



**NVTAG**

Nederlandse Vereniging voor Technology Assessment in de Gezondheidszorg

# The EU-HTA regulation and its impact on access to innovative technologies

12 October 2023





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**Anke van Engen**  
**IQVIA**



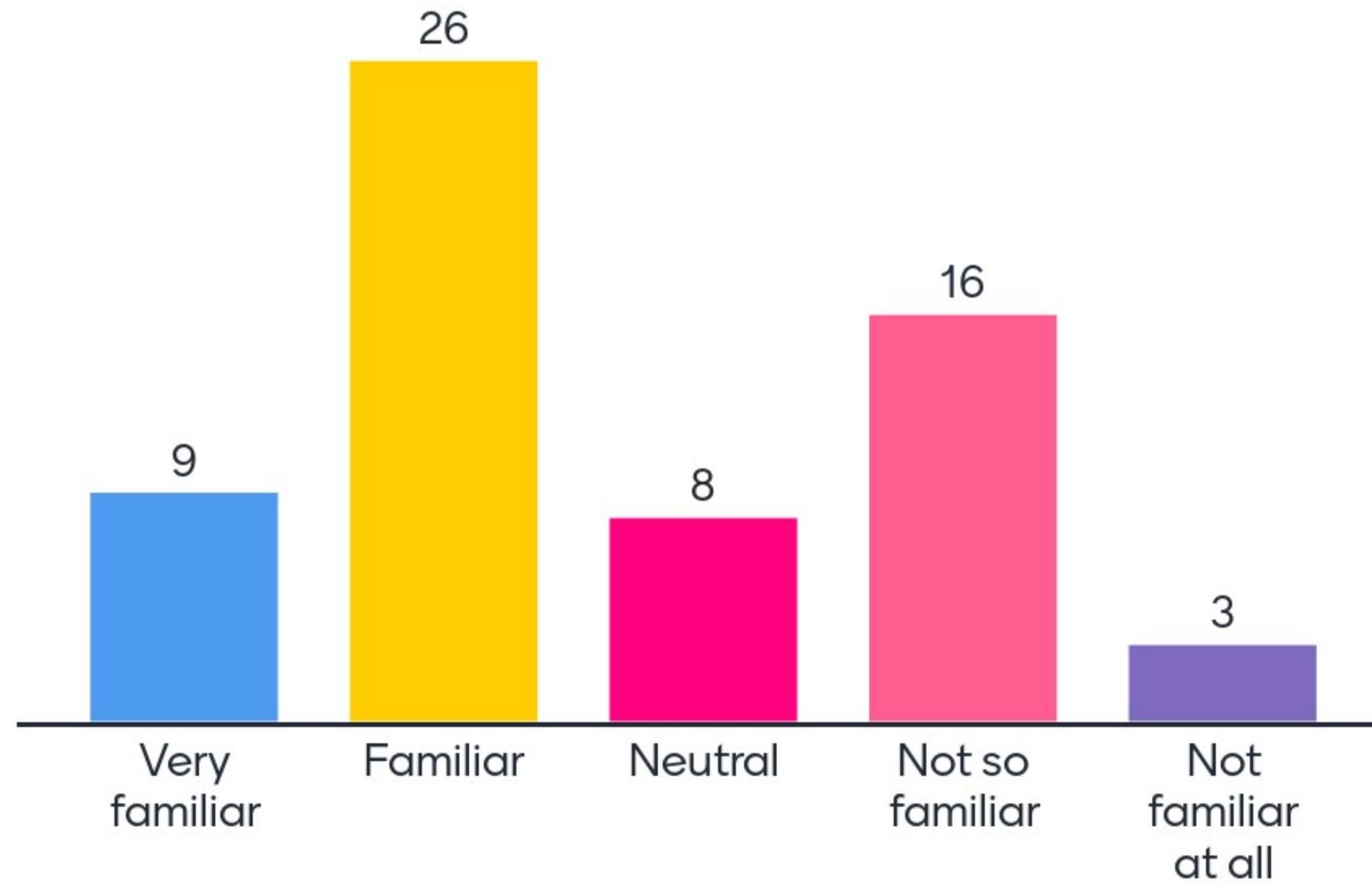
# EU HTA Regulation – What, Why, When?

