EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 September 2016
EMA/175527/2016

2015 Annual report on independence

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5505
Send a question via our website www.ema.europa.eu/contact

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. EMA policies on independence have been discussed at a number of occasions at the Management Board in 2015 and 2016.

The Management Board discussed the implementation of the revised Policy on handling declarations of interests for scientific committees' members and experts (Policy 0044)[1] in March 2015 and endorsed a revised Breach of Trust procedure for scientific committees' members and experts[2]. The revised Policy on the handling of competing interests of Management Board members (Policy 0058)[3] was discussed at the June and October 2015 Management Board meetings and endorsed together with a revised Breach of Trust procedure for Management Board members[4] at the December 2015 Management Board meeting.

This report 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 2015. It includes results of breach of trust procedures and any controls (*ex ante* or *ex post*) which were carried out in 2015. The report also elaborates on initiatives undertaken in 2015 and planned initiatives for 2016, and identifies recommendations for further improvement.

2. Scientific committees' members and experts

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

The revised Policy 0044 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 took into account the experience gained since its last revision in 2012, and the outcome of the EMA public workshop on conflicts of interests held in September 2013. The revision aimed at achieving the right balance between ensuring the impartiality and independence of experts involved in the Agency's work, versus the need to secure the best-possible scientific expertise to continually deliver high-quality scientific expertise.

The most important changes introduced relate to the introduction of a three year cooling-off period for the majority of declared interests with restrictions in involvement decreasing over time. However, in case of a previous executive role in a pharmaceutical company or a lead role in the development of a medicinal product during previous employment with a pharmaceutical company, this now results in a lifetime (i.e. during the term of the mandate) non-involvement with the company concerned or the medicinal product. For some interests, such as financial interests, there continues to be no cooling-off period once the financial interest ceased to exist.

[1] European Medicines Agency policy on the handling of declarations of interests of scientific committees' members and experts (Policy/0044)(EMA/626261/2014, Corr. 1)
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2010/10/WC500097905.pdf
[2] European Medicines Agency breach of trust procedure on declarations of interests for scientific committees' members and experts (EMA/154320/2012, Rev. 1)
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/04/WC500124976.pdf
[3] European Medicines Agency policy on the handling of competing interests of Management Board members (Policy/0058)(EMA/ EMA/MB/715362/2015 Adopted)
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/04/WC500124975.pdf
[4] European Medicines Agency breach of trust procedure on declarations of competing interests for Management Board members (EMA/MB/309079/2012, Rev. 1)
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/06/WC500129044.pdf

The requirements for experts who are members of scientific committees remained stricter than for those participating in advisory bodies and *ad hoc* expert groups. Similarly, requirements for chairs and members in a leading role, e.g. rapporteurs, remained stricter than those for the other committee members.

The electronic declaration of interests (e-DoI) form was revised accordingly and all scientific committee members and experts were required to submit an up-to-date declaration of interests before 30 January 2015.

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 5 April 2016:

Interest level	CHMP	CVMP	CAT	COMP	HMPC	PDCO	PRAC	All experts*
1 – no interests	49	53	54	27	55	47	62	2,765
2 – indirect interests	10	8	7	7	6	14	6	365
3 – direct interests	6	1	3	2	1	3	1	438
Total	**65**	**62**	**64**	**36**	**62**	**64**	**69**	**3,568**

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

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 and amended in line with the experience gained since the introduction of the procedure in 2012.

In particular, an additional step was introduced by which the Agency seeks clarification/information from the expert before the procedure is formally launched. This step which cannot exceed 7 calendar days allows the expert to clarify the situation, in particular by providing the rationale for the absence of the information to be declared and by completing the e-DoI with any missing information. The Agency subsequently assesses the information provided in order to establish whether the omission of the expert needs to be considered as a breach of trust.

The new procedure came into effect on 24 April 2015. No breach of trust procedure was formally initiated in 2015.

