



EUROPEAN ASSOCIATION OF HEARING AID PROFESSIONALS

Statement of the “EUROPEAN ASSOCIATION OF HEARING AID PROFESSIONALS (AEA)” on the EU Commission’s proposal to strengthen the cooperation of the member states in the field of Health Technology Assessment (HTA)

Hannover, October 2018 – On January 31, the European Commission has submitted a proposal for a regulation of the European Parliament and the Council, on the assessment of health technologies and a modification of the EU directive 2011/24/EU. The Commission’s proposal is currently under discussion in the committees of the European Parliament.

This project aims at a harmonization of the assessment of health technologies (HTA). The Commission’s proposal negatively interferes with the existing national health systems. It foresees, that in the future, the individual member states will no longer have the opportunity to carry out their own evaluations of new drugs and medical products.

Health trades such as optometry, hearing acoustic, orthopaedic shoemaking and technology as well as dentistry adapt medical products to the individual needs of patients. These professions need to rely on reliable (clinical) assessments of medical products to prevent potential health risks for their patients.

While the methodically complex assessment and approval process of active ingredients or technologies to be covered by statutory health insurances, puts a focus on the (additional) medical benefit, in many other EU member states the cost-benefit ratio is clearly prioritized. The importance of clinical studies is only secondary. The Commission wants to counteract this by means of implementation acts and detailed procedural rules for joint clinical assessments.

From the health trades point of view, this will imply that all EU health care systems will have to orientate their evaluation procedures based on the lowest (quality) standard. Furthermore, the proposal no longer provides for any individual assessments in the member states. This would mean a considerable risk of lowered quality standards in our health care provision.

The health care professions therefore demand to put this project on hold. In case it is realized after all, the individual member states must be at liberty to undertake national assessments. Especially, since it is foreseeable, that the planned joint assessment will not match nationally set standards or be incompatible with established national decision systems.

The EUROPEAN ASSOCIATION OF HEARING AID PROFESSIONALS (AEA) shares the doubts of many European countries regarding the contractual basis of the Commission’s proposal. The planned harmonization of the assessment of drugs and medical products represents an interference into the national responsibility of the member states for the regulation and organization of their health care systems and medical care. Many European health care systems were mainly supported by joint contributions of employers and employees and is, as such, subject to self-administration and does not fall into the EU Commissions regulatory competence.

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