14 January 2025
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European Medicines Agency

Outcome of Public consultation on Policy 0044

Summary of comments and EMA feedback

1. Background

In the context of the revision of its policy on handling of competing interests of scientific committee members and experts (Policy 0044), EMA invited stakeholders invited to comment on the draft revised policy between 10 October and 10 November 2024.

EMA's handling of competing interests reflects the balance the Agency has to strike to fulfil its legal obligations: the requirement of impartiality and independence of its experts (Article 63(2) of Regulation (EC) No 726/2004) and the public interest of providing the best possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use referred to the Agency (Article 57(1)).

The policy sets out the ground rules on which EMA involves experts in its work. It has provided a robust framework for managing competing interests over many years, by applying restrictions to scientific committees' members' and experts' involvement in a proportionate manner, considering in particular the nature of the declared interest and the type of activity where the expert was involved (e.g. decision-making committees vs advisory bodies).

Recent Court rulings (i.e. the appellate judgments of the Court of Justice in Joined Cases C-6/21 and C-16/21 P and Case C-291/22 P) have required the Agency to adjust certain aspects of its approach. The proposed revisions to the policy ensure alignment with the Court's findings and aim to rule out any possible doubts as to the objective impartiality of EMA's assessments.

The scope of the policy relates to the handling of competing interests of members, alternates and experts involved in the activities of the Agency's scientific committees, working parties and other groups (e.g. scientific advisory groups (SAGs), ad hoc expert groups (AHEGs)) as well as other bodies (i.e. Emergency Task Force (ETF), Medicines Shortages Steering Group (MSSG), Medical Devices Shortages Steering Group (MDSSG)).

As a general rule, EMA's policy has always prohibited individuals currently employed by or holding financial interests in a pharmaceutical company from participating in the Agency's activities, and this will remain unchanged. However, in case of other interests (e.g. role as investigator or close family member's interests), an individual's participation in certain activities may be possible, but subject to pre-defined restrictions. The revision of the policy is driven by the following elements:

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

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

As a consequence, the main changes proposed to the policy include:

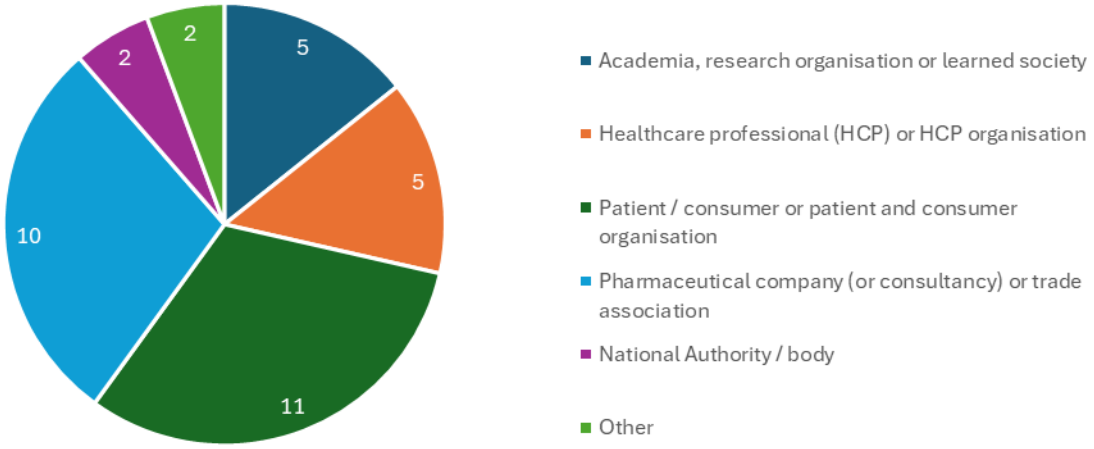
- Increased and aligned restrictions across roles and groups for experts with a **current interest** in a product: in such cases, experts will continue to be excluded from procedures related to the product concerned but now also for products in the same declared condition. Experts with an interest as **principal investigator** and **investigator** will now be subject to the same restrictions.
- Aligned restrictions across roles and groups, in case of **past employment** in a pharmaceutical company, of a past consultancy or strategic advisory role and of past activity as (principal) investigator, with a unified three-year cooling-off period. Consequently, the same rules that already applied to committee members will now also apply to experts who may be brought into the assessment process on an ad-hoc, consultative basis to provide their input on specific points.
- Strengthened handling of competing interests in the **medical device industry**, in light of EMA's extended mandate in this area. Similarly to the existing provisions for the pharmaceutical industry, it is proposed that current employment, consultancy or strategic role on general matters and financial interests in the medical device industry will not be compatible with any involvement in EMA's activities.
- Introduction of new rules to handle certain interests in **research organisations**, notably in case of involvement in a unit that develops or manufactures medicinal products or medical devices or acts as a marketing authorisation applicant or holder for a medicinal product. In such cases, proportionate mitigating measures are proposed by analogy to what applies to the pharmaceutical industry.
- The revised policy continues to allow and further clarifies the use of **'expert witnesses'**: such experts can be called upon by EMA, in situations where specific expertise is required that can only be provided by a few individuals, e.g. in niche areas, but who have certain competing interests. In such cases it might be in the interest of public health to invite these individuals to testify and give specialist advice on specific issues, yet without allowing them to take part in the deliberations of the relevant body.

