DECISION

No. 1/22.04.2013

on approval of the organisational 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 organisational 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. 1/22.04.2013

ORGANISATIONAL STRATEGY OF THE NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES 2013 - 2015

The National Agency for Medicines and Medical Devices (NAMMD) is a public institution operating under the Ministry of Health, set up through Emergency Government Ordinance no. 72 of 30 June 2010 on reorganisation of healthcare facilities and amendment of public health legislation, as a result of the merger of the National Agency for Medicines and Medical Devices with the Technical Office for Medical Devices. NAMMD organisation and operation have been approved through Romanian Government Decision no. 734 of 21 July 2010.

The NAMMD is the Romanian competent authority in the field of medicinal products for human use, ensuring marketing authorisation, surveillance of the safety of medicinal products in therapeutic use, authorisation of clinical trials and issuance of regulations in the field of the medicinal product, approved by the Ministry of Health.

In the field of medical devices, the responsibility of the NAMMD lies in control of performance and safety of medical devices in use as well as assessment of capability of the organisations providing services in this domain.

This organisational strategy is set up and updated in the context of the legal framework establishing the relation between the NAMMD and the Ministry of Health, as well as with its stakeholders. It covers the period 2013 – 2015 and allows update depending on the overall and pharmaceutical legal framework.

Additional details and information on NAMMD work can be found on its website, at www.anmdm.ro.

MISSION, VISION AND STRATEGIC OBJECTIVES OF THE NAMMD

The *Mission* and *Vision* of an organisation are a set of well individualised values to be adopted and applied in the organisation's life, strongly reflecting and being reflected in the content of the management culture.

They are an expression of the represent the course and possibilities for development.

The features of strong *Mission and Vision* are as follows:

• suitability – they are appropriate for the respective organisations, in the given context, matching the history and values of the organisation, with its performance and achievements and provide an assessment of desired situations possible to reach if specific pathways are taken;

• defining character of the organisation's purpose – they confer the actual meaning and significance to the life of the organisation and to the role of its employees;

• ability to initiate and support encouraging messages to employees for full intellectual and emotional involvement in the development of organisation activities;

• capacity to convey messages in an easily accessible manner, so as to be able to guide decisions and actions of those called upon to implement them;

• capacity to stimulate employees towards transcending their own limits in order to ensure attainment of strategic goals of the organisation;

• singularity at national level, in the community context of distinct competencies in the field of medicinal products for human use.

Mission of the NAMMD:

- **Evaluation at the highest scientific competence** of documentation for authorisation in view of marketing high quality, safe and effective medicinal products for human use;
- **Surveillance of the safety of medicinal products for human use** in therapeutic use by means of inspection and pharmacovigilance activities;
- **Maintenance of a high level of performance and safety of medical devices in use throughout healthcare networks in the country, irrespective of ownership;**
- **Most demanding assessment of technical-medical units providing services in the field of medical devices, for optimum delivery of competent and quality prosthetic and repair-maintenance services;**
- **Ensuring access for patients and healthcare professionals** to useful and accurate information on medicinal products for human use authorised for marketing in Romania;
- **Ensuring institutional administrative effectiveness, efficiency** and transparency of practices and procedures in use.

Vision of the NAMMD:

- **Strengthening of its status as reference national authority** in the field of the medicinal product for human use and control of the performance and safety of medical devices in use;
- **Strengthening of its status as expert and reliable source of accurate information and timely information** in the field of medicinal products for human use, provided to stakeholders.

Strategic objectives of the NAMMD are as follows:

- **Protection and promotion of public health**, by accomplishment of the NAMMD primary role, namely warranty of compliance of authorised medicinal products with the required standards, their efficacy and their acceptable level of safety;
- **Protection and promotion of public health**, by accomplishment of the NAMMD primary role, namely warranty of compliance of medical devices with the required standards, their intended purpose and acceptable level of safety;
- **Fulfilment of the NAMMD role as a communicator**, as an expert and reliable source of accurate and timely information, by providing clear and timely information to healthcare professionals, patients and the general public;
- **Contribution to the shaping of the future legal frame** in the field of medicinal products for human use, through promotion of NAMMD efficient European and international relations;
- **Contribution to the shaping of secondary legislation** in the field of medicinal products for human use and medical devices.

- **Coordination of an organisation** endowed with quality and adequately qualified workforce, **able to cope with future challenges**.

