10 April 2024
EMA/2304/2025, Rev 1
European Medicines Agency

Overview of comments received on the draft revision of EMA's Policy on handling competing interests of scientific committee members and experts ('Policy 0044', EMA/54457/2024)

Please refer to Outcome of Public consultation on Policy 0044 - Summary of comments and EMA feedback *for a summary of all comments received and how these have been addressed by EMA in the final policy adopted by the Agency's Management Board in December 2024.*

Interested parties (organisations or individuals) that commented on the draft Policy revision as released for consultation and which agreed to the publication of their comments:

Stakeholder number	Name of organisation or individual	Stakeholder type
1	BioArctic AB	Pharmaceutical company (or consultancy) or trade association
2	BioMed Alliance	Healthcare professional (HCP) or HCP organisation
3	Cancer Patients Europe (CPE)	Patient / consumer or patient and consumer organisation
4	Dr Sharon Batt, Dalhousie University, Canada Dr Cinzia Colombo, Mario Negri Institute, Italy Dr Courtney Davis, King's College London, UK Dr Alice Fabbri, University of Bath, UK Prof Adriane Fugh-Berman, Georgetown University, USA Prof Barbara Mintzes, University of Sydney, Australia	Academia, research organisation or learned society

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
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Stakeholder number	Name of organisation or individual	Stakeholder type
	Dr Piotr Ozieranski, University of Bath, UK Dr Lisa Parker, University of Sydney, Australia	
5	Eisai	Pharmaceutical company (or consultancy) or trade association
6	European Association for Clinical Pharmacology and Therapeutics (EACPT)	Academia, research organisation or learned society
7	European Association of Nuclear Medicine (EANM)	Healthcare professional (HCP) or HCP organisation
8	European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)	Pharmaceutical company (or consultancy) or trade association
9	European Federation of Allergy and Airways Diseases Patients' Associations (EFA)	Patient / consumer or patient and consumer organisation
10	European Federation of Pharmaceutical Industries and Associations (EFPIA)	Pharmaceutical company (or consultancy) or trade association
11	European Hematology Association (EHA)	Academia, research organisation or learned society
12	European Organisation for Rare Diseases (EURORDIS)	Patient / consumer or patient and consumer organisation
13	European Patients' Forum (EPF)	Patient / consumer or patient and consumer organisation
14	European Society of Cardiology (ESC)	Healthcare professional (HCP) or HCP organisation
15	European Society of Endocrinology (ESE)	Healthcare professional (HCP) or HCP organisation
16	Eva Stumpe	Patient / consumer or patient and consumer organisation
17	Federación de Asociaciones Científico Medicas Españolas	Healthcare professional (HCP) or HCP organisation
18	Finnish Medicines Agency (Fimea)	National Authority / body
19	Health Action International (HAI)	Patient / consumer or patient and consumer organisation
20	Julian Isla Gomez	Patient / consumer or patient and consumer organisation
21	Läkemedelsverket / Swedish Medical Products Agency	National Authority / body
22	Lif Sweden	Pharmaceutical company (or consultancy) or trade association
23	Lymphoma Coalition	Patient / consumer or patient and consumer organisation

Stakeholder number	Name of organisation or individual	Stakeholder type
24	Michael Lassmann	Academia, research organisation or learned society
25	Myeloma Patients Europe (MPE)	Patient / consumer or patient and consumer organisation
26	Orexigen Therapeutics Ireland Limited	Pharmaceutical company (or consultancy) or trade association
27	Parkinson's Europe	Patient / consumer or patient and consumer organisation
28	Pharma Mar S.A.	Pharmaceutical company (or consultancy) or trade association
29	Prescrire	Other: A not-for-profit continuing education organisation committed to better patient care
30	SwedenBIO	Pharmaceutical company (or consultancy) or trade association
31	Viviana Mascilongo	Other: European Stakeholder, Lead Auditor ISO 9001:2015, Caregiver

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1. BioArctic AB	BioArctic's response to the proposed revision of the policy on handling of competing interests of scientific committee members and experts ('Policy 0044'). We believe that the suggested draft will have a substantial debilitating impact on Europe's ability to study and evaluate new, transformative, first-in-class treatments and will result in limited access to treatments among European patients. BioArctic advocates for a process that allows for public affirmation of potential or actual conflicts of interest and a transparent evaluation of opinions. Inhibiting experts due to their experience and involvement in drug development will not only limit knowledge transfer but also make it more difficult to conduct clinical trials in the EU, inducing a reluctance among key opinion leaders and clinicians to participate in trials. Considering the already diminishing number of clinical trials being performed in the EU (global share of clinical trials falling from 25% in 2013, to 19% in 2023), this would be a detrimental development for EU's competitiveness in such an essential industry area as the pharmaceutical field.	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 whilst ruling out any possible doubts as to the objective impartiality of EMA's assessments.
	The current proposal eliminates experts who have connections with industry, leaving only scientific or academic "experts" with limited clinical knowledge of the relevant indication eligible to provide testimony. 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	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

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	stated their belief in competing scientific theories and thus skepticism about the approval to be discussed.	committee members and experts involved in EMA activities, highlights the principles of integrity, objectivity and respect for others.
	In certain fields, such as rare diseases, the few experts, patients, and industry work in collaboration and co-creation to develop treatments. To put a ban on this collaboration by excluding experts and patient representatives from providing expert consultation to the EMA will severely limit the ability to develop new treatments for this vulnerable group of patients. As treatments become more patient-specific and precision-based, the number of experts with actual knowledge about a particular disease or mode of action will decrease even further. BioArctic believes it is important that all knowledgeable voices be heard in the scientific review and approval process for drugs in the EU to properly evaluate new, innovative treatments. By using open and verifiable disclosures and waivers, each expert's opinion can be fairly regarded and valued. The policy can set a framework for considering bias rather than trying to eliminate it. BioArctic advocates for an open and transparent process that allows for public affirmation of potential or actual conflicts of interest and a transparent evaluation of opinions – from all sides.	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, whilst ruling out any possible doubts as to the objective impartiality of EMA's assessments. 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

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		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'.
2. BioMed Alliance	Medical experts play a key role and contribute to the regulatory system for medicines and medical devices, and it is important that any conflicts of interest are managed in a balanced manner taking into account the different roles and responsibilities that many clinical experts have. The BioMed Alliance, representing 35 European medical and research societies, therefore shares its views on the EMA Draft Revision of Conflict of Interest Policy, highlighting key concerns that may prevent the involvement of experts in regulatory processes at EU level. Regulatory authorities must align and collaborate to ensure that COI policies are implemented in a way that enhances transparency whilst ensuring that the necessary expertise can be brought in, in the interest of patients and public health systems. It is therefore essential to avoid an unnecessarily rigid interpretation of COI policies. This is particularly the case in fields where there the pool of experts is already small, such as in rare diseases or for certain paediatric indications, where experts are much sought after. Many scientists and clinicians with the necessary expertise to provide an authoritative review of a new medicine or medical device, and particularly the leading experts, are likely to be involved in a variety of research,	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 whilst ruling out any possible doubts as to the objective impartiality of EMA's assessments. 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

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	academic and regulatory roles. Transparency on these activities is key, and a balanced and sufficiently flexible approach to managing conflicts is necessary to prevent the exclusion of high-quality clinical expertise, while taking into account the specificities of different medical fields. The BioMed Alliance recognises the importance of having clear rules on managing conflict of interest, and which most biomedical societies have also established within their own organisations. However, the BioMed Alliance would like to express several concerns with the recent proposed changes in the EMA's Conflict of Interest Policy, which we believe may unduly affect availability of highly qualified experts and, ultimately, the quality of scientific advice provided. We welcome the EMA's mentioning of the need to have its approach guided by the principle of proportionality and has to be balanced with the need to secure the best (specialist) scientific expertise for involvement in the Agency's activities related to medicinal products for human and veterinary use or medical devices'. While blatant conflicts of interest need to be prevented, a balanced approach should be taken, and the priority must be to ensure that the best scientific expertise can be involved.	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'.
	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	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

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	out research. It therefore needs to be specified when research is seen as the primary goal of these organisations. However, the guidance also mentions that some departments of research organisations may be considered at the same level as a manufacturer: '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'.	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.
	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. Experts develop ATMPs or in-house devices as healthcare services to meet their patients' needs, and often because there is no viable alternative available. Clear conflicts of interest must be avoided, but these special circumstances must be taken into account to make a careful assessment of the potential conflicting interest, to prevent a large number of experts from being excluded. Learned societies bring together large numbers of healthcare professionals in their fields and can be good partners in identifying experts with specific knowledge, while their established, generally strong conflict of interest	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. EMA would also like to highlight that in its previous version, the policy already included

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	policies enable them to also consider such aspects when identifying experts.	that any unit, department, section or entity within research organisations, that manufacturers medicinal products, including ATMPs under hospital exemption, or is a marketing authorisation applicant/holder, shall be considered as a pharmaceutical company for the purpose of this policy. Staff members of such units, sections, departments or entities are considered to be equivalent to staff members of a pharmaceutical company. Other parts of the organisation to which the unit, section, department or entity belongs can be excluded from this definition of a pharmaceutical company. This is also in line with the Court ruling. In the latest revision, these interests have now been grouped under interests in research organisation, to provide clarity and enable consistent declaration and evaluation.
3. Cancer Patients Europe (CPE)	Cancer Patients Europe welcomes the opportunity to contribute to the EMA's consultation on revising the handling of competing interests for committee members and experts (Policy 0044). We welcome this revision, especially following recent court rulings that highlight the importance of independent advisory roles and underscore the need for a conflict-of-interest framework that does not hinder patient access to essential treatments. Patient representatives play a critical role in regulatory discussions within EMA's committees, working parties, and advisory groups. Their presence	The EMA fully agrees that patients and consumers bring a 'real-life' experience as well as specific knowledge and expertise to scientific discussions on medicines and on the impact of regulatory decisions. EMA has an established framework for engagement between with patients and consumers and their organisations which

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	ensures that patient perspectives are considered alongside scientific and clinical data, adding a valuable dimension to decision-making. We particularly value the revised policy's clarity on managing conflicts from engagements in research, pharmaceutical, and medical device activities. In light of recent legal guidance, this conflict-of-interest policy enhances transparency and strengthens EMA's commitment to integrity. It's vital that conflict-of-interest management remains both fair and practical. Patient advocates often interact with the pharmaceutical industry through trials, advocacy, and advisory roles, which are essential for advancing treatments. However, these interactions should not lead to the exclusion of patient voices from regulatory discussions due to excessively rigid rules. These interactions help create an informed, expert patient, who brings both unique lived experience and critical insights to the regulatory process, enhancing the relevance and depth of these discussions. The revised policy offers a welcome distinction between "direct" and "indirect" interests, allowing representatives from organizations receiving grants to still participate in EMA activities. This proportional approach to conflicts of interest helps avoid unnecessary exclusions while maintaining a balance between transparency and expertise. Given the limited pool of experienced patient advocates, particularly in rare and pediatric cancers, we recommend flexibility where appropriate to ensure patient voices remain integral. Maintaining public trust in EMA's processes is crucial. By ensuring a balanced approach to conflict management, this policy can uphold	outlines the basis for involving patients and consumers in Agency activities. Collaborating with these groups supports transparency and improves regulatory processes. 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 ensure access to expertise, including that of patients.