*October 12<sup>th</sup> 2023*

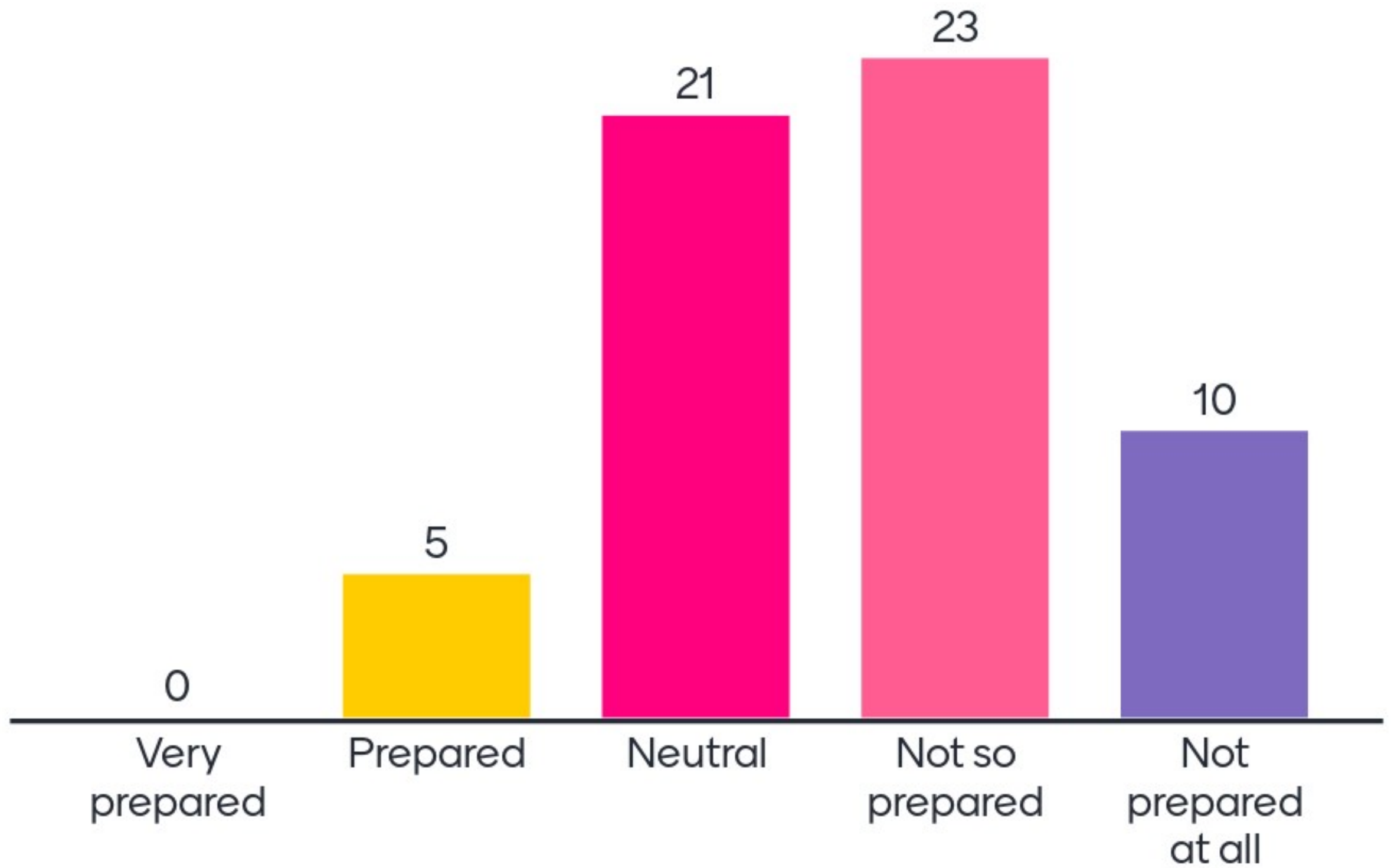
*Anke van Engen, Senior Principal, IQVIA*