Table of contents:

1. Introduction

1.1. – Medicinal products for human use

Since its set up in 1999, in its various stages of development, the Agency has witnessed significant developments in the legal field, both nationally (by harmonisation of national and European legislation), and on European level (European legislation which the agency sought harmonisation with was itself undergoing major changes), such as:

• Gradual replacement of former national legislation with harmonised European legislation;

• Major revision of the EU body of medicinal product legislation (amendment of Directive 2001/83/EC);

• Introduction of regulatory provisions for harmonisation of authorisation procedures and conduct of clinical trials throughout the EU (Good Clinical Practice directives);

• Introduction of regulatory provisions meant to increase availability of authorised medicinal products, particularly for the treatment of children (the Paediatric Regulation);

• Introduction of regulatory provisions in the field of traditional herbal medicinal products (by supplementation of Directive 2001/83/EC);

• Introduction of a new regulatory system concerning safety and quality of homeopathic medicinal products (by supplementation of Directive 2001/83/EC).

• Introduction of legislation in the field of tissue engineering medicinal products and their use (Regulation on advanced therapies);

• Introduction of new regulatory pharmacovigilance provisions (by Regulation and Directive for amendment of Directive 2001/83/EC);

• Introduction of new regulations for preventing the entry into the legal supply chain of falsified medicinal products (by Directive 2001/62/EU of the European Parliament and of the Council for amendment of Directive 2001/83/EC).

Medical devices

Since its set up in 2005, by reorganisation of the SVIAM, the Technical Office for Medical Devices (TOMD), currently part of the NAMMD, the organisation has actively participated in generation of national regulatory documents in the field of medical devices, by:

• set up and revision of the legal framework for conduct of control by periodic check of medical devices;

• set up and revision in compliance with European legislation of the legal framework for assessment of service providers in the area of medical devices;

• set up and revision of the legal framework for ascertaining and sanctioning the violations in the field of medical devices;

1.2. - The NAMMD has implemented a number of important specific initiatives meant to improve performance of its basic activities, extend its role through appropriation of new fields of activity and improved communication with healthcare professionals and the general public, as well as the latter's improved communication with the Agency, through:

• Enforcement of a major restructuring of medicinal product operational departments, which has led to a more consistent surveillance of medicinal products throughout their lifecycle;

• Major reorganisation of operational departments in the field of medical devices, leading more efficient use of staff;

• Introduction of a new and important information system in support of the decision-making process and work in agency-level electronic format;

• Appointment of the largest possible number of NAMMD experts for participation in committees and working groups of European medicinal product institutions, ensuring NAMMD ability to continue its active contribution to the EU legal and decision-making process;

• Participation with NAMMD experts in ASRO committees in the field of medical devices, ensuring NAMMD capacity further make an active contribution to the standardisation process;

• Improvement of the information flow provided to healthcare professionals;

• Improvement of NAMMD profile as a communicator.

1.3. – This organisational strategy takes into account the viewpoints expressed by stakeholders and outlines the principles and main directions of NAMMD interests and activities for the next 3 years.

2. Protection and promotion of public health

2.1. - Protection and promotion of public health is the NAMMD general objective, as well as the core of its activity throughout the process related to surveillance of the development and control of the use of medical devices.

The NAMMD performs assessment at the highest level of scientific competence of documentation for marketing authorisation of quality, safe and effective medicinal products for human use.

The NAMMD carries out inspections of all aspects concerning medicinal product development and manufacturing process, taking measures against the companies or persons who fail to comply with their obligations.

The NAMMD authorises conduct of clinical trials with medicinal products in various stages of development and seeks, by intervention of specialised inspectors, implementation of Good Clinical Practice rules.

The NAMMD monitors safe use of medicinal products for human use throughout their lifecycle, by means of a well-developed adverse reaction reporting system, so as to ensure maintenance of an acceptable risk/benefit balance for the respective products, as well as careful information in that respect of relevant interested parties, patients and healthcare professionals.

The NAMMD assesses all aspects related to service delivery in the field of medical devices.

The NAMMD ascertains violations of the law and takes measures against companies or individuals failing to comply with their duties pursuant to Law 176/2000 on medical devices, as amended.

2.2. - Significant improvement of the NAMMD safety monitoring systems and their underlying legislation as well as increased NAMMD efforts for better patient and public understanding of the benefits and risks associated with medicinal product use have been apparent in late years.

