EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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2016 and 2017 European Medicines Agency Annual Reports 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 put on the agenda of the Management Board annually. EMA policies on independence have been discussed at a number of occasions at the Management Board in 2015 and 2016. The first annual review of independence was presented to the Management Board at its October 2016 meeting.

In the first annual report the status of all independence policies and their implementation, including controls, was reviewed. Concerning the scientific committees' members and experts, no breach of trust procedure was formally launched in 2015, and *ex ante* and *ex post* controls did not identify any major issues. Overall transparency was achieved through appropriate publication of declarations of interests (DoIs), Curriculum Vitae (CV) and minutes including restrictions applicable to meeting participation. For the members of the Management Board the findings were similar, although *ex ante* and *ex post* controls were not planned for 2015 and hence no controls were undertaken. For EMA staff 28 applications to engage in an occupation within two years of leaving EMA were received and examined, resulting in authorisation with restrictions in 5 cases. As a result of the review, inconsistencies in the alignment of the independence policies for scientific committees' members and experts, Management Board members and the rules for EMA staff were detected and addressed through revisions submitted to the Management Board at the October 2016 meeting. The term competing interest was introduced instead of conflict of interest in both policies and the rules for EMA staff.

This report covers the years 2016 and 2017 and reflects the status of the various policies relating to independence for scientific committees' members and experts, Management Board members and Agency staff and their implementation as of the end of 2017. It includes results of breach of trust procedures and any controls (*ex ante* or *ex post*) which were carried out in 2016 and 2016. The report also elaborates on initiatives undertaken in 2016 and 2017 as well as the planned initiatives for 2018, and identifies recommendations for further improvement.

2. Scientific committees' members and experts

2.1. Brief outline of the most recent changes to EMA Policy 0044

The revised Policy 0044 for Scientific Committees' members and experts was endorsed by the Management Board in March 2014 and published in November 2014. It became effective as of 30 January 2015.

The revision of the policy in October 2016 took into account the experience gained since its last revision in 2015, and aligned the policy where relevant with that of the Management Board members and introduced clarifications in the area of previous employment with a pharmaceutical company in an executive role or lead role in the development of a product.

The wording of the policy in relation to restrictions for grants/other funding was maintained for Policy 0044 (but changed for Policy 0058 for Management Board members), whereas the restrictions for scientific committees' members with close family members' interests were strengthened in line with the wording of Policy 0058.

The specific situations relating to previous employment with a pharmaceutical company (i.e. either executive role within a pharmaceutical company, or lead role in the development of a medicinal product) resulting in lifetime non-involvement (for respectively any medicinal product for which the pharmaceutical company is the MAH, or for that medicinal product), should be understood as "during

the term of the mandate". Therefore, in order to avoid confusion "lifetime non-involvement" was replaced by "non-involvement during the term of the mandate".

Full restriction on further involvement in the Agency's activities were introduced for any committee, working party or SAG members intending to become an employee in a pharmaceutical company.

2.2. Facts and figures

2.2.1. Declared interests and resulting restrictions

The distribution of the declared interests for the scientific committees (members and alternates) and experts was as follows on 31 December 2016 and on 31 December 2017:

Distribution per 31 December 2016

Interest level	CHMP	CVMP	CAT	COMP	HMPC	PDCO	PRAC	All experts*
1 – no interests	50	51	53	28	52	51	63	2,736
2 – indirect interests	11	6	6	6	4	9	7	395
3 – direct interests	4	1	4	2	1	3	0	458
Total	**65**	**58**	**63**	**36**	**57**	**63**	**70**	**3,589**

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

Distribution per 31 December 2017

Interest level	CHMP	CVMP	CAT	COMP	HMPC	PDCO	PRAC	All experts*
1 – no interests	52	56	53	30	55	54	61	3,021
2 – indirect interests	9	5	7	5	4	12	7	419
3 – direct interests	3	1	4	1	1	3	2	536
Total	**64**	**62**	**64**	**36**	**60**	**69**	**70**	**3,976**

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

In 2016, 7 experts (2 scientific committee members, 4 working party members, 1 expert) 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.

