DECISION
No. 1/23.03.2010

on approval of the organisational strategy of the National Medicines Agency 2010-2014

The Scientific Council of the National Medicines Agency, set up based on Minister of Public Health Order No. 1027/22.05.2008, as amended, reunited on summons of the National Medicines Agency President in the ordinary meeting of 23.03.2010, in accord with Article 10 of Government Ordinance no. 125/1998 related to the set up, organisation and functioning of the National Medicines Agency, approved as amended through Law No. 594/2002, as further amended, agrees on the following

DECISION

Single article. – The organisational strategy of the National Medicines Agency 2010-2014 is approved, in accordance with the Annex which is integral part of this Decision.

PRESIDENT
of the Scientific Council
of the National Medicines Agency

Acad. Prof. Dr. Victor Voicu

ANNEX

ORGANISATIONAL STRATEGY OF THE NATIONAL MEDICINES AGENCY 2010 - 2014

The National Medicines Agency (NMA) is a public institution operating under the Ministry of Health, set up on 1st January 1999 by Government Ordinance No. 125/1998, through the reorganisation of the „Petre Ionescu – Stoian" Institute for the State Control of Medicinal Products and Pharmaceutical Research (ICSMCF).

The NMA represents the Romanian competent authority in the field of medicinal products for human use, which ensures marketing authorisation, market surveillance and issuance of regulations approved by the Ministry of Health.

On 1st January 2000, the Centre for Public Control of Biological Products for Human Use was also included in the NMA structure, based on Order of the Minister of Health No. 802/1999. With this occasion, the Agency also assumed the role of Romanian competent authority in the field of biological medicinal products for human use, which involved the acquirement of additional tasks and extension of the range of stakeholders.

This organisational strategy is issued in the context of the legal framework establishing the relation between the NMA and the Ministry of Health, as well as between the NMA and its stakeholders. It covers a 5-year period 2010 - 2014 and is updated every year.

Additional details and information on the NMA may be found on its website, www.anm.ro.

MISSION AND STRATEGIC OBJECTIVES OF THE NATIONAL MEDICINES AGENCY

Mission of the NMA:

The mission of the National Medicines Agency is to contribute to the protection and promotion of public health through:

- evaluation at the highest scientific competence of documentation for authorisation in view of marketing high quality, safe and effective medicinal products for human use;
- supervision of the safety of medicinal products for human use in the therapeutic circuit by means of inspection and pharmacovigilance activities;

- 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.

Strategic objectives of the NMA are as follows:

- **Public health protection**, by accomplishment of the NMAs primary role, namely the warranty of compliance of authorised medicinal products with the required standards, their efficacy and their acceptable level of safety;
- **Fulfilment of the NMA role of communication**, as an expert and trustworthy source, by providing clear and timely information to healthcare professionals, patients and the general public;
- **Contribution to the projection of the future legal frame** in the field of medicinal products for human use, through the use of NMA efficient European and international relations;
- **Coordination of an organisation** endowed with quality and adequately qualified workforce, **able to cope with future challenges**.

Table of contents:

1. Introduction

1.1. – Since its set up, the NMA has witnessed significant developments in the legal field, both nationally (by harmonisation of national and European legislation), and on a European level (European legislation which the NMA was aiming to align with was itself undergoing major changes):

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

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

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

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

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

• Introduction of legislation in the field of traditional herbal medicinal products (by complementation of Directive 2001/83/EC);

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

1.2. – The NMA has enforced 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:

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

• 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 number of NMA experts possible for the committees and working groups of European medicinal product institutions, ensuring NMAs ability to continue its active contribution to the EU legal and decision-making process.

1.3. – While simultaneously performing the continuous dynamics of the context for its activity and on the verge of fulfilling another 5-year operation cycle, the NMA wishes to take this opportunity not only as a chance to count its achievements, but also to reflect upon the challenges anticipated for the years to come.

1.4. – The present organisational strategy takes into account the viewpoints expressed by stakeholders and emphasis will be placed on the core and general direction of NMA concerns in the following 5 years.

1.5. – The NMA intends to issue a set of success indicators and indices, useful in the performance of a more accurate assessment of progress made in enforcement of changes and improvements included in the present Organisational strategic plan.

2. Public health protection

2.1. – Public health protection represents the NMAs general objective, as well as the core of its activity throughout the entire process related to development and use of medicinal products for human use.

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

The NMA authorises the performance of clinical trials with medicinal products in various stages of development and is responsible for deciding whether they are granted marketing authorisations.

