



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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2021 - European Medicines Agency Annual Report on Independence

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1. Background

The European Commission requested in January 2015 that "*the independence policy and its state of implementation*" should be on the agenda of the Management Board annually. The first annual review of independence was presented to the Management Board in October 2016, the second annual review of independence for the period 2016-2017 was presented in March 2018, the third review for 2018-2019 in March 2020, and the fourth review for 2020 in March 2021.

This report is the fifth annual review which covers 2021. It reflects the status of each of the independence policies (for scientific committees' members and experts, for Management Board members, and for EMA staff) including their implementation as of the end of 2021. This report provides facts and figures (including information on the launch and outcome of Breach of Trust procedures), gives information on initiatives taken in 2021 and identifies recommendations for further improvement, in 2022 in particular due to the legislation regarding the extended mandate for the Agency.

2. Scientific committees' members and experts

2.1. Status of EMA Policy 0044

The current Policy 0044 for scientific committees' members and experts has been effective since 1 January 2021 (endorsed by the Management Board on 11 June 2020). The changes included for CAT members and alternates the introduction of interests to be declared in the biotechnology and medical device sectors as foreseen in art. 22 of Regulation 1394/2007 and for all experts the introduction of interests to be declared of their personal or organisation's involvement in the repurposing of a medicinal product. In addition, restrictions were introduced for inspectors declaring close family interests and grants/funding to align with current practice in the majority of EU member states and at the FDA.

Other new provisions were the inclusion in the definition of financial interests of stock warrants, introduction of a definition of partner and inclusion of reference to the new EU GDPR legislation. These are the same provisions as introduced in the policy for Management Board members and in the decision on rules for Agency staff.

Under this policy, EMA requires an annual update of the electronic declaration of interest (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 scientific committees members and alternates and experts with no, indirect or direct interests declared in their e-DoI was as follows on 31 December 2021:

Distribution per 31 December 2021

Interest level	CHMP	CVMP	CAT	COMP	HMPC	PDCO	PRAC	All experts*
1 – no interests	53	57	52	30	52	50	58	3087

Interest level	CHMP	CVMP	CAT	COMP	HMPC	PDCO	PRAC	All experts*
2 – indirect interests	7	4	4	4	3	9	8	345
3 – direct interests	3	0	6	3	0	4	1	436
Total	63	61	62	37	55	63	67	3868

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

For the handling of DoIs submitted by scientific committees' members and experts, a 2-step procedure applies: firstly, an interest level is automatically assigned to the e-DoI based on whether the expert has any interests, whether these are direct or indirect and whether they are current or past as set out in the policy. Subsequently the level of participation in the Agency's activities is determined by active screening the DoI by the Agency's secretariat for each procedure or activity where the relevant expert would be involved.

Involvement of an individual scientific committee member or expert in the Agency's activities is determined taking into account 3 factors: the nature of the declared interest, the timeframe during which such interest occurred, as well as the type of activity. The restrictions applicable in the event that direct or indirect interests are declared, are set out in the policy in annex 1 "Scientific committees' members and experts allowed involvement in medicinal product related matters based on declared interests in the pharmaceutical industry" and in annex 2 "CAT members and alternates allowed involvement in medicinal product related matters based on declared interests in the biotechnology sector or the medical device sector". Some interests result in an exclusion of the expert from any involvement in the Agency's activities, other interests result in a restricted involvement, e.g. no involvement in procedures on the declared product or any product from the declared company while committee membership is allowed.

Taking into account the pool of experts available, the Agency works to ensure that the experts involved in a specific procedure does not have competing interests for the procedure. A proactive approach is also applied with respect to the search for alternative experts in the field. In 2021, the applied restrictions for scientific committee members, alternates and experts did not have an impact on the overall performance of the committees' work.

In 2021, 5 delegates (3 scientific committee members: 2 x CHMP, 1 X CAT, 2 working party members: 1 x MSWP, 1 x GMDP IWG) informed the Agency of their intention to become an employee in a pharmaceutical company. In line with the guidance document, the members were immediately fully restricted from further involvement in any Agency activity. The imminent employment in a company did not constitute a conflict for any of the ongoing assessment procedures.

2.2.2. Outcome of Breach of Trust procedures

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

EMA launched no BoT procedures in 2021.

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

2.2.3.1. *Ex ante* controls 2021

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.

