EU HTA Impact on Innovations: Expectations and Challenges of EU HTA for Germany - HTA perspective -

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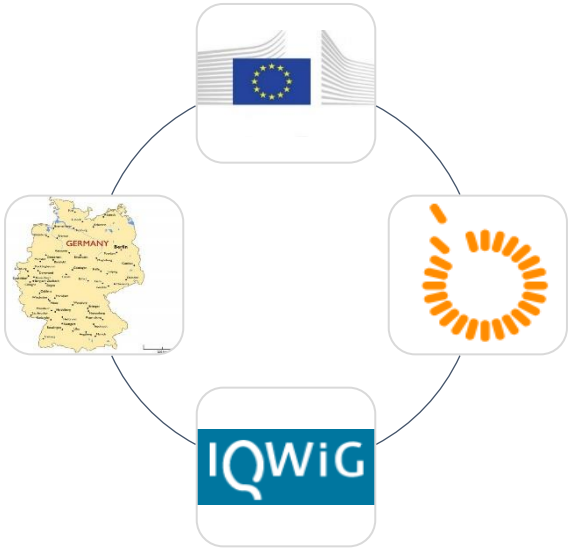
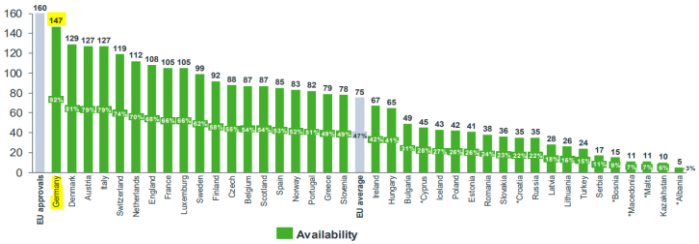
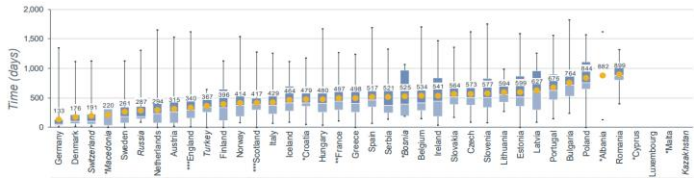