In Romania, pharmacovigilance work is based on European regulatory grounds, transposed and implemented into national legislation.

In accordance with public documents of the European Commission, pharmacovigilance can be defined as "the science relating to the detection, assessment and prevention of occurrence of adverse effects to medicinal products and all related activities".

The National Pharmacovigilance Centre functions within the NAMMD.

Among others, NAMMD pharmacovigilance activity includes assessment and transmission of adverse reactions into the EudraVigilance system (the European data-processing network and database management system), assessment of Periodic Safety Update Reports (PSURs), of pharmacovigilance systems of marketing authorisation holding companies, assessment of Risk Management Plans, harmonisation of Summaries of Product Characteristics (SmPCs) by implementation of the decisions of the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) in sections dealing with medicinal product safety.

Since 1976, the NAMMD has been a member of the World Health Organisation (WHO) Collaborating Centre for international monitoring of medicinal product safety.

The WHO has played an important role in development of pharmacovigilance by means of its monitoring centre in Uppsala (Sweden), handling an international database of adverse reactions to medicinal products. The number of national centres - active members of the WHO scheme for international monitoring of the medicinal product has now reached 98, while the number of adverse reactions in the database has grown to over 5 million.

Starting with 2012, the new Directive 2010/84/EU of the European Parliament and of the Council of 15 December 2010 has come into force, amending, in terms of pharmacovigilance, Directive 2001/83/EC on the Community Code relating to medicinal products for human use, transposed through Emergency Ordinance 35/2012. This Directive has brought changed and added to the legal pharmacovigilance assignments of Member States.

It is the NAMMD intention to develop the national pharmacovigilance system in accordance with provisions of the new directive and pay particular attention to its collaboration with European bodies and competent authorities as far as medicinal products are concerned.

The NAMMD seeks to further highlight the value of reports received by providing prompt feedback to reporters and continued development of public and patient level of understanding of decisions concerning the risk/benefit balance of medicinal products for human use available on the Romanian pharmaceutical market.

At the same time, the NAMMD is intent on furthering its efforts towards guidance and encouragement of healthcare professionals for adverse reaction reporting.

Over the past years, significant improvement has been apparent of NAMMD systems for control of medical devices in use and monitoring of service providers in the same field, of legislation underlying this control activity as well as enhanced Agency efforts for better patient and user understanding of the benefits and risks associated with the use of medical devices.

For the years to come, the NAMMD envisages continued development of its working system, so as to ensure that throughout Romania medical devices are used in accordance with the law, and that prosthetic works of any kind, maintenance and repair of medical devices are performed in line with the highest quality standards.

The NAMMD seeks to pursue its efforts to educate healthcare professionals and encourage their reporting of incidents with use of medical devices.

2.3. - At the same time, the NMA plans on active involvement in development of the European community system for monitoring of medicinal product safety, which, through combined information from the 27 Member States included in the EudraVigilance database, will further strengthen the elements underlying decision-making in safety matters.

EudraVigilance is one of the basic components of the *European Risk Management Strategy* related to medicinal products.

Risk Management represents the joint action of the European Medicines Agency and of national competent authorities in the EU for strengthened pharmacovigilance activity.

Furthermore, the NAMMD plans to get actively involved in implementation of the European Risk Management Strategy related to medicinal products, whose primary actions are as follows:

a) implementation of European community legislation;

b) taking complementary initiatives for establishing an improved medicinal product monitoring system as regards:

- communication of risks and initiatives in insufficiently developed pharmacovigilance areas (vaccines and paediatrics)
- risk detection, assessment and minimisation;

c) additional consolidation of the European pharmacovigilance system;

d) initiation of a Management plan of incidents within the EU regulatory system, meant to handle medicinal product crisis situations in the EU, regardless of the procedure for their authorisation;

e) implementation of the project concerning a ENCePP-European Network of Centres for Pharmacoepidemiology and Pharmacovigilance, coordinated by the European Medicines Agency.

2.4. – Starting with 2013, the new Directive 2011/62/EU as regards prevention of the entry into the legal supply chain of falsified medicinal products, amending Directive 2001/83/EC on the Community Code relating to medicinal products for human use, has been implemented into Member States national legislations. This Directive has made essential additions to legal assignments of competent authorities, as well as to manufacturers, importers and distributors in their fight against falsified medicinal products.

