NATIONAL MEDICINES AGENCY
ACTIVITY REPORT FOR THE YEAR 2004

Introduction

In observance of the practice adopted during the past two years, the activity of the National Medicines Agency (NMA) developed in 2004 aimed at fulfilment of the strategic objectives established by the Report of the NMA President for the previous year, approved and adopted by the Administration Council.

Compared to previous years, the year 2004 has raised a series of problems specific to the present development stage of the institution, problems of organisational, functional and operational, professional nature, efficiency, responsibility and adaptability pertaining to the final objective targeted for the NMA as specialized state institution in the field of medicinal products policy, as well as to preparations of the institution for functioning and operation in the European system, after Accession.

In this context, it has been necessary to take further account of qualitative and quantitative acquisitions, the integration of the institution's effort into the general state policy, as well as NMA organisational and functional consolidation.

In this perspective, the year 2004 can be appreciated as marking one more step towards increased professionalism of the activity, the institution being in progress towards the targeted European model, that of a modern, stable and efficient institution.

Regarding former considerations, the NMA activity in the past year can be characterized by a perceptible increase in all levels.

With a different visibility in the NMA complex system, each department has contributed to achievement of generally good results. From this point of view, visibility has been influenced by both the role attributed through organisational structure and the institution's own effort, determination and involvement demonstrated in achieving specific objectives. It has been here that differences in appreciation have occurred the attitude of departments resulting in a positioning on a performance scale, going from satisfactory to very good.

Naturally, the most significant contribution has been that of specialised departments, particularly the Department for evaluation-authorization, a department providing syntheses, which achieves most of the NMA activity objective.

Support departments have made efforts to integrate into the general rhythm of the unit. Certain dysfunctions have persisted here though, especially in the administrative activity are and it is the the NMA intention to eliminate such irregularities in 2005. For this reason, NMA attention shall be directed towards turning to good account positive experience acquired and correcting deficiencies partially coming from more difficult adaptation to new legislative requirements as well as from passive attitude.

Taking into account the special organisation and functioning of the NMA in the group of public institutions, special attention is required for correct and efficient functioning of the administrative sector. The NMA is organised based on the principles of economical and financial self–administration, being an entirely self-funded institution, for which achievement of the desired and expected results depends on administration of financial resources. From this standpoint, the NMA cannot allow that its administrative departments function and operate unevenly.

The achievements of each organisational structure in itself are presented in the different chapters of the Report.

2005 priorities are determined by the NMA commencement of the European pre–Accession period, characterized by major mutations in the activity of the instituion.

These elements impose an adequate financial policy, based on assuring the balance between incomes and expenses.

A simple analysis of expense chapters in the budget leads to the conclusion that its largest part is made up of staff and material expenses.

For the year 2005, administrative measures shall pursue the appropriate clarification of the situation of certain activity sectors high consumers of financial resources and the maximal reduction of material expenses.

Appropriate attention shall be further given to the fulfilment of specific attributions, responsibilities and tasks specific at high parameters, to NMA participation in external activites and legislative regulation it is connected to.

Together with our social partners, we shall negotiate the new collective labour contract at site level, at maximum standards allowed by the institution's own posssibilities and legislation in force.

As far as the administrative management is concerned, it is fully available for 2005, a better year than previous ones.

A. Activities developed in 2004

1. Activity of the Scientific Council of the National Medicines Agency (NMA)

According to provisions of Government Ordinance No. 125/1998 regarding the setting–up, organisation and functioning of the NMA, approved with changes and completions through Law No. 594/2002, with further changes and completions, the Scientific Council establishes the scientific policy of the NMA, according to its attributions.

Meetings of the Scientific Council discuss regulations concerning NMA professional activity, which are approved as Decisions of the Scientific Council.

Decisions of the Scientific Council of ruling character are subject to Minister of Health approval and are published as minister of health orders in the Official Gazette of Romania; the other Decisions of the Scientific Council are sent for Minister of Health approval and applied within 15 working days after transmission, if Minister of Health disagreement is not communicated; they are then published in the NMA Informative Bulletin.

The Decisions of the Scientific Council which transpose European Directives are notified to the Ministry of European Integration, approved through Minister of Health Order and published in the Official Gazette of Romania.