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	confidence among stakeholders while benefiting from the valuable insights of patient experts. We appreciate the opportunity to provide input and remain available to engage further in this consultation process.	
4. Dr Sharon Batt, Dalhousie University, Canada Dr Cinzia Colombo, Mario Negri Institute, Italy Dr Courtney Davis, King's College London, UK Dr Alice Fabbri, University of Bath, UK Prof Adriane Fugh-Berman, Georgetown University, USA Prof Barbara Mintzes, University of Sydney, Australia Dr Piotr Ozieranski, University of Bath, UK	We thank the EMA for the opportunity to comment on Policy 0044, concerning competing interests for members of scientific committees and experts. Representing an international group of researchers committed to transparency, we aim to further strengthen its clarity, scope, and enforceability.	
	1. Definitional ambiguities 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 (1). 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/).	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.
	2. Scope limitations 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 a marketing activity, creating a sense reciprocity towards the company (2). We recommend including such payments, as is done under the US Sunshine Act.	'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

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Dr Lisa Parker, University of Sydney, Australia	The policy implicitly excludes hospitality payments, which have been shown to influence clinical decision-making (3). These payments should be reported.	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.
	The policy lacks specifics on indirect payments from intermediaries (e.g., medical communications companies) and patient organisations who themselves receive industry funding (e.g., a patient organisation may be financed indirectly through another organisation coordinating a project funded by a pharmaceutical company). We recommend that the EMA require reporting of such indirect payments.	Noted. However, it would be disproportionate to expect an individual to report indirect industry funding when these are not specifically used to support their activities.
	Another limitation is that the adopted definition of close family members' interests does not include stable, but not registered partners. The definition should be extended to stable but not registered partners.	The definition is in line with the definition of family member in Article 2(2) of Directive 2004/38/EC (Free Movement Directive).
	Additionally, to minimise the risk of undue influence we recommend a "cooling off" period exceeding 3 years, at least for decision-makers.	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

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		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. Institutional financial interests Guidelines for institutional interests are not specified, omitting situations where an expert is involved in grant approvals, consultancies or research projects on behalf of their institution, without necessarily being directly involved in their implementation or management. We recommend that the policy includes provisions for institutional conflicts. Declarations from representatives of patient or health consumer organisations do not seem required, while such organisations often receive industry funding. We recommend that all industry payments to such organisations be reported, including those routed through intermediaries.	When falling under the definition specified in the policy, consultancies or research projects, whether conducted by the expert or on behalf of their institution, are required to be declared. Participation of patient or consumer organisations in the Agency's activities as an expert is subject to submission and evaluation of a declaration of interest in accordance with Policy 0044. Grant and funding to the organisation concerned are required to be declared as defined in the policy.
	4. Verification, transparency and process The policy lacks verification details for ensuring the declarations' completeness and accuracy. Yet, research underscores underreporting of interests among clinical trialists, guideline committee members, and advocacy groups (1, 4). EMA should detail processes for updating, verifying, and maintaining declarations. All declarations of interest should be retained in a public register for at least 5 years. Also, minutes of the	EMA systematically conducts *ex ante* controls on any new experts being registered in its Experts Management Tool. These controls check that the information has been entered in the correct sections of the declaration of interest (DoI) and that the time periods in the DoI match with those given in the expert's CV.

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	scientific committees should include all declarations of interests of Committee chairs, members, and experts, and not just cases where restrictions were applied.	*Ex post* controls are also carried out every year on a sample of declaration of interests. These controls are conducted on a defined sample in order to check the correct completion of the DoI by experts, the correct evaluation of the DoI and implementation of restrictions applicable to the experts by the Agency as well as the correct reflection in the meeting's minutes of the level of participation in the meeting. Outcome of *ex ante* and *ex post* controls are reported in EMA's annual report on independence. Declaration of interests of committee chairs, members and experts are continuously available on EMA's website: European experts
	5. User interface 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.	EMA conducts comprehensive assessments of competing interests in line with the process defined in the policy and relevant standard operating procedures. Transparency related to declaration of interests is in line with the requirements from the legislation. EMA takes note of the comment and may consider increased search functions' feasibility in the future.
	6. Enforcement and sanctions	The breach of trust procedure outlines the steps taken where the Agency has knowledge of

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	The "Breach of trust procedure" addresses noncompliance but adherence would benefit from graded sanctions based on the severity of noncompliance. Stricter and more explicit sanctions for repeat offences or undisclosed indirect interests would underscore the importance of thorough declarations. We also recommend creating an ethics office and appointing a deontologist to facilitate compliance with the regulations. 1. Mandeville KL, Barker R, Packham A, Sowerby C, Yarrow K, Patrick H. Financial interests of patient organisations contributing to technology assessment at England's National Institute for Health and Care Excellence: policy review. BMJ. 2019;364:k5300. 2. Wazana A. Physicians and the Pharmaceutical IndustryIs a Gift Ever Just a Gift? JAMA. 2000;283(3):373-80. 3. DeJong C, Aguilar T, Tseng C-W, Lin GA, Boscardin WJ, Dudley RA. Pharmaceutical Industry–Sponsored Meals and Physician Prescribing Patterns for Medicare Beneficiaries. JAMA Internal Medicine. 2016;176(8):1114-22. 4. Saleh RR, Majeed H, Tibau A, Booth CM, Amir E. Undisclosed financial conflicts of interest among authors of American Society of Clinical Oncology clinical practice guidelines. Cancer. 2019;125(22):4069-75.	potential incomplete or incorrect declaration of interest. Decisions taken by the Executive director take into account the nature of the information missing from the declaration of interest as well as whether this was done intentionally or through gross negligence. A dedicated team at EMA oversees the management of scientific committee and other bodies members and expert's declarations of interest. They are in charge of *ex ante* controls. Together with the Institutional and Policy department and where appropriate the legal department, they support compliance with Policy 0044. The Institutional and Policy Department also monitors the implementation and compliance with Policy 0044. This is reflected in the annual reports on independence, which may include recommendations for future policy revisions.
5. Eisai	We have 2 concerns with the proposed revisions to Policy 0044: 1. The proposed revisions will severely restrict the EMA's ability to obtain feedback from leading experts involved in the diagnosis, management and treatment of diseases. Input from experts, who have direct expertise with	This revision of the policy, whilst having to adjust certain principles in line with the Court rulings, still aims to preserve as much as

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	the disease under discussion, is an important part of regulatory decision making. Limiting scientific discussion to a smaller group of individuals (such as the case for Scientific Advisory Group (SAG) core membership), who may not have expertise in the specific therapeutic area under discussion, does not support the intended purpose of soliciting expert input. 2. 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. Collaboration between regulators, the pharmaceutical industry and experts is essential for the delivery of novel therapies to help patients. Industry engages with experts specifically because they are at the forefront of science, understand the clinical environment, have an understanding of the patient need, and have an understanding of the clinical drug development process (such as patient selection, assessments, etc). It is troubling that those at the forefront of advances in the diagnosis, management and treatment of diseases will not be appropriately consulted in regulatory processes. Further we are deeply concerned about the high level of influence being given, again to only a limited number of individuals (such is the case for the SAG Core membership) whose background, per Policy 0044, is limited.	possible EMA's capacity to secure the best scientific expertise whilst ruling out any possible doubts as to the objective impartiality of EMA's assessments.. 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'.

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	The current policy and proposed revisions focus only on restricting experts who have worked with industry (for example those who have participated as an Investigator in a clinical trial, provided feedback on scientific advisory boards etc.). This is only one source of potential conflict of interest. What is not considered by the EMA in the current policy, nor the proposed revisions, is the use of experts who make public statements or commentary about medicines for which they are then later asked to provide feedback on by the EMA as an expert. The demonstrated pre-determination by these experts is explicit (documented commentary that conveys a fixed position or opinion before review of the information provided by the EMA and/or an Applicant), yet this issue is not addressed by the EMA in the current policy, nor the proposed revisions. It is essential that this source of conflict of interest/impartiality be addressed in the proposed revisions to this policy, particularly as advice from these experts is considered by the CHMP in regulatory decision making. We are also troubled by the predetermination exhibited by some experts currently utilized by the EMA, and the EMA's view that this is acceptable. We encourage the EMA to address this as part of the revisions to the policy. We suggest consideration be given to managing conflicts of interest, where they exist, through appropriate disclosures, with consideration also given to the relevant expertise and experience of the experts who have been called upon to provide opinions or evidence. It is no answer to exclude relevant expertise from the discussion or voting, such as in the case of SAGs, when these votes are considered by the EMA in the drug review and approval process. Indeed, it is questionable as to why the EMA would not want to hear directly from experts when the stakes are so high for patients. Additionally, the inference that any interaction with industry	With respect to the comment on the use of experts who make public statements, EMA would like to remind that 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.

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	means that an expert is biased or weighted in favor of industry is also unfair to the experts who, in our experience, work with urgency to help their patients and have their best interest in mind. In summary, we encourage the EMA to give further consideration to this policy; and rather than introduce more restrictions, introduce a balanced approached that takes into consideration the reality that experts are those at the forefront of the diagnosis, management and treatment of diseases, and therefore these are exactly the types of expert views that are urgently needed. Furthermore, consideration in the policy regarding experts who exhibit predetermination via public commentary is also needed, as a policy that leaves this unaddressed is unbalanced.	
	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.	As indicated above, 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'. Modalities and transparency with respect to the use of expert witness are being developed to ensure these are applied in a consistent manner. Experience with the use of expert witnesses may be reflected in EMA's annual report on independence.
6. European Association for Clinical	The European Association of Clinical Pharmacology and Therapeutics (EACPT) fully endorses the participation of experts in the European Medicines Agency`s (EMA) activities and considers that such a collaboration is a fundamental and necessary asset in order to count on the	

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Pharmacology and Therapeutics (EACPT)	highest level of scientific expertise. Clinical pharmacologists, as specialists with broad training and expertise (e.g., regarding clinical, regulatory and methodological aspects in medicine and HTA evaluations) have the ideal profile to collaborate in different roles, and actively participate in EMA's activities as clinical assessors, committee members and/or independent experts participating in ad hoc scientific consultations. Keeping this in mind, the EACPT has several concerns regarding the draft document revising EMA's "Policy 044".	
	• A distinction between "financial" vs. "scientific" interests should be established when handling potential conflict of interests, since they have different nature, weights and implications. While it can be agreed that financial interests pose an objective source of bias, and, therefore, require stricter mitigation policies, special considerations should be made regarding "scientific" interests. Scientific interests, which are those that apply to academic experts and clinical scientists working in the field and do not carry any personal financial gain, should never preclude said experts from providing an informed and realistic opinion and advise. Clinical pharmacologists, due to their comprehensive scientific competencies, often provide support, collaborate and/lead projects in academic research. These projects usually involve topics that lack commercial interest for the pharmaceutical industry (e.g., repurposing of medicinal products) but respond to relevant clinical needs, and would not be conducted if not led by academic research groups. In addition, academic initiatives contribute to grant patient access to patients to new treatments in the context of medical disorders with a high unmet medical need, as was seen repeatedly during the COVID-19 pandemic. Dispensing with	Noted. While not using specifically the terms 'financial' and 'scientific', EMA would like to point that the policy defines different types of interests as direct and indirect. The nature of the interest is one of the factors taken into account when establishing the adequacy of an individual's participation to the Agency's activities or the level of restrictions that is required. In line with the policy, engaging in an academic research is not an interest to be declared, unless these are conducted subject to an agreement with a pharmaceutical company or if the research is subject to regulatory engagement with EMA (e.g. submission of a request for scientific advice). Proportionate restrictions have been established in the policy in this respect, not necessarily leading to the

