



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

16 March 2023  
EMA/2588/2023  
Institutional and Policy Department

## 2022 - 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](http://www.ema.europa.eu/how-to-find-us)

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

An agency of the European Union



# Table of Contents

<b>1. Background .....</b>	<b>3</b>
<b>2. Scientific committees' members and experts .....</b>	<b>3</b>
2.1. Status of EMA Policy 0044 .....	3
2.2. Facts and figures.....	4
2.2.1. Declared interests.....	4
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.....	7
2.3. Initiatives launched in 2022.....	7
<b>3. Management Board members .....</b>	<b>9</b>
3.1. Status of EMA Policy 0058 .....	9
3.2. Facts and figures.....	9
3.2.1. Declared interests.....	9
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.....	10
3.3. Initiatives launched in 2022.....	10
<b>4. EMA staff .....</b>	<b>11</b>
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 .....	12
4.2.3. Outcome of <i>ex ante</i> and <i>ex post</i> controls.....	13
4.2.4. Transparency measures.....	14
4.3. Initiatives launched in 2022.....	14
<b>5. Recommendations for further improvement.....</b>	<b>14</b>
5.1. Recommendations resulting from legislative changes impacting aspects of the existing EMA policies on independence .....	15
5.1.1. Recommendations for EMA Policy 0044 .....	15
5.1.2. Recommendations for EMA Policy 0058 .....	15
5.1.3. Recommendations for the Management Board Decision on rules for EMA staff .....	15
5.2. Recommendations resulting from the 2022 <i>ex post</i> controls.....	15
5.3. Other recommendations.....	15
<b>6. Planned initiatives for 2023.....</b>	<b>16</b>
<b>7. Conclusions .....</b>	<b>16</b>

# 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.<sup>1</sup> The report is presented annually and this report is the sixth annual review which covers 2022. It reflects the status of each of the independence policies (for scientific committees' members and experts, for Management Board members, and for EMA staff) including their implementation as of the end of 2022. 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 2022 in particular related to EMA's new responsibilities in the area of medical devices and EMA's reinforced role in crisis preparedness and management and identifies recommendations for further improvement in 2023.

## 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 2022 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) 2022/123, 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.

The main changes in Policy 0044 were:

- A definition of a medical device company has been included, replacing the current definition of "medical device sector" (linked to ATMPs), and building on the current definition of a pharmaceutical company used in Policy 0044.
- Medical device interests are reflected throughout the policy including which interests need to be declared and the principles that apply to the declared interests, as relevant.
- For CHMP, CAT, ETF and MSSG<sup>2</sup> members who declare current direct or indirect<sup>3</sup> medical device related interests, the necessary restrictions will be applied, i.e. they are not excluded from membership, but they will not be involved in procedures concerning medical devices linked to the declared medical device manufacturer or notified body. No restrictions will be applied in case of past medical device related interests.

---

<sup>1</sup> The first annual review of independence was presented to the Management Board in October 2016, the second annual review for 2016-2017 was presented in March 2018, the third review for 2018-2019 in March 2020, the fourth review for 2020 in March 2021 and the fifth review for 2021 in March 2022.

<sup>2</sup> Emergency Task Force (ETF), Executive Steering Groups on Shortages and Safety of Medicines (MSSG) and on Shortages of Medical Devices (MDSSG).

<sup>3</sup> Direct interest: employment, consultancy, strategic advisory role, financial interest.

Indirect interest: (principal) investigator, grants/funding to organisation/institutions, close family member interests

- Members of MDSSG are included in the revised policy and restrictions will be applied in relation to medical device or pharmaceutical interests declared.

Under this policy, EMA requires an annual update of the electronic declaration of interest (e-DOI) as well as an updated e-DOI for any change in the status of a member or an expert. EMA also has an advisory committee in place, the Declaration of Interests Advisory Group (DIAG), which is an internal committee to provide advice on the evaluation of e-DoIs of scientific committees' members and experts.

