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AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES
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CODE OF CONDUCT OF THE AGENCY FOR MEDICINAL PRODUCTS AND MEDICAL DEVICES 4th edition, September 2008

INTRODUCTION

The role and responsibility of the Agency for Medicinal Products and Medical Devices (hereinafter: Agency) in the expert assessment of medicinal products for human use, medical and homeopathic devices have a significant influence on the protection of human health. The integrity and high standards of professional conduct of all involved in the tasks entrusted to the Agency (director, managers, experts, all Agency staff, members of all committees or working groups of the Agency, institutions and experts conducting a part of the tasks in any way) are imperative for the independence of the Agency and its reputation. Agency employees must carry out the tasks entrusted to them conscientiously, upholding the Constitution, laws, Agency Status and other rules and regulations of the profession, and to abide by the instructions of the Agency director and senior staff. The Agency makes every attempt to ensure that all employees have integrity, transparency and independence in their work.

In the sense of their own standards of conduct, all persons participating in the activities of the Agency, particularly when their contribution can influence Agency decisions, must report and describe any possible conflict of interest in the appropriate early phase of activity.

SCOPE

The scope of this Code of Conduct (Code of Ethics), which regulates the rules of good conduct towards clients of the Agency and in mutual relations, is that every employee or other involved person is informed with the Agency policies relating to conduct and confidentiality. In carrying out their tasks, Agency employees shall apply the principles laid down by law pertaining to them, and other regulations, in addition to these rules.

STATUTORY AND OTHER REQUIREMENTS

The Statute of the Agency for Medicinal Products and Medical Devices was adopted by the Executive Council of the Agency on 30 September 2003, and in Articles 29 and 30 lays down the confidentiality requirements.

The Rules on protection of confidentiality of data and business secrets, adopted by the Agency Director on 19 June 2004 prescribes the measures and procedures for the establishment, use and protection of confidential data.

Article 7 of the Rules on authority and work of the Committee for Medicinal Products of the Agency, adopted by the Agency's Executive Council on 14 June 2004, states that the chairperson, deputy chairperson and members of the Committee may be appointed from among those persons not having a conflict of interest pertaining to the work of the Committee, which each person individually confirms by a written statement.

Article 12 of the Rules of procedure on the work of the Committee for Medicinal Products of the Agency, adopted by the Committee for Medicinal Products on 16 June 2004 prescribes that members of the Committee are obliged to inform the Committee chairperson about any possible conflict of interest regarding individual items on the daily agenda.

PROTECTION OF REPUTATION

Agency employees must ensure while carrying out their tasks and conducting themselves in public places, that they do not affect their personal reputation and faith in the work of the Agency.

In all forms of public appearances and activities in which they represent the Agency, the Agency employee is obliged to present the Agency's position, in line with the regulations, authorities vested to them, expert knowledge and provisions of this Code of Conduct.

In public appearances in which the employee does not represent the Agency, but which are thematically tied to the Agency, the employee is required to emphasise that he or she is expressing his or her personal position.

In expressing the positions of the Agency and personal positions, an employee shall give regard to personal reputation and the reputation of the public service.

In performing private business, the employee may not use the official symbols or authority of his or her position in the Agency.

CUSTOMER RELATIONS

In relations with customers, the employee shall behave in a professional, unbiased and courteous manner.

In carrying out official duties, the employee shall apply his or her expert knowledge in such a manner as to assist clients in obtaining their rights, while acting in line with the principle of legality and the principle of protecting public interests.

The employee shall conduct him or herself equally towards all clients, without discrimination or privilege on any basis.

EMPLOYEE MUTUAL RELATIONS

Mutual relations of employees shall be based on mutual respect, trust, cooperation, courtesy and patience.

Employees shall mutually exchange opinions and information on expert issues.

Senior employees shall encourage employees to carry out their public service in a high quality and effective manner. They shall also encourage employees to act with mutual appreciation, respect and cooperation, and to ensure appropriate relations with customers.

Employees shall not disrupt other employees in the performance of their duties.

The director shall protect the dignity of employees for the duration of performance of their duties so as to ensure working conditions in which they will not be subject to harassment.

PUBLIC APPEARANCES

Agency employees must ensure, while carrying out their tasks and conduct themselves in public places, that they do not affect their personal reputation and faith in the work of the Agency.

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In public appearances in which the employee does not represent the Agency, but which are thematically tied to the Agency, the employee is required to emphasise that he or she is expressing his or her personal position.

In expressing the positions of the Agency and personal positions, the employee shall give regard to personal reputation and the reputation of the Agency.

CONFIDENTIALITY

Agency employees and other hired persons are obliged to protect all data marked as confidential that they may have learned during the course of procedures on clients and their rights, obligations and legal interests, pursuant to the law.

Employees are obliged to protect official or other confidential data established by law or other regulations. The obligation of protecting official or other confidential data shall continue following the cessation of service or involvement, for a maximum period of years from the cessation of service, unless otherwise provided by a special law.

The Agency Director may exempt an employee from the obligation of protecting official or other confidential data in court or administrative proceedings, if this concerns data without which it would not be possible to establish the state of facts and pass a legal decision.

Pursuant to Article 29 of the Statute, the Agency Director establishes which information of the Agency are deemed confidential, the degree

of confidentiality, the manner of use and keeping of that information and the procedure and measures of interest for the keeping of the confidential information. The Director establishes the above pursuant to the Rules on protection of confidentiality of data and business secrets.

Information considered official confidential information pursuant to the Rules on protection of confidentiality of data and business secrets may only be disclosed by the Agency to other persons by the Agency Director or persons so authorized by the Director.

