17 March 2025
EMA/573980/2024 – Endorsed
Institutional and Policy Department

2024 - European Medicines Agency Annual Report on Independence

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Table of Contents

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 2016. This report reflects the status of each of the independence policies (for scientific committees' members and experts, for Management Board members, for EMA staff and the expert panels in the field of medical devices (so-called 'EXPAMED')) including their implementation as of the end of 2024.

This report to the Management Board provides facts and figures (including information on the launch and outcome of Breach of Trust procedures), gives information on initiatives taken in 2024 and identifies recommendations for further improvement in 2025.

2. Scientific committees' members and experts

2.1. Status of EMA Policy 0044

The current version of Policy 0044 for scientific committees' members and experts was approved by the Management Board in December 2022 and entered into force on 1 January 2023. The revision resulted from:

- the additional responsibilities for the Agency, following its involvement in certain medical device and in vitro medical device procedures, as set out in Regulations (EU) 2017/745 and 2017/746, which requires members and experts now to declare also interests in the medical device industry which could affect their impartiality;
- the Agency's extended mandate in accordance with Regulation (EU) 2022/1231, which reinforced its role in crisis preparedness and management and which established new bodies within EMA (Emergency Task Force, Medicines Shortages Steering Group and Medical Devices Shortages Steering Group) to which the policy will also apply;

In 2024, EMA undertook a comprehensive revision of the policy in the light of emerging court judgments (see section 2.3 for more details). Following a public consultation, the revised policy was adopted by the Management Board in December 2024 and will apply as of 1 May 2025.

2.2. Facts and figures

2.2.1. Declared interests

Policy 0044 applies to members and experts of EMA's scientific committees, working parties, and other bodies, such as the Emergency Task Force (ETF), the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG), and the Executive Steering Group on Shortages of Medical Devices (MDSSG).

EMA requires an annual update of the declaration of interest (DoI) as well as an updated DoI for any change in the status of a member or an expert. EMA also has a Declaration of Interest/Conflict of Interest community composed of EMA staff members with experience in handling of competing interest, who can provide advice on the evaluation of DoIs of scientific committees' members and experts.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32022R0123

The distribution of experts by interest level (i.e. no, indirect or direct interests[2] declared in their DoI) as of on 31 December 2024 is presented in Figure 1 below. The distribution of chairs, members and alternates by interest level across scientific committees and other bodies (ETF, MSSG and MDSSG) is presented in Annex (Table 1).

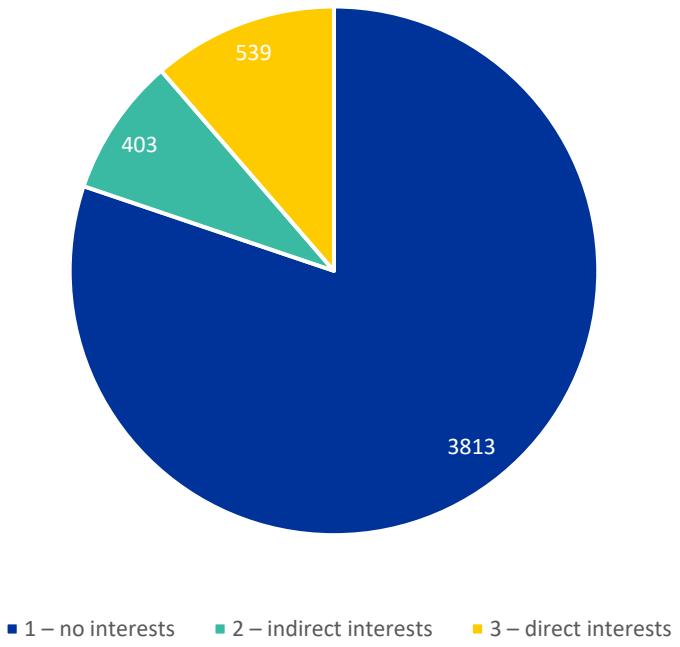

Figure 1. Distribution of all medicines experts (n=4,755) by interest level (31 December 2024)

For the handling of DoIs submitted by members and experts of scientific committees' and the Agency's other bodies, a 2-step procedure applies: firstly, an interest level is automatically assigned to the 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 of 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 annexes. Some interests result in an exclusion of the expert from any involvement in the Agency's activities, other interests result in a restricted involved, e.g. no involvement in procedures on the declared product or any product from the declared company while committee membership is allowed.

