IQWiG’s General Methods 5.0: What’s New?
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BACKGROUND
• The Institute for Quality and Efficacy in Health Care (IQWiG [Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen]) is an independent health technology institute that supports evidence-based decision making in the German health care system.
• IQWiG publishes their General Methods, which describe principles and scientific tools for preparing or evaluating health technology assessments (HTAs).
• These General Methods are updated on a regular basis, to incorporate changes in HTA methodology or to incorporate new legislation.
• In 2015, the Health Care Strengthening Act (HCSA), which promotes integrated care and the type and scope of potential evaluations in the statutory health insurance system, was passed and updates to the Fifth Book of the Social Insurance Code (GKV-SGB V) were made, necessitating an update to the General Methods.
• Two main changes that were passed in that act required changes in IQWiG’s General Methods 5.0:
  - Medical devices (§139a SGB V)
    - A new paragraph was added stating that insured and other interested individuals can propose the assessment of medical treatments (excluding drugs) of selected diseases, if those treatments are provided under the statutory health insurance scheme.
  - High-risk-classative and investigational treatment methods (§137 SGB V)
    - A new section (§157 SGB V) for the assessment of new investigational and treatment methods (NfU) [Neue Untersuchungs- und Behandlungsverfahren] for high-risk-class medical products was introduced.

OBJECTIVE
• Compare IQWiG’s General Methods version 5.0 (July 10, 2017) with the previous version 4.2 (April 22, 2016).1

METHODS
• An overview of IQWiG’s General Methods 4.2 and 5.0 was created in Microsoft Word to identify changes and additions.

RESULTS
Revisions, Additions, and Updates Important for Early Benefit Assessment and Economic Models
• Intense rework of chapter 8 on data information retrieval, specifying Benefit Assessment and Economic Models Revisions, Additions, and Updates Important for Early Benefit Assessment.
  - Involvement of affected persons in the preparation of the Institute’s systematic reviews and HTA report is the established international standard within the benefit assessment and is now formalized in the Institute’s new methods.
  - Involvement should occur at the beginning of report preparation, when defining patient-relevant endpoints and subgroups, or during a hearing (see Table 2).
  - Affected persons are defined as patients or potential participants in prevention measures, rather than representatives of support groups.
• IQWiG’s update on guideline synopsis: international guidelines (which are usually relevant when developed in one of the 35 Organisation for Economic Co-operation and Development (OECD) countries) should be reviewed, along with applicable national guidelines unless those recommendations are very specific. The Appraisal of Guidelines for Research and Evaluation II (AGREE II) instrument for assessment should be used.

Additional IQWiG Products
• Two new IQWiG products were introduced, and patient involvement in the preparation of those products was specified (Table 2, in bold).

CONCLUSIONS
• IQWiG’s General Methods 5.0 includes new paragraphs that align procedures and methodology with changes in German law.
• Expanded details are provided for the conduct of systematic literature reviews, especially with regard to information retrieval and meta-analyses, which are important parts of early benefit and HTA assessment. These updates and revisions provide greater clarity for the preparation of AMNOG (Arzneimittelmarktneuordnungsgebet) dossiers.

REFERENCES

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