EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 June 2020
EMA/425399/2019

2018 - 2019 European Medicines Agency Annual Reports on Independence

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

Table of Contents

1. Background

The European Commission requested in January 2015 that *"the independence policy and its state of implementation"* should be put on the agenda of the Management Board annually. First discussions as per the European Commission's request were held at the Management Board in 2015 and 2016, with the first annual review of independence being presented at the October 2016 Management Board meeting. The second annual review of independence covering 2016-2017 was presented to the Management Board at its March 2018 meeting.

This report is the third annual review and covers the years 2018 and 2019. It reflects the status of the various independence policies (for scientific committees' members and experts, for Management Board members, and for EMA staff) including their implementation as of the end of 2019. This report provides facts and figures (including information on the launch and outcome of Breach of Trust procedures), gives information on initiatives taken in 2018 and 2019, 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 2016. It was endorsed by the Management Board on 6 October 2016. It became effective as of 1 December 2016. 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 2018:

Distribution per 31 December 2018

Interest level	CHMP	CVMP	CAT	COMP	HMPC	PDCO	PRAC	All experts*
1 – no interests	51	54	51	31	52	53	58	3078
2 – indirect interests	10	5	6	3	4	10	6	387
3 – direct interests	3	1	7	2	2	3	6	545
Total	**64**	**60**	**64**	**36**	**58**	**66**	**70**	**4010**

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

In 2018, 5 delegates (2 scientific committee members, 3 working party members) informed the Agency on 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.

Distribution per 31 December 2019

Interest level	CHMP	CVMP	CAT	COMP	HMPC	PDCO	PRAC	All experts*
1 – no interests	50	54	54	31	52	50	57	3126
2 – indirect interests	9	5	2	3	5	10	8	387
3 – direct interests	5	1	8	2	1	4	6	539
Total	**64**	**60**	**64**	**36**	**58**	**64**	**71**	**4052**

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

In 2019, 4 delegates (1 scientific committee member, 1 working group member and 2 experts) informed the Agency of their intention to become an employee in a pharmaceutical company. All 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 procedure was subsequently amended in line with the experience gained since 2012. The revised BoT procedure was endorsed by the Management Board in March 2015 and came into effect on 24 April 2015.

EMA launched 3 BoT procedures in 2018 and a further 4 BoT procedures in 2019.

2018 BoT case details

Declaration of interest cases:

One committee member provided training to a pharmaceutical company and one committee member provided a lecture for a pharmaceutical company; these activities are considered as consultancy. After assessment of additional information provided by the committee members, they were invited to a hearing at the Agency in order to gather their views on the facts and to provide replies to remaining questions. The outcome of these BoT procedures was that the engagement in activity or the acceptance of the financial interest was negligence on the part of each member to comply with the EMA policy, but it was unintentional, and it was not through gross negligence. The procedure of each case was closed with a request to each committee member to study the policy and to attend training on the policy.

Confidentiality case:

A working party member disclosed confidential information from an ongoing procedure in a presentation at a public scientific conference. As the disclosure occurred through gross negligence, in line with the BoT procedure after requesting clarifications and inviting the member to a hearing, EMA took appropriate measures against this working party member, i.e. a 12-months exclusion from involvement in any EMA activity.

2019 BoT case details

Declaration of interest cases:

One committee member accepted a lecture fee from a pharmaceutical company for a presentation at a scientific conference which is considered as a financial interest. One committee member organised a

workshop for healthcare professionals on request of a pharmaceutical company which is considered as consultancy. After assessment of additional information provided by the committee members, they were invited to a hearing at the Agency in order to gather their views on the facts and to provide replies to remaining questions. The outcome of these BoT procedures was that the engagement in the activity or the acceptance of the financial interest was negligence on the part of the members to comply with the EMA policy, but it was unintentional, and it was not through gross negligence. The procedure of each case was closed with a request to the committee members to study the policy and to attend training on the policy. The two committee members for personal reasons voluntarily resigned from the committee during the procedure, one because of the high workload as committee member and the other because of a preference to continue with the activity.

