EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Institutional and Policy Department

# 2025 - 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 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 2025.

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 2025 and identifies recommendations for further improvement in 2026.

# 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 2024 and entered into force on 1 May 2025.

This latest revision aimed to align with the findings in the rulings of the Court of Justice in Joined Cases C-6/21 and C-16/21 P and Case C-291/22 P.

The main changes were the following:

- Increased and aligned restrictions across roles and groups for experts with a current interest on a product, including exclusion from procedures related to the product concerned and also products in the same declared condition. Experts with an interest as principal investigator and investigator will be subject to the same restrictions.
- Aligned restrictions across roles and groups, including a unified 3-year cooling-off period for past employment in a pharmaceutical company, consultancy / strategic advisory role, and past activity as (principal) investigator. The same rules will apply to experts involved on an ad-hoc basis that apply to Committee members.
- Strengthened handling of competing interests in the medical device industry.
- New rules to handle certain interests in research organisations.
- Clarification on the use of expert witnesses for providing specialist advice on specific issues.

## *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.

The distribution of experts by interest level (i.e. no, indirect or direct interests[1] declared in their DoI) as of on 31 December 2025 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).

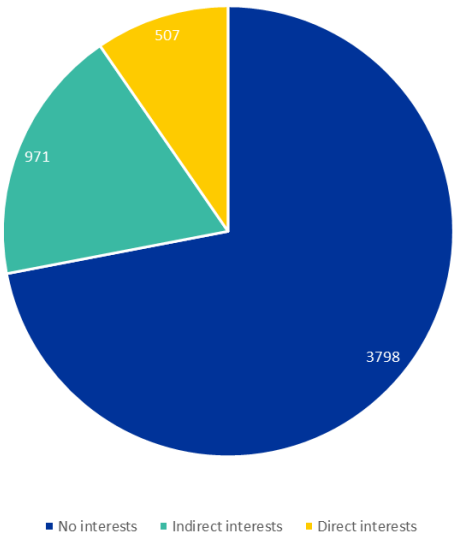


**Figure 1. Distribution of all medicines experts (n=5,276) by interest level (31 December 2025)**

Due to the implementation of the revised policy 0044 (see section 2.1 and 2.4), all members and experts were contacted to update their DoI for any involvement in EMA activity after 1 May 2025.

Only very few (4) scientific committee or other group members had an interest incompatible with membership in accordance with the revised policy. All ceased the interests in order to remain member.

As a consequence to this revision, an increase in the number of experts with indirect interests was also noted compared to 2024 (403 in 2024 vs 971 in 2025). This is mainly due to the new requirement for members and experts to declare current affiliation to a research organisation as an indirect interest, as many members and experts also work for universities or hospitals. However, instances where members or experts would be subject to restrictions to their participation in light of these new declared interests from the revised policy were very limited, as universities or hospital are rarely applicants of submissions to EMA.

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

[1] Direct interests: employment, consultancy/strategic advisory role, financial interest in a pharmaceutical company, a medical device company or company in the biotechnology sector, involvement in a unit of a research organisation that manufactures medicinal products (including ATMPs under the hospital exemption) or medical devices, or that acts as a marketing authorisation applicant or holder for a medicinal product, involvement in the conduct of research and development activities at a research organisation for a medicinal product or a medical device subject to an agreement with a company.
Indirect interests: (principal) investigator for a study instigated/sponsored by a company, grants/funding to organisation/institutions, close family member direct interests, regulatory engagement on academic research, affiliation to a research organisation.

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, in procedures on products in the same condition as declared or any product from the declared company.

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.

### 2.2.2. Intention to become engaged in occupational activities

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 company or in activities in research organisation that are incompatible with participation in any activities at the Agency, the member shall immediately inform the Agency.

In 2025, 1 PRAC member and 1 MWP member 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.

### 2.2.3. Outcome of Breach of Trust procedures

The EMA breach of trust (BoT) procedure for competing interests and disclosure of confidential information of scientific committee members and experts was introduced in 2012.

