Communication strategy
of the National Agency for Medicines and Medical Devices
(2017-2020)

Development 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 focussing its decisions on promotion of innovation and warranty of patient safety, whose duty at the same involves time to ensure information of all stakeholders on relevant aspects within its scope.

I. INTRODUCTION

1. Overall strategy context

Romania's accession to the European Union (EU) has created the frame for the communication policy of the National Agency for Medicines and Medical Devices (NAMMD), rapidly customising its response to requirements of effective communication and information exchange for coordination and collaboration with EU fellow institutions.

Approach of an adequate communication strategy, by phrasing and distribution of clear, accurate and timely information, addressing all stakeholders (healthcare and research professionals, industry representatives, healthcare institutions, patients, the general public, the mass-media) allows the NAMMD to strengthen its credibility with its partners in full proof of its ability to meet its role as guardian and promoter of public health in Romania.

This primary strategic objective of the NAMMD may be met by warranting compliance with required standards of medicinal products authorised for marketing, to ensure their efficacy and an acceptable level of safety.

Regular and adequate preparation and update of a communication strategy is the foundation of professional approach of interactions with stakeholders both internally and externally. The strategy will support achievement of NAMMD goals as a member of the European regulatory network. Improvement of dialogue and communication means will contribute to strengthening stakeholders' confidence, who are required to establish themselves as true and active exchange partners.

2. Scope and purpose

The need for a program supporting preparation and implementation of a communication strategy addressing all stakeholders has been clearly identified at the level of the European bodies.

The process requires heads of competent national authorities to review the key principles underpinning "good practices" embedded in the communication strategies adopted, for to implementation of comprehensive and mature strategies.

This type of approach requires description of the principles and benefits of their implementation alongside the risks of their disregard.

The Communication strategy outlines the frame for NAMMD internal and external communication work, by establishing key actions required to develop the communication of the Agency as a national regulatory and control authority in its fields of competence: human medicine, medical technology evaluation, medical devices.

The preparation of the NAMMD transparency-based communication strategy and its submission for approval by the Agency's top management and by members of the NAMMD

Scientific Council is the task of the Department for Policies and Strategies and the strategy is meant to ensure:

• internally, knowledge sharing and validation of activities

• externally, information and communication directed towards the various stakeholders

• as an interface with professional organisations and patient associations as users of the healthcare system

• adaptation of messages to the needs and perception abilities of external target audiences (mainly healthcare professionals and patients).

Accomplishment of communication strategy goals is a task for the Department for Policies and Strategies with support from and participation of the entire Agency personnel.

All Agency specialist staff, whether pharmacists, physicians, or biologists or personnel 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:

• NAMMD continually develop a communication strategy in line with and supporting the objectives of the European network of national competent authorities in the field of human medicines, to ensure a comprehensive approach in terms of both scope and content as well as implementation means;

• NAMMD communication strategy outline shared policy areas among the various stakeholders while at the same time acknowledging potential differences;

• NAMMD be aware of the negative impact of the lack of a shared communication policy among authorities within the European network, with regard to their profile, credibility and goals.

There are several factors that defining the need for a communication strategy as concerns European bodies and institutions in the field:

• Recent legislation, focussing on means to improve access to information and higher transparency, calls for new ways for communication and interaction with stakeholders, other than traditional ones. In order to avoid confusion and complaints from stakeholders, stemming from different approaches among EU Member States, a few fundamental issues need to share the same understanding, among which:

- the meaning of the phrase "publicly available information";

- the agenda, minutes and recordings of the meetings to be made public;

- the so-called “commercially confidential information” to be removed from public documents;

- pharmacovigilance communications involving all EU Member States.

• **Synchronisation**, communication of information in a timely manner, is a key element in communication;

• Changes in social life and technology have increased general society’s awareness of health issues, while users become more active in their own treatment planning. Increase of the self-medication tendency requires authorities to provide high quality information to the public.

• Rapid dissemination of news via e-mail, social networks and the Internet faces authorities with increased demand for accurate and rapid information in both crisis and everyday situations in current communication.

• Increasing general interest. Most stakeholders, among the general public, healthcare professionals, journalists and politicians) have become more and more sensitive to healthcare issues, demanding increased access to information on the assessment process (effectiveness, safety, quality).

