

# Comment on the commission implementing regulation (EU) on management of conflict of interest in European HTA

## Key asks

- Pragmatic involvement of the best available expertise for high-quality joint work
- Transparent documentation instead of exclusion based on conflict of interest
- Involvement of patients and experts representing organizations

## Introduction

The Regulation (EU) 2021/2282 on health technology assessment (HTA) stipulates that the joint work should aim to achieve the highest level of quality, transparency and independence. To preserve the scientific integrity of the joint clinical assessments and joint scientific consultations, rules should be developed to ensure the independence and impartiality of patients, clinical experts and other relevant experts involved, and avoid conflicts of interest. The European Commission is seeking feedback on the draft Implementing Regulation laying down rules for the application of the EU Regulation on Health Technology Assessment (Regulation 2021/2282), regarding conflict of interest.

The Implementing Regulation contains definitions and procedural aspects relating to the declaration and identification of conflicts of interest and their management. The rules apply to individuals, both representatives of the HTA Coordination Group (HTACG) and their subgroups and individual external experts in the health technology developers' industrial sector (i.e. patients, clinical experts and other relevant experts) who participate in the joint work of the Coordination Group and its subgroups. The rules should ensure that these individuals have no financial or other interest, which could affect their independence and impartiality.

The vfa supports a policy that aims for a high level of quality, transparency and independence in joint work. However, the European Commission's proposal to guarantee independence is not balanced in terms of ensuring quality. The vfa is concerned that the proposed strict rules for dealing with conflicts of interest will exclude the right people with relevant, in-depth expertise and will ultimately reduce the scientific quality of the joint work. The vfa recommends a pragmatic approach to involving the best available expertise, including individuals representing organizations, with transparent documentation of the declared interests.

## Exclusions of experts with conflicts of interests

The European Commission lays down strict rules for dealing with conflict of interests. The declaration form comprises a wide range of aspects, such as employment, consultancy, strategic advisory roles, financial interest, investigator, lead member in an organization receiving funding and interests of immediate family members. Based on stated interests, individuals are rigorously excluded or severely restricted from participating in the joint work, while those representing organizations are fundamentally omitted.

These strict rules harbor the risk that patients and experts with relevant, in-depth specialist expertise will be excluded from the joint work. There is

especially the risk that individuals with the greatest expertise on the type of health technology or therapeutic area in question or on issues related to clinical trial design will be excluded. The exclusion of these experts or the involvement of individuals with less relevant expertise will impair the scientific quality of the joint work. The proposed regulation thus jeopardizes the policy goal of EU HTA to achieve highest scientific quality and reflect the state of the art.

Germany has gained valuable but negative experience with a strict conflict-of-interest-framework in dossier assessments of IQWiG. In the last 12 months, 20 % did not involve experts and 60 % no patients. At the same time, involved experts were less specialized and recognized in the medical-scientific community. The G-BA handles conflicts of interest more pragmatically. The participation of patients and experts in public consultations and hearings is not restricted based on conflict of interest. Individuals, including representatives of organizations, are involved even in the event of declared interests. The process ensures that the best available expertise in Germany is not excluded. Experience of vfa shows that individuals involved by G-BA have or represent more relevant expertise compared to IQWiG's experts. The G-BA publishes a transparent summary of the declared interests without financial details. Following this approach, Germany can achieve a high level of quality, transparency and independence.

### Recommendation

The involvement of patients and experts should also include individuals representing organizations. The participation should not be restricted based on conflicts of interest. Rather, the joint work should incorporate the best available expertise, even if there is a declared interest. The conflict of interest should be handled transparently, including documenting the conflict of interest and commenting on aspects of the assessment with potential risks due to the involved experts' conflict of interest. Mitigation actions should be documented.

### Exceptions to include experts with conflicts of interest

The draft regulation provides exceptions for the strict rules for dealing with conflict of interest. Where in exceptional cases only individual experts with conflicts of interests are available, the work of the HTACG should ensure their appropriate involvement in the joint work considering their conflicts of interest, while ensuring transparency.

These exceptions are an important addition to the draft regulation to ensure the involvement of experts in the joint work in situations when only experts with conflict of interest are available. However, the exceptional clause does not consider the level of expertise of the experts with or without conflict of interest. Especially, the rules are insufficient to ensure the involvement of the best available expertise. Despite the exceptional rule, the most relevant or specialized expert might be still excluded if a less specialized expert without conflict of interest would be available. Including less specialized experts poses a potential risk for the scientific quality of the joint work.

### Recommendation

The exceptional rule should be extended to consider the level of expertise of experts with or without conflict of interest. The rule should ensure the involvement of the best available expertise to enable high-quality joint work.

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