For best implementation of the new Directive, the NAMMD will set up a specialised structure within the Pharmaceutical Inspection Department, meant to handle and monitor complex issues related to prevention of entry of falsified medicinal products into the legal supply chain.

In the current context of falsified medicinal products becoming increasingly stronger reason for concern for regulatory authorities and the public, the NAMMD has initiated and continued cooperation with national institutions involved in fight against sale of falsified medicinal products, particularly over the internet, as well as with correspondent institutions in EU or non-EU member states, to establish new permanent connection points, meant to limit such criminal phenomena.

Thus, one of its main objectives has been to establish an overall frame for bilateral cooperation and exchange of information related to falsified medicinal products for human use with the General Inspectorate of the Romanian Police.

The main directions of NAMMD cooperation with the General Inspectorate of the Romanian Police are as follows:

- Compliance with legislation concerning medicinal products for human use;
- Exchange of information, to meet their legal assignments;
- Conduct of market studies and analyses, for most accurate knowledge of the Romanian market of medicinal products for human use, particularly as regards manufacturing, import and distribution;

- Surveillance of the operation of markets to identify non-compliances with national and/or community law for falsified medicinal products and legal provisions for medicinal products for human use, for measures to be taken by the two authorities as required, according to their respective competencies and their correlation;
- Communication and information of the public and economic agents active on markets of medicinal products for human use concerning measures taken in case of violation of national and/or community legislation relating to falsified medicinal products;
- Mutual support to ensure efficient operation of and safety in the medicinal products for human use sector, required legal changes included.

2.5. - For the following 3 years, the NAMMD envisages the following:

• Insurance of authorised medicinal products compliance with the adequate quality, safety, efficacy standards and authorisation in the shortest time possible;

• Authorising changes/variations to the marketing authorisations of medicinal products for human use (for new strengths or pharmaceutical forms etc.) in the shortest time possible, while safeguarding public health;

• Further authorisation of clinical trials and investigations only providing adequate warranty for patients, in accordance with harmonised community regulations;

• Further development of the National Pharmacovigilance Centre operating within the NAMMD and improvement of the adverse reactions/events reporting system, so that collection of information is allowed from the most comprehensive sources, reporting is undertaken in the simplest manner and feedback is quickly delivered to encourage participation;

• Increased transparency and improved communication in the field of medicinal product safety;

• Performance of actions to ensure efficient surveillance of medicinal products for human use throughout Romania;

• Insurance of full NAMMD undertaking of its role in implementation of EU legislation for increased number of medicinal products particularly authorised for the treatment of children;

• Providing support to governmental initiatives in handling of severe public health risks (e.g. pandemic flu, bioterrorism) and fulfilling the NAMMD role in ensuring availability of relevant products to cover any increased demand;

• Provision to the public of adequate information/instructions on safe use of medicinal products, as well as warnings concerning their use under risk situations, when needed, for both on-prescription and over-the-counter (OTC) medicinal products;

• Maximum use of available instruments in support and consolidation of monitoring the safety of medicinal products for human use;

• Promotion of a risk-based approach in inspection activities, in line with NAMMD public health responsibilities and optimal use of resources;

• Taking efficient and prompt measures to prevent the entry of falsified medicinal products into the legal supply chain, in the context of NAMMD legal assignments as derived from provisions of Emergency Ordinance no. 91/2012, transposing Directive 2011/62/EU as regards prevention of the entry into the legal supply chain of falsified medicinal products.

• Developing cooperation with other institutions and bodies involved in this activity and increasing public awareness of falsified medicinal products hazards.

• Review of regulatory documents governing control activity through periodic check-ups of medical devices, so that the list of controlled medical devices and the regularity of check-ups are compliant with the degree of device risk;

• Continued improvement of procedures for assessment and surveillance of organisations seeking to service medical devices and assertion of establishment of labour conditions at European level;

• Investigation of all incidents involving medical devices together with in conjunction with habilitated institutions, in view of determining and minimising the causes.

3. Information and communication

3.1. - Most regulatory activities result in communication of updated information on medicinal products for human use as new knowledge thereof emerges during their use. This is usually undertaken as either provision of information to healthcare professionals or revised versions of the Patient leaflet. The quality of the information provided by the NAMMD is thus essential in fulfilling its role to protect public health.

The ever increasing degree of in-use knowledge of medicinal products for human use and their manner of regulation will also contribute to media and public understanding of the safety issues and the exceptional circumstances requiring product recall from the market.