Pursuant to Article 30 of the Statute, employees of the Agency and members of Agency bodies who learn of information established to be official confidential data in any way are obliged to keep said data as official confidential data and may not disclose these data to other persons or make them available to others.

Disclosure to the Minister responsible for health or to the Agency or other agency of a similar type with which the Agency has a confidentiality contract is not excluded; however, the Agency shall decide on the circumstances under which such disclosure shall be made possible.

EMPLOYMENT/APPOINTMENT

Employment shall be carried out in line with objective and transparent criteria. All activities relating to employment shall be carried out in an open and objective manner that ensures the selection is made based on real values.

A condition for employment is signing of the Statement of Confidentiality and fulfilment of the Declaration of Interests.

The Agency Director or person so authorised by the Director shall be obliged to acquaint new employees and other involved persons with the provisions of the Code of Conduct.

PERFORMANCE OF DUTIES

Employees are obliged to carry out the tasks as outlined in the job description correctly, in a timely fashion, conscientiously, professionally and not for reasons of personal benefit. In carrying out their duties, employees are obliged to do so in accordance with the principle of legality and the protection of public interests, and the abuse of authority in dealing with clients and partners for the purpose of achieving

personal interests or the interests of other natural or legal persons is prohibited.

Employees are obliged to perform their duties efficiently and in a timely manner and, pursuant to the law, to offer legal assistance in order to avoid unjustified complex and difficult to execute procedures, and to avoid situations that could lead to procedures which are detrimental to protecting the legal interests of the clients or the state.

The employee is obliged to provide the public with all necessary information about executed tasks, in accordance with the provisions regulating the right to access of information, in the manner prescribed in the Agency. It is the duty of the employee to ensure a substantiation on all procedures carried out and decisions made during the course of performing duties.

STATEMENT ON CONFIDENTIALITY

The Agency demands that all tasks performed in its competence be carried out in confidentiality and in an objective manner, in accordance with the appropriate regulations. All Agency employees and other contracted persons (members of its committees or working groups or external experts working for the Agency) are obliged to protect official confidential data, regardless of the manner of learning of the information or obtaining or acquiring the possibility of insight into the confidential information (it is not permitted to disclose any information or data obtained while working for or in the Agency, nor the results of work if that data or information is official confidential information).

Every employee of the Agency and other contracted person shall sign a Statement that they are familiar with the Rules on protection of confidentiality of data and business secrets. Signing such a statement is a prerequisite for signing the employment contract, author's contract or appointment into a committee or working group of the Agency, i.e. for any kind of hiring of persons to perform tasks of the Agency.

Signing the statement shall not relate to data that are already public or to knowledge of the person prior to taking on tasks for the Agency. Signing the statement means the signee is obliged to keep official and other confidential data as prescribed by the Rules and upon the

cessation of service, to a maximum period of five years from the cessation of service.

DISCLOSURE OF INTERESTS

Each employee of the Agency or other contracted person is required to sign a Declaration of Interests pertaining to a specific case given as a task. Should any employee or person have an interest in the case, the following steps shall be taken:

- interests and the nature of the interest must be disclosed in advance,
- the person may not influence or request to have influence in decision-making concerning that case,
- the person shall not participate in making decision in the case,
- the person shall be exempted from the procedure if so requested, and shall not be reintroduced until he or she so requests.

PROCUREMENT

All persons involved in the procurement of goods or services for the benefit of the Agency are obliged to act in the interests of the financial integrity of the Agency and to attempt to obtain the best price. Procurement shall be performed in accordance with the legal regulations, by obtaining the prescribed number of bids and aligning the selection with the valid regulations.

All activities relating to financial transactions, procurement or employment of persons shall be carried out in an objective and open manner that ensures that the selection is made on the basis of real values.

Conflict of interest requirements must be abided by with regard to companies that can sell goods or services to the Agency.

INVITATIONS AND GIFTS

With regard to receiving gifts from companies, memberships in companies, executive or management boards of companies and compensation for such membership, the regulations on preventing conflicts of interest in the performance of public service shall be applied appropriately.

Gifts are considered to be money, things without regard to their value, rights and services provided without charge that put or can

put the receiver of said gifts into a position of dependence or create an obligation towards the giver.

Agency employees may not accept any gifts, money, regardless of the amount, nor any other security or precious metal.

Employees are prohibited from requesting or accepting gifts for their personal benefit, the benefit of their families or organisations, for the favourable resolution of an administrative case or other procedure.

INTERNAL COMMUNICATION

Written communication between employees (notices, requests, etc.) shall be carried out within the Agency via forms provided on the Agency's internal computer network.

According to the Labour Rules, harassment is prohibited (protection of worker dignity). In the case of harassment, the employee has the right to report the same to the Director, who will take measures as laid down in the Ordinance.

Communication with applicants and other clients shall take place in the prescribed premises of the Agency in a manner suiting employees of the Agency and determined under this Code of Conduct.

COMPLAINTS ON VIOLATIONS OF THE CODE OF CONDUCT

Employees and clients may make their complaint to the Agency Director on the conduct of employees considered to be contrary to the provisions of the Code of Ethics, including complaints relating to the protection of worker dignity.

The director or person entrusted thereof shall consider the complaint and, where necessary, initiate proceedings on the violations of official duty as established by law or other regulation. A response to the complaint must be given no later than 30 days from the date of its submission.

The director shall appoint a person who, in addition to him or herself, shall be authorized to receive and resolve complaints pertaining to the protection of worker dignity.

*Code of Conduct of the Agency for Medicinal
Products and Medical Devices, 4th edition,
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Agency Director

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