## 2.2. Facts and figures

### 2.2.1. Declared interests

The distribution of scientific committees members and alternates and experts with no, indirect or direct interests declared in their e-DoI was as follows on 31 December 2022:

Distribution per 31 December 2022

Interest level	CHMP	CVMP	CAT	COMP	HMPC	PDCO	PRAC	All experts*
1 – no interests	53	55	52	29	53	47	58	3,288
2 – indirect interests	8	3	4	3	2	10	6	359
3 – direct interests	3	0	7	2	0	4	4	470
<b>Total</b>	<b>64</b>	<b>58</b>	<b>63</b>	<b>34</b>	<b>55</b>	<b>61</b>	<b>68</b>	<b>4,117</b>

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

For the handling of DoIs submitted by scientific committees' members and experts, a 2-step procedure applies: firstly, an interest level is automatically assigned to the e-DoI based on whether the expert has any interests, whether these are direct or indirect and whether they are current or past as set out in the policy<sup>4</sup>. 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 (EMA/MB/89351/2020) in annex 1 "Scientific committees' members and experts allowed involvement in medicinal product related matters based on declared interests in the pharmaceutical industry" and in annex 2 "CAT members and alternates allowed involvement in medicinal product related matters based on declared interests in the biotechnology sector or the medical device sector." Some interests result in an exclusion of the expert from any involvement in the Agency's activities, other interests result in a restricted involvement, e.g. no involvement in procedures on the declared product or any product from the declared company while committee membership is allowed.

Taking into account the pool of experts available, the Agency works to ensure that the experts involved in a specific procedure does not have competing interests for the procedure. A proactive approach is also applied with respect to the search for alternative experts in the field. In 2022, the applied

<sup>4</sup> Direct interest: employment, consultancy, strategic advisory role, financial interest.

Indirect interest: (principal) investigator, grants/funding to organisation/institutions, close family member interests

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

In 2022, 8 delegates (2 scientific committee members: 2 CHMP, 6 working party members: 3 SAWP, 1 PCWP, 1 ONCWP, 1 drafting group) informed the Agency of their intention to become an employee in a pharmaceutical company. In line with the guidance document, the members were immediately fully restricted from further involvement in any Agency activity. The imminent employment in a company did not constitute a conflict for any of the ongoing assessment procedures.

### 2.2.2. Outcome of Breach of Trust procedures

The EMA breach of trust (BoT) procedure for competing interests of scientific committee members and experts was introduced in 2012. A revision in 2018 was endorsed by the Management Board that extended its scope to cases of disclosure of confidential information by a scientific committee member or expert.

The BoT procedure was revised again in 2022 to align it to the latest changes to Policy 0044. The revised BoT procedure was endorsed by the Management Board in December 2022. The revised procedure also states that the procedure will also apply to the other bodies that have been established within the Agency under the Extended Mandate (e.g. Emergency Task Force, both Shortages Steering Groups).

EMA launched two BoT procedures in 2022 and one of these will be concluded in 2023; this latter case will be included in the 2023 report. For the BoT case concluded in 2022 a committee member did not declare a lecture honorarium received from an individual pharmaceutical company which was found to be incompatible with committee membership and should not have been accepted. It was found that the failure to declare the financial interest was not intentional and did not occur due to gross negligence. The committee member was required to update their declaration of interest to declare the interest as consultancy and restrictions will be applied for three years regarding the products of the relevant pharmaceutical company. The committee member was required to study in detail the EMA policy on the handling of competing interests members and experts, to attend training on handling of competing interests organised at the level of the committee and instructed to refrain, during membership, of the committee, from accepting any financial interest from a pharmaceutical company, as well as engaging in consultancy to a pharmaceutical company or in a strategic advisory role for a pharmaceutical company.

