ORGANISATIONAL STRATEGY
OF THE NATIONAL AGENCY FOR MEDICINES
AND MEDICAL DEVICES
2011 - 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 certain healthcare facilities and amendment of public health legislation, as a result of the merger of the National Agency for Medicines and the Technical Office for Medical Devices. NAMMD organisation and operation have been approved by Government Decision No. 734 of 21 July 2010.

Brief history

For over 50 years, the present Agency has represented the drug regulatory authority in Romania. Known as the *Institute for Medicinal Product Control and Pharmaceutical Research* on its setup in 1956, the name of the institution was further changed in 1960 to become the *Institute for the State Control of Medicinal Products and Pharmaceutical Research* (ICSMCF). Between 1999-2010, by reorganisation of the former ICSMCF, the institution operated as the National Medicines Agency.

The activity related to medical devices was set up 50 years ago as well.

As early as 1958, the technical directorate of the Ministry of Health set up its own laboratory for technical testing of medical equipment, which became a distinct entity in 1973 within the Station for Verification and Maintenance of Medical Devices (SVMMD).

As of 1 February 2005, the SVMMD has been reorganised under the name of the Technical Office for Medical Devices (TOMD), which in its turn merged with the National Medicines Agency (NMA) in 2010.

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

As far as medical devices are concerned, the NAMMD is in charge of control of the performance and security of medical devices in use as well as assessment of the capability of organisations providing services in this area.

This organisational strategy is issued and updated in the context of the legal framework establishing the relation between the NAMMD and the Ministry of Health, as well as between the NAMMD and its stakeholders. It covers a 5-year period 2011 - 2015 and is updated every year.

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

MISSION, VISION AND STRATEGIC OBJECTIVES OF THE NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES

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;
- **Maintaining of a high level of performance and safety of medical devices in use in 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 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 medicinal products 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 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 authorised *medical devices* with the required standards and intended purpose as well as of their acceptable level of safety;

- **Fulfilment of the NAMMD role of communication**, 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 projection of the future legal frame** in the field of medicinal products for human use, through promotion of efficient NAMMD 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**.

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1. Introduction

1.1. – Medicinal products for human use

As of 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 a European level (European legislation which the Agency 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 certain regulatory provisions envisaging harmonisation of authorisation procedures and conducting clinical trials throughout the EU (Good Clinical Practice directives);

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

• Introduction of regulatory provisions 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);

• Introduction of regulatory provisions on manufacturing of tissue engineering products and their use (Regulation on Advanced Therapies);

• Introduction of the new regulatory provisions on Pharmacovigilance (Regulation and Directive for amendment of Directive 2001/83/EC).

Medical devices

As of set up in 2005, through reorganisation of the former SVMMD, the TOMD, currently part of the NAMMD, has taken active part in generation of national regulatory acts in the field of medical devices, through:

• set up and revision of the legal framework for control through regular verification 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 of violations in the area of medical devices.

1.2. - The NAMMD 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, i.e.:

• 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 restructuring of operational departments in the area of medical devices, leading to 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 number of NAMMD experts possible for the committees and working groups of European medicinal product institutions, ensuring NAMMD's ability to continue its active contribution to the EU legal and decision-making process.

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

• Improved flow of information to healthcare professionals;

• Improved NAMMD profile as a communicator.

1.3. - The present organisational strategy takes into account the viewpoints expressed by stakeholders and emphasis will be placed on the core and general direction of NAMMD concerns and activities in the following 5 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 entire process related to surveillance of the development and use of medicinal products for human use and control of the use of medical devices.

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

The NAMMD conducts assessment of all aspects related to service delivery in the area of medical devices.

The NAMMD 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 careful information in that respect of relevant interested parties, patients and healthcare professionals.

The NAMMD ascertains violations of the law and takes measures against companies and persons who fail to comply with their legal obligations as per Law 176/2000 on medical devices, as amended.

2.2. - Significant improvement of the NAMMD safety monitoring systems and their legislation underlying this activity as well as increased NAMMD 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 NAMMD plans to further develop the adverse reactions/events reporting system, in order to ensure solid proof for its regulatory decisions.

The NAMMD pursues further emphasis of 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 NAMMD pursues to carry on its efforts directed towards the education and encouragement of healthcare professionals in view of adverse reaction reporting.

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

For the years to come, the NAMMD aims at further development of its operation system, so as to make sure of lawful use of medical devices throughout the country as well as highest standard of any kind of prosthesis, maintenance and repair of medical devices.

It is the NAMMD intention to continue its efforts towards the training of healthcare professionals and their encouragement with regard to reporting of incidents occurring in the use of medical devices.