The BoT procedure was last revised in December 2025 (EMA/154320/2012 Rev 4) in order to bring further clarity in particular between the 'investigation' and actual 'initiation' and conduct of the procedure and on the factors triggering the initiation of the procedure, focusing on cases with apparent intention or gross negligence (see section 2.4).

In 2025, the Agency conducted two investigations following information or knowledge of possible omission to declare an interest. In these cases, experts omitted to declare interests that were not compatible with their participation in EMA activities (financial interests and current consultancy for a pharmaceutical company, respectively). Following clarifications and exchanges with the experts concerned, relevant remedial actions were undertaken resulting in the disposal of the interest in one case and cessation of the expert's participation in EMA activities while the interest remains in the other case. In both cases, the Agency concluded that breach of trust procedures were not warranted as the omissions to declare were not intentional or done through gross negligence.

## 2.2.4. Outcome of *ex ante* and *ex post* controls

### *2.2.4.1. Ex ante controls 2025*

*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 (EMT). 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 2025, 934 new experts registered in the Experts Management Tool and their DoI were checked. An error was noted in 46 DoIs (4.9%). The errors were related to:

- omission by the expert to declare in their DoI their recent employment, consultancy or (principal) investigator interests (in the past 3-year period) for a pharmaceutical or medical device company mentioned in their CV (15);
- omission to declare in their DoI their current affiliation to a research organisation mentioned in their CV as required by the latest version of Policy 0044 (14);
- declaration of an interest which was not required to be declared in accordance with the policy or procedure guidance (10);
- inaccuracies in the completion of the DoI (e.g. incorrect section or dates) (7).

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 new nominated 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.

### *2.2.4.2. Ex post controls 2025*

*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 2025 focused on members of EMA's scientific committees and other bodies (ETF and MSSG) working parties and other groups as well as scientific advisory groups (SAGs) and Ad hoc expert groups (AHEGs). The control also looked at a small sample of observers from EDQM and WHO. The control covered meetings held between 1 May 2025 and 31 December 2025, following the implementation of the revised policy. A total of 225 members (and alternates where applicable) were randomly selected across these groups. The control was completed in February 2026.

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 23 findings (10,2% of the selected samples) were identified:

- For two working parties, while the evaluation of competing interest was performed adequately, the records and documents related to the steps taken to assess DoIs prior to meetings were found to be insufficiently detailed.
- Two findings related to incomplete or inaccurate information in the list of participants and applicable restrictions in meeting minutes.
- In 17 cases, inconsistencies were observed between experts' DoIs and CV or between different versions of experts' DoI available in the EMT, which should have required clarifications from the experts concerned.
- Two findings related to the use of an outdated DoI for the purpose of evaluation prior to participation in a meeting.

However, none of these findings resulted in the participation of experts with competing interests in a meeting and/or on specific agenda topics.

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.

## *2.3. Transparency measures*

The DoIs, their assigned interest levels and the CVs of all scientific committees' and other groups' 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, CHMP, CVMP and CAT since December 2013 and MSSG since May 2022). The minutes include information on the restrictions applicable to meeting participation following the assessment of the DoIs by Agency staff.

## *2.4. Initiatives launched in 2025*

The following initiatives were launched or implemented in 2025:

- **Implementation of the revised Policy 0044**

  In order to support the implementation of the revised policy from 1 May 2025, an update of EMA's Experts Management Tool (EMT) was undertaken: this included changes to the DoI form and the DoI evaluation functionality in the EMT in alignment with changes in Policy 0044.

  Subsequently, to comply with the new policy, all members and experts were requested to submit an update to their DoI in EMT for any involvement in EMA activities after 1 May 2025.

  Between March and April 2025, several information and training sessions were provided to scientific committees and other groups' members and EMA staff involved in the evaluation of DoI. In additional, all experts registered in the EMT were invited to a training session aimed at providing an overview of the revised policy and guidance to facilitate the update of their DoI.