The purpose of this document is to provide a high-level overview of the contributions received during the public consultation and how comments have been addressed by EMA in the final policy adopted by the Management Board in December 2024.

All comments and individual responses can be found on the EMA website page on Handling competing interests.

2. Contributors

In total, 35 contributions were received from a wide range of stakeholders. The distribution of respondents by stakeholder type is reflected in the chart below.



3. Summary of main points raised and EMA responses

All comments received during the public consultation have been analysed. Due to the amount and diversity of the comments made, this summary report will focus on the recurrent topics or main issues raised by stakeholders. A compilation of the comments related to those topics or issues are presented in annex for information.

3.1. Overall feedback

In general, stakeholders across all types recognise the importance of clear rules on managing competing interests. Several stakeholders from academia, research organisations or learned societies, Healthcare professionals (HCP) or HCP organisations, Patient/consumer or patient and consumer organisations (hereafter referred to as 'patient organisations') and pharmaceutical industry (pharmaceutical company or trade associations) acknowledged EMA's efforts to achieve this in a balanced and proportionate way.

Some stakeholders expressed their concern on the impact that the revised rules may have on the Agency's ability to involve relevant and necessary expertise in light of the new restrictions to be imposed following the Court rulings, in particular to experts involved in clinical research.

EMA feedback

This revision of the policy, whilst having to adjust certain principles in line with the Court rulings, still aims to preserve as much as possible EMA's capacity to secure the best scientific expertise.

The new rules should have no or minimal impact on the composition of EMA's scientific committees, from which rapporteurs are appointed based on the criteria of the best scientific expertise across Member States, and who are mostly longstanding employees of national competent authorities.

However, where the Agency may need to involve additional expertise (e.g. in the context of scientific advisory groups) on specific matters, this might become more challenging. This may require the Agency to expand its pool of experts to reach out not only to experts who may have participated in

clinical trials in the disease concerned but also to clinicians with experience in the management of patients with the condition in question.

Whilst the Agency will continue to make every effort to involve experts who fully comply with the rules set out in this policy, it also foresees the possibility to involve individuals as 'expert witnesses'.

3.2. Interests in research organisations

Inclusion of 'learned societies' in the definition of research organisation

Several stakeholders from academia, research organisations or learned societies and patient organisations observed that the definition of research organisation was too broad, in particular with respect to the inclusion of 'learned societies', since most do not conduct research as such.

EMA feedback

The definition of research organisation includes 'learned societies' as an example of entities '*whose primary goal is to pursue scientific research or to do so alongside the provision of educational and/or healthcare services*'. EMA agrees that most learned societies do not normally conduct research. Therefore, involvement in learned societies is not expected to be considered as an interest to be declared, unless the individual is involved in a learned society that is specifically engaging in activities defined as a competing interest for the purpose of the policy.

Involvement in manufacturing of in-house medicinal products or medical devices

The need for clarification on the involvement in the manufacturing of in-house medicinal products, medical devices, diagnostic tests or radiopharmaceuticals was also highlighted by several stakeholders from academia, research organisations or learned societies and healthcare professionals organisations.

On the other hand, comments were raised by stakeholders from the pharmaceutical industry expressing support for restrictions on individuals involved in a research organisation´s unit that manufacture ATMPs under the hospital exemption or suggesting considering such involvement in the same way as a contract research organisation.

EMA feedback

With the exception of the manufacturing of ATMP under hospital exemptions, involvement in a unit manufacturing so-called 'in-house' medicinal products or medical devices is excluded from the scope of the policy in light of the footnotes included which refer to Article 3 of Directive 2001/83/EC and Article 5(5) of Regulation 2017/745, respectively. With these footnotes, involvement in a unit manufacturing, for example, magistral preparations or medical devices used only within the health institution are not considered competing interests for the purpose of the policy. The footnotes have been clarified.

The restrictions applied to individuals involved (through employment or collaboration) in a unit of a research organisation that manufactures medicinal products (including ATMPs under the hospital exemption) or medical devices are the same as those applicable to employees of a pharmaceutical company or a CRO because such units will be considered in the same way as a pharmaceutical company or a medical device company for the purpose of the policy.

Involvement in the conduct of research and development activities at a research organisation for a medicinal product or a medical device together with a company'

Several patient organisations and healthcare professionals organisations suggested further clarification with respect to the '*Involvement in the conduct of research and development activities at a research organisation for a medicinal product or a medical device together with a company'*, in particular to

ensure that this would not exclude patients involved in research and development activities or research centres receiving grants from industry to perform fundamental research.

EMA feedback

The interest has been clarified to refer to '*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'.*

3.3. Definitions

Definition of consultancy/strategic advisory role

Two patient organisations proposed to exclude involvement in Community Advisory Boards (CABs) from the definition of consultancy/strategic advisory role. They considered that involvement in such advisory boards, which are created and /or governed by patient organisations providing patient perspective to pharmaceutical companies, should be differentiated from e.g. advisory boards of companies.

