



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 March 2024
EMA/114673/2023
Institutional and Policy Department

2023 - European Medicines Agency Annual Report on Independence

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



Table of Contents

1. Background	3
2. Scientific committees' members and experts	3
2.1. Status of EMA Policy 0044	3
2.2. Facts and figures	3
2.2.1. Declared interests	3
2.2.2. Outcome of Breach of Trust procedures	5
2.2.3. Outcome of <i>ex ante</i> and <i>ex post</i> controls	5
2.2.4. Transparency measures	6
2.3. Initiatives launched in 2023	7
3. Management Board members	8
3.1. Status of EMA Policy 0058	8
3.2. Facts and figures	8
3.2.1. Declared interests	8
3.2.2. Outcome of Breach of Trust procedures	10
3.2.3. Outcome of <i>ex ante</i> and <i>ex post</i> controls	10
3.2.4. Transparency measures	11
3.3. Initiatives launched in 2023	11
4. EMA staff	11
4.1. Management Board Decision on rules relating to Articles 11, 11a and 13 of the Staff Regulations	11
4.2. Facts and figures	12
4.2.1. Declared interests	12
4.2.2. Outcome of Joint Committee procedures	13
4.2.3. Outcome of <i>ex ante</i> and <i>ex post</i> controls	14
4.2.4. Transparency measures	14
4.3. Initiatives launched in 2023	14
5. Expert panels in the field of medical devices (EXPAMED)	15
5.1. Status of Policy (Expamed document D 4.3)	15
5.1.1. Declared interests	15
5.1.2. Transparency measures	16
6. Recommendations for further improvement	16
7. Planned initiatives for 2024	17
8. Conclusions	17
Annex	18

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, and for EMA staff) including their implementation as of the end of 2023. Following the transfer of the expert panels in the field of medical devices (so-called 'EXPAMED') to the EMA in March 2022, the report now also reflects on the status of EMA's activities under the independence policy pertaining to that activity.

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 2023 and identifies recommendations for further improvement in 2024.

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.

2.2. Facts and figures

2.2.1. Declared interests

Under policy 0044, 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 interests² declared in their DoI) as of on 31 December 2023 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).

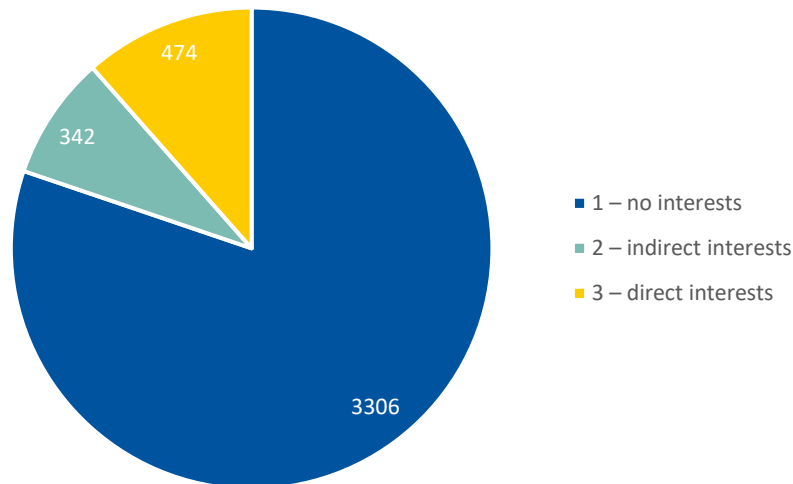


Figure 1. Distribution of all medicines experts (n=4,122) by interest level (31 December 2023)

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 in annex 1 “Scientific committees’ members and the Agency’s other bodies and experts allowed involvement in medicinal product or medical device related matters based on declared interests in pharmaceutical company or a medical device company” and in annex 2 “CAT members and alternates allowed involvement in medicinal product related matters based on declared interests in the biotechnology sector or medical device companies where the medical device is used or to be used in combined ATMPs.” Some interests result in an exclusion of the expert from any involvement in the Agency’s activities, other interests

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.