The name structure of the Scientific Council is established through Minister of Health Order and in accordance with provisions of Government Ordinance No. 125/1998, made up of: 4 NMA members, one representative of the Academy for Medical Sciences, one representative of the National Sanitary–Veterinary Agency, 4 representatives of Medicine Faculties, 4 representatives of Pharmacy Faculties; 4 experienced physicians of various specialisations, an immunologist, an epidemiologist, a dentist, proposed by specialised commissions of the Ministry of Health, a hospital pharmacist proposed by the Ministry of Health, a representative of the Ministry of Economy and Commerce, a representative of the Ministry of Education, Research and Youth, a representative of the College of Pharmacists in Romania, a representative of the College of Physicians in Romania, a representative of the Association of Romanian Medicines Manufacturers and a representative of the Romanian Association of International Producers of Medicines.

In the year 2004 the activity of the NMA Scientific Council has been conducted within **4** working sessions and has been put into practice by the adoption of **41** decisions.

2. Activity of the NMA Administration Council

According to provisions of Government Ordinance No. 125/1998 regarding the setting–up, organisation and functioning of the NMA, approved with changes and completions by the Law No. 594/2002, with further changes and completions, the Administration Council carries out the following activities:

- approves NMA economic and financial policy;

- proposes the organisational structure of NMA departments;
- approves the income and expenses budget;
- analyses the opportunity and possibilities to conclude collaboration and services contracts;
- proposes tariffs and emergency tariffs for NMA activities, as well as the value of quota for maintaining marketing authorizations in force, which are published in the Official Gazette, Part I, after approval through Minister of Health Order;
- issues the NMA annual activity report;
- approves NMA organisation and functioning statutes and regulations;
- approves NMA internal regulations.

The name composition and structure of the Administration Council is established through Minister of Health Order and, according to provisions of Government Ordinance No. 125/1998 it includes the President, Vicepresident and heads of departments within the NMA, the Director of the General Pharmaceutical, Pharmacy Inspection and Medical Devices Directorate within the Ministry of Health, the Director of the Budget and Acquisitions General Department of the Ministry of Health, the Director of the Department of Relationships with the Parliament, Legislation and Claims Office of the Ministry of Health and the General Director of the National Health Insurance House.

In the year 2004, the activity of the NMA Administration Council has been carried out in **8** working sessions and has led to the adoption of **29** decisions, of which **3** of ruling character, approved through Minister of Health Order and published in the Official Gazette of Romania, Part I.

3. Regulatory Activity

According to the legislative programme for support of the process for Romania's accession to the EU, with commitments assumed in the Position Document referring to the chapter "Free Circulation of Goods" and following conclusions resulted from the meetings of the inter–ministerial working group, set up to determine to trade, the NMA Scientific Council has drafted/updated regulations regarding NMA professional activity, in accordance with communitary regulatory documents.

In 2004, of the **41** Decisions adopted by the NMA Scientific Council, **25** have been adopted through minister of health order and have been published or are in progress of being published in the Official Gazette of Romania and **9** Decisions, approved in the meeting of the NMA Scientific Council dated 10.12.2004, are in process of approval through minister of health order.

From a total of **41** Decisions adopted by the NMA Scientific Council in 2004, **16** have transposed European Regulations in the field of medicinal products, namely:

– Directive 2001/83/EC of the European Parliament and Council, of November 6, 2001, on the Communitary Code regarding medicinal products for human use.

Title IX – Chapter1 – Pharmacovigilance

– 3 European guidelines concerning the pharmacovigilance activity

– Directive 2001/20/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use

– 10 European guidelines concerning conduct of clinical trials

– Guideline regarding the investigation of bioavailability and bioequivalence.

4. Activity of NMA Commissions

4.1. Commission for Marketing Authorization

The commission for marketing authorization is set up through Decision of the NMA President and includes the NMA Vicepresident, the heads of evaluation–authorization departments, control of raw materials and finished products, assessment and control of

biological products, pharmacy inspection, as well as the heads of services and offices within the department of evaluation–authorisation.

The Commission discusses on evaluation reports in order to formulate an opinion regarding the marketing authorisation as well as other marketing authorization related problems of the medicinal products for human use.

In 2004, the activity of the Comission for marketing authorization has been conducted within **76** working sessions, wherein the evaluation reports for **982** products have been discussed, in order to formulate an opinion on the marketing authorization.