# How familiar are you with the EU HTA regulation?



# How prepared are we in the Netherlands to successfully implement the EU HTA regulation?





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# **Suzette Matthijsse**

## **Lumanity**

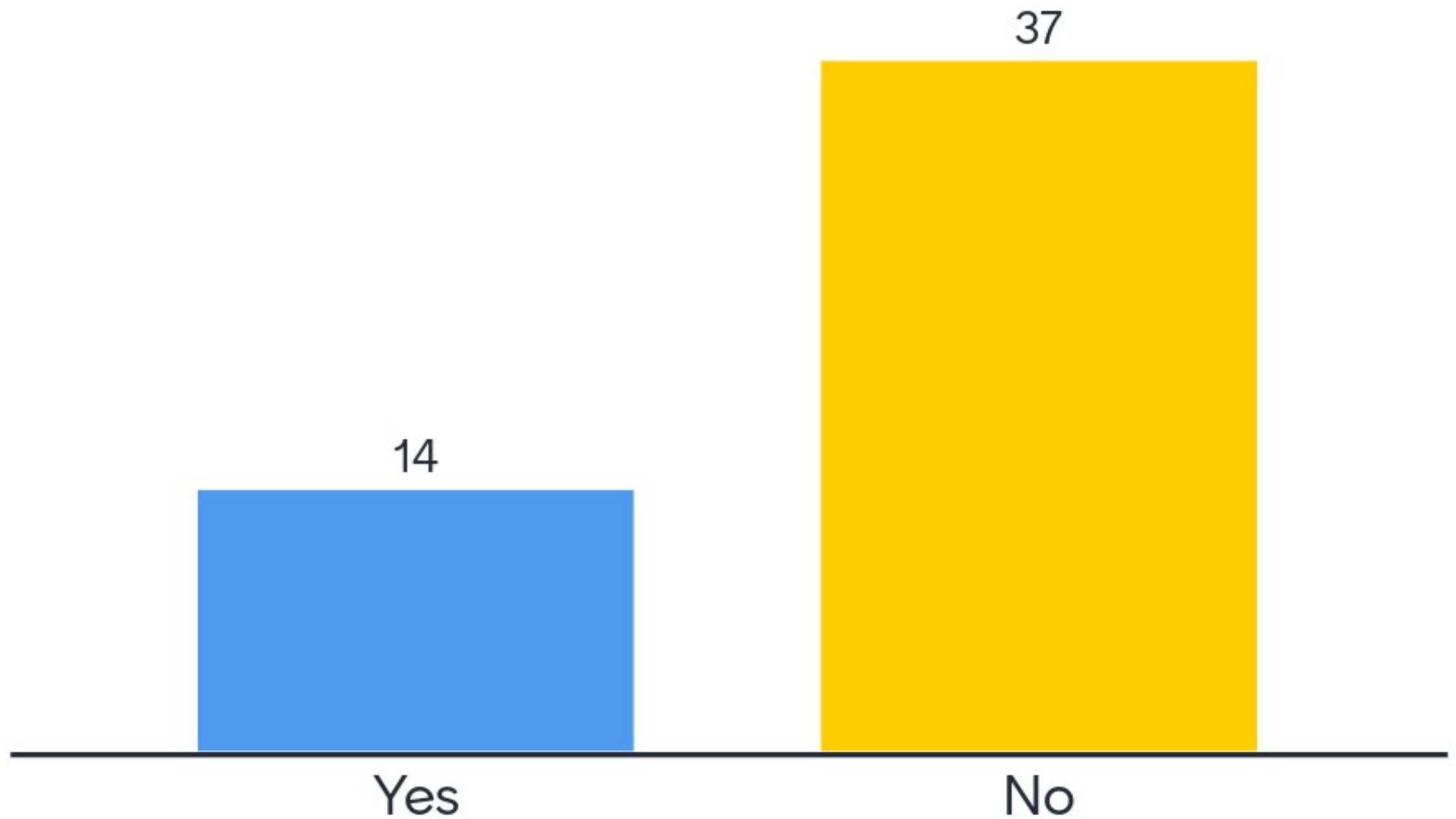
