

3 October 2019
EMA/MB/414689/2019
Management Board meeting of 3 October 2019

Charter of tasks and responsibilities of the Executive Director as authorising officer

applicable from 4 October 2019

1. Preamble

- 1.1 The 'Charter of the tasks and responsibilities of the Executive Director as authorising officer' (hereinafter the 'Charter') was drawn up in accordance with the provisions of the Staff Regulations and the Financial Regulation applicable to the budget of the European Medicines Agency (hereinafter, 'Agency's Financial Regulation'). It identifies the tasks entrusted to the Executive Director as authorising officer, his/her rights and duties and the responsibilities (s)he assumes in his/her role as authorising officer.
- 1.2 The Charter provides the Executive Director with a framework within which (s)he is empowered to develop reliable and effective management control systems while upholding the principle of zero tolerance of fraud. The general context is one of transparency designed to determine the responsibility of the Executive Director as authorising officer in achieving the objectives set each year.
- 1.3 The Charter is part of a drive towards transparency and accountability. It is neither an exhaustive nor a restrictive description of the duties of the Executive Director as authorising officer; these are laid down in the Agency's Financial Regulation.
- 1.4 The Charter aims to ensure that the Executive Director as authorising officer is able to provide a reasonable assurance concerning sound financial management and the legality and regularity of operations for which (s)he is responsible (see declaration relating to the annual activity report). The results obtained by the Executive Director as authorising officer are evaluated in the light of the risks inherent in the activities and the resources they are provided with to achieve his/her objectives.
- 1.5 The Charter is part of a coherent set of documents spelling out the relationship between the European Medicines Agency and its financial actors and is annexed to the Internal Rules on the implementation of the budget of the European Medicines Agency.

2. Appointment of the Executive Director as authorising officer

- 2.1 The Executive Director shall be a temporary agent appointed by the Management Board in accordance with Article 64 of Regulation (EC) No 726/2004 and shall be subject to the Staff Regulations.
- 2.2 The Executive Director as authorising officer shall perform operations to implement the budget of the European Medicines Agency in accordance with the provisions of the Agency's Financial Regulation as well as the Staff Regulations.
- 2.3 The Executive Director must follow as soon as possible after his/her appointment the appropriate training course(s) for the tasks and responsibilities (s)he assumes as authorising officer. The training requirement may be waived if the Executive Director can demonstrate, by means of qualifications or appropriate professional experience, that (s)he has sufficient knowledge, experience and skills for the tasks and responsibilities (s)he must assume.

3. Termination of duties of the Executive Director as authorising officer

- 3.1 In the event of a change of Executive Director, the outgoing Executive Director shall draw up for the successor or replacement a declaration setting out the state of ongoing cases. This declaration shall take the format of an interim annual activity report. The incoming Executive Director may include observations on the cases transferred from the previous Executive Director, in the qualifications contained in the declaration relating to the annual activity report.
- 3.2 Unless specifically amended or revoked by the newly appointed Executive Director, the delegation of powers granted by his/her predecessor shall remain valid.
- 3.3 The Agency shall inform the European Parliament and the Council within two weeks of the appointment or termination of duties of its Executive Director.

4. Appointment of delegated authorising officers

- 4.1 The Executive Director has general powers of implementation under Article 64 of the Agency's Founding Regulation (EC) 726/2004 as well as Article 45(1) of the Agency's Financial Regulation. The latter powers are delegated to authorising officers by delegation.
- 4.2 Regularly, but at minimum annually, the Executive Director shall review the designation of the authorising officers by delegation for each budget line and its financial limits.

5. Mission of the Executive Director as Authorising Officer

- 5.1 The mission of the Executive Director as authorising officer covers the entire management process, which comprises:
 - definition, on the basis of the policy decisions and the objectives, of the measures to be applied to achieve the objectives, the outcomes expected from application of these measures and, as far as possible, corresponding measurable indicators;
 - implementation of these measures, including programming, planning and monitoring of actions prior to budget implementation and of proper budget implementation;

- evaluation of these measures and reporting thereon.

