

## **DECISION**

**No. 9/07.06.2010**

**on approval of the communication strategy  
of the National Medicines Agency  
(2010-2014)**

The Scientific Council of the National Medicines Agency, set up based on Order of the Minister of Public Health No. 1027/22.05.2008, as amended, reunited on summons of the National Medicines Agency President in the ordinary meeting of 07.06.2010, in accord with Article 10 of Government Ordinance No. 125/1998 related to the set-up, organisation and operation of the National Medicines Agency, approved as amended through Law No. 594/2002, as further amended, agrees on the following

## **DECISION**

**Sole article.** – The communication strategy of the National Medicines Agency (2010-2014) is approved, according to the Annex which is integral part of this decision.

**PRESIDENT  
of the Scientific Council  
of the National Medicines Agency,**

**Acad. Prof. Dr. Victor Voicu**



## **COMMUNICATION STRATEGY OF THE NATIONAL MEDICINES AGENCY (2010-2014)**

### ***Introduction***

The most important strategic objective of the NMA is promotion and protection of public health, by accomplishment of the NMA primary role, namely warranty of compliance of authorised medicinal products with the required standards granting their efficacy and an acceptable safety degree. For successful attainment of this goal, the NMA will further strengthen its status as expert and reliable source of accurate and timely information in the field of medicinal products for human use, provided to its most important stakeholders, namely healthcare professionals, patients and general public.

### ***Scope and purpose***

This document outlines the frame for internal and external communication activities for 2010-2014, is updated annually and establishes key actions necessary for developing communication during this time.

The Communication strategy is devised by the Communication, institutional relations and pharmacopoeia service within the Department for policies and strategies but implementation of its objectives cannot be performed without support and cooperation of the entire Agency personnel. Therefore, enforcement of the communication strategy requires actual involvement of the entire NMA staff in issues related to relationships with the mass-media, development of the NMA website, finding stakeholders' needs and organisations of meetings with them.

The general objective of the Communication strategy is achievement of a higher level of understanding of risk/benefit balance assessment and NMA decision – making for performance of its duties as well as stimulation of adverse reactions/events reporting.

The purpose of the NMA de communication strategy envisages:

- development of communication through improvement and development of infrastructure responsible for this activity;

- coming into prominence in relation to other bodies, i.e. acknowledgment of NMA status as expert and reliable source of accurate information in the field of medicinal products for human use;
- ensuring wide availability of information and their immediate accessibility;
- ensuring bilateral quality communication with the various stakeholders (by means of message exchanges and response to questions);
- maintaining NMA reliance through continued and constant attainment of all objectives established, irrespective of difficulties encountered in resolution of emerging problems.

As a living document, endowed with sufficiently flexible objectives to respond to a continually changing external context, the communication strategy will necessarily be subject to permanent NMA leadership assessment, to ensure its adaptation to emerging changes.

### ***Key messages***

In order to attain its most important strategic objective related to protection and promotion of public health, the Agency must be able to constantly outline the content of activities it performs in that respect. The following key messages outline the activity of the Agency and represent key messages at the highest level, which the NMA will attempt to convey through implementation of this communication strategy:

- **The NMA is responsible for ensurance of authorised medicinal products compliance with required standards as well as efficacy of medicinal products for human use and their acceptable safety.**
- **There is no adverse reaction-free medicinal product, the essential fact being a positive risk-benefit balance.**
- **The NMA performs safety surveillance of in-use medicinal products for human use through inspection and pharmacovigilance activities by prompt adoption of appropriate decisions for public health protection whenever needed.**
- **The NMA pursues provision of access to information to the greatest possible degree.**
- **The NMA pursues ensurance of transparency of institutional practices and procedures.**

The above key messages in fact correspond to elements of the NMA mission, expressing objectives pursued by the Agency in clear and accessible terms. Implementation of this strategy will mean that NMA will communicate and reinforce these key messages, whenever necessary, while at the same time ensuring through continuing self-assessment, that they continue to communicate, clearly and accurately, to the target audience of the institution.