# Impact of the EU HTA Regulation

Global industry perspective

12 October 2023

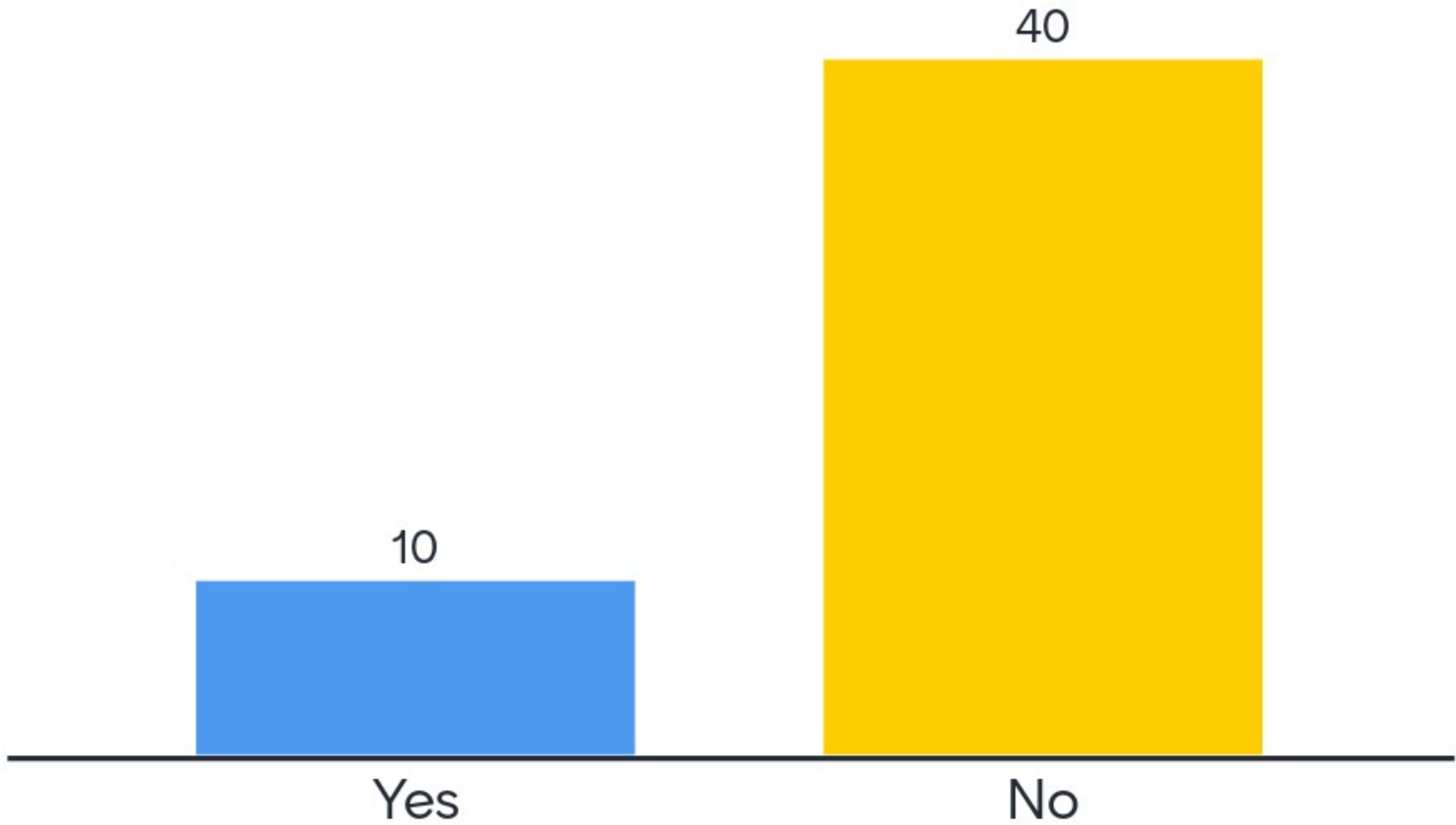
Presented by: Suzette Matthijsse

# Do you feel you are well informed and know enough about the new EU HTA Regulation?

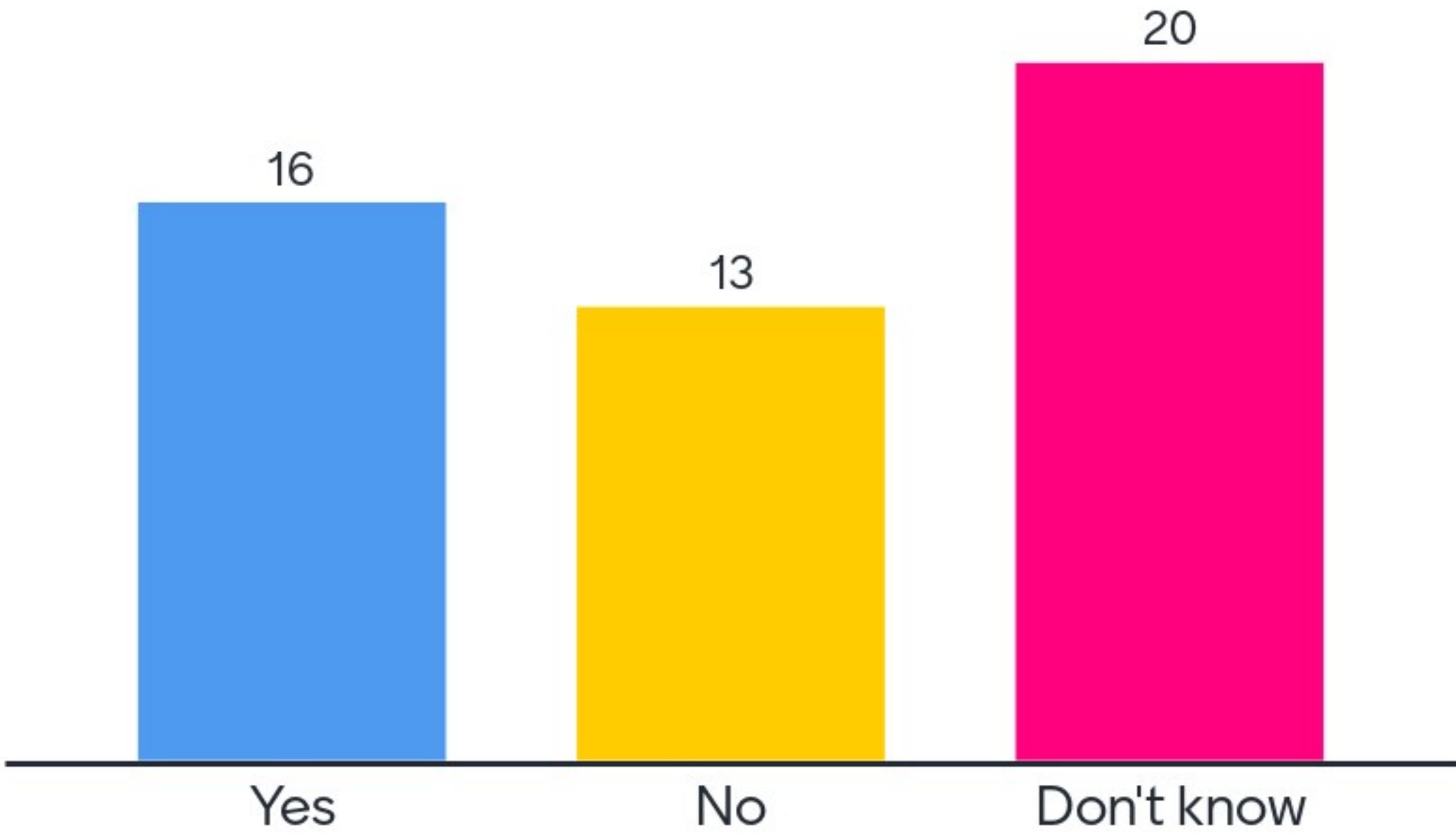




# Are you clear on how the EU HTA regulation will affect your organisation's EU HTA operations?



# Are you encountering any obstacles within your organisation to plan for the EU HTA Regulation's full implementation?





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**Anne Willemssen**  
**ZIN, EUnetHTA**