[2] Direct interest in a pharmaceutical company, a medical device company or the biotechnology sector: employment, consultancy, strategic advisory role, financial interest, repurposing.
Indirect interest in a pharmaceutical company, a medical device company or the biotechnology sector: (principal) investigator, repurposing, grants/funding to organisation/institutions, close family member direct interests.

Taking into account the pool of experts available, the Agency works to ensure that the experts involved in a specific procedure do 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 accordance with the policy, if a scientific committee/other (scientific) expert group member intends to be engaged in occupational activities (such as employment) with a pharmaceutical company, medical device company or in the biotechnology sector, the member shall immediately inform the Agency. In 2024, 12 delegates (7 scientific committee members: 1 CHMP, 3 CAT, 1 PRAC, 2 COMP; 5 working party members: 1 MWP, 1GCG, 3 inspectors working group) informed the Agency of their intention to become an employee in a pharmaceutical company. The members were immediately fully restricted from further involvement in any Agency activity.

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 in 2012.

The BoT procedure was last revised in December 2022 (EMA/154320/2012 Rev 3) to align it to the latest changes to Policy 0044. The revised procedure now also applies to the other bodies that were established within the Agency under the Extended Mandate (i.e. ETF, MSSG and MDSSG).

One BoT procedure was initiated and concluded in 2024. The case concerned an expert who had not declared current and past consultancy interests in pharmaceutical companies which were incompatible with participation as expert in the activity concerned It was found that the failure to declare the interest constituted negligence to comply with the EMA policy, but it had not occurred intentionally or through gross negligence. The expert was no longer allowed to be involved in the ongoing EMA activity concerned and was required to read and study the policy, take it into consideration for any future involvement in EMA activities and was reminded to update their declaration of interests when interests change or new interests arise.

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

2.2.3.1. Ex ante controls 2024

Ex ante controls have been carried out by the Agency systematically on all new nominated experts since June 2013, at time of registration in the Experts Management Tool. The *ex ante* controls check that

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

In 2024, 951 new experts registered in the Experts Management Tool and their DoI were checked. An error was noted in 36 DoIs (3.8%). The nature of the errors in 2024 (19 out of 36) was that these experts failed to declare in their DoI their recent employment, consultancy or (principal) investigator interests (in the past 3-year period) for a pharmaceutical company. EMA asked the experts to correct their DoI, resulting in a higher or same interest level being assigned to their DoI. This EMA *ex ante*/preventive check of each expert is important and is maintained to ensure a low number error on the DoIs of experts and to ensure that the necessary restrictions will be imposed on the expert.

2.2.3.2. Ex post controls 2024

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 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 correct reflection in the meeting's minutes by the Agency of the level of participation in the meeting (full or restricted involvement).

The *ex post* control carried out in 2024 focused on members of EMA's scientific committees and other bodies (ETF and MSSG) as well as the implementation of additional measures taken resulting from the appellate judgement of the Court of Justice in Case C-291/22 P (see section 2.3 for further details). For the control, 180 members and alternates, who participated to meetings of EMA's scientific committees or other bodies during the period 1 June to 31 December 2024, were randomly selected. The control was completed in February 2025.

Overall, the control showed that the system for handling declarations of interests works well with no major weaknesses identified in the processes in place.

The following six findings (3% of the selected samples) were identified:

- Four findings of incorrect evaluation of DoI and/or incorrect implementation of restrictions, which resulted in restrictions not being applied to three members (although not in Rapporteur/leading role) during meeting discussions on relevant procedures
- The DoI of one member was incomplete, with information reported in the CV missing from the DoI. The adequate restrictions had nevertheless been identified based on the CV and a DoI submitted in the context of another EMA activity.
- Restrictions applied to one member were stricter than required by the policy.

Where required, corrective actions have been taken for these findings (e.g. correction of DoI and of evaluation). In addition, EMA identified a few process improvements based on this *ex post* control.

2.2.4. Transparency measures

The 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 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 DoIs by Agency staff.