4.2. The Inspection Commission for Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), Good Analytical Laboratory Practice (GPAL), Good Clinical Practice (GCP)

The Commission is set up through decision of the NMA President and is made up of the NMA President and Vicepresident, the heads of the departments for pharmacy inspection, evaluation–authorization, control of raw materials and finished products, evaluation and control of biological products as well as the inspectors for GMP, GLP, GPAL, GCP within the Department for pharmacy inspection.

The Commission discusses inspection reports drafted by NMA inspectors, reports relating to inspected sites compliance with GMP, GLP, GPAL, GCP rules and/or other problems regarding the activity of the Department for pharmacy inspection. The Commission is competent to confirm or invalidate decisions made by inspectors as mentioned in the inspection report.

In the year 2004, the activity of the Commission for the GMP, GLP, GPAL, GCP inspections has taken place within **16** working meetings, wherein **60** inspection reports have been discussed.

4.3 Commission for Coordination of the Romanian Pharmacopoeia

The Commission is set up by decision of the NMA President and is made of the President and Vicepresident of the NMA, the Deans of the Pharmacy Faculties, the Director of the General Pharmaceutical, Pharmacy Inspection and Medical Devices Directorate of the Ministry of Health, the heads of NMA professional departments and specialists.

The attributions of the Commission consist in the analysis of the technical–scientifical aspects related to Romania's signing of the "European Pharmacopoeia Convention" of the European Council.

The Commission for Coordination of the Romanian Pharmacopoeia has continued to coordinate the translation and harmonization of the general monograpfhs and general methods of analysis of the European Pharmacopoeia, in view of including and officializing them in the Supplements of the Romanian Pharmacopoeia, the 10th edition.

In 2004, the electronic system of collaboration between NMA, members and experts has been implemented, which led to more dynamic revision and approval of monograpfhs and methods of analysis taken from the European Pharmacopoeia. The chapters of the 2004 Supplement project of the Romanian Pharmacopoeia, the 10th edition, have been discussed and approved in order to be published within **2** full meetings of the Commission for Coordination of the Romanian Pharmacopoeia.

The 2004 Supplement of the Romanian Pharmacopoeia, the 10th edition was published in November 2004.

5. Evaluation–Authorization and Related Activities

5.1.Marketing Authorization

In 2004, the NMA has received **927** applications for marketing authorization, of which:

– **99** applications for authorization through simplified procedure of the Collaboration Agreement of competent authorities in the field of medicinal products, in countries associated

to the European Union (Collaboration Agreement between Drug Regulatory Authorities in European Union Associated Countries = CADREAC) for products authorized in the European Union (EU) through centralized procedure;

– **72** applications for authorization through simplified CADREAC procedure for products authorized in the EU through mutual recognition procedure;

– **756** application for the authorization through national procedure.

In 2004, the NMA has issued a number of **962** marketing authorizations (MA), of which:

– **106** MAs through simplified CADREAC procedure for products authorized in the EU through centralized procedure;

– **55** MAs through simplified CADREAC procedure for products authorized in the EU through mutual recognition procedure;

– **801** MAs through national procedure.

Medicinal products authorized for marketing in 2004 have been published on the NMA site (**www.anm.ro**) and published at the beginning of 2005 in the Classified List of medicinal products for human use, annually published by the NMA.

The total number of medicinal products entitled for circulation on 31.12.2004 was **5402,** corresponding to **942** International Non–Proprietary Names (INN).

Of these, 1**567** are Romanian medicinal products and **3835** are imported medicinal products. Of all medicinal products entitled for circulation, **849** are medicinal products to be released without prescription (Over the Counter = OTC).

5.2 Approval of variations of marketing authorisation terms

In 2004, the NMA has received a number of **3902** applications for type I and of type II variations, changes allowed by regulations, transfers of marketing authorisations.

