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2020 - European Medicines Agency Annual Report on Independence

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1. Background

The European Commission requested in January 2015 that *"the independence policy and its state of implementation"* should be on the agenda of the Management Board annually. The first annual review of independence was presented to the Management Board in October 2016, the second annual review of independence 2016-2017 was presented in March 2018, the third review 2018-2019 in March 2020.

This report is the fourth annual review which covers 2020. It reflects the status of each of the independence policies (for scientific committees' members and experts, for Management Board members, and for EMA staff) including their implementation as of the end of 2020. This report provides facts and figures (including information on the launch and outcome of Breach of Trust procedures), gives information on initiatives taken in 2020 and identifies recommendations for further improvement.

2. Scientific committees' members and experts

2.1. Status of EMA Policy 0044

Policy 0044 for scientific committees' members and experts was last revised in 2020. It was endorsed by the Management Board on 11 June 2020. The new provisions concern for CAT members and alternates the introduction of interests to be declared in the biotechnology and medical device sectors as foreseen in art. 22 of Regulation 1394/2007 and for all experts the introduction of interests to be declared of their personal or organisation's involvement in the repurposing of a medicinal product. Restrictions were introduced for inspectors declaring close family interests and grants/funding to align with current practice in the majority of EU member states and at the FDA. Other new provisions are the inclusion in the definition of financial interests of stock warrants, introduction of a definition of partner and inclusion of reference to the new EU GDPR legislation. These are the same provisions as introduced in the policy for Management Board members and in the decision on rules for Agency staff. The revised Policy 0044 became effective as of 1 January 2021.

Under this policy, EMA requires an annual update of the e-DOI as well as an updated e-DOI for any change in the status of a member or an expert. EMA also has an advisory committee in place, the Declaration of Interests Advisory Group (DIAG), which is an internal committee to provide advice on the evaluation of e-DoIs of scientific committees' members and experts.

2.2. Facts and figures

2.2.1. Declared interests

The distribution of the declared interests for the scientific committees (members and alternates) and experts was as follows on 31 December 2020:

Distribution per 31 December 2020

Interest level	CHMP	CVMP	CAT	COMP	HMPC	PDCO	PRAC	All experts*
1 – no interests	49	51	54	30	48	46	58	3293
2 – indirect interests	7	4	3	4	3	8	8	377
3 – direct interests	4	0	6	1	0	0	3	488
Total	**60**	**55**	**63**	**35**	**51**	**54**	**69**	**4158**

(* with an up-to-date e-DoI)

In 2020, 6 delegates (3 scientific committee members, 1 CMD member, 1 working group member, 1 expert) informed the Agency of their intention to become an employee in a pharmaceutical company. In line with the guidance document, the members were immediately fully restricted from further involvement in any Agency activity. The imminent employment in a company did not constitute a conflict for any of the ongoing procedures.

2.2.2. Outcome of Breach of Trust procedures

The EMA breach of trust (BoT) procedure for competing interests of scientific committee members and experts was introduced first in 2012. The BoT procedure was last revised in 2018 to extend its scope to cases of disclosure of confidential information by a scientific committee member or expert and was endorsed by the Management Board on 4 October 2018.

EMA launched no BoT procedures in 2020.

2.2.3. Outcome of *ex ante* and *ex post* controls

2.2.3.1. Ex ante controls 2020

An *ex ante* control has been carried out systematically on all new experts since June 2013. The *ex ante* control checks that

- the information has been entered in the correct section(s) of the e-DoI, and
- the time periods in the declaration of interests match with those given in the Curriculum Vitae.

	2020
New expert e-DOI checked before upload to EMA data bases	617
Error rate	22/3.6%
Nature of error	
Previous employment from CV not declared on DoI	16
Current grant from CV not declared in DoI	-
No details of close family members	-
Date difference between CV and e-DOI	-
Interest declared in wrong section of e-DOI	-
Information on an interest missing	2
Inconsistencies in the e-CV	-
Interest declared unnecessarily	4
Action taken after update of e-DOI	
Higher interest level	13
Unchanged interest level	3
Lower interest level	6

In 2020, 617 e-DoIs of new experts were checked and an error was noted in 22 e-DoIs (3.6%).

The nature of the errors in 2020 (16 out of 22) was that the experts failed to declare in their e-DoI their recent employment (in the past 3-year period) within a pharmaceutical company. The EMA asked the experts to correct their e-DoI, resulting in a higher interest level being assigned to their e-DoI. This EMA preventive check of each expert is important and is maintained.

