



The European Agency for the Evaluation of Medicinal Products  
*Executive Director*

London, 1 June, 1999  
EMEA/D/15007/99/EN

**Decision of the European Agency for the Evaluation of Medicinal Products  
of 1 June 1999**

**concerning the terms and conditions for internal investigations in relation to the  
prevention of fraud, corruption and any illegal activity detrimental to the  
Communities' interests**

The European Agency for the Evaluation of Medicinal Products

Having regard to Council Regulation (EEC) No 2309/93<sup>1</sup> of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products ('the Agency'),

Having regard to the decision of 6 May 1999 of the Management Board of the Agency endorsing the commitment of the Agency to cooperate with the European Anti-Fraud Office,

Whereas:

- (1) Regulation (EC) No 1073/1999 of the European Parliament and of the Council<sup>2</sup> of 25 May 1999 and Council Regulation (Euratom) No 1074/1999<sup>3</sup> concerning investigations conducted by the European Anti-Fraud Office provide that the Office is to initiate and conduct administrative investigations within the institutions, bodies and offices and agencies established by or on the basis of the EC Treaty or Euratom Treaty,
- (2) The responsibility of the European Anti-Fraud Office as established by the Commission extends beyond the protection of financial interests to include all activities relating to the need to safeguard Community interests against irregular conduct liable to give rise to administrative or criminal proceedings,
- (3) The scope of the fight against fraud must be broadened and its effectiveness enhanced by exploiting existing expertise in the area of administrative investigations,
- (4) Therefore, on the basis of their administrative autonomy, all the institutions, bodies and offices and agencies should entrust to the Office the task of conducting internal administrative investigations with a view to bringing to light serious situations relating to the discharge of professional duties which may constitute a failure to comply with the obligations of officials and servants of the Communities, as referred to in Articles 11, 12, second and third paragraphs, 13, 14, 16 and 17, first paragraph, of the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Communities ('the Staff Regulations'), detrimental to the interests of those Communities and liable to result in disciplinary or, where appropriate, criminal proceedings, or serious misconduct, as referred to in Article 22 of the Staff Regulations, or a failure to comply with the analogous obligations of the Members, heads or members of staff of the

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<sup>1</sup> OJ L 214, 24.8.1993, p. 1

<sup>2</sup> OJ L 136, 31.5.1999, p. 1

<sup>3</sup> OJ L 136, 31.5.1999, p. 8

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institutions, bodies and offices and agencies of the Communities not subject to the Staff Regulations,

- (5) Such investigations should be conducted in full compliance with the relevant provisions of the Treaties establishing the European Communities, in particular the Protocol on privileges and immunities, of the texts implementing them and the Staff Regulations,
- (6) Such investigations should be carried out under equivalent conditions in all the Community institutions, bodies and offices and agencies; assignment of this task to the Office should not affect the responsibilities of the institutions, bodies, offices or agencies themselves and should in no way reduce the legal protection of the persons concerned,
- (7) Pending the amendment of the Staff Regulations, practical arrangements should be laid down stipulating how the Members of the institutions and bodies, the managers of the offices and agencies and the officials and servants of the institutions, bodies and offices and agencies are to cooperate in the smooth operation of the internal investigations,

HAS DECIDED AS FOLLOWS:

#### ARTICLE 1

##### Duty to cooperate with the Office

The Executive Director, the services and any official or servant of the Agency shall be required to cooperate fully with the Office's agents and to lend any assistance required to the investigation. With that aim in view, they shall supply the Office's agents with all useful information and explanations.

#### ARTICLE 2

##### Duty to supply information

Any official or servant of the Agency who becomes aware of evidence which gives rise to a presumption of the existence of possible cases of fraud, corruption or any other illegal activity detrimental to the interests of the Communities or serious situations relating to the discharge of professional duties which may constitute a failure to comply with the obligations of officials and servants of the Communities liable to result in disciplinary or, in appropriate cases, criminal proceedings or a failure to comply with the analogous obligations of the Members, managers or members of staff not subject to the Staff Regulations, shall inform without delay his Head of Unit or, if he considers it useful, Executive Director or the Office directly.

The Executive Director and Heads of Unit of the Agency shall transmit without delay to the Office any factual element of which they are aware from which existence of irregularities as referred to in the first paragraph may be presumed.

Managers, officials or servants of the Agency must in no way suffer inequitable or discriminatory treatment as a result of having communicated the information referred to in the first and second paragraphs.

#### ARTICLE 3

##### Assistance from the Security Office

At the request of the Director of the Office, the Agency's Security Office shall assist the Office in the practical conduct of investigations.

## ARTICLE 4

### Informing the interested party

Where the possibility of the implication of a manager, official or servant emerges, the interested party must be informed rapidly as long as this would not be harmful to the investigation. In any event, conclusions referring by name to a official or servant of the Agency may not be drawn once the investigation has been completed without the interested party's having been enabled to express his views on all the facts which concern him.

In cases necessitating the maintenance of absolute secrecy for the purposes of the investigation and requiring the use of investigative procedures falling within the remit of a national judicial authority, compliance with the obligation to invite the manager, official or servant of the Agency to give his views may be deferred in agreement with the Chairman of the Management Board or the Executive Director.

## ARTICLE 5

### Information on the closing of the investigation with no further action taken

If, following an internal investigation, no charge can be upheld against a manager, official or servant of the Agency against whom allegations have been made, the internal investigation concerning him shall be closed, with no further action taken, by decision of the Director of the Office, who shall inform the interested party in writing.

## ARTICLE 6

### Waiver of immunity

Any request from a national police or judicial authority regarding the waiver of immunity from jurisdiction of a manager, official or servant of the Agency concerning possible cases of fraud, corruption or any other illegal activity shall be transmitted to the Director of the Office for his opinion.

## ARTICLE 7

### Effective date

This Decision shall take effect on 1 June 1999.

Done at London, 1 June 1999

For the European Agency for the Evaluation of Medicinal Products

Fernand Sauer  
Executive Director