Annex
to Scientific Council Decision No. 1/2015

Organisational Strategy of the National Agency for Medicines and Medical Devices 2015 - 2017

The organisational strategy of the National Agency for Medicines and Medical Devices (THE NAMMD) is a reflection of the Agency's priorities and thematic focus for the next three years.

The NAMMD is a public institution under the Ministry of Health, established through Ordinance No. 72 of 30 June, 2010 for reorganisation of healthcare institutions and amending certain healthcare laws, in result of consolidation by merger of the National Agency Medicines and the Medical Devices Technical Office. THE NAMMD organisation and operation were approved through Government Decision No. 734 of 21July, 2010, as amended.

Government Decision No. 315 of 23 April 2014, amending Government Decision 734/2010 for organisation and operation of the NAMMD, redefine the main duties of the Agency in the field of medicinal products for human use (including assessment of documentation for marketing authorisation, safety surveillance by pharmacovigilance inspection of medicinal products already in the therapeutic circuit and authorisation of clinical trial sites and conduct, medicinal product regulation approved by the Ministry of Health) plus setup of the list of reimbursed and free of charge medicines. In 2014, the NAMMD became the competent national authority for assessment of health technologies.

Law no. 132 of 9 October 2014 for Approval of Emergency Government Ordinance No. 2/2014 for amendment of Law No. 95/2006 for healthcare reform, also amending certain other regulatory acts, designates the NAMMD as national competent and decision making authority for medical devices.

The NAMMD authorises conduct of clinical investigations of medical devices on human subjects, according to regulations in force; the NAMMD is responsible for monitoring the performance and safety of medical devices in use as well as for assessment of service providers' capability in this field.

The NAMMD drafts proposals for submission to the Minister of Health of regulatory acts transposing European directives or creating a framework for implementation of European Union (EU) regulations concerning medicinal products or medical devices, respectively.

This organisational strategy is developed and updated within the legislative framework establishing the relationship between the NAMMD and the Ministry of Health as well as stakeholders. The current document covers the period 2015 - 2017, providing for adjustment for the general and pharmaceutical legislative framework.

Additional information on THE NAMMD work may be found on its website, at www.anmdm.ro

NAMMD MISSION, VISION AND STRATEGIC OBJECTIVES

An organisation's *Mission and Vision* are a well individualised set of values meant for adoption and implementation at organisational level, at the same time strongly reflecting and a reflexion of the management culture content.
They are an expression of the way forward and development opportunities.
Features of a powerful mission and vision are:

• Adequacy - appropriateness for their respective organisations, in the given context, in line with the history and values of the organisation as well as with its performance, at the same time providing assessment of desired situations, attainable on condition certain courses of action are taken;
• Characterising the organisational purpose - provide true meaning and significance to the purpose of the organisation and the role of its employees;
• Proficiency in initiation and maintenance of urges to employee uncompromised intellectual and emotional involvement in development of organisation's work;
• Proficiency in conveying messages in an accessible form, so as to guideline decisions and actions of individuals called to their implementation;
• Proficiency in stimulating employees to self-improvement, to ensure accomplishment of strategic objectives of the organisation;
• Nationally unique character, in the context of distinctive competencies characteristic to the field of medicinal products and medical devices.

NAMMD MISSION:

- **Assessment at the highest scientific competence** of documentation for authorisation for marketing of high quality, safe and effective medicinal products for human use;
- **Implementation of a mechanism for prompt assessment of health technologies**, based on analyses and assessment reports of EU member states, for decision-making, with approval from the Ministry of Health;
- **Surveillance of the safety of medicinal products for human use** in therapeutic use by means of inspection and pharmacovigilance activities;
- **Registration of medical devices marketed or set in operation** in Romania, of national manufacturers, authorised representatives and distributors of medical devices, according to regulations in force;
- **Set up and update of the national data base** in line with national legal provisions transposing European directive related to medical devices;
- **Authorisation of the programme** for implementation of the procedure for clinical investigation/assessment of performance with medical devices for clinical investigations;

- **Ensuring activities related to the Agency's duty for surveillance of the medical device market**, in line with legislation in force;
- **Registration and assessment of information on incidents and corrective action reported in relation with medical devices** and implementation of the vigilance procedure provided for in harmonised regulations in force;
- **Maintaining of a high level of performance and safety of medical devices in use by healthcare networks throughout the country, irrespective of ownership;**
- **Most demanding assessment of service providing medical-technical units in the area of medical devices, for optimum delivery of competent and quality prosthetic and repair – maintenance services;**
- **Ensuring patient and healthcare professional access** to useful and accurate information on medicinal products for human use authorised for marketing in Romania as well as on medical devices;
- **Ensuring institutional administrative effectiveness, efficiency** and transparency of practices and procedures in use.

