National Health Care Institute

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Open letter to Editors

Date: 16 December 2020

Dear Editors,

The European Network of Health Technology Assessment (EUnetHTA) is a consortium of over 80 European public health institutions committed to collaborate in the field of HTA. In my capacity of the Chair of the Executive Board, I am writing to you to highlight a problem the network regularly experiences.

One of our key activities is the production of joint HTA reports on pharmaceuticals, medical devices and diagnostics. For each product, a limited group of EU HTA bodies conducts the assessment using common criteria and methodologies. Once published, the joint HTA reports can be used by the other European institutions in order to support and facilitate their own national decision making processes.

The process of production of a joint HTA report entails close collaboration between EUnetHTA and the developer/manufacturer of the product under assessment, who submit a dossier with key information needed by the HTA assessors, in particular systematic reviews of scientific literature and Network Meta-Analyses to allow indirect comparisons between the product and existing alternatives.

However, at times the implementation of our joint work can be jeopardised. **Developers often wish to publish their own analyses/studies on peer reviewed journals, requesting EUnetHTA to either apply an embargo for their publication in our reports or not to publish them at all. At times the main reason for their concern is that peer reviewed journals would deem disclosure of their analyses in our reports as conflicting with submission policies, hence rejecting publication.** On the other hand, leaving out such analyses, which are a fundamental part of EUnetHTA's HTA reports, would seriously impact the perceived quality of our work and the use that several European national HTA bodies make of our reports.

A waiver to publication restrictions on scientific journals may indeed be applied in such cases. This would also be aligned with current practice with European Public Assessment Reports (EPARs) issued by the European Medicines Agency, where data on clinical studies are often included prior to their publication

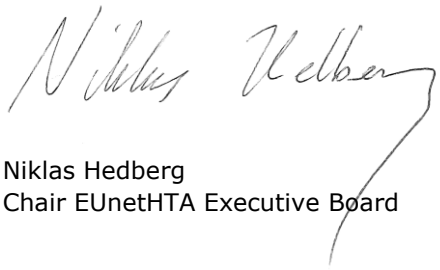
on scientific journals. To us it would be reasonable to see that early publication of the results of clinical studies in EUnetHTA reports should be judged the same way. We have noted that issues related to this have been highlighted in a recommendation from the International Committee of Medical Journal Editors. However, the possible exceptions mentioned in the recommendation *"… major therapeutic advances; reportable diseases; or public health hazards, such as serious adverse effects of drugs, …"* is not fully applicable to HTA work http://www.icmje.org/icmje-recommendations.pdf.

Again, we would like to stress the importance of this matter and underline to you that at times your standards may influence the transparency and quality of our work, which serves public health interest especially in facilitating earlier patient access to new therapies across the EU.

EUnetHTA would be willing to contribute in any context where possible criteria or extended recommendations of this issue can be further discussed or even resolved.

We remain at your disposal for any questions or clarifications you may need.

Yours Sincerely,
Niklas Hedberg
Chair of the EUnetHTA Executive Board



Niklas Hedberg
Chair EUnetHTA Executive Board

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December 16, 2020