A number of **4320** applications have been approved, of which:

– **3237** applications for type I variations
– **918** applications for type II
– **83** applications for transfers
– **82** applications for other types of changes

5.3 Approval of clinical trials

In 2004, the NMA has received a number of **214** applications for the approval of clinical trials, of which:

– **4** applications for the approval of **stage I** clinical trials
– **34** applications for the approval of **stage II** clinical trials
– **89** applications for the approval of **stage III** clinical trials
– **13** applications for the approval of **stage IV** clinical trials
– **74** applications for the approval of bioequivalence studies

Before the end of 2004, the following clinical trials have been approved:

– **3 stage I** clinical trials
– **34 stage II** clinical trials
– **78 stage III** clinical trials
– **10 stage IV** clinical trials
– **104** bioequivalence studies

5.4 Approval of advertising material

The approval of advertising materials for medicinal products for human use is carried out according to Regulations regarding advertisment of medicinal products for human use, approved through Minister of Health Order No. 263/25.03.2003 published in the Official Gazette of Romania, transposing *Title VIII – Advertisement, of Directive 2001/83/EC of the*

European Parliament and Council, of November 6, 2001, on the Communitary Code regarding medicinal products for human use.

During the year 2004, the NMA has received **189** applications for approval of advertising materials of medicinal products and has approved **179** advertising materials.

5.5 Pharmacovigilance Activity

The activity of the National Center for Pharmacovigilance, which functions and operates within the NMA, is conducted according to regulations in force, transposing European regulations.

In 2004, pharmacovigilance activity has resulted in the administration of the following reportings:

– **244** spontaneous reports from Romania;

–**2500** reports in the format of the Council for International Organisations of Medical Sciences (CIOMS)

– **592** Periodic Safety Updated Reports (PSUR)

Measures have been taken to revigorate pharmacovigilance activity conducted by practicing physicians through granting of credits.

6. Activity of GMP, GLP, GPAL, GCP inspection, of good pharmacovigilance practice and market supervision

Before the end of 2004, inspection activity has been carried out through:

- **53 GMP** inspections, of which **46** at production sites in the country and **7** abroad; inspections abroad are carried out by the NMA on request by interested companies, as member of the Pharmacy Inspection Cooperation Scheme (PIC/S) and participant in the International Medicines Inspectorates Databasis (IMID)

– **21 GCP** inspections

– **1 GLP** inspection

– **1 GPAL** inspection

– **5** prior marketing authorization inspections

– **31** inspections following complaints on the quality of certain medicinal products

– **1020** inspections within the annual plan of market supervision

– **72** authorization inspections for operation of medicinal products manufacturing sites

– **2** pharmacovigilance inspections at MA holders

– **817** consultant visits on pharmacovigilance problems

7. Activity of Medicinal Product Quality Control

In the year 2004, within the Control Department for raw materials and finished products, **2854** imported and domestic products have been analysed, for which **5831** analysis bulletins have been issued. Of these, **2093** have been chemical products and **761** have been biological products. **679** technical import sheets have been issued as well.

In 2004, within the Evaluation and Control Department for biological products, **915** series of biological products have been analysed, for which **2500** tests have been carried out. Also, **50** biological products have been evaluated in view of being authorized for marketing.

8. Pharmacopoeia related Activity

By Romania's signing of the European Pharmacopoeia Convention of the European Council and therefore acquisition of full membership status on 24.09.2003, quality standards of the European Pharmacopoeia have become mandatory for all raw materials and medicinal products for human use both imported by and manufactured in Romania.

The NMA has organised meetings with Romanian medicinal product manufacturers, which have finally been turned into evaluation of material possibilities for implementation of European Pharmacopoeia provisions in production of medicinal products in Romania.

In 2004, drafting was finalised of the 2004 10th edition Supplement of the Romanian Pharmacopoeia; the 315 pages of the volume provide 24 general monograpfhs of pharmaceutical forms, the chapter of general provisions, 120 reagents and 9 monograpfhs and revised methods of analysis, Standard Romanian terms for pharmaceutical forms, administration routes and primary packaging, in accordance with those adopted by the European Pharmacopoeia

The 2004 10th edition of the Supplement of the Romanian Pharmacopoeia was published in November 2004 and is now available.

The 2004 10th edition of the Supplement of the Romanian Pharmacopoeia represents a continuation of the translation and harmonization of European Pharmacopoeia provisions, an effort to support users by provision of an Romanian official version of the general part of the European Pharmacopoeia, harmonized with specific Romanian terms in the field, as well as with Romanian standard terms approved for pharmaceutical forms, administration routes and primary packaging, in accordance with those adopted by the European Pharmacopoeia.