5.2 The Executive Director as authorising officer shall put in place and maintain, in accordance with the internal control framework adopted by the Management Board and with allowance for the management environment and the nature of the actions and projects financed,

- the organisational structure,
- the management and internal control systems and procedures adapted to the performance of his/her duties, including ex ante and ex post verifications, in accordance with Article 45(2) of the Agency's Financial Regulation,
- procedures and systems for managing and evaluating risks deriving from the management environment and the nature of the operations; in the case of multi-annual programmes, the Executive Director shall establish a multi-annual control strategy, specifying the nature and extent of controls over the period and the manner in which the results are to be measured year-on-year for the annual assurance process,
- procedures and systems for sound, efficient and effective financial management, with the purpose of achieving a regular, legal and planned implementation of the budget,
- procedures and system for checking whether the objectives set have been achieved (evaluation of the relevance and impact of measures), whether the expected outcomes have been produced (evaluation of the effectiveness of measures), and whether the implementation arrangements were appropriate (evaluation of efficiency).

5.3 The Executive Director as authorising officer shall take the action required for the performance of his/her tasks. To this end (s)he shall make the necessary legal and budgetary commitments.

The Executive Director as authorising officer shall also put in place procedures and systems for the management, evaluation and reporting on:

- evaluation of risks deriving from the management environment and the nature of the operations;
- avoidance of a surge of budget implementation at the end of the year, this being incompatible with sound financial management and efficient and effective internal control;
- the obligations concerning publicity and transparency;
- checks whether the objectives set have been achieved (evaluation of the relevance and impact of measures), whether the expected outcomes have been obtained (evaluation of the effectiveness of measures), and whether the implementation methods were appropriate (evaluation of efficiency).

5.4 The Executive Director is responsible for implementing the management and internal control systems which have been or are to be set up in the Agency in accordance with the Internal Control Framework adopted by the Management Board¹. These systems shall be evaluated regularly by the Strategic Planning and Governance Department (A-SG) and by the Internal Audit Capability (AF-AUD). The Executive Director has the management and internal control procedures described in a document accessible to all staff in the Agency. The procedures shall be updated regularly.

5.5 Operations connected with the implementation of the budget shall include:

¹ EMA/11654/2018

- establishing budget and legal commitments and handling all the preliminaries for these commitments;
- validating and authorising expenditure;
- preparing estimates of amounts receivable;
- establishing entitlements to be recovered and issuing recovery orders;
- sending debit notes to the Agency's debtors;
- making justified decisions with regard to the waiving of recoveries of income;
- taking individual decisions awarding grants or public procurement contracts.

Where periodic payments are made with regard to services rendered or goods delivered, and subject to his/her risk analysis, the authorising officer may order the application of a direct debit system.

The budgetary commitment and the corresponding legal commitment shall be signed by the same person (Executive Director or authorising officer by delegation), with the exception of provisional budgetary commitments and certain other cases referred to in Article 111(2) of Regulation (EU, Euratom) 2018/1046 and in the Internal Rules on the implementation of the budget of the Agency.

The Executive Director shall ensure that systems and controls are in place for payment orders to be issued in accordance with the rules, meaning that an appropriate validation decision has been taken in advance in the form of a 'passed for payment' endorsement, the beneficiary's particulars are correct and that the amount is due.

- 5.6 For the management of assets, the Executive Director shall put in place appropriate management systems for keeping track of them, in agreement with the Accounting Officer, in order to provide the Accounting Officer with all the information required to draw up the Agency's balance sheet. This information shall be certified by the Executive Director in his/her capacity as authorising officer.
- 5.7 With a view to using the appropriations, the Executive Director shall distribute the resources between the divisions and departments of the Agency in the most effective manner, if possible by reference to the objectives set with due account for the findings of the analysis of resources judged necessary to implement the measures in question, which was conducted when the Agency set these objectives. Each year (s)he shall conduct a critical analysis of the use made of these resources, using in particular workload indicators and efficiency criteria as far as possible.
- 5.8 The Executive Director as authorising officer shall provide replies to the observations of the Court of Auditors and the European Commission's Internal Audit Service and to the questions and reports of the European Parliament, in particular to questions on action taken in response to the discharge.
- 5.9 The Executive Director shall draft a consolidated annual activity report, which shall include the relevant accounts and the declaration of assurance. This report shall be established in line with Article 48 of the Agency's Financial Regulation and the minimum standard requirements defined in the Commission's Standing Instructions for the preparation of the annual activity reports. It shall include information on the implementation of the Agency's work programme, budget and staff resources referred to in Article 38 of the Agency's Financial Regulation and as such:
 - the results of programmes, operations or actions by reference to the objectives set;

- the risks associated with these programmes, operations or actions;
- the use made of the resources provided;
- the efficiency and effectiveness of the internal control system – and any shortcomings which may have material impact on the budget.