	2021
New expert e-DOI checked before upload to the EMA Experts database	639
Error rate	12 / 1.9%
<i>Nature of error</i>	
Previous employment from CV not declared on DoI	8
Current grant from CV not declared in DoI	-
No details of close family members	-
Date difference between CV and e-DOI	-
Interest declared in wrong section of e-DOI	-
Information on an interest missing	-
Inconsistencies in the e-CV	2
Interest declared unnecessarily	2
<i>Action taken after update of e-DOI</i>	
Higher interest level	7
Unchanged interest level	3
Lower interest level	2

In 2021, 639 e-DoIs of new experts were checked and an error was noted in 12 e-DoIs (1.9%). The nature of the errors in 2021 (8 out of 12) was that these experts failed to declare in their e-DoI their recent employment (in the past 3-year period) within a pharmaceutical company. EMA asked the experts to correct their e-DoI, resulting in a higher or same interest level being assigned to their e-DoI. This EMA *ex ante*/preventive check of each expert is important and is maintained to ensure a low number error on the e-DOIs of experts.

2.2.3.2. *Ex post* controls 2021

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

The *ex post* controls were conducted to check

- the correct completion of the e-DoI by experts,

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

The 2021 control focused on Scientific Advisory Group (SAG)/Ad Hoc Expert Group (AHEG). 20 experts (out of estimated 250), who were invited to meetings at the Agency during the period 1 January to 31 October 2021, were randomly selected. The review of this control will be completed in Q1/2022 and the findings will be reported to the Management Board at its June meeting.

2.2.4. Transparency measures

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

2.3. Initiatives launched in 2021

The following initiatives were implemented in 2021:

- **Technical follow up to revision of Policy 0044**

Following the revision of Policy 0044 in June 2020, the e-DoI form to be completed by experts and the DoI evaluation form to be completed by the meeting secretariat when involving experts in Agency activities was revised. The updated e-DoI form was introduced in December 2020 with a requirement for all experts to submit an updated DoI by 1 January 2021. The updated DoI evaluation form was implemented for all EMA activities as from 1 January 2021.

A training on the operation of revised policy was provided to EMA staff in January 2021.

- **New business/IT solution for handling experts DOI**

To replace the Agency's current Experts database, business functionalities for a new business/IT solution for handling experts, including the submission, evaluation and management of DoIs, were listed. In view of the EMA extended mandate, additional requirements to handle Medical Devices Experts Panels (EXPAMED) members were included. Different options were considered and a request for a project to start in 2022 was prepared.

- **Impact of General Court Judgment**

The Agency continued to maintain the minimum implementation measures following the General Court Judgment on the Aplidin case, i.e. for SAGs and AHEGs, experts that are employed by universities or university hospitals performing development or manufacturing activities in respect of any medicinal products actually or potentially competing with the (candidate) product under review, are not allowed to be involved in the procedure. The Agency intervened in support of the appellate proceedings which were launched by two Member States in January 2021 and an outcome of the appeal is expected in 2022.

- **EMA extended mandate**

Regulation (EU) 2022/123 of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices was adopted in January 2022. The implications of the extended mandate with new

tasks and responsibilities for EMA regarding medical devices and medicines in respect of competing interests have been considered for:

- *Medical Devices Expert panels (EXPAMED)*

As from 1 March 2022, EMA is hosting the panels and providing a secretariat function on behalf of the European Commission. The Commission has put in place a policy on the management of competing interests for EXPAMED members with a focus on the medical device industry and notified bodies. This policy is similar to EMA Policy 0044. EMA will maintain and apply this separate policy for EXPAMED members that is specific to this function. Based on experience gained in the coming years, it can be considered if and/or how the EXPAMED policy and Policy 0044 should be amended. Any changes to the EXPAMED policy will need to be proposed to the Commission for its consideration.

- *Medical Devices Shortages Steering Group (MDSSG)*

This new Steering Group is established as part of EMA. It is considered that Policy 0044 should apply to this Steering Group and its working parties. The Rules of Procedure of the Steering Group will state that Policy 0044 applies. A revision of Policy 0044 to further elaborate on medical devices interests and their restrictions on involvement in this new EMA activity is envisaged.