  In addition, the procedural guidance to scientific committees' members and experts on completing the EMA declaration of interests in the EMT was revised and published on the EMA website. The purpose of this guidance is to help experts to complete the DoI in the EMT in accordance with Policy 0044, as well as for EMA staff to guide experts in completing the DoI correctly. It highlights

key aspects of declaring interests and clarifies what information should be mentioned in which section of the DoI.

EMA also supported the Heads of Medicines Agency (HMA) in the revision of its Guide to Managing Declarations of Interests to align it with Policy 0044.

- **Revision of the guidance on handling EMA scientific committee, Management Board or other group member's intention to engage in occupational activities**

  In line with Policy 0044, members of EMA's scientific committees and other groups shall immediately inform the Agency if they intend to engage (either solicited or not) in paid or unpaid occupational activities. Upon notification, the Agency will promptly restrict their involvement in EMA activities.

  A guidance, in place since 2015, details the operational steps the Agency takes following such notification. A revision of this guidance was initiated following the revision of Policy 0044 and the main changes relate to the inclusion of interests in medical device companies and research organisations from the revised policy 0044 requiring immediate notification to the Agency, inclusion of a reference to the obligation of professional secrecy after ceasing activities with EMA and streamlining of the steps to be taken by the Agency. In addition, reference is included to Management Board members in view of the similar obligation in Policy 0058 (see section 3.4).

- **Revision of the Breach of trust procedure for competing interests and disclosure of confidential information by European Medicines Agency's scientific committees' members and experts**

  In 2024, an internal audit on the effective management of competing interests recommended the development of internal guidances to supplement and facilitate implementation of the actual breach of trust (BoT) procedures. During the development of the internal guidances, EMA also undertook a review of cases handled over the past years and the steps described in the BoT procedures.

  As a result, changes were made to the BoT procedures to bring further clarity in particular between the 'investigation' and actual 'initiation' and conduct of the procedure and to provide clarification on the factors triggering the initiation of the procedure, focusing on cases with apparent intention or gross negligence.

  The revised procedure (EMA/154320/2012 Rev 4) was adopted by the Management Board in December 2025 and published on the EMA website.

# 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 2024 and entered into force on 1 May 2025. The policy had been revised to align with the revised 'Policy 0044' (see section 2.1) including the introduction of rules to handle interests from Management Board members related to involvement or affiliation in a research organisation.

## *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[2] declared in their DoI) of the Management Board members on 31 December 2025 is presented in Figure 2 below. There has been a minor increase in indirect interest related to declared close family members interests.

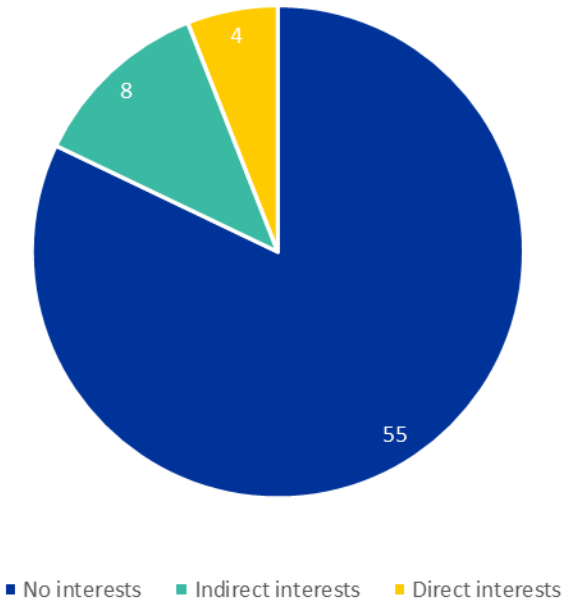


**Figure 2. Distribution of Management Board members (n=67) by interest level (31 December 2025)**

In line with the Policy, the Management Board Secretariat ensures that all members have a valid DoI before participation to any Board-related activities, including attendance at meetings and receipt of correspondence.