Confidentiality cases:

A committee member and an expert each disclosed the outcome of a non-finalised regulatory procedure in a press release while the committee meeting was still ongoing. The disclosure by each person was unintentional and did not occur through gross negligence, therefore, no further disciplinary sanctions were required. The procedure of each case was closed with a request to study the rules on confidentiality and to refrain from disclosing confidential information in future.

Breach of trust cases	2018	2019
EMA alerted of an interest that potentially should have been declared in the e-DOI	2 committee members	2 committee members
EMA alerted of disclosure of confidential information	1 working party member	1 committee member and 1 expert
BoT not initiated as the assessment, following clarification provided, concluded that there was no requirement to declare or that the omission or the disclosure was not intentional	-	-
BoT initiated	3 – Yes	4 -Yes
Action taken	1 working party member – gross negligence, 12 months exclusion from any EMA activity 2 committee members - closed, unintentional and not through gross negligence	4 - closed, unintentional and not through gross negligence

Revision of BoT procedure

In light of the cases in 2018, there was a need to fine tune the BoT procedures in two areas:

- To document the decision not to formally initiate a BoT procedure following the review of additional information.
- To include situations where an expert deliberately engages in an activity which results in a competing interest following EMA advice not to engage in that activity.

In light of experience gained it was also decided to extend the scope of the BoT procedure to cases of disclosure of confidential information by a scientific committee member or expert.

The BoT procedure was revised accordingly and the revised BoT procedure was endorsed by the Management Board on 4 October 2018, and subsequently published on the EMA corporate website.

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

2.2.3.1. Ex ante controls 2018 - 2019

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.

	2018	2019
New expert e-DOI checked before upload to EMA data bases	756	595
Error rate	14/1.8%	23/7.7%
Nature of error		
Previous employment from CV not declared on DoI	3	13
Current grant from CV not declared in DoI	-	-
No details of close family members	-	-
Date difference between CV and e-DOI	1	3
Interest declared in wrong section of e-DOI	-	-
Information on an interest missing	-	-
Inconsistencies in the e-CV	5	2
Interest declared unnecessarily	5	5
Action taken after update of e-DOI		
Higher interest level	2	10
Unchanged interest level	7	9
Lower interest level	5	4

In 2018, 756 e-DoIs of new experts were checked and an error was noted in 14 e-DoIs (1.8%). In 2019, 595 e-DoIs were checked with 23 errors noted (7.7%).

The error rate in the e-DoIs of new experts was found to have increased significantly at 7.7% in 2019. The nature of the errors in 2019 (13 out of 23) 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 risk level being assigned to their e-DoI. This EMA preventative check of each expert is important and is maintained.

2.2.3.2. Ex post controls 2018 - 2019

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 2018 control was conducted to check

- the correct completion of the e-DoI by scientific committee members and experts,
- the correct evaluation of the DoI by the Agency,
- the correct implementation of restrictions applicable to the experts by EMA, and
- the implementation of improvements recommended in 2017 were also verified: error correction, ensure that restrictions are recorded for topics added to the agenda after the meeting has started, reinforce for SAG meetings that the experts have submitted a signed e-DOI and are included in the experts database before or shortly following the meeting.

Seventy-five experts (out of 5,672), who were invited to meetings at the Agency during the period 1 January to 30 June 2018, were randomly selected. The selection was stratified so that 30% of the sampled experts participated in a SAG or Ad Hoc Expert Group meeting (regardless of the interest level of the e-DoI) and 70% of the sampled experts participated in any other type of meeting with the following sub-stratification: 30% of the experts had a risk level 1, 20% a risk level 2 and 50% a risk level 3.

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.

Two experts did not sign off their initial DoI before the meeting and their CV was still awaited at the time of the control. For both experts, the information had not been uploaded in the Experts database at the time of the control.

The evaluation of the DoI was incorrect in two cases because no restrictions were identified for a previous consultancy interest and a previous employment interest, respectively.

One expert did not declare in his latest DoI an interest from his previous DoI.

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

The following improvements were recommended:

- Request the experts to validate their DoI and submit a CV.
- Correct the errors found.
- Reinforce for SAG meetings the requirement that participants must have a signed e-DoI prior to involvement in the SAG activity.

