

MINISTRY OF HEALTH

ORDER

for the approval of the Ethics and Deontology Code for the personnel with inspection attributions in the National Medicines Agency

Taking into consideration the provisions of the Art. 10 paragraph (9) 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 Pharmaceutical General Direction, Pharmaceutical Inspection and Medical Devices No. OB 1.506 of 17 February 2004,

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 Ethics and Deontology Code for the personnel with inspection attributions in the National Medicines Agency is approved in accordance with the Annex, which is part of the present Order.

Art. 2. – The National Medicines Agency will fulfill the provisions of the present Order.

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

The Minister of Health
Ovidiu Brînzan

Bucharest, 17 February 2004.
No. 160.

THE ETHICS AND DEONTOLOGY CODE

for the personnel with inspection attributions in the National Medicines Agency

Art. 1. – The purpose of this document is to put at the disposal of personnel with inspection attributions [for Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP) (pharmaco-toxicological laboratory), Good Analytical Laboratory Practice (GALP) (laboratory for quality control of medicinal products), Good Clinical Practice (GCP), Good Practice in the Pharmacovigilance Activity (GPPA)] a basic ethics and deontology code, which is to be respected during the inspection.

Art. 2. - (1) The personnel with inspection attributions in the National Medicines Agency (NMA) – The Pharmaceutical Inspection Department (PID), as a representative of the NMA, have to observe in its activity the medicinal products legislation, the Regulations that enact the NMA functioning, the provisions of the NMA Internal Regulation, the job description and the provisions of the present code.

(2) In all situations the personnel with inspection attributions has to act so as to promote a positive image of neutrality and professionalism of NMA.

(3) In order to ensure the objectivity and the lack of any possibility of influence, the personnel with inspection attributions has to respect the highest standards of moral and professional behavior.

(4) The personnel with inspection attributions should not be influenced by the inspected facility.

(5) The personnel with inspection attributions shall not inspect any facility he or she was involved in as consultant in projecting or maintaining the unit facilities, or in other commercial agreements.

(6) The payment of the personnel with inspection attributions is independent of the inspections outcome.

Art. 3. – As representative of the national competent authority, the personnel with inspection attributions has to permanently prove the professional competence given by this function in the relationship with the producer, with the distributor, and where necessary, with the consumer.

Art. 4. - (1) Integrity must be the main trait of the personnel with inspection attributions, so as to ensure they act always correctly, are honest, are reliable persons and that they respect a strict ethical code ; integrity of the personnel with inspection attributions includes their capacity to fulfill their job accurately, precisely impartially and justly.

(2) The personnel with inspection attributions shall respect the confidential information obtained in his/her inspection activity and never use them in personal interest.

Art. 5. - (1) The personnel with inspection attributions may have other responsibilities, may have other activities paid or unpaid, but with no connection to the inspection function.

(2) These activities should be declared and should not create a conflict of interests real or apparent; these activities should not influence the efficiency of the personnel with inspection attributions, should not request a part of their official working-time or involve their information or professional resources.

(3) The personnel with inspection attributions are not allowed to:

a) commit himself to an activity by which NMA can be identified as an active part in marketing a medicinal product;

b) negotiate, with or without payment, with the inspected facility, certain contracts in order to perform services or to deliver goods;

c) represent NMA in a problem in which a conflict of interests can be identified;

d) engage in consulting activities for a company or its partner, which are subject to NMA inspection

e) ensure the training of the inspected facilities;

f) solicit or accept directly or indirectly presents or other favors.

Art. 6. - (1) The inspectors have to be dignified, polite and tactful.

(2) The behavior of the personnel with inspection attributions should be decided without creating a stressful atmosphere in the inspected facility; one should not have an inflexible behavior, a superiority appearance, arrogance or authoritative attitude.

(3) In case the representatives of the inspected facility have an aggressive attitude which appears from their tone of voice and behavior, the inspector can stop the inspection and ask the support of the police.

Art. 7. - (1) The personnel with inspection attributions should have an adequate, practice and common sense clothing.

(2) It is necessary to use the protection gear during the inspection, for the protection and safety of the medicinal products.

Art. 8. – The personnel with inspection attributions from the NMA should sign an agreement (provided in the Annex of the present code), demonstrating in this way that they consent and respect the provisions of the Ethics and Deontology Code.