2.2.3.2. Ex post controls 2020

Ex post controls are performed on different aspects of the process since 2012. The checks to be undertaken are decided based on a risk analysis and performed according to a pre-defined protocol.

The *ex post* controls were conducted to check

- the correct completion of the e-DoI by experts,
- the correct evaluation of the DoI by the Agency,
- the correct implementation of restrictions applicable to the experts by the Agency.

The 2020 control focused on Scientific Advisory Group (SAG)/Ad Hoc Expert Group (AHEG) and Working Party members and experts who declared direct or indirect interests (interest level 2 or 3 DoI). Forty experts (out of estimated 2,200), who were invited to meetings at the Agency during the period 1 January to 30 June 2020, were randomly selected. The selection was stratified so that 50% of the sampled experts participated in a SAG or AHEG meeting and 50% of the sampled experts participated in a working party meeting.

Overall, the control showed that the system for handling declarations of interests for meeting participation works well. No major problems with the e-DoI completion by the experts or the e-DoI evaluation by EMA staff were identified.

The findings were as follows:

- Four experts had not been uploaded in the Experts database prior to the meeting or at the time of the control;
- One expert had no valid, up to date DoI at the time of the meeting (only a week later);
- For one expert, the updated DoI, received prior to the meeting, was not verified for the meeting;
- For two experts, restrictions were identified unnecessarily for past interests;
- For one expert, the DoI evaluation form was absent;
- For six working parties, there was insufficient recording of restrictions or their absence in meeting minutes.

None of the findings had an impact on the participation of the experts in the concerned meeting.

The following improvements were recommended:

- Timely upload of the experts in the Experts database;
- Preparation of pre-meeting and post-meeting list of participants with restrictions applied for the meeting;
- Reminder on the requirement to regularly check for updates of DoIs and to complete DoI evaluation forms;

- Include the learnings from the ex post control into the design of the future operating model for meeting secretariats considering activities that are better centralised for increased control and activities that can be handled in a decentralised manner;
- Present a list of business functionalities for the business/IT solution required for handling experts including the evaluation and management of DoIs.

2.2.4. Transparency measures

The e-DoIs, their assigned interest levels and the CVs of all scientific committees' members and experts have been published on the EMA website, since 30 September 2011 (for e-DoIs), 29 February 2012 (for assigned interest levels) and 9 September 2013 (for CVs). EMA has published the minutes of the scientific meetings (PDCO, COMP and PRAC since July 2012, HMPC since November 2013 and CHMP, CVMP and CAT since December 2013). The minutes include information on the restrictions applicable to meeting participation following the assessment of the e-DoIs by Agency staff.

2.3. Initiatives launched in 2020

The following initiatives were implemented in 2020:

- **Revision of the policy**

  The policy was revised to introduce for CAT members and alternates the requirement to declare interests in the biotechnology and medical device sectors as foreseen in art. 22 of Regulation 1394/2007 and for all experts to declare interests of their personal or organisation's involvement in the repurposing of a medicinal product. Restrictions were added for inspectors declaring close family interests and grants/funding to align with current practice in the majority of EU member states and at FDA. In addition, some new provisions were incorporated, i.e. the inclusion in the definition of financial interests of stock warrants, introduction of a definition of partner and inclusion of reference to the new EU GDPR legislation.

  Consequently, the e-DoI form to be completed by experts and the DoI evaluation form to be completed by the meeting secretariat when involving experts in Agency activities was revised. The updated DoI template was introduced in December 2020 with a requirement for all experts to submit an updated DoI by 1 January 2021.

  Furthermore, the e-DoI form was updated in June 2020 to include tick boxes for experts when signing the e-DoI to confirm that they have read and understood Policy 0044 and to undertake submitting an e-DoI at least on an annual basis and when changes occur.

- **Review the practical implementation of pharmaceutical company restrictions on procedures dealing with a high number of medicinal products**

  Signals and PSUSA procedures handled by PRAC are individually complex and can involve a large number of affected CAP and/or NAP medicinal products. This number may vary prior to or during the procedure. The Annual Report on Independence 2018-2019 recommended a review of the practical implementation of competing interest restrictions for these procedures dealing with a high number of medicinal products.

  The review has shown that the approach in operation for several years at PRAC is precautionary to avoid competing interests and/or a perception of bias which is protective of PRAC's reputation and the integrity of its decisions.