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

2.2.3.1. Ex ante 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 (CV).

In 2015, 491 e-DoIs were checked before the new experts were uploaded in the EMA's experts database. For 18 experts (3.7%), 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 (11), a different date was declared in the e-DoI compared to the CV (3), an interest was declared in the wrong section of the e-DoI (2), or

part of the information on an interest was missing in the e-DoI (2). All experts were requested to submit an updated e-DoI with a higher (9), same (8) or lower (1) interest level than the original e-DoI. For 5 experts (1.0%), a minor error was noted in the e-DoI, i.e. an interest was declared unnecessarily. Updated e-DoIs were submitted with a lower (4) or the same (1) interest level than the original e-DoI.

2.2.3.2. Ex post controls

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

An *ex post* control was conducted in 2015 to check the current e-DoI against the e-CV and the previous e-DoI, to check documented evaluation of the e-DoIs and documented implementation of restrictions at meetings.

A hundred experts, who were invited to meetings at the Agency during the period 1 February to 31 July 2015, 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 SAG expert did not have an up-to-date e-DoI on the date of the meeting. No restrictions were, however, applicable to the expert based on the updated e-DoI which was received after the meeting. Two experts had up-to-date but unsigned e-DoIs on the day of the meeting. These e-DoIs have subsequently been signed.

In one case the assessment of the declared interests was incorrect; however, this would not have had an impact on the involvement of the expert in the meeting. It was noted that the experts participating in the inspectors working group were assessed as either scientific committees' and working parties' members, or as SAGs and *ad hoc* expert group experts, while this should have been as scientific committees and working parties members. This did not affect the restrictions applicable to these experts.

For three experts the information had not been uploaded in the experts database, i.e. the expert nomination process was not yet finalised and the e-DoI and e-CV were not yet published on the Agency's website. For two working parties the restrictions applicable following the assessment of the declaration of interest had not been documented in the minutes of the meetings.

The following improvements were recommended:

- Reinforcing for SAG meetings the requirement that participants are 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.
  Note: It should be acknowledged that the submission and validation of e-DoIs include several administrative steps to be undertaken by the expert, often in a short timeframe. In particular for SAGs, experts are usually academics from universities and hospitals, attend mostly in a one-off meeting and frequently require support for completing their e-DoI. This makes the handling of e-DoIs in particular for SAGs a resource intense procedure. Efficiency gains could be investigated on condition that the principles for managing e-DoIs are not affected.
- Reinforcing for all meetings the requirement that participants are to be uploaded in the experts' database prior to their first involvement in an EMA activity. If not feasible, in exceptional circumstances, e.g. SAGs, this should be done shortly after the meeting.
- Introducing the same principles for the evaluation of e-DoIs to all inspector working groups by applying to all of them the rules applicable for scientific committees' and working parties' members.
- Including applicable restrictions following the assessment of e-DoIs or absence thereof in the meeting minutes of the CHMP Vaccine working party and CMDh Paediatric Regulation working party to harmonise the wording used across committees and working parties.
- Creating a virtual dedicated internal forum to address complex situations not covered by the policy and procedural guidance on the handling of declarations of interests of scientific committees' members and experts.

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 (e-DoIs), 29 February 2012 (assigned interest levels) and 9 September 2013 (CVs). There is, 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 has been found yet.

In addition the Agency started publishing the minutes of the scientific meetings (PDCO, COMP and PRAC as of July 2012, HMPC November 2013 and those of 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.

2.3. Initiatives launched in 2015

The following has been initiated in 2015:

- A check of all human and veterinary scientific committees' members' and alternates' e-DoI versus their CV and previous e-DoI has been completed in January 2015 following the implementation of the revised Policy.

Based on lessons learned in the first months of implementation of the revised Policy, the procedural guidance on inclusion of declared interests in the e-DoI form[5] was updated in April 2015 to provide clarifications on the definition of a previous executive role in a pharmaceutical company and a previous lead role in the development of a medicinal product.

The Agency updated its Policy in April 2015 to restrict involvement of experts in the assessment of medicines if they plan to take up a job in pharmaceutical industry. This restriction is reflected in a new guidance document[6].

The Policy states that *"if a scientific committee/working party/SAG/ad hoc expert group member intends to be engaged (either solicited or not) in occupational activities with a pharmaceutical company (such as employment) during the term of the mandate, the member shall immediately inform the Agency and refrain from any activities which may have an impact on the pharmaceutical company concerned, and shall comply with any additional conditions or limitations which the Agency may consider appropriate to impose."* The revision to the Policy and the development of the guidance document were introduced to ensure a consistent approach to the handling of such situations.