In 2017, 7 experts (3 scientific committee members, 1 CMD member, 3 working party members) informed the Agency of such intention and the same restriction was immediately applied.

2.2.2. Outcome of Breach of Trust procedures

A revised Breach of Trust procedure was endorsed by the Management Board in March 2015. The procedure was aligned with the revised Policy 0044 and amended in line with the experience gained since the introduction of the procedure in 2012.

The new procedure came into effect on 24 April 2015.

In 2016 the EMA was made aware of an interest which potentially should have been declared in their declaration of interests for 3 experts. In accordance with the procedure as a first step, clarifications were requested from the experts. Assessment of the additional information received concluded either that according to the policy there was no requirement for the expert to declare the interest or that the omission was not done intentionally by the expert. Therefore, there was no need to go beyond the first step and initiate a breach of trust procedure for the concerned experts.

In 2017 the EMA was informed on an interest which potentially should have been declared in their declaration of interests for 2 experts. Again, assessment of the additional information received concluded that the omission was not done intentionally by the expert and there was no need to go beyond the first step and initiate a breach of trust procedure for the concerned experts.

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

An *ex ante* control is 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 that the time periods in the declaration of interests match with those given in the Curriculum Vitae.

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

2.2.3.1. Ex ante controls 2016

In 2016, 629 e-DoIs were checked before the new experts were uploaded in the EMA's experts database. For 24 experts (3.8%), an error was noted in the e-DoI, i.e. an interest mentioned in the CV was not declared in the e-DoI, as follows: previous employment (2), a different date was declared in the e-DoI compared to the CV (9), an interest was declared in the wrong section of the e-DoI (6), or part of the information on an interest was missing in the e-DoI (2), or inconsistencies in the e-CV (5) were observed. All experts were requested to submit an updated e-DoI with a higher (4) or same (20) interest level than the original e-DoI.

2.2.3.2. Ex post controls 2016

Two *ex post* controls were performed in 2016.

The first 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 and the correct implementation of the restrictions applicable to the experts by the Agency.

Seventy-five experts (out of 5,862), who were invited to meetings at the Agency during the period 1 January to 30 June 2016, were randomly selected. The selection was stratified so that 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.

One expert did not sign off his updated DoI before the meeting, but only 5 months after the meeting and for one expert the information had not been uploaded in the Experts database at the time of the control. For two experts the DoI was not evaluated prior to the meeting, however, this would not have had an impact on their involvement in the meeting. The evaluation of the DoI was incorrect in four cases because the experts were evaluated as inspectors instead of correctly being evaluated as

scientific committees and working parties members. This did not, however, affect the restrictions applicable to the experts.

For two experts the outcome of the DoI evaluations was not correctly reflected in the minutes, but this did not have an impact on their participation in the meeting. For two working parties the outcome of the DoI evaluation was not recorded in the minutes of the particular meeting.

The following improvements were recommended:

- Reinforcing for SAG meetings the requirement that participants need to have an up-to-date and signed e-DoI prior to involvement in the SAG activity in order to allow for the correct restrictions to be applied where necessary.
- Include more SAG members in the sample for the 2017 *ex post* control.
- Correct the errors found and a organise meeting with the relevant meeting secretariat.
- Prepare a proposal to include Drafting groups as activity in the DoI evaluation form.

The second control was conducted to verify that the rapporteur appointment procedure was followed correctly i.e. checking the correctness of the verification on the lack of competing interests at the time of rapporteur appointment and the administrative tasks of entering the name of the rapporteurs into the product database and on the letters to the applicants.

Ten out of 80 rapporteur appointments to CHMP, PRAC and CAT in 2016 were checked.

Overall, the control showed that the procedure for checking for lack of competing interest at the time of rapporteur appointment to CHMP, PRAC and CAT works without any major problems. No mistakes were found in the checking of possible competing interests for the appointed rapporteurs.