2.3. Initiatives launched in 2024

The following initiatives were launched or implemented in 2024:

- **Delivery of the appellate judgment in Joined Cases C-6/21 P and C-16/21 P and in Case C-291/22 P**

  On 22 June 2023, with its judgment in Joined Cases C-6/21 P and C-16/21 P, the Court of Justice set aside the first-instance judgment of 28 October 2020 in Case T-594/18, *Pharma Mar v Commission*. The case concerned whether a university hospital may be classified as a "pharmaceutical company" for the purpose of EMA's Policy on the handling of competing interests of scientific committees' members and experts (Policy 0044).

  In its appellate judgment, the Court of Justice took note of the fact that Policy 0044 seeks to ensure an appropriate balance between the requirement of impartiality of experts involved in EMA's activities and the requirement of scientific excellence. After reviewing Policy 0044, the Court of Justice found that a university hospital should not be qualified in its entirety as a pharmaceutical company, even when there is an entity within that organisation that would satisfy the definition of a pharmaceutical company under this Policy.

  In that connection, the appellate judgment recognised the important contribution that the staff of a university hospital represent in the context of EMA's scientific evaluation procedures.

  On 14 March 2024, with its judgment in Case C-219/22 P, the Court of Justice set aside the first-instance judgment of 2 March 2022 in Case T-556/20, *D & A Pharma v Commission and EMA*. The appellate judgment examined questions related to the organisation of EMA's Scientific Advisory Groups (SAGs) and ad-hoc expert groups (AHEGs), including questions related to the holding of current interests by members of these groups in products that are considered rival to the medicine under evaluation. SAGs and AHEGs are groups of scientific experts that are called upon to respond to specific questions posed by EMA's committees during the evaluation of a medicine.

  EMA immediately considered the impact of the appellate judgment on the evaluation of Hopveus and other ongoing or recently concluded regulatory procedures and took appropriate measures. Measures were also introduced to ensure the immediate implementation of the findings of this appellate judgment for prospective procedures, until the revision of Policy 0044 had been concluded.

- **Revision of Policy 0044 following court rulings**

  The above-mentioned Court rulings have required the Agency to adjust certain aspects of its approach. A comprehensive revision of Policy 0044 was undertaken to ensure alignment with the Court's findings and to rule out any possible doubts as to the objective impartiality of EMA's assessments.

  The revision of the policy was driven by the following elements:

  - Any current interest in a product should lead to restrictions not only for the product under evaluation but also for products in the same declared condition;
  - Related restrictions of an individual's participation should apply not only to final deliberation and voting but also to discussions;
  - The handling of competing interests should be aligned, to the extent necessary, across EMA activities (i.e. between committees and SAG / AHEGs) and across roles.

A draft revised version was open for public consultation from 10 October to 10 November 2024. EMA received comments from a wide range of stakeholders, including academia, research organisations or learned societies, patients' and healthcare professionals' organisations, and the pharmaceutical industry.

The revised policy was adopted by the Management Board in December 2024 and will apply as of 1 May 2025 to allow sufficient time to update the Experts Management Tool and related guidances.

- **Internal audit on the effective management of conflict of interest further to the recent release of the Experts Management Tool**

  In 2024, an internal audit was conducted in accordance with the Agency's 2024 Audit Plan adopted by the Management Board. The objective was to assess the effective management of conflict of interest of Management Board members and scientific experts, in view of the implementation of the Agency's new Experts Management Tool, and related operational processes as well as the internal controls (e.g. *ex post* controls) around management of conflict of interest.

  The internal audit concluded that, overall, the design of the internal control systems in place at the EMA for the management of conflict of interest of Management Board members and scientific experts supported by the new Experts Management Tool is adequate and is efficiently and effectively implemented in compliance with the applicable regulatory framework and guidelines, and is adequate to achieve its objectives. The audit report highlights certain areas of improvement and risks that need to be addressed to further enhance the Agency's ability to manage conflict of interest effectively through the Experts Management Tool.

3. Management Board members

3.1. Status of EMA Policy 0058

The current version of the policy for handling the competing interests of Management Board (MB) members (Policy 0058) was approved by the Management Board in December 2022 and entered into force on 1 January 2023. The purpose of the revision was to align with the changes due to the Agency's extended mandate taking into account the role of the MB and to align with the changes to Policy 0044 including the same definition of a medical device company. Restrictions are applied to a MB member declaring interests in medical devices and there are stricter requirements for the chair and the vice/chair.