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 2023, the applied restrictions for scientific committee members, alternates and experts did not have an impact on the overall performance of the committees' work.

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 2023, 10 delegates (6 scientific committee members: 2 CHMP, 3 CAT, 1 PRAC; 4 working party members: 2 SAWP, 1 BWP, 1 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).

No BoT procedure was initiated in 2023. One procedure initiated in 2022 was concluded in 2023: the case concerned a committee member who had not declared a close family member's interest in a pharmaceutical company. It was found that the failure to declare the interest constituted negligence to comply with the EMA policy, but it had not occurred through gross negligence. The committee member was not allowed to be involved in EMA activities for a period of 9 months and a new member for the Committee concerned was appointed by the nominating body.

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

2.2.3.1. *Ex ante* controls 2023

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 DoI, and
- the time periods in the DoI match with those given in the Curriculum Vitae.

In 2023, 826 DoIs of new experts were checked and an error was noted in 12 DoIs (1.5%). The nature of the errors in 2023 (5 out of 12) was that these experts failed to declare in their DoI their recent employment (in the past 3-year period) within 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.

2.2.3.2. Ex post controls 2023

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 2023 focused on scientific committee members in view of the revised policy which was implemented on 1 January 2023. For the control, 40 committee members and alternates, who participated to committee meetings at the Agency (during the period 1 July to 31 December 2023), were randomly selected. The review of these controls was completed in February 2024.

No major errors with the DoI completion by committee members and or alternates or the DoI evaluation by EMA staff were identified.

The findings were:

- 15% of the checks (6 out of 40) had a minor error,
- for one committee, the standard wording on the absence of declared interests for of members with had no interests level 1 declared was missing in the list of participants,
- for one member, a restriction was missing from a declared interest due to technical problem,
- for one member, the DoI evaluation was missing in the Experts Management Tool,
- for one member, information in the CV may be an interest to be declared in DoI,
- for one member, information in the CV may lead to a higher level of restriction than that stemming from the DoI,
- an error in the wording in the DoI form in the Experts Management Tool was discovered.

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 2023

The following initiatives were launched or implemented in 2023:

- **Revision of Policy 0044 due to EMA's extended mandate and new legislation in the area of medical devices**

Further to the revision of Policy 0044 that came into effect on 1 January 2023, all scientific committees' members and experts were asked to submit an updated DoI at the latest by July 2023.

- **New EMA IT tool for handling experts DOI – Experts Management tool**

On 29 March 2023, the Agency launched its new Experts Management tool to replace the old Experts database. The tool holds the DoIs and CVs of all scientific committees' and other bodies' members and experts involved in EMA's medicines and medical devices related activities falling under Policy 0044. Information from existing experts was migrated from the old database to the new tool and all experts were requested to update their DoI in the new tool by 1 July 2023 in line with the revised policy. The tool now also includes the DoIs and CV of Management Board members falling under Policy 0058 and those of the EXPAMED members falling under the applicable EC Policy.

The new tool is more user-friendly for new experts to register in the tool, i.e. to provide their contact details, areas of expertise, DoI and CV, and for existing experts to submit an annual DoI or to update their information. The tool also facilitates the evaluation of DoIs of members and experts involved in EMA activities, as well as the management of memberships in committees, bodies and other groups.

- **Revision of guidance**

The Guidance on handling scientific committee/other (scientific) expert group member's declared intention to become an employee in a pharmaceutical company, a medical device company or in the biotechnology sector (EMA/267183/2015 Rev 1) has been updated in July 2023 to align it with the revised Policy 0044. Changes were introduced as a result from the additional responsibilities for the Agency following its involvement in certain medical device and in vitro diagnostic procedures as set out in Regulations (EU) 2017/745 and 2017/746, as well as from its extended mandate in accordance with Regulation (EU) 2022/123. In particular, guidance relating to the intention to become an employee in a medical device company, the biotechnology sector or become involved in the repurposing of a medicinal product has been introduced as well as considerations relating to the existence of the following new bodies - ETF, MSSG and MDSSG. The reference to the EMA Experts Management tool has replaced the reference to the Experts database.

