

EU HTA and Stakeholder Management - Be aware of pitfalls

Implication of the definition of conflicts of interests as defined in the Implementing Acts



Background

Involvement of experts in EU HTA is great. Not so great is the far reaching definition of conflicts of interests as defined in the Implementing Acts. As this Implementing Act is hard to read, we prepared this overview. It does not cover every detail - so consult the Implementing Acts before making final choices.

Note that conflicts of interests lead to an exclusion from the respective EU HTA procedure (JSC or JCA). Review of conflicts of interests usually take the last 3 years into account (calculating backwards from initiation of the procedure). So be mindful when engaging with patient representatives and clinical experts.

4 Excluded for specific health technology (for any HTD) as expert:

- Former role in a HTD with product responsibility with this technology or in a consultancy or consulting (or being a strategic advisor) on this technology (all within the last 3 yrs)
- (Principal) investigator in a clinical trial for this technology (current or within the last 3 yrs)
- Immediate family members currently with shares or ownership to this technology or intellectual property rights to this technology

1 Generally excluded as expert:

- Current role at a HTD (executive, horizontal or product responsibility)
- Current role as consultant or scientific advisor to HTD
- Currently holding shares of or (co-)owning any HTD or intellectual property rights related to any HTD



2 Excluded for a specific HTD as expert:

- Executive role at a HTD within the past 5 yrs or horizontal responsibility within the last 3 yrs
- Consultant or strategic advisor to HTD within the last 3 yrs
- Received payment from HTD (current or within the last 3 yrs)
- (Principal) investigator in a clinical trial for this technology (current or within the last 3 yrs)
- Lead members of organisation receiving funds from this HTD in current or previous financial year
- Immediate family members currently with shares or ownership in this HTD or intellectual property rights in this HTD

3 Excluded for a specific HTD for a specific therapeutic area as expert:

- Consultant or strategic advisor to HTD within the last 3 yrs for this therapeutic area
- Received payment from HTD (current or within the last 3 yrs) in relation to this therapeutic area

Contact

Dr. Thomas Ecker
Tel.: +49 40 4133081-10



t.ecker@ecker-ecker.de
t.ecker@accessus-health.eu

www.ecker-ecker.de
www.accessus-health.eu

References and disclaimer

No responsibility is taken for the completeness of the information. For all details see: Commission Implementing Regulation (EU) 2024/2745 of 25 October 2024 (Link: https://eur-lex.europa.eu/eli/reg_impl/2024/2745/oj)