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

[2] 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.

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 2025, 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.

### 3.2.2. Intention to become engaged in occupational activities

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 2025, no Management Board member informed the Agency of their intention to become an employee in a pharmaceutical company.

### 3.2.3. 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 2025 (EMA/MB/309079/2012 Rev.4) to bring further clarity in particular between the 'investigation' and actual 'initiation' and conduct of the procedure and on the factors triggering the initiation of the procedure, focusing on cases with apparent intention or gross negligence (see section 3.4).

No BoT procedure was initiated in 2025 for Management Board members.

### 3.2.4. 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.

Only one minor inconsistency was detected in the submissions received in 2025 and corrected by the member accordingly.

In 2025, 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).

Thirty (30) Management Board members who attended MB meetings between 1 May 2025 and 31 December 2025 (following the revision of Policy 0058) were randomly selected. The control was completed in February 2026.

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 5 findings (16.7% of the selected sample) were identified:

- In 4 findings, DoI evaluations were performed in the Experts Management Tool prior to the meetings concerned but not 'approved' by relevant EMA staff prior to the meeting.
- One finding pertained to an updated DoI submitted on the first day of a meeting which was not re-evaluated in the Experts Management Tool during the meeting itself.

None of these findings had an impact on Management Board decision-making. EMA identified a few process improvements based on this *ex post* control.

## *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 2025*

The following initiatives were launched or implemented in 2025:

- **Implementation of the revised Policy 0058**

  In order to support the implementation of the revised policy from 1 May 2025, an update of EMA's Experts Management Tool (EMT) was undertaken: this included changes to the DoI form and the DoI evaluation functionality in the EMT in alignment with changes in Policy 0058.

  Subsequently, to comply with the new policy, all MB members were requested to submit an update to their DoI in the EMT for any involvement in the EMA Management Board after 1 May 2025.

- **Revision of the guidance on handling EMA scientific committee, Management Board or other group member's intention to engage in occupational activities**

  In line with Policy 0058, members of EMA's Management Board shall immediately inform the Agency if they intend to engage (either solicited or not) in paid or unpaid occupational activities. Upon notification, the Agency will promptly restrict their involvement in EMA activities.

  As indicated in section 2.4, a guidance, in place since 2015, details the operational steps the Agency takes following such notification and was updated following the revision of Policies 0044 and 0058. The guidance now includes a reference to Management Board members in view of the similar obligation in Policy 0058.

- **Revision of the Breach of trust procedure for competing interests and disclosure of confidential information by members of the European Medicines Agency's Management Board**

  In 2024, an internal audit on the effective management of competing interests recommended the development of internal guidances to supplement and facilitate implementation of the actual breach of trust (BoT) procedures. During the development of the internal guidances, EMA also

undertook a review of cases handled over the past years and the steps described in the BoT procedures.

As a result, changes were made to the BoT procedures to bring further clarity in particular between the 'investigation' and actual 'initiation' and conduct of the procedure and on the factors triggering the initiation of the procedure, focusing on cases with apparent intention or gross negligence.

The revised procedure (EMA/MB/309079/2012 Rev.4) was adopted by the Management Board in December 2025 and published on the EMA website.

# 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 and adopted by the Management Board on 20 March 2025 to align, where relevant, to the revision of Policy 0044.

The main changes included:

- Update to the definitions to fully align to the definitions in Policy 0044;
- Alignment of restrictions for EMA staff based on duties;
- Unified 3-year cooling-off period for **past employment** in a pharmaceutical company, consultancy / strategic advisory role, and past activity as (principal) investigator;
- Strengthened handling of competing interests in the **medical device industry** (no financial interests in the medical device industry permitted);
- New rules to handle certain interests in **research organisations.**

To support the implementation of the revised Decision from 1 May 2025, the DoI form was updated in the Agency's HR tool. Subsequently, all staff were requested to submit an updated DoI after 1 May 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, e.g. no involvement in relation to any medicinal product from the declared company.

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 their 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[3].