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	these experts due to an erroneous interpretation of scientific interests could expose the evaluation system to an unacceptable risk of failure, unjustified by the nature and impact of this type of interest.	exclusion of the individual from participating in EMA activities.
	• The need for balancing the "best expertise" vs. being "reasonably free" of conflicts of interest experts is critical, yet complicated to achieve. While acknowledging the recent Court rulings regarding this topic, in our opinion, aiming for "100% conflict-free" expertise is an unrealistic and unreachable goal that can seriously compromise the quality and value of experts' contributions. In particular, it is concerning that the experts' participation in research, including academic-lead research, appears to be "penalized". It should be noted that conducting research is one of our core competencies as practicing physicians and healthcare professionals, along with others, such as maintaining our clinical skills and teaching. Furthermore, being active in research allows us to acquire and maintain up-to-date knowledge and expertise in the relevant fields of our specialty. Therefore, any experts not actively participating in research are likely to have outdated, incomplete knowledge of their fields. Final conclusions The exclusions and restrictions currently proposed under Annex I should be revised to avoid the omission of true and relevant expertise in EMA's activities. In particular: • Policy 044 should clearly separate "financial" and "scientific" interest and take a more flexible approach in the management of the latter.	In addition to the above clarifications with respect to the proportionate restrictions related to participation in certain academic research, EMA would like to recall that the 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 whilst ruling out any possible doubts as to the objective impartiality of EMA's assessments.. 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

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		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'.
	• The focus of conflict-of-interest management should be placed on full-disclosure, enhancing the transparency and comprehensiveness of the declarations of interest, and on establishing clear and predictable handling criteria and mitigation strategies, according to the level of potential conflict. In this context, including several experts in the assessments could also serve, on itself, as a reliable tool to control bias and to mitigate or dilute any potential conflicts of interest, in the benefit of obtaining a consistent, reliable, informed and realistic assessment. • Finally, in the EACPT's opinion, by insisting on the current rigid proposal, there is a very likely potential to exclude relevant and true expertise in the EMA's activities, and therefore, a high potential for jeopardizing the excellence in the evaluation and supervision of medicines in the European Union (EU).	EMA would like to highlight that it already operates a transparent approach as outlined in its current and revised policy on conflict of interests. The operations of the centralised procedure also already involves multiple experts and opinions are adopted by committees composed of representatives of all member states. Despite the above, recent Court rulings have required the Agency to adjust certain aspects of its approach to handling competing interests with the aim to preserve as much as possible EMA's capacity to secure the best scientific expertise whilst ruling out any possible doubts as to the objective impartiality of EMA's assessments.

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7. European Association of Nuclear Medicine (EANM)	The European Association of Nuclear Medicine (EANM) appreciates the opportunity to comment on the European Medicines Agency's (EMA) policy on handling competing interests among scientific committees' members and experts. EMA's commitment to balance securing the best scientific expertise with impartiality is commendable and should be further pursued. The EMA is renowned for its impartial scientific assessments of medicines, weighing their clinical benefits against potential risks. This reputation hinges on a transparent and detailed conflict of interest policy. EMA's handling of competing interests must balance its legal obligations: ensuring that committee members and experts do not have conflicts of interest with pharmaceutical companies that could compromise their impartiality, while still securing the best scientific expertise.	Noted.
	While EANM strongly supports a robust framework for managing competing interests with thorough restrictions on experts' involvement with industry, this must be done proportionately to avoid limiting EMA's access to top-tier experts. The scientific community is concerned that the new EMA policy on handling competing interests might restrict access to scientific excellence. In nuclear medicine, as in many specialties, key experts and opinion leaders are at the forefront of innovation, engaged in fundamental research, and supported by various grants. They are best positioned to provide valuable input and expertise to the EMA. More specifically, the EANM, representing healthcare professionals involved in research organisations, would like to comment on some indirect links as mentioned on Annex 3 –Handling of current and past interests in research organisations.	Noted. EMA would like to provide the reassurance that 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 whilst ruling out any possible doubts as to the objective impartiality of EMA's assessments.

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	Most radiopharmaceuticals have a very short shelf life and therefore need to be prepared extemporaneously in-house, e.g. in the institution so that they can be used within minutes or hours after preparation, to avoid that they lose their radioactive potentials by physical decay. In that respect, 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.	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. This includes the manufacturing of radionuclides in the form of sealed sources. For the purpose of this policy, preparation or reconstitution of medicinal products including radiopharmaceuticals, for their use by patients within the hospital or institution is not expected to be declared as an interest.
	Additionally, a second clarification would be welcomed regarding „Involvement in the conduct of research and development activities together with a company." 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	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'.*

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	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.	
	Finally, the EANM would like to emphasize that some further clarification would also be needed on grant or other funding to the expert's organisation/institution (section 3.2.2.2). Therefore, experts supporting services activities as performed routinely in clinical practice, should be excluded from this category, provided that the expert is not the main recipient of the grant.	EMA would like to highlight that the definition for grant or other funding to the expert's organisation/institution includes any funding from a company received by the organisation/institution to which the member or expert belongs, or for which he/she performs any kind of activity, and which is used specifically to support any activity of the member or expert. EMA would like to clarify that, as per its policy, all members and experts are required to declare grant or funding from companies to their organisation. The policy foresees balanced and proportionate measures with respect to the handling of such interest, taking into consideration the role of the expert.
8. European Confederation of Pharmaceutical Entrepreneurs (EUCOPE)	EUCOPE appreciate EMA's ongoing commitment to enhancing the robustness of Policy 0044 to manage competing interests effectively. However, while safeguarding impartiality is crucial, it is equally important that the updated policy does not inadvertently stifle innovation or slow down the delivery of essential medicines to patients.	EMA's policy on the handling of competing interests always had the objective to provide a robust framework for managing possible competing interests, by applying restrictions to experts' involvement in a proportionate and transparent manner.

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	Maintaining a thriving pharmaceutical ecosystem in the EU requires policies that promote long-term investments and foster innovation, particularly in areas of high unmet medical need. Overly rigid restrictions on expert participation, especially those involved in specialised fields like advanced therapies (ATMPs) or rare diseases, risk creating bottlenecks in the regulatory process. These fields rely on a limited pool of highly specialised experts, many of whom are engaged in industry-funded research. A stringent conflict-of-interest approach could make it challenging to secure the necessary expertise, thereby risking delays in patient access to critical treatments. We urge EMA to consider a more flexible approach, particularly in areas where expertise is scarce. Policies that allow nuanced participation of qualified experts—while ensuring transparency and appropriately managing conflicts—would strike a better balance between impartiality and the need for robust scientific input. 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.	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 whilst ruling out any possible doubts as to the objective impartiality of EMA's assessments. The new rules should have no or minimal impact on the composition of EMA's scientific committees as their members 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'.

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	Additionally, 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. In conclusion, we support EMA's goals for impartiality but call for pragmatic strategies in Policy 0044 to mitigate potential disruptions, ensure efficient regulatory reviews, and prevent delays in medicine delivery. A balanced, transparent approach that leverages the best available expertise will be pivotal to upholding the EU's leadership in pharmaceutical innovation and ensuring timely access to groundbreaking treatments for European patients.	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. 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.
9. European Federation of Allergy and Airways Diseases Patients' Associations (EFA)	EFA supports EMA's intention of introducing a transparent, robust, and balanced framework for assessing competing expert interests, while differentiating between interests and competing interests. Increased scrutiny of expert involvement improves impartiality and independence in assessing experts. However, EFA is concerned the additional restrictions and exclusions related to interests and involvement in certain activities risks excluding patient experts, for two reasons; patient associations must rely much on corporate funding sources, mainly pharmaceutical industry in	Noted, however EMA would like to clarify that as per its Policy, members and experts are required to declare grant or funding from companies to the organisation to which they belong, or for which he/she performs any kind of activity, and which is used specifically to support any activity of the member or expert. The policy foresees balanced and proportionate

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	absence of other funds. Second, patient involvement is also required to advise healthcare companies to be more patient-centred, and crucially, to develop their products which are intended for patients while addressing the needs of real patients. This leads to justified contractual arrangements between companies and individual patient experts. EMA should balance its policy between the objective of inclusivity and exclusivity and embrace expertise. There is a fine balance between trust, mistrust, perceived and real conflict of interest (CoI) which EMA needs to strike.	measures with respect to the handling of such interest, taking into consideration the role of the expert. EMA acknowledges the key role patients are playing in supporting patient-centred developments. However, EMA considers that an individual patient that advises a pharmaceutical company should duly declare this interest and have their participation in EMA activity limited as per Policy 0044. This does not prevent EMA from seeking input of other patients who may not have conflicts of interest in the meaning of the Policy. EMA engages with a network of eligible patients and consumers organisations, ensuring that their needs and concerns are represented via direct contact with the Agency. Eligible organisations frequently assist in the identification of experts for product-specific matters. Eligible and any other patient organisation can therefore play an important role in ensuring awareness of EMA's policy on the handling of competing interests.
	EFA asks EMA to specify which 'other interests' may be applicable to members of scientific committees and which register will be used for entering indirect interests to EMA.	Policy 0044 defines the interests to be declared. EMA requires each expert participating in EMA's scientific committees, working parties and other

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		bodies to provide information on their interests in the pharmaceutical industry and in the medical-device industry in a declaration of interests (DoI) in its Experts Management Tool.
	EFA discourages the exclusion of experts based on their involvement in scientific advisory groups and activities such as meeting attendance, involvement in the scientific assessment and guidance development, as this would hugely impact patient representatives, whose expertise in the patient perspective of medicinal product is essential in its assessment.	EMA would like to clarify that interests to be declared pertain to those conducted for/with pharmaceutical or medical device companies. These will be evaluated to confirm acceptability of involvement in EMA activities (such as participation in scientific advisory groups or scientific assessment). Prior involvement in EMA activities are not interests to be declared and will not be subject to exclusions or restrictions.
	EFA is concerned that the CoI cases handled by National Competent Authorities (NCA) will not be handled to the same degree across Member States and asks EMA to clarify NCA's obligations in the text.	EMA would like to provide reassurance that the approach taken by NCAs for the handling of conflict of interests is aligned with Policy 0044. In line with the Memorandum of Understanding concluded between National Competent Authorities (NCA) and the Agency, NCAs are responsible for handling conflicts of interest of the staff and experts involved at national level in the services provided to the Agency. In accordance with Article 126b of Directive 2001/83/EC, "In order to guarantee independence and transparency, the Member States shall ensure that members of staff of the

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		competent authority responsible for granting authorisations, rapporteurs and experts concerned with the authorisation and surveillance of medicinal products have no financial or other interests in the pharmaceutical industry which could affect their impartiality. These persons shall make an annual declaration of their financial interests". Although it is within the remit of the individual NCA to determine as to how the requirements of Directive 2001/83/EC are met, a Guide to Managing Declarations of Interests has been agreed by the Heads of Medicines Agency (HMA) and aims at assisting NCAs in setting up internal policies and procedures for the handling of conflict of interests. NCAs should note that as a minimum the definitions from the guidance should apply; NCAs can decide to apply stricter rules if required by national legislation or standards. This HMA guidance is regularly updated to align with Policy 0044 and its revision is ongoing in light of the latest changes. For further details, please refer to Heads of Medicines Agencies: HMA Working Group of Quality Managers