EMA feedback

EMA acknowledges that the objective of CABs differs from that of a pharmaceutical company. However, these are groups established to facilitate discussions on the latest developments and challenges related to medical research and procedures in a particular disease area with a company or body conducting the research, helping to guide medicinal product development. Therefore, the EMA takes the view that participation in CABs should be declared as consultancy/strategic advisory role.

Definition of financial interests

In the current policy, reimbursement of reasonable expenses directly related to a conference/seminar attendance is not considered a financial interest, and therefore does not need to be declared. This approach remains unchanged in the revised policy.

While a patient organisation welcomed that payment or reimbursement of reasonable expenses directly related to a conference/seminar attendance is not considered as a financial interest, other stakeholders expressed different views: one stakeholder from academia, research organisation or learned society, one from patient and consumer organisation and an 'other' stakeholder considered that this should be declared in light of the link to a pharmaceutical company and that 'reasonable expenses' was too vague or would be impossible to objectively clarify.

EMA feedback

'Compensation, fees or honoraria […] paid by a company to the individual in a personal capacity' are added in the definition of financial interests in the revised policy which may cover payments to attend a conference. However, EMA considers that *reimbursement of expenses* does not constitute a conflict as long as the expenses are reasonable. Such reimbursements support experts' participation in conferences and seminar and contribute to their continued development. The EMA Code of Conduct, that also applies to scientific committee members and experts involved in EMA activities, provides some guidance with respect to invitation and gifts, including on hospitality. In addition, national laws are in place to regulate promotion and advertising of medicinal products.

3.4. Cooling-off period

Several comments pertained to the cooling-off period during which restrictions apply for past interests.

For some interests (such as past employment, consultancy/strategic advisory role in a company and past (principal) investigator role), restrictions may be applied during a 3-year cooling-off period after the interest has ended. For other interests such as financial interests, grant or other funding to the expert's organisation/institution and close family member interests, no restrictions are applied once the interest has ended.

Divergent positions were expressed by stakeholders with respect to cooling-off periods.

Some stakeholders raised comments towards the need to apply longer periods:

- A pharmaceutical company considered that an expert should never at any time be allowed to assume the role of Rapporteur for products produced by his/her previous company.
- A patient organisation recommended extending the cooling-off period to four years.
- An 'other' stakeholder considered that all interests should be subject to a cooling-off period.

Other stakeholders expressed views towards possible reductions of cooling-off periods for interests related to participation in clinical research:

- A healthcare professionals organisation was of the view that the cooling-off period of 3 years for (principal) investigator may effectively lock out the critical expertise for a prolonged period of time.
- A pharmaceutical industry trade association recommended to avoid excessive restrictions to experts after their involvement in commercial trials.
- A patient organisation suggested a risk-based approach to avoid that the cooling-off periods and restrictions on indirect interests excludes specialized expertise.

EMA feedback

Cooling-off periods enable EMA to apply restrictions to guarantee impartiality in a balanced and proportionate manner, focusing on either the company or the product(s) for/on which the expert used to work. These are applied only for interests where it is considered warranted to minimise legitimate doubts of impartiality in relation to prior engagement with a company. This is however not considered warranted for some interests such as financial interests or close family member interests once the interest has ended as this would be disproportionate.

The length of 3 years, which has been applied for most interests in the policy over the past decade, is considered to be an adequate period of time, and is also within the range of those applied by other institutions.

Overall, while EMA has duly considered the different views expressed by stakeholders, no changes of the cooling-off period are proposed at present. In the context of the regular review of the policy, EMA will continue assessing the adequacy and impact of the cooling-off periods with a view to maintaining a balanced and robust framework.

3.5. Application of restrictions to medicinal products in the same declared condition

Several comments concerned the application of restrictions to 'products in the same declared condition' in case of interests declared on a specific medicinal product(s).

Two pharmaceutical companies, one patient organisation and one stakeholder from academia, research organisation or learned society shared views that the scope of restrictions was too narrow or insufficiently defined.

On the other hand, a stakeholder from the pharmaceutical industry highlighted that the interpretation could potentially be too broad and cover a wider range of products and may therefore further limit experts' involvement in EMA activities in certain areas.

EMA feedback

The EMA considers that the application of restrictions to medicinal products in the same declared condition reflects adequately the requirements expressed by the Court of Justice. Moreover, this approach ensures that access to essential expertise is not hindered, which would otherwise occur if exclusions were applied too broadly.

3.6. Expert witness

Several stakeholders from patient organisations, healthcare professionals organisations as well as from the pharmaceutical industry welcomed that the policy retains the possibility to use expert witnesses.

Some stakeholders also commented on the need for further clarifications on the circumstances, modalities and transparency regarding the engagement of expert witnesses.

EMA feedback

It is considered that further elements on how the Agency plans to work with expert witnesses in practice, should not be provided in the policy itself. The Agency will ensure that circumstances, modalities and transparency will be applied in a consistent manner. Experience with the use of expert witnesses may be reflected in EMA's annual report on independence.

3.7. Conflict of opinion

Two pharmaceutical companies, and a patient organisation made comments with respect to possible bias or impartiality related to matters other than interests with a company (e.g. scientific bias as expressed in public statements or opinions expressed against a company).

EMA feedback

EMA's scientific committees and other groups are composed of multiple members who bring different perspective and views. EMA considers that any pre-selection and exclusion of experts on the basis of previously expressed views would not be suitable as it would not respect freedom of speech and could also go materially beyond the requirement to ensure impartiality, which is the objective of the policy.

