Connection to the AMNOG process

Dr. Beate Wieseler sees the usual procedure in a new light

The benefit assessment cannot be seen in isolation from the respective health systems but must consider the context of the different systems, stresses Dr. Beate Wieseler from the IQWiG. She believes that „this is the only way that decisions and their impacts on patient care can be supported practically by the European benefit assessment".

opg: You are directly involved in the coordination group – as chair of the sub-group that is concerned with the development of methodological and procedural guidelines. Could you tell us a little about how the preparations are going?

Wieseler: The coordination group is the top decision-making committee of the European HTA process. Currently, the group meets each quarter to advance the implementation of the HTA Regulation. The decisions from the coordination group are prepared in more substantive sub-groups, one of which is the sub-group for methodological and procedural guidelines. Monthly meetings are planned for these sub-groups. In the coordination group and the sub-groups it is planned to have a mixture of virtual and hybrid meetings with the option of taking part on site or virtually.

In a first step, a work schedule has been prepared, which describes the building blocks of the EU HTA process that are to be developed, regulates the responsibilities of the individual sub-groups and also identifies topics that should be processed jointly by several sub-groups.

opg: What are the main challenges for the work carried out in your sub-group? And which topics can be prepared more smoothly than expected?

About Beate Wieseler

Dr. Beate Wieseler has been head of the department of drug assessment at the Institute for Quality and Efficiency in Health Care (IQWiG) since 2011. The biologist is closely involved in designing the EU-HTA process – in the coordination group as head of the sub-group for the development of methodological and procedural guidelines, a key position.


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„The aim of the European benefit assessment is to provide an assessment of new drugs and medical devices to support decisions in the individual member states", says Dr. Beate Wieseler. © stock.adobe.com, Sasha

Wieseler: The aim of the European benefit assessment is to provide an assessment of new drugs and medical devices to support decisions in the individual member states. Therefore, the HTA Regulation envisages that the so-called assessment scope – or the scientific questions of the assessment – will be defined by the member states. These questions will be influenced by characteristics of the respective health systems, for example, by the health care standards or the requirements for reimbursement decisions. These parameters must be taken into account appropriately when methods, data to be submitted and processes for the European process are being defined. The work plan for the transition period until the start of the assessments in 2025 could be agreed without any problem; there is agreement on the necessary preparations.

opg: In Europe there are very different competence levels with regard to health technology assessments in the different countries. How are you dealing with this in the preparations?

Wieseler: Primarily, the differences are in the resources that are currently available for HTA in the different member countries. This is also due to the issues that the member states support through HTA. One measure for mutual support that is currently being discussed is the formation of topic-specific expert groups from the HTA agencies, which can become involved when necessary.

opg: The IQWiG is also represented in EUnetHTA 21: how should we imagine the collaboration and handover between the coordination group and this organisation?

Wieseler: EUnetHTA21 is a project in which a consortium of HTA agencies from twelve member states develops methodological guidelines and processes that are required for a benefit assessment on EU level in preparation for the implementation of the HTA regulation. The IQWiG and G-BA represent Germany. The results of the project work will be provided to the coordination group. The responsible sub-groups will check the material and discuss necessary changes. In particular, the views of the member states that are not represented in EUnetHTA 21 will be obtained. The coordination group is then responsible for the subsequent decisions regarding the methods and processes. I hope that the results from EUnetHTA21 facilitate and accelerate the development of the fundamentals for the European process.

opg: To what extent could the German AMNOG process benefit from the harmonised European HTA process?

Wieseler: Developing the European process with the necessity of explaining our own requirements and fitting them into the European context requires a fresh look at the usual process. This could lead to sensible changes.

opg: In what respect do you fear negative impacts?

Wieseler: The HTA Regulation envisages that the needs of the member states will be taken into account in the implementation of the benefit assessment at EU level. In addition, decisions regarding additional benefits and the resulting consequences for health care are made at national level. Requirements for completeness of the data and transparency are the same as with the German process. Therefore, I don't fear any negative impacts from the European assessment.

opg: How do you assess the need for national adjustments in Germany as a result of the European procedure?

Wieseler: In May this year, in response to a minor question from the CDU/CSU parliamentary group, the German government clarified that the proven results of the benefit assessment under the AMNOG procedure should continue to be achieved. In this respect it will be necessary to link the result of the European benefit assessment to the AMNOG process and, where relevant, supplement the documents at national level. Potentially, a change in the timeline would be sensible in order to take account of the time when the European report of the benefit assessment is available.

opg: What is the most important insight that you have gained during the current preparations for the European HTA process?

Wieseler: In the discussion about the HTA process in the individual member states I realised that the benefit assessment cannot be seen in isolation from the respective health systems but must consider the context of the different systems. This is the only way that decisions and their impacts on patient care can be supported practically by the European benefit assessment. ◀

Patient representatives „only as an exception"

Dr. Martin Danner criticises limited participation possibilities

German patients have mixed feelings about the European HTA process: for example, Dr. Martin Danner, managing director of BAG SELBSTHILFE, the head organisation of around 120 self-help organisations in Germany, criticises that in study assessments the involvement of persons concerned is envisaged „only as an exception". Also with regard to patient-relevant benefits, he currently sees no clear methodological orientation to the patient's perspective.

opg: What do German patients expect from a harmonised European HTA – more of an improvement or a worsening of access to new health technologies?

Danner: In a European comparison, German patients have very good access to innovative medicines and medical devices. Because of this, expectations with regard to the aspect of faster access are rather low.

opg: Expectations of patients in other European countries are likely very different to those of Germans, aren't they?

Danner: In most European countries, the positive HTA is a requirement for patients to access innovative medicines. In Germany, access is automatic once the drugs have been approved and the main significance of the HTA relates to pricing. Admittedly, low prices can also result in products being removed from the market. But that is not usually the case. Against this background, it is completely natural that expectations differ among the European countries. But even in other European countries the discussions are not focused exclusively on HTAs. Many health systems will be overtaxed to pass on available medical advances to the citizens, even if the HTAs are positive.

About Martin Danner

Dr. Martin Danner is managing director of BAG SELBSTHILFE for people with disabilities and chronic illnesses and their relatives. The lawyer is also the spokesperson for patient representation in the Joint Federal Committee (G-BA).


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