3.2. - Healthcare professionals as well need clear information and recommendations to rely on when discussing options of treatment with their patients, whereas patients and the public look for access to information on medicinal products they use in their own care, related to their mode of action, the benefits which may be expected, the risks associated with their use, as well as better understanding of the manner in which the benefit/risk balance is established.

3.3. - The NAMMD has elaborated a Communication Strategy (2013 – 2015), describing the frame for internal and external communication throughout this period and establishing the key actions required for communication development. The communication strategy can be updated depending on the overall and pharmaceutical legal framework.

The main objective of the NAMMD communication strategy will be achievement of a higher degree of understanding of the risk/benefit balance assessment and of the manner of NAMMD decision-making for performance of its assignments as well as stimulation of adverse reactions/events reporting.

To be able to attain the most important strategic objective concerning protection and promotion of public health, the Agency must be able to constantly describe the content of its work.

The NAMMD communication strategy has established the core messages defining the Agency's activity and representing the key messages at the highest level has been conveying in order to meet the objectives this strategy provides for.

3.4. - The NAMMD is seeking that the public fully trust the medicinal product regulatory system, acting towards their best interest, by applying an approach best described by openness and transparency.

Much has been accomplished to this end over the past years and the NAMMD will further improve the transparency of its own activities and their accessibility to the public. The NAMMD will also promote transparency in the activity of the industry under its regulatory scope.

3.5. - Among the NAMMD strategic priorities mention should be made of the need for, closer and more effective engagement with patient associations and the general public, as well as identification of general ways of bringing patient perspective in its work. This activity has been initiated previously and will be continued and developed.

The NAMMD will continue to:

• Take action in view of strengthening its status as an expert and reliable source for the most recent information concerning medicinal products for human use on the market, by implementation of the NAMMD Communication Strategy;

• Make sure that the information accompanying medicinal products are easy to use, through full compliance with requirements established for user testing of the leaflets;

• Establish ways to enhance transparency throughout the decision making process, on both NAMMD and industrial level under its regulatory scope;

• Address healthcare professionals with targeted information, for improved adverse reactions/events reporting and promotion of safe use of human medicinal products (e.g. by adequate description, search and request of adequate information from the NAMMD);

• Make targeted information available to the public, in view of better adverse reaction reporting by the patient, promotion of better informed patient decision concerning the use of medicinal products for human use;

• Further develop its own website so as to be acknowledged as an expert and reliable source of the latest information on medicinal products for human use;

• Contribute to better understanding by the public and/or healthcare professionals of the benefit/risk balance of medicinal products for human use;

• Cooperate with professional bodies, academic staff and others, in order to ensure an adequate content of training programmes for healthcare professionals, in such issues as safety and risk in prescription and use of medicinal products for human use;

• Devise and implement new ways of increasing patient and public involvement in NAMMD activity and optimal utilisation of their contribution to the decision making process.

4. Shaping of a balanced legal framework

On European level

4.1. - The NAMMD will continue in its role as the Romanian and EU competent authority in the medicinal product field, fully integrated in the operations of EU competent authorities as well as in the work of medicinal product committees and working groups of European bodies.

As of 2008, the NAMMD also acts as Reference Member State in the coordination of assessments of marketing authorisation applications submitted for authorisation through European procedures, particularly through the decentralised procedure, thus proving its expertise in the ongoing development of the Agency's assessors.

Following ratification of the Convention for the European Pharmacopoeia, within the Council of Europe, Romania has become a full member as of 2003. As member of the European Pharmacopoeia Commission, the NAMMD assigned representative actively participates in its working sessions.

The Agency aims at maintaining its very important contribution to the activity of the European network of competent authorities in the field of the medicinal product as well as to the activity of the Official Medicines Control Laboratories (OMCL) network.

4.2. – The NAMMD will continue to:

• Ensure active participation in technical and scientific debates regarding the setup of new legal provisions in the field of medicinal products for human use;

• Ensure the most efficient possible operation of the present regulatory system in the field of medicinal products for human use and promptest implementation of future changes brought to the European regulatory framework in this field;

• Strengthen surveillance of the Romanian/European market through closer cooperation and collaboration with the other European medicines agencies;

• Provision of knowledge and expertise to other states, signatories of *the Collaboration Agreement of Drug Regulatory Authorities in European Union Associated Countries (CADREAC)]/New Collaboration Agreement between Drug Regulatory Authorities in Central and Eastern European Countries (nCADREAC).*

On an international level

4.3. – Particularly following Accession, within the European pharmaceutical regulatory system, the NAMMD cooperates with all national competent authorities in the European Union (EU) and in the European Economic Area (EEA), as well as with the European Medicines Agency (EMA).

