NEW THERAPIES ASSESSMENT NEWS

CLINICAL GUIDANCE AND HTA DECISION MAKING - A NEW BALANCING ACT?

GERMANY





CONTEXT

European HTA agencies not only assess evidence and value of new treatments but are also involved in developing, informing, or directing clinical guidance development. HTA agencies' level of involvement differs across markets. in Germany, IQWiG (the Institute for Quality and Efficiency in Healthcare) proposes to develop evidence reports for clinical guidance.





IQWiG published on 25 Aug 2021 for consultation its new methods paper (6.1). This paper proposes a process to develop evidence reports that inform clinical guidelines developed by the AWMF (Association of the Scientific Medical Societies in Germany). According to the proposal, AWMF will formulate specific research questions, and IQWiG will develop evidence reports that will directly inform the clinical guidelines development.

CONCLUSIONS & POTENTIAL DIRECTION

The industry should prepare for the following:

- 1. HTA agencies and affiliated bodies may direct and influence clinical guidelines more strongly in the future
- 2. Across Europe, HTA agencies already either develop (England) or influence (Germany) clinical guidelines
- 3. Clinical guidelines and mapping of the patient pathways described in clinical guidelines - will grow increasingly important in market access planning and preparing for value demonstration, including impact of a new treatment on health services

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