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 2025 is presented in Figure 3 below.

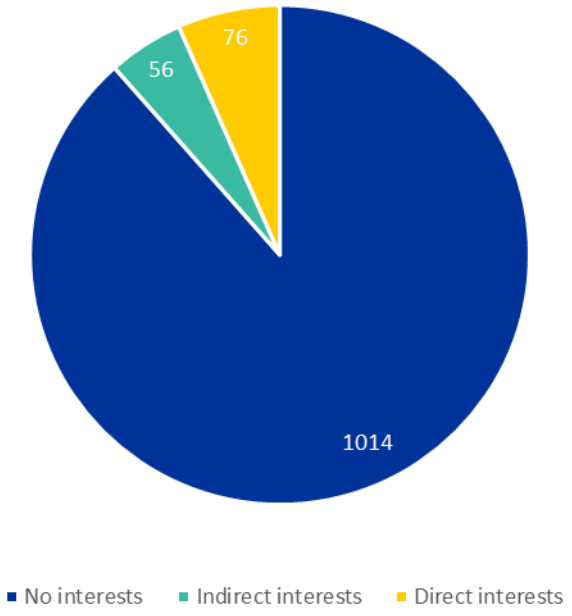


**Figure 3. Distribution of EMA staff (n=1,146) by interest level (31 December 2025)**

[3] Direct interests: employment, consultancy/strategic advisory role, financial interest in a pharmaceutical company or a medical device company, involvement or affiliation in a research organisation.
Indirect interest in a pharmaceutical company or a medical device company: (principal) investigator, grants/funding to an organisation/institution to which the staff member belongs or for which they perform any kind of activity, close family member direct interests.

### 4.2.2. Intention to engage in an occupational activity after leaving the European Medicines Agency

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.

The Agency's annual activity 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.

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 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.

In 2025, EMA staff and Seconded National Experts (SNEs) made a total of 13 applications pursuant to Article 16, which were reviewed and finalised within the year. Of these, there were 9 authorisations without restrictions and 4 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.

An e*x post* control will be carried out during 2026 on a random sample of 2025 declaration of interests of all EMA staff to review the implementation following the revision of the rules on handling declared interests of staff and candidates before recruitment in May 2025.

### 4.2.4. Transparency measures

The completed DoIs and CVs for management staff are available on the EMA website under Agency structure (since 29 February 2012). The DoIs of all other staff are available upon request.

## 4.3. Initiatives launched in 2025

- Revision of the Management Board Decision for EMA staff on rules relating to Articles 11, 11a and 13 of the Staff Regulations to align with the revised Policy 0044 adopted in March 2025 (see section 4.1).
- Awareness sessions for all staff and managers took place during April 2025 on the revised Management Board Decision on handling declared interests of staff and candidates before recruitment.
- A comprehensive update of EMA's Code of Conduct was completed and endorsed by the Management Board in June 2025. The revised Code of Conduct reflects the evolving landscape of regulatory requirements and ethical standards, clarifies its scope and applicability and provides practical examples and links to relevant legal provisions. The Code of Conduct was presented to all EMA staff and introduced to all EMA scientific committees throughout 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.[4]

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[5] declared in their DoI) as of 31 December 2025 is presented in Figure 4 below. The distribution across the different expert panels is presented in Annex (Table 2).