The EMA would like to recall that the Code of Conduct, which also applies to scientific committee members and experts involved in EMA activities, highlights the principles of integrity, objectivity and respect for others.

3.8. Transparency

Several stakeholders from the pharmaceutical industry made comments related to transparency in the selection of experts. Other stakeholders (from academia, research organisation or learned societies and 'other') called for increased transparency in the activities in which an expert is involved as well as steps taken/ restrictions applied.

One stakeholder (type 'other') suggested that EMA publishes an annual report, providing information on the handling of EMA's policy with detailed information on shortcomings, non-compliance and any anomalies witnessed. It was also suggested that cases of non-disclosure of interests should be published on the EMA website and sanctions should be applied.

EMA feedback

Since the establishment of EMA, transparency has been an important feature of the Agency's operations.

Declarations of interest and CVs of all scientific committee members, SAG members and experts are published on the EMA website and, where applicable, any restrictions applied to individual members/experts are reflected in all published meeting minutes.

EMA has robust rules of procedures and processes in place for the nomination of members and experts. Members of scientific committees and SAGs are nominated on the basis of their expertise. The appointment of the rapporteur/co-rapporteur, who are supported by a team of assessor and experts, is made on the basis of objective criteria, which ensure the provision of objective scientific opinions and will allow the use of the best and available expertise[1]. Additional experts involved are also nominated on the basis of their expertise in the therapeutic area or field to be covered.

The EMA would like to recall that, since 2015, it publishes annual reports on independence which provide information on how the independence policies have been concretely applied to EMA's activities and its experts in a given year. It includes facts and figures on the distribution of experts by interest level and outcome of the controls performed by EMA, as well as any recommendations for future updates of the policy based on experience, if applicable. The report also includes information on the launch and outcome of Breach of Trust procedures (which sets out how it deals with incorrect or incomplete declarations of interest by scientific experts and committee members).

4. Conclusion

EMA welcomes that several stakeholders appreciated the balanced approach EMA endeavours to strike in order to fulfil its legal obligations: ensuring that committee members and experts involved in the Agency's activities have no conflicts of interest that could affect their impartiality and independence, while also securing access to the best scientific expertise.

While some stakeholders have raised concerns on the impact that some of the restrictions introduced may have on the Agency's ability to access relevant expertise, it should be reminded that these changes have been introduced to ensure an adequate alignment of the Agency's policy with the recent judgments of the Court of Justice of the European Union.

Therefore, following due review and consideration of comments raised by a wide range of stakeholders, the Agency has not introduced any changes to the main principles as published for consultation on 10

[1] Procedural Advice on CHMP/CAT/PRAC Rapporteur/Co-Rapporteur appointment principles, objective criteria and methodology in accordance with Article 62 (1) of Regulation (EC) No 726/2004
Procedural advice on appointment and responsibilities of the CVMP rapporteur and co-rapporteur in accordance with Article 140(6) of Regulation (EU) 2019/6, and peer reviewer

October 2024. However, the Agency has introduced a number of clarifications to some definitions and also improved the readability and understanding of the policy.

The Agency will continue monitoring the impact and implementation of the policy as part of its annual reports on independence. The policy shall be reviewed after 3 years or at an earlier stage if considered necessary.

Annex – Extracted comments raised by topics or issues

Interests in research organisations

Stakeholder type	Comment
Healthcare professional (HCP) or HCP organisation	'The revised guidance now details how to manage the involvement of experts in research organisations , which are defined as '…any entity, including but not limited to universities, hospitals or learned societies, whose primary goal is to pursue scientific research or to do so alongside the provision of educational and/or healthcare services'. We believe that this definition is quite broad, and may need additional clarification, considering that, for instance, not all hospitals or learned societies carry out research. It therefore needs to be specified when research is seen as the primary goal of these organisations.'
Patient / consumer or patient and consumer organisation	'Including learned societies under the definition of research organizations could lead to misperceptions. Most societies, particularly in medical fields, do not conduct research directly but focus on fostering collaboration and knowledge sharing. They primarily serve as platforms for knowledge dissemination and professional development. For transparency and patient and public trust, it is important to clarify this distinction in the policy to avoid unnecessary restrictions on the participation of society representatives, whose contributions can enrich regulatory discussions without posing significant COI risks.'
Academia, research organisation or learned society	'Page 5, definition of 'Research organisation' This paragraph includes "learned societies" under organizations that have pursuit of scientific research as primary or one of their main goals. However, most medical societies don't conduct research themselves. [Stakeholder] supports researchers and research collaborations, but we do not commission nor conduct research. To avoid confusion or misperception regarding the role of learned societies, [Stakeholder] would welcome rephrasing of the text in a way that makes clear that conducting or commissioning medical research is not the "primary goal" of most learned societies. This same section states that "any unit within a research organisation that develops or manufactures medicinal products (including ATMPs under the hospital exemption) or medical devices or acts as a marketing authorisation applicant or holder for a medicinal product may be considered in the same way as a pharmaceutical company or a medical device company for the purpose of this policy". It must emphasized that in-house development of medicinal products, devices and diagnostic tests is widely used in academic hospitals and laboratories to meet the needs of patients who require highly specialize care, with no alternative available. To avoid the exclusion of experts who can provide such highly specialized care, careful and balanced assessment of competing interests is particularly important.'
Healthcare professional (HCP) or HCP organisation	'In-house preparations of medicinal products, in-house devices and diagnostic tests are widely used in the health sector. In certain fields such as rare diseases, the top experts may be involved in the development of ATMPs or in-house devices. A sufficiently flexible approach is necessary, along with a clear