• Lack of grasp of the regulatory system. Patients, journalists, and even healthcare professionals are often firmly confident either that the role and influence of national authorities

are far greater than in actuality, or that they are helpless. There are issues requiring authorities in the field to provide accurate information about the system and the assessment process.

• The complexity of the regulatory context. Regulators continue to be added to the European network. Effective and efficient communication with the European Medicines Agency (EMA), the Heads of Medicines Agencies (HMA), the Council of the European Union, the European Quality of Medicines Directorate (EDQM), the European Commission (EC) etc. is another application and goal of the communication strategy. It should be noted that, given the special mission of pharmacovigilance globally, communication at the EMA level with the United States Food and Drug Administration (FDA) in particular on various medicines efficacy and safety related aspects has been of major importance in recent years.

The following are proof of ANMDM sharing European bodies' opinion on the purpose and benefits of successful communication strategies:

• Open acknowledgment of NAMMD commitment to dialogue with all stakeholders;

• Proactive management of regulatory communications;

• Improved communication in both crisis and everyday situations;

• Reinforcement of the "principle of trust", meant to provide stakeholders with the confidence in the competent national regulatory and control authority as the best source of up-to-date and quality information;

• Strengthening of NAMMD participation in the exchange of information within the European regulatory network, as foundation of the decision-making process;

• Optimisation of relations with stakeholders;

• Development of mechanisms for managing relationships with media representatives.

In the same context, absence of a consistent communication strategy may pose risks such as:

• Inconsistent approach of the subject in question, resulting in the communication of dissimilar messages from multiple sources;

• communication of inconclusive or incomplete data; substandard quality of information.

II. OVERVIEW

1. *General objective of the Communication strategy*

The general objective of the Communication strategy is improvement of communication capacities for 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 examiners, pharmacists, medical assistants, midwives) and patients.

2. Specific objectives of the Communication strategy

The communication strategy is an evolving document, setting goals sufficiently flexible to respond to the ever-changing external environment. This is the reason why, once developed and implemented, the communication strategy is permanent subject to assessment by the NAMMD management, to updates whenever required by the dynamics of the pharmaceutical legislative framework, in order to ensure its permanent adaptation to changes arising in time.

Communication must be a strategic tool in support of the NAMMD vision. The aim of the communication strategy is to demonstrate NAMMD involvement of in the development of relations with stakeholders in full alignment with EMA and HMA policy in this area.

Specific objectives of the NAMMD communication strategy are as follows:

- To improve the capacity 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 prominence 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); evaluation by stakeholders is an important element in establishing specific objectives of the communication strategy. For effective and efficient communication, the NAMMD is to clearly determine what needs to be conveyed as well as the appropriate recipients together with the achievements of communication. NAMMD awareness of dissimilarities among the various stakeholders and tailoring of its communication to the specific recipient targeted is essential;

- exchange of information/"best practices" with other EU network authorities on the time and manner of communication with regard to:

  - proactive communication
  - current, routine communication
  - crisis communication
  - confidentiality/embargo agreements

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

3. Content

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

The strategy has been developed and updated following wide research for material, by study of other corresponding European agencies' communication strategies, by reference to national and European actual circumstances.

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;

- In 2013, the European Union 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, capitalisation

First and foremost, one key objective is the decision as to what specific information is relevant to the target audience and the media and, secondly, clear, comprehensive and prompt transmission of all the relevant information to healthcare professionals, the public and the media.

In a world where communication is a constant daily means and the collection of therapeutic implements undergoes huge expansion in number and specificity, whereas public attention as well is riveted on pharmacological therapy, the NAMMD will focus on the need for adequate approach of communication activities for achievement of uninterrupted delivery of scientifically accurate and useful information.

Current communication best practices are a measure of success in crisis management as well as the best preparation for crisis situations.