- *Medicines Shortages Steering Group (MSSG) and Emergency Task force (ETF)*

This new Steering Group is established as part of EMA. It is considered that Policy 0044 should apply to this Steering Group and its working parties.

Policy 0044 applies already to the current ETF members and no change in practical operation in this respect is needed towards the new ETF.

A revision of the scope of Policy 0044 to include the Medicines Shortages Steering Group and the ETF will be prepared.

3. Management Board members

3.1. Status of EMA Policy 0058

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

3.2. Facts and figures

3.2.1. Declared interests

The distribution of the levels of declared interests of the Management Board members and their alternates, as well as the Management Board observers and their alternates was as follows on 31 December 2021:

Interest level	Members	Observers*
1 – no interests	47 members/alternates	5 observers
2 – indirect interests	2 member, 3 alternates	0
3 – direct interests	3 members, 1 alternate	0
Total	56	5

(* Iceland, Liechtenstein and Norway)

The Management Board secretariat reviews the DoIs of all meeting participants prior to the meeting. An interest level is assigned to the DoI based on whether the member has any interests, whether these are direct or indirect and whether they are current or past as set out in the policy. Involvement in Management Board activities takes into account several factors: the nature of the declared interest, the timeframe of the interest, the type of Management Board activity, the likelihood of impact on the industry, and the action requested from the Management Board member. Where a direct or indirect interest is declared by the Management Board member and creates a competing interest for an agenda item, the individual Management Board member will be restricted from participating and voting, if applicable, regarding that agenda point. Such restrictions are announced for each individual affected with the agenda points indicated at the outset of the meeting and the persons affected and the agenda points restricted are reflected in the meeting minutes. In 2021, the occasions where a Management Board member was restricted regarding a topic on the agenda were limited and had no impact on the work of the Management Board.

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

In 2021, one Management Board member informed the Agency of their intention to become an employee in a pharmaceutical company. In line with the guidance document, the member was immediately fully restricted from further involvement in any Management Board activity. The imminent employment in a company did not constitute a conflict for any of the ongoing activities of the Board.

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 2021 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 2021.

No *ex post* controls were performed in 2021 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 2021

The Management Board is accountable for all EMA activities, including as from 2022 the new activities on medical devices. Given the decision-making role of the Management Board in many areas of EMA activities and the existing alignment of Policy 0058 with Policy 0044 for reasons of consistency, it is proposed to ask Management Board members to declare interests in the medical device industry. Where such interests are declared the member in question would be restricted from participating in decisions of a related nature for topics on the agenda of the Management Board. Policy 0058 for Management Board members will be revised accordingly.

4. EMA staff

4.1. 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 is aligned, where relevant, to the policies in place for the Management Board members (Policy 0058) and the scientific committees' members and experts (Policy 0044). The changes endorsed by the Management Board in October 2020 were the inclusion in the definition of financial interests of stock warrants, and introduction of a definition of partner. The rules apply in general to all temporary and contract agents, national experts on secondment, trainees, interims and visiting experts, as well as to candidates before recruitment. Information guidance is provided to reporting officers on how the evaluation of the declared interests should be done, the criteria for the identification of risks and which risk mitigation measures to apply for either scientific/regulatory or administrative/technical duties.