Only minor issues in the administrative tasks were identified. The priority level of the bid as indicated by a bidding national competent authority had in one case been wrongly copied over into the rapporteurship internal report. This finding had no impact on the rapporteurship appointment. In another case the letter to the applicant was dated incorrectly and the name of the peer reviewer was not included in the list of names of persons in cc of the letter. The peer reviewer had, however, been sent a copy of the letter.

The following improvements were recommended:

- Remind the involved staff members to copy information correctly.
- In view of the low number of possible rapporteurs with an interest level of 2 or 3 and to optimise the checking of the absence of interests with regard to rival products, sample for future *ex post* controls the rapporteurs with interest level 2 and 3 and check the absence of competing interests for the products that have been assigned to them.

2.2.3.3. Ex ante controls 2017

In 2017, 795 e-DoIs were checked before the new experts were uploaded in the EMA's experts database. For 31 experts (3.9%), an error was noted in the e-DoI, i.e. an interest mentioned in the CV was not declared in the e-DoI, as follows: previous employment (8) and current grant (1), no details on close family member interests could be provided (1), a different date was declared in the e-DoI compared to the CV (7), an interest was declared in the wrong section of the e-DoI (5), an interest was declared unnecessarily (1), or there were inconsistencies in the e-CV (8). All experts were requested to submit an updated e-DoI with a higher (9), same (19) or lower (3) interest level than the original e-DoI.

2.2.3.4. Ex post controls 2017

As in previous years, the 2017 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 and the correct implementation of the restrictions applicable to the experts by the Agency.

One hundred experts (out of 5,544), who were invited to meetings at the Agency during the period 1 January to 30 June 2017, were randomly selected. The sample size was increased compared to the 2016 control to focus on SAG experts in follow-up to findings from the 2015 and 2016 *ex-post* controls. 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.

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

For one expert, the most up-to-date DoI was not evaluated prior to the meeting; however, this would not have had an impact on involvement in the meeting.

One expert did not declare in his DoI an interest mentioned in his CV.

For three experts, the outcome of the DoI evaluation for the meeting was not correctly reflected in the minutes, but this did not have an impact on their participation in the meeting.

The following improvements were recommended:

- Correct the errors found.
- Ensure that restrictions, if any, are recorded for topics added to the agenda after the start of the meeting.
- Reinforce for SAG meetings the requirement that participants are to have a signed e-DoI prior to involvement in the SAG activity and are included in the Experts database before or at the latest shortly after the meeting.

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, as of 30 September 2011 (for e-DoIs), 29 February 2012 (for assigned interest levels) and 9 September 2013 (for CVs). There was, however, an ongoing issue with respect to GMP inspectors in one of the German Länder, objecting to the online publication on the EMA website of e-DoIs and e-CVs containing personal information. Despite lengthy exchanges with the ZLG (Zentralstelle der Länder für Gesundheitsschutz) no agreement had been found. This resulted in a decision from the Agency to no longer involve inspectors objecting to the online publication in EMA activities as from February 2017.

In addition the Agency started publishing the minutes of the scientific meetings (PDCO, COMP and PRAC as of July 2012, HMPC as from November 2013 and CHMP, CVMP and CAT as of 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 2016

The following has been initiated in 2016:

- In 2016, the Declaration of Interests evaluation Advisory Group (DIAG) was re-activated. DIAG is a cross-Agency group with the objective to give advice to EMA staff members dealing with complex situations encountered with DoI evaluations for experts. DIAG provided advice on 2 complex evaluations. In addition, several interesting cases were included in an overview of complex and particular DoI evaluations.
- For scientific committees' members and alternates, the Agency continued to perform a pre-screening of the declared interests, requesting the nominating authority to confirm acceptability of identified restrictions prior to any formal acceptance of a nomination from the nominating authority. This practice was already in place for all new CHMP and CVMP members and alternates since 2012 and was extended at the end of 2015 to all other scientific committees, including members nominated by the European Commission. In case a nominating authority would appoint a member or alternate to a scientific committee or other forum, or an expert for participation in an activity of the Agency where the expert has declared interests which are incompatible with involvement in the Agency's activities, the Agency would not allow this member or expert to participate, and would inform the nominating authority accordingly.