Management of crisis situations and risk communication to patients is vital to public confidence in the NAMMD and other public institutions involved in the national healthcare system. NAMMD risk and crisis communication will further focus on compliance with the following principles:

- Expedited and open information is the only means to maintain confidence under crisis circumstances because transparency, predictability and coordination of communication at public institution level are reason for concern, particularly for patients, the public, the media;
- Cooperation with the Ministry of Health and other relevant national authorities involved is key for ensuring public and mass media confidence.
- Proactive approach is the optimal means for avoidance of situations of media holding the control.
- State-of-the art daily reporting to stakeholders (absence thereof constitutes a news story in itself!)
- Information on safe and effective use of medicinal products is an accepted responsibility for public health man it needs communicated to healthcare professionals and relevant partners in all stages of risk management;
- All new or emerging information on safety as well as changes in the risk-benefit ratio require prompt delivery, primarily by healthcare professionals (in practice, direct communications to healthcare professionals are only delivered after the news are cast in the media, who relays EMA and NAMMD press releases, respectively);

• Information (facts and messages) delivered is EU-wide harmonised and it must be unequivocal, concise and as comprehensive as possible, presented objectively and avoid misleading;

• Communication in risk and crisis situations requires cooperation and coordination among all partners, including the media and patient organisations, to assess effectiveness;

• To assess effectiveness, understanding and compliance of information delivered, its impact needs to be measured and evaluated;

• NAMMD messages under risk and crisis situations must be answer five key issues. i.e. what we know, what we don't know, why we don't know, steps to be taken for risk minimisation and when to come back with more information.

In the coming period ((2017-2020), the NAMMD communication strategy will pursue:

- 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 approaches 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;

- 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 and unreasonable medicines use though inappropriate advertising 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 academics 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;

- Actual involvement of all Agency professionals in:

  • Preparation of responses to media and/or any other stakeholder request for information, for delivery of specialist information to all partners,

  • development of the NAMMD website,

  • determining new needs of Agency partners,

• organisation and actual participation in meetings with Agency partners. The Agency must needs adopt increased openness towards more efficient communication with all its partners in the field, in that respect the NAMMD being determined to continue its meetings with marketing authorisation holders, associations of medicinal product manufacturer (international and Romanian), patients, associations of clinical studies co-ordinating companies, medicinal product wholesalers and retail associations etc.

- Organising and sustaining professional training courses for partners: healthcare professionals, patient associations, media representatives, on topics of major interest (legislation, good manufacturing and control practices, pharmacovigilance etc.), meant to facilitate dialogue between the NAMMD as a national regulator and control authority and stakeholders.

III. EVALUATION OF THE CURRENT SITUATION

Whereas, during pre-accession to the European Union, the 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 within its scope, the Agency's communication strategy in 2017 mainly pursues to maintain and even increase all stakeholders' confidence in work carried out by its structures, able to perform their regulatory and control function in human medicines.

1. SWOT analysis

Strengths:

- National competent authority in the field of human medicinal products, medical devices and assessment of health technologies
- Considerable appreciation at EU level
- Communication service able to communicate efficiently
- Adequately delivered and verifiable information
- In various forms or on different occasions, each staff is involved in the process of communicating with the different stakeholders.

Weaknesses:

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

Opportunities:

- Establishment, preservation and strengthening of NAMMD partnership with civil society and the media, based on communication and transparency
- Increased involvement of NAMMD partners in the Agency's activity, meant to reinforce support by stakeholders
- Reinforcement of the medicinal product legislative context by establishing partner relationships with civil society and the media, based on communication and transparency
- Increased interest from healthcare professionals, the media, patients and the general public for medicinal product related issues
- Participation in experience and information exchanges in meetings of the HMA Working Group of Communications Professionals (WGCP)

- Demonstration of conjugated operation of the European medicinal product regulatory network (EMA, the European Council, EC, the Council of Europe and national competent authorities).

Threats

- Decreased level of public confidence and credibility in the current social and political context
- 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 medicinal product and medical devices competent authorities at both EU and national levels
- The communication strategy cannot meet its objectives outside real partnership with civil society.