In 2004, the project was started for the 10th edition 2005 Supplement of the Romanian Pharmacopoeia, through which translation and harmonization of the general part of the European Pharmacopoeia are continued. Drafting and approval of Romanian new and revised standard terms for pharmaceutical forms, administration routes and primary packages, have been continued, in accordance with those adopted by the European Pharmacopoeia, to be published in the NMA Informative Bulletin and the future 10th edition 2005 Supplement of the Romanian Pharmacopoeia.

9. Quality Management Activity

In 2003, the NMA system of quality management was evaluated by a team of Member States and candidate countries auditors, within the program of the PanEuropean Regulatory Forum (PERF).

The conclusions of the evaluation were the following :

"The National Medicines Agency has a well established system of quality management which is based on ISO 17025 in the field of laboratory control and ISO 9001 for the regulatory activity. The Quality Handbook and other documents of the quality management system are drafted and it is obvious that within the organisation the process–based approach is implemented. The management at the highest level is deeply involved in activities related to the system of quality management and the whole staff is motivated and understands clearly the mission and objectives of quality. The employees are well trained in the problems of the quality management system".

In 2004, quality management activities mainly focused on improvement of the existing system.

In this respect, the documentation of the quality management system has been completed in 2004 by drafting the policy for ensuring the labour security and health and by drafting new documents:

– **3** new general Standard Operation Procedures (SOP)
– **1** new inter–departamental SOP
– **30** new specific SOP

The following have been drafted:
– annual working programs for each department
– annual training program for the NMA staff
– annual program of internal audit

In 2004, **8** internal quality audits have been carried out, according to the annual internal audit schedule, approved by the higher management.

The operation of the NMA system for quality management is presently based on quality documents (mission, quality objectives and policies in the quality field, established by the higher management, NMA Quality Handbook, departamental quality handbooks, annual working programs of the departments, annual training schedule for the NMA staff, annual internal audit program, 500 general and specific SOPs) as well as on the good training of the staff and determined management involvement in the operation of the system.

10. Insuring communication and transparency

The NMA pays special attention to ensure good communication with interested parties and full transparency in its activity.

10.1. External communication

Apart from the quarterly publishing of the bilingual NMA Informative Bulletins, which is already a tradition, NMA interest for 2004 also included development of information placed on the NMA bilingual website.

New information added in 2004 to the NMA website includes:

– abbreviations and acronyms of interest for NMA beneficiaries;

– information letters to physicians

– press releases regarding safety of medicinal products

– summaries of product characteristics for medicinal products authorized in Romania through simplified CADREAC procedures for products authorized in the EU through centralized or mutual recognition procedures.

Taking into account the diversity and multitude of information on the NMA website, a fast search engine has been created in 2004, which is very appreciated by users.

The proof of increased interest of concerned parties for information placed on the NMA website is the high number of visitors, which in 2004 has been of **45.600,** a monthly average of **3.800** visitors respectively.

The NMA has also continued the practice of organising meetings with marketing authorization holders, with associations of medicinal product manufacturers, in order to debate problems of wide interest, especially related to problems of European integration.

In 2004, the NMA has been preoccupied to inform interested parties on its activity through other publications as well, other than its own Informative Bulletin.

Therefore, the annual report of the NMA for the year 2003 has been published as a bilingual brochure, appreciated by similar EU competent authorities.

Articles related to various aspects of NMA activities have been published in Romanian specialized magazines in 2004, as well as in the "Parliament Magazine" of the European Parliament.

10.2. Internal Communication

In 2004, special attention has been given to information provided to NMA employees through the intranet, in order for them to be better and faster informed on professional and organisational issues. As an example of information available to NMA employees on the intranet, the following can be mentioned: Presidential Instructions, NMA quality policies, information regarding training courses organised by specialiased companies, reports of staff participating in trainings, status of staff training, glossary of quality assurance terms, useful forms, results of the staff motivation survey, Regulations, electronic versions of the European Pharmacopoeia and the American Pharmacopoeia.

11. International Relationships

In 2004, NMA participations in activities of various European collaborating institutions and, have continued as follows:

11.1. Participation in activities carried out by the European Medicines Agency (EMEA)

Following the provisional closing in the year 2003 of Chapter 1 “Free Circulation of Goods“, sub–chapter 1.1 “Pharmaceutical products“, the NMA received EMEA’s invitation in September 2003 to nominate its representatives for participation as active observers in the 18 scientific committees, work groups and groups for implementation of information technology dedicated to medicinal products for human use.

