DECISION

No. 2/22.04.2013

on approval of the Communication Strategy of the National Agency for Medicines and Medical Devices (2013-2015)

The Scientific Council of the National Agency for Medicines and Medical Devices (NAMMD), established based on Order of the Minister of Health no. 158/18.02.2013, reunited on summons of the President of the National Agency for Medicines and Medical Devices in the ordinary meeting of 22.04.2013, in accordance with Article 12(5) of Government Decision no. 734/2010 on establishment, organisation and operation of the National Agency for Medicines and Medical Devices, as amended, adopts the following

DECISION

Sole article. – The Communication Strategy of the National Agency for Medicines and Medical Devices (2013-2015) is approved, in accordance with the Annex which is integral part of this Decision.

PRESIDENT
of the Scientific Council
of the National Agency for Medicines and Medical Devices,

Acad. Prof. Dr. Leonida Gherasim

ANNEX
to SCD no. 2/22.04.2013

Communication strategy
of the National Agency for Medicines and Medical Devices
(2013-2015)

The drafting and implementation of the Communication Strategy of the National Agency for Medicines and Medical Devices (NAMMD) are an essential prerequisite for strengthening the status as European institution in the medicinal product field, a model of efficient and transparent performance.

I. INTRODUCTION

1. The overall context of the strategy

Romania's accession to the European Union (EU) has created the particularly favourable context for development of the communication policy of the National Agency for Medicines and Medical Devices (NAMMD). Approach of an adequate communication strategy allows the NAMMD to strengthen its credibility with its partners and may become an actual protector and promoter of public health in Romania.

For competent authorities throughout the EU in the field of medicinal products for human use, one of the most important objectives is setup of an efficient connection with all stakeholders, namely healthcare professionals and professionals in fields such as research and industry, patients and the general public, the media.

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 and intended purpose as well as of their 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, who have to turn into actual and active communication partners.

2. Scope and purpose

The Communication strategy outlines the frame for internal and external communication activities performed by the NAMMD, by establishing key actions necessary for developing Agency communication, as national regulatory and control authority in the field of the medicinal products for human use.

The Communication strategy is devised, set up and implemented by the Communication, institutional relations and pharmacopoeia service within the Department for policies and strategies, but implementation of its objectives cannot be achieved without support and cooperation of the entire Agency personnel.

The entire Agency staff, be they specialists such as pharmacists, physicians, or biologists involved in activities related to assessment of authorisation dossiers, control and/or inspection thus contribute to implementation of the Communication strategy. Therefore, it is mandatory that professionals in the Agency be actively involved in the draft of responses requested by the mass-media and/or any stakeholder, in conveying specialised information to all its partners and, last but not least, to the general public, in the development of the NAMMD website, in

identification of stakeholders' emerging needs, in organising meetings and actual participation. The NAMMD needs to manifest increased openness for more efficient communication with all partners in the field; in that respect, the NAMMD has organized and plans on further setting up meetings with Marketing Authorisation Holders (MAHs), with Romanian and international associations of manufacturers of medicinal products and of patients, with associations of companies coordinating clinical trial conduct and associations of medicinal product distributors.

The NAMMD finds it necessary to continue organisation and provision of professional training courses on topics subjects of major significance to its partners (legislation, good manufacturing and control practices), whose final goal is to facilitate communication between the NAMMD as national regulatory and control competent authority and the stakeholders.

Ensuring effective communication with all European bodies in the field (the European Medicines Agency, the Heads of Medicines Agencies, the Council of the European Union, the European Directorate for the Quality of Medicines and Healthcare, the European Commission etc.) is in itself an additional application and purpose as such communication strategy.

II. OVERVIEW

1. General objective of the Communication strategy

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 by healthcare professionals (physicians, medical examiner, pharmacists, medical assistants, midwives) and patients.