No *ex post* control was carried out in 2019 due to the business contingency status of the Agency.

2.2.4. Transparency measures

The e-DoIs, their assigned interest levels and the CVs of all scientific committees' members and experts are 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 2018 - 2019

The following initiatives were initiated in 2018:

In the 2018 *ex post* control, SAG and Ad Hoc Expert Group participants were maintained (originally added in 2017) and included in the sample follow-up to findings from the previous *ex post* controls.

In 2018 a revision was made to the EMA BoT procedure for competing interests of and also disclosure of confidential information by scientific members and experts. The Management Board endorsed the revised BoT procedure on 4 October 2018 and the revised BoT procedure was subsequently published on the corporate website.

Due to the business contingency status of the Agency, it was not possible to launch other initiatives in 2018 and 2019.

3. Management Board members

3.1. Status of EMA Policy 0058

The current policy has been in effect since 1 December 2016. The last revisions were introduced in 2016. No changes were introduced in 2018 - 2019. 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 in December 2018 and 2019:

December 2018

Interest level	Members	Observers*
1 – no interests	60	6
2 – indirect interests	5	0
3 – direct interests	1	0
Total	**66**	**6**

(* Iceland, Liechtenstein and Norway)

December 2019

Interest level	Members	Observers*
1 – no interests	59	5
2 – indirect interests	7	1
3 – direct interests	0	0
Total	**66**	**6**

(* Iceland, Liechtenstein and Norway)

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 2018 or 2019 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 2018 - 2019.

No *ex post* controls were performed in 2018 - 2019 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 2018 - 2019

In 2019 the BoT procedure was revised to align with the BoT procedure for scientific committees' members and experts. No other initiatives were launched in 2018 - 2019 due to the business contingency status of the Agency.

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 for 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.

4.2. Facts and figures

4.2.1. Declared interests

A staff member or a candidate is assigned by the reporting officer to one of the following interest levels based on his/her declared interests

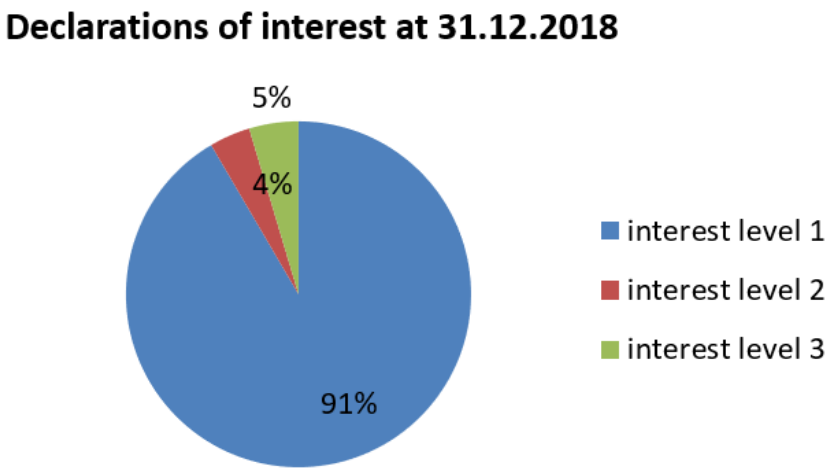
- Level 3: If the staff member or candidate has declared direct interests.
- Level 2: If the staff member or candidate has declared indirect interests.
- Level 1: If the staff member or candidate has not declared any direct or indirect interests.

2018: The graph below shows the distribution of staff's interest levels for all EMA staff on 31 December 2018.

Staff assigned interest level 1: 91.55% with no declared direct or indirect interests.

Staff assigned interest level 2: 3.82% who declared indirect interests.

Staff assigned interest level 3: 4.61% who declared direct interest.

