MANDATORY JOINT CLINICAL ASSESSMENT – WHAT IS THE ADDITIONAL INSIGHT FROM EUNETHTA VS. EMA?

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BACKGROUND

With the draft EU regulation from early 2018 for a European Health Technology Assessment (EUHTA), the voluntary HTA co-operation existing since 2006 within the framework of the European Network for Health Technology (EUnetHTA) shall become mandatory within the scope of a joint clinical assessment. The EUHTA will largely rest on the evidence that is already assessed by CHMP within EMA when marketing approval authorization is requested.

OBJECTIVES

This poster provides an answer as to what is the additional informational insight provided by EUnetHTA compared to EMAs European Public Assessment report (EPAR) – regarding:

- Evidence
- Outcomes
- Overall conclusion

METHODS

This analysis compares the key findings from EMA using the EPAR and from EUnetHTA using the respective assessment report. Basis for this analysis are the four most recent EUnetHTA assessments of medicinal products. The reports from both institutions are compared applying the following categories:

• Evidence EUnetHTA vs. EPAR:	⇔ identical	↓ less	↑ more
• Outcomes EUnetHTA vs. EPAR:	⇔ identical	↓ less	↑ more
• Overall conclusion EUnetHTA vs. EPAR:	⇔ identical	⊖ worse	⊕ better

Given the fact that the EUnetHTA assessments resulted from a handful of pilot projects, the present analysis is only explorative and descriptive but nevertheless important in the current political discussion.

RESULTS

Procedure	EUnetHTA assessment compared to EMA regarding…		
	Evidence	Outcomes	Overall conclusion
Alectinib (Alecensa®) *Lung carcinoma (1st line)* EUnetHTA: Feb 2018 EMA EPAR: Oct 2017	↓ Supportive study (lower dosage) not included ↑ Additional network meta-analysis vs. ceritinib	↓ Progression and response are not included	⊖ Supportive study not considered as confirmation of pivotal study, indirect evidence has serious limitations
Midostaurin (Rydapt®) *Acute myeloid leukaemia* EUnetHTA: Nov 2017 EMA EPAR: Jul 2017	↓ Later data cut-off (15 months additional follow-up) not included ↓ Indirect comparison for older patients with historic control not included ↑ Indirect comparison vs. high-dose daunorubicin	⇔ Identical	⊖ No evidence for > 60 years because indirect comparison has serious limitations
Regorefenib (Stivarga®) *Hepatocellular carcinoma* EUnetHTA: Oct 2017 EMA EPAR: Jul 2017	↓ Later data cut-off (11 months additional follow-up) not included	↓ Progression, response and biomarker are not included	⇔ Identical
Ramucirumab (Cyramza®) *Gastric cancer* EUnetHTA: Mar 2015 EMA EPAR: Sep 2014	↑ 3 additional indirect comparisons	↓ Response is not included	⇔ Identical regarding direct evidence, indirect evidence is not robust to draw conclusions

- **Similar evidence**
  - Direct evidence is identical, but EUnetHTA does not include supportive studies and later data cut-offs
  - Additional indirect evidence in some assessments, but notion that serious limitations apply
- **Limited set of outcomes**
  - Progression and response outcomes are not included
- **Overall conclusions identical,…**
  - … except when supportive studies have not been accepted

CONCLUSIONS

- EUnetHTA does not present new (direct) evidence but rather less evidence – even though EUnetHTA is published after EPAR.
- Indirect evidence is presented as new but it is rated as not relevant due to serious limitations (according to EUnetHTA).
- Overall conclusions differ only where supportive evidence is not included by EUnetHTA. Hence, additional informational value of EUnetHTA remains unclear.
- No need for separate EUHTA assessment next to a more detailed assessment already prepared by EMA, as long as it is only limited to a reproduction of already known information and to the generation of additional (indirect) evidence which has serious limitations.

REFERENCES

- European Public Assessment Reports (EPARs): http://www.ema.europa.eu/ema/
- EUnetHTA Joint Assessments: https://www.eunethta.eu/assessments/

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