In 2015, 4 experts notified the Agency of such intention, and were immediately restricted from any further involvement in the Agency's activities.

- For scientific committees' members and alternates, the Agency performs a pre-screening of the declared interests and requests 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. 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.

3. Management Board members

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

Policy 0058 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.

The involvement in Management Board activities now takes into account four factors: the nature of the declared interest, the timeframe of the interest, the type of Management Board activity/topic and the likelihood of impact on the industry (the pharmaceutical industry or any other industry related to any declared personal interests) and what action is requested from the Management Board.

The policy came into effect on 1 May 2016.

[5] Procedural guidance on inclusion of declared interests in the European Medicines Agency's electronic declaration of interests form (for scientific committees' members and experts) (EMA/627294/2014, Rev.1) http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2014/11/WC500177570.pdf

[6] Guidance on the handling of declarations of interests in case of a scientific committee member/other (scientific) forum member's intention to become an employee in a pharmaceutical company (EMA/267183/2015) http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2015/05/WC500186536.pdf

3.2. Facts and figures

3.2.1. Declared interests and resulting restrictions

The distribution of the levels of declared interest of the Management Board members and their alternates, as well as the Management Board observers and their alternates was as follows in December 2015:

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

3.2.2. Outcome of Breach of Trust procedures

In December 2015, the Management Board also endorsed a revised Breach of Trust procedure[7] 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 procedure for scientific committees' members and experts.

No breach of trust procedures were initiated in 2015 for Management Board members.

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

No *ex ante* or *ex post* controls were performed in 2015.

3.2.4. Transparency measures

The e-DoIs of all Management Board members and alternates, along with their professional profiles, 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.

3.3. Initiatives launched in 2015

As the revised policy is to be implemented as of May 2016 no other initiatives were undertaken.

4. EMA staff

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

The Agency has in place implementing 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. These rules were amended in 2014 following the reform of

[7] 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

the Staff Regulations in January 2014, whereby, prior to recruiting temporary and contract agent staff and for staff returning from unpaid leave, the Agency must examine any personal interest which may impair the independence of the staff member. The rules apply in general to all temporary and contract agents, national experts on secondment, trainees, interims and visiting experts.

The implementing rules apply to both staff members and 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 studies.

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 risk 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 risk levels for all EMA staff on 19th January 2016 (total of 893 staff members including temporary agents, national experts, contract agents, interims and trainees). 87% of staff members have been assigned risk 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 (3%).

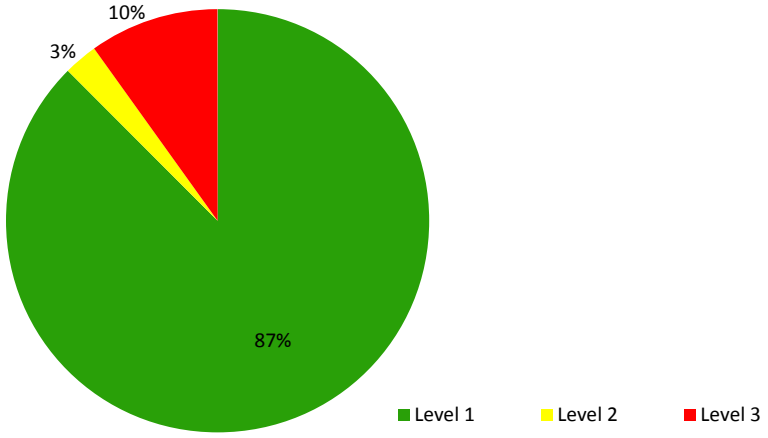

Figure 1: EMA staff risk level

The graph in Figure 2 shows the distribution of risk levels 2 and 3 across the different roles and responsibilities of staff members within the Agency (i.e. manager, scientific administrator, assistant). Half of staff members with risk levels 2 and 3 are, as anticipated, scientific administrators. In addition, a number of seconded national experts and interim staff have also been assigned risk levels 2 and 3. However, there is a very small number of managers with an assigned risk level of 2 or 3. The graph also illustrates that there is a large proportion of trainees assigned with a risk level 3, which is a result of their past industry experience.