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

On 22 June 2023, 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.

Following the setting aside of the first-instance judgment, the Court of Justice referred the case back to the General Court so that it can examine the remaining elements of the case. EMA is a party to those proceedings (Case T-594/18 RENV); and a judgment might be expected in 2025.

The EMA implementation measures which were introduced following the delivery of the first-instance judgment have been discontinued.

3. Management Board members

3.1. Status of EMA Policy 0058

The policy for handling the competing interests of Management Board (MB) members (Policy 0058) was revised 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.

The revised version was approved by the Management Board in December 2022 and entered into force on 1 January 2023.

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 members, alternates and observers.

The distribution of the levels of declared interests (ie no, indirect or direct interests³ declared in their DoI) of the Management Board chair, members and their alternates, as well as the Management Board observers and their alternates on 31 December 2023 is presented in Figure 2 below.

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.

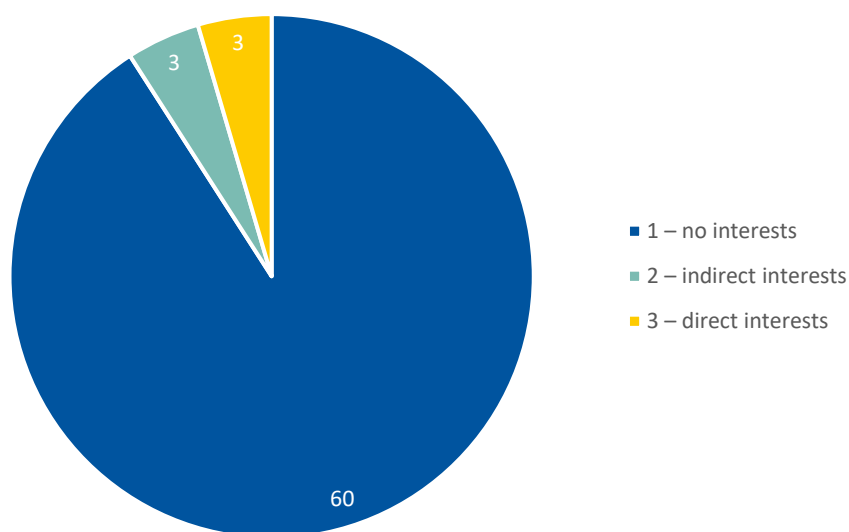


Figure 2. Distribution of Management Board chair, members, observers and alternates (n=66) by interest level (31 December 2023)

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 2023, 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 2023, 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 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. The current BoT procedure is effective from 1 January 2023.

No BoT procedure was initiated in 2023 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 2023.

In 2023, an *ex post* control was undertaken on a select number of DoIs submitted by Management Board members. 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 (restrictions on involvement).

A total of 20 Management Board members who attended MB meetings during the year of 2023 were randomly selected. The control was completed in February 2024.

No major errors with the DoI completion by Management Board members and or alternates or the DoI evaluation by EMA staff were identified.

The findings were:

- 25% of the checks (5 out of 20) had a minor error,
- in 4 cases, although the minutes included reference to topics for which restrictions had to be applied and although the concerned members had been informed about the relevant restrictions before the meeting, the meeting minutes did not specify the names of the members to which restrictions had been applied (normally done in the list of participants).
- for 1 member, the DoI was evaluated prior to the meeting outside of the EMT.

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 2023

- **Revision of Policy 0058 due to EMA's extended mandate and new legislation in the area of medical devices**

The Management Board is accountable for all EMA activities, including as from 2022 on EMA's 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, the Management Board endorsed that its members will be requested to declare also 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. Accordingly, Policy 0058 for Management Board members was revised in alignment with Policy 0044 and the new legislation applicable to the Agency. The current Policy 0058 became effective from 1 January 2023. All Management Board members and alternates were asked to submit an updated DoI in April 2023 following the launch of the new Expert Management tool on 29 March 2023.