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

4.2. Facts and figures

4.2.1. Declared interests

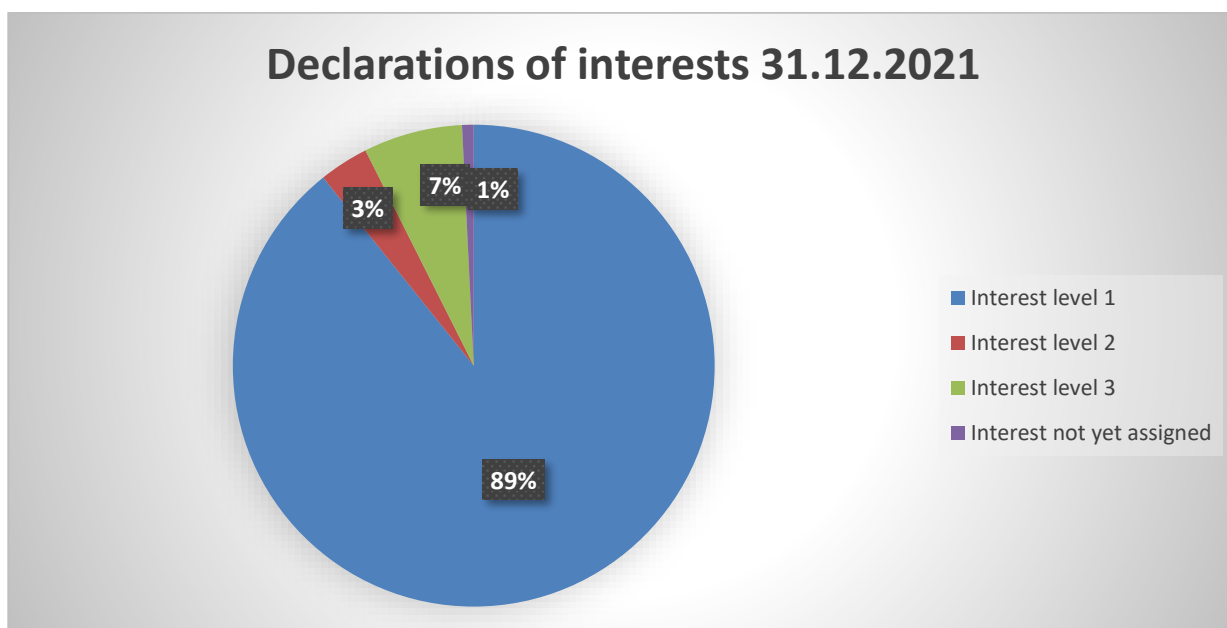
Each staff member or a candidate is assigned by the reporting officer to one of the interest levels, detailed below, based on his/her declared interests.

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

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

The graph below shows the distribution of staff's interest levels for all EMA staff on 31 December 2021.

- Staff assigned interest level 1: 89% with no declared direct or indirect interests.
- Staff assigned interest level 2: 3% who declared indirect interests.
- Staff assigned interest level 3: 7% who declared direct interest.
- Staff with no interest level assigned yet to their latest DoI: 1%



4.2.2. Outcome of Joint Committee procedures

On leaving the Agency, all EMA staff members are required to seek permission to engage in an occupation within a period of two years of leaving the Agency, in accordance with Article 16 of the Staff Regulations. Applications are reviewed to establish any potential competing interests, and if so required, based on an opinion of the Agency's Joint Committee, the Executive Director (or the Management Board in the case of the Executive Director) will issue a decision, which may impose restrictions on the staff member's intended occupation to mitigate any potential competing interests. Examples of restrictions include: a distance clause, whereby the former staff member may not contact

individual Agency staff as regards any professional activity he/she may have dealt with in the performance of his/her responsibilities while at the Agency, e.g. 6-12 months; explicit prohibition of handling medicinal-product dossiers on which they have worked during their employment at EMA.

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

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

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

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

For the period from 1 January 2021 to 31 December 2021, staff and Seconded National Experts (SNEs) made a total of 26 applications, resulting in 19 authorisations without restrictions, 5 staff authorisations with restrictions, and 2 SNE cases with restrictions.

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

4.2.3.1. *Ex post* control 2021

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

Following the ex-post control carried out in 2020 on staff DoI with an interest level 2 and 3, reporting officers were contacted to correct mistakes where identified. The internal instruction (SOP 0101 on conducting checks for conflict of interests of EMA employees) was updated in August 2021 to reflect the new organisational structure. A close monitoring of DoI compliance, including reminders to reporting officers to assign the interest level on time, has taken place during 2021. A first refresher training on Ethics at EMA, including information on EMA's code of conduct and conflict of interest was delivered in 2021 and more sessions will take place in 2022. Furthermore, specific training targeting reporting officers on declarations of interests will be developed during 2022.

No *ex post* controls were performed in 2021 due to the business contingency status of the Agency.

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 2021

In view of the extended mandate of the Agency, the management of EMA staff declaration of interests has been reviewed. EMA staff will provide support to medical devices-related procedures from the EXPAMED panels and the Medical Devices Shortages Steering Group. Therefore, it is envisaged to ask all staff to declare interests in the medical device industry, including Notified Bodies. EMA staff shall not hold any current direct interests in medical device industry, i.e. employment, consultancy, strategic advisory role, financial interests. Staff would be required to divest themselves of any medical device financial investments within a 6-month period. Restrictions would be applied to staff with a past employment history or other past interests in the medical device industry with a similar approach as currently applies for interests in the pharmaceutical industry. EMA staff nominated in an expert capacity to the ETF are asked to make an e-DOI as an expert which is published along with their CV.

