Ministry of Health

ORDER

regarding the approval of the Statute of the personnel with inspectors attributions from the National Medicines Agency

Taking into consideration the provisions of Art. 10, paragraph (9) of the of the Government Ordinance No. 125/1998 regarding the setting up, organization and functioning of the National Medicines Agency, approved with changes and completions through Law No. 594/2002, with further changes and completions,

Seeing the approval report of the General Pharmaceutical Direction, Pharmaceutical Inspection and Medical Equipment No. IB 5.881 from 28 November 2003,

In accordance with the Government Decision No. 743/2003 regarding the organization and functioning of the Ministry of Health,

Minister of Health emits the following Order:

Art. 1. – The ”Statute of inspectors from the National Medicines Agency” is approved in accordance with the Annex to the present Order.

Art. 2. – The National Medicines Agency will carry out the implementation of the present Order.

Art. 3. – The present Order will be published in the Official Monitor of Romania, Part I.

Interim Minister of Health,
Ionel Blănculescu

Bucharest, 27 November 2003.

No. 1.102.

ANNEX

STATUTE
of the personnel with inspectors attributions from the National Medicines Agency

CHAPTER I

Generalities

Art. 1. – The provisions of the present statute apply to the personnel with attributions of inspectors for Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), Good Analytical Laboratory Practice (laboratory for control of medicinal product quality\, GALP), Good Pharmacovigilance Activity Practice (GPAP) which perform inspection activities in accordance with the provisions of the Government Emergency Ordinance No. 152/1999 regarding medicinal products for human use approved with changes and completions by Law No. 336/2002 with further changes and completions and with the ones of the Government Ordinance No. 125/1998 regarding the setting up, organization and functioning of the National Medicines Agency, approved with changes and completions through Law No. 594/2002, with further changes and completions.

Art. 2. – The personnel with inspector's attributions are conducting their activity within the Pharmaceutical Inspection Department (PID) of the National Medicines Agency (NMA), in accordance with the organizational structure approved by Minister of Health Order.

Art. 3. – The activity domains of the PID are integrated within the NMA's activity and are directed for ensuring the quality, efficacy and safety of medicinal products for human use through:

-elaboration, evaluation and certification of Good Practice Regulations of units and independent laboratories for control of medicinal product quality;

-verification of compliance with Good Practice Regulations at the clinical testing units;

-verification of compliance with Good Pharmacovigilance Practice Regulations;

-surveillance of medicinal products quality by specific actions (annual sampling plan, thematic programs, complaints and rapid alerts solving).

Art. 4. – The present statute regulates:

-the functions, competencies, obligations and rights of the personnel with inspectors attributions;

-the conditions for employment for the positions for the personnel with inspectors attributions at the NMA;

-the training and evaluation system for personnel with inspectors attributions;

-the rate setting and the salary of personnel with inspectors attributions.

CHAPTER II

Functions, competencies, obligations and rights of the personnel with inspector's attributions

Art. 5. – The personnel with inspectors attributions is recruited among specialists which fulfill the study conditions (pharmacist, doctor, biologist, chemist engineer licensee/diploma) and have the capacity to completely exercise the rights in accordance with the Code of ethic and deontology of the personnel with inspector's attributions of the NMA).

Art. 6. – The framing of the personnel with inspectors attributions relating to the professional grades is done based on contest conducted in accordance with the methodology elaborated by the NMA and approved by the Ministry of Health.

Art. 7. – The head functions of the PID of the NMA are the following and can be occupied only by contest:

-Head of Pharmaceutical Inspection Department;

-Head of Service within the Pharmaceutical Inspection Department;

-Head of territorial unit for inspection and control;

-Head of territorial unit for inspection.

Art. 8. - (1) The personnel with inspectors attributions have also obligations of professional and moral nature, which guaranty the performing of NMA's activities in the domain of surveillance of medicinal product quality in Romania.

(2) The obligations and rights of the personnel with inspector's attributions are those, which result from the legislation in force and from the present statute.

(3) In addition to the basic norm, the personnel with inspector's attributions can exercise also activities outside the NMA under the conditions mentioned by Law. At hiring or at any time a change occurs, as personnel with inspectors attributions, he should declare the other activities.

Art. 9. – The personnel with inspectors attributions respond disciplinary for infringing the obligations which are incumbent according to the individual working contract as well as for infringing the Code of ethic and deontology of the personnel with inspectors attributions of the NMA.

CHAPTER III

Occupancy the positions by the personnel with inspectors attributions

Art. 10. - (1) Occupancy the positions by the personnel with inspections attributions is done by contest organized by the NMA based on a methodology elaborated by itself and approved by Ministry of Health Order.

(2) The personnel with inspector's attributions work fulltime at the NMA.

(3) When there are needed specific evaluations, at the inspection activity are co-opted specialists of the NMA, which perform their activity in other departments.

Art. 11. – In special cases, which require complementally scientific competencies, it can appeal to external specialist, which will be hired in accordance with the legislation in force.

CHAPTER IV
Training and evaluation system

Art. 12. – The training of the personnel with inspector's attributions from the PID is foreseen in the annual plans of the NMA and is specific to competencies of the individual job description. The instruction programs and their periodicity are established in accordance with the European organisms requests (Pharmaceutical Inspection Cooperation /Scheme - PIC/S, European Medicines Evaluation Agency - EMEA, Collaboration Agreement between Drug Regulatory Authorities in European Union Associated Countries - CADREAC) regarding the harmonization of the competencies.

Art. 13. - (1) The evaluation of professional performances is done based on the training, experience criteria and results obtained in the inspection activity, established by own regulations of the NMA.

(2) The evaluation of professional activities of the personnel with inspector's attribution is done annually by the Head of the Department based on the general evaluation criteria established for the entire personnel of the NMA and customized for inspection activities.

CHAPTER V
The rate setting and salary of the personnel with inspector's attributions

Art. 14. – The rate setting and salary of the personnel with inspector's attributions is done in accordance with the legislation in force and with the own regulations of the NMA.