the basis for all inter-regulatory communication and would be the agreed basis for all information sharing and dissemination. In the past failures to communicate effectively have contributed to delays in taking action; frustration on the part of both regulators and public, combined with a lack of availability of good quality information.

Consistency and timing can be addressed across the regulatory network through the establishment of formal agreements, for example, confidentiality and mutual agreements in the context of an agreed framework for communication with all parties.

In summary the reasons for communication with stakeholders are:-

- Protection of public health through:-
- Rapid communication of appropriate, quality information to a clearly identified audience
- Information sharing – ‘Information is power’
- Informed decision making
- Creating awareness about the role of the regulator
- Influencing the regulatory and wider environment
- Improved relationship with stakeholders
- Role as ‘quality information’ provider

**A strategic planning process can be summarised as follows:**

- Analysing the situation: Defining the information problem
- Strategy: Planning
- Implementation: Action and communication
- Assessment: Evaluation

**Strategic Approach for dealing with Stakeholders:**

- Improved stakeholders consultation to provide input into the planning and policymaking of the agency as necessary. The purpose of this approach is to be more proactive and to anticipate stakeholder issues
- Making plans and activities in a cooperative framework between the agency and its stakeholders, thereby minimising the gap of legitimacy for the agency’s policies, decisions and actions
- Knowing the needs and wishes of stakeholders before selecting the methods for communication.
- Establishing a dialogue with the stakeholders to ensure the regulatory agency is aware of issues of importance to the stakeholders.
- Making the affected stakeholders (i e patient organisation) aware of the agency’s policies and decisions through the consultative process, and offering them the opportunity to ask questions and give their opinion

- Avoiding dialog about issues in the media, whereby journalists have the ability to “stage manage” the situation
- Building networks and alliances as a basis for trust and effective flow of information to and from the target groups.

### 3. What information do we wish to communicate with our stakeholder(s)?

Aristotle told us, in 350 B.C., '***if communication is to change behaviour, it must be grounded in the desires and interests of the receivers...***' and it is this realisation that is visualised in the new era of openness and transparency in the medicines regulation arena.

In order to ensure that we are communicating successfully, we must examine the stakeholder considerations and design our communication content and mechanisms accordingly.

A matrix that supports the classification of communications within the regulatory network is provided in Figure 1.

A selection of specific communication mechanisms might be:

- Rapid Alerts (Pharmacovigilance)
- Rapid Alerts (Quality Defects)
- Product Recalls
- Press Releases / ‘Question & Answer’ Documents
- Agreed ‘Dear Doctor’ wording
- Media briefings/interviews
- Newsletters
- Annual Reports
- Letters/emails to stakeholders
- Interactive Web Based Information
- Meetings
- Shared information within the organisation (all of the above)

**Figure 1**

	General Information	Specific Information	Commercially Sensitive Information	Health Care Professional – Information	Regulatory Sensitive Data
<b>General Public</b>	√				
<b>Patient Groups</b>		√			
<b>Pharmaceutical Industry</b>			√	√	
<b>Regulatory Network – EU partners</b>			√		√
<b>Regulatory Network - Non-EU</b>				√	√
<b>Health Care Professionals</b>				√	
<b>National Government</b>		√			√
<b>Internal</b>	√	√	√	√	√

<b>Organisation</b>					
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#### **4. When should we communicate with our stakeholders?**

Communication timing can be loosely broken down into: -

- Proactive Communication
- Reactive Communication

This topic is a subject for another group (Germany, Portugal and Norway) and is not addressed within this document.

#### **5. What are the most appropriate mechanisms for effective communication?**

A communication model that supports a number of mechanisms for sharing and disseminating information is the most appropriate in the regulatory environment.

Communication methods are strategically linked to the target audience and it is essential to recognise the differences between stakeholders and the way in which they receive or access information. In identifying the most appropriate method it is worthwhile noting that whatever mode is selected it should facilitate two-way communication.

Timeliness is one of the principal goals embodied within all communication strategies and the method chosen must support this goal. Advances in modern technology now provide opportunities to reach large numbers of people rapidly. This has significant advantages and should be routinely utilised, where appropriate. The establishment of a confidential network (EudraNet) across the European regulatory community is also a significant advance and agencies should build its usage into their communication policy.

A number of the current mechanisms used to communicate with stakeholders are listed hereunder:

- Formal and informal dialogue e.g. meetings with or without a report
- Structured meetings e.g. EU working groups; CHMP; PhVGWP
- General media
- Public Relations Consultants
- Professional media
- Professional groups
- Email; Eudralink; EudraNet
- Workshops or information days
- Mail Shot
- Facsimile
- Web Site(s)
- Workshops and Open Days
- Radio/Television
- Video presentations
- Lectures
- Surveys

#### **6. Challenges to effective communication?**

We exist in a growing regulatory environment made up of many partners e.g. EMEA, EC, EU, FDA. Managing the regulatory relationship is complex. Decisions are more regularly reached through a centralised process and this process can in itself make effective and

timely communication difficult. Ensuring a consistent message across the regulatory network has also proved difficulty – with stakeholders receiving mixed messages from different partners.

Communication with industry forms part of the day-to-day business for all regulatory agencies, but the commercial sensitivities surrounding drug information and its dissemination remains an influencing factor and also impacts on our ability to share information with the wider community.

In developing a communication strategy we are required to develop a policy that supports information sharing in a consistent, understandable and timely way.

Anything that prohibits this policy can be seen as an obstacle to good communication and every effort should be made to recognise and avoid the pitfalls listed below.

- Poor use of, or inappropriate language for the target audience
- Inconsistent with EU policies on sharing and distribution of information
- Non user-friendly terminology
- Legal issues/obstacles
- Lack of timeline
- Confidentiality agreements
- Commercial sensitivities
- Reluctance to communicate or share information
- Inability to obtain the necessary information to communicate or share
- Information overload; too much useless information
- Defensiveness; distorted perceptions, transference, bias; distortions from the past
- Cultural differences
- Inconsistency of approach; different messages from multiple sources
- Poor or incomplete data; substandard information quality
- Lack of empathy or understanding of the stakeholder perspective

In order to determine how well our communication strategy is effective we should endeavour to ensure the following:-

All communication is:

- clear
- concise
- has a clearly defined action plan
- targets appropriate audience
- allows constructive feedback; follow-up to determine effectiveness
- acted upon
- proactive rather than reactive
- follows agreed timeline

## 7. Main conclusions

Communication with stakeholders must be a part of the daily life of the organisation, with well-developed communication routines and competence in using different methods to communicate with different stakeholder groups. Knowledge about stakeholder's opinions, expectations, knowledge and needs must be collected and understood by the regulatory body.

The development of strategies to support effective internal and external communication is essential to the successful future of the regulatory network. Agencies must develop their competency in this area and ensure that they have the resource to support this strategic activity within their organisations.

The HMA's commitment to the development of such a strategy for communication will benefit all within the regulatory community, while recognising the different circumstances that challenge the individual organisations within the network.

- Communication with stakeholders must be incorporated into the daily routine
- of the organisation and a formal policy should be established accordingly.
- Legislation and a changing environment is changing the target audience for regulators
- Different methods are required to support successful communication with varying groups of stakeholders
- An agreed communications policy would benefit all within the regulatory network
- Each organisation should develop its competency in the communications area

Topics of interest not addressed within this document:-

- Communication within the organisation is as important as outside the organisation:
- Strategy for managing external communication
- Strategy for managing internal communication
- Communication is a 2-way process:
- Communication culture aligned with service based approach
- Legislation facilitates/supports data transparency