2. Strategic priorities

Currently, ten 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;
- Assessment of documentation for authorisation of clinical trial conduct in Romania and respective sites;
- Assessment of health technologies based on regulatory developed scientific criteria for inclusion/non-inclusion/maintenance in and exclusion from the Annex List to Government Decision no. 720/2008 of International Nonproprietary Names of on-prescription medicinal products as provided to insurants, irrespective of personal contribution, in the frame of the health insurance system, as well as of International Non-proprietary Names of medicinal products provided in national healthcare programs;
- Surveillance of the safety of medicinal products for human use in therapeutic use by means of inspections and pharmacovigilance activities;
- Ensuring access for healthcare professionals, pharmaceutical industry, patients and public to useful and accurate information on medicinal products authorised for marketing in Romania;
- Maintaining high performance and security of medical devices in use in domestic healthcare networks, regardless of ownership;
- Strictest assessment of technical and medical units providing medical devices related services, for best quality and competence of all prosthetic and repairing-maintenance medical device related services;
- Development of specific technical procedures in medical devices;
- 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:

3. Improved NAMMD communicator profile

3a. Direct NAMMD involvement in national support and implementation of communication actions as an integral part of key priorities of the Heads of Medicines Agencies (HMA) Multi-Annual Work Plan (MAWP)

The NAMMD is fully aware of the importance of effective communication and information sharing within the European network in the field, component of key priorities of the HMA Multi-Annual Work Plan developed after competion of the EMA/HMA High Level Strategy to 2020.

The HMA Working Group of Communications Professionals was established in 2008, mainly for setup of a network as well as for sharing best practices between communication professionals in national competent authorities (NCAs) and the European Medicines Agency (EMA). Among other things, the MAWP provides the group, composed of representatives of all Member States (including an NAMMD representative), with the task of developing a means for exchange of information on important issues across the entire communication network. The MAWP comprises five strategic communication-related actions to be implemented by the WGCP (activities 48, 49, 50, 51, 52), an action together with the HMA Management Group (47) and one further action (8) to be developed in cooperation with the HMA Timely Access sub-group, where Romania is represented by the NAMMD president).

HMA MAWP communication activities to be carried out by the WGCP and the HMA Subgroup on Timely Access to Medicines were prioritized in December 2016 as outlined in the following table and will be conducted with Member States' (NAMMD included) contribution and direct implementation in their own communication strategies:

Priority	**Action in strategy**	**Conducted by**	**Performance indicator**	**HMA priority**
International collaboration	8. HMA will work in the following years to explore how to improve the involvement of patients/users, Health Care professionals and academic community in those regulatory activities which have an impact on them or on which they can influence. Moreover, the collaboration with other key bodies (such as HTAs, pricing and reimbursement authorities and payers) has to be reinforced to enable appropriate decision	WGCP on patient contribution HMA Timely Access subgroup for work with HTA, payers and P&R authorities HCP and academic community	Number of HMA interactions with patients/users at national and EU level, Health Care professionals and academic community through stakeholder meetings Conduct of an assessment of the impact of any measure taken by the system to facilitate the collaboration with HTA/pricing and reimbursement bodies	Medium

	making and exchange of information to allow optimal market access.			
Optimisation of the regulatory operations	47. Increase transparency and proactivity in communicating the remit of HMA and NCAs in relation to our role in protecting public and animal health whilst ensuring a joined-up communications approach with EMA.	HMA Management Group	Development and implementation of an agreed clear strategy for network decisions made by NCAs Evidence in place of closer links with EMA communications	Short
Optimisation of the regulatory operations	48. Develop a strategic narrative for the work of HMA, its alignments with the objectives of the HLS and its practical implementation through the MAWP as part of a five-year communication plan. Enhance regular communication from HMA to stakeholders, including exploring new ways to communicate as appropriate	HMA WGCP	Establishment and publication of a HMA communication narrative	
Optimisation of the regulatory operations	49. Evaluate current mechanisms for sharing information between national communication teams and strengthen if necessary.	HMA WGCP	Conduct of an evaluation of information sharing	Short
Optimisation of the regulatory operations	51. Map key stakeholders at EU level. Agree key strategic areas of interactions. Plan for proactive	HMA WGCP	Development of a plan for proactive engagement and interaction with each identified stakeholder. Identification of key	Medium/Long