2. Specific objectives of the Communication strategy

The NAMMD Communication strategy has the following specific objectives:

- To improve the ability of Agency specialists to analyse, debate, suggest, update and convey regulations in the field of medicinal products for human use in full compliance with European legislation and standards in force;
- To develop communication activities through improvement and development of its infrastructure;
- To reinforce procedures and processes in order to clarify the roles and responsibilities in the context of the NAMMD mission;
- To attain increased visibility among other bodies, i.e. recognition of NAMMD status as expert and reliable source of accurate information in the medicinal product field;
- To strengthen the impact of communication upon NAMMD partners by ensuring ample and immediate availability of information;
- To insure bilateral, quality communication with the various stakeholders (by means of message exchanges, questions and answers);
- maintaining NAMMD perception as trustworthy source 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 the continually changing external context, once drafted and implemented, the Communication strategy will remain under permanent NAMMD leadership assessment, undergoing updates as required by the rapid dynamic of the pharmaceutical field, so as to insure its permanent adaptation to emerging changes.

3. Content

This document analyses the various aspects of NAMMD activity, the Agency's relationship with its partners, stakeholders' expectations, thus establishing a Communication strategy.

The strategy has been issued following wide research for material, by study of other corresponding European Agencies' Communication strategies, by reference to national and European realities

In order to meet the top strategic objective, namely protection and promotion of public health, the Agency must be able to constantly describe the content of its work. to this end.

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:

- There is no adverse reaction-free medicinal product, the essential being a positive risk-benefit balance;
- 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;
- The European Union has introduced a new medicinal product labelling process subject to particularly close monitoring by regulatory authorities in the field of the medicinal products for human use. Such products will be provided with a black triangle printed on the leaflet and on the Summary of Product Characteristics, as additional protection and information for patients and healthcare professionals.
- The NAMMD performs surveillance of in-use medicinal products for human use through inspection and pharmacovigilance activities, however there are products subject to more careful monitoring. The black symbol shows that there is less information available on such products, due to their "novel product" status or to limited data concerning their long-term use.
- The NAMMD promptly adopts appropriate decisions for public health protection whenever needed.
- The NAMMD encourages patients to report any suspected adverse reactions directly to the authority and discuss any medicinal product related unclear issues or concerns with their physicians.
- The NAMMD seeks to ensure, as much as possible, public access to information.
- The NAMMD pursues to ensure transparency of practices and procedures employed in the institution.

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.

4. Solutions, valorisation

- 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 of transparency 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 directly not only to the physician but also to the competent authority, in light of the new approach of pharmacovigilance in the EU, aiming to gain patients'trust;
- Making information available to the general public to promote a better informed decision of the patient regarding the use of medicinal products for human use;
- Harmonisation with the Communication Strategy of the European Medicines Agency (EMA) on additional monitoring of medicinal products (tagged with the black symbol and the associated warning text under Product-related information) by launching its own campaign addressing patients and healthcare professionals until March 2014;
- Development and permanent update of the NAMMD website for strengthened status as reliable source for 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, Good Clinical Practice rules etc.;
- 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.

III. ANALYSIS OF THE CURRENT SITUATION

1. Period of pre-accession to the European Union: challenge and opportunity

During pre-accession to the European Union, the National Medicines Agency's communication activity of that time was the same with the aspiration for EU accession, aiming to become the first public voice in the field of medicinal products for human use to guide this

process due to its ability to perform national scale communication on accession requirements and expected outcomes. At the time, the key preoccupation of the Agency's communication strategy was to increase reliability of its structures, able to perform their regulatory and control function and to successfully implement the objective of EU accession.

2. SWOT analysis

Strengths:
- National competent authority in the field of human medicinal products
- Considerable appreciation at EU level
- Communication service able to communicate efficiently

Weaknesses:
- Lack of funding for appropriate financing of communication activities
- Lack of staff trained for communication
- Lack of adequate procedures to facilitate communication with all stakeholders

Opportunities:
- Reinforcement of the medicinal product legislative context by establishing partner relationships with civil society and the media, based on communication and transparency
- Involvement of NAMMD partners in the Agency's activity reinforces public support
- Healthcare professionals, the media, patients and the general public willing to receive more information about medicinal products
- Availability of a relatively small number of employees able to facilitate communication between the NAMMD and stakeholders' representatives
- Participation in meetings at European level of the working groups on communication
- Demonstration of conjugated operation of the European medicinal product regulatory network (EMA, EC and national competent authorities).

Threats:
- Low level of public confidence and credibility
- Lack of a consolidated relationship with part of the media
- The Communication strategy may become unproductive in want of real partnership with the media, which may possibly turn into a patient and public manipulation factor through conduct of a campaign for defamation of community competent authorities and of the national medicinal product competent authority
- The communication strategy cannot meet its objectives outside a real partnership with civil society.