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	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. EFA 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. EFA considers the scope of activities which are considered as consultancy or strategic advisory role in a company too broad. Patients are excluded on the assumption that they will be biased, or holding 'interests' incompatible with EMA, regardless of contractual arrangements or forms of remuneration. EFA also asks EMA to clarify which 'influence of output' in advisory boards it is referring to. EFA urges EMA to recognise that collaboration between patients and industry is essential in creating transparency and synergies in the development of medicinal products. Patient experts and representatives work in a total ecosystem of healthcare. Even if the person contributing to the EMA process on behalf of a patient association is not a patient themselves, EMA must recognise patient representatives as patient experts. Patients often participate in their patient associations on a voluntary basis and EMA processes require large time and cost investment from patients. EFA is concerned that grants or other funding paid by a company to patient experts are seen as CoI. Patients should not be asked to provide their expertise free of charge to pharmaceutical companies and institutions aimed at improving their quality of life. Very often, the nature of these	EMA would like to clarify that patient organisations are indeed not expected to be meeting the definition of pharmaceutical companies. The EMA fully agrees that patients and consumers bring a 'real-life' experience as well as specific knowledge and expertise to scientific discussions on medicines and on the impact of regulatory decisions. EMA has an established framework for engagement between with patients and consumers and their organisations which outlines the basis for involving patients and consumers in Agency activities. Collaborating with these groups supports transparency and improves regulatory processes. In this respect, EMA regularly involves patients, carers or patient representatives as experts in its activities. 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 ensure access to expertise, including that of patients, whilst

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	activities is similar, such as consultancy on patient needs, product development/evaluation, clinical trials, quality of life insights, and other activities also required by EMA. In any case, these activities are covered by the relevant Codes of Ethics, guaranteeing the independence of the expert patient.	ruling out any possible doubts as to the objective impartiality of EMA's assessments.
	EFA welcomes that payment or reimbursement of reasonable expenses directly related to a conference/seminar attendance is not considered as a financial interest.	Noted.
	EFA welcomes EMA's distinction between advisory and decision-making roles and a cooling off period for past employment in a pharmaceutical company and the possible exceptions to this, subject to certain restrictions.	Noted.
	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.	Noted.
	EFA welcomes the transparency of EMA's approach to publishing all nominated experts on EMA's website. EFA urges EMA to instruct all patient experts to not reveal their patient related health information in their CVs.	When completing their CV, it is fully acceptable for patients to only refer to being a patient representative in their CV, without need to provide any additional health related information.
	EFA encourages EMA to inform and provide support to patients on the necessary steps for them to input in the Agency Experts Management tool.	Dedicated "Patients liaison" staff members within EMA's Public and Stakeholders Engagement Department are available to support patients involved in EMA activities,

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		including in the administrative steps and submission of declaration of interests.
10. European Federation of Pharmaceutical Industries and Associations (EFPIA)	EFPIA supports the EMA's aim to balance the requirement of impartiality and independence of its experts with the public interest in obtaining the best possible scientific advice on matters concerning the evaluation of the quality, safety and efficacy of medicinal products for human or veterinary use. As EFPIA, we strongly believe in the importance of expertise-driven scientific assessment. Therefore, we welcome an approach grounded in proportionality, balancing impartiality with the need to secure the best (specialist) scientific expertise for involvement in the Agency's activities. EFPIA appreciates that the revised policy clarifies the management of potential conflicts of interest, particularly those arising from activities within research organizations. However, we emphasize that Europe faces significant workforce challenges across the board. Strict interpretations of "conflict of interest" could worsen this issue, especially as research grows increasingly specialized. Additionally, recent data—such as the recently published IQVIA report[1] on clinical trial (CT) analysis—indicates a concerning decline in EU clinical research, with non-commercial CTs dropping from 1,250 in 2018 to 966 in 2023. Clinical research often serves as a surrogate marker of scientific expertise and capability development; the investigators running the trials are the forefront of medical innovation and are often used as experts of the particular therapeutic area in other contexts as well. Unless this negative trend reverses, the availability of qualified medical/scientific experts may be further constrained in the coming years.	Noted. However, EMA would like to highlight that 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.

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	We suspect that some of the proposed changes to EMA's Policy 0044 could impact innovation by potentially limiting access to suitable experts. It is crucial that the policy's implementation does not restrict the participation of individuals with the required expertise. Please find below some specific comments and improvement proposals to mitigate the risks of unintended consequences and to increase clarity. Interests of Research Organisations (RO) The revised policy provides clarity on the handling of interests in research organizations (ROs), including a specific definition of ROs, a new list and definition of relevant interests, and an additional Annex (Annex 3) detailing restrictions related to these interests. We consider the following aspects of the proposed inclusion and/or restrictions on experts with RO interests to be appropriate: - Research organisations that undertake roles such as manufacturing of medicinal products or medical devices or are acting as marketing authorisation applicant/holder should indeed be treated similarly as pharmaceutical and medical device company experts. - The proposed restrictions on members or experts who have declared to be "engaged in occupational activities" are appropriate. - We support maintaining restrictions on individuals involved in a research organization unit that manufactures ATMPs under the hospital exemption. - Interests relating to manufacturing and marketing authorization holding are accurately captured.	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'.

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	- To maintain sufficient expertise for the Agency's work, involving "individuals with other interests in research organizations" with "appropriate restrictions based on declared interests and the Agency's activity to be involved in".	
	We offer the following suggestions to further refine the criteria: - There is room to better define restrictions related to an RO's independent R&D of medicinal products, particularly in repurposing contexts (e.g., when not conducted with a company, outside regulatory engagement, or prior to market authorization). This could be further clarified in Section 3.2.2.1 on Direct Interests and Section 4.2.1 on Achieving a Robust Process.	In general, academic research, e.g. conducted by research organisations independently from pharmaceutical companies, are not considered as an interest for the purpose of EMA's Policy 0044. The policy however has defined circumstances where such activities fall under interests to be declared, e.g. when the research is subject to an agreement with a pharmaceutical company or where it is subject to a regulatory application with EMA. EMA considers this is a balanced and proportionate approach.
	- We suggest including "collaboration" activities (which we understand as broader than "affiliation") as part of "affiliation to a research organization," in line with the reference to "interests in research organizations" on p. 10. Contractual arrangements or remuneration should not solely determine a person's involvement or affiliation with an RO unit.	In the revised policy, the objective of the addition of 'Affiliation to a research organisation' is to enable to restrict an individual's involvement if and when their organisation submits an application to EMA. EMA considers that collaboration on e.g. specific research on medicinal products is already covered by other interests as defined in the policy. Broadening these restrictions to individuals who collaborate

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		on other matters with a research organisation is considered disproportionate.
	- Based on the tables in Annex 1 and 2, persons with interests in ROs could not be involved in decision-taking roles, but their opinion will serve as input to the functions who take the decision. This could be clarified further in the policy's main text.	Annexes 1 and 2 pertain to the handling of interests from pharmaceutical companies whereas Annex 3 pertains to the handling of interests in research organisations. Each of these annexes defines the handling taking into account the group or role the individual will undertake.
	- The management of situations in which persons intend to be engaged in "occupational activities" is already covered by the Policy. As "occupational activities" are not defined, the scope of the Policy rules in section 4.2.1. addressing these situations is, however, not clear. These activities should be defined, or at a minimum cover consultancy as well as employment. - In addition, it would make sense that, under section 4.2.1., the EMA has an opportunity to restrict a person's further involvement in its activities if they notify their intent to undertake any activity that is subject to restrictions under the Policy. Considering the revision of the restrictions on ROs, this section should therefore refer also to ROs.	A specific guidance supplements the policy with respect to the intent to be engaged in occupational activities. The guidance is available on EMA's website and will be updated following the revision of the policy, The paragraph of the policy relating to the intention to be engaged in occupational activities has been updated to include 'activities in research organisation that are incompatible with participation in any activities at the Agency.'
	Rival Products vs Products "in declared condition" EFPIA 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	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

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	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. Considering the above, we ask for confirmation in the Policy 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.	otherwise occur if exclusions were applied too broadly. The policy has been clarified to refer to 'few individuals who have competing interests that would normally be incompatible or limit their involvement in the Agency's activities as a member or expert.'
	Conflict of Interest Declaration Acknowledging the inherent challenges in achieving complete neutrality, we propose a flexible, transparent approach for conflict of interest declarations, aligned with frameworks used by other regulatory agencies, such as by the Health Technology Assessment (HTA) bodies. This may include establishing clear thresholds for allowable earnings or other forms of engagement with pharmaceutical companies, which would enable experts to remain eligible without compromising integrity. Such measures would promote transparency, minimize bias, and ensure European investigators and evaluative bodies operate on a comparable playing field with other global regulatory entities.	The rules developed by the European Commission as part of the draft Commission implementing regulation on the management of conflicts of interest for HTA joint work are aligned with EMA's current Policy 0044 on many aspects. However, the joint HTA work of Member States on the one hand and regulatory assessment conducted by EMA on the other are based on different legislative frameworks. The outcomes of the joint work under the HTA Regulation will be used by the Member States in their national

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		HTA processes hence the management of conflicts of interest in the HTA takes these needs under account. The differences of remits and responsibilities of EMA and of the Member State Coordination Group on HTA account for some of the differences in the handling of competing interests.
	EU Regulatory Network's Resource Constrains We call on the European Commission and the European Medicines Agency (EMA) to undertake a comprehensive review of regulatory system resourcing. This review should incorporate an in-depth assessment of how current conflict of interest policies contribute to resourcing limitations and examine strategies for mitigating them. We recommend the exploration of targeted programs or pilot initiatives that proactively identify and engage highly qualified experts. Furthermore, we appreciate that both public and private sector compete for the same experts when it comes to pharmaceutical innovation. Evaluating the potential for enhanced incentives to retain expert participation in public regulatory processes/expert tasks could mitigate the risk of losing key contributors to industry roles. We further urge the EMA to prioritize the active involvement of experts from EU member states, recognizing their indispensable role in supporting the robust, diverse expertise necessary for thorough scientific assessments.	The Agency will continue monitoring the impact and implementation of the policy as part of its annual reports on independence. Furthermore, the Agency is currently reviewing its processes supporting the identification and use of experts. EMA would like to provide reassurance that its experts from EU Member states constitute the core of the expertise that is involved in the work of its scientific committees and working parties.
	Review Cycle of Revised Policy Finally, the EMA's previous commitment to review the policy after three years (or sooner if necessary) has been removed in the current revision.	A statement has been introduced in the adopted policy that it shall be reviewed within 3 years or at an earlier stage if considered necessary.

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	We propose reinstating this commitment and that EMA confirms their intention to review the policy based on the experiences gained about the impact of the proposed changes. [1] IQVIA, Assessing the clinical trial ecosystem in Europe, October 2024, https://efpia.eu/media/3edpooqp/assessing-the-clinical-trial-ecosystem-in-europe.pdf	
11. European Hematology Association (EHA)	The European Hematology Association (EHA) welcomes the opportunity to comment on the draft revision of the European Medicines Agency (EMA) policy on the handling of competing interests of scientific committees' members and experts (Policy/0044). Clear rules for handling competing interests are essential for ensuring that the involvement of experts in EMA's work is based on principles of transparency, independence and impartiality. However, pragmatism in applying policy is vital to ensure that EMA has access to the best available experts, for the benefit of Europe's patients and health systems. This is especially the case in rare diseases, such as certain types of hemophilia where the 'key opinion leaders' can number fewer than a handful, with each, inevitably and necessarily, involved in a number of advisory roles including for pharmaceutical companies.	Noted
	EHA recognizes that a review of EMA's policy was inevitable in light of recent court judgements. We applaud EMA for revising the policy in a sensible and balanced way. In particular, we find that the need for proportionality in applying the policy and the need for balancing conflict of interest considerations with "the need to secure the best (specialist)	Noted.