The approach being followed is to assign rapporteurships for signal and PSUSA procedures including NAPs to a delegation to either the member or to the alternate who does not have any declared interests. Flexible assignment between the member and the alternate within a delegation overcomes occasional individual competing interests for either the member or the alternate and preserves continuity of scientific expertise provided by the delegation. It has not occurred to date, however, in the rare case that both the member and the alternate of a delegation would have declared interests then the rapporteurship will be assigned to an alternative delegation.

EMA will continue to follow the approach currently in place.

- **Impact of General Court Judgement**

  By its judgment of 28 September 2020, the General Court annulled the Commission Decision refusing the granting of a Marketing Authorisation (MA) for Aplidin on the basis that two SAG experts had alleged Conflicts of interest as they are employed by an institute that controls and exercises a significant influence on a university hospital which hosts a cell therapy centre manufacturing a product competing with Aplidin, as well as on a clinical research centre which performs development activities for pharmaceutical companies. EMA was not a party in the lawsuit and is of the view that the General Court interpreted incorrectly EMA's policy on the handling of competing interests of scientific committee's members and experts.

  The judgment is immediately binding on the European Commission and the re-examination procedure for the MA Application for Aplidin needed to be restarted.

  EMA has taken immediate minimum measures for the immediate implementation of the judgment not only for the Aplidin case, but also for ongoing and planned regulatory procedures as from November 2020. For SAGs and AHEGs, experts that are employed by universities or university hospitals performing development or manufacturing activities in respect of any medicinal products actually or potentially competing with the (candidate) product under review, are not allowed to be involved in the procedure.

  The adverse impact of the judgment on EMA's operations, but also on the NCAs', is considered very significant in terms of finding the best specialist expertise, a trend that has already been observed and which may lead to decreasing the robustness of the scientific assessment and possible important delays in the assessment of MAAs. The Management Board at its meeting in December 2020 endorsed continuation of the minimum implementation measures pending the outcome of an appeal that has been launched by member states in January 2021.

3. Management Board members

3.1. Status of EMA Policy 0058

The current policy has been in effect since 1 July 2020. The last revisions were introduced in June 2020. The new provisions are the inclusion in the definition of financial interests of stock warrants, introduction of a definition of partner and inclusion of reference to the new EU GDPR legislation. These are the same provisions as introduced in the policy for scientific committees' members and experts and in the decision on rules for Agency staff. Under this policy, EMA requires an updating annually of the e-DOI as well as an updated e-DOI for any change in the status of the member.

3.2. Facts and figures

3.2.1. Declared interests

The distribution of the levels of declared interests of the Management Board members and their alternates, as well as the Management Board observers and their alternates was as follows on 31 December 2020:

Interest level	Members	Observers*
1 – no interests	59	6
2 – indirect interests	3	0
3 – direct interests	2	0
Total	**64**	**6**

(* Iceland, Liechtenstein and Norway)

Management Board representatives failing to submit a valid DOI are notified, by the Secretariat, of their exclusion from Board-related activities, including attendance at meetings and receipt of correspondence, until such a time as their completed DOI and CV are provided for assessment.

3.2.2. Outcome of Breach of Trust procedures

In December 2015, the Management Board endorsed a revised BoT procedure for Management Board members that is aligned to the BoT procedure for scientific committee members and experts. This procedure sets out how the Agency deals with incorrect or incomplete declarations of interests by Management Board members. In light of the changes to the BoT procedure for scientific committees' members and experts, described above, the BoT for Management Board members was revised in 2019 and subsequently published on the EMA website.

No BoT procedure was initiated in 2020 for Management Board members.

3.2.3. Outcome of *ex ante* and *ex post* controls

Since 2016 an *ex ante* control has been carried out systematically on all DoIs submitted by Management Board members. The *ex-ante* control checks that

- the information has been entered in the correct section(s) of the DoI,
- the time periods in the DoI match with those given in the CV, and
- the DoI is published on the EMA website.

No inconsistencies were detected in the submissions received in 2020.

No *ex post* controls were performed in 2020 due to the business contingency status of the Agency.

3.2.4. Transparency measures

Since 2012, the DoIs of all Management Board members and alternates, along with their individual CV, have been published on the Agency's website. In addition, the agendas and minutes of the Management Board meetings have been published since 2009. The outcome of the DoI *ex ante* control is stated prior to the start of each MB meeting with mitigating actions applied at agenda point level.

Since 2016, the minutes include information on the restrictions applicable to meeting participation following the assessment of the DoIs.