	engagement with such stakeholders. Agree plan of action with such stakeholders. National competent authorities should strengthen national level links to agencies including pricing and reimbursement and health technology assessment and to patients and the public.		strategic aims for interaction. Development of a plan to achieve aims.	
Optimisation of the regulatory operations	52. Develop more streamlined mechanisms to obtain regular feedback from key stakeholders on the operation of HMA activities and the quality of the output.	HMA WGCP	Define mechanisms for obtaining feedback and measurable improvement in the quality and effectiveness of feedback from stakeholders.	Short
Support for improved use of medicines	50. Improved communication tools for patients and HCP's to improve use of medicines including embracing new approaches to optimise communication in different media mediums, tailoring guidance on prescriptions and improving information to patients	HMA WGCP	Evidence of increased use and breadth of communication to patients	Short

3b. Improved information flow to healthcare professionals

The NAMMD is aware that patients and the general public's routine first contact involves healthcare services and treating healthcare professionals. Therefore, healthcare professionals should be provided with timely, accurate, high-quality information to help them advise patients on use of medicinal products.

That is why the Agency has focused on providing information that is key to healthcare professionals and will continue to do so at the same pace, to adequately support the work of professionals or other people involved in patient care.

In that respect, the NAMMD is to pursue:

- Completing the new its website desktop version, optimised for mobile devices (phone and tablet), for increased accessibility to information for all stakeholders; the new version ensures better organisation of information and a new search engine also facilitating more expedited access to information;

- Assessment of currently used communication channels in relation to healthcare professionals: rapid alerts, current pharmacovigilance issues (direct healthcare professionals communications, press releases of the European Medicines Agency on efficacy and safety issues, notifications to practitioners, regulations on pharmacovigilance, pharmaceutical inspection, presentation of Summaries of Product Characteristics, Patient Leaflets etc.).

- Extended use of the NMMD Facebook page to facilitate socialisation through the Internet with stakeholders, particularly patients/patients' associations and the media.

3c. The NAMMD as pro-active and reactive communicator

In exercise of its role as a proactive and reactive communicator as well as by continued improvement of its communicator profile, the Agency aims at ensuring balance between its work and routine issues it is faced with.

It is a well-known truth that confidence and positive public image take years to build and just a few moments to destroy. Therefore, the NAMMD is fully aware how important it is to improve its communicating abilities and that the best way to prepare for crisis situations and manage emergency communication is current effective communication activities, among which the following stand out:

- a communication strategy in place accompanied by communication skills at the level of both leadership and the communication structure per se;
- integrating communication into all mainstream processes, specifically consisting of current practices of risk information sharing and dialogue with stakeholders;
- crisis communication and management should be carried out according to a plan established by the Crisis Management Commission operating based on Decision of the NAMMD President and in accordance with its own organisation and operation rules, approved by decision of the Administration Council.

The NAMMD fully assumes responsibility for fair and efficient communication with the media, 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.

The media works round the clock under fast news-flow delivery conditions due to electronic networks and the internet. Therefore, the NAMMD is faced with growing demands for current and accurate information as well as need for prompt measures in crises situations, as media and citizens alike find delays almost inacceptable. The communication and information process on safety issues is increasingly soldered to pharmacovigilance operations, at the same time time-consuming and demanding expert human resources.

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 optimum

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.

3d. 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 complementing 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 feedback potential;
    - increased feedback promptness;
    - 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.

3e. Improved patient involvement in Agency work

Priority will be given by the NAMMD to continued direct communication with patients' 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.

3f. Promotion of further informed debates and information and/or awareness campaigns 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 legible leaflets able to ensure a high level of understanding, patient role in reporting adverse reactions to both healthcare professionals (physicians, pharmacists, medical assistants) and

directly to the NAMMD, clinical trials: legislation and enrollment possibilities, assessment of medical technologies: Romanian patient's access to modern, innovative treatments etc.

- Debates on the issue of no risk-free medicinal products, the key point being that a positive benefit/risk ratio is meant to 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.
- Continued debates on 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; debates regard multiple adverse reaction reporting possibilities.
- Continued stake holder (particularly patient and mass media) information on 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.

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 XVIII – The medicinal product, on transparency issues.