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	expertise for involvement in the Agency's activities" are well explained (section 4.1, and also in 4.2.1) and clearly reflected in the proposed approach for applying the stricter criteria. Overall, EHA considers that the document is well written. However, we recommend some clarification on two aspects of the policy.	
	1. 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. EHA supports researchers and research collaborations, but we do not commission nor conduct research. To avoid confusion or misperception regarding the role of learned societies, EHA 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	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. 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

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	care, careful and balanced assessment of competing interests is particularly important.	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.
	2. Page 12, section 4.3.1. Nomination process The nomination processes as outlined in the document maintain the status quo in the sense that both appointments for scientific committees' members and nominations for experts continue to be primarily the remit of Member States. The policy does mention the potential need for "…additional expertise, not covered by nominations made by the Member States" and stipulates that the Agency will undertake the nomination of the identified expert in such situations. Here, 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 EHA, 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, EHA 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 medicines. Reliance on collective rather than just	EMA is committed to working closely with its expanding network of healthcare professional organisations and encourages all eligible, not-for-profit organisations to get involved. To this effect, the EMA has since 2011 established a framework for interaction between EMA and healthcare professionals and their organisations. The framework describes the objectives and the terms of reference for this interaction, which include the aim to support the Agency in accessing the best independent expertise in any matter related to medicines. In practice, healthcare professional organisations are contacted by EMA when seeking specific expertise (e.g. for participation in a scientific advisory group) and frequently assist in the identification of experts for product-specific matters.

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	individual expertise also helps to mitigate the impact of any competing interests on the part of individual experts.	
12. European Organisation for Rare Diseases (EURORDIS)	General comments EURORDIS takes notes of the rulings of the European Court of Justice and understands the need to revise EMA Policy 0044 on the handling of competing interests of scientific committees' members and experts. EURORDIS shares the objective to balance the need for impartial expertise and the need for the best scientific expertise in the Agency's decision-making and all other activities related to medicinal products for human or veterinary use or medical devices. As per prior versions of Policy 044, there will always be situations where expertise can only be provided by a few individuals who have competing interests that would normally limit their involvement in the Agency's activities as a member or expert. This is often the case in rare diseases.	Noted.
	Specific comments 1. 3.2.2.1 Direct interests: Consultancy or strategic advisory role to a company 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	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.

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	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.	
	2. 3.2.2.2 Indirect interests a. 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". EURORDIS 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.	Noted. However, 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.

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	b. Regulatory engagement on academic research: this should apply only when the engagement is at the initiative of the academic organisation/researcher (for clarification) Situations when the regulators initiated the engagement does not fall under indirect interests (for example when a registry study is commissioned by a scientific committee via DARWIN EU, the researchers / academics working in the department should not have indirect interests and should not have restrictions when invited to provide their expertise to the regulators).	EMA agrees that the interest 'Regulatory engagement on academic research' pertains to engagement with EMA on studies conducted at the initiative of the research organisation.
	3. 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.	In the present policy, EMA considered that further elements on how the Agency plans to work with expert witnesses in practice, should not be provided in the policy and it Annexes 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.
13. European Patients' Forum	The European Patients' Forum (EPF) welcomes the revamping of the European Medicines Agency (EMA)'s rules on conflict of interest as a crucial step to enhance the integrity and credibility of regulatory assessments. Maintaining high standards for the assessment of medical products is key to ensuring trust and acceptance of the Agency's regulatory decisions by patients and the public more broadly. Integrity implies accountability of	Noted.

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	those involved and transparency and reliability of the sources that inform the decision-making process. We fully support the inclusion of rules on competing interests for medical devices, aligning them with established standards for pharmaceutical companies. The introduction of a unified three-year cooling-off period strengthens the consistent application of restrictions, further safeguarding the integrity of assessments. We further welcome the document's emphasis on transparency and on the need for accurate, comprehensive, up-to-date, and publicly available declarations of interests for all experts involved in EMA activities. Patient involvement in EMA processes and committees improves the outcomes of regulatory decisions, which ultimately contributes to the quality of medicines' evaluations and to products that better address patients' needs. We emphasise the need for a balanced approach to addressing conflicts of interest of patient representatives to ensure proportionate restrictions are applied while maintaining continued access to expertise.	
	EPF recognises that restrictions on research organisation participation may limit the pool of patients able to participate in EMA processes and committees, particularly in rare diseases where patient populations are very small or conditions with low survival rates. Patients engage actively and collaboratively with researchers at various stages of the research process, contributing to the enhancement of studies and ensuring that research is more relevant to patients' needs.	In general, it is not foreseen that collaboration of patients with researchers are interests to be declared in accordance with the definitions of interests in research organisation from the policy. However, depending on the nature of the activity and sponsor of the study, this may fall in interests in pharmaceutical companies.

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	In addition, we call on EMA to ensure a balanced approach to handling of current and past interests in the case of grants/other funding to the expert's organisation/institution. Patient organisations channel the voice of the communities they represent in a united way and therefore provide collective and representative input. Many patient organisations have long-standing collaborations with EMA and have acquired extensive expertise in regulatory processes. However, patient organisations have increasing difficulties in securing sustainable funding to support their daily operations and are often forced to look to private funding in the absence of public support. We call on EMA to adopt a proportionate and transparent approach to restrictions on participation of experts affiliated with patient organisations that receive funding from pharmaceutical/medical devices companies or research organisations. Importantly, we call on EMA to consider the existence of appropriate governance structures and strict safeguards when assessing the potential conflicts of interest of these experts.	EMA would like to clarify that, as per its policy, all members and experts are required to declare grant or funding from companies to their organisation. The policy foresees balanced and proportionate measures with respect to the handling of such interest, taking into consideration the role of the expert.
	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 with public health interests. This clarity will	EMA 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.

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	facilitate more effective and meaningful patient input into the evaluation of medicines.	
	Maintaining a broad pool of patients for participation in regulatory processes is essential. Relying on the same patient representatives can lead to tokenism and reduce the overall representativeness of the community, thereby limiting the robustness of the evidence provided.	EMA does maintain a database of individual patients and contacts with eligible organisations for the identification of patients for involvement in EMA activities. The creation of a pool of experts who will also be remunerated for their work at EMA will contribute to broadening the pool of available patients.
	Patient organisations play a crucial role in managing conflicts of interest by educating their communities on these policies and promoting transparency in funding and activities. It is critical to invest in the capacity-building of these organisations as key partners in maintaining transparency and credibility throughout the regulatory process.	EMA actively participates in training initiatives from its eligible organisations and has also created its own training where competing interests are explained.
	EPF will continue to work with EMA to ensure that its policies effectively address the needs of patients and ensure meaningful participation in EMA's processes. We will also continue advocating for sustainable and reliable funding for patient organisations and for appropriate remuneration of patient representatives involved in EMA activities.	Noted. Although not in the scope of the public consultation, EMA would like to highlight that provisions for EMA remuneration of experts involved in EMA activities are in place, subject to a Call for expression of interest for medical device and in-vitro diagnostics medical devices experts (EXPAMED) and patient, consumer and healthcare professional experts (P&HCP).
	The European Society of Cardiology (ESC) appreciates the opportunity to provide feedback on this critical policy, central to the European Medicines	

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14. European Society of Cardiology (ESC)	Agency's (EMA) operations and aimed to access the best expertise, while effectively managing conflicts of interest.	
	The ESC fully supports clear and effective policies and procedures to ensure the transparent, timely, and effective management of competing interests. At the same time, we are concerned that their inadequate handling may lead to poor expertise feeding into scientific evaluations and other regulatory activities, ultimately affecting patients' safety and treatment outcomes. This concern was also raised in our feedback to the Draft Implementing Regulation (EU) 2024/2745 on conflict-of-interest rules under the EU Health Technology Assessment Regulation <https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13751-Health-technology-assessment-procedural-rules-for-assessing-and-managing-conflicts-of-interest/F3470363_en>. This is due to the wide range of activities and roles in which clinical experts are involved, which is naturally proportionate to their level of expertise. Clinical experts are actively involved in all stages of treatment development, from early feasibility studies to pivotal trial design and conduct of post-marketing studies on safety and efficacy. This comprehensive experience is crucial for contributing effectively to scientific evaluations and other advisory activities, as it enables experts to provide deep insights into trial design, patient safety, and data integrity. In this respect, it is certainly essential to distinguish between "having interests" and having current or past "competing interests," providing their clear definitions and timelines. Therefore, the ESC endorses the passage in the policy stating that "having interests is not to be confused with having a competing interest, as the	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

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	interests, experiences and activities contribute to an individual gaining expertise in a certain field." Accordingly, we advocate for a balanced and pragmatic approach to the issue, ensuring transparency of these activities and managing the risk of bias while preventing the exclusion of high-quality clinical expertise.	the rules set out in this policy, it also foresees the possibility to involve individuals as 'expert witnesses'.
	Keeping in mind that the goal should be to provide the best available expertise, we also suggest that clear criteria to assess the level of expertise needed for defined roles and tasks (e.g., qualifications, publications, etc.) should also be provided. This is key to ensure that advisors possess the best available knowledge and relevant experience to make informed, credible contributions.	Noted, however, the scope of the policy is not to define level of expertise.
	In this respect, medical societies like the ESC – which involves more than 100.000 healthcare professionals covering the full spectrum of cardiology - can be instrumental in identifying the right expertise for specific disease areas and technologies. We would also like to highlight that many medical societies often have their own policies aimed at identifying and managing conflicts of interest. This is the case of ESC, which has a detailed "Declaration and Management of Conflict-of-Interest Policy" <https://www.escardio.org/The-ESC/About/Policies/esc-declaration-and-management-of-conflict-of-interest-policy> in place to foster transparency and maintain the integrity of its activities. This document, together with the paper "Governing Policy for the writing of Clinical Practice Guidelines" and the Biomed Alliance Code of Conduct <https://www.biomedeurope.org/about-us/code-of-conduct/>, represent the trilogy of policies which inspire and regulate the ESC's	EMA is committed to working closely with its expanding network of healthcare professional organisations and encourages all eligible, not-for-profit organisations to get involved. To this effect, the EMA has since 2011 established a framework for interaction between EMA and healthcare professionals and their organisations. The framework describes the objectives and the terms of reference for this interaction, which include the aim to support the Agency in accessing the best independent expertise in any matter related to medicines. In practice, healthcare professional organisations are contacted by EMA when seeking specific expertise (e.g. for participation

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	objective of providing unbiased daily practice, expertise and advocacy, with the highest ethical standards. In conclusion, the ESC commends the collaborative approach fostered through this consultation and reaffirms its commitment to support regulators in their efforts to ensure the best treatment outcomes for patients across Europe.	in a scientific advisory group) and frequently assist in the identification of experts for product-specific matters.
15. European Society of Endocrinology (ESE)	The European Society of Endocrinology represents more than 22 000 clinical endocrine experts across the geographical Europe. The diseases in the field of endocrinology represent some of the biggest health care challenges (diabetes, obesity, fertility and cancer) but also more than 400 endocrine diseases that fall under the definition of rare or ultra-rare diseases.	
	Specifically in this last area, 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.	EMA would like to highlight that experts with an interest as investigator or principal investigator are not excluded from participating in any EMA activity. In line with the revised policy, they may not be involved in applications pertaining to the product concerned, as well as products in the same declared condition if the interest is current. They may however contribute to other EMA activities. The 3-year cooling-off period enables EMA to apply these restrictions in order to guarantee impartiality in a balanced and proportionate manner.