### *Objectives*

- Support of the NMA mission of protecting and promoting public health through timely provision of the latest and most accurate information on medicinal products for human use;
- Ensuring a high level of accessibility to information;
- Finding ways to ensure the highest possible degree of transparency in decision-making on the level of both the NMA and the industry under its regulatory scope;
- Appropriate information of healthcare professionals for improved reporting of adverse reactions and events, promotion of safe use of medicinal products for human use (for instance, by means of suitable prescription, search and request for adequate information from the NMA);
- Total compliance with requirements established for patient leaflet and labelling information readability and user testing;
- Making information available to the general public to be able to first initiate and then develop the process of adverse reaction reporting by the patient and promotion, respectively, of patient's better informed decision on use of medicinal products for human use;
- Development and permanent update of the NMA website for strengthened status as reliable source of the latest information on medicinal products for human use;
- Promotion of risk understanding and directing public attention towards the danger of purchase of medicinal products over the internet;
- Contribution to better understanding by healthcare professionals and the general public of the fact that, although there are no risk-free medicinal products, their benefits for the patient and the public fully justify the risks as long as the risk/benefit balance remains positive;
- NMA collaboration with professional bodies and academic staff etc. in the field, so as to ensure appropriate content for healthcare professionals' training and education in matters of risk and safety in prescribing and use of medicinal products for human use;
- Ensuring recognition of NMA status as a competent authority through understanding the manner for NMA actual regulation of the medicinal product field;

- Design and implementation of new ways to improve patient and general public involvement in NMA work and maximum valorisation of their contribution to the decision-making process.

### *Strategic priorities*

For attainment of its mission, the NMA sets itself certain strategic priorities related to development of communication activities:

#### *1. Improved flow of information to healthcare professionals*

The NMA is aware that the first contact of most patients and the general public is public healthcare services and treating healthcare professionals, respectively. Therefore, healthcare professionals should be timely provided accurate high quality information able to aid them in advising their patients on use of medicinal products for human use.

That is why the Agency has focussed its entire attention on continued efficient provision of key information for healthcare professionals in that respect, in order to adequately support their or other people's patient care activity.

In that respect, the NMA will pursue:

- Review and update of its website for better accessibility of information for all stakeholders, healthcare professionals included;
- Assessment of communication channels currently used in relation to healthcare professionals: rapid alerts, current pharmacovigilance issues (information letters for physicians/direct communications to healthcare professionals, notifications to medical practitioners, pharmacovigilance regulations, submission of Summaries of Product Characteristics, patients leaflets etc.)

#### *2. Improved NMA profile as a communicator*

The NMA fully assumes responsibility for the communication on relationship with the mass media, in a context of increased demand for interviews for printed press and television.

In exercise of its duty as a proactive and reactive communicator, the Agency aims at ensuring a balance between its work and the issues it faces.

#### *3. Improved internal communication*

Internal communication takes place on several levels, contributing to the fulfillment of Agency objectives. Like many other organisations, the NMA uses the intranet and the electronic mail, because its speed and ease of use. Other

internal communication alternatives are: operative meetings of the NMA management with the heads of the various internal structures and Agency committees, meetings on department/service/bureau level, inter-departmental meetings, internal publications on the intranet etc.

The Agency aims at:

- continuous monitoring of the development of more effective communication skills of its employees in respect of interpersonal or face-to-face communication;

- improved vertical communication mechanism ("top-down" – in line with the hierarchical organisation, and "bottom up" – from the lower to the upper hierarchical levels), in particular as regards:

- ensured possibility for feedback receipt;

- increased speed of feedback receipt;

- improved communication mechanism on group level, manifest in departments, services, laboratories, offices. This level focuses on sharing of information, discussion of issues, coordination of tasks, resolution of problems and reaching consensus.

