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**Statement**

**of the Federal Umbrella Organization of**

**national Organization Self-Help of people with disabilities,**

**chronic illness and their relatives e.V.**

**(BAG SELBSTHILFE)**

**We comment the Implementing Act pursuant to Regulation (EU) 2021/2282 on health technology assessment, procedural rules for the interaction during, exchange of information on, and participation in the preparation and update of joint clinical assessments of medicinal products for human use at Union level as follows:**

1. We fully agree with the coordination group that the JCA Subgroup should give the opportunity to patient organizations to provide their input on joint clinical assessments. (15)

This should include the right to propose the patient experts, which will be involved in the assessment.

The European umbrella organizations should be put in a position to organize trainings on the methodology of the assessments and the regulatory rules of the procedures to empower the persons which will be proposed. This includes the provision of financial resources to implement such trainings and to coordinate the participation of the patient experts in the assessments.

1. We point out that the JCA Subgroup won’t be able to select patients who have the required expertise in the therapeutic area of the joint clinical assessment. (13)

It is up to the patient organizations in Europe to identity suitable representatives and to coach them for the most feasible participation.

We also want to point out that the participation should not aim to select individuals to get to know individual insights but to identify persons which are able to transfer collective experiences and patient preferences into the assessment.

1. We fully agree with the coordination group that it has to be ensured that only patients take part in the assessments who are free from conflicts of interests and who have signed a confidentiality agreement. (14)

On the other hand, we like to point out that involved patients might recognize during the assessment, that it would be helpful to involve other patient experts of a specific sup population, gender or age.

The agreement of confidentiality will impede the communication with other patient which could give the specific information.

So it is absolutely necessary that the advice of the patient experts to involve other persons will be respected, checked an followed by the assessor.

1. We fully agree with coordination group that the commission should get procedural rules to ensure the patient who are involved in the assessment, will be given the opportunity to provide input on the draft and the summary reports. (24)

These procedural rules should ensure that the patient organizations will have enough information and enough time to identify suitable patients and to coach them for their tasks.

The procedural rules should also ensure that the patients have the possibility of giving insights on all elements of the PICO especially patient preferences on behalf of the endpoints which have to be discussed.

Therefore, it is necessary that patients will be provided by a summary of the assessment basics at the beginning of their involvement.