NAMMD vision:

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

NAMMD strategic objectives

- **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, and warranty of compliance of medical devices 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 to warrant compliance by medical devices with mandatory standards, intended purpose and an acceptable safety level;
- Fulfilment of the NAMMD role of communication, as a permanent expert and reliable source of accurate and timely information related to the medicinal product for human use, by providing clear and timely information to healthcare professionals, patients, the pharmaceutical industry and the general public;
- **Contribution o the design of the future legal frame** in the field of medicinal products for human use, by promotion of more effective working relations on European and international level;

· **Contribution to the design of implementation rules** in the fields 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**.

Contents:

1. Introduction

1. 1. - Medicinal products

Since the time of its establishment in 1999, in its various stages of development, the Agency has undergone significant regulatory developments, both internally (by harmonisation of national and European legislation) and at European level (European legislation the Agency sought alignment with was subject to major transformations itself), i.e. :

• Gradual replacement of former national legislation with harmonised European legislation;
• Major revision of EU medicinal product legislation in its entirety (amendment of Directive 2001/83/EC);
• Introduction of regulations to harmonise procedures for authorisation and conduct of clinical trials across the EU (Directive on Good Clinical Practice);
• Introduction of regulations designed to increase availability of medicines specifically authorised for the treatment of children (the Paediatric Regulation);
• Introduction of provisions for regulation of herbal traditional medicines (by amending Directive 2001/83/EC);
• Introduction of a new system for regulating the safety and quality of homeopathic medicines (by amending Directive 2001/83/EC).
• Regulation of manufacture of tissue engineered products and their use (the Advanced Therapies Regulation);
• Introduction of new regulatory pharmacovigilance provisions (Regulation and Directives amending Directive 2001/83/EC)
• Introduction of new regulations to prevent falsified medicines from entering the legal supply chain (Directive 2011/62/EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83/EC)

Medical devices

Since its very establishment in 2005, by reorganisation of the former SVIAM and OTDM, now part of THE NAMMD, has taken active part in generation of national regulatory documents on medical devices by:

• Creation and revision of the legal framework for conduct of controls by periodic inspection of medical devices;
• Creation and revision in line with the European provisions of the legal framework for assessment of service providers in the field of medical devices;
• Creation and revision of the legislative frame for the finding of breaches of regulatory provisions in the field of medical devices and imposition of penalties thereof;
• Revision of the legislative framework for authorisation of conduct of clinical investigations of medical devices concerning human subjects;
• Revision of the legislative framework for registration of medical devices placed on the market and those put into service on Romania's territory;
1. 2 – The NAMMD has implemented a number of important initiatives to improve conduct of its core activities, to broaden its role, by embracing new spheres of activity and improving communication with healthcare professionals and the general public as well as the latter's communication with the Agency, namely:
• Major restructuring of operational departments related to medicines, leading to more consistent medicinal product surveillance throughout its life cycle;
• Major restructuring of operational departments related to medicines, leading to more effective market surveillance of medical devices, as well as to better use of personnel resources;
• Development of the department related to regulation, authorisation and market surveillance of medical devices;
• Introduction of a new and important information system to support decision making and work in electronic format within the Agency;
• Appointment of a larger number of the NAMMD experts for participation in committees and working groups of European bodies in the field of medicines and medical devices, to provide for the NAMMD ability to further active contribution to the legislative and decision-making process in the EU;
• Participation in ASRO committees for medical devices with the NAMMD experts, ensuring the NAMMD capacity to continue active contribution to the standardisation process;
• Organisation of vigilance activities related to medical devices;
• Improvement of the flow of information to healthcare professionals;
• Improvement of the NAMMD profile as a communicator.
1. 3. – The current organisational strategy takes account of views expressed by stakeholders during workshops, conferences, symposia, various forums, etc. and outlines the principles and guidelines of the NAMMD concerns and activities for the next three years.