In 2024, EMA has undertaken a comprehensive revision of its policies (see section 2.3 for more details). The revised policy was adopted by the Management Board in December 2024 and will apply as of 1 May 2025.

3.2. Facts and figures

3.2.1. Declared interests

Under Policy 0058, EMA requires an annual update of the DoI as well as an updated DoI for any change in the status of the Management Board chair, members, alternates and observers (hereafter referred to as 'members').

The distribution of the levels of declared interests (ie no, indirect or direct interests[3] declared in their DoI) of the Management Board members on 31 December 2024 is presented in Figure 2 below.

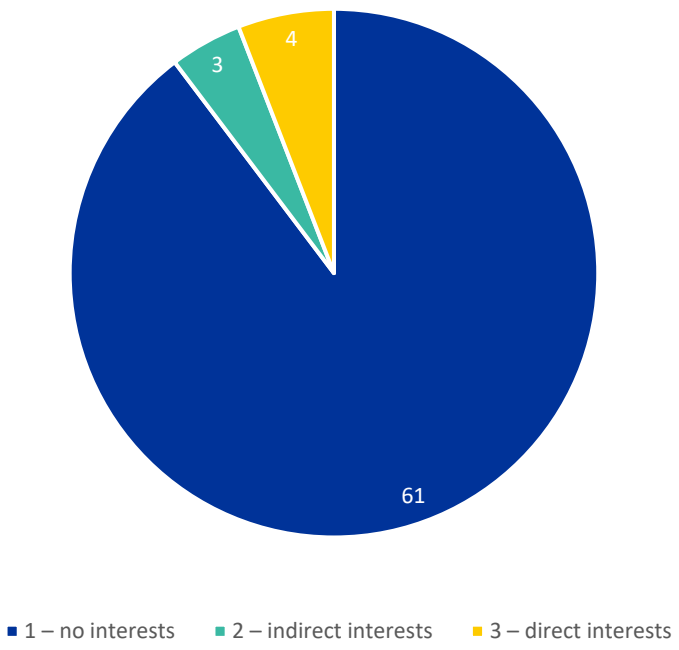

Figure 2. Distribution of Management Board members (n=68) by interest level (31 December 2024)

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 2024, 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.

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

[3] Direct interest in a pharmaceutical or a medical device company: employment, consultancy, strategic advisory role, financial interest.
Indirect interest in a pharmaceutical or a medical device company: (principal) investigator, grants/funding to organisation/institutions, close family member direct interests.

In accordance with the policy, if a Management Board member intends to be engaged in with a pharmaceutical or medical device company (such as employment) during the term of the mandate (irrespective if an employment contract with a company has been signed or not), the member shall immediately inform the Agency. In 2024, no Management Board member informed the Agency of their intention to become an employee in a pharmaceutical company.

3.2.2. Outcome of Breach of Trust procedures

Similarly to EMA's Breach of Trust (BoT) procedure for scientific committee members and experts, the Management Board BoT procedure sets out how the Agency deals with incorrect or incomplete declarations of interests and disclosure of confidential information by Management Board members. The BoT for Management Board members was last revised in 2023 (EMA/MB/309079/2012 Rev.3) to take account of the Agency's extended mandate and to align with the updated Policy 0058.

No BoT procedure was initiated in 2024 for Management Board members.

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

Ex ante controls have been carried out by the Agency systematically on all DoIs submitted by Management Board members since 2016. The *ex ante* controls check 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 2024.

In 2024, an *ex pos*t control was undertaken on DoIs submitted by Management Board members, to check:

- the correct completion of the DoI by members,
- the correct evaluation of the DoI by the Agency,
- the correct implementation of restrictions applicable to the members, alternates or observers by the Agency,
- the correct reflection in the meeting's minutes by the Agency of the level of participation in the meeting (restrictions on involvement).

Twenty (20) Management Board members who attended MB meetings during the year of 2024 were randomly selected. The control was completed in February 2025.

Overall, the control showed that the system for handling declarations of interests works well with no findings identified on the selected sample.

3.3. Transparency measures

Since 2012, the DoIs of all Management Board members 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.

3.4. Initiatives launched in 2024

- **Revision of Policy 0058**

  Policy 0058 on the handling of competing interests of Management Board members was revised to align as needed with the revised Policy 0044, including the introduction of rules to handle interests from Management Board members related to involvement or affiliation in a research organisation.