3. Strategic priorities

Currently, 6 years after Accession, the Agency's mission and strategic objectives follow the same evolutionary path as any of other EU competent authorities. The credibility of the Agency's message is currently supported by its structures' capacity to demonstrate harmonisation with European values and standards, setup and maintenance of consistent cooperation with European competent institutions, bodies and authorities in this field.

The Communication strategy hereby expresses the strategic priorities for attainment of the NAMMD mission in the field of medicinal products for human use, to contribute to protection and promotion of public health through:

- Evaluation at the highest scientific level of authorisation dossiers for the marketing of safe, quality and effective medicinal products;
- Surveillance of the safety of medicinal products for human use in therapeutic use (while placing emphasis on additional monitoring of medicinal products whose leaflet and SmPC are inscribed with the black symbol), by means of inspections and pharmacovigilance activities;
- Provision of access to healthcare professionals, pharmaceutical industry, patients and public to useful and accurate information on medicinal products authorised for marketing in Romania;
- Insurance of Agency's administrative effectiveness and efficiency and transparency of its practices and procedures.

The NAMMD seeks to continue approach of the above strategic priorities for development of communication activities, such as:

3a. *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 with accurate high quality information able to aid them in advising their patients on utilisation of medicinal products for human use.

Hence, the Agency has focussed 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.

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 (direct communications to healthcare professionals, EMA press releases concerning efficacy and safety issues, notifications to medical practitioners ads, pharmacovigilance regulations, submission of Summaries of Product Characteristics, patients leaflets etc.)

3b. *Improved NAMMD profile as a communicator*

The NAMMD fully assumes responsibility for communicating with the media relationship, in a context of increased demand for printed press and television interviews, thus continuing 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.

***3c**. Improved internal communication*

Internal communication takes place on several levels, contributing to fulfilment of the Agency's objectives. In the same was as many other organisations, the NAMMD uses the intranet and the electronic mail, for their speed and ease of use. It aims at supplementing and updating employee directed information on the Intranet, to ensure rapid quality professional information and/or proper organisational aspect.

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, 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 NAMMD mission;
- collaboration with the Department for Human Resources, Payroll to develop a training program concerning better NAMMD employee communication skills;
- revaluation of existing channels of internal communication and focussing efforts towards developing of bilateral written and verbal communication.

***3d.** 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, within 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.

3e. *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 ensure a high level of understanding, reporting adverse reactions to healthcare professionals, physicians, pharmacists, medical assistants) and to the NAMMD etc.*

- Debates on the issue of non-existence of risk-free medicinal products, the essential point being that a positive benefit / risk ratio would provide better understanding of the Agency's 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 innovative medicinal products.
- Initiation of debates on the involvement of healthcare professionals (physicians, medical examiners, pharmacists, medical assistants, midwives) and patients in implementation of the new 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, transposed into national legislation through Emergency Ordinance no. 35/2012 amending Law 95/2006 in terms of the new approach of pharmacovigilance in the EU.
- Launch of a personal information campaign meant for patients and healthcare professionals, until March 2014, concerning the significance of the black symbol as a novelty on future leaflets and SmPCs of medicinal products undergoing additional monitoring of their post-authorisation safety as of July 2013.

IV. ANTICIPATED OUTCOMES

1. Ensuring communication and transparency

The NAMMD is intent on paying particular attention to ensuring effective information and communication with the media and other stakeholders in accordance with provisions of Law 544/2001 on free access to public information and Law 95/2006 on healthcare reform, Title XVII – The medicinal product, concerning transparency in competent authorities' activity in the medicinal product field in the EU.

1a. External communication

The Agency will ensure proper and adequate notification of its partners about activities performed in all fields under its scope.

The NAMMD will continue quarterly publication on its website of the bilingual Newsletter mirroring the Agency's legislative and regulatory activity in the field of medicinal products for human use, in accordance with European legislation, as well as other priority activities. The following are posted in the Newsletters:

- Laws, ordinances, government decisions in the field of medicinal products for human use or other fields of NAMMD interest;
- Orders of the Minister of Health for approval of NAMMD Scientific Council Decisions and Orders of the Minister of Health related to NAMMD other fields of interest;
- NAMMD Scientific Council Decisions;
- NAMMD Administration Council Decisions;
- The quarterly list of marketing authorisation/renewal applications forwarded to the NAMMD;
- The quarterly list of the new EMA centrally authorised medicinal products, for which a marketing price was established in Romania;
- The quarterly list of medicinal products authorised for marketing by the NMA/NAMMD;
- The quarterly list of medicinal product batches recalled by the NAMMD because of quality non-compliances.