2. Protection and promotion of public health

2. 1. - The protection and promotion of public health is the NAMMD overall objective and its core activity throughout surveillance of the development and

use of medicinal products for human use and control over the use of medical devices.
The NAMMD ensures assessment at the highest levels of scientific competence of documentation submitted for marketing authorisation of quality, safe and effective human medicines.
The NAMMD grants authorisations for special needs and authorisations for compassionate use of medicinal products for human use.
The NAMMD implements a mechanism for rapid assessment of health technologies, based on the criteria, methodology and methodological tools approved through Order of the Minister of Health no 861/July 2014, for grant of decisions on inclusion, extension of indication, non-inclusion into or exclusion of medicinal products from the List of reimbursed and free of charge medicines.
The NAMMD provides technical support to the Ministry of Health in preparation of annex lists to orders of the minister for amendment of Order of the Minister of Health no. 456/04. 02. 2013 for approval of the List of INNs at important shortage risk, a provided to insurants in the healthcare security system and measures to ensure their availability on the Romanian market.
The respective Order refers to temporary suspension, pursuant to Law 95/2006, of distribution outside Romania of medicinal products specified in the Annex List.
The NAMMD inspects all aspects related to medicinal product development and manufacturing, application of rules for good manufacturing practice and good practice for wholesale distribution of medicinal products, taking action against companies or individuals in breach of their respective obligations.
The NAMMD authorises clinical trial sites and conduct of clinical trials with medicinal products in different stages of development, whereas its specialised inspectors monitor observance of good clinical practice rules.
The NAMMD monitors safe use of medicines for human use over their entire life cycle, through a system of adverse reaction reporting (by both professionals and patients), therefore allowing for maintenance of acceptable risk/benefit for products concerned and careful information in this regard of stakeholders, patients and healthcare professionals.
The NAMMD provides centralised registering and assessment of all information received on reported incidents related to medical devices and takes action according to the law.
The NAMMD carries out assessment of all service provision aspects related to medical devices.
The NAMMD decides on infringements and takes measures against natural or legal persons found in violation of their obligations under Title XIX of Law No. 95/2006 for health reform, as amended.
2. 2. - In recent years, significant improvement has been achieved of NAMMD systems for safety monitoring, of legislation underlying this activity as well as

intensified efforts towards better understanding by patients and the public of the benefits and risks associated with medicinal product use.

In Romania, pharmacovigilance activities are undertaken based on European legislation transposed and implemented into national law.

According to official documents of the European Commission, pharmacovigilance can be defined as "the science and related activities concerned with the detection, assessment, and prevention of adverse reactions to medicines"

The NAMMD also acts as the National Pharmacovigilance Centre operating within the Pharmacovigilance and risk management service.

NAMMD pharmacovigilance activities include, among others, assessment and submission of adverse reactions to the EudraVigilance system (the European network for processing and management of pharmacovigilance data), assessment of Pharmacovigilance Safety Updated Reports (PSURs), of pharmacovigilance systems held by Marketing Authorisation Holders, of Management Plans Risk assessment, harmonisation of the Summaries of Product Characteristics (SmPC) by implementing decisions of the Committee for Human Medicinal Products (CHMP) of the European Medicines Agency (EMA) in sections on medicinal product safety

Since as early as 1976, the NAMMD is a member of the WHO Collaborative Centre for international monitoring of medicines.

The WHO has played an important role in the development of pharmacovigilance through its Monitoring centre of Uppsala-Sweden, which maintains an international database of adverse medicinal product reactions. There are now 98 national centres assigned as active members of the WHO programme for international medicinal product monitoring and the number of adverse reactions entered 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, amending, as regards pharmacovigilance, Directive 2001/83/EC establishing a Community Code human medicines, has entered into force, as transposed through Emergency Ordinance No. 35/2012. This directive amended and supplemented legal duties incumbent on Member States as regards pharmacovigilance.

The NAMMD aims to develop the national pharmacovigilance system in line with the new directive and pay special attention to cooperation with European bodies and competent authorities in matters related to the safety of medicines.

The NAMMD seeks to further emphasise the value of reports submitted by providing rapid feedback to reporters and by ongoing development of public and patient understanding of decisions regarding the risk/benefit ratio in the field of medicinal products available in the Romanian pharmaceutical market.