- **New EMA IT tool for handling experts DOI – Experts Management tool**

On 29 March 2023, the Agency launched its new Experts Management tool to replace the old Experts database. The tool holds the DoIs and CVs of all scientific committees' and other bodies' members and experts involved in EMA's medicines and medical devices related activities falling under Policy 0044. The tool now includes also the DoIs and CV of Management Board members falling under Policy 0058 and those of the EXPAMED members falling under the EC Policy.

The new tool is more user-friendly for MB members to register in the tool, i.e. to provide their contact details, areas of expertise, DoI and CV, and for existing MB members to submit an annual DoI or to update their information. The tool also facilitates the evaluation of MB members, as well as the management of MB Board memberships.

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

The Decision for staff has also been revised due to the legislation regarding the extended mandate that introduced new tasks for the Agency in the area of medical devices. Following the statutory consultation of the Staff Committee and the European Commission under Article 110 of the Staff Regulations, the decision was adopted by the MB and came into effect on 1 March 2023. Consequently, staff were required to update their declarations of interests as part of the annual declaration of interest exercise.

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 interests⁴.

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 2023 is presented in Figure 3 below.

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

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.

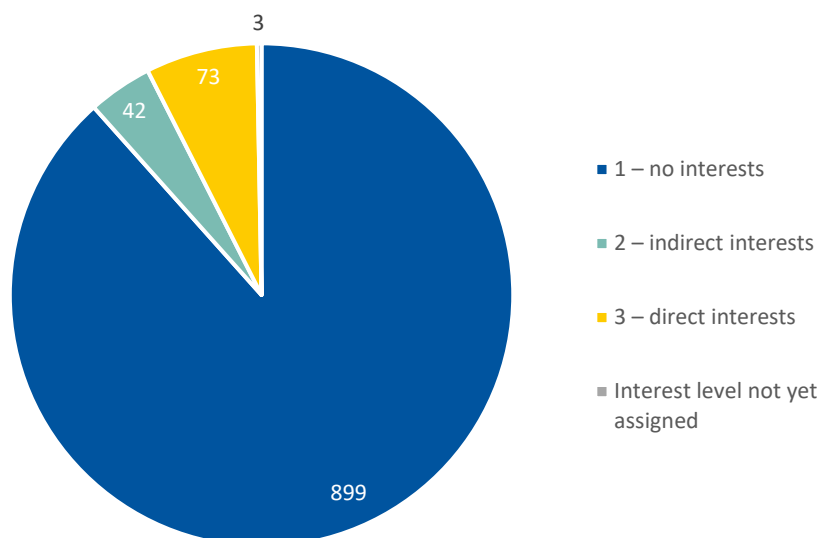


Figure 3. Distribution of EMA staff (n=1,017) by interest level (31 December 2023)

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.

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 2022 was finalised in 2023 and resulted in an authorisation with restriction. In 2023, staff and Seconded National Experts (SNEs) made a total of 16 applications, 15 of which were finalised within the year. These resulted in 3 applications where the general opinion was issued, 8 authorisations without restrictions, 2 staff authorisations with restrictions, and 2 SNE cases with restrictions. 1 application will be finalised in 2024.

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 in 2023 on staff DoI with an interest level 2 and 3 identified minor errors. Reporting officers were contacted to correct mistakes where identified, or to remind of the timelines to assess declarations. In the cases where an error was identified reporting officers confirmed that there had been no restrictions were compromised. Monitoring of DoI compliance, including reminders to reporting officers to assign the interest level on time takes place regularly. Ethics training (including information on EMA's code of conduct and conflict of interest) is delivered at regular intervals for all new staff and managers. Following the revision of the rules on handling declared interests of staff and candidates before recruitment, a specific awareness session was organised for all staff in March 2023.

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 2023

Similarly to Policy 0044, the MB decision on rules relating to the handling of declared interests of staff and candidates was updated with regards to interests in the medical devices industry and the EMA's extended mandate. The revised MB decision was adopted by the MB and came into effect on 1 March 2023.