The NAMMD will continue to issue and post on its website the Index of medicinal products for human use, which contains all medicinal products allowed for circulation on the Romanian pharmaceutical market, as well as information about their trade name, International

Non-proprietary Name (INN), Marketing Authorisation Holder, pharmaceutical form, strength, route of administration, manner of packaging, manner of release etc. The electronic versions of the Summaries of Product Characteristics (SmPCs), leaflet and labelling information will be implemented.

The NAMMD will permanently develop and update the information posted on its website. In this respect, the following information and documents will be further posted and updated on the NAMMD website:

- EMA press releases on medicinal product safety;
- NAMMD important announcements, responses to certain written press and TV issues related to the Agency's medicinal product policy, to the attention of stakeholders;
- Direct Healthcare Professional Communications;
- Notifications to the attention of Marketing Authorisation Holders (MAHs) or other stakeholders related to issues of interest;
- The List of NAMMD employees assigned as full members or alternates in the Management Board, scientific councils and working groups of the European Medicines Agency (EMA);
- The list of NAMMD appointed EMA experts.

A new section related to the national procedure has been added to the NAMMD website; just as the other two sections dedicated to the centralised and MRP-DCP procedures, this hosts information about contact persons, special warnings, SmPC, leaflets and labelling information. Moreover, the "National procedure" section of the new NAMMD website will further provide the "List of parallel import authorisations" issued by the Agency since 2009.

Because of the interest it bears with external users of the website, the sections will be updated with:

- Medicinal product legislation, structured according to the type of the regulatory document:
  - Laws, Ordinances, Government Decisions;
  - Minister of Health Orders;
  - NAMMD Scientific Council Decisions;
  - NAMMD Administration Council Decisions;
  - Index of medicinal products for human use authorised for marketing in Romania;
  - Forms;
  - Useful information.

The NAMMD will also continue to inform stakeholders about activities in relation with other publications, apart from its Newsletters. Thus, its website will continue to host the activity report for the previous year (in English as well).

Moreover, the NAMMD will carry on publication of articles dealing with various issues related to the Agency's activity in Romanian professional magazines ("Farmacist.ro", "Medical Business", "Viaţa Medicală", "Pharma Business", "Medica Academica", "Practica farmaceutică" etc.).

NAMMD representatives will further submit professional papers for various scientific events organised in Romania (and abroad) for pharmacists and physicians. Communication can thus be insured between two professions - physicians and pharmacists, both in the service of sick people.

1b. Internal communication

The NAMMD will continue supplementation and update of information available to employees on the local network (Intranet) to ensure the fastest and optimal professional and/or organisational information, such as:

- Instructions of the NAMMD president;
- NAMMD policies in the field of quality;
- NAMMD regulations;
- Glossary on quality insurance;
- Departmental activity plans;
- Useful forms;
- Information of the Pharmacopoeia Service;
- Information on training courses organised by NAMMD/specialised companies;
- Reports set up by participants in training in Romania and abroad;
- Situation of staff training;
- Outcomes of the staff motivation poll ;
- Useful information;
- Useful addresses etc.

2. Forthcoming actions, conduct of funding activities to meet proposed strategic goals

2a. Staff recruitment

Depending on the progress of the economic crisis and of the legal framework, the NAMMD intends to carry out efficient actions to maintain and recruit highly qualified and motivated staff, with communication skills necessary to attain the goals and priorities of the Agency's communication strategy.

2b. Funding of communication activities

Despite obstacles created in 2009-2010 by the unfavourable economic context, 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, printed publication of both the Agency's quarterly newsletter and the NAMMD Annual Report brochure has been further cancelled, these being only posted on the Agency website. Distribution of such specific illustrative work in written format 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, considering that an 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.

2c. NAMMD funding through communication activities

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

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 an EU member state.

The most important NAMMD strategic objective is protection and promotion 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.