3.3. Initiatives launched in 2020

The policy was revised in line with the new provisions introduced for the policy for scientific committees' members and experts and the decision on rules for staff, i.e. the inclusion in the definition of financial interests of stock warrants, introduction of a definition of partner and inclusion of reference to the new EU GDPR legislation.

4. EMA staff

4.1. Brief outline of the Management Board Decision on rules relating to Articles 11, 11a and 13 of the Staff Regulations

The Agency has rules in place to reinforce a systematic approach to assess the declared interests of EMA's staff, and to provide the required assurance of the independence of its staff members to stakeholders and the public. The legal basis for the handling of DoIs of staff is the Decision on rules relating to Articles 11, 11a and 13 of the Staff Regulations and Article 63(2) of Regulation 726/2004.

The Decision on rules for staff has been aligned, where relevant, to the revised policies in place for the Management Board members (Policy 0058) and the scientific committees' members and experts (Policy 0044). The rules apply in general to all temporary and contract agents, national experts on secondment, trainees, interims and visiting experts, as well as to candidates before recruitment. Information guidance is provided on how the evaluation of the declared interests should be done, the criteria for the identification of risks and which risk mitigation measures to apply for either scientific/regulatory or administrative/technical duties.

Under this Decision on rules, EMA requires an updating annually of the DoI as well as an updated DoI for any change in the status of the staff member.

4.2. Facts and figures

4.2.1. Declared interests

Each staff member or a candidate is assigned by the reporting officer to one of the interest levels, detailed below, based on his/her declared interests.

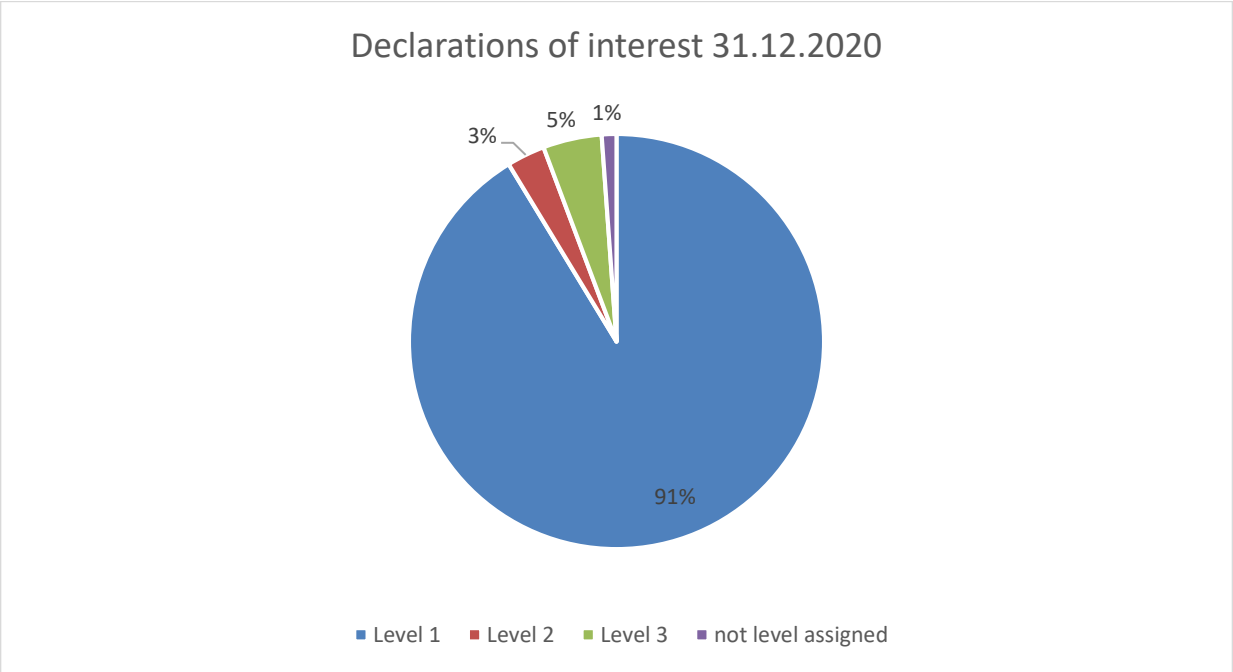
- Level 3: If the staff member or candidate has declared direct interests.
- Level 2: If the staff member or candidate has declared indirect interests.
- Level 1: If the staff member or candidate has not declared any direct or indirect interests.