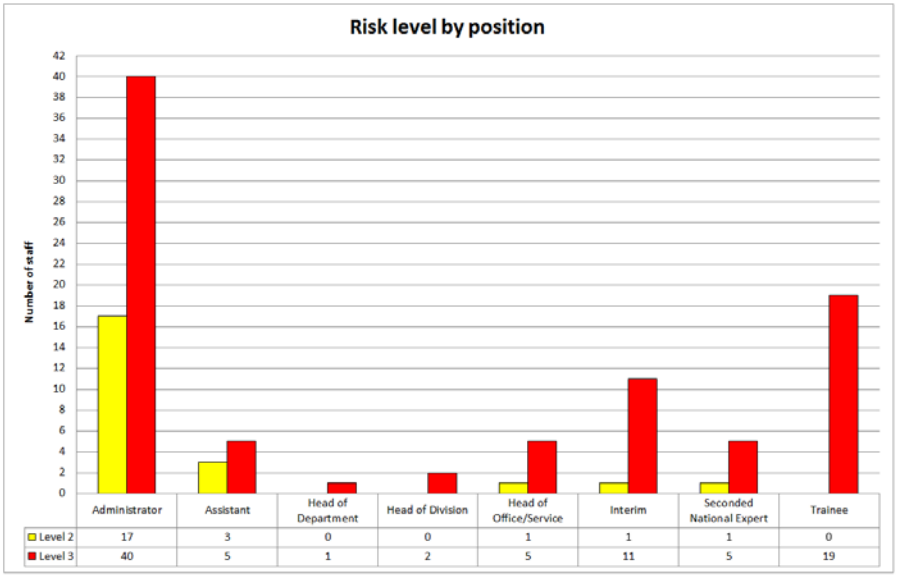

Figure 2: EMA staff with risk levels 2 and 3 classified by position

Figure 3 below displays the distribution of risk levels across the different types of declared interests. A large majority of staff members have been assigned a risk level 3 due to previous employment or other paid work in pharmaceutical industry. However, although staff members are required to declare previous employment in the pharmaceutical industry for a period of 5 years and thus are assigned a risk level 3, restrictions are currently only applied for the first 2 years. Hence not all staff assigned to a risk level 3 due to previous employment in pharmaceutical industry have restrictions applied to them. Similarly staff members with previous financial interest in pharmaceutical industry (past 5 years) are also assigned to a risk level 3, even though no restrictions are applied. However, restrictions are always applied to staff members allocated a risk level 2 due to close family members' current direct interests in pharmaceutical industry.

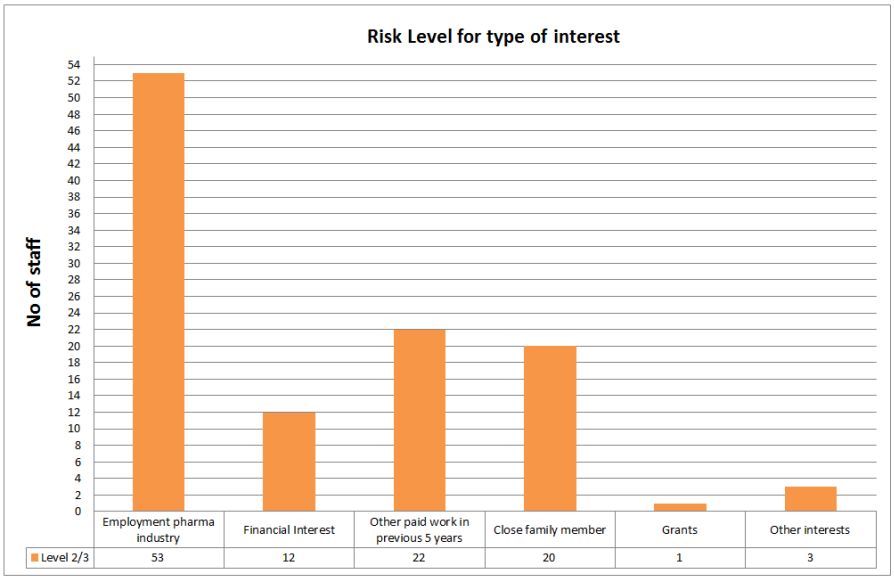

Figure 3: EMA staff with risk levels 2 and 3 classified by type of declared interest

As explained above, staff members who have been assigned a risk level 2 or 3 may, in some cases, have restrictions applied to them. In fact, although 13% of the staff have been assigned risk levels 2 and 3 (see Figure 1), restrictions are only applied to 48 out of a total of 893 staff members. The table below describes the distribution of staff members with risk levels 2 and 3 together with the number of corresponding restricted staff across each Division at the Agency.