Stakeholder type	Comment
	definition and information on the practical application, for instance within healthcare institutions and academia.'
Healthcare professional (HCP) or HCP organisation	'In-house preparations of medicinal products, in-house devices and diagnostic tests are widely used in the health sector. In certain fields such as rare diseases, the top experts may be involved in the development of ATMPs or in-house devices. A sufficiently flexible approach is necessary, along with a clear definition and information on the practical application, for instance within healthcare institutions and academia.'
Healthcare professional (HCP) or HCP organisation	'We would very much welcome a clarification of the „involvement in a unit that manufactures medicinal products or medical devices ". Indeed, this declared interest in a research organisation does suit the nuclear medicine ecosystem, as in that respect, all the professionals working in a research organisation having its own cyclotron (which is the case for most leading research organisations in Europe) would be excluded from interacting with EMA. We therefore invite the European Medicines Agency to differentiate between manufacturing of medicinal products to put in the market and medicinal products to be used by the producing institution.'
Pharmaceutical company (or consultancy) or trade association	'We support maintaining restrictions on individuals involved in a research organization unit that manufactures ATMPs under the hospital exemption.'
Pharmaceutical company (or consultancy) or trade association	'The strict restrictions that apply to experts affiliated with a research centre with manufacturing activities are justified also in relation to experts affiliated with a research centre's unit that is involved in the development of a medicinal product by carrying out activities close to the market in the interest of specific manufacturers. The most consistent approach would be to use the notion of 'Contract Research Organisation' instead of the notion of 'manufacturing' to define the units of a research organisation whose experts are subject to the strictest restrictions.'
Patient / consumer or patient and consumer organisation	'EMA's strict CoI approach for collaboration between patient associations and pharmaceutical companies in (research) projects may simplify categorisation and improve transparency but can adversely impact patient participation in EMA activities. [Stakeholder] urges EMA not to consider patient experts, patients' organizations and caregivers as pharmaceutical companies. Patients are human experts, and patient testimonials should be recognised by EMA as an essential resource in all stages of its processes.'
Patient / consumer or patient and consumer organisation	'Section 3.2.2.1 Direct interests: Involvement in the conduct of research and development activities at a research organisation for a medicinal product or a medical device together with a company [Stakeholder] feels that more clarity could be provided on the type of involvement considered here. Would it include only commercial arrangements or advisory roles as well? [Stakeholder] would like to point out that the involvement of patients in research and development activities can help make products better suited to patients' needs. While it is important to ensure the impartiality of the EMA processes and thus limit participation of patients with

Stakeholder type	Comment
	competing commercial interests, perhaps advisory roles without the power to influence decisions could be considered separately?'
Healthcare professional (HCP) or HCP organisation	'To ensure that experts from leading research centres in Europe and those performing fundamental research can contribute to meaningful EMA discussions, the nuclear medicine community would call the EMA to distinguish between "involvement in the conduct of research and development activities funded by a research grant for fundamental research supported by the industry" and the "involvement in the evaluation of products directly with a company". This would ensure that leading experts involved in fundamental research can continue contributing to EMA discussions on innovative matters.'

Definition of consultancy/strategic advisory role

Stakeholder type	Comment
Patient / consumer or patient and consumer organisation	'Consultancy or strategic advisory role to a company: There is a notable difference between providing advice and the ability to vote/influence decisions. [Stakeholder] feels that a clear differentiation should be made here between interests and competing interests and further guidance could be provided to clarify what each category would include. For example, would unpaid patient community advisory boards providing patient perspectives to companies or research organisations on unmet needs ("advice"), without any voting rights or power to influence decisions, be considered as a competing interest?'
Patient / consumer or patient and consumer organisation	'The interest should be declared as direct only if the (scientific) advisory board, steering committee or executive committee has been created and is governed by the company in question. This is for clarification, to make it explicit that the interest is direct only in this situation, as opposed to advisory boards created and governed by patients' organisations (Community Advisory Board), and/or learned societies. Proposed writing: This includes lectures, presentations or training organised by individual companies, participation (with a right to vote/influence the outputs) in a(n) (scientific) advisory board, steering committee or executive committee *created and/or governed by the company* with the role of providing advice/expressing opinions on the (future) strategy, direction and development activities of the company concerned.'