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

#### 2.2.3.1. *Ex ante* controls 2022

An *ex ante* control has been carried out systematically on all new experts since June 2013. The *ex ante* control checks that

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

	2022
New expert e-DOI checked before upload to the EMA Experts database	813
Error rate	21 / 2.6%
<i>Nature of error</i>	

2022	
Previous employment from CV not declared on DoI	13
Current grant from CV not declared in DoI	-
No details of close family members	-
Date difference between CV and e-DOI	1
Interest declared in wrong section of e-DOI	1
Information on an interest missing	-
Inconsistencies in the e-CV	-
Interest declared unnecessarily	6
<i>Action taken after update of e-DOI</i>	
Higher interest level	9
Unchanged interest level	8
Lower interest level	4

In 2022, 813 e-DoIs of new experts were checked and an error was noted in 21 e-DoIs (2.6%). The nature of the errors in 2022 (13 out of 21) was that these experts failed to declare in their e-DoI their recent employment (in the past 3-year period) within a pharmaceutical company. EMA asked the experts to correct their e-DoI, resulting in a higher or same interest level being assigned to their e-DoI. This EMA ex ante/preventive check of each expert is important and is maintained to ensure a low number error on the e-DOIs of experts.

### **2.2.3.2. Ex post controls 2021 and 2022**

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

The *ex post* controls were conducted to check

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

The last two *ex post* controls carried out in 2021 and 2022 focused on Scientific Advisory Group (SAG)/Ad Hoc Expert Group (AHEG). Both of these *ex post* controls are reported on in this report. For each year, 20 experts (out of estimated 250), who were invited to meetings at the Agency (during the period 1 January to 31 October in 2021 and also between 1 January and 15 December in 2022), were randomly selected. The review of these controls was completed respectively on 29 March 2022 and 17 February 2023.

No major problems with the e-DoI completion by SAG/AHEG experts or the e-DoI evaluation by EMA staff were identified.

The findings were:

- *in 2021*: 45% of checks (9 out of 20) had at least one minor error (eight experts had not been uploaded in the Experts database prior to the meeting or at the time of the control; for two experts, a

DoI was available prior to the meeting but was still not signed off by the expert at the time of the control; for one expert, the CV was absent in the Experts database at the time of the control; for two experts, the DoI evaluation form was not signed off; for two experts, the meetings' minutes did not correctly report the justification for the applied restrictions)

- *in 2022*: 15% of checks (3 out of 20) had at least one minor error (four experts had not been uploaded in the Experts database prior to the meeting or at the time of the control; for two experts, a DoI was available prior to the meeting but was still not signed off by the expert at the time of the control; for one expert, the CV was absent in the Experts database at the time of the control).

#### **2.2.4. Transparency measures**

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

### **2.3. Initiatives launched in 2022**

The following initiatives were implemented in 2022:

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

Following the adoption of the Medical Device and *in vitro* Medical Device Regulations (Regulations (EU) 2017/745 and 2017/746<sup>5</sup>), EMA's scientific committees' consultation by Notified Bodies is foreseen for specific categories of medical devices/*in vitro* medical devices. EMA's Extended Mandate Regulation (Regulation (EU) 2022/123<sup>6</sup>) (adopted in January 2022) introduced new tasks for the Agency in the area of medical devices. These new tasks specifically entail supporting the expert panels on medical devices and *in vitro* diagnostic devices (EXPAMED), handling of medical device shortages as well as the establishment of the Executive Steering Groups on Shortages and Safety of Medicines (MSSG) and on Shortages of Medical Devices (MDSSG). The Extended Mandate Regulation also established the Emergency Task Force (ETF) as a new scientific body. Members and experts involved in the activities of these other bodies may not have interests in the pharmaceutical or medical device industries that would affect their impartiality. Policy 0044 was revised to take account of these legislative changes and the establishment of the new bodies to which the policy will also apply.

The revised Policy 0044 came into effect on 1 January 2023. All CAT members and alternates were asked on 20 January 2023 to update their DoI form in light of the requirements, i.e. to declare any competing interests regarding medical devices as set out in the revised Policy 0044 (using section 2.10 Other interests of the existing DoI form). When the new Experts Management Tool is available in Q2/2023 all other scientific committees' members and experts will be asked to submit an updated DoI.

---

<sup>5</sup> Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices.

<sup>6</sup> Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.