At the same time, the Romanian competent authority also aims to continue efforts towards guidance and urge of healthcare professionals with regard to adverse reactions reporting.
In recent years there has been significant improvement of NAMMD systems for control of medical devices in use and monitoring of sites providing medical device services, of legislation underpinning such control operations as well as more resolute focus of Agency efforts towards better understanding by patients and users of the benefits and risks associated with medical devices.
By strengthened market surveillance activities, the NAMMD shall ensure that all necessary steps are taken required for placement on the Romanian market and/or putting into service of medical devices compliant with regulations only.
For the coming years, the NAMMD aims at further development of its operation systems so as to ensure throughout the country working in accordance with the law of medical devices and all prostheses, irrespective of type, as well as maintenance and repair of medical devices at the highest quality.
The NAMMD aims to continue its efforts for education of healthcare professionals and their strong advisement towards reporting of incidents in use of medical devices.
2. 3. - At the same time, the NAMMD seeks active involvement in the development of the European Community system for the monitoring of medicinal product safety, which, by bringing together information submitted by the 28 Member States in the EudraVigilance database will further enhance elements underpinning safety decisions.
The EudraVigilance is one of the main components of the *European Risk Management Strategy* related to medicinal products.
Risk Management is the joint action of the European Medicines Agency and national competent authorities of the European Union to strengthen pharmacovigilance activities.
The NAMMD communicate with the Commission and other Member States of the European Union on measures taken or envisaged to minimise the risk of incidents related to use of medical devices.
The NAMMD also aims at active involvement in the application of European Risk Management Strategy on medicinal products, whose priority actions are:
a) implementation of European Union law;
b) complementary initiatives to achieve a more intensive monitoring system of medicines regarding:
- Risk communication and initiatives in underdeveloped areas of pharmacovigilance (paediatric vaccines and medicines);
- Risk identification, assessment and minimisation.
c) Further strengthening of the European pharmacovigilance system;
d) Initiating a Plan for incident management in the EU regulatory system, meant to manage crises related to medicines in the EU, regardless of their authorisation procedure;

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

2. 4. - The new Directive 2011/62/EU for the prevention of entry into the legal supply chain of falsified medicinal products, amending Directive 2001/83/EC on the Community code of human medicines has been implemented in national laws of the Member States since 2013. Key elements have been added by this Directive with regard to legal responsibilities incumbent to competent authorities, as well as to manufacturers, importers and distributors in activities directed against counterfeiting of medicines.

For better implementation of the new directive, the NAMMD will create a specialised structure within the Pharmaceutical Inspection Department, in charge of management and monitoring of complex issues related to preventing the entry into the legal supply chain of falsified medicines.

Given that falsified medicines are a matter of increasingly strong concern for both regulators and the public, the NAMMD has initiated and continued collaboration with national institutions involved in combating the sale of counterfeit medicinal products, in particular over the Internet, as well as with similar institutions of EU Member States or outside of the EU, for establishment of permanent liaison points, meant to limit such criminal phenomena.

Thus, one of the main objectives has been to establish the framework for bilateral cooperation and exchange of information with the Romanian General Police Inspectorate concerning falsification of medicinal products for human use. The main directions of cooperation of the NAMMD with the Romanian General Police Inspectorate are as follows:

• Observance of legislation in the field of medicinal products for human use and medical devices;

• Sharing of information to meet legal respective obligations;

• Conduct of studies and market analyses more accurate knowledge of the human medicines market in Romania, especially as concerns their manufacture, import and distribution;

• Supervision of markets operation to identify breaches of national and/or EU legislation relating to counterfeiting of medicinal products and legal provisions on human medicines, to take the necessary steps by the two authorities, according to their respective powers and their correlation;

• Information of the public and businesses operating in markets of medicinal products for human on measures taken for breach of national and/or EU legislation concerning falsification of medicines;

• Mutual support for effective functioning and safety of the medicinal product sector, necessary legislative changes included.

2. 5. - For the next three years, the NAMMD aims to:

• Ensure compliance of marketing medicinal products authorised by the appropriate standards of quality, safety and efficacy, and their approval within a period as short as possible;
• Ensure authorisation of changes/variations to marketing authorisations of medicinal products for human use (for new strengths or pharmaceutical forms etc.) within a period as short as possible, while safeguarding public health;
• Further authorisation of clinical trials and clinical investigations only providing adequate assurance for patients, according to harmonised EU rules;
• Further development of the National Pharmacovigilance Centre operating within the NAMMD and improvement of the system for reporting of adverse reactions/events ensuring the collection of information from the widest possible sources, a simple manner of reporting and prompt feedback, to encourage participation;
• Increased transparency and improved communication on the safety of medicinal products and medical devices;
• Take action to ensure effective supervision of medicinal products and medical devices all over Romania;
• Ensure full ownership of the NAMMD role in implementation of EU legislation to increase the number of medicinal products authorised specifically for the treatment of children;
• Support to government initiatives to address serious risks to public health (e.g., pandemics, bioterrorism) and accomplishment of NAMMD role to ensure availability of products relevant to cover any increased needs;
• Provision of public information/instructions on use of safe medicinal product use and warnings for safe use in risk situations, where appropriate, for both on-prescription and over-the-counter medicines (OTCs);
• Provision of information to the public on conditions to be met by medical devices sold through pharmacies and other distribution facilities;
• Best use of instruments available for support and strengthening of safety monitoring of medicines for human use;
• Promotion of a risk-based approach in inspections, consistent with NAMMD responsibilities relating to public health and optimum use of resources;
• Take prompt and effective measures to prevent falsified medicines from entering the legal supply chain in the context of NAMMD legal duties arising from Emergency Ordinance no. 91/2012, transposing Directive 2011/62/EU for preventing entry of falsified medicines into the legal supply chain.
• Development of relationships with other institutions and bodies involved in this activity and raising awareness on the dangers of counterfeit medicines.
• Reanalysis of regulations governing control work by periodic examination of medical devices, for consistency between the list of medical devices subject to control and frequency of and their risk degree.