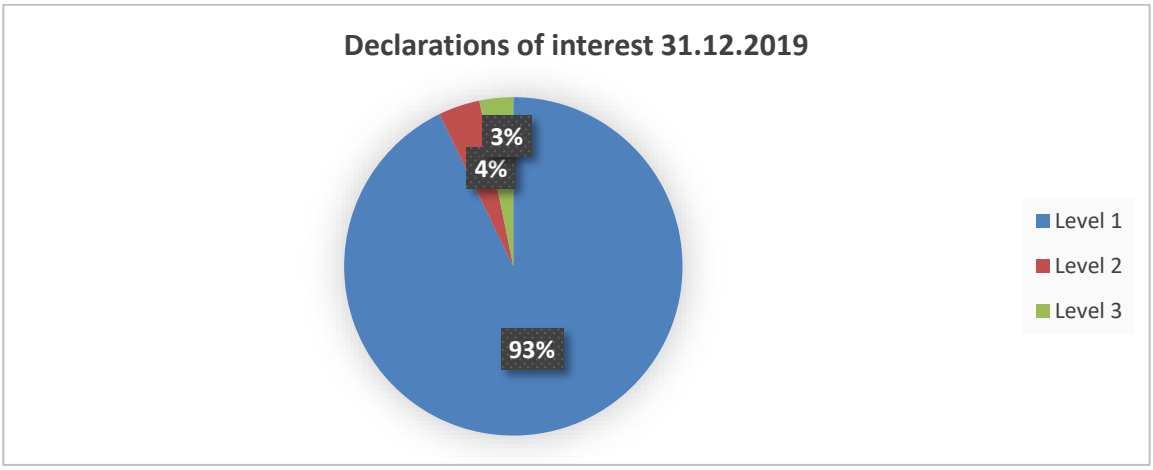


2019: The graph below shows the distribution of staff's interest levels for all EMA staff on 31 December 2019.

Staff assigned interest level 1: 92.81% with no declared direct or indirect interests.

Staff assigned interest level 2: 3.97% who declared indirect interests.

Staff assigned interest level 3: 3.22% who declared direct interests.



4.2.2. Outcome of Joint Committee procedures

On leaving the Agency, 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 will issue a decision, which may impose restrictions on the staff member to mitigate any potential competing interests. 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.

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. 3-12 months; explicit prohibition of handling medicinal-product dossiers on which they have worked during their employment at EMA.

The Agency adopted on 4 October 2018 the Commission decision on outside activities and assignments and on occupational activities after leaving the service. Under the new 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 2018 to 31 December 2018, staff made a total of 34 applications, resulting in 18 authorisations with restrictions, 12 authorisations without restrictions, 5 SNE cases (4 with no and 1 with restrictions). Examples of restrictions (that are grade and role related) imposed include: a distance clause, whereby the former staff member may not contact individual Agency staff for a period of time, e.g. 6-12 months.
- For the period from 1 January 2019 to 31 December 2019, staff made a total of 30 applications, resulting in 21 authorisations without restrictions, 7 staff authorisations with restrictions, 2 SNE

cases had restrictions. Examples of restrictions (that are grade and role related) imposed include: a distance clause, whereby the former staff member may not contact individual Agency staff for a period of time, e.g. 6 - 12 months.

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

In 2018 - 2019 no *ex post* controls were carried out due to the Agency's business contingency status.

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 a risk level and apply mitigating actions if needed before the person can start the contract.

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 2018 - 2019

In the second annual report on Independence (2016 - 2017) one recommendation referred to the action to be undertaken to address the suggestion from the European Ombudsman regarding the declaration by EMA staff of current and past intellectual property rights related to medicinal products or uses of such products, including patent ownership and patent applications (EO case 1606/2016/JAS). Under the applicable rules, EMA staff are not allowed to hold property rights related to medicinal products or uses of such products, including intellectual property such as patent ownership or beneficiary of patents. The rules did not include the need for staff to declare patent applications or intellectual property rights held in the past.