- *Medical Devices Expert panels (EXPAMED)*

Since 1 March 2022, as a new responsibility and function, EMA has hosted the panels and provided a secretariat function on behalf of the European Commission. EMA applies the policy, put in place by the European Commission, on the management of competing interests for EXPAMED members that is specific for their functions and has a focus on the medical device industry and notified bodies. This policy is similar to EMA Policy 0044. Based on experience gained in the coming years, it can be considered if and/or how the EXPAMED policy and Policy 0044 should be amended. Any changes to the EXPAMED policy will need to be proposed to the Commission for its consideration.

- *Medical Devices Shortages Steering Group (MDSSG)*

This new Steering Group has been established as part of EMA. The revised Policy 0044, effective 1 January 2023, applies to the MDSSG and its working parties. The policy elaborates on medical devices interests and their restrictions on involvement in EMA activity.

- *Medicines Shortages Steering Group (MSSG)*

- This new Steering Group has been established as part of EMA. Policy 0044 has applied from 2022 to this Steering Group and its working parties. The revision of the scope of the current Policy 0044 specifically includes the Medicines Shortages Steering Group.

- *Emergency Task force (ETF)*

Policy 0044 was applied from 2022 to the ETF members. The revision of the scope of the current Policy 0044 specifically includes the ETF.

Following adoption of the updated policy and BoT procedure in December 2022, EMA will include information on the outcome of DoI checks for MDSSG, MSSG and ETF in future annual independence reports.

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

A project started in 2022 to replace EMA's current Experts database that holds the members' and experts' DoIs and CVs with an improved new Experts Management Tool. The business functionalities for the submission, evaluation and management of DoIs, were identified. Following EMA's extended mandate, additional requirements to handle Medical Devices Experts Panels (EXPAMED) members' DoIs were included as well as providing for members and experts involved in other committees, other bodies or other EMA activities to declare medical device interests. The project is expected to be concluded in Q2/ 2023. The project will export the existing DoI records to the new tool and when the new Expert Management tool is launched, all members and experts will have historic information available to them and will be asked to check and to update their DoI in the new tool.

- **Impact of General Court Judgment**

The Agency continued to maintain the implementation measures following the General Court Judgment on the Aplidin case, i.e. for SAGs and AHEGs, experts that are employed by universities or university hospitals performing development or manufacturing activities in respect of any medicinal products actually or potentially competing with the (candidate) product under review, are not allowed to be involved in the procedure. The Agency intervened in support of the appellate proceedings which were launched by two Member States in January 2021. A judgement by the Court of Justice is expected in 2023. Following the outcome of this appeal case, as needed, Policy 0044 will be reviewed and by extension also Policy 0058.



## 3. Management Board members

### 3.1. Status of EMA Policy 0058

The policy for handling the competing interests of Management Board (MB) members 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 policy for Management Board (MB) members and alternates, applicable throughout 2022 had been in effect since 1 July 2020. The earlier revisions for the version of the policy effective 1 July 2020 were the inclusion in the definition of financial interests of stock warrants, introduction of a definition of partner and inclusion of reference to the new EU GDPR legislation and were in alignment to the same changes to Policy 0044.

Under this policy, EMA requires an updating annually of the e-DOI as well as an updated e-DOI for any change in the status of the Management Board member.

An electronic DoI form for MB members is part of the Experts Management Tool project being finalised in 2023. The project will export the existing DoI records to the new tool and when the new Expert Management tool is launched, the MB members will have historic information available to them. MB members will be asked to update their DOI when the new electronic form in the new tool is available in Q2/ 2023.

### 3.2. Facts and figures

#### 3.2.1. Declared interests

The distribution of the levels of declared interests of the Management Board members and their alternates, as well as the Management Board observers and their alternates was as follows on 31 December 2022:

Interest level	Members	Observers*
1 – no interests	56 members/alternates	5 observers
2 – indirect interests	2 member, 2 alternates	0
3 – direct interests	1 member, 1 alternate	0
<b>Total</b>	<b>62</b>	<b>5</b>

(\* Iceland, Liechtenstein and Norway)