• Continuous improvement of procedures for assessment and monitoring of organisations seeking the right to provide medical device-related services and imposition of European standard working conditions;
• Investigation together with in-charge authorities of all incidents involving medical devices in order to determine their causes and limitation of their number as much as possible.

3. Information and communication

The Agency aims to act as both a reactive and proactive communicator. The communication strategy is based on SWOT analysis and stakeholders' (professional colleges, media representatives, patients, the industry) feedback provided through regular questionnaires.

Communication activity in the field of medicines and medical devices aim at continuous adaptation to the constant dynamic of EU regulations in the field as well as at balance between current activity and difficulties facing the Agency.

Given the NAMMD main objective of public health protection and promotion, the Agency will engage in combat of public misinformation through the media with regard to medicines for human use.

3. 1. - Most regulatory actions resulting in communication of updated information about human medicines, in line with knowledge arising from their use. This is usually achieved either in the form of briefings to healthcare professionals or through revised versions of the Patient Leaflet.

The quality of information provided by the NAMMD is therefore crucial to exercise of its role in protecting public health.

Permanently increasing knowledge on human medicines and their regulation will also help understanding by the media and the general public of issues related to emergence of safety issues and exceptional circumstances requiring withdrawal of a product from the market.

3. 2. – Healthcare professionals need clear information and advice on as support for discussion with patients on treatment options and patients and the public require ready access to information about medicinal products used in their own care with respect to their action, benefits to be expected, risks associated with their use, as well as better understanding of the manner for establishing the benefit/risk ratio.

3. 3. - The NAMMD has developed a communication strategy for 2013 - 2015, describing the frame for internal and external communication in this period, setting out key actions to be taken to develop communication. The communication strategy can be updated according to the general and pharmaceutical legislative framework.

The overall objective of the communication strategy is to achieve a higher level of understanding regarding assessment of the benefit/risk as well as of the manner for NAMMD decision-making for exercise of its powers, and

stimulation of the activity for the reporting of adverse reactions/events by healthcare professionals (doctors, pharmacists, nurses) and directly by patients.
To achieve the most important strategic objective in protection and promotion of public health, the Agency must be able to constantly describe the content of its work in this regard. The communication strategy established by the NAMMD has set out fundamental messages defining Agency work, representing top level key messages at the highest level, continually relayed to meet objectives of this strategy.
Communication regarding medicinal product safety must submit:
- Clear and concise information;
- New important information;
- Rationale for publication/dissemination of information;
- Any recommendations for the patient and healthcare professionals.
Safety information should not be biased, misleading, promotional or aimed at boosting sales.
NAMMD safety communication will use the current communication tools and channels in the European Union Network:
- Direct health professionals communications (to take certain measures or to adapt their healthcare practices in the interest of public health);
- Communication with the media;
- Communications posted on the NAMMD website;
- “Questions and Answers” documents.
- Communication among authorities ("Lines to Take" -LTT);
- Newsletters;
- Scientific publications;
To conclude on safety communication as well as on its role in minimizing the risk, the following may be listed:
- Risk communication is a key element in the pharmacovigilance process:
- EMA coordination and communication with Member States on medicinal product safety issues is extremely important;
- Ensuring access to pharmacovigilance information and related decisions underpins stakeholder involvement;
- Involvement of stakeholders in effective communication is essential for risk minimisation;
- Measuring the impact of safety communication on risk management is vital.
3. 4. - NAMMD approach is characterised by openness and transparency, seeking to ensure highest public confidence possible in the regulatory system related to medicinal products and medical devices, the system acting in its support.
Much has been achieved in this direction in recent years, and the NAMMD will continue to improve the transparency of its work as well as its accessibility to the public. The NAMMD will also promote transparency in what concerns businesses in its regulatory domain.