2.4. Initiatives launched in 2017

The following has been initiated in 2017:

- In the 2017 *ex post* control, more SAG and Ad Hoc Expert Group participants were included in the sample in follow-up to findings from the 2015 and 2016 *ex post* controls.
- As of February 2017, GMP inspectors from one of the German Länder objecting to the online publication of their e-DoIs and e-CVs were no longer involved in EMA activities, in line with the provisions laid down in Policy 0044.

After internal discussion, it was decided that there was no need to include Drafting Groups as a separate activity in the DoI evaluation form.

3. Management Board members

3.1. Brief outline of the most recent changes to EMA Policy 0058

Policy 0058 for Management Board members was revised in December 2015 to achieve a better balance in managing declarations of interests of Management Board members versus the specific role and responsibilities of the Management Board and to maintain alignment with Policy 0044 for Scientific Committees' members and experts.

The policy was further revised in October 2016 to address an observed inconsistency between Policies 0044 and 0058 as regards restrictions for grants/other funding to an organisation/institution, as well as for close family members. The restrictions for grants/other funding were therefore aligned with those in Policy 044, whilst maintaining the restrictions for close family members as stated in Policy 0058.

In line with the revised wording of the Decision for EMA staff a provision was introduced that interests resulting from positions in a governing body of a professional organisation with an interest in the field of pharmaceuticals other than a pharmaceutical company should not in principle result in mitigating measures but should always be declared for transparency reasons. However, in exceptional cases such interests may result in restrictions, to be decided on a case-by-case basis.

The revised policy came into effect on 1 December 2016.

3.2. Facts and figures

3.2.1. Declared interests and resulting restrictions

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 2016 and in December 2017:

December 2016

Interest level	Members	Observers*
1 – no interests	58	6
2 – indirect interests	6	0
3 – direct interests	2	0
Total	**66**	**6**

(* Iceland, Liechtenstein and Norway)

December 2017

Interest level	Members	Observers*
1 – no interests	62	6
2 – indirect interests	2	0
3 – direct interests	2	0
Total	**66**	**6**

(* Iceland, Liechtenstein and Norway)

3.2.2. Outcome of Breach of Trust procedures

In December 2015, the Management Board also endorsed a revised Breach of Trust procedure[1] for Management Board members. This sets out how the Agency deals with incorrect or incomplete declarations of interests by Management Board members, and it has been aligned with the Breach of Trust procedure for scientific committees' members and experts.

No breach of trust procedures were initiated in 2016 or in 2017 for Management Board members.

[1] European Medicines Agency breach of trust procedure on declarations of competing interests for Management Board members (EMA/309079/2012 Rev. 1)
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/06/WC500129044.pdf

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

As of 2016 an *ex ante* control is systematically carried out 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, that the time periods in the DoI match with those given in the CV and that the DoI is published on the EMA website. No inconsistencies were detected in the submissions received in 2016 or in 2017.

No *ex post* controls were performed in 2016 or in 2017.

3.2.4. Transparency measures

The DoIs of all Management Board members and alternates, along with their CV, are published on the Agency's website as of 2012. In addition the agendas and minutes of the Management Board meetings have been published since 2009. Since 2016, the minutes include information on the restrictions applicable to meeting participation following the assessment of the DoIs.

3.3. Initiatives launched in 2016 and 2017

No new initiatives were launched in 2016 other than the systematic *ex ante* checking and the recording of restrictions in Management Board minutes as mentioned above. No new initiatives were undertaken in 2017.

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 in place rules to reinforce a systematic approach to assessing declared interests of the Agency's staff, and to provide the required assurance on 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 revision of the rules also addressed the need to streamline the process for the handling of declared interests of EMA staff taking into account identified opportunities for improvements. The rules became effective as of 1 January 2017.

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 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.