The NMA monitors safe use of medicinal products for human use throughout their entire lifecycle, by means of an advanced adverse reaction reporting system, so as to ensure maintenance of an acceptable risk/benefit balance for the respective products, as well as its careful explanation to the relevant interested parties, patients and healthcare professionals.

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

For the years to come, the NMA plans to further develop the adverse reactions/events reporting system, in order to ensure solid proof for its regulatory decisions.

The NMA wishes to further highlight the value of reports received by providing quick 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.

Moreover, the NMA wishes to carry on its efforts directed towards the education and encouragement of healthcare professionals for adverse reaction reporting.

2.3. – At the same time, the NMA plans on being actively involved in expected talks concerning future development of a European community system for monitoring medicinal product safety, which, through combined information from the 27 Member States, will further reinforce the elements underlying decision-making in safety matters.

2.4. – In the context in which regulatory authorities and the public find counterfeited medicinal products an increasingly strong reason for concern, the NMA will enforce an anti-counterfeits strategy, whose main objectives will envisage transformation of Romania into a hostile environment for counterfeiting, by warranted identification and interception of counterfeits and prosecuting the offenders, whenever possible.

2.5. – For the following 5 years, the NMA envisages the following:

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

• Insurance of new medicinal products compliance with the adequate quality, safety, efficacy standards and their authorisation as soon as possible;

• Authorising modifications/variations to medicinal products for human use (new strengths or pharmaceutical forms etc.) in a timely manner, while safeguarding public health;

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

• The performance of actions for ensuring firm and efficient surveillance of medicinal products for human use throughout Romania;

• Insurance of full NMA undertaking of its role in enforcing EU legislation on increasing the number of authorised medicinal products, particularly for the treatment of children;

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

• Provision of certain adequate information/instructions to the public on the safe use of medicinal products, as well as warnings concerning their safe use, 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 risk-based approach in inspection activities, in line with NMA public health responsibilities and optimal use of resources;

• Taking measures, within the larger frame of NMA responsibilities in enforcement of the law, to implement a Strategy to combat counterfeiting and improve public awareness of the risks it is exposed to because of counterfeited medicinal products.

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 information of healthcare professionals or revised versions of the Patient leaflet.

The quality of the information provided by the NMA is thus essential in fulfilling its role in protection of public health. Reliable and quality information is particularly important in purchasing of medicinal products for human use by the public itself, since a well-informed consumer is able to better exercise his/her ability to opt for and handle his/her own healthcare.

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 NMA will elaborate a Communication Strategy, whose main objective will be achievement of a higher degree of understanding of the risk/benefit balance assessment and of the manner of NMA performance of its assignments and decision making, as well as encouragement of adverse reactions/events reporting. This is expected to also contribute to increased public confidence in the NMA.

3.4. – It is the NMAs wish that the public fully trust the medicinal product regulatory system, acting towards its best interest, by enforcing an approach best described by openness and transparency.

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

3.5. – Among the NMA strategic priorities, closer and more effective engagement will be necessary with patients and general public associations, as with identification of general ways of bringing patient perspective in its work. This activity will be elaborated and enforced during the period covered by this strategy.

The NMA will continue to:

• Take action in view of becoming an expert and reliable source for the latest information concerning medicinal products for human use on the market, by enforcing a general 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 NMA 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 NMA);

• 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 trustworthy 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 NMA 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 NMA will continue to assume 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 NMA also acts as Reference Member State in the coordination of assessments of marketing authorisation applications submitted in view of authorisation through the mutual recognition/decentralised procedure.

The Agency aims at maintaining its very important contribution to the activity of the European network to ensure effective and efficient functioning of these procedures.

4.2. – The NMA will continue to:

• Ensure active participation in technical and scientific debates regarding the set up of new legal provisions in the field of medicinal products for human use, support of an efficient activity of the European medicines agencies network;

• Ensure an as efficient as possible operation of the present regulatory system in the field of medicinal products for human use and the promptest possible 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 NMA 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 NMA 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 NMAs belief that, for efficient performance of its regulatory attributions 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 provided with medicine development abilities, which increasingly represent a significant source of supply for the EU market.

The NMA will elaborate an international strategy in support of the information and knowledge exchange with other major regulatory institutions, whose development is anticipated in the next few years.

4.4. – The NMA considers it advisable that regulatory authorities worldwide find a way to cooperate in set up of harmonised standards, applicable to global relations with the pharmaceutical industry.