Via the EMA, the NAMMD hopes to be able to also further develop international connections with the United States Food and Drug Administration (FDA), within the cooperation framework established between the EMA/EU and the FDA/USA.

It is the NAMMD belief that, for efficient performance of its regulatory assignments in the field of medicinal products for human use, for public health benefit, it also needs good working relationships with non-EU countries, particularly with those displaying abilities for the development of medicines, which increasingly represent a significant source of supply for the EU market.

4.4. – The NAMMD considers it advisable that regulatory authorities worldwide be able to cooperate for setup of harmonised standards, applicable to global connections to the pharmaceutical industry.

4.5. – The Agency will further:

• Develop its international and cooperative relations in the field of medicinal products for human use, in the context of a global market for medicinal products;

• Support proceedings concerning harmonisation of regulations of the International Conference on Harmonisation (ICH) in the medicinal product field;

• Develop cooperation established with competent authorities in strategically important countries, such as China, India and Korea, which will become an increasingly important source for manufacturing and development of medicinal products for human use, subject to NAMMD authorisation and surveillance.

Implications of scientific and technological progress

4.6. - The NAMMD anticipates significant scientific and technological progress with potential impact on regulation of medicinal products in the following fields:

• Biotechnology products;

• Progress in the fields of molecular biology, genomics, gene and cell therapy;

• Use of new screening technologies and mechanisms, better adapting medicinal products to patients, development of “personalised” and “niche” medicinal products and diagnostic tests, for identification of suitable patients;

• Development of products combining a medicinal product with its own release system, into a medicinal product/medical device association;

• Use of nanotechnology, biomedical science, microelectronics and computer technology;

• Tissue engineering.

4.7. – The NAMMD may contribute to the development of efficient treatments to benefit health by promoting a supportive context for conduct of clinical trials in Romania, according to European legislation in force.

The Agency will continue its collaboration with partner organisations and support European efforts for harmonised approach of the requirements for clinical trial authorisations, by diminishing inconsistencies and bureaucracy while maintaining safety measures regarding trial participants.

4.8. – The NAMMD will further:

• • Ensure preservation, through contribution with adequate expertise in debates of scientific committees organised by European bodies, of the legislative ability to establish a proper balance between cautious approach of the safety issue and the freedom of innovation;

• Establish contacts with academic and professional centres of renown in the field of medical, pharmaceutical and legislative sciences, for ensured NAMMD capacity to rely on optimal abilities and knowledge in preservation of its own expertise;

• Promote an optimal internal context for clinical research and cooperation with EU bodies for harmonisation of regulations on clinical trial authorisation.

Towards Better Medicinal Product Regulation

4.9.1. – The NAMMD Scientific Council establishes the Agency's scientific policy, in accordance with its assignments.

Meetings of the Scientific Council discuss and approve, as Scientific Council Decisions, regulations in the medicinal product field, as well as regulations concerning the professional activity of the Agency..

NAMMD Scientific Council decisions of ruling character are approved by the Minister of Health and are published as Minister Orders in the Official Gazette of Romania, Part I.

4.9.2. – It is the NAMMD duty to ensure that medicinal product regulatory activity is proportionate with and adequately reflects the current level of knowledge regarding benefits and risks.

This amounts to NAMMD ongoing self-assessment and insurance that it adequately reflects the needs of stakeholders, provision of an effective regulatory service and direction of activities towards compliance with the Agency's main objective of protecting public health.

Considering the lack of specialised personnel, the NAMMD is unable to engage in scientific advisory activities; however, it frequently gives advice on regulatory issues.

4.10. - The NAMMD intends to carry on its risk-based approach in the inspection field, allowing focus on issues of potential concern, to fully capitalize on its inspection resources.

The Agency undertakes to further explore the scope of a risk-based approach of the NAMMD regulatory functions and search for fields providing room for regulatory practice improvement, compliant with both the law and the NAMMD role in protecting public health.

4.11. - The NAMMD is also aware of the need to ensure concise and unambiguous legal provisions underlying any of its regulatory activities.