Germany is in a predestined position

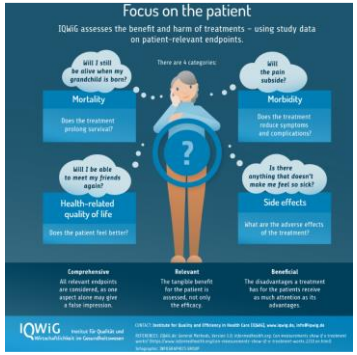


Almost all new drugs are available

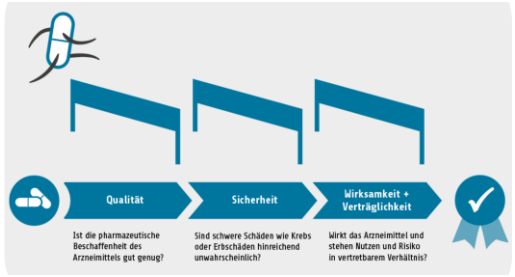


Almost all new drugs are early available

Almost all new drugs are reimbursed



Patient relevance is a high priority, enshrined in law



No fourth hurdle

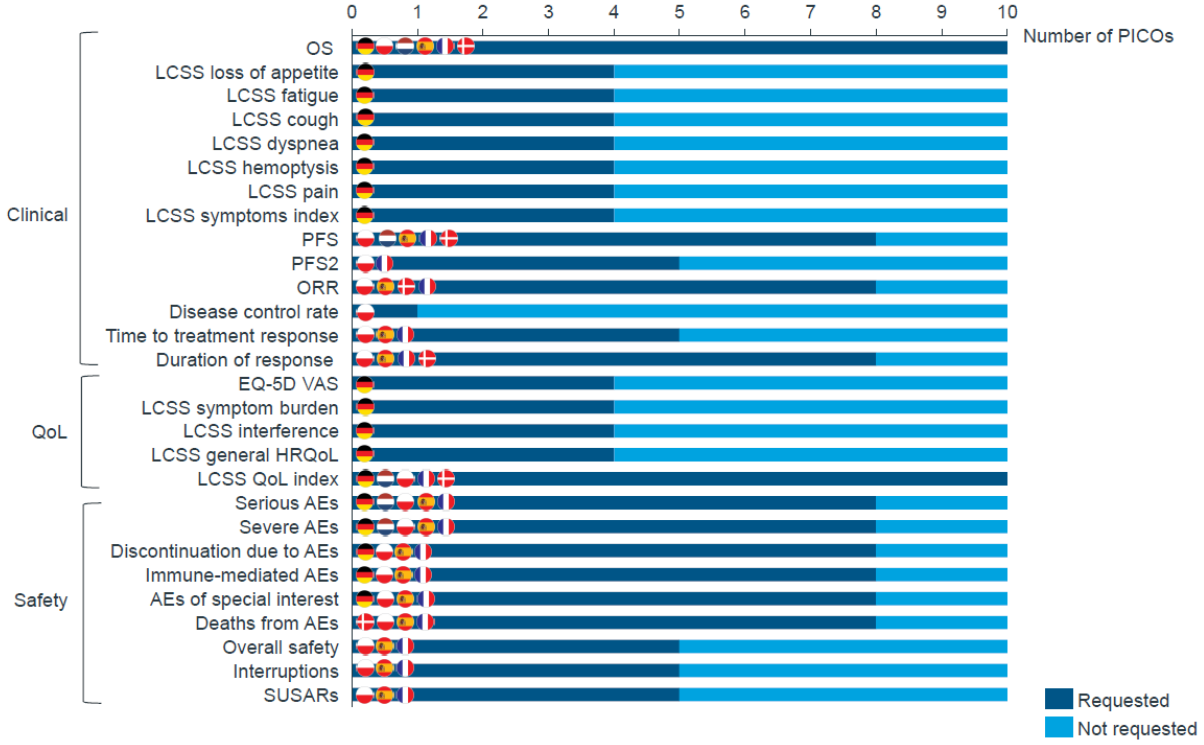
IQWiG, Wikimedia Commons, EFPIA Patients W.A.I.T. Indicator 2021 Survey. 2022.

The EU HTA procedure has strong parallels with the AMNOG procedure

- The EU HTA methods were developed in close collaboration between IQWiG and the G-BA.
- The Methods and Procedures subgroup is chaired by the Head of the Pharmaceuticals Department at IQWiG.
- An employee of the G-BA is the vice-chair of the JSC.
- IQWiG and the G-BA are also represented in all committees.

EU HTA must serve the needs of Member States

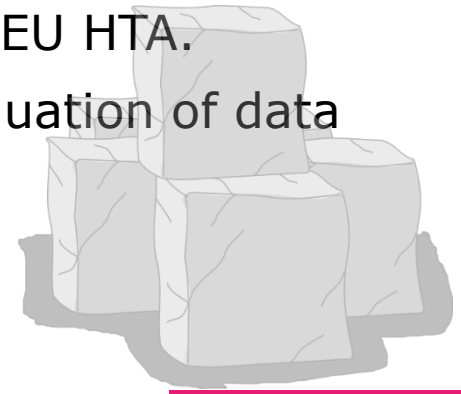
- Germany - like other member states - contributes its requirements by submitting its PICO.
- The PICO is to be served by the EU HTA.



Van Engen et al. HTA97. ISPOR 2022.

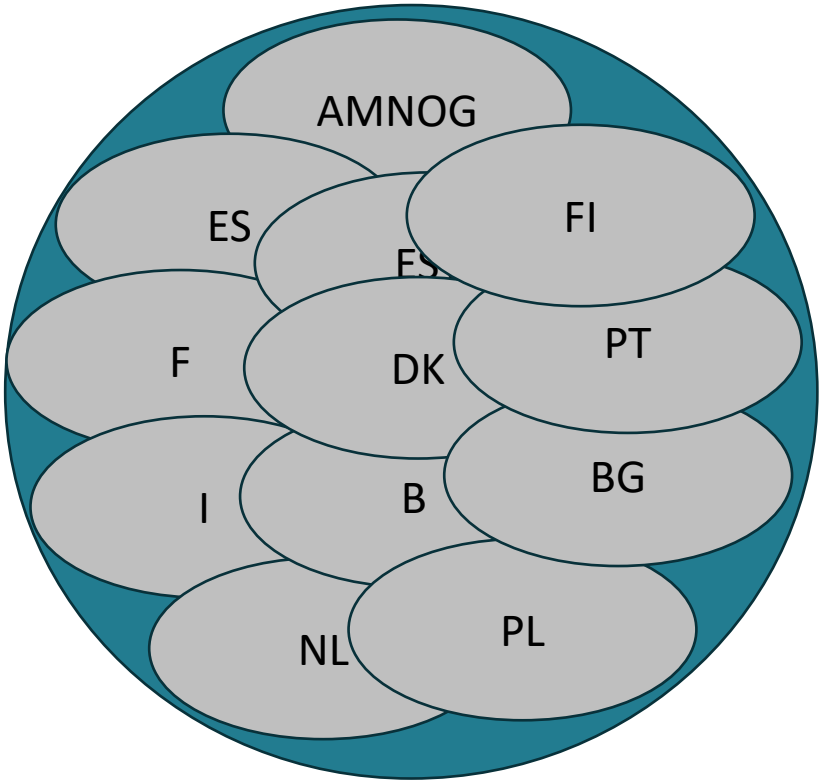
However, Germany does not have to adopt the EU HTA analyses

