EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1 September 2013
EMA/264257/2013
Administration

The European Medicines Agency Code of Good Administrative Behaviour

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8660
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

An agency of the European Union

The European Medicines Agency Code of Good Administrative Behaviour

The Executive Director,

Having regard to Regulation (EC) No 726/2004 of 31 March 2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, hereafter referred to as 'the Agency',

Having regard to the provisions on openness in the Lisbon treaty, and in particular Article 15 of the Treaty on the functioning of the European Union, and Article 41 of the Charter of the Fundamental Rights of the European Union

Having regard to the recommendations of the European Ombudsman on a Code of good administrative behaviour for agents or other servants in their relations with the public,

Having regard to the opinion of the Staff Committee,

Whereas the Staff Regulations set out the rights and duties of staff and in particular Article 11a and 13 regarding conflict of interest,

Whereas, in order to bring the administration closer to the citizens and to guarantee a better quality of administration, a Code should be adopted that contains the basic principles of good administrative behaviour when dealing with the public,

Considering it therefore desirable to confirm the Code governing the principles of good administrative behaviour which the staff of the Agency should respect in their relations with the public, which has been in place since 1999 and to make this Code publicly available,

HAS DECIDED AS FOLLOWS:

1. Scope

The Code of good administrative behaviour applies to all Agency staff employed under the Staff Regulations and the Conditions of employment of other servants. It further applies to other persons working for the Agency such as national experts on secondment, trainees, persons employed under private law contracts (interims), visiting experts in any work they perform in the context of the Agency's role and in their relations with the public. Hereinafter, these persons are collectively referred to as 'staff''.

This Code contains the general principles of good administrative behaviour which apply to all relations of the staff unless they are governed by specific provisions. The principles set out in this Code do not apply to the relations between the Agency and its staff. Those relations are governed by the Staff Regulations.

2. Lawfulness

The staff of the Agency shall act according to law and apply the rules and procedures laid down in EU legislation, in particular Regulation (EC) No 726/2004 and other legislative texts relevant to the Agency's competences. In addition and in general, they shall ensure that decisions which affect the rights or interests of individuals have a basis in law and that their content complies with the law. They shall also follow any memoranda of understanding or contracts in relation to the execution of the processes and procedures under Regulation (EC) No 726/2004, or Directive 2001/83 EU.

3. Absence of discrimination

In dealing with requests from the public and in taking decisions, the staff of the Agency shall ensure that the principle of equality of treatment is respected. Members of the public who are in the same situation shall be treated in a similar manner. If any difference in treatment is made, the staff of the Agency shall ensure that it is justified by the objective relevant features of the particular case. The staff of the Agency shall in particular avoid any unjustified discrimination between members of the public based on nationality, sex, racial or ethnic origin, religion or belief, disability, age, or sexual orientation.

4. Proportionality

When taking decisions, the staff of the Agency shall ensure that the measures taken are proportional to the aim pursued. They shall in particular avoid restricting the rights of the citizens or imposing charges on them, when those restrictions or charges are not in a reasonable relation with the purpose of the action pursued. When taking decisions, they shall strike a fair balance between the legitimate interests of private persons and the general public interest.

5. Absence of abuse of power

Powers shall be exercised solely for the purposes for which they have been conferred by the relevant provisions. The staff of the Agency shall in particular avoid using those powers for purposes which have no basis in the law or which are not motivated by any public interest.

6. Impartiality and independence

The staff of the Agency shall be impartial and independent, and respect principles of scientific integrity. They shall abstain from any arbitrary action adversely affecting members of the public or the Agency's stakeholders, as well as from any preferential treatment on any grounds whatsoever.

The staff of the Agency shall not be guided by any outside influences of whatever kind, including political or national influences, or by personal interests. They shall abstain from being involved in the taking of a decision on a matter concerning their own interests, or those of their family, relatives, and/or friends. In performing their role within the context of the Agency's work scientific independence shall be ensured.

7. Objectivity

When taking decisions, the staff of the Agency shall take into consideration the relevant factors and give each of them its proper weight in the decision, whilst excluding any irrelevant element from consideration.

8. Legitimate expectations and consistency

The staff of the Agency shall be consistent in their own administrative behaviour as well as with the administrative action of the Agency. They shall follow the Agency's normal administrative practices, unless there are legitimate grounds for departing from those practices in an individual case.

They shall respect the legitimate and reasonable expectations that members of the public have in the light of how the Agency has acted in the past, taking into account where circumstances require evolution of the Agency's position.

9. Fairness

The staff of the Agency shall act fairly and reasonably.

10. Courtesy

The staff of the Agency shall be service-minded, correct, courteous, and accessible in relations with the public. When answering correspondence, telephone calls and e-mails, they shall try, as much as possible, to be helpful and to reply to the questions which are asked, within the boundaries of confidentiality. If the Agency is not responsible for the matter concerned, they shall direct the citizen to the appropriate agent or other servant.

If an error occurs which negatively affects the rights or interests of a member of the public, they shall apologise for it on behalf of the Agency.

11. Reply to letters in the language of the citizen

The staff of the Agency shall ensure that every citizen of the Union or any member of the public who writes to the Agency in one of the Union official languages receives a written answer in the same language.

12. Right to be heard and to make statements

In cases where the rights or legitimate interests of individuals are involved, the staff of the Agency shall ensure that, at every stage in the decision-making procedure, the rights of defence are respected.