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		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.
	The guidance also mentions that some departments of research organisations may be considered at the same level as a manufacturer: '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'. In-house preparations of medicinal products, in-house devices and diagnostic tests are widely used in the health sector. In the above mentioned field of rare diseases, the top experts may be involved in these developments, to meet their patients' needs, and often because there is no viable alternative. A sufficiently flexible approach is necessary, along with a clear definition and information on the practical application, for instance within healthcare institutions and academia.	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 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.	In line with the Court rulings, restrictions of an individual's participation should apply not only to final deliberation and voting but also to discussions. The revised policy continues to allow and further clarifies the use of 'expert witnesses' where it

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		might be in the interest of public health to invite these individuals to testify and give specialist advice on specific issues. The Agency will ensure that circumstances, modalities and transparency will be applied in a consistent manner with respect to the use of expert witnesses.
16. Eva Stumpe	Dear EMA Team, I went through the draft version of EMA´s new policy on the handling of competing interests of scientific committees' members and experts. I was a volunteer patient advocate at the EMA for spinal muscular atrophy for some time until my involvement with the EMA ended because I had declared in my annual CoI document that I held shares in FRESENIUS Medical Care, a pharmaceutical company that deals is operates in dialysis care and not SMA at all - yet this was my knockout criterion for attending a particular EMA meeting. I then decided to stop my EMA involvement completely. It's still not entirely clear to me whether - under the new draft - holding shares in pharmaceutical companies is generally CoI that needs to be declared as direct CoI, or whether a declaration is only required if you hold shares in a company that operates in the disease area in which you are an expert. I think it is quite unrealistic to expect patient advocates, clinical experts or experts from a regulatory body who have a good income in their real life not to invest part of their income in shares of a pharmaceutical industry. I fully agree that owning shares in a company related to the intervention	In line with the legislation, members of the Management Board, members of the committees, rapporteurs and experts shall not have financial or other interests in the pharmaceutical industry which could affect their impartiality. Patients involved in EMA activities are falling under the category of 'expert'. In line with its current and revised policies, holding of shares in *any* pharmaceutical company is considered a direct interest which is incompatible with involvement in any EMA activities. As the declarations of interests of EMA experts are published along with their CV for transparency. Experts with investments in different pharmaceutical companies who are consulted for EMA procedures, even related to a company or a therapeutic area different to that

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	under discussion should be reported as CoI, but considering pharmaceutical shares as general CoI is far removed from the reality of how people who are lucky enough to have some spare cash usually invest some of their savings. So it would be very helpful to explain this clause in more detail, otherwise I don't think most people are telling the full truth in their CoIs. I have really enjoyed dealing with EMA issues, but this has made me really angry. Hope this comment will help to understand why further clarification is necessary.	of the investment, can be perceived as a competing interest.
17. Federación de Asociaciones Científico Medicas Españolas	The revision of the policy should aim to ensure that the EMA counts on the participation of experts who will contribute to the excellence of the assessment while publicly ensuring the assessment does not suffer from bias and undue influence. To achieve that purpose, it is necessary to make a much greater distinction between members of Committees, who assume responsibility for assessment reports and approvals, and experts who provide their opinions during the assessment process but do not hold any decision-making authority. Committee members are NCA staff (or assimilated to NCA staff) and a highly restrictive policy on conflict of interest should be applied to them. However, for consulted clinical experts, the procedure should be based on full disclosure of interests and transparency, instead of limiting experts' participation due to the unavoidable fact that a real expert does collaborate with other stakeholders, including health technology developers, regional	Noted, however, in line with the Court rulings, the handling of competing interests needs to be consistent across EMA activities (i.e. between committees and SAG / AHEGs) and across roles.

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	and national health care providers, other research groups and scientific societies for Clinical Practice Guidelines. Most scientists and clinicians with recognised expertise in a field will have worked as investigators in clinical trials, have advised for developments, or may have experience evaluating competing products. Research integrated into medical care is needed to ensure excellence in healthcare. It is hard to imagine a valuable clinical expert who does not have any contact with health technology developers and works in an institution that does not collaborate with companies performing biomedical research. Even more, the lack of those activities could well be indicative of a lack of expertise. To facilitate the assessment of the declaration of interests by the clinical experts, it is relevant to better distinguish direct financial interests (personal financial gain) from scientific and medical interests related to the participation in research and education activities in the expert's field of knowledge. In addition, the EMA may consult several experts for a single assessment. Having several experts willing to maintain their reputation and credibility is a useful tool to prevent biased opinions. They will bring their different personal experiences and first-hand knowledge of different treatment alternatives. Both their divergent opinions and their consensus will be valuable to the agencies' staff in making their own assessments. The EMA policy should therefore aim to endorse the participation of several external clinical experts and protect the EMA from claims of suspected bias due to consultation with experts. In view of the recent rulings of the Court of Justice, more effort should be made to clearly distinguishing the responsibility of decision-makers from those who simply provide their	

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	expert opinion but are not responsible for the final opinion or decision. The line should be to defend the knowledge and impartiality of the well-trained members of decision-making bodies (staff of the authorities), advocating that they have fully considered, in their evaluations and final reports, the declared interests of the several experts consulted. Of note, this is what they do when they take into account the interests of the company submitting the dossier that the assessors use to prepare their reports, and this is not considered a bias. On the contrary, taking the line of increasing the restrictions in the EMA Policy on the interests declared by the consulted experts has two negative consequences: 1) expel the experts and their knowledge out of the system and 2) has a paradoxical effect, as it may increase the possibility to challenge the decisions of the Agency on the basis of experts' bias.	
18. Finnish Medicines Agency (Fimea)	The Finnish Medicines Agency (Fimea) draws attention to and expresses concern that, despite revising and tightening EMA´s policy on handling of competing interests of scientific committee members and experts (Policy 0044), the best possible expertise will continue to be available to the EMA's scientific committees and other bodies mentioned in the policy. Furthermore, Fimea notes that policy should be interpreted and applied in individual cases using the discretion provided by the regulations, so that the interpretation is not too strict and does not unnecessarily prevent experts from participating in the work of the intended bodies.	Noted and considered during the revision of the policy.
	Additionally, Fimea wants to highlight that the use of policy with intent to cause harm (such as when pharmaceutical companies invoke the policy to delay and complicate the handling of matters of competing pharmaceutical companies in the bodies mentioned in the policy) should be avoided. Fimea	Noted and agreed that this should be avoided.

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	emphasizes that the potential misuse of policy must be carefully monitored to ensure fair and efficient processing of matters.	
19. Health Action International (HAI)	Health Action International (HAI) welcomes the draft revision of Policy 0044 in alignment with the recent Court of Justice of the European Union rulings on joined cases C-6/21 and C-12/61 P, as well as Case C-291/22 P. We underscore the importance of ensuring impartiality and eradicating biased interests in the conduct of activities related to the European Medicines Agency (EMA) mandate and welcome the diligent work of the EMA in this regard. As competing interest policies vary across regulators, the EMA must aspire to setting the highest standard. With regard to the growing overlap between regulatory affairs, research as well as lobbying and outreach activities, we call for a more granular approach to uphold the highest ethical standards for professionals once engaged in providing expertise or assisting in the conduct of EMA activities. Particular aspects of the revised policy we welcome include: - The inclusion of research organisations within this policy connected to the unit that develops or manufactures medicinal products (including Advanced Therapy Medicinal Product (ATMPs) under 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 medical devices company. - The definition whereby a competing interest exists whenever an individual has an interest that may be reasonably perceived to affect their impartiality.	Noted.

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	- The distinction and further information provided on current and past interests. - The definition of financial interests not limited by a monetary amount. - The introduction of further restrictions on the permissions of expert witnesses.	
	However, we believe that certain key aspects of the policy may be more robust. These are the following: - 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.	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.
	- On financial interests, 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.	'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

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		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.
	- Also in line with WHO, we propose including declaration of interests of other parties with whom one has substantial common interests and which may be perceived as unduly influencing judgment.	Noted. EMA considers that such considering interests of other parties with whom one has substantial common interests would be disproportionate and potentially hinder its access to expertise. However, 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.
	- We recommend extending the three year cooling period to four years.	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

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		with a view to maintaining a balanced and robust framework.
	- We regret the lack of explicit mention of other organisations of relevance to the present policy, including patients organisations, consumer organisations, public interest non-government organisations and others similar non-profit entities. Both the organisation and its representatives may hold competing interests. We argue that the definition of grant or other funding to the expert's organisation/institution under indirect interests remains too narrow, as it must be used specifically to support any activity of the member or expert. We believe that any funding to the expert's institution (which may be a patient or consumer organisation) would constitute an indirect interest. We reaffirm our commitment to the activities of the EMA and support its endeavours in revising and strengthening Policy 0044, as well as its implementation and periodic revisions.	Policy 0044 applies to all experts participating to EMA activities as defined in the scope, irrespective of the type of organisation to which they belong. The comment with respect to the definition of grant/funding to the expert's organisation is noted. However, EMA would like to clarify that the definition is considered a proportionate approach: EMA acknowledges that some organisations may rely on fundings from private entities and this needs to be considered when to ensure that access to the required expertise is maintained. However, the definition allows to adequately focus on individuals that are specifically benefiting from the funding.
20. Julian Isla Gomez	Lack of Clarity on Definitions: While the policy provides definitions, some terms, like "indirect interests" or "affiliation," could benefit from further clarification. This would help avoid ambiguity in interpreting what constitutes an interest, especially regarding consultancy roles or collaboration with research organizations.	Noted. Definitions are provided with respect to what is considered 'indirect interests' in the policy as well as other terms, as appropriate.
	Complexity in Handling Different Interests: The policy outlines different restrictions based on the type of interest (e.g., current vs. past interests, financial vs. advisory roles). However, the detailed differentiation,	Noted. However, the EMA considers such differentiation is required to enable a balanced

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	especially the various roles and their associated restrictions, may be overly complex. A more streamlined approach could reduce confusion.	and proportionate approach to its handling of competing interests.
	Potential Over-Reliance on Self-Disclosure: The policy seems to rely heavily on individuals accurately declaring their interests. While quality assurance checks are mentioned, there could be more robust mechanisms to independently verify declarations, considering the potential for omissions.	EMA systematically conducts *ex ante* controls on any new experts being registered in its Experts Management Tool. These controls check that the information has been entered in the correct sections of the declaration of interest (DoI) and that the time periods in the DoI match with those given in the expert's CV. *Ex post* controls are also carried out every year on a sample of declaration of interests. These controls are conducted on a defined sample in order to check the correct completion of the DoI by experts, the correct evaluation of the DoI and implementation of restrictions applicable to the experts by the Agency as well as the correct reflection in the meeting's minutes of the level of participation in the meeting. Outcome of *ex ante* and *ex post* controls are reported in EMA's annual report on independence.
	Handling of Family Member Interests: While restrictions are applied based on interests held by close family members, there may not be enough detail on how broadly "close family" should be interpreted. This could be	The definition of close family member is included in the policy.