Risk levels (2 and 3) by Division	Level 2	Restricted Level 2 staff	Level 3	Restricted Level 3 staff
Human Medicines Evaluation (E)	6	4	15	7
Human Medicines Research & Development Support (D)	2	1	16	6
Inspections & Human Medicines Pharmacovigilance (P)	2	1	13	7
Procedure Management & Committees Support Division (C)	5	1	20	10
Stakeholders & Communication (S)	2	1	7	3
Veterinary Medicines (V)	2	1	5	3

Risk levels (2 and 3) by Division	Level 2	Restricted Level 2 staff	Level 3	Restricted Level 3 staff
Legal Department (AF-LD)	1	0	2	1
Senior Medical Officer (AF-SMO)	0	0	1	0
Chief Policy Adviser (AF-CPA)	0	0	1	0
International Affairs (AF-INT)	0	0	1	0
Information Management (IM)	3	1	7	1
Total	**23**	**10**	**88**	**38**

The table shows that less than half of staff members with risk levels of 2 and 3 have restrictions applied to them. Divisions involved in the development, evaluation and monitoring of medicinal products for human use (E, D, C and P) have the highest number of staff members with restrictions. However, it is important to highlight that within these Divisions, the majority of staff members restricted are trainees to whom restrictions apply. All restricted staff members will not be involved in procedures for medicinal products from the companies for which they have declared a direct or indirect interest.

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 conflict of 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 against any potential conflict of interests.

For the period from 1 January 2015 to 31 December 2015, a total of 28 applications were made, resulting in 23 authorisations without restrictions and 5 applications with restrictions. Examples of restrictions imposed include: (1) 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; (2) he/she should not represent/assist a third party in any case lodged with the ECJ, national or international courts which he/she dealt with while in service at the Agency; (3) refraining from holding managerial or executive roles in companies that provide IT services to the Agency.

For staff who are still at EMA the current provisions will be further strengthened to ensure that restrictions are applied for that period of time.

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 to be done are selected based on a risk analysis and performed according to a pre-defined protocol.

An *ex post* control was performed in 2015 on the checking of conflicts of interests of EMA Product Leads (EPLs) in the Scientific and Regulatory Management Department within the Human Medicines Evaluation Division. The purpose of the *ex post* control was to verify if the procedure for checking of

conflicts of interests of EPLs was followed correctly and in a timely manner prior to product allocation to the staff member. The sample for the *ex post* control was selected from the EPL allocations made during the period from 1 January to 31 August 2015 for products submitted for initial marketing authorisation. It consisted of 29 EPL nominations for staff with a declaration of interest with a risk level 2 or 3.

The results showed that for one staff member with an risk level 2 a decision for checking of conflicts of interests was not completed at the time of product allocation, but has subsequently been done and restrictions were not necessary. This corresponds to 3.4% of the total number of EPL nominations investigated. Overall the control showed that the procedure is being properly followed. No major findings were found and no need for improvements was identified.

4.2.4. Transparency measures

The completed declaration of interests and CV for management staff are available under Agency structure (since 29 February 2012). All other staff DoIs are available upon request.

4.3. Initiatives launched in 2015

No new initiatives have been taken during 2015 in view of an imminent revision of the MB Decision, to be finalised in 2016.