  The revised policy was adopted by the Management Board in December 2024 and will apply as of 1 May 2025 to allow sufficient time to update the Experts Management Tool and related guidances.

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 Management Board 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 for the Agency's scientific committees' members and experts (Policy 0044).

The Decision for staff was revised in 2023 due to the legislation regarding the extended mandate that introduced new tasks for the Agency in the area of medical devices. The Decision for staff is being further revised to align, where relevant, to the revision of Policy 0044. It is expected to be finalised and adopted by the Management Board in March 2025.

The rules apply in general to all temporary and contract agents, national experts on secondment, trainees, interims, collaborating 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 for staff, EMA requires an annual update 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[4].

[4] Direct interest in a pharmaceutical company or a medical device company: employment, consultancy, strategic advisory role, financial interest.

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 distribution of staff's interest levels for all EMA staff on 31 December 2024 is presented in Figure 3 below.

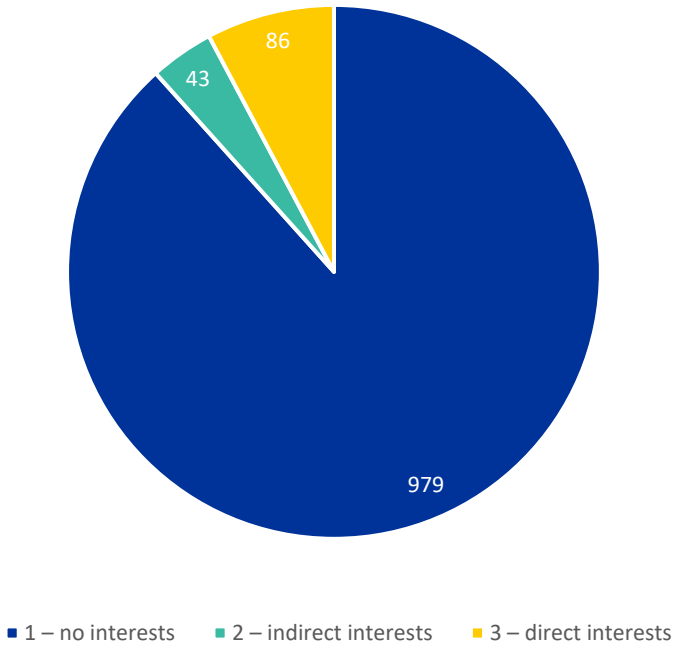

Figure 3. Distribution of EMA staff (n=1,108) by interest level (31 December 2024)

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 chair 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.

Indirect interest in a pharmaceutical company or a medical device company: (principal) investigator, grants/funding to an organisation/institution where the staff member was/is involved, close family member direct interests.

Since 18 December 2020, EMA's decisions regarding senior staff members leaving EMA are publicly available in the register on the EMA corporate website, 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's annual reports provide a summary on all staff, including senior staff, that were subject to Article 16 restrictions in a given year. It also describes the restrictions that apply for each role.

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.

One staff application initiated in 2023 was finalised in 2024 and resulted in an authorisation with restrictions. In 2024, EMA staff and Seconded National Experts (SNEs) made a total of 6 applications, which were finalised within the year. These resulted in 1 authorisation without restrictions, 3 staff authorisations with restrictions, and 2 SNE authorisations with restrictions.

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

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.

The *ex post* control carried out on a random sample of the 2024 staff declarations with an interest level 2 and 3 identified some errors in relation to the assignment of the interest level and restriction levels. However, none of these errors resulted in involvement of the relevant staff member in activities subject to restrictions. Reporting officers were contacted to correct mistakes where identified, or to remind of the timelines to assess declarations.

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 2024

- The Agency introduced a mandatory online training course on ethics for all new staff members in 2024, including a specific topic for conflict of interests. The course is also accessible to existing staff through the Agency's learning platform.
- Revision of the Management Board Decision for staff to align with the revised Policy 0044, started at the end of 2024 and is expected to be adopted in March 2025.

5. Expert panels in the field of medical devices (EXPAMED)

5.1. Status of Policy (Expamed document D 4.3)

The European Commission's Joint Research Centre (JRC) created the expert panels according to the mandate from the Medical Device Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR). The expert panels were transferred to the EMA on 1 March 2022, following the applicability of the Extended Mandate Regulation (EU) 2022/123 on the reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.