The Management Board secretariat reviews the DoIs of all meeting participants prior to the meeting. An interest level is assigned to the DoI based on whether the member has any interests, whether these are direct or indirect and whether they are current or past as set out in the policy. Involvement in Management Board activities takes into account several factors: the nature of the declared interest, the timeframe of the interest, the type of Management Board activity, the likelihood of impact on the industry, and the action requested from the Management Board member. Where a direct or indirect interest is declared by the Management Board member and creates a competing interest for an agenda item, the individual Management Board member will be restricted from participating and voting, if

applicable, regarding that agenda point. Such restrictions are announced for each individual affected with the agenda points indicated at the outset of the meeting and the persons affected and the agenda points restricted are reflected in the meeting minutes. In 2022, 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 2022, 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**

In December 2015, the Management Board endorsed a revised BoT procedure for Management Board members aligned to the BoT procedure for scientific committee members and experts. This procedure sets out how the Agency deals with incorrect or incomplete declarations of interests by Management Board members. The BoT for Management Board members was revised in 2019 again to align to the procedure for scientific committee members and experts.

In 2022, the procedure has been further updated 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 2022 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 2022.

No *ex post* controls were performed in 2021 or in 2022 due to the business contingency status of the Agency.

### **3.2.4. Transparency measures**

Since 2012, the DoIs of all Management Board members and alternates, along with their individual CV, have been published on the Agency's website. In addition, the agendas and minutes of the Management Board meetings have been published since 2009. The outcome of the DoI *ex ante* control is stated prior to the start of each MB meeting with mitigating actions applied at agenda point level. Since 2016, the minutes include information on the restrictions applicable to meeting participation following the assessment of the DoIs.

## **3.3. Initiatives launched in 2022**

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, in 2022, Policy 0058 for Management Board members was revised in alignment with Policy 0044 and the new legislation applicable to the Agency. The revised Policy 0058 is effective from 1 January 2023.

## **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. In this regard, the Management Board endorsed the main principles for the revision of the Decision on rules for staff in October 2022. The main principles were:

- To request all staff members to declare any medical device interests
- No exclusion from employment in case of current financial interests but staff will be restricted from involvement in procedures concerning medical devices linked to the declared company
- No restrictions in the case of past medical devices interests

The Decision on rules for staff was, therefore, revised in the last quarter of 2022 taking into account the above-mentioned principles. It also includes the definition of a medical device company in alignment with policies 0044 and 0058. The revised Decision, was submitted for the statutory consultation of the Staff Committee and also sent to the European Commission for its opinion under Article 110 of the Staff Regulations. Following conclusions of this part of the official process, the revised Decision on rules for staff will be submitted to the MB for adoption in 2023. Staff will be required to update their declarations of interests, in 2023, based on the revised Decision on rules for staff in the annual declaration of interest exercise.

The rules apply in general to all temporary and contract agents, national experts on secondment, trainees, interims and visiting experts, as well as to candidates before recruitment. Information guidance is provided to reporting officers on how the evaluation of the declared interests should be done, the criteria for the identification of risks and which risk mitigation measures to apply for either scientific/regulatory or administrative/technical duties.