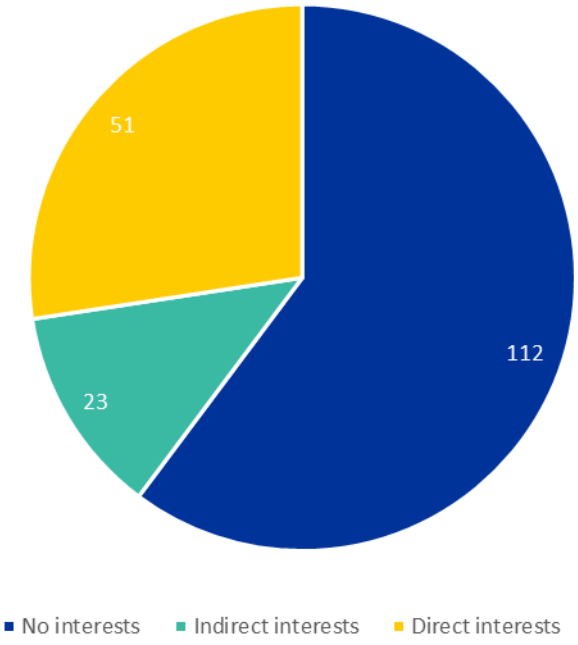


**Figure 4. Distribution of all EXPAMED experts (n=186) by interest level (31 December 2025)**

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,

[4] EXPAMED document D4.3: https://health.ec.europa.eu/system/files/2023-04/policy-mngt-conflicts_en.pdf
[5] 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.

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 2025, 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 evaluation consultation procedures (CECP) and scientific advices of certain high-risk medical devices and specific in vitro diagnostic medical devices. The control was completed in February 2026.

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 3 findings (7,5 % of the selected sample) were identified:

- During the control, a technical issue with the Experts Management Tool was identified in relation to 3 DoI evaluations being no longer accessible.
- One DoI evaluation 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.
- One DoI evaluation was performed but not for the correct role (Rapporteur instead of Reviewer).

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 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 2025 with the operation of the various policies on independence, the following recommendations are made:

- The implementation of the revised Policy 0044 and 0058 will continue to 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.

# 7. Planned initiatives for 2026

- 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.
  - *Ex ante* and *ex post* controls will continue for EMA staff.
  - *Ex post* will continue for EXPAMED.
- Monitor the implementation of EMA Policy 0044.
- Monitor the implementation of EMA Policy 0058.
- Monitor the implementation of the Management Board Decision on EMA staff.

# 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 taken into account and the necessary revision of the relevant policies were duly implemented and came into effect in 2025.

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, 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.

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.

# Annex

**Table 1. Distribution of Scientific committees and other bodies (ETF, MSSG and MDSSG) chairs, members and alternates by interest level (31 December 2025)**

| Interest level | CHMP | CVMP | CAT | COMP | HMPC | PDCO | PRAC | ETF | MSSG | MDSSG* |
|---|---|---|---|---|---|---|---|---|---|---|
| No interests | 42 | 50 | 37 | 21 | 31 | 32 | 44 | 24 | 21 | 9 |
| Indirect interests | 21 | 9 | 24 | 11 | 19 | 26 | 20 | 10 | 11 | 5 |
| Affiliation of research organisation only | 15 | 6 | 15 | 6 | 17 | 16 | 11 | 9 | 6 | 3 |
| Other indirect interests | 6 | 3 | 9 | 5 | 2 | 10 | 9 | 1 | 5 | 2 |
| Direct interests | 1 | 1 | 3 | 1 | 3 | 3 | 3 | 1 | 1 | 0 |
| **Total** | **64** | **60** | **64** | **33** | **53** | **61** | **67** | **35** | **33** | **14** |

** Lower numbers reported for the MDSSG compared to previous years are due a number of pending nominations by Member States and update of DoI by members for the upcoming renewal of the MDSSG mandate in March 2026.*

**Table 2. Distribution of EXPAMED expert panels' members by interest level (31 December 2025)**

| 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 | 28 | 12 | 15 | 9 | 2 | 1 | 7 | 1 | 2 | 2 | 1 | 17 | 112 |
| 2 – indirect interests | 9 | 4 | 5 | 2 | - | 1 | - | - | - | - | - | 2 | 23 |
| 3 – direct interests | 19 | 3 | 7 | 2 | 1 | - | 3 | 1 | 2 | 1 | 1 | 3 | 51 |
| **Total** | **56** | **19** | **27** | **13** | **3** | **2** | **10** | **2** | **4** | **3** | **2** | **22** | **186** |

(* with an up-to-date DoI)