The expert panels support the conformity assessment of high-risk medical devices by Notified Bodies through the opinions for the clinical evaluation consultation procedure and for in vitro diagnostics through the views from the performance evaluation consultation procedure. The expert panels also provide advice to manufacturers in the field of high-risk medical devices. The experts can be assigned one of 5 roles: Chair, Vice-chair, Rapporteur, Co-Rapporteur and reviewer. The Agency provides administrative, technical and scientific support to the expert panels.

According to Article 106 and Article 107 of the MDR, expert panel members shall perform their tasks with impartiality and shall not have financial or other interests in the medical device industry which could affect their impartiality. To this effect the European Commission adopted a Policy on the management of competing interests of members of the expert panels on medical devices and in vitro diagnostic medical devices.[5]

Interests from members of the expert panels are declared and evaluated by EMA in accordance with this policy: a DoI needs to be completed by all candidates applying to the call for expression of interest for expert panels on medical devices and in vitro diagnostic medical devices. Moreover, a DoI needs to be completed and regularly updated by all advisors appointed as expert panel members. The DoI should be updated without delay if there is a change of interests or new interests declared during the course of the term.

5.2. Declared interests

The distribution of all experts involved in expert panels by interest level (ie with no, indirect or direct interests[6] declared in their DoI) as of 31 December 2024 is presented in Figure 4 below. The distribution across the different expert panels is presented in Annex (Table 2).

[5] EXPAMED document D4.3: https://health.ec.europa.eu/system/files/2023-04/policy-mngt-conflicts_en.pdf
[6] Direct interests in a medical device company: employment, consultancy, strategic advisory role, financial interests. Indirect interests in a medical device company: (principal) investigator, grant/other funding to the expert's organisation/institution, close family member direct interest.

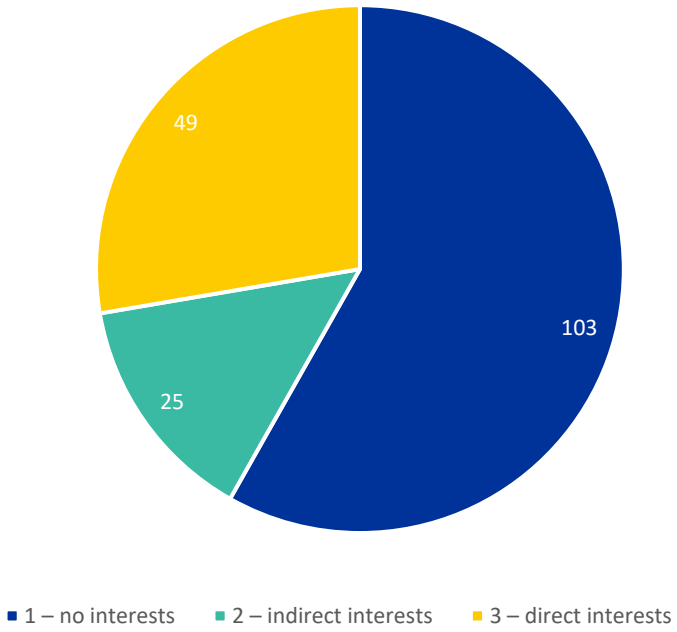

Figure 4. Distribution of all EXPAMED experts (n=177) by interest level (31 December 2024)

The handling of declared interests is based on a two-step procedure. Following receipt of the DoI an interest level is assigned 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 expert panel activities is determined taking into account the assigned interest level, the task at hand, the envisaged role of the expert as well as the relevant interest and resulting restrictions.

The restrictions applicable in the event that direct or indirect interests are declared, are set out in Annex 1 of the Policy. Some interests result in an exclusion of the expert from any involvement in the expert panel, other interests result in a restricted involved, e.g. no involvement in procedures on the declared medical device or any medical device from the declared company, while membership in the panel is allowed.

5.3. Outcome of ex post control

In 2024, an *ex post* control was undertaken on DoIs submitted by members of the expert panels to check:

- the correct completion of the DoI by experts,
- the correct evaluation of the DoI by the Agency prior to involvement in a panel task,
- the correct implementation of restrictions applicable to the expert by the Agency (i.e. no involvement of the expert).