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	expanded to clarify whether extended family relationships or financial dependencies are considered.	
	Cooling-Off Period Inconsistencies: The policy specifies different cooling-off periods for various roles, which could lead to inconsistencies. For example, past consultancy roles may have a different cooling-off period than employment roles. Aligning these periods might make the policy fairer and easier to enforce.	In this revised policy, a unified cooling-off period of 3 years is applied to certain past interests for which restrictions are applied. Past consultancy and past employment are subject to the same cooling-off period.
	Inclusion of Chairs in Decision-Making: Although there are stricter rules for committee chairs, the policy might not go far enough in preventing conflicts of interest. It may be beneficial to apply uniform, stricter rules to all chairs to ensure consistency across different committees.	Chairs of all scientific committees are subject to the same rules.
	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.	A dedicated team at EMA oversees the management of scientific committee and other bodies members and experts' declarations of interest. They are in charge of *ex ante* controls. Together with the Institutional and Policy department and where appropriate the legal department, they support compliance with Policy 0044. The Institutional and Policy Department also monitors the implementation and compliance with Policy 0044. This is reflected in the annual reports on independence which are prepared and published by the Agency since 2015. The annual report on independence provides information on how the independence policies

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		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).
	Gaps in Specific Situations: The policy may not address certain scenarios, such as temporary advisory roles or consulting for companies outside the EU that still influence EU markets. Including provisions for such cases could strengthen the policy.	EMA would like to clarify that interests should be declared irrespective of whether the role are temporary or location of the company for which they are undertaken. In the policy, it is also emphasised that some of the definitions cannot address all the various scenarios which may arise. Furthermore, individuals may declare additional information regarding current or past activities, beyond the interests required to be declared as defined in the policy. They can decide, at their own initiative, not to participate in a specific activity. In any such cases or if other relevant information is brought to the attention of the Agency, EMA will apply appropriate measures in

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		order to ensure compliance with the requirement of impartiality, as needed.
21. Läkemedelsverket /Swedish Medical Products Agency	On page 10 in the policy We would like to better understand the rationale behind the special restrictions applied for CAT only and not for other relevant working groups and committees.	Article 22 of Regulation (EC) No 1394/2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 states (***emphasis added***) that ***CAT members and alternates*** shall not have financial or other interests in the biotechnology sector and medical device sector that could affect their impartiality.
22. Lif Sweden	The balance between the requirement of impartiality and independence of experts and the public interest of obtaining the best possible scientific advice on matters concerning the evaluation of the quality, safety and efficacy of medicinal products is crucial for the trust and reliance in EMA:s work. Lif Sweden welcomes the efforts made to establish a policy based on proportionality and balancing of interests. However Lif Sweden has concerns about the consequences that the proposed policy might have on the innovative power of the EU as it may result in stricter interpretations that hinder innovation instead of supporting it. Lif Sweden supports the detailed comments and proposals made by Efpia and would like to emphasize the following. Europe faces significant workforce challenges. Strict interpretations of ""conflict of interest"" could worsen this issue, especially as research grows increasingly specialized. It is crucial that the policy's implementation does not restrict the participation of individuals with the required expertise. Experts should not have to choose between contributing to industry or	Noted. However, EMA would like to highlight that 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

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	regulatory bodies. Instead, the European Medicines Agency (EMA) must be able to balance competing interests. Conflicting interests should as far as possible be mitigated by transparency and by using experts with different perspectives and backgrounds. It is particularly important to make the best use of the possibility of using expert witnesses. The rules on this could be clarified for example it could be confirmed 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.	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'.
	We call on the European Commission and the European Medicines Agency (EMA) to undertake a comprehensive review of regulatory system resourcing. This review should incorporate an in-depth assessment of how current conflict of interest policies contribute to resourcing limitations and examine strategies for mitigating them.	The Agency will continue monitoring the impact and implementation of the policy as part of its annual reports on independence. Furthermore, the Agency is currently reviewing its processes supporting the identification and use of experts. EMA would like to provide reassurance that its experts from EU Member states constitute the core of the expertise that is involved in the work of its scientific committees and working parties.

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23. Lymphoma Coalition	On behalf of Lymphoma Coalition, I want to express our gratitude for the opportunity to contribute to this important consultation. We acknowledge EMA's efforts to revise its policy on competing interests for scientific committee members and experts, aligning with recent court rulings and evolving public expectations. This update is a critical opportunity to build public trust while ensuring robust, patient-focused regulatory outcomes. From a patient advocacy perspective, it is essential that EMA's policies on competing interests do not inadvertently exclude experts who provide real-world insights into patient care. Academic researchers, clinicians, and patient representatives often bridge the gap between scientific evidence and practical outcomes. Their involvement ensures regulatory decisions consider not only clinical efficacy but also the broader impacts on patients' quality of life, access, and long-term care. We commend EMA for recognizing the need to balance COI management with securing top-tier expertise. Patients benefit when decisions draw from a wide range of knowledge, including insights from experts on innovative therapies such as ATMPs. These experts, often engaged in public-private collaborations, bring essential understanding of complex therapies. Safeguarding their contributions through a proportional COI approach is crucial to maintaining both innovation and patient access. Transparency in managing COI is key to maintaining trust. We appreciate EMA's commitment to publishing declarations of interest (DoI) and meeting minutes, allowing patients and the public to see how potential conflicts are identified and rigorously managed. Patients deserve clear information on how decisions impacting their health are made, ensuring safety and reinforcing EMA's role as a patient-centered agency.	Noted.

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	The policy's proportional approach to COI, distinguishing between direct and indirect interests, strikes a vital balance: preserving integrity while allowing access to critical insights. This is particularly important for ATMP academic experts, whose work involves collaborative research. However, 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.	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.
	Scientific societies and academic experts are indispensable for quality, patient-focused decision-making. Their perspectives enhance regulatory deliberations by providing depth and independence. 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.	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.
	Patients are the ultimate beneficiaries of regulatory decisions, and their voices must remain central to EMA's processes. Patient representatives bring unique perspectives, aligning regulatory outcomes with real-world needs. Many are well-equipped to provide patient experience data, bridging the gap between scientific rigor and everyday challenges.	EMA agrees that patients and consumers bring a 'real-life' experience as well as specific knowledge and expertise to scientific discussions on medicines and on the impact of regulatory decisions. To this respect, EMA has an

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	Including lived experience ensures frameworks reflect patient realities, enhancing both scientific robustness and relevance to patient care. The policy could further strengthen patient-centricity by recognizing the value of expertise rooted in direct care and lived experience. Clinicians involved in collaborative research or patient advocacy offer a dual perspective: understanding both the scientific and clinical aspects of therapies while being deeply attuned to patient challenges. Their contributions are vital to shaping frameworks that holistically serve patients. We applaud EMA's commitment to balancing independence and scientific excellence. Including scientific societies, academic researchers, and patient representatives will enhance the robustness of regulatory evaluations. By maintaining transparency, proportional restrictions, and patient-centricity, EMA can continue delivering safe, effective treatments to those who need them most. Thank you for considering our input. We remain committed to collaborating in this process to ensure patient interests remain central to EMA's decision-making framework.	established framework of interactions to support its engagement and involvement of patients and consumers. A public workshop on Patient Experience Data was held in 2022 and EMA is also preparing a reflection paper on Patient Experience Data that will be shared for public consultation this year. Many internal discussions are occurring, and changes being implemented to better reflect patient experience data all along the medicines regulatory lifecycle.
24. Michael Lassmann	In Nuclear Medicine, where there are only a limited number of scientifically active centers in Europe, industry will work with the best of the best. If the proposed CoI-policy will be in place, EMA will have to work with those that industry has not yet chosen to work with. This will affect the quality of the documents drafted by EMA, the quality of advice we can give, etc, both in the short and long term.	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.

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	I propose that we continue to respect "indirect interests" as a viable means of working with EMA for providing advice.	
25. Myeloma Patients Europe (MPE)	Myeloma Patients Europe response to public consultation on "European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts" Myeloma Patients Europe (MPE) is a pan-European organisation representing 52 multiple myeloma and amyloidosis patient groups from 33 countries, of which 21 are EU Member States. Multiple myeloma is a rare blood cancer and amyloidosis is a group of rare conditions affecting the structure of various proteins. Amyloid light-chain (AL) amyloidosis, the most common form of amyloidosis, is sometimes connected with multiple myeloma. MPE is also a member of the Patients' and Consumers' Working Party of the European Medicines Agency (EMA). MPE is grateful for the opportunity to comment on the draft revision of EMA's policy on handling competing interests of scientific committee members and experts ('policy 0044'). MPE welcomes the use of proportionality as a principle guiding this policy, where the need for members and experts involved in EMA's activities to be free of interests in companies or research organisations should be balanced with "the need to secure the best (specialist) scientific expertise for involvement in the Agency's activities" (section 4.1 Objectives of the policy). Achieving a balanced approach is translated into acknowledging the difference between interests and competing interests (section 1 Introduction and purpose), as well as further differentiating between direct	Noted.

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	and indirect competing interests (section 3.2.2 Direct versus indirect interests). 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).	
	However, MPE considers that the policy could provide further clarity and better account for nuance, situation, rarity of disease, type of involvement/interests in companies or research organizations. We are concerned that in cases where the pool of expertise is already limited such as for Advanced Therapy Medicinal Products (ATMPs) and/or for products targeting rare diseases, the restrictions introduced by this policy risk limiting access to the best possible expertise. Specifically, MPE would like to draw attention to the following points:	
	• Section 3.2.2.1 Direct interests: Consultancy or strategic advisory role to a company There is a notable difference between providing advice and the ability to vote/influence decisions. MPE 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	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

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	needs ("advice"), without any voting rights or power to influence decisions, be considered as a competing interest?	that participation in CABs should be declared as consultancy/strategic advisory role.
	• 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 MPE 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? MPE 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 competing commercial interests, perhaps advisory roles without the power to influence decisions could be considered separately?	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'.*
	• Section 3.2.2.2 Indirect interests: Affiliation to a research organisation MPE wonders if affiliation to any research organisation is not too broad here. Would perhaps an affiliation to an organisation with a clear link to a product or a disease constitute a clear competing interest in this case?	In the revised policy, the objective of the addition of 'Affiliation to a research organisation' is not to exclude a member of expert but rather to enable to restrict their involvement if and when their organisation submits an application to EMA.
	MPE welcomes the EMA's dedication to ensure impartiality, as well as access to the best available expertise. To this end, MPE hopes that EMA would consider adding more nuance to some of the provisions of this policy to ensure the inclusion of patients from the already small pools of expertise such as ATMPs or rare diseases.	

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	MPE remains committed to supporting the work of EMA and remains available for any clarifications on the comments detailed above.	
26. Orexigen Therapeutics Ireland Limited	We will take this opportunity to highlight what we perceive as problematic updates which would not only fail to enhance the effect of the policy but would be in contradiction to or otherwise misalignment with the legal authority which the EMA cites as the impetus for these updates, Court of Justice Cases C-6/21 and C-16/21 P and Case C-291/22 P. The Court emphasizes that given the broad discretion enjoyed by the EMA in making complex technical assessment, it is necessary for the EMA to formulate in its policy objectively justified criteria to manage competing interests to ensure the impartiality and independence of the individuals contributing to the preparation of the EMA's scientific opinions. 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	The Court in Case C-291/22 P of 15 April 2024 confirmed unambiguously that the notion of rival product (included in the effective version of the policy at the time) should cover all products that may be considered as a valid alternative to the product under evaluation. The Court referred to previous case-law where the "therapeutic substitutability and interchangeability" amongst products had been considered as the leading criterion for deciding which products are rival to each other. The Court considered that when assessing whether an interest pertains to a rival product of the medicinal product under evaluation, all products that may be considered as a valid alternative to the medicinal product under evaluation should be considered. In paragraphs 98 to 105 of Case C-291/22 P the Court provided some guidance for such an assessment. EMA considers that the application of restrictions to medicinal products in the same declared condition reflects adequately the requirements

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	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 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	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, as suggested in this comment.