The most important changes introduced to align the rules with the Policies 0044 and 0058 relate to a revision of key definitions and the principles for identification and mitigation of competing interests in relation to a staff member's scientific/regulatory duties or administrative/technical (non-scientific) duties. Changes were also introduced with respect to the cooling off period to "current" and "0-3 years" for scientific and non-scientific staff and a 5 year cooling off period for managers with a scientific/regulatory role. A declaration of a previous position in a governing body of a professional

organisation with an interest in the field of pharmaceuticals was also introduced in the interest of transparency.

The categorisation of staff for the purpose of the handling of declared interests was also revised to match the new Agency organigram and a yearly check of competing interests was introduced for all categories of staff. Clear rules were also established for staff members leaving the Agency whereby existing activities could be restricted depending on the post-employment occupational activities and the time period until they leave the Agency.

As a result of these changes, the handling of the declared interests of staff was also amended. The DoI form of staff was updated and all staff completed the new DoI form by 1 February 2017. The submission and evaluation of the DoI is now performed in SAP-HR.

Training was provided to all EMA staff and dedicated training sessions for managers were organised to facilitate implementation of the revised rules.

The following main changes have been made in the Annex of the revised rules for staff:

Changes to ensure alignment with Policies 0044 (Scientific Committees' members and experts) and 0058 (Management Board members), where relevant

- Key definitions have been revised.
- The principles for identification and mitigation of competing interests have been revised in relation to a staff member's scientific/regulatory duties or administrative/technical (non-scientific) duties.
- The cooling off period has been changed to "current" and "0-3" for both scientific and non-scientific staff.
- A 5-year cooling-off period has been introduced for managers (with a scientific/regulatory role) with a previous executive role in pharmaceutical industry/lead role in the development of a medicinal product.
- Position in a governing body of a professional organisation with an interest in the field of pharmaceuticals should be declared for transparency reasons.

Changes to streamline the process for handling declared interests of EMA staff

- Updated categorisation of EMA staff to match the new organigram.
- Checks for competing interests in relation to all categories of staff will take place yearly, at the time of the annual update of the DoI of staff members, in order to streamline the process while maintaining the robustness of the system and making it more efficient. Therefore, the current process whereby managers have to check categories of EMA staff both once a year and prior to product allocation has been simplified.
- Reporting officers will maintain an inventory of staff members with interest levels 2 and 3 and based upon the information gathered will assign duties or allocate products to ensure that there are no competing interests that could unduly influence.
- For a staff member leaving the Agency, the reporting officer shall immediately reassess the declared interest of the staff member and subsequently apply any necessary restrictions on existing activities taking into account the intended post-employment occupational activities and this for the time period until they leave the Agency.

Changes proposed in order to address the perception issue

- Name change: handling of “competing interests” instead of “conflict of interests” across all documents.
- No reference to terminology such as conflict, risks, etc. but use of more neutral language.

As a result of these changes, the DoI form of staff was updated and all staff completed the new DoI form in early 2017. The submission and evaluation of the DoI is now performed in SAP-HR.

Training was provided to all EMA staff and dedicated training sessions for managers were organised to facilitate implementation of the revised rules.

4.2. Facts and figures

4.2.1. Declared interests and resulting restrictions

A staff member or a candidate is assigned by the reporting officer to one of the following interest levels on the basis of 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.

The graph below shows the distribution of staff’s interest levels for all EMA staff on 30 June 2016 (total of 872 staff members including temporary agents, national experts, contract agents, interims and trainees). 88% of staff members have been assigned interest level 1 since they have not declared any direct or indirect interests. Staff members who have declared direct interests account for 10% of the total of staff members. Only a small percentage of staff members have declared indirect interests (2%).