As part of the Agency's digital transformation initiatives, a new on-line training course on Ethics at EMA has been developed in 2023. The course will include a specific section on conflict of interest and will be available to all staff in 2024.

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.

5.1.1. Declared interests

The distribution of all experts involved in expert panels by interest level (ie with no, indirect or direct interests⁶ declared in their DoI) as of 31 December 2023 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-mnqt-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.

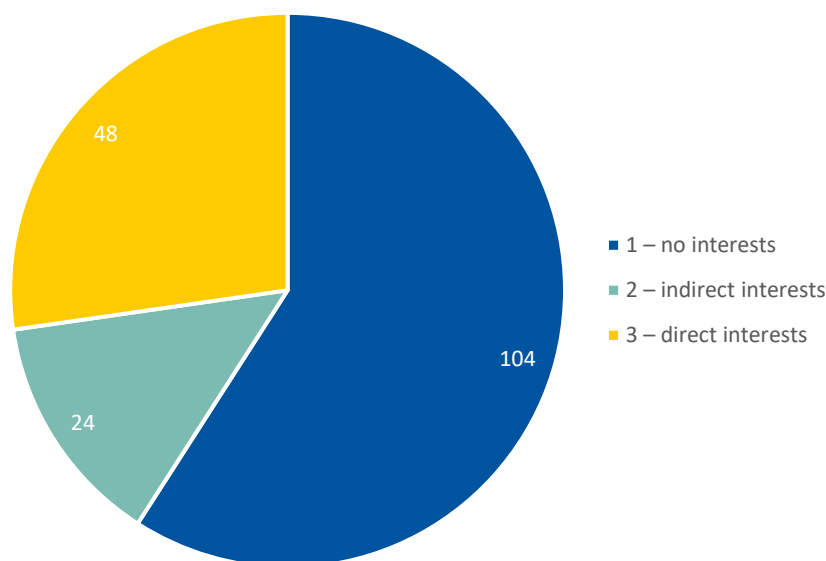


Figure 4. Distribution of all EXPAMED experts (n=176) by interest level (31 December 2023)

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 involvement, 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.

5.1.2. 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 2023 with the operation of the various policies on independence, the following recommendations are made:

- Policy 0044 and 0058 and the rules for staff will be revised to provide further clarity and guidance in particular on the handling of competing interests related to certain activities in research organisations and taking into account recent court judgments.
- The Experts Management Tool will be reviewed to implement changes due to the policies revision as well as for any further improvements.

- Specific training targeting reporting officers on declarations of interests will be delivered during 2024.

7. Planned initiatives for 2024

- Implementing the aforementioned recommendations.
- Revise the procedural guidance on inclusion of declared interests in EMA's DOI form to take account of the changes to Policy 0044 and the introduction of the Experts Management Tool.
- Launch a newly designed Ethics at EMA on-line training course that all existing staff and managers will be invited to enrol for this training. The training will be mandatory for all new staff.
- 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.

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 legislative changes have been taken into account and the necessary extension and revision 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.

Annex

Table 1. Distribution of Scientific committees and other bodies (ETF, MSSG and MDSSG) chairs, members and alternates by interest level (31 December 2023)

Interest level	CHMP	CVMP	CAT	COMP	HMPC	PDCO	PRAC	ETF	MSSG	MDSSG	All experts*
1 – no interests	53	55	49	26	49	46	58	28	28	30	3,306
2 – indirect interests	8	2	6	4	2	11	9	2	1	1	342
3 – direct interests	3	1	8	3	0	2	2	1	7	3	474
Total	64	58	63	33	51	59	69	31	36	34	4,122

(* with an up-to-date DoI)

Table 2. Distribution of EXPAMED expert panels' members by interest level (31 December 2023)

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	31	12	15	9	2	2	7	1	2	2	2	15	104
2 – indirect interests	10	4	5	2	-	-	-	-	-	-	-	2	24
3 – direct interests	16	3	7	2	1	1	3	1	3	1	-	3	48
Total	57	19	27	13	3	3	10	2	5	3	2	20	176

(* with an up-to-date DoI)