

Section 3: Communication and Information

Introduction

The overall goal for the HMA communication strategy is to strengthen the European network as well as the internal HMA communication. Because of increasing number of actors in the system, the communication strategy also has to define the roles and responsibilities of parties involved

Effective communication and information sharing is the backbone of the entire regulatory network.

The HMA's vision and commitment to the development of a communication strategy strengthens its role within the regulatory network and provides a mechanism to influence the wider community.

In developing a communication strategy the HMA will build a professional approach to dealing with both external and internal stakeholders. This strategy will support the objectives of the individual national competent authorities and the overall HMA group and underpin the European Regulatory Network. Stakeholder confidence in the HMA will be enhanced and the principle of trust will be developed through improved two-way communication.

The work undertaken by the drafting group clearly identified the need for a work programme to support the development and implementation of a communications strategy for all players.

As part of this process the HMA is requested to review the fundamental 'best practice' principles embodied in this document with a view to implementing a fully developed communications strategy for the network. This paper sets out the rationale for an HMA approach to communications, the principles that should underpin that approach, together with the benefits of implementing that approach and the risks of not doing so. **HMA are asked to agree the principles set out, and to endorse the next steps set out in section 5.**

The HMA is asked to consider the following:-

- That the development and implementation of a communication strategy to support the European regulatory network is imperative
- That the necessary resources will be developed within the regulatory agencies to ensure that the strategy is comprehensively addressed in both scope, content and implementation
- That the strategy will seek to outline the areas of common policy between the various players – while recognising the differences that may exist
- That the absence of a common communication policy may have a negative impact on the profile, credibility and ambitions of the European regulatory network

1. Why do we need a Communication Strategy?

There are a number of factors driving the need for a communication strategy:

- **New legislation** which focuses on the introduction of improved access and transparency is challenging the way in which we have traditionally communicated with many of our stakeholders. In order to avoid confusion towards the European public and complaints from the stakeholders because of different approaches between Member States, there has to be a common understanding on, among others:
 - The meaning of “making publicly available”;

- The content and moment of agendas and records of meetings to be made publicly available;
 - Whether or not withdrawals and refusals should be made publicly available (MRP – DP – national);
 - The “commercially confidential information” to be deleted from the public documents;
 - A pharmacovigilance communication that involves all concerned Member States ;
- **Timing** - information timeliness is one of the key challenges in communicating effectively. It is essential that mechanisms to improve the timeliness of information and its communication are enhanced.
 - **Changes in society and technology** have also brought about new mechanisms through which to access information (and sometimes also misinformation) on medicines and medical treatment. Society is generally more informed on health matters and the consumer has become more active in planning their own treatment. This will result in a greater demand for high quality information.
 - **News** travels fast in electronic networks and via the Internet. The authorities are faced with growing demands for current and accurate information as well as need for quick responses in crises as well as in “daily life” situations. Delays are unacceptable to the media or to the citizens.
 - **Increased general interest.** Most of the key stakeholders (general public, health professionals, journalists, and politicians) have become increasingly sensitive to issues concerning health products and increasingly they request greater access to information relating to the product evaluation process (efficacy, safety and quality).
 - **Lack of understanding of the regulatory system.** We have to increase the global understanding of the regulatory system, be clear about the boundaries to our responsibility, and explain how we will take account of public opinion. As a matter of fact, patients, journalists and health professionals are often genuinely convinced either that the role and powers of the national authorities are far bigger than in the real world, or that we are completely helpless. So it is important that we provide accurate information about the process and the system.
 - **Complex regulatory environment.** The system consists of increasingly more partners, e.g., EMEA, EEA, and FDA. This puts further demands on communication.

2. Stakeholder analyses

National Competent Authorities that regulate Medicines and medical devices have a wide range of different stakeholder groups with different needs. The NCAs should not neglect any of their key stakeholders, and must ensure that they have a comprehensive understanding of their stakeholders.

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?
- Who we wish to convey the information to?
- What action we wish to result from the communication?

As medicines regulators we are required to present information that is accurate, meaningful of practical value to a very varied audience – and this issue presents one of the greatest challenges to the regulatory network. 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.