National legislation in the field of medicinal products for human use has undergone significant changes over the years, but as of entry into force of Law 95/2006, Title XVII – The medicinal product, it has been fully harmonised with European legislation and amended in accordance with emerging European regulations.

4.12. – The NAMMD will continue to:

• Develop its risk-based inspection and search for other opportunities for reducing unnecessary legal obligations, as well as find areas allowing for attainment of the Agency's objective concerning substantiation of regulations on risk and proportionality;

• Support the European Commission's initiative for better regulation and continued contribution to this issue on national and European level;

• Strengthen and rationalize the law in the field of medicinal products for human use.

5. Leadership of a successful organisation

5.1. - Given the dynamic context for its operation, the NAMMD needs to preserve its influence in its own field, as well as its flexibility and ability to respond to changes.

The coming into force of the new European legislation has generated significant changes in workload, therefore enabling the Agency to anticipate the further development of specific EU aspects, whereas others may remain constant or even diminish.

The NAMMD will take the necessary measures to maintain its flexibility and ability to adapt to a fluctuating workload, namely to increased/decreased demand, which would be an advantage for both the Agency and the industry.

5.2. – The NAMMD needs good working relationships with the industry under its regulatory scope, created through efficient dialogue with the leading manufacturers' associations and marketing associations in the field of the medicinal product for human use, as well as with healthcare professionals and patients taking these medicinal products.

Good cooperative relations need to be preserved with other governmental bodies, whose activity is closely related to NAMMD work.

5.3. – The Agency will further:

• Make investments and develop efficient information management systems in support of its own activity and undertake an active role in the context of the EU debate on elaboration and enforcement of adequate and consistent systems;

• Ensure that its own work reflects the needs of interested parties, thus meeting its main objective of protecting public health;

• Maintain efficient relations with other governmental bodies;

• Maintain and improve collaboration and cooperation with the pharmaceutical industry and maintain adequate contacts with leading manufacturers' associations and marketing associations in the field of medicinal products for human use.

• Maintain and improve collaboration and cooperation with the medical devices industry as well as appropriate connections with the ASRO, RENAR and the national health insurance houses.

Agency staff

5.4. – Its own staff is the Agency's chief resource. Enforcement of efficient regulation to protect public health involves **maintenance of highly qualified and motivated workforce**.

This goal is particularly difficult to achieve under the present circumstances when current public system possibilities to reward its employees can hardly compete with opportunities on the private market, that have attracted specialists whose expertise is due to their work in the Agency.

The NAMMD will have to further its efforts to preserve its currently available staff with regulatory and scientific expertise, providing at least motivation through adequate assessment of performance and acknowledgment of professional competence, respectively, until creation

of a favourable legislative context allowing for appropriate financial motivation for reward of special professional merits.

5.5. – Depending on progress of the current economic crisis, the NAMMD seeks to:

• Undertake efficient recruitment and selection of new staff, particularly from among new graduates of medical-pharmaceutical higher education.

• Implement promotion policies to ensure the human resources in the NAMMD, mainly in areas where analysis reveals deficits of personnel of higher education;

• Provide staff with a wide range of professional training and opportunities for improvement, for developed human resources..

Financing of Agency operation

5.6. – At the end of 2009, **the Agency was reorganised as a public institution wholly financed from the state budget**, in accordance with Law 329/2009 on reorganisation of certain authorities and public authorities, rationalisation of public expenditure, support to business and compliance with the framework agreements with the European Commission and the International Monetary Fund.

Considering that the Agency used to be self-financed before 2009,, subsequent fiscal-financial measures have had a major negative impact on human resources management and implicitly on financing of the Agency's entire work.

The NAMMD seeks to at least maintain its financial stability through a balanced budgetary exercise, within the allocated budget, an in observance of legislation in force.

5.7. – The NAMMD periodically updates its tariffs depending on changes in its activities.

The NAMMD aims at further finding activities able to enhance its income, such as organising conferences, training sessions etc.

Conclusions

The NAMMD is a mature institution, fully able to manage the activities arising from its status as an EU competent authority.

This is also the case in European context, where the NAMMD is met with recognition and appreciation as Romania's competent authority in the field of medicinal products for human use.

The context for NAMMD operation has been subject to numerous changes, which it has strived to understand and adapt to requirements of the process related to the shaping of developments and the enforcement of new policies

Relying on its long and efficient activity, the NAMMD, will have to prepare to cope with any challenges future may bring.