Participation of NMA representatives as active observers in EMEA scientific committees and work groups is the most efficient means to maintain the NMA connected to European activities in the field of medicinal products, in view of Romania’s preparation for Accession to the EU in 2007.

11.2. Participation in CADREAC activities

The NMA has organised the annual CADREAC 2004 meeting in Bucharest, particularly successful in both importance of topics and organisation.

According to provisions of the agreement, the NMA has taken over the CADREAC secretarial office for 2004.

The NMA has also taken the initiative to set up the new CADREAC agreement, an undertaking of maximum interest for new candidate countries as wel as other Central and South–Eastern European countries interested in European medicinal products standards.

11.3. Participation in activities of the European Pharmacopoeia Commission

After ratification of the European Pharmacopoeia Convention of the European Council, Romania has gained full membership starting with 24.09.2003. and the NMA has therefore continued collaboration with the Secretarial Office of the European Pharmacopoeia Commission in view of finding a solution for legal and technical–scientifical aspects resulting from Romania's signing the Convention.

The representative appointed by the NMA has actively participated in 2004 working sessions of the European Pharmacopoeia Commission.

11.4. Participation in PIC/S activities

In 2004, NMA representatives have taken part in 2 working sessions of the Committee of PIC/S Officials and the annual training seminar on "Inspection of manufacturers of active pharmaceutical substances".

11.5. Participation in activities of the European Network of the Official Medicines Control Laboratories (OMCL)

NMA representatives have participated in the annual OMCL meeting of May 2004, organised by the European Directorate for the Quality of Medicines (EDQM).

Specialists of NMA laboratories participated in 3 studies for testing competence level among official laboratories for medicinal products control organised by the EDQM and 3 studies organised by the Dutch Scientific Pharmaceutical Institute under the auspices of the Laboratories and Medicines Control Services Section of the International Pharmaceutical Federation (LMCS–FIP).

12. Staff policy

12.1. Objectives pursued by the NMA in 2004 in the human resources field have been as follows:

– assurance of specialised staff with university degrees, competent, appropriately trained, with adequate abilities and experience, able to contribute to achieveetn of NMA mission;

– stimulation of each employee for self–training;

– delegation of reponsibilities on each managerial level in order to ensure individual contribution to the achievement of quality objectives;

– establishment of competences/tasks, responsibilities and communication thereof to agency staff;

– planning of human resources for best achievement of organisation competences;

– promotion of staff involvement in achievement of quality related objectives and better organisational efficacy and efficiency;

– assurance of staff training according to job (position) requirements;

– assurance of access for various organisational and management structures (departments, services, offices, compartments) to specific Human Resources Department (HRD) information requierd for ongoing improvement of activities;

– assurance of an adequate working climate stimulating motivation, satisfaction, development and performance of organisational staff;

– assurance of confidentiality of information handled by the HRD.

12.2. Staff employment carried out in 2004 have been correlated with staff objectives established.

Therefore, **10** university graduates have been employed in 2004, of which:

– **4** physicians

– **5** pharmacists

– **1** chemist

2 economic–administrative staff with university degree, 2 economists, respectively have also been employed.

In 2004, **23** promotions have been performed, of which **7** to management positions.

In view of accomplishing objectives related to employees' professional development and implementation of the quality management system in the NMA, **62** training sessions have been organised at home and abroad in 2004.

13. Organisational Activity

In 2004, the NMA has been preoccupied by the improvement of certain organisational aspects of the activity identified as sources for dysfunctionalities. Therefore:

– special areas have been organised for the storage of hazardous chemical substances according to legal provisions in force;

– appropriate and sufficient space has been arranged for storage of documentation of marketing authorization for medicinal products, of documentation regarding the inspection activity and laboratory control and logical organisation of archives, thus ensuring confidentiality and traceability of information;

– areas available after entry into operation of the new microbiology laboratory have been allocated to the Department for evaluation–authorization, in order to allow operation at European standards of the department which has a decisive role for NMA activity in the perspective of EU accession;

– the physical destruction of inventory objectives and fixed assets has been carried out;

– the activity and perspectives of the territorial units and farms has been assessed and based on this evaluation, activities have been reorganised, areas and staff have been redimensioned in order to meet real needs, thus achieving savings of tens of billions Lei;

– the Office of Financial Audit for improving implementation of provisions of Law No. 672/2002 regarding internal public audit and Minister of Health Order No. 840/2003 regarding methodological rules for the organisation and execution of public internal audit within the Ministry of Health.