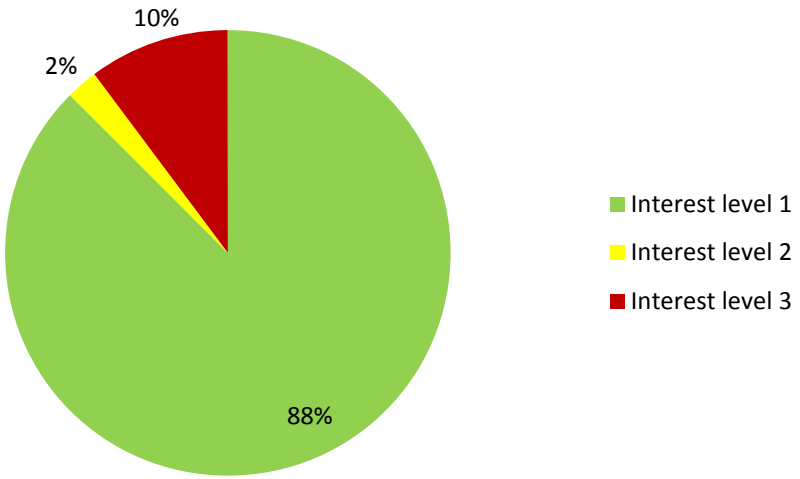

Figure 1: EMA staff interest levels in Jun 2016

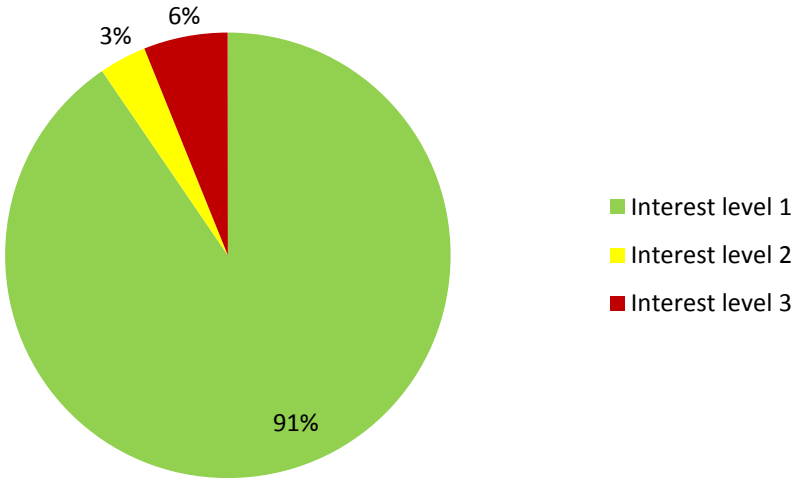

Figure 2: EMA staff interest levels in July 2017

The graph above shows the distribution of staff's interest levels for all EMA staff in July 2017 (total of 902 staff members including temporary agents, national experts, contract agents, interims and trainees). There was a small increase in the number of staff members with an interest level 1. The percentage of staff members with an interest level 3 has decreased from 10% to 6%.

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, on the basis of 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.

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 the Agency; and a requirement that opinions given in public presentations must state that they are the former staff member's own opinion and not linked to their previous employment at the Agency. The decision includes a reminder of the binding obligation of confidentiality after leaving.

In the period from 1 January 2016 to 31 December 2016, a total of 21 applications were made, resulting in 16 authorisations without restrictions and 5 applications with restrictions.

In the period 1 January 2017 to 31 December 2017, a total of 20 applications were made. Ten did not require a discussion by the Joint Committee, as the employment could not create any potential conflict (e.g. employment by a national competent authority) and overall 15 applications were approved without restrictions. Five Joint Committee recommendations to the Executive Director included restrictions as exemplified above. As of 2017 the process is managed paperless to save resources.

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

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

No *ex post* control was undertaken in 2016 as regards the handling of declared interests of staff due to the upcoming revision of the rules for staff.

In 2017 no *ex post* control was performed since the new rules had just been implemented. Instead, the Agency focused mainly on providing training to staff members.

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.

4.3. Initiatives launched in 2016 and 2017

No other new initiatives were undertaken in 2016 and in 2017 in view of the revision of the MB Decision which was finalised in 2016, except for the implementation of a new DoIs form and the handling of the DoIs by the reporting officer in SAP-HR in 2017.

5. Recommendations for further improvement

Taking into account experience gained in 2016 and 2017 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 a further alignment of some aspects of the existing EMA policies on independence

5.1.1. Recommendations for EMA Policy 0044 (Scientific Committees' members and experts)

Recommended changes to EMA Policy 0044

- 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*'.