1a. External communication

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

It is worth mentioning that, in the context of the medicines disruptions of supply manifest as of 2015, a recurrent topic of the press at both national and European and international level, the ANMDM manages the lipsamedicament@anm.ro e-mail address established at Ministry of Health request in February 2015.

Daily coordination of responses to complaints using the respective address from patients, patients, hospitals, open and hospital circuits, patient associations, families or carers, open and in-house pharmacies, wholesale distributors, medical companies, doctors, redirected by the Ministry of Health from the site dedicated to reporting drug shortage, is based on interdepartmental collaboration within the Agency, as well as, in some cases involving contacting representatives of the Unifarm national company and/or certain wholesalers to effectively support particular patients with up-to-date information.

The NAMMD will further constant update of its website in the section created on 01.06.2016 for posting information on notifications received from marketing authorisation holders regarding temporary or permanent disruption of the availability of certain medicines in the distribution chain in Romania.

In accordance with provisions of Article 5 of *Order of the Minister of Health no. 269/14 March 2017 on the obligation to provide adequate and continuous medicinal product supplies*, the obligation has been imposed on marketing authorisation holders and wholesale distributors as of March 2017 to notify the NAMMD, 10 working days in advance, on intra-Community supply, including transactions between two or more representative offices of the same company, located in different countries, by submission of a statutory declaration of

compliance with the public service obligation. Within 5 days of submission of the notification, the identification data of the respective medicinal product (trade name / International Non-Proprietary Name / pharmaceutical form / pack size / quantity / batch) are posted on the NAMMD website, at http://www.anm.ro/anmdm/med_notificari_livrari_intracomunitare.html. This is obviously a measure designed to ensure continued availability of medicines on the Romanian pharmaceutical market. In addition, based on provisions of the same Order no 269/ March 2017, the NAMMD will continue its extensive investigative work on complaints under Article 2 (9), regarding wholesale distributors' failure to justify their orders.

Management of the ANMDM Facebook page (preparation of NAMMD notices and press releases, posting of European Medicines Agency's press releases on reassessment of certain medicines'/medicinal product classes' safety profiles, preparation of responses to direct messages on the socialisation page) will be further integrated in the institution's communication activity.

The NAMMD will continue to organise meetings, round tables with representative associations of patients, healthcare professionals, the pharmaceutical industry on topics of major interest.

In the coming period, the new NAMMD website desktop version will be optimised for mobile devices (phone and tablet), for increased accessibility to information for all stakeholders; the new version ensures better organisation of information and a new search engine also facilitating more expedited access to information.

At the same time, 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 further implemented.

The NAMMD will constantly 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), Heads of Medicines Agencies (HMA), the European Directorate for the Quality of Medicines (EDQM), the Coucil of Europe, the European Council, the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and the European Commission.

- Information on marketing authorisation procedures (centralised, European MRP-DCP and national): data about contact persons, special warnings, SmPC, leaflets and labelling information. Moreover, the "National procedure" section 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.

Information related to:

- clinical trials,
- pharmacovigilance,
- pharmaceutical inspection,
- assessment of medical technologies
- advertising
- falsified medicines

will be constantly posted on the website as of major interest to NAMMD partners.

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).

At the same time, the section on NAMMD activity as a competent national authority in the field of medical devices will be developed and updated periodically.

Moreover, the NAMMD will further inform stakeholders on work carried out by publications other than its Newsletter, thus, the NAMMD activity report for the preceding year will be also posted on the website in both Romanian and English.

Publication of articles dealing with various issues related to the Agency's activity in Romanian professional magazines ("Politici de sanatate", "Farmacist.ro", "Medical Business", "Viaţa Medicală", "Pharma Business", "Medica Academica", "Practica farmaceutică" etc.) will further be pursued.

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;
- Status 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 status and of the legal framework, the NAMMD intends to carry out efficient actions to both 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

The agency is at least aiming at further maintaining its financial stability through a balanced budget year, in accordance with the laws in force.

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.

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.

To successfully meet its most important strategic objective, i.e. protection of public health, 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.

By implementing a coherent communication strategy, the NAMMD will ensure more accurate estimate by healthcare professionals, internal and external partners, patients of the Agency's constant efforts for wide acknowledgement of its status as European competent authority in its area of competence.