14. Investments

In 2004, investments have been carried out in fields of maximum interest for NMA preparation in view of EU accession. Therefore:

– the microbiology laboratory investment has been finalised;

– NMA endowment with high-quality computing equipment has been completed, thus ensuring a network of 150 quality computers, compatible with the European computer system;

– NMA Internet connection has been improved by replacing the CATV connection with optical fibre connection, required by the intense NMA information exchange with European bodies and similar agencies in Member States, especially following the temporary closing of Chapter 1 "Free Circulation of Goods";

– a heating power station has been purchased and commissioned, to insure heating of the main headquarters according to NMA needs, also saving tens of billions Lei annually;

– the sanitary groups of the central headquarters have been refurbished;

– 11 rooms of the Evaluation–Authorization Department have been re–divided and cleaned.

B. Deficiencies of Activity

Although continuing efforts have been made to eliminate delays in finalizing evaluation of documentation submitted by applicants for marketing authorization, delays have occurred in 2004 as well, mainly determined by applicants' delayed payment of authorization fee and tariff and/or delay in the submission to the NMA of requested completions.

C. Difficulties

The main problem the NMA has met during 2004 has been insufficient number of quality evaluators – pharmacists, mainly determined, on the one hand, by massive staff departures from the institution between 1999–2002 and, on the other hand, by the fact that well paid labour offer in the private sector is still high enough.

D. Intended measures for increased efficiency of institutional activity

– improvement of pay and motivation of specialised staff with the purpose to maintain existing staff in the institution and attract young specialised staff;

– tariff modification for NMA services offered to cover expenses related to services provided by the NMA;

– continuation of NMA internal reorganisation, in view of increased compatibility of functional units and staff structure with requirements of NMA functioning in the European network of competent authorities in the medicinal products field;

– continuation of staff in – job training, in the country and abroad, for professional improvement and preparation for operation in the European system;

– continuation of NMA infrastructure improvement and particularly of the information system in order to make it compatible with operational requirements in the European system.

E. Problems requiring urgent resolution

According to provisions of Government Ordinance No. 125/1998, approved with changes and completions through Law No. 594/2002, with further changes and completions, the mandate of the NMA Scientific Council is 3 years. Taking into account the fact that the mandate of the present Scientific Council, appointed through Minister of Health Order No. 30/15.01.2002 is due on 15.01.2005, issuance of a new Minister of Health Order is required to set up a new Scientific Council of the NMA.

F. Proposals for 2005 Activities

NMA prioritary activities for 2005 consist of :

– improvement of the institution's organisational structure for assurance of optimal functioning compatibility with the European system, with emphasis on reorganisation of the two control departments;

– increased efficiency of activity organisation, aimed at reducing the time for proposed objectives solutioning;

– steady continuation of drafting/updating regulations regarding NMA professional activity, in accordance with new comunity regulatory papers (especially with Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending the Community code relating to medicinal products for human use and 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending, as regards traditional herbal medicinal products, the Community code relating to medicinal products for human use);

– continous improvement of the quality management system and participation in activities of comparing the performance level of the already implemented system, especially to those organised by the EMEA;

– improvement of communication with interested parties and activity transparency;

– assurance of financial resources necessary for participation in international activities, thus contributing to maintain permanent institution contact with similar institutions and European institutions of the same profile;

– assurance of human and financial resources appropriate for good activity development;

– implementing a new staff evaluation and pay system based on performance criteria;

– conclusion of a new collective labour contract on unit level containing all the changes in the past two years;

– assurance of professional training of staff at European standard level, thus contributing to facilitated NMA integration in the European system after Accession;

– continuation of preparations for the organisation of PIC/S officials' meetings and of PIC/S seminar scheuled to take place in Bucharest in September 2005;

– continuation of actions for finalisation of the setting–up of the new CADREAC agreement.