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	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. 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.	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

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		with a view to maintaining a balanced and robust framework.
27. Parkinson's Europe	The policy doesn't clearly take into account patient organisations who are connected to or support research endeavours, not just from a funding perspective but also from an advocacy perspective.	EMA acknowledges the key role patients are playing in supporting the development of medicinal products. Policy 0044 applies to all experts participating to EMA activities as defined in the scope, irrespective of the type of organisation to which they belong. The policy defines interests to be declared by individuals, which including funding to their organisation as well as activities the individual undertakes such as consultancy and strategic advisory role to pharmaceutical company. In this respect, EMA considers that an individual patient that advises a pharmaceutical company should duly declare this interest and have their participation in EMA activity limited as per Policy 0044. This does not prevent EMA from seeking input of other patients who may not have conflicts of interest in the meaning of the Policy.
28. Pharma Mar S.A	Pharma Mar welcomes the EMA's initiative to review its policy on the handling of competing interests (EMA Policy) and the opportunity for stakeholders to provide comments. 1. Preventing procedural breaches through a hearing officer	The suggestion is noted and might be considered taking into account the legal framework applicable to the Agency.

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	The experience gained by the European Commission on safeguarding procedural rights in competition law cases through a hearing officer could be relevant to the EMA. After the necessary institutional reform, the 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. The possibility of introducing a hearing officer at other EU institutions has been discussed in scientific publications, particularly in relation to the ECB (CMLR No. 61, 2024, pp. 1191–1222), and could be seen as the natural adoption by EMA of existing best practices to ensure compliance with EU law. Moreover, it would position it among the world's leading agencies equipped with robust mechanisms to protect the integrity of their procedures, as the FDA does through its compliance department.	The Agency is doing its utmost to ensure that scientific assessments are carried out in compliance with the requirement of impartiality as interpreted by the Court of Justice, and Policy 0044 has been revised and updated accordingly.
	2. Safeguards prior to confirming appointments PharmaMar welcomes the improvements in the screening of potential conflicts of interest before the appointment of experts. However, there is no mechanism for gathering the most relevant information needed to adhere to the standards set by caselaw, particularly regarding the principle of objective impartiality. Indeed, it is settled caselaw that objective impartiality under EU law is not based on an abstract assessment of information but on the perception of a third-party observer (C-680/16 P, EU:C:2019:257, para. 39). For this reason, PharmaMar respectfully proposes that before experts are appointed, any interested party should be granted the opportunity to put	Policy 0044 sets out the ground rules on which EMA involves experts in its work. It has provided a robust framework for managing possible competing interests over many years, by applying restrictions to experts' involvement in a proportionate manner. It has been revised on a regular basis and in this latest revision to align with the case-law of the Court of Justice, demonstrating EMA's commitment to its obligation to manage potential conflicts of interest.

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	forward written questions and to obtain clarification about candidates' potential conflicting interests.	EMA has extensive experience in the conduct of assessments of competing interests in line with the process defined in the policy and relevant standard operating procedures. In addition, the transparency of the declarations of interests of all experts involved in its evaluation activities, enables scrutiny of the public and interested parties.
	3. Safeguards after appointments PharmaMar positively views that – under Section 4.2.1 of the EMA Policy – specific safeguards have been established for relying on the expertise of individuals in situations "where specific expertise is required that can only be provided by a few individuals who have competing interests that would normally limit their involvement in the Agency's activities as a member or expert". Although it remains unproven that this situation is realistic in the UE-27 if expertise in all the Member States is equally considered, and although it remains to be seen how these additional safeguards will be applied in actual cases, the scope of one of these safeguards should be revisited as part of the EMA Policy's review. Indeed, the requirement that the interested company be granted the right to attend any oral testimony provided by such experts and the opportunity to ask questions should be broadened to all circumstances in which oral testimony is provided by any expert in relation to a medicinal product for which authorisation is uncertain (i.e., whenever the procedure enters the re-examination stage).	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.

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	There are other leading agencies such as the FDA that include a similar transparency mechanism for situations in which authorisation is uncertain. In relation to oncologic medicinal products, e.g., public hearings are envisaged for the Oncologic Drugs Advisory Committee (ODAC), and experts need to justify their position as regards the medicinal product under examination.	
	4. Annex 3 – research centres' units with and without manufacturing 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.	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.
	5. All annexes – restrictions need to be expanded to competing or rival products 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 the product developed by the organisation they are	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 as suggested in this comment.

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	or were affiliated with, but that no legitimate doubts would arise in relation to their involvement in the assessment of competing or rival products.	
29. Prescrire	Experts impartiality and independence is key to support quality advice from EMA: EMA should build up a network of independent experts We are puzzled by the fact that EMA presents the requirements of impartiality and independence of its experts on the one side and EMA's task to provide the best possible scientific advice relating to the evaluation of medicines on the other side as contradictory and thus needing to be reconciled (p. 2). By doing this, EMA remains in denial of the effect of undue influence on the decision-making process. In our view these principles go hand in hand and are complementary. To relay on independent and impartial experts is fundamental for a trustworthy evaluation of the safety and efficacity of medicinal products. Expert's independence is at the service of quality and patient safety. Financial or other interests in the health technology industry undermine the quality of expertise. The policy should abstain from spreading the fallacious message that the best experts have necessarily interests with companies (p. 2, last sentence, topic 1). The article 63(2) of Regulation (EC) No 726/2004 is very clear: members of the scientific committees and experts shall not have financial or other interests in the pharmaceutical and health technology industry that could affect their impartiality. This principal should be fully respected by the EMA policy under discussion. EMA's policy on handling competing interests should be simple and rely on clear principles	Noted. However, the statements referred to in the comments are intended to provide the background on how EMA needs to fulfil all the obligations set out in legislation with respect to involvement of experts, both on the need to access the best expertise and the need to guarantee impartiality. EMA would like to reiterate that not all activities in which an expert take part are to be considered as a competing interests. It is also widely accepted, as commented by several other stakeholders, that experience may be gained while taking part in some activities (e.g. being an investigator in a clinical trial). Overall, it is precisely the objective of its policy to set out rules and principles for the handling of interests that could affect the impartiality of its experts.

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	Both direct and indirect interests shall be avoided to fulfill the requirement of impartiality and independence.	
	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.	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. 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.
	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	'Compensation, fees or honoraria […] paid by a company to the individual in a personal capacity' are added in the definition of financial

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	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.	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.
	Part 3.2.2.2 on Indirect interests (cf. p. 7): Paragraph on "investigator": in our view, when the investigator and/or the members of the data monitoring committees are paid by the company, this should be considered as a direct interest. The participants in the data monitoring committees are presented as independent external experts. To make such a claim, clarity is needed on who selected the experts and who paid for their service. If this is done by the company, they should not be presented as independent experts.	EMA considers that payment an individual or their institution may receive with respect to their participation in a clinical trial as investigator or in a data monitoring committees are a compensation that do not quality as a financial interest. EMA also considers that the restriction applied for this type of interest is proportionate and comparable to those applied with regard to employment or consultancy for a pharmaceutical company.
	Objectives of the policy In part, "4.1. Objectives of the policy", we ask for the deletion of	EMA's handling of competing interests reflects the balance the Agency has to strike to fulfil its legal obligations: the requirement of impartiality

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	• "This objective is guided by the principle of proportionality and has to be balanced with the need to secure the best (specialist) scientific expertise for involvement in the Agency's activities related to medicinal products for human and veterinary use or medical devices." "strive for the optimal balance between applying".	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)).
	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	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.
	4.2.3 Achieving a transparent process (cf. p. 12) Transparency should be further improved. 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.	EMA conducts comprehensive assessments of competing interests in line with the process defined in the policy and relevant standard operating procedures. Transparency related to declaration of interests is in line with the requirements from the legislation. EMA takes note of the comment and may consider increased search functions' feasibility in the future.
	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	A dedicated team at EMA oversees the management of scientific committee and other bodies members and expert's declarations of interest. They are in charge of *ex ante* controls which are systematically conducted on any new

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	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	experts being registered in its Experts Management Tool. These controls check that the information has been entered in the correct sections of the declaration of interest (DoI) and that the time periods in the DoI match with those given in the expert's CV. Together with the Institutional and Policy department and where appropriate the legal department, the team support compliance with Policy 0044. The Institutional and Policy Department also monitors the implementation and compliance with Policy 0044. This is reflected in the annual reports on independence which are prepared and published by the Agency since 2015. The annual report on independence provides 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

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		incomplete declarations of interest by scientific experts and committee members).
30. SwedenBIO	SwedenBIO's response to the proposed revision of the EMA policy on handling of competing interests of scientific committee members and experts, 0044 SwedenBIO is the trade organization for the Swedish life science industry, and we would like to raise some serious concerns for the consequences on the innovative power of Europe from the suggested policy. As the commission states in the communication about the upcoming life science strategy: "Life sciences and biotechnology are widely recognized to be, after information technology, the next wave of the knowledge-based economy, creating new opportunities for our societies and economies". For Europe to capitalize on this potential, it needs a supportive regulatory framework that advances the industry rather than holding it back While policies to combat corruption are essential, overly restrictive measures may unintentionally hinder progress. The life sciences industry must have access to top experts to drive projects forward efficiently, especially in areas with limited expertise and high unmet medical needs. Preventing the EMA from getting access to the best competence for expert consultations based on perceived conflicts of interest is suboptimal for European patients. Disqualifying all experts with industry connections limits the pool to those with potentially less relevant experience and sometimes even opposing scientific agenda. The future of life sciences will be relying on enhanced collaboration—not just with industry and healthcare professionals, but also with patient	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

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	organizations, which offer valuable insights and share a vested interest in advancing treatment options. Excluding patient advocates from expert roles due to their involvement in development is counterproductive and does not serve society's best interests. A new policy on competing interest should prioritize transparency but also reflect the authority's independence and discretion to select the most qualified experts. Experts should not have to choose between contributing to industry or regulatory bodies. Instead, the European Medicines Agency (EMA) must balance these competing interests, ensuring that the best expertise is accessible to both sides in a transparent and fair manner. Potential and actual conflicts of interests need to be assessed publicly and not exclude necessary competence without grounds.	the rules set out in this policy, it also foresees the possibility to involve individuals as 'expert witnesses'.
31. Viviana Mascilongo	Dear All, here below the technical comments for Your evaluation: 1. If it is possible to add the European main current law concerning the rule of the conflict of interest as bibliographic reference in the section "5. Related documents".	In this policy, EMA has taken the approach to quote relevant legislation in the policy and include in section 5 related documents such as additional EMA guidance.
	2. With reference to " MDCG 2019-07 Rev.1 Guidance on Article 15 of the medical device regulation (MDR) and in vitro diagnostic device regulation (IVDR) on a 'person responsible for regulatory compliance' (PRRC) December 2023" if it is possible to include a list of selected persons responsible for regulatory compliance as qualified experts into the Executive Steering Groups on Shortages and Safety of Medicines (MSSG) and on Shortages of Medical Devices (MDSSG).	Out of scope.

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	3. If the Executive Steering Groups on Shortages of Medical Devices (MDSSG) could be part in the Eudamed Portal https://webgate.ec.europa.eu/eudamed/landing-page#/	