2.3. - At the same time, the NAMMD 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 NAMMD has initiated and furthered collaborations with national institutions involved in combating sale of counterfeit medicinal products particularly over the Internet, as well as with its counterparts in Member States or outside the EU in setting up permanent contact points meant to limit such criminal activities.

2.5. - For the following 5 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 modifications/variations to marketing authorisation 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 those clinical trials and investigations only that give appropriate warranty to patients, in line 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 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 NAMMD 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 NAMMD 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 NAMMD public health responsibilities and optimal use of resources;

• Taking measures against counterfeiting within the larger frame of NAMMD responsibilities in enforcement of the law, development of collaboration relationships with other institutions and bodies involved in this activity and raising public awareness of the risks it is exposed to because of counterfeited medicinal products.

• Resumed analysis of regulatory acts governing control of medical devices through regular verifications, so as the list of medical devices controlled and the regularity of verifications comply with the risk degree of medical devices;

• Ongoing improvement of procedures concerning assessment and surveillance of organisations applying for the right to deliver services in the area of medical devices and imposition of European level labour conditions;

• Investigation together with competent institutions of all incidents involving medical devices, to determine their causes and reduction of their numbers as much as possible.

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 NAMMD is thus essential in fulfilling its role in protection of 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 5-year Communication Strategy, describing the frame for internal and external communication in this period, establishing key actions for developed communication. The Communication Strategy is renewed on a yearly basis.

The main objective of the Communication Strategy is attainment of a higher degree of understanding of the risk/benefit balance assessment and of the manner of NAMMD decision making in performance of its assignments, as well as encouragement of adverse reactions/events reporting.

In order to be able to reach the highest strategic objective, i.e. promotion and protection of public health, the Agency must be able to constantly describe the implications of its activity in that respect. The NAMMD Communication strategy has established the key messages defining the activity of the Agency, at the same time the key messages on the highest level that the NAMMD desires to and will further convey to attain the objectives provided in this strategy.

3.4. - It is the NAMMD wish that the public fully rely on 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 NAMMD will further improve the transparency of its own activities and its 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, 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 NAMMD will continue to:

Take action in view of strengthening its status as an expert and reliable source for the latest information concerning medicinal products for human use on the market, by enforcing 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 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 NAMMD 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 NAMMD 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 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 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 NAMMD will continue to improve its information and knowledge exchange with other major regulatory institutions, whose development is anticipated in the next few years.

4.4. - The NAMMD 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;

• Aware of the global market for medicinal products, it is the NAMMD intention to become as much as possible involved in international cooperation in the field;

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

• Develop cooperation established with NAMMD 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 NAMMD authorisation and surveillance.

Implications of research and innovation progress

4.6. - The NAMMD foresees significant scientific and technological progress with potential impact on the regulatory manner medicinal products for human use, in the following fields:

• Biotechnology products

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

• 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.

4.7. - The NAMMD may contribute to the development of efficient treatments to benefit health through promotion of 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 partners for more consistent enforcement of the clinical trials directive.

Towards better regulation

4.9. - It is the NAMMD duty to ensure that medicinal product regulatory activity is proportional, adequately reflects the current level of knowledge in benefits and risks.

This amounts to NAMMD 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.

Taking into account the specialised personnel shortage, the NAMMD is not able to engage in scientific advisory activities but instead it very frequently engages in regulatory counselling.

4.10. - 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 NAMMD has started to implement and enforce.

4.11. - The NAMMD 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 NAMMD regulatory functions and search for fields with room for regulatory practice improvement, compliant with both the law and the NAMMD role in protecting public health.

4.12. - The NAMMD is also aware of the need to ensure clear 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.

4.13. – The NAMMD will continue to:

• Develop NAMMD 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. Running 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 change.

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 specific activities, whereas other activities/domains may remain constant or even diminish.

The NAMMD 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 stakeholders.

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 using these medicinal products.

Good co-operative relations need to be preserved with other governmental bodies, whose activity is closely related to the NAMMD 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.

• Maintain and improve collaboration and cooperation with the medical devices industry and preserve appropriate contact with the ASRO, RENAR and the Health insurance houses.

Agency staff

5.4. - Staff represents the NAMMD 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, 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 the development of the current economic crisis, the NAMMD seeks to:

• Perform 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 operations

5.6. - At the end of 2009, the **Agency 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.

On legislative level, in 2009-2010, regulation has continued of certain financial-fiscal measures with significant negative impact on the management of human resources and implicitly on the funding of the entire operation of the Agency.

Set up in July 2010 through NMA merger with the of the TOMD, the NAMMD aims at least maintaining its financial stability by means of a balance budget exercise within the limits of the allocated budget in compliance with 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.

<u>Conclusions</u>

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 the European area, 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.

Focusing on its achievements while learning from all its past undertakings, the NAMMD will have to be prepared to cope with any possible challenges in the future.