This approach is conservative and the most transparent option and consistent with the rules applicable to staff as regards with medicinal products. The decision on rules for staff will be updated accordingly and presented to the Management Board for adoption in 2022.

EMA has been recruiting and onboarding staff since Q4/2021 for the EXPAMED Secretariat functions. As the current decision on rules for staff does not address explicitly competing interests in the medical device industry and in a cautious approach, EMA has applied directly Art. 11 of the Staff Regulations. Pending a revision of the Management Board Decision on handling staff declarations of interest, new staff are being asked, specifically, to declare interests in medical devices industry, including current financial interests and close family members current interests. The staff are being alerted that they would need to dispose of their own financial interests and once the decision on rules for staff is amended.

5. Recommendations for further improvement

Taking into account the legislative changes that take effect in 2022 and the experience gained in 2021 with the operation of the various policies on independence, the following recommendations for further improvement are made:

5.1. Recommendations resulting from legislative changes impacting aspects of the existing EMA policies on independence

5.1.1. Recommendations for EMA Policy 0044

- For the purpose of defining the medical device industry the definition from the EXPAMED policy will be considered.
- Policy 0044 will be amended with regards to interests in the medical device industry and to include with its scope the Medicines Shortages Steering Group, Medical Device Shortages Steering Group and Emergency Task Force as relevant.

- The EC policy for EXPAMED panel members will be applied to the activities of the panels. A breach of trust procedure, based on the EMA breach of trust process and procedure, will be proposed to the Commission for its consideration.

5.1.2. Recommendations for EMA Policy 0058

- Policy 0058 for Management Board members will be amended to require Management Board members to declare any interests in the medical device industry and to define relevant restrictions on involvement in Management Board activities.

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

- The Management Board decision on rules for EMA staff will be amended to require candidates and EMA staff to declare any interests in the medical device industry and to define relevant restrictions on involvement in EMA activities. EMA staff shall not hold any current direct interests in medical device industry, i.e. employment, consultancy, strategic advisory role, financial interests. The staff would be required to divest themselves of any medical device financial investments within a 6-month period. The role of EMA staff as ETF experts and the related need for an expert e- DOI will be included.
- Specific training targeting reporting officers on declarations of interests will be developed during 2022.

5.2. Recommendations resulting from the 2021 ex post controls

The 2021 findings will be considered following the conclusion of the ex post control focused on Scientific Advisory Group (SAG)/Ad Hoc Expert Group (AHEG) that is planned to be completed by the end of Q1/2022. The findings and related recommendations will be reported to the Management Board.

5.3. Other recommendations

- EMA will continue to maintain the minimum implementation measures following the General Court Judgment on the Aplidin case and, as an intervener, will continue to support the appellate proceedings launched by two Member States.
- EMA will consider any impact to Policy 0044 following the delivery of the judgment in the appellate proceedings.
- The EMA Experts database replacement project is in preparation to create a new tool which will include also DoIs for the EXPAMED members.
- Further refresher training to EMA staff on Ethics at EMA, including information on EMA's code of conduct and conflict of interest will be delivered in 2022.

6. Planned initiatives for 2022

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

- Monitor the implementation of EMA Policy 0058.

- Monitor the implementation of EMA Policy 0044.
- Monitor the implementation of the Management Board Decision on rules relating to Articles 11, 11a and 13 of the Staff Regulations concerning the handling of declared interests of EMA staff.
- Training for EMA staff on the operation of Policy 0044 and the Management Board decision on rules for EMA staff will be organised as required
- 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.
 - *Ex ante* controls will continue in the context of EMA Policy 0058. An *ex post* control will be undertaken.
 - An *ex post* control will be undertaken in the context of the Management Board Decision on rules for Agency staff with interest level 2 and 3.

7. Conclusions

The Agency, through its various policies and rules, has implemented clear rules with robust measures and controls in its processes and systems that mitigate the risks arising from competing interests. The impact of the recent legislative changes have been taken into account and the necessary extension of the relevant policies has been undertaken. The Agency shall continue to review and adapt its rules in light of any relevant guidance that may emerge from the Court of Justice of the European Union.

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.