- Nationally irrelevant endpoints such as QALYs do not need to be adopted.
- Irrelevant comparators, such as therapy standards that are no longer used in Germany, need not be included.
- Indirect comparisons need not be included.
- Surrogate parameters need not be included.
- Each country selects from the data package the analyses it needs for its national assessment procedure.
- The weighting and assessment of endpoints is done nationally.
- Only pure statistical measures are provided in the EU HTA.
- The EU HTA is a comprehensive collection and evaluation of data that Germany can use for the AMNOG procedure.

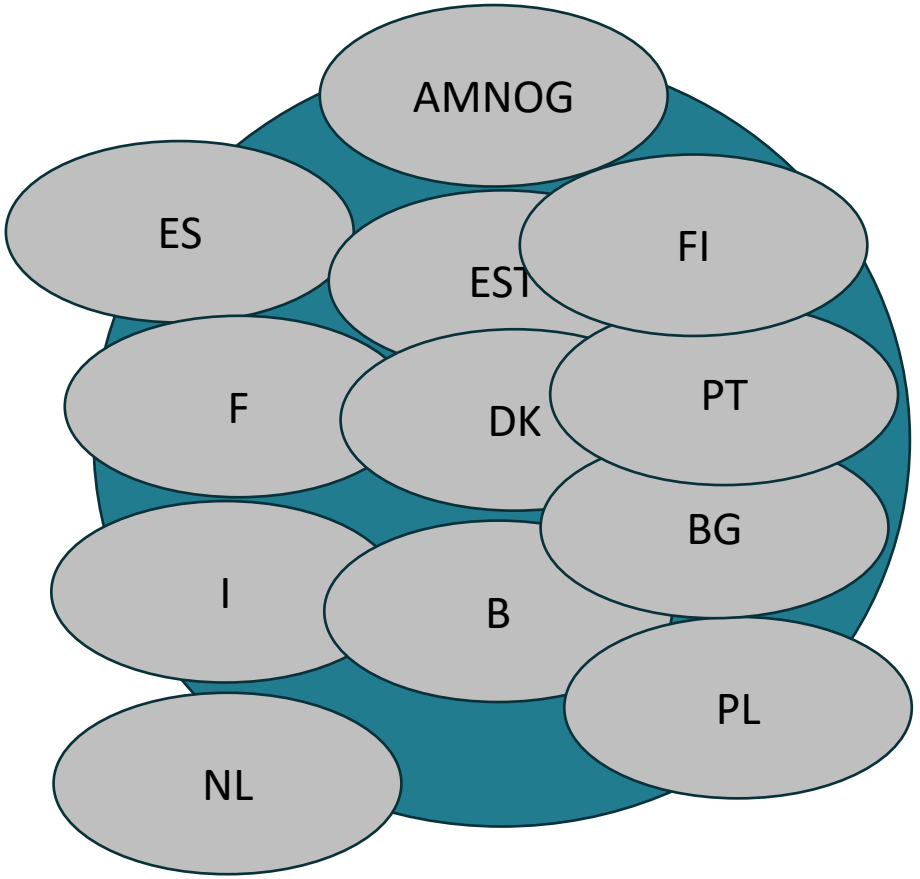


EU HTA will not cover all national needs

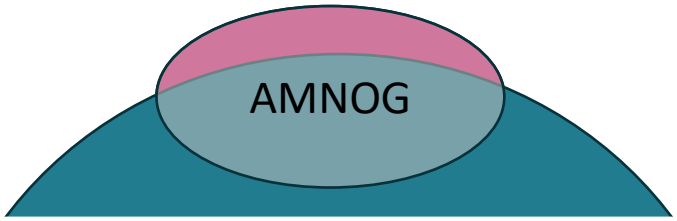
Expectation



Reality (?)