Every member of the public shall have the right, in cases where a decision affecting his or her rights or interests has to be taken, to submit written comments, and, to present oral observations before the decision is taken. The rights for “oral explanations” have been imbedded in the procedures that are applied by the Agency in relation to the authorisation of medicines and in other procedures under the competence of the Agency.

13. Reasonable time-limit for taking decisions

The staff of the Agency shall ensure that a decision on every request or complaint to the Agency is taken within a reasonable time limit, without delay, and in any case no later than two months from the date of receipt. The same rule shall apply to answering letters from members of the public.

If a request or a complaint to the Agency cannot, because of the complexity of the matters which it raises, be decided upon within the above-mentioned time limit, the staff of the Agency shall inform the author thereof as soon as possible. In that case, a definitive decision should be notified to the author in the shortest time.

14. Duty to state the grounds of decisions

Every decision or recommendation of the Agency which may adversely affect the rights or legitimate interests of a private person shall state the grounds on which it is based by indicating clearly the reasons or motivations for the decision, relevant facts, and the legal basis of the decision expressed in an understandable manner.

The staff of the Agency shall avoid making decisions which are based on brief or vague grounds or which do not contain individual reasoning.

If it is not possible, because of the large number of persons concerned by similar decisions, to communicate in detail the grounds of the decision and where standard replies are therefore made, the staff shall guarantee that they subsequently provide the citizen who expressly requests it with an individual reasoning.

15. Indication of the possibilities of appeal

A decision or recommendation of the Agency which may adversely affect the rights or interests of a natural or legal person, e.g. private person or company, shall contain an indication of the appeal possibilities available for challenging the decision or recommendation. It shall in particular indicate the nature of the remedies, the bodies before which they can be exercised, as well as the time limits for exercising them.

16. Notification of the decision or recommendation

The staff of the Agency shall ensure that decisions or recommendations which affect the rights or legitimate interests of individual persons are notified in writing, as soon as the decision has been taken, to the person or persons concerned. They shall abstain from communicating the decision to other sources until the person or persons concerned have been informed.

17. Data protection

The staff of the Agency who deal with personal data concerning a citizen shall respect the principles laid down in Regulation (EC) No 1049/2001 on the protection of individuals with regard to the processing of personal data and the free movement of such data. They shall in particular avoid processing personal data for non-legitimate purposes or the transmission of such data to non-authorised persons.

18. Requests for information

The staff of the Agency shall, when they have responsibility for the matter concerned, provide members of the public with the information that they request. They shall take care that the information communicated is clear and understandable. If an oral request for information is too complicated or too comprehensive to be dealt with, the staff of the Agency shall advise the person concerned to formulate his or her demand in writing.

If, because of its confidentiality, they may not disclose the information requested, they shall, in accordance with chapter 14 above, indicate to the person concerned the reasons why he or she cannot communicate the information.

If a letter or a complaint or correspondence to the Agency is addressed or transmitted to a unit, or sector or section which has no competence to deal with it, its services shall ensure that the file is transferred without delay to the competent service of the Agency. The service which originally received the letter or complaint or correspondence shall notify the author of this transfer and shall indicate the name, email and the telephone number of the staff agent or other servant to whom the file has been passed.

Further to requests for information concerning another EU institution or body, the staff or other concerned persons of the Agency shall direct the requester to that institution or body.

Every correspondence to the Agency shall receive an acknowledgement of receipt within a period of two weeks, except if a substantive reply can be sent within that period. In any case and in accordance

with chapter 13, a reply shall be sent no later than 2 months from the date of receipt. The reply or acknowledgement of receipt shall indicate the name, email and the telephone number of the staff who is dealing with the matter, as well as the service to which he or she belongs.

No acknowledgement of receipt and no reply need be sent in cases where letters or complaints are abusive because of their excessive number or because of their repetitive or pointless character.

19. Requests for public access to documents

For requests for access to documents of the Agency, the staff of the Agency shall give access to these documents in accordance with Regulation (EC) No 1049/2001 and with the European Medicines Agency Policy on access to documents.[1] Requests for access to documents or other information should be put in writing whenever possible.

20. Keeping of adequate records

The Agency's divisions, departments, services, and offices shall keep adequate records of their incoming and outgoing mail, of the documents they receive, and of the measures they take[2].

21. Public access to the Code

The Agency will take the necessary measures in order to ensure that this Code enjoys the widest possible publicity amongst the citizens. It will in particular make it available on its Internet site and will provide a copy of this Code to any citizen who requests it.

22. Right to complain to the European Ombudsman

Any failure of staff of the Agency to comply with the principles set out in this Code may be the subject of a complaint to the European Ombudsman in accordance with Article 195 of the Treaty establishing the European Union and the Statute of the European Ombudsman.

23. Entry into force

This Decision takes effect from 1 September 2013 and replaces the previous decision of 1 January 2005.

Guido Rasi
Executive Director

[1] The European Medicines Agency Policy on access to documents (related to medicinal products for human and veterinary use), Policy/0043 (EMA/110196/2006).
[2] Policy on Mail management, Policy/0063 (EMA/360508/2012), Policy on Records Management, Policy/0026 (EMEA/590678/2007 and EMA Business Classification Scheme, EMA/488357/2010 and EMA/506416/2012.