Definition of financial interests

Stakeholder type	Comment
Patient / consumer or patient and consumer organisation	'[Stakeholder] welcomes that payment or reimbursement of reasonable expenses directly related to a conference/seminar attendance is not considered as a financial interest.'
Academia, research	'The policy excludes "payment for or reimbursement of expenses incurred with the research work or reimbursement of reasonable expenses directly related to a conference/seminar attendance". Yet, such payments are likely to be part of

Stakeholder type	Comment
organisation or learned society	a marketing activity, creating a sense reciprocity towards the company […]. We recommend including such payments, as is done under the US Sunshine Act. The policy implicitly excludes hospitality payments, which have been shown to influence clinical decision-making […]. These payments should be reported.'
Patient / consumer or patient and consumer organisation	'We argue that the reimbursement of expenses directly related to attending a professional conference or seminar should also be declared. The exception currently provided ("beyond reimbursement of reasonable expenses") remains too vague and could encompass undue rewards or compensations. Declaring all non-monetary and in-kind support including paid travel, research assistants, staff support, equipment subsidies, etc. would be preferable, and in line with the World Health Organization's (WHO) own approach to competing interests. It is unfortunate that this has been removed from the EMA's current policy.'
Other	'Part 3.2.2.1 on direct interests The last paragraph at p. 6 concerns financial interests in a company. In our view, these payments should be listed as financial interest as they indicate a link between the expert and the company. It would be impossible to objectively clarify which reimbursements go beyond reasonable expenses. In national sunshine laws, industry is invited to indicate payments to experts for such costs. Numerous studies have shown that even small gifts given by pharmaceutical companies influence healthcare professionals' prescribing behavior.'

Cooling-off period

Stakeholder type	Comment
Pharmaceutical company (or consultancy) or trade association	'There are instances where individuals serving in capacities overseeing the scientific assessment of numerous products for which the individual's prior employer is the MAH. If the purpose of the revision is to align with the position of the European Courts to remove conflicts of interest that may arise, an expert should never at any time or under any circumstances be allowed to assume the role of Rapporteur for products produced by his/her previous company, particularly in circumstances where there exists alternative experts who can assume the same role.'
Patient / consumer or patient and consumer organisation	'We recommend extending the three year cooling period to four years.'
Other	'As regards the cooling-off period, it is difficult to understand why they are applied for some interests but not for others. Such exceptions do not improve the system but makes it too complicated. We advise to apply cooling-off periods for all different interests.'

Stakeholder type	Comment
Healthcare professional (HCP) or HCP organisation	'The exclusion of experts engaged in clinical research as investigator or principal investigator is a matter of concern, and the cooling off period of 3 years for such an engagement may effectively lock out the critical expertise for a prolonged period of time. Where EMA indicates in the introduction and purpose of the policy the need to reconcile the need for impartiality with the public interest - which in first instance needs to relate to the interest of patients affected by a disease - the nature of rare diseases implies that clinicians need to be engaged with clinical research to build large enough cohorts to generate date for regulatory filings, while at the same time being able to provide innovative treatment options for the patients.'
Pharmaceutical company (or consultancy) or trade association	'as the EU aims to accelerate clinical research, it is expected that more experts will engage in commercial trials. Recognising this, we recommend that EMA's Policy 0044 avoids excessive restrictions on such experts, allowing for their involvement post-trial where their expertise remains valuable. Overly broad exclusions risk severing ties with top experts who are essential to advancing the EU's innovation and regulatory goals.'
Patient / consumer or patient and consumer organisation	'Current cooling-off periods and restrictions on indirect interests risk excluding specialized expertise vital for patient outcomes. A nuanced, risk-based approach, tailoring restrictions to the potential bias level, would uphold impartiality while ensuring access to the expertise necessary to advance patient care.'

Application of restrictions to medicinal products in the same declared condition

Stakeholder type	Comment
Pharmaceutical company (or consultancy) or trade association	'Our concerns primarily apply to a conceptual shift in the draft policy prioritizing the significance of a specific product's indication regardless of whether the very same active substance is marketed by one MAH for one or more additional indications. That is, if "Active Substance A" is developed by a company for one initial indication ("Indication 1"), and Active Substance A is subsequently or even simultaneously approved for one or more separate indications ("Indication 2"), restrictions on participation of, for instance, a Rapporteur during the "cooling off period" would only apply to the extent an individual actively worked on Indication 1 during their time with the organization. This is despite the fact that the individual in this example was instrumental in developing Active Substance A, and it just so happened that the initial indication was Indication 1. This is clearly problematic as it is doubtless the case that an organization's development efforts are necessarily unified or otherwise fully integrated to an extent. When a product is approved for an additional indication as part of the incremental product development, a developer does not start with a blank slate. Development efforts (often including members of the same teams) for the active substance and initial indication are the basis for and used to accelerate approval for any additional indication. Development of Active Substance A, even if initially approved for Indication 1, is necessarily and inextricably connected to Indication 2 from the perspective of drug development, and a party's contributions to the