The Agency acted on the European Ombudsman's suggestion and carried out a survey of staff requesting them to declare current and past applications for, ownership of and benefits from any intellectual property rights related to medicinal products. In addition to patents, the declarations were required to cover trademarks, know-how and copyrights. Staff members were asked to state whether they are named as inventor on any patent or patent application related to medicinal products. Based on the replies received, only 1 staff member reported to have been a trademark owner prior to joining the Agency and 8 staff members confirmed that they were inventor on patents or patent applications related to medicinal produces. No staff member was found to currently receive any direct or indirect financial benefit from any patent claiming a medicinal product or a manufacturing method for, or a therapeutic use of such product, or from any other intellectual property right related to a medicinal product covering the period up to five years preceding the start of their employment at the Agency. The outcome of this survey was reported to the European Ombudsman on 5 April 2018 (EMA/185602/2018). This aspect was included in the December 2018 revision of the Management Board Decision for staff. In addition, the Decision was updated to refer to the processing of personal data in accordance with Regulation (EU) 2018/1725 on the protection of natural persons with regard to the processing of personal data by Union institutions, bodies, office and agencies and on the free movement of such data. The revised Decision for staff was adopted by the EMA Management Board in December 2018 and became effective as of 1 January 2019.

The e-DoI form was amended in Q3 2019 to allow staff to declare patent applications or intellectual property rights held in the past 5 years. Likewise, the declaration of candidates prior to the start of their contract also includes this additional question.

5. Recommendations for further improvement

Taking into account experience gained in 2018 - 2019 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

Although the Agency planned to undertake the following changes to this policy as per the Management Board's agreement, these could not be undertaken in 2018 - 2019 due to the Agency's business contingency status, and therefore have been listed again as they are still valid:

- Revise the definition of financial interests to include warrants (equally applicable to Policy 0058 for Management Board members and the Management Board Decision on rules for EMA staff).
- Introduce a definition of partner in the context of close family member interests, i.e. registered partnership certifying a stable non-marital partnership (equally applicable to Policy 0058 for Management Board members and the Management Board Decision on rules for EMA staff).
- Review the restrictions applicable to inspection related activities to bring them in line with current practice in the majority of EU member states, as well as at FDA, where inspectors declaring close family interests are not allowed to perform inspections in the declared company(ies).
- Look into the specific provisions relating to the Committee for Advanced Therapies (CAT). Article 22 of Regulation (EC) No 1394/2007 states that '*in addition to the requirements laid down in Article 63 of Regulation (EC) No 726/2004, members and alternates of the Committee for Advanced Therapies shall have no financial or other interests in the biotechnology sector and medical device sector that could affect their impartiality. All indirect interests that could relate to these sectors shall be entered in the register referred to in Article 63(2) of Regulation (EC) No 726/2004*'.

In addition, other changes to the policy or its implementation are recommended:

- Refer to the processing of personal data in accordance with Regulation (EU) 2018/1725 on the protection of natural persons with regard to the processing of personal data by Union institutions, bodies, office and agencies and on the free movement of such data.
- Review the practical implementation of pharmaceutical company restrictions on procedures dealing with a high number of medicinal products, e.g. rapporteurships for signal assessment and periodic safety update single assessment involving only nationally authorised products at the level of the Pharmacovigilance Risk Assessment Committee (PRAC).

Furthermore, a number of technical changes are recommended:

- Introduce the necessary changes to the e-DoI form to consider the aforementioned recommendations, including also a tick box for experts to confirm that they have read and understood Policy 0044 when signing the e-DoI.
- Update the experts' database with the aim to facilitate the submission of the DoI and e-CV by experts and to improve search possibilities for areas of expertise mentioned in the CV by the expert, to include information for which EMA activities an expert is currently involved in or has previously been involved in in order to support the evaluation by EMA staff of the DoIs of experts.

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 2018 ex post controls

Reinforce for SAG meetings the requirement that participants must have an up-to-date and signed e-DoI prior to involvement in the SAG activity.

5.3. Other recommendations

Conduct an ex post control for staff members with interest level 2 and 3.

6. Planned initiatives for 2020

The implementation of the aforementioned recommendations will depend on the availability of the necessary resources. Priority will be given in 2020 to updating the various policies on independence. 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.
- 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.

- Introduce amendments to Policy 0044 in view of the repurposing project which foresees a champion role for patients' organisations with submission of scientific advice requests. Taking into account the current principles of the policy, restrictions are considered necessary for representatives of these patient organisations involved in EMA activities, depending on the exact scenario.

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. The Agency plans to make its proposals to the Management Board in June 2020 regarding the necessary and prioritised changes and to implement these changes in 2020, some of which involve an implementation period going beyond 2020.