3. 5. – An important NAMMD strategic priorities is the need for closer and more effective engagement with patient associations and the general public, as well as finding general means for introducing patient perspective in its work. As an activity initiated earlier, this will be continued and developed.
The NAMMD will further:
• Act for consolidation of its status as an expert and reliable source for latest information on human medicinal products on the market through implementation of the NAMMD Communication Strategy;
• Ensure that the information accompanying medicinal products are ready for use, in due observance of requirements set for Leaflet user testing;
• Identify ways for increased transparency in decision making, at both NAMMD and pharmaceutical industry level;
All the above objectives may only be achieved through organisation of workshops and meetings with representatives of patient organisations, professional associations, the academia, associations of medicinal product manufacturers, associations of wholesale distributors of medicinal products, to identify possible problems for more effective approach of pharmacovigilance, to find solutions to prevent entry of falsified medicines into the authorised distribution chain, to identify measures for reduction of the risk for medicinal product shortage, to create the national legal framework enabling implementation as of 2016 of the new Regulation no. 536 on clinical trials/April 2014, and others.

4. Design of a balanced regulatory framework

4. 1. - The NAMMD will continue to act in line with its role as national competent authority for medicinal products for human use and medical devices in Romania, as a EU member state, fully integrated into activities of EU Competent Authorities for Medicines and Medical Devices and work of committees and working groups of European bodies in the field of medicinal products and medical devices.
As of 2008, the NAMMD also acts as Reference Member State in coordinating assessments of applications for authorisation submitted for marketing authorisation through European procedures, mainly through the decentralised procedure, showing its expertise in continuous professional development of agency assessors.
Following ratification of the Convention for elaboration of the European Pharmacopoeia, within the Council of Europe, Romania has been a full member since 2003. The designated NAMMD representative as member of the European Pharmacopoeia Commission takes active part in its working sessions.
The Agency intends to further its very important contribution to the work of the European Network of competent authorities in the field of medicines and the work of the European Official Medicines Control Laboratories OMCL.

The Agency aims to increase its contribution to the joint work of competent authorities in the field of medical devices and working groups of the European Commission.

4. 2. - The NAMMD continues to:

• Ensure active participation in technical and scientific deliberations for development of new legislation concerning medicinal products and medical devices;

• Ensure effective operation of the current regulatory system related to medicinal products for human use and medical devices, as well as a prompt implementation of future regulatory changes in the European framework in these areas;

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

• Increase supervision of medical devices on the Romanian market and permanent cooperation with the competent authorities in this field;

• Provide knowledge and expertise to other signatories of the Agreement for cooperation of drug competent authorities of countries associated with the European Union [*Collaboration Agreement of Medicinal product Regulatory Authorities in European Union Associated Countries (CADREAC)]/New Collaboration Agreement between Medicinal product Regulatory Authorities in Central and Eastern European Countries (nCADREAC)]*.

4. 3. - Within the European pharmaceutical regulatory system the NAMMD cooperates with all national competent authorities of the European Union (EU), the European Economic Area (EEA) and the European Medicines Agency (EMA).

The NAMMD hopes to develop future and international connections through the EMA with the US Food and Medicinal product Administration (FDA) within the EMA/EU and FDA/US cooperation.

It is the NAMMD belief that, for effective accomplishment of its regulatory duties related to human medicines for the benefit of public health, good working relations with countries of outside the EU are also necessary, particularly with countries with capabilities for medicinal product development, increasingly acting as supply sources for the EU market.

4. 4. - The NAMMD considers it advisable for regulators worldwide to work jointly to develop harmonised standards applicable to overall relations with the pharmaceutical industry.

4. 5. - The Agency will continue to:

• Develop its international relations and cooperation with regard to antivirals for human use, in the context of a global medicinal product market;

• Support the effort for harmonisation of regulations of the International Conference for Harmonisation (ICH) relating to medicinal products;

• Develop cooperation established with competent authorities of countries of strategic importance, such as China, India, Korea, as increasingly important

source of development and manufacturing of medicines for human use, subject to NAMMD authorisation and supervision.

4. 6. - The NAMMD anticipates substantial progress in science and technology, of potential impact on regulation of medicinal products for human use in the following areas:

• Biotech products;

• Advances in molecular biology, genetics, gene and cell therapy;

• Use of new screening technologies and mechanisms for better adaptation of medicines to patients, development of "customised" and "niche" medicinal products and diagnostic tests for identification of suited patient;

• Development of products combining medicinal products with their own delivery system, in medicinal product/device associations;

• Use of nanotechnology, biomedical science, μ-electronics and computer technology;

• Tissue engineering.