4.5. – The Agency will further:

• Develop its international and cooperative relations, in accordance with the International strategy which it will elaborate;

• Involvement as much as possible in international cooperation in the global medicinal product market;

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

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

Research and innovation

4.6. – The NMA foresees significant scientific and technological progress with potential impact on the regulatory manner in the field of medicinal products for human use, which may influence the activities of the Agency in several ways:

• The NMA is required to ensure that regulatory activity does not affect innovation;

• The NMA needs to benefit from continued access to relevant and most up-to-date expertise, so as to maintain its ability to make adequate regulatory decisions concerning innovative medicinal products.

4.7. – For the years ahead, the NMA anticipates significant scientific progress with impact on the regulation of the following fields:

• Biotechnology products;

• New development technologies, which can shorten the time to actual marketing;

• 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, in a medicinal product/medical device association;

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

• Tissue engineering.

4.8. – The NMA owns an important role in promoting a context that is supportive for clinical research, thus contributing to the development of efficient treatments for health benefit.

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.

4.9. – The NMA 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 NMA 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 partners for more consistent enforcement of the clinical trials directive.

Towards Better Regulation

4.10. - It is the NMAs duty to ensure that medicinal product regulatory activity is proportional, adequately reflects the current level of knowledge in benefits and risks and does not obstruct innovation by imposing additional costs or futile administrative tasks on the industry.

This amounts to NMA ongoing assessment of its own activity and insurance that it adequately reflects the needs of a broad range of stakeholders, provision of an effective regulatory service and orientation of activities towards compliance with the Agency's main objective of protecting public health.

4.11. – The European Commission has launched the Better Regulation initiative, by developing a package aimed at simplification of the handling of variations/changes to the terms of the marketing authorisation of medicinal products for human use, which the NMA has started to enforce and apply.

4.12. – The regulatory process is more and more risk-adapted as increasing resources are granted to products on which less information is available as well as to ease the approach of problematic issues.

The NMA intends to carry on its risk-based approach in inspection, allowing it to 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 NMA regulatory functions and search for fields with room for regulatory practice improvement, compliant with both the law and the NMA role in protecting public health.

4.13. – The NMA 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, being amended in accordance with new European regulations.

4.14. – The NMA 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 NMA needs to preserve its influence in its own field, as well as its flexibility and ability to respond to changes.

In recent years, 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 certain EU economy aspects, whereas others may remain constant or even diminish.

The NMA will take the necessary measures to maintain its flexibility and capacity 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 NMA 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 using these medicinal products.

Good Cooperative relations need to be preserved with other governmental bodies, whose activity is closely related to the NMA work.

5.3. – The Agency will further:

• Make investments and develop efficient information management systems in support of its own activity and assume 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 and thus meets 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 to continue adequate contacts with leading manufacturers' associations and marketing associations in the field of the medicinal product for human use.

Agency staff

5.5. – Staff represents the NMAs most important resource. Enforcement of efficient regulation for protection of public health requires **preservation of highly qualified and motivated workforce**.

This goal is particularly difficult under the present circumstances when current public system possibilities to reward its employees can hardly compete with opportunities on the private market.

Moreover, the NMA must both preserve its currently available staff with regulatory and scientific expertise and recruit staff with other type of expertise, depending on developments in the field. This will be a difficult task, particularly as new technologies emergence in medicinal product development and the increasing adaptation of medicinal products to the specific needs of certain population groups and individuals.

5.6. – Depending on the development of the current economic crisis, the NMA seeks to:

• Perform efficient recruitment and staff preservation activities along with enforcement of promotion policies to ensure the appropriate and suitably qualified personnel allowing accomplishment of the NMA objectives and attributions;

• Provide a wide range of learning and development opportunities for its entire staff, by actively supporting ongoing professional development, acquisition of specific skills and management/leadership programs, for up to date ability level and staff training in view of responding to new roles.

Financing of Agency operation

5.7. – At the end of 2009, the NMA has been reorganised as a public institution fully funded from the state budget, in accordance with Law No. 329/2009 on the reorganisation of certain authorities and public institutions, the rationalisation of public expenditure, support to business and compliance with the framework agreements with the European Commission and the International Monetary Fund.

The Agency further aims to preserve its financial stability by means of a balanced budget exercise, generating a small surplus as backup for future investment or in case of unforeseen circumstances.

5.8. – The NMA periodically updates its tariffs depending on changes in its activities.

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

Conclusions

Since the set up of the National Medicines Agency 11 years ago, a number of important initiatives have been undertaken to establish a fully consistent organisation, building on its predecessors' achievements.

The context for NMA 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.

The NMA 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 the European area, where the NMA is met with recognition and appreciation as Romania's competent authority in the field of medicinal products for human use.

Focusing on its achievements while learning from all its past undertakings, the NMA will be prepared to face any future challenges.