It shall also contain:

- remarks on action taken to follow up on the observations made in connection with earlier budget discharges and/or reports by the Court of Auditors or internal auditors;
- remarks on action taken on any reservations contained in earlier declarations, where such qualifications pointed to measures taken or to be taken to remedy malfunctioning;
- an accounting annex based on the model set by the Commission's Accounting Officer and provided as part of the above mentioned minimum standard requirements.

5.10 When sending the consolidated annual activity report to the Management Board, the Executive Director shall sign a declaration, relating to this annual report, drawn up on the basis of the assessment of the functioning of the management and internal control systems conducted within the Agency. The purpose of this declaration shall be to confirm, on the basis of the facts in his/her possession, that

- the information contained in the report gives a true and fair view, except as otherwise specified in any reservations related to defined areas of revenue and expenditure,
- the resources assigned have been used for their intended purpose and in accordance with the principle of sound financial management,
- the control procedures put in place give the necessary guarantees concerning the legality and regularity of underlying transactions (see model declaration annexed to this Charter).

The declaration may contain reservations designed to highlight issues or weaknesses in the management and control systems associated with the operations and actions managed by the Agency. The reservations may contain observations concerning the management of cases taken over from his/her predecessor(s). The reservations should not make the declaration meaningless, but may point to malfunctioning in the design or application of management and internal control systems; in this case there should also be an indication of the impact on the declaration as a whole and the remedial measures taken or planned by the Executive Director.

6. Liability of the Executive Director as Authorising Officer

6.1 Liability arising from the Staff Regulations

The liability of the Executive Director as authorising officer shall be governed by the provisions of the Staff Regulations (in particular Articles 11, 11a, 12, 12a, 21, 21a, 22, 22a and 86 and Annex IX). In accordance with the second paragraph of Article 21 of the Staff Regulations, the responsibility of his/her subordinates shall in no way release him/her from his/her own responsibility. It shall be measured against the risks inherent in his/her work and the resources allocated to achieve his/her objectives.

In accordance with Article 22 of the Staff Regulations, the Executive Director may be required to make good, in whole or in part, any damage suffered by the European Union and the Agency as a result of serious misconduct on his/her part. The obligation to pay compensation shall apply in particular in the cases referred to in Article 56 of the Agency's Financial Regulation.

The Executive Director may be held liable in the event of serious negligence, in particular where the wrongdoing was made possible by inadequacies in the internal control systems devised and put in place under his/her responsibility.

In cases that do not involve intentional wrongdoing such as fraud, corruption, misappropriation of funds or theft, the Management Board, as appointing authority, shall base its decision to initiate the procedure for finding the Executive Director as authorising officer liable for disciplinary action and payment of compensation on the opinion of the panel referred to in Article 57 of the Agency's Financial Regulation.

- 6.2 Delegation of powers to authorising officers by delegation does not affect the liability of the Executive Director as authorising officer, who must exercise supervision to ensure the effectiveness and efficiency of the activities delegated and who remain answerable for the powers (s)he has delegated.

7. Fraud, corruption, conflict of interest

7.1 Principles

The provisions of this Charter are without prejudice, in cases of fraud or corruption, to the liability under criminal law of the Executive Director as authorising officer as laid down in the national law applicable and in the provisions in force concerning the protection of the financial interests of the Agency and the fight against corruption involving staff of the Agency.

7.2 Conflicts of interest

Any measures of budget implementation which may give rise to a conflict of interest between the Executive Director, or staff for whom (s)he is responsible, and a third party supplying revenue for the budget or receiving expenditure shall be prohibited. If a case of this kind arises, the Executive Director shall refrain from acting and shall refer the matter to the Management Board.

In accordance with Article 11a of the Staff Regulations, the Executive Director as authorising officer shall not, in the performance of duties, deal with a matter in which, directly or indirectly, (s)he has any personal interest such as to impair his/her independence, and, in particular, family and financial interests.

8. Disqualification

In the event of failure to comply with the rules contained in this Charter, the Executive Director may at any time be temporarily or definitively suspended from his/her duties as authorising officer by the Management Board, without prejudice to any disciplinary action.

9. Repeal and entry into force

This charter replaces and repeals all previous charter of tasks and responsibilities of the Executive Director as authorising officer.

This charter shall enter into force on 4 October 2019.

Amsterdam, 3 October 2019

[Signature on file]

Christa Wirthumer-Hoche
Chair of the Management Board