Stakeholder type	Comment
	development of Active Substance A and Indication 1 directly contribute to development efforts of Indication 2 even if such individual is not nominally involved in discrete approval efforts for Indication 2. Many active substances are now increasingly being developed in parallel for multiple indications on the basis of the same mechanism of action, and such substances are also being marketed in the EU with multiple therapeutic indications in such diverse therapeutic areas as metabolic diseases, autoimmune diseases, oncology, respiratory diseases. We do not consider that the policy shift in the revised guidance is compatible the key legal principles of the established case-law to ensure that the regulatory system is established "to offer sufficient guarantees to exclude any legitimate doubt as to any bias". It would appear that the EMA's suggested language conveys the effect of permitting cross-pollination, thus clearly creating an appearance of bias. This concern applies to two sections of the proposed policy language. The first is related to restrictions relative to "rival products" which have been removed wholesale. Previously, the concept of rival products related to situations where there were only a small number of rival products. The concept of 'rival products' was the subject of extended discussions by the General Court at first instance and Court of Justice on appeal for the purpose of assessing competing interests that could give rise to a legitimate concern over a conflict of interests. The second applies to the new section which reads, in pertinent part, "…individuals cannot act as Rapporteurs on the medicinal product in relation to which they declared interest and on medicinal products intended for the same therapeutic condition as that declared in the interest during the cooling-off period." It is patently obvious that development work on an active substance would be inextricably connected to an organization's marketing and promotion of the active substance regardless of indication.'
Academia, research organisation or learned society	'The term "products in the same declared condition" is insufficiently defined, without considering applications where products might be comparable or indirectly related. The importance of considering financial interests in competitor products is paramount […]. We recommend a wider definition, similar to the ICMJE guidance, which broadly defines relevant marketed and pipeline products (https://www.icmje.org/disclosure-of-interest).'
Patient / consumer or patient and consumer organisation	'The definition of interest associated to a specific medicinal product is still too narrow. Widening the declaration of interest to the therapeutic group would ensure stronger safeguards within the activities of the EMA.'
Pharmaceutical company (or consultancy) or trade association	'In those instances that experts are restricted to intervene in the EMA's activities for products produced or developed by the organisation they are affiliated with, PharmaMar respectfully invites the EMA to expand such restrictions also in relation to competing or rival products. It is unreasonable to assume that a third-party observer would have legitimate doubts about the impartiality of an expert who participates in the EMA's activities in relation to

Stakeholder type	Comment
	the product developed by the organisation they are or were affiliated with, but that no legitimate doubts would arise in relation to their involvement in the assessment of competing or rival products.'
Pharmaceutical company (or consultancy) or trade association	'[Stakeholder] supports the removal of the "rival products" definition and references to "rival products" throughout the policy. However, if the term "any product in the declared condition" is used in its place, this may lead to divergences in interpretation and practical application of the related restrictions. This term could potentially cover a wider range of products than "rival products," which is based on similarity in target patient population and capacity to constitute commercial competition, in addition to similarity of clinical objective (i.e., treating, preventing or diagnosing a particular condition). The introduction of this new concept may therefore further limit experts' involvement in EMA activities in areas where expertise is already limited (e.g., gene therapy). The introduction of a caveat to the restrictions that apply also to "any product in the declared condition" to the effect that they do not apply when there are very few products in the declared condition, or the treatment approach is novel, may be difficult to operate in practice. It is therefore particularly important to leverage the rules on expert witnesses in such cases.'

Expert witness

Stakeholder type	Comment
efa	'EFA welcomes that 'expert witnesses' are invited to provide oral testimonies and meet with companies. This collaboration is essential for reaching an outcome that considers every day- and unmet needs of the community, but expert witnesses should be involved at every stage.'
Pharmaceutical company (or consultancy) or trade association	'The introduction of a caveat to the restrictions that apply also to "any product in the declared condition" to the effect that they do not apply when there are very few products in the declared condition, or the treatment approach is novel, may be difficult to operate in practice. It is therefore particularly important to leverage the rules on expert witnesses in such cases. We ask for confirmation that expert witnesses can be brought in even when they are otherwise barred (not just limited, as the current text suggests) from involvement in the activity in question.'
Patient / consumer or patient and consumer organisation	'We welcome the "expert witness" status, which enables experts including patient representatives with potential conflicts of interest to contribute under defined conditions, such as when only few individuals have the necessary expertise to provide input. This flexibility allows diverse patient insights to enhance the scientific evaluation without compromising assessment integrity. However, clearer criteria for expert witness involvement are essential to ensure the systematic inclusion of the patient voice and to draw on the valuable lived experience of patients. We urge clarification of the circumstances in which the involvement of expert witnesses can be aligned

Stakeholder type	Comment
	with public health interests. This clarity will facilitate more effective and meaningful patient input into the evaluation of medicines.'
MPE	'MPE believes that it is critical for EMA processes to include the best and most relevant expertise while ensuring impartiality and transparency. To this effect MPE welcomes the dedication to involve, with limitations, as expert witnesses, the best available expertise even in the case of competing interests (section 4.2.1 Achieving a robust process: General principles).'
European Society of Endocrinology (ESE)	'The suggested policy risks excluding a large number of top experts from EMA consultations. The option for EMA to call in experts as expert witness is critical, but without having an engaged role in the further discussions this may risk undermining the quality and outcomes of these processes.'
Patient / consumer or patient and consumer organisation	'Annex 1: Expert Witness status not mentioned in the tables: As opposed to the prior policy 044 from 2016, Expert witnesses do not have their own column anymore. Restrictions that apply to them are explicit in the text of the policy, but their absence from the annex tables makes it more difficult to understand 1/ this role exists, 2/ which restrictions apply. It is important to make this status more visible in EMA activities, and for this they should appear in the table.'
Other	'Expert witness (cf. p. 9) In line with the principle of transparency, we call on to make their testimonies publicly available together with the minutes of the meeting. EMA should explain the reasons and for which specific expertise the expert was invited.'
HAI	'Particular aspects of the revised policy we welcome include: […] The introduction of further restrictions on the permissions of expert witnesses.