4. 7. - The NAMMD can help develop effective treatments to benefit health by promoting a supportive environment for conduct of clinical trials in Romania, according to European legislation.

The Agency will continue its work with partner organisations and support European efforts towards implementation of EU Clinical Trial Regulation no. 536/April 2014, of harmonised approach to requirements of clinical trial authorisation, reducing inconsistencies and bureaucracy, while maintaining safety measures for enrolled subjects.

4. 8. - The NAMMD will further:

• Ensure, by contribution with appropriate expertise to debates of scientific committees of European bodies, the capability of the legislative frame to establish the right balance between precautionary approach of safety and the freedom of innovation;

• Establish liaisons with academic and professional centres of excellence in medical, pharmaceutical and legislative sciences, to ensure NAMMD capability to rely on optimal skills and knowledge to maintain its own expertise;

• Promote an internal environment encouraging clinical research and cooperation with European bodies for harmonisation of regulations on clinical trial authorisation.

4. 9 - The NAMMD will continue its active involvement in improving the regulatory framework in the field of medicinal products for human use:

4. 9. 1. – The NAMMD Scientific Council establishes the Agency’s scientific policy, in accordance with its powers.

Scientific Council sessions focus on discussion and approval, as Decisions of the Scientific Council, of drug regulatory provisions and rules professional operation of the Agency.

Ruling decisions of the NAMMD Scientific Council are subject to approval by the Minister of Health and published in the Official Gazette of Romania as

orders of the minister of health. As a result of its constant preoccupation with demands and expectations of its stakeholders (healthcare professionals, the pharmaceutical industry, patients, the general public, the media) the NAMMD will continue its efforts to ensure a policy of appropriate, responsible regulation in its area.

4. 9. 2. – It is the NAMMD obligation to ensure that medicinal product regulation is proportionate and properly reflects the current level of knowledge of benefits and risks.

This translates into NAMMD duty to continuous self-assessment of its own work, to ensure adequate reflection of stakeholders' needs, effective regulation of services and targeting activities towards accomplishment of the Agency's primary objective, protection of public health.

Given the scarcity of specialised personnel, the NAMMD is unable to be involved in provision of scientific advice, very frequently providing advice on regulatory issues instead.

4. 10. - The NAMMD aims to further addressing risk-based inspection work, allowing focus on challenges as well as full capitalisation of inspection resources.

The Agency is committed to investigation in greater depth of the scope of risk-based approach to NAMMD regulatory functions and seeking areas for improvement of regulatory practices, consistent with both legislation and the NAMMD role in protection of public health.

4. 11. - The NAMMD is also fully aware of the need to ensure clear and unambiguous legislation underpinning 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, subject to amendments in line with new European regulations.

4. 12. - The NAMMD will continue to:

• Develop risk-based approach to NAMMD inspection work and seek new opportunities to reduce unnecessary legal obligations as well as identify areas allowing it to meet the Agency's objective for risk and proportionality based regulation;

• Support the European Commission's initiative for better regulation and further contribution to the same at national and European level;

• Consolidate and rationalise legislation in the field of medicinal products for human use.

4. 13 - The NAMMD will continue to be actively involved in improvement of the regulatory framework for medical devices.

EU legislation in force (i.e. the three European directives for medical devices) has been transposed into national legislation by Government Decisions no.

54/2009, no. 55/2009 and no. 798/2003, as amended, providing a unified framework for the free movement of CE European certified medical devices.
Currently, the NAMMD takes active part in discussions for two draft regulations to replace the three Directives, intending elimination of shortcomings and gaps, strengthening of the current medical device regulation and increased patient safety. The aim is to establish a robust, transparent and sustainable, "fit for purpose" regulatory framework.

5. Running a successful organisation

5. 1. - Given the dynamic environment of its operation, the NAMMD must remain as influential in its own sector and maintain its flexibility and responsiveness to change.
Entry into force of the new European Directive has resulted in significant changes in workload, allowing the Agency to anticipate further development of specific activities, while other activities/areas may remain constant or reduce in size and importance.
The NAMMD will take the necessary steps to maintain its flexibility and ability to adjust to fluctuating workload and adapt to growth or reduction requirements, to the its own benefit as well as that of its stakeholders.
5. 2. - The NAMMD needs good working relationships with the industry within its regulatory scope, relying on effective dialogue with leading manufacturers' and trade associations as well as with healthcare professionals and patients using these medicinal products.
It is necessary to maintain good relationships with other government bodies, whose work is closely related to NAMMD work.
5. 3. - The Agency will continue to:
• Invest and develop effective management information systems to support its work and take an active role in the EU debate regarding development and implementation of appropriate and harmonised standards;
• Ensure reflection of stakeholders' needs in its own activities, thereby meeting its primary objective related to protection of public health;
• Maintain effective relationships with other governmental bodies;
• Maintain and improve collaboration and cooperation with the pharmaceutical industry as well as appropriate liaisons with major manufacturers' and trade.
• Maintain and improve collaboration and cooperation with the medical device industry and as well as appropriate liaisons with ASRO, the RENAR and Health Insurance Houses.