A total of 40 members of expert panels were randomly selected among those involved in the provision of screening decisions and scientific opinions/views in relation to the clinical/performance evaluation

consultation procedures (CECP/PECP) of certain high-risk medical devices and specific in vitro diagnostic medical devices. The control was completed in February 2025.

Overall, the control showed that the system for handling declarations of interests works well with no major weaknesses identified in the processes in place.

The following 9 findings (22,5 % of the selected sample) were identified:

- No records were found for the evaluation of the DoI of one expert in relation to their assignment to a panel task.
- In 8 findings, evaluation of the DoI was conducted in the Experts Management Tool but not 'approved' by relevant EMA staff, as foreseen in the internal process, prior to the assignment of the panel task.

However, none of these experts had competing interests with the medical device or company concerned by the procedure in which they were involved.

Where required, corrective actions have been taken with respect to approval of the evaluations in the Experts Management Tool. In addition, EMA identified minor process improvements (e.g. clarification of internal processes and trainings) based on this *ex post* control.

5.4. Transparency measures

The DoIs and the CVs of all expert panel members are published on the European Commission's website.

6. Recommendations for further improvement

Taking into account experience gained in 2024 with the operation of the various policies on independence, the following recommendations are made:

- The implementation of the revised Policy 0044 and 0058 will be monitored, in particular with respect to the use of expert witnesses and access to relevant expertise. This shall be reported to the Management Board in its next annual report on independence.
- The Experts Management Tool will be updated to implement changes to the DoI and to the performance of evaluations due to the policies revision.
- Information session and training for scientific committees' members and experts and EMA staff on the operation of the revised Policy 0044 will be organised as required.

7. Planned initiatives for 2025

- Implement the revised policies from 1 May 2025. Until then, EMA continues to apply the current effective policy, taking into account the mentioned court rulings.
- Revise the relevant procedural guidances to take account of the changes to Policy 0044 and the introduction of the Experts Management Tool.
- Revise 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 and monitor its implementation.

- Organise a training for EMA managers on the revised Management Board decision on rules for EMA staff.
- Revise the EMA Code of conduct, in particular to align aspects related to competing interests with the revision of the policies.
- 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* and *ex post* controls will continue in the context of EMA Policy 0058.
- Monitor the implementation of EMA Policy 0044.
- Monitor the implementation of EMA Policy 0058.

8. Conclusions

The Agency, through its various policies and rules, continues to implement 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 Court rulings have been immediately taken into account while the necessary revision of the relevant policies has been undertaken. The Agency shall continue to review and carefully monitor the impact of the implementation of the revised Policy 0044, in particular with regards to the use of Expert Witnesses and access to relevant expertise. This shall be reported to the Management Board in its next annual report on independence.

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.

Annex

Table 1. Distribution of Scientific committees and other bodies (ETF, MSSG and MDSSG) chairs, members and alternates by interest level (31 December 2024)

Interest level	CHMP	CVMP	CAT	COMP	HMPC	PDCO	PRAC	ETF	MSSG	MDSSG	All experts*
1 – no interests	53	55	52	24	48	46	57	26	26	29	3,813
2 – indirect interests	6	3	8	7	2	13	9	2	2	1	403
3 – direct interests	4	0	5	2	1	2	1	1	7	2	539
Total	**63**	**58**	**65**	**33**	**51**	**61**	**67**	**29**	**35**	**32**	**4,755**

(* with an up-to-date DoI)

Table 2. Distribution of EXPAMED expert panels' members by interest level (31 December 2024)

Interest level	Screening Panel	Orthopaedics, traumatology, rehabilitation, rheumatology	Circulatory system	Neurology	Respiratory system, anaesthesiology, intensive care	Endocrinology and diabetes	General and plastic surgery and dentistry	Obstetrics and gynaecology	Gastroenterology and hepatology	Nephrology and urology	Ophthalmology	In vitro diagnostic medical devices	All experts*
1 – no interests	30	12	16	9	2	1	8	1	2	2	2	17	103
2 – indirect interests	9	4	7	2	-	1	-	-	-	-	-	2	25
3 – direct interests	18	3	7	2	1	2	3	1	4	1	1	3	49
Total	**57**	**19**	**30**	**13**	**3**	**4**	**11**	**2**	**6**	**3**	**3**	**22**	**177**

(* with an up-to-date DoI)