

**COMMUNICATION STRATEGY  
OF THE NATIONAL AGENCY FOR MEDICINES  
AND MEDICAL DEVICES  
(2011-2015)**

***Introduction***

The most important strategic objective of the NAMMD is promotion and protection of public health, by accomplishment of the NAMMD primary role, namely warranty of compliance of authorised medicinal products with the required standards as well as of their efficacy and acceptable level of safety. For successful attainment of this goal, the NAMMD 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 the general public.

***Scope and purpose***

This document outlines the frame for internal and external activities for 2011-2015, 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 NAMMD staff in issues related to relationships with the mass-media, development of the NAMMD 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 assessment and NAMMD decision – making for performance of its duties as well as stimulation of adverse reactions/events reporting.

The purpose of the NAMMD communication strategy envisages:

- Development of communication through improvement and development of its infrastructure;
- coming into prominence in relation to other bodies, i.e. acknowledgment of NAMMD status as expert and reliable source of accurate information in the field of medicinal products for human use;
- insuring wide availability of information and their immediate accessibility;
- insuring bilateral quality communication with the various stakeholders (by means of message exchanges and response to questions);

- maintaining NAMMD reliance through continued and constant attainment of all objectives established, irrespective of difficulties encountered in resolution of emerging problems;

As a live document, endowed with sufficiently flexible objectives to respond to a changing external context, this will remain under permanent NAMMD leadership assessment, to insure its adaptation to emerging changes.

### *Key messages*

In order to attain its most important strategic objective related to promotion and protection 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 NAMMD will further convey through implementation of this communication strategy:

- **The NAMMD is responsible for insurance 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 NAMMD performs 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 NAMMD pursues provision of access to information to the greatest degree possible.**
- **The NAMMD pursues insurance of transparency of institutional practices and procedures.**

The above key messages in fact correspond to elements of the NAMMD mission, expressing objectives pursued by the Agency in clear and accessible terms. Implementation of this strategy will mean NAMMD continued communication and support of key messages, whenever necessary, while at the same time ensuring through self-assessment their uninterrupted impact on the target audience of the institution.

### *Objectives*

- Continued support of the NAMMD mission of promoting and protecting public health through timely provision of the latest and most accurate information on medicinal products for human use;
- Insuring a high level of accessibility to information;
- Finding ways to insure the highest degree possible in decision-making on the level of both the NAMMD and the industry under its regulatory scope;
- Finding appropriate methods to appeal to healthcare professionals for improved reporting of adverse reactions and events;
- Adequate information of healthcare professionals to promote safe use of medicinal products for human use (for instance, by means of suitable prescription, search and request for adequate information from the NAMMD).
- Pursuance of thorough observance of requirements established for improved readability and understanding of patient leaflet information and labelling 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 NAMMD 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;
- Promotion of risk understanding and directing public attention towards the danger of encouraging self-medication through inappropriate advertisement of medicinal products for human use;
- 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 ratio remains positive;
- NAMMD collaboration with professional bodies and academic staff etc. in the field, so as to insure appropriate content for healthcare professionals' training and education in matters of risk and safety in prescribing and use of medicinal products for human use;
- Insuring recognition of NAMMD status as a competent authority through understanding the manner for NAMMD actual regulation of the medicinal product field;
- Design and implementation of new ways to improve patient and general public involvement in NAMMD work and maximum valorisation of their contribution to the decision-making process.

## *Strategic priorities*

For attainment of its mission, the NAMMD aims at continued approach of those strategic priorities related to development of communication activities, as for example:

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

The NAMMD 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 this respect, the NAMMD 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 ads, pharmacovigilance regulations, submission of Summaries of Product Characteristics, patients leaflets etc.)

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

The NAMMD fully assumes responsibility for the communicating with the media relationship, in a context of increased demand for printed press and television interviews, the NAMMD will continue to promote a fair and efficient relationship with the press, given the increasing societal role of the media in recent years. Accurate, rapid and impactful information conveyed in appropriate terms in the field of medicinal products for human use as well is a vital source for any type of decision, and the media is their main means of dissemination to the general public.

Considering that, in addition to its informative role, the mass media can also be used to shape opinion and ideas and develop attitudes, the NAMMD relationship with the press must be built in such a way as to insure accurate, clear and appropriately expressed medicines-related body of information, particularly related to safe use, in order to achieve a maximum degree of understanding by the general public. To a lesser or greater extent, this relates to the Agency's control over information on medicinal products for human use, and a good relationship with the press is mandatory to achieve this goal.

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

### *3. Improved internal communication*

Internal communication takes place on several levels, contributing to the fulfilment of Agency objectives. Like many other organisations, the NAMMD uses the intranet and the electronic mail, because its speed and ease of use. Other internal communication alternatives are: operative meetings of the NAMMD 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, manifested 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 NAMMD mission;
  - collaboration with the Department for Human Resources, Payroll to develop a training program concerning better NAMMD 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 NAMMD 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, in the context of its collaboration with the NAMMD, 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 the various aspects involved in medicinal products for human use: the benefit/risk balance, generic versus innovator medicinal products, patient role in development of readable leaflets able to assure a high level of understanding, reporting adverse reactions, etc.*

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

- Continued debate on generic versus innovator medicinal product and initiation of debates on the involvement of professionals and patients in implementation of the new European Directive 2010/84/EU for amendment of Directive 2001/83/EC establishing a Community code on medicinal products for human use in terms of pharmacovigilance.

### ***Funding in view of reaching the proposed strategic objectives***

#### ***1. Funding of the communication activity***

Despite the obstacles created in 2009-2010, of the unfavourable economic and legislative context, the NAMMD the agency is at least aiming at further maintaining its financial stability through a balanced budget year, in accordance with the laws in force.

It is worth mentioning that, for economic reasons, print publication of both the Agency's quarterly newsletter and the NMA/NAMMD Annual Report brochure have been further 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 NAMMD 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, print 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 the general public), the various advantages and disadvantages of each instrument and, last but not least, the communication budget.

## *2. NAMMD 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 NAMMD communication strategy*

Depending on the evolution of the economic crisis and the legislative framework, the NAMMD aims at performance of efficient action towards 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 Agency for Medicines and Medical Devices, 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 NAMMD strategic objective is promotion and protection of public health, by accomplishment of the NAMMD 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 NAMMD must continue as 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.