Conflict of opinion

Stakeholder type	Comment
Pharmaceutical company (or consultancy) or trade association	'Neither the current policy, nor the proposed revisions, consider the potential conflict of interest that arises through the use of experts who make public statements or comments about medicines for which they are then later asked to provide feedback on. It is essential that this source of conflict of interest/impartiality also be addressed in the proposed revisions to this policy, particularly as advice from these experts is considered by the CHMP in regulatory decision making.'
Pharmaceutical company (or consultancy) or trade association	'An issue not addressed with this particular group of academic experts is that the current competing interest statement does not cover scientific bias or impartiality among experts who have strongly engaged in a competing scientific theory as exemplified by the recent Neurology SAG meetings regarding the Lecanemab review, where remaining experts had publicly stated their belief in competing scientific theories and thus skepticism about the approval to be discussed.'

Stakeholder type	Comment
Patient / consumer or patient and consumer organisation	'Not having had an interest in a clinical trial is no guarantee of impartiality in the assessment of the pharmaceutical product concerned. (Principal) Investigators with current or past (0-3 yrs) interests have now more restrictions in all activities compared to the previous policy, whereas other clinical experts who do or did not serve as (principal) investigators have no restrictions. The absence of interests as (principal) investigator is certainly not a guarantee of impartiality, as clinical experts who were not invited to join a clinical trial might express partial opinions against the interests of the clinical trial sponsor, for example out of a sense of "revenge" or "punishment". [Stakeholder] is aware of situations where clinical experts who were not invited to join a clinical trial adopted positions against a product from the pharmaceutical company in question, and yet were prescribing the product to their patients, ie on a compassionate basis.'

Transparency

Stakeholder type	Comment
Pharmaceutical company (or consultancy) or trade association	'Consideration could be given to adopting a more transparent approach similar to that utilized by the US Food and Drug Administration (FDA) for example, whereby any relationships with industry are vetted by FDA leadership (benefits are weighed with potential limitations) and that this vetting is publicly disclosed. The FDA also remove from consideration any proposed experts who make public comments in advance of providing their expert advice at an Advisory Committee meeting.'
Pharmaceutical company (or consultancy) or trade association	'Potential and actual conflicts of interests need to be assessed publicly and not exclude necessary competence without grounds.'
Pharmaceutical company (or consultancy) or trade association	'Expanded transparency around the expert selection process, particularly for highly specialised fields, would also enhance stakeholder confidence and help identify potential improvements in timely expert appointment.'
Pharmaceutical company (or consultancy) or trade association	'Before experts are appointed, any interested party should be granted the opportunity to put forward written questions and to obtain clarification about candidates' potential conflicting interests.'
Academia, research organisation or learned society	'We would welcome specific reference in the policy to the consultation role which medical societies can and should play in the selection of experts. European medical societies, such as [Stakeholder], can help identify and engage the appropriate experts across Europe, including – and crucially – in rare or ultra-rare diseases, for which often only a small number of experts is available across the continent. Importantly, [Stakeholder] and other medical societies play a key role in ensuring that individual expertise is grounded in 'collective expertise', through their clinical and scientific expert networks and development of consensus and evidence-based clinical practice guidelines and (through tools such as the MCBS:H) assessment of the clinical benefit of new

Stakeholder type	Comment
	medicines. Reliance on collective rather than just individual expertise also helps to mitigate the impact of any competing interests on the part of individual experts.'
Pharmaceutical company (or consultancy) or trade association	'EMA could also introduce a hearing officer in its own procedures, which could reduce unnecessary litigation by providing an independent assessment of possible violations of the EU Charter of Fundamental Rights and the general principles of EU law.'
Other	'Appointment of a "deontologist" to improve the independence of assessments of declaration of interests: We call on EMA to appoint a deontologist to ensure the compliance with the obligations to declare interests and prevent CoI. For the daily work, the deontologist should be supported by an ethic unit, in charge of the analyses of CoI declarations and verification of their completeness. All declarations shall be systematically assessed. Cases of non-disclosure of interests should be published on the EMA website and sanctions should be applied. The "deontologist" should present a detailed annual report, providing information on the handling of EMA's CoI policy with detailed information on shortcomings, non-compliance and any anomalies witnessed. The report should be addressed to the ECA, the EP and the EU Ombudsman. It should be made publicly available on the EMA website.'
Academia, research organisation or learned society	'Publishing individual declarations, including in the minutes, is important but is impractical for comprehensive assessment of interests. An additional solution would a searchable database, modelled on the US Open Payments, where users can review experts' interests and any connections to advice provided in meetings.'
Other	'Together with the publication of the declaration of interests and CV, the EMA website should also include information on the activities the expert is involved in. Public access should be provided on steps taken by EMA to restrict/exclude conflicted experts from EMA activities going beyond statements in meeting minutes.'
Patient / consumer or patient and consumer organisation	'Transparency and Public Access: The policy mandates publishing Declarations of Interest, but it could expand to include periodic reviews of public disclosure practices and feedback mechanisms. This would enhance public trust in the transparency process.'