A "delta" dossier will have to be submitted

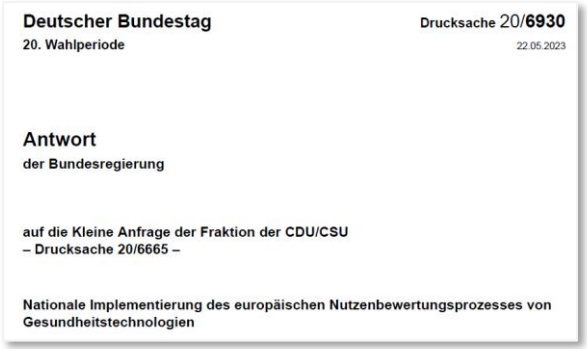


„Delta" dossier
(examples for contents)

- Module 3
  - patient numbers in Germany
  - cost per year of intervention and comparator
  - quality-assured application
- Module 4
  - QoL domains
  - responder analyses of continous outcome data (15% threshold)
  - adverse events (SMQ, PT, AESI)
  - subgroups
  - **new datacuts**

The German government is sticking with the proven AMNOG process

- "The results of the European assessments are duly taken into account in the national procedure.
- Information, data, analyses or other evidence submitted by pharmaceutical companies at EU level will not be requested at national level.
- The Government is committed to maintaining all relevant AMNOG procedures.



Deutscher Bundestag — Drucksache 20/6930
20. Wahlperiode — 22.05.2023

Antwort
der Bundesregierung

auf die Kleine Anfrage der Fraktion der CDU/CSU
– Drucksache 20/6665 –

Nationale Implementierung des europäischen Nutzenbewertungsprozesses von Gesundheitstechnologien

- The national AMNOG process will continue to enable national decision-making taking into account the national context.
- The national AMNOG process [...] has proved its worth and should be retained as far as possible.
- The Regulation stipulates that the joint clinical evaluations are not legally binding on the Member States.
- It is stipulated that Member States should take the joint clinical evaluations into account in their national evaluations.
- The Regulation does not prohibit additional national assessments."

EU HTA does not reduce work burden

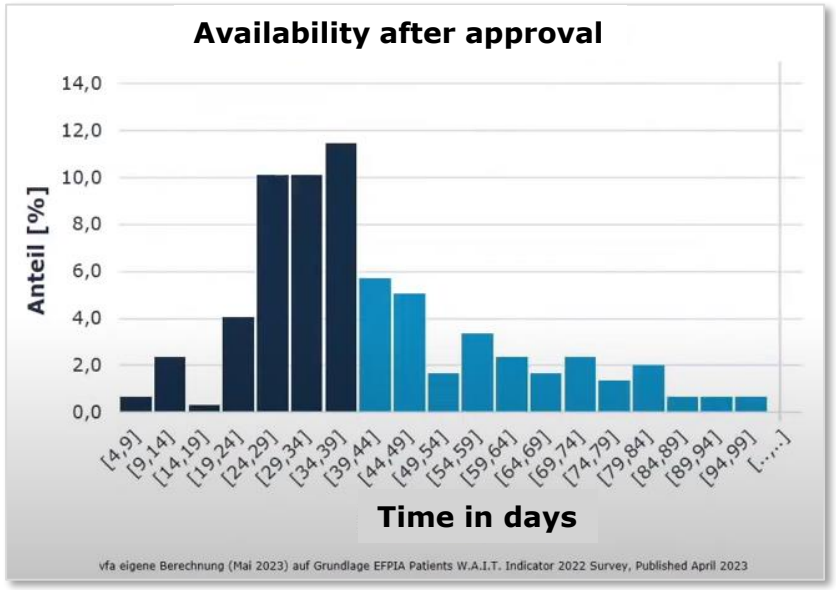
- G-BA and IQWiG have to submit a PICO scheme in a very short time and with the involvement of the relevant committees.
- IQWiG has to screen the EU HTA, which is likely to be many 100 pages long, for relevant data and extract and evaluate them for its assessment.
- Additional clinical data may need to be requested from the pharmaceutical company, evaluated, and placed in context with the EU HTA analyses.

The evaluation result remains unchanged

- There is no requirement to reach consensus with other countries in the national assessment.
- There is no requirement to positively assess endpoints or indirect comparisons that were previously viewed critically.
- However, there is a requirement to ensure consistency of assessments, the framework for which is defined by
  - German law,
  - German regulation,
  - IQWiG's procedural rules, and the
  - IQWiG Methods Paper.

The procedure may delay the availability of drugs

- The report must be approved by consensus of the Coordinating Group no later than 30 days after approval.
- The Commission will conduct a procedural review within 10 working days.
- The national benefit assessment cannot start until the report is available, especially since only 90 days are available for it anyway.
- However, 40% of new drugs in Germany are launched within the first 40 days after approval.



Conclusion

Relevance	Burden	Chances

• current situation:
  • all new drugs are reimbursed
  • very early access
  • fast, exhaustive and transparent assessment procedure established
  • high acceptance by all stakeholders
	• additional work:
	  • screening and assessment of EU HTA for relevant data
	  • request additional data
	  • short-term submission of a PICO scheme (even if consultation with the manufacturer has not yet taken place)
		• help other countries get better access
		• supporting the integration of Europe

So it will not be relevant for stakeholders in Germany. Or will it?

Not from the AMNOG point of view

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