- scheduled meetings within the Agency to monitor employee awareness about the role of the communication function, the importance of ensuring good internal communication envisaging attainment of the NMA mission;

- collaboration with the Department for Human Resources to develop a training program concerning better NMA employee communication skills;

- reevaluation of existing channels of internal communication and focusing efforts towards developing of bilateral written and verbal communication.

#### *4. Improved involvement in Agency work of patients and the general public*

Priority will be given by the NMA to continued direct communication with patients' and general public associations allowing identification of more opportunities for their involvement in agency work, such as:

- planning meetings with patient/public groups of interests for proposal of specialists to participate in their meetings;

- creating a patient/public "reference group" able to, within its collaboration with the NMA, contribute to improved decision making and level of understanding of safety issues and risk in prescription and use of medicinal products for human use.

## *5. Promotion of informed debates on aspects related to the benefit/risk balance, underlying NMA work*

- Debates on the issue of non-existence of risk-free medicinal products, the essential point being a positive benefit/risk balance will provide better understanding of Agency work and set an example for transparency promotion in NMA policy and strategy, as the national regulatory authority in the field of medicinal products for human use.

### *Funding to achieve the proposed strategic objectives*

#### *1. Funding of communication activities*

Despite the fact that, at the end of 2009, the NAM was reorganised as a public institution only funded from the state budget (as per *Law 329/2009 on reorganisation of certain public authorities and institutions, rationalisation of public expenditure, support of business and compliance with the framework agreements with the European Commission and the International Monetary Fund*), the Agency is aiming at further maintaining its financial stability through a balanced budget year, allowing for excedent for either possible investments or as a reserve for difficult and unforeseen circumstances.

It is worth mentioning that, for economic reasons, print publication of both the Agency's quarterly newsletter and the NMA/NMA Annual Report brochure have currently been cancelled, these being only posted on the Agency website. Distribution of such specific illustrative work on paper to certain interested state institutions, faculties of pharmacy and medicine abroad and at home, to certain medical and pharmaceutical personalities as well as to other national medicinal product regulatory authorities would more widely insure a successful agency communication strategy. Therefore, the NMA pursues to resume printing/distribution of such publications as soon as feasible from a financial standpoint; this will ensure an opportunity for more accurate estimate by healthcare professionals, internal and external partners of constant Agency efforts towards recognition of its reinforced status as European competent authority in medicinal products for human use.

Depending on financial, material and human resources, the Agency aims at development and diversification of communication instruments of, considering that effective communication strategy combines some or all of the following tools: Internet, printed publications and other printed materials, press releases, interviews, important notifications, conferences etc. The tools used depend on the strategic objectives, the profile of the target audience (healthcare professionals, research and industry, patients and general public), the various advantages and disadvantages of each instrument and, last but not least, the communication budget.

## *2. NMA funding through communication activities*

The Agency aims continued identification, organisation and promotion of fundraising activities based on communication, such as conferences, training sessions etc.

### *Staff involved in implementation of objectives of the NMA communication strategy*

Depending on the evolution of the economic crisis, the NMA aims at performance of efficient action towards both maintenance and recruiting of highly qualified and better motivated personnel, endowed with the communication skills necessary to meet the objectives and priorities of the Agency's communication strategy.

## **CONCLUSIONS**

The National Medicines Agency, whose foundations were laid in 1999, is currently recognised on European and international level as an institution fully able to meet requirements imposed by consolidation of its status as regulatory authority in medicinal products for human use of a EU member states.

The most important NMA strategic objective is protection and promotion of public health, by accomplishment of the NMA primary role, namely warranty of compliance of authorised medical devices with the required standards and intended purpose as well as of their acceptable level of safety.

To successfully meet this goal, the NMA must be an expert and reliable source of accurate and timely information in the field of medicinal products for human use for the most important stakeholders, including healthcare professionals, research and industry, patients and the general public.