Recommended changes to the implementation of EMA Policy 0044

- 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).

Recommended technical changes

- Update the experts' database with the aim 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 as well as the outcome of previous evaluations. This would increase efficiency as duplication of assessments could be avoided.

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 2016 and 2017 ex post controls

- Reinforce for SAG meetings the requirement that participants are (1) to have an up-to-date and signed e-DoI prior to involvement in the SAG activity in order to allow for the correct restrictions to be applied where necessary and, are (2) to be included in the Experts database before or at the latest shortly after the meeting.
- Include more SAG and Ad Hoc Expert Group participants in the sample for the 2018 *ex post* control.
- Ensure that restrictions, if any, are recorded for topics added to the agenda after the start of the meeting.

5.3. Other recommendations

- Address the suggestions 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). Already under the current 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. Although there is currently no need for staff to declare patent applications or intellectual property rights held in the past, the Agency will undertake this as per the request of the European Ombudsman, requesting staff to declare covering the period up to five years preceding the start of their employment at the Agency.
- Discuss the application of restrictions from Article 16 of the Staff Regulations to EMA staff leaving the Agency due to Brexit, in particular in view of the Agency's relocation to a new host city, to facilitate the staff member to find new employment.
- Conduct an *ex post* control for staff members with interest level 2 and 3.

6. Planned initiatives for 2018

The implementation of the aforementioned recommendations will depend on the availability of the necessary resources, in particular in view of the impact of Brexit on the Agency's activities. Priority will be given in 2018 to those initiatives not requiring changes to IT systems. The initiatives requiring changes to IT systems (°) will only be undertaken once the necessary resources have become available.

- Monitoring the implementation of EMA Policy 0058 (Management Board members).
- Monitoring the implementation of EMA Policy 0044 (Scientific Committees' members and experts).
- Monitoring 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.
- Preparing the 2018 Annual report on independence, including identification of recommendations for further improvement.
- Revising EMA Policies 0044 and 0058 as well as the Management Board Decision on rules for staff which do not require changes to IT systems as per the recommendations described in section 5.
- Reviewing the Breach of Trust Procedures to address the situation in case an expert deliberately engages in an activity which results in a competing interest as regards involvement in EMA activities, following the Agency's advice to the expert not to engage in such an activity.
- Conducting *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 for Scientific Committees' members and experts including an *ex post* control of SAG members.
  - *Ex ante* controls will continue in the context of EMA Policy 0058 for Management Board members.
  - 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.
- Depending on the availability of resources, undertaking further work in the field of the handling of competing interests in the following areas:
  - Suppliers and contractors working at the EMA, either on or off site.
  - In the context of responses to tenders following receipt of guidance from the Court of Auditors.
  - Experts involved in EMA activities falling outside the scope of EMA Policy 0044 for Scientific Committees' members and experts (i.e. outside the field of the authorisation and surveillance of medicinal products for human and veterinary use), with particular focus on networks of research centres (Enpr-EMA (European Network of Paediatric Research) and ENCePP (European Network of Centres for Pharmacoepidemiology and Pharmacovigilance)).
- (°) Undertaking the necessary changes to IT systems.

7. Conclusions

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, a number of additional initiatives have been undertaken in 2016 and 2017 as regards the Agency's

handling of declared interests. The policies on the handling of DoIs of scientific committees' members and experts, as well as Management Board members were revised in 2016 to strengthen the handling of DoIs whilst maintaining the right balance between impartiality and best expertise. The rules concerning the handling of declared interests of EMA staff were also revised in 2016 and implemented in 2017. The updating of the independence policies and rules also included aligning these policies and rules.

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

Transparency is another important pillar in ensuring 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.

Further room for improvement has been identified, and recommendations are made in this report to take this forward. In this respect, due consideration will have to be given on how and when to best implement these recommendations taking into account the particular challenge the Agency is facing over the next few years as a result of its relocation to a new host city due to the UK's decision to leave the European Union.