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

## 4.2. Facts and figures

### 4.2.1. Declared interests

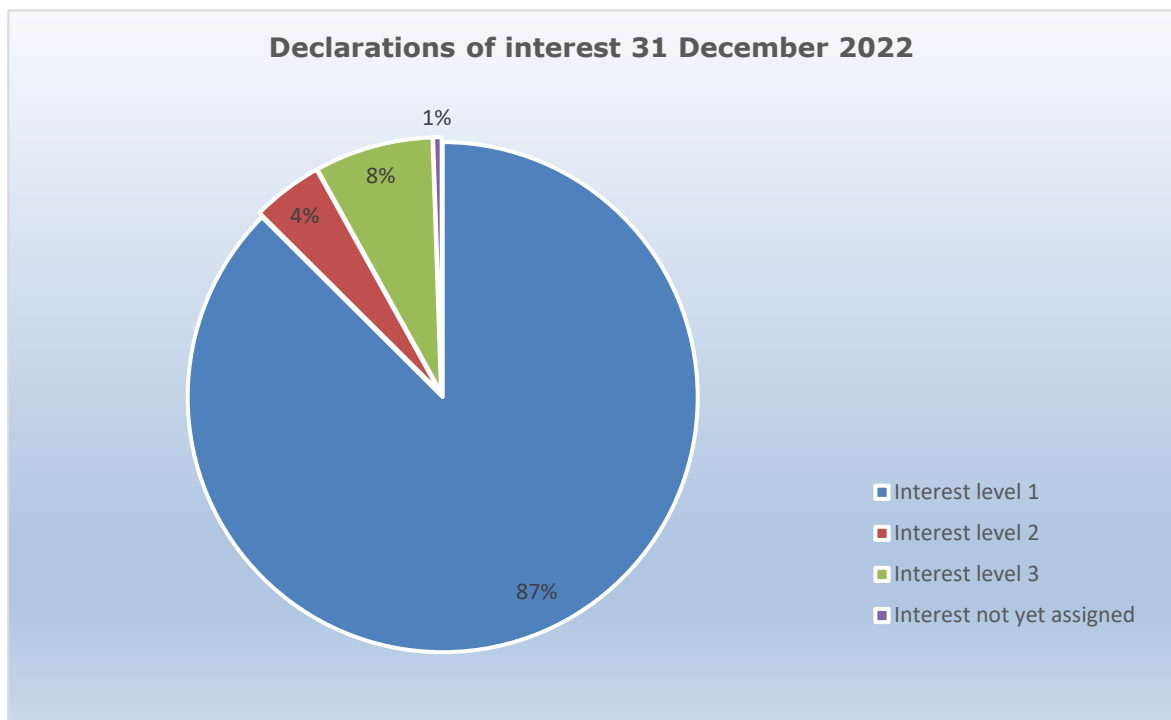
Each staff member or a candidate is assigned by the reporting officer to one of the interest levels, detailed below, based on his/her declared interests.

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

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

The graph below shows the distribution of staff's interest levels for all EMA staff on 31 December 2022.

- Staff assigned interest level 1: 87% with no declared direct or indirect interests.
- Staff assigned interest level 2: 4% who declared indirect interests.
- Staff assigned interest level 3: 8% who declared direct interest.
- Staff with no interest level assigned yet to their latest DoI: 1%



### 4.2.2. Outcome of Joint Committee procedures

On leaving the Agency, all EMA staff members are required to seek permission to engage in an occupation within a period of two years of leaving the Agency, in accordance with Article 16 of the Staff Regulations. Applications are reviewed to establish any potential competing interests, and if so required, based on an opinion of the Agency's Joint Committee, the Executive Director (or the

Management Board in the case of the Executive Director) will issue a decision, which may impose restrictions on the staff member's intended occupation to mitigate any potential competing interests. Examples of restrictions include: a distance clause, whereby the former staff member may not contact individual Agency staff as regards any professional activity he/she may have dealt with in the performance of his/her responsibilities while at the Agency, e.g. 6-12 months; explicit prohibition of handling medicinal-product dossiers on which they have worked during their employment at EMA.

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

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

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

The Agency'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.

In 2022, staff and Seconded National Experts (SNEs) made a total of 22 applications, 21 of which were finalised within the year. These resulted in 2 applications where no opinions were required, 14 authorisations without restrictions, 3 staff authorisations with restrictions, and 2 SNE cases with restrictions. 1 application will be finalised in 2023.

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

#### **4.2.3.1. *Ex post* control 2022**

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 2022 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. The reporting officers confirmed that there had been no breach of

conflict of interest concerning the staff members that should have been assigned restrictions in the DoI process (2 cases). 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. Specific training will be organised in 2023 in line with the revised rules for handling conflict of interest of staff.

#### **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 2022**

In view of the extended mandate of the Agency, the management of EMA staff declaration of interests was reviewed. EMA has recruited and onboarded staff since Q4/2021 for the EXPAMED Secretariat functions. EMA staff provide support to medical devices-related procedures from the EXPAMED panels and the Medical Devices Shortages Steering Group.

The decision on rules for staff (applicable in 2021 and 2022) did not address explicitly competing interests in the medical device industry. In a cautious approach, EMA directly applied Article 11 of the Staff Regulations, pending a revision of the Management Board Decision on handling staff declarations of interest, new staff were asked, specifically, to declare interests in the medical devices industry. Staff involved in the medical device related procedures (with a focus on staff members involved in the handling of the Expert Panels on Medical Devices (EXPAMED) were asked to declare interests in the medical device industry, including Notified Bodies.