Staff members and/or candidates with interest level 2 or 3 are subject to a documented risk-based assessment, which includes mitigating actions to reduce the risk, prior to their involvement in EMA activities.

The graph below shows the distribution of staff's interest levels for all EMA staff on 31 December 2020.

- Staff assigned interest level 1: 91% with no declared direct or indirect interests.
- Staff assigned interest level 2: 3% who declared indirect interests.
- Staff assigned interest level 3: 5% who declared direct interest.

- Staff with no interest level assigned yet to their latest DoI: 1%



4.2.2. Outcome of Joint Committee procedures

On leaving the Agency, all EMA staff members are required to seek permission to engage in an occupation within a period of two years of leaving the Agency, in accordance with Article 16 of the Staff Regulations. Applications are reviewed to establish any potential competing interests, and if so required, based on an opinion of the Agency's Joint Committee, the Executive Director (or the Management Board in the case of the Executive Director) will issue a decision, which may impose restrictions on the staff member's intended occupation to mitigate any potential competing interests. Examples of restrictions include: a distance clause, whereby the former staff member may not contact individual Agency staff as regards any professional activity he/she may have dealt with in the performance of his/her responsibilities while at the Agency, e.g. 6-12 months; explicit prohibition of handling medicinal-product dossiers on which they have worked during their employment at EMA.

All decisions include a reminder of the binding obligation of confidentiality after leaving, and a requirement that opinions given in public presentations must be stated to be the former staff member's own and not linked to their former employment at the Agency.

As of 18 December 2020, EMA's decisions regarding senior staff members leaving EMA are publicly available in the register on the EMA corporate website, link, for a two-year period following their end of employment at the Agency. For the purposes of this register, EMA defines senior staff as staff members who held any of the following positions during their final three years of service:

- Executive Director
- Deputy Executive Director
- Adviser
- Head of Division
- Head of Task Force

- Head of Legal Department

The Agency adopted on 4 October 2018 the Commission decision on outside activities and assignments and on occupational activities after leaving the service. Under these rules, taking up employment at a European Union institution does not trigger the obligation for a staff member to inform the Agency, when leaving, as working for another EU institution does not create the status of leaving the service of the Union for the purpose of applying Article 16 of the Staff Regulations. Therefore, any staff member leaving EMA to take up employment with another EU institution is not required to seek prior authorisation.

For the period from 1 January 2020 to 31 December 2020, staff made a total of 36 applications, resulting in 28 authorisations without restrictions, and 8 staff authorisations with restrictions, SNE cases had no restrictions.

4.2.3. Outcome of *ex ante* and *ex post* controls

4.2.3.1. Ex post control 2020

It is important to note that an *ex ante* check is undertaken of the declaration of interest of each candidate in the process of being recruited by the Agency. The manager of the prospective staff member must assign an interest level and apply mitigating actions if needed before the person can start the contract.

An ex post control was performed on DoI with interest level 2 and 3 with checks undertaken on four criteria:

- If the correct DoI level was assigned by the reporting officer
- If the correct DoI restriction template was filled in, where applicable, by the reporting officer
- If the correct restriction was assigned, by the reporting officer
- If the DoI process was completed on time by both staff member and the reporting officer (30 days, from start to finish)

It was decided to focus on 50% of the DoIs with level 2 and 3, i.e. 34 out of 67 DoIs.

- 48% equal to 13 DoI of level 2
- 52% equal to 21 DoI of level 3

The findings of the ex post control were as follows:

Of the 34, 53% contained between 1-3 errors each, of the criteria chosen for this exercise. It is a significant error rate and indicates that reporting officers lack full understanding of the process and require further training on the subject of correctly assigning staff members an interest level and implementing the right risk mitigation measures for either their scientific/regulatory or administrative/technical duties. None of the findings had an impact on the participation of the staff members in their EMA activities.

A break-down of the findings is below:

- DoIs were assigned with the wrong interest level
- DoIs with the wrong restriction template used by the manager
- DoIs with the wrong restriction applied
- DoI process was not completed within the deadline (30 days, from start to finish)

- Incomplete DoIs

An improvement action plan to follow up on the outcome of this ex post control which will be implemented in 2021 is set out below:

- Reporting officers to be contacted to correct the mistakes identified
- Reporting officers to be reminded of their obligation to assign an interest level to their staff's DoI within the deadline, or before assigning duties; adhering to the timeframe to complete the DoI assignment process, i.e. 30 days from being launched, or prior to assignment of duties, whichever applies first
- Reporting officers to be reminded to always refresh their knowledge by reading the rules before assigning an interest level
- Further training to reporting officers to be considered, in the areas of:
  - Applying the right interest level to staff members
  - Using the correct template where applicable
  - Putting in place the correct restrictions in accordance to the rules
- Performing an ex-post control on a yearly basis, on completed DoIs with level 2 and 3, to ensure compliance with the rules
- Updating SOP 0101 to reflect the new organisational structure
- Additional control mechanism upon completion to be considered and implemented, by second line manager or HR.