5. Planned initiatives for 2016

Planned initiatives for 2016 include:

- Implementing the revised Policy 0058 by 1 May 2016 and monitoring such implementation, as well as developing training material to be provided as part of the provisions in the revised Policy 0058.
- Monitoring the implementation of Policy 0044.
- Revising the 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 2015 Annual report on independence, including identification of recommendations for further improvement.
- 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.
  - Experts involved in EMA activities falling outside the scope of Policy 0044 (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) as well as TAGs (Technical Advisory Groups).
- With respect to the EMA quality assurance system, 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 Policy 0044, albeit that for *ex post* controls the scope will be broadened to include the concept of rival products, the aim being to check the correctness of the checks performed at the time of CHMP rapporteur appointment.

- With respect to Policy 0058, systematic *ex ante* controls will be undertaken in 2016.

6. Recommendations for further improvement

In addition to the planned initiatives for 2016 as described in the previous section, the following recommendations for further improvement are made:

6.1. Recommendations resulting from the need for a further alignment of some aspects of the existing EMA policies on independence[8]

6.1.1. Recommendations for Policy 0044

- Introducing the term "competing interests" in line with Policy 0058.
- Clarifying for those 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) that 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" will be replaced by "non-involvement during the term of the mandate".
- Addressing 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, as follows:
  - Maintaining the restrictions for grants/other funding as outlined in Policy 0044.
  - Strengthening the restrictions for close family members as outlined in Policy 0058.

6.1.2. Recommendations for Policy 0058

- Addressing 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 (see also section 6.1.1, as follows:
  - Aligning the restrictions for grants/other funding to those included in Policy 0044.
  - Maintaining the restrictions for close family members as outlined in Policy 0058.
- Introducing in the subsection 4.2.1.2. (Declared interests – Personal interests, other than interests in pharmaceutical industry), aligned with the wording in the revised Decision for EMA staff, 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.

6.2. Recommendations resulting from the 2015 ex post controls

- Reinforcing for SAG meetings the requirement that participants are 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.

[8] It needs to be emphasised that because of practical reasons the most recent revisions of these policies could not be undertaken in parallel.

Note: It should be acknowledged that the submission and validation of e-DoIs include several administrative steps to be undertaken by the expert, often in a short timeframe. In particular for SAGs, experts are usually academics from universities and hospitals, attend mostly in a one-off meeting and frequently require support for completing their e-DoI. This makes the handling of e-DoIs in particular for SAGs a resource intense procedure. Efficiency gains could be investigated on condition that the principles for managing e-DoIs are not affected.

- Reinforcing for all meetings the requirement that participants are to be uploaded in the experts' database prior to their first involvement in an EMA activity. If not feasible, in exceptional circumstances, e.g. SAGs, this should be done shortly after the meeting.
- Introducing the same principles for the evaluation of e-DoIs to all inspector working groups by applying to all of them the rules applicable for scientific committees' and working parties' members.
- Including applicable restrictions following the assessment of e-DoIs or absence thereof in the meeting minutes of the CHMP Vaccine working party and CMDh Paediatric Regulation working party to harmonise the wording used across committees and working parties.
- Creating a virtual dedicated internal forum to address complex situations not covered by the policy and procedural guidance on the handling of declarations of interests of scientific committees' members and experts.

6.3. Other recommendations

- Further looking 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*'. These provisions apply both to the selection process by the European Commission and to the participation in the work of the CAT.
- Further updating the experts' database. The aim is 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 as well as the outcome of previous evaluations. This would increase efficiency as duplication of assessments could be avoided.
- Addressing the outstanding issue with one of the German Länder as regards the online publication of e-DoIs and e-CVs of GMP inspectors. EMA will indicate that if these GMP inspectors maintain their current viewpoint, they can no longer participate in inspections carried out on behalf of EMA, in line with the provisions laid down in policy 0044.

7. Conclusions

In line with the Agency's commitment to continuously review its operations in order to identify further room for improvement, and the importance that it places on independence, a number of initiatives have been undertaken in 2015. The policies on handling declarations of interests of scientific committees' members and experts, as well as Management Board members have recently been revised or are undergoing revision. All revisions aim to strengthen the handling of declarations of interests whilst maintaining the right balance between impartiality and best expertise.

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

Transparency is another important pillar in ensuring independence. EMA publishes the e-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. The minutes of the scientific committees meetings include information on the restrictions applicable to meeting participation following the assessment of declared interests.

Further room for improvement has been identified, and recommendations are made in this report to take this forward.