EMA staff shall not hold any current direct interests in medical device industry, i.e. employment, consultancy, strategic advisory role. Restrictions are applied to staff with a past employment history or other past interests in the medical device industry with a similar approach as currently applies under Policy 0044. EMA staff nominated in an expert capacity to the ETF were asked to make an e-DOI as an expert which is published along with their CV.

A revision of the MB decision on rules relating to the handling of declared interests of staff and candidates was prepared in alignment with the changes to Policy 0044. The proposed changes were presented to and endorsed by the MB in October 2022. Staff Committee consultation on the revised rules is required and was ongoing as of the end of 2022. Consultation of the European Commission is also required in line with Article 110 of the Staff Regulations which was ongoing as of the end of 2022. With conclusion of the consultations required, the revised MB decision will be circulated to the MB for adoption in 2023.

## **5. Recommendations for further improvement**

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

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

### **5.1.1. Recommendations for EMA Policy 0044**

- The EC policy for EXPAMED panel members has been applied to the activities of the panels. A breach of trust procedure, based on the EMA breach of trust process and procedure, will be proposed to the Commission for its consideration.
- All scientific committee members and experts will be asked to update their DOI in the new Experts Management tool when it is available in 2023.

### **5.1.2. Recommendations for EMA Policy 0058**

- All MB members will be asked to update their DOI in the new Experts Management tool when it is available in 2023.

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

- The revised Management Board decision on rules for EMA staff in alignment with Policy 0044 will be presented for adoption by the MB. The role of EMA staff as ETF experts and the related need for an expert e- DOI will be included.
- All staff will be required to provide an update DOI in line with the revised MB decision on rules for EMA staff in the 2023 annual declaration exercise.
- Specific training targeting reporting officers on declarations of interests will be developed during 2023.

## **5.2. Recommendations resulting from the 2022 ex post controls**

The 2022 findings following the conclusion of the ex post control focused on Scientific Advisory Group (SAG)/Ad Hoc Expert Group (AHEG) are reported upon in this report. Close monitoring of the will be maintained and a further ex post control will be carried out in 2023. The findings and related recommendations of the ex post control in 2023 will be reported to the Management Board.

## **5.3. Other recommendations**

- EMA will continue to maintain the implementation measures adopted in 2020 further to the General Court Judgment on the Aplidin case. As an intervener in the appellate proceedings, the Agency will await the Court of Justice's judgement on the matter and assess its impact on its Policies 0044 and 0058.
- The Experts Management Tool project will be concluded to create a new tool which will include DoIs for the Scientific Committee members and experts, EXPAMED members as well as MB members.
- Further refresher training to EMA staff on Ethics at EMA, including information on EMA's code of conduct and conflict of interest will be delivered in 2023.

## 6. Planned initiatives for 2023

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

- 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.
- Revise the guidance on handling a declaration of interest in case of a scientific committee member / other (scientific) forum member intentions' to become an employee in a pharmaceutical company to take account of also the instance of a medical device company.
- Monitor the implementation of EMA Policy 0058.
- Monitor the implementation of EMA Policy 0044.
- Monitor the implementation of the Management Board Decision on rules relating to Articles 11, 11a and 13 of the Staff Regulations concerning the handling of declared interests of EMA staff.
- Training for EMA staff on the operation of Policy 0044 and the Management Board decision on rules for EMA staff will be organised as required.
- Conduct *ex ante* and *ex post* controls in accordance with the agreed schedule, including identification of recommendations for further improvement:
  - *Ex ante* and *ex post* controls will continue in the context of EMA Policy 0044.
  - *Ex ante* controls will continue in the context of EMA Policy 0058. An *ex post* control will be undertaken.
  - An *ex post* control will be undertaken in the context of the Management Board Decision on rules for Agency staff with interest level 2 and 3.

## 7. Conclusions

The Agency, through its various policies and rules, 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.