4.2.4. Transparency measures

The completed DoIs and CVs for management staff are available on the external website under Agency structure (since 29 February 2012). The DoIs of all other staff are available upon request. All staff DoIs are updated annually.

4.3. Initiatives launched in 2020

The decision on the rules for staff was updated in October 2020 and aligned with the policy for scientific committees' members and experts and for Management Board members. The new provisions are the inclusion in the definition of financial interests of stock warrants, introduction of a definition of partner. The reference to the new EU GDPR legislation had been included previously.

5. Recommendations for further improvement

Taking into account experience gained in 2020 with the operation of the various policies on independence, the following recommendations for further improvement are made:

5.1. Recommendations resulting from the need for further clarification/alignment of some aspects of the existing EMA policies on independence taking into account experience gained

5.1.1. Recommendations for EMA Policy 0044

- Training for EMA staff on operation of the revised policy should be undertaken.

5.1.2. Recommendations for EMA Policy 0058

See Section 5.1.1., where applicable.

5.1.3. Recommendations for the Management Board Decision on rules for EMA staff

See Section 5.1.1., where applicable.

5.2. Recommendations resulting from the 2020 ex post controls

The following recommendations from the 2020 ex post controls will be actioned:

- Include the learnings from the ex post control in the design of the future operating model for meeting secretariats considering activities that are better centralised for increased control and activities that can be handled in a decentralised manner.
- Present a list of business functionalities for a new business/IT solution for handling experts including the submission, evaluation and management of DoIs**.**

5.3. Other recommendations

- The EMA will continue to maintain the minimum implementation measures following the General Court Judgement on the Aplidin case and follow the proceedings of the independent appeals by two Member States.

EMA staff improvement action plan arising from the 2020 ex post control:

- Managers will be reminded of their obligation to assign an interest level to their staff's DoI within the deadline, i.e. 30 days from being launched, or prior to assignment of duties, whichever applies first
- Managers will be reminded to always refresh their knowledge by reading the rules before assigning an interest level
- Perform an ex-post control annually, on completed DoIs with level 2 and 3, to ensure compliance with the rules
- Updating SOP 0101 to reflect the new organisational structure
- Additional control mechanism upon completion to be considered and implemented, by second line manager or HR.

6. Planned initiatives for 2021

The implementation of the aforementioned recommendations will be undertaken but may have to be revised in case a reprioritisation of the Agency's activities is needed due to unavailability of the necessary resources. The initiatives requiring changes to IT systems will only be undertaken if the necessary resources are available. In addition, the following will be done:

- Monitor the implementation of EMA Policy 0058.
- Monitor the implementation of EMA Policy 0044.

- Monitor the implementation of the Management Board Decision on rules relating to Articles 11, 11a and 13 of the Staff Regulations concerning the handling of declared interests of EMA staff.
- Training for EMA staff on the operation of the policy will be undertaken.
- Conduct *ex ante* and *ex post* controls in accordance with the agreed schedule, including identification of recommendations for further improvement:
  - *Ex ante* and *ex post* controls will continue in the context of EMA Policy 0044 including an *ex post* control of SAG members.
  - *Ex ante* controls will continue in the context of EMA Policy 0058. *Ex post* controls will be introduced.
  - An *ex post* control will be undertaken in the context of the Management Board Decision on rules for Agency staff with interest level 2 and 3.

7. Conclusions

The Agency, through its various policies and rules, has implemented clear rules with robust measures and controls in its processes and systems that mitigate the risks arising from competing interests.

Transparency is a further important pillar to ensure independence. EMA publishes the DoIs and CVs of all scientific committees' members and experts, Management Board members and Agency management, as well as agendas and minutes of the scientific committees and Management Board meetings. These minutes include information on the restrictions applicable to meeting participation following the evaluation of declared interests.

In line with the Agency's commitment to continuously review its operations in order to identify further room for improvement, and in view of the importance that the Agency places on independence, recommendations are made in this report to take these recommendations forward, resources allowing.