Agency personnel

5. 4. - NAMMD staff is its most important resource. Effective regulation to protect public health requires maintenance of a highly skilled workforce and a high degree of motivation.

This challenge is particularly difficult, given that current potential to reward employees in the public system is hardly able to compete with that of the private market, an option many Agency trained specialists have preferred.
Until evolvement of a favourable legislative frame allowing for and motivation with adequate salaries as reward for superior professional merits, the NAMMD will need to continue efforts to maintain personnel with scientific expertise available today, attempting motivation at least through proper evaluation of performance and acknowledgment of professional skills.
The NAMMD is intent on continued efforts to raise awareness of the main credit officer on personnel challenges encountered and their impact on the Agency‘s ability to meet duties assigned.
5. 5. - THE NAMMD aims at:
• Effective action for recruitment and selection of new staff (started at the end of 2013 and continued in 2014), aimed particularly at university graduates in the medical and pharmaceutical fields;
• Implementation of promotion policies to ensure NAMMD human resources in the, especially in what concerns areas with proven shortages of skilled manpower;
• Provision of ample opportunities for employee training and development meant to develop human resources.

Agency funding
5. 6. - In late 2009, the Agency was reorganised as a public institution financed from the state budget, according to Law No. 329/2009 for the reorganisation of public authorities and institutions, rationalisation of public expenditure, business support and compliance with framework agreements with the European Commission and the International Monetary Fund.
Given that, by 2009, the Agency was a self-financing institution, subsequent fiscal measures have had significant negative impact on management of human resource and therefore the financing of the entire Agency work.
The NAMMD aims to at least maintain financial stability through a balanced budget, within allocated funds, compliant with legislation in force.
5. 7. – The NAMMD periodically updates its fees according to changes in the organisation's activities.
The NAMMD means to further lucrative activities resulting *in* increased revenues, as for instance by giving training courses, organising conferences etc.

Conclusions
The NAMMD is a mature institution, able to cope with activities deriving from its status a competent authority of an EU Member State in the field of medicinal products for human use and medical devices.
Agency’s strategic objectives are defined in the context of the regulatory framework in force.

The NAMMD aims at continuous adaptation to national and European requirements. The Agency's top management envisages engaging its entire staff in permanent self-assessment for continued improvement in the two areas, i.e. human medicinal products and medical devices.
In the context of issues addressed in the Commission Communication for effective, accessible and resilient health systems - COM (2014) 215 final, the NAMMD aims at growing involvement in resolution of certain issues raised for:

1. Support to the strengthening of health systems effectiveness/quality of healthcare, patient safety included, by**:**

- Promotion of the new pharmacovigilance legislation with both professionals and patients;
- Constant call, by various means, on reporting of adverse reactions;
- Monitoring of accomplishment of the public service obligation by marketing authorisations holders/wholesalers;
- Monitoring of elimination of deficits in medicinal product supply to the Romanian public.

2. Increased affordability of healthcare systems:

As provided for in Government Decision no. 315/2014, the NAMMD is the competent national authority in the field of health technology assessment.
As such, the NAMMD works together with the Ministry of Health and the National Health Insurance House in setting up the list of medicinal products for human use in the Index of medicines provided to insurants based on medical proscription, irrespective of individual contribution.
Order of the Minister of Health no. 861 of 23 July 2014 on approval of the criteria and methodology of Health Technology Assessment (HTA), the documentation to be submitted by applicants, methodological tools used in the evaluation process for medicinal product inclusion/non-inclusion into/exclusion from the List of reimbursed and free of charge medicinal products, ensuring transparency of measures regulating medicinal product inclusion in the scope of national health insurance systems, makes legislative changes of utmost importance, such as:

- HTA for List amendment becomes an ongoing process
- As of 2015, the List is updated at least once a year, by approval through Government Decision.

3. Improved resilience of health systems

The European Commission estimates Health Technology Assessment (HTA) as a useful approach for improving the resilience of EU health systems.
The NAMMD intends that HTA become an effective tool for:

- Improving patient access to innovative technologies;
- Support more efficient budget allocation.