Stakeholders have been identified as falling into the following key groups:-

- Pharmaceutical industry and medical devices industry
- Pharmacies and wholesalers
- Patient groups
- General public
- Health care professionals
- Other regulators within the EU/EMA/EC
- Other non-EU regulators
- National government
- Media
- Internal communication (within NCAs and between NCAs and EMA)

3. What can we gain from developing a Communication Strategy?

Communication should be a strategic tool to support the HMAs vision for the regulatory network. A communication strategy will demonstrate the HMAs commitment to the development of stakeholder relationships and thereby position the HMA in a position of influence with regard to the future of European and global medicines regulation.

A successful communications strategy will deliver a number of benefits:

- Recognition of the HMA's commitment to the concept of two-way stakeholder communication
- Proactive management of regulatory communications
- Improved crisis communications as well as "daily life" communication
- Establishment of the principal of 'trust' - the stakeholder community will feel confident that the regulatory network is the best source of up-to-date, quality information
- Opportunity to influence the wider regulatory environment
- Information sharing across the regulatory community has become the lifeblood of decision-making and the development of a strategic policy will strengthen this process
- Improved relationships with stakeholders
- Mechanisms to manage the role of the media can be shared and developed

4. What problems do we face, if we do not formulate a consistent Communication Strategy?

Poor communications runs the risk of losing credibility in the eyes of the public, and threatening the future of the regulatory network. It also makes it more difficult for regulators to operate on an equal basis with each other and with policy makers.

In particular, poor communications can result in the following problems:

- Communications that focuses solely on national purposes and thereby does not fulfil its full potential to support the European regulatory network and influence the wider European community
- Poor image of the European regulatory network as a negative and fragmented grouping
- Communications strategy will be driven by 'external players' e.g. media

- Inconsistency or breach of EU policies and legislation in respect of information sharing and distribution
- Poorly defined timelines to support communications activities
- Lack of confidentiality agreements
- Inability to obtain the necessary information to communicate or share
- Inconsistency of approach; different messages from multiple sources
- Poor or incomplete data; substandard information quality

5. What actions are required to develop a consistent Communication Strategy?

The steps to build a Communication Strategy will involve the following elements:

The HMA is invited to endorse the mandate for the **Communication Network** at the HMA Meeting in November 2005. The Network will consist of representatives from the EU Medicines Agencies, from the EEA countries, the EMEA and the European Commission. The network is proposed in order to improve the communication on an overall level and to set up a forum of discussion and information/experience sharing among EU Medicines Agencies and the other partners. The network will help the implementation of the communication strategy agreed to by the HMA and therefore contribute to reinforce credibility of regulatory authorities and consolidate the image of the European Medicines Regulatory Network. Furthermore the network will constitute an early warning system for the detection of crisis communications situations and represent a useful barometer to evaluate different stakeholder demands.

Develop a **communications “toolkit”** containing models and templates for the communications resources needed in a mass communications exercise, and guidance on how to use them. This could include:

- Key messages documentation
- A press release
- A question and answer document for media interviews
- A patient information sheet
- An “evidence base” document
- A question and answers document for patients
- A telephone helpline briefing sheet
- A web-based communication resource template
- A communication to healthcare professionals
- A communication to key opinion formers (eg members of government, parliament etc)

It is not intended that the toolkit should be prescriptive – different countries will have different approaches and formats for documents. Instead, it will aim to define good practice in each type of document, and raise questions/issues which need to be considered in communication situations. In effect, it could be a detailed checklist which can be used as an aide memoire in developing communications tools.

Use **the HMA website** to present the regulatory system to our stakeholders. One of the first actions suggested would be to merge the veterinarian and human website

Create a **HMA focal point** for communication with industry. This should position the HMA Management Group as the key point of contact for industry in relation with national procedures.

Share best practices on when and how to communicate on:

- a. Precommunication
- b. Daily life communication
- c. Crisis communication
- d. Confidentially /embargo agreements

In any incident or emerging issue, the **designation of a member state(s)** responsible for producing and circulating briefing materials

The creation of a **distribution mechanism** for circulating briefing materials and an early warning system for crisis situations.

The HMA should decide who should be **responsible** (Communication Network, Permanent Secretariat, NCA's) for the above mentioned action points.

The work carried out by the Communications and Information Topic group has been summarised in this document. The detailed analyses in support of each area can be found in the following Appendices. The groups were the following five:

1. Stakeholders
2. Defining communication roles
3. Legal environment
4. Crisis communication vs. daily life communication
5. Solutions and actions