Zorginstituut Nederland

# Impact of EU-HTA Regulation

Decision-making perspective

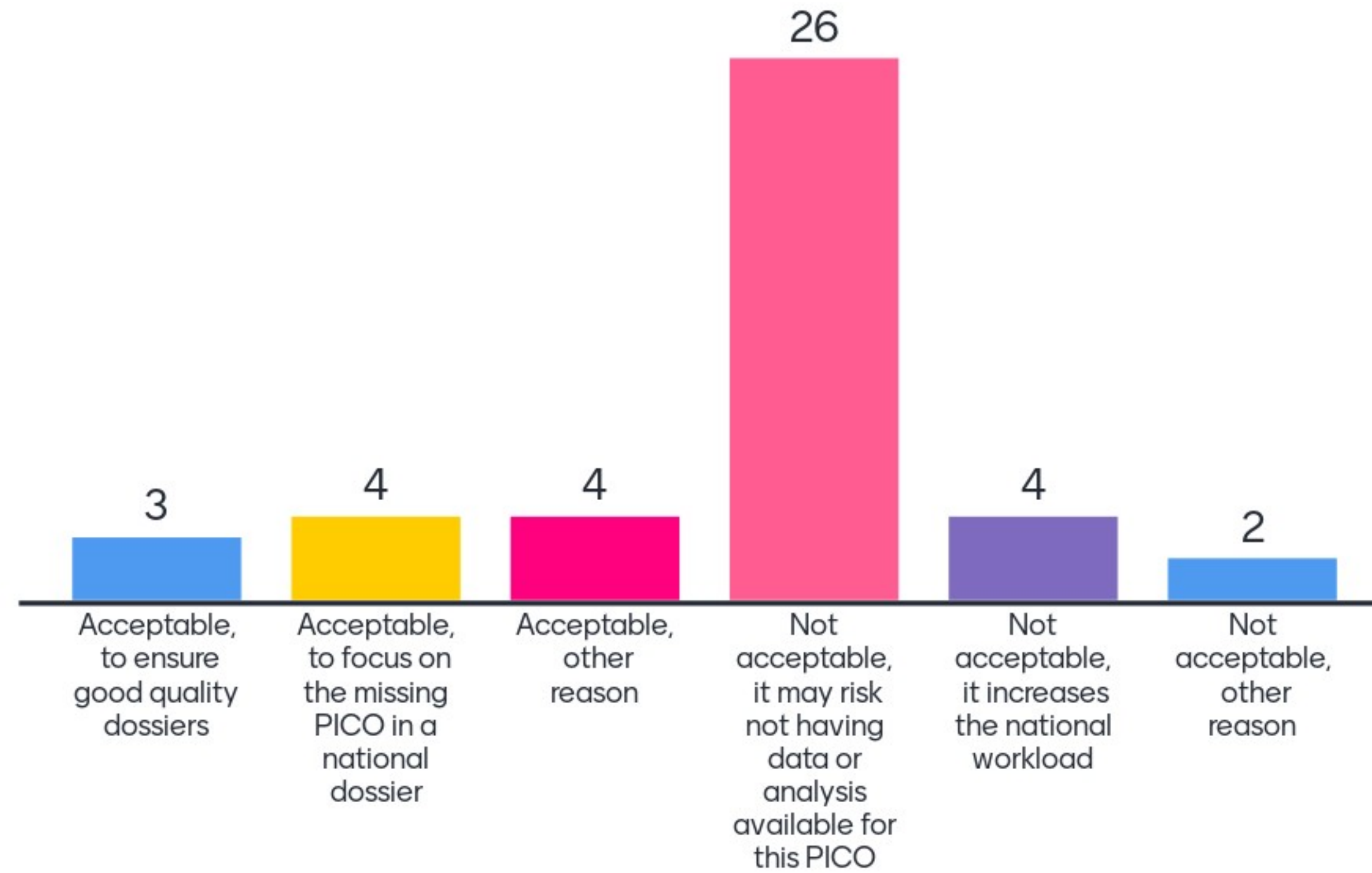
Anne Willemsen, Dutch National Healthcare Institute  
(Zorginstituut Nederland)

Co-Chair JCA Subgroup under the HTA Coordination  
Group

12 oktober 2023



# Omitting a national PICO in the consolidated PICOs for a EU JCA is ...





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**Rick Vreman**  
**Roche**

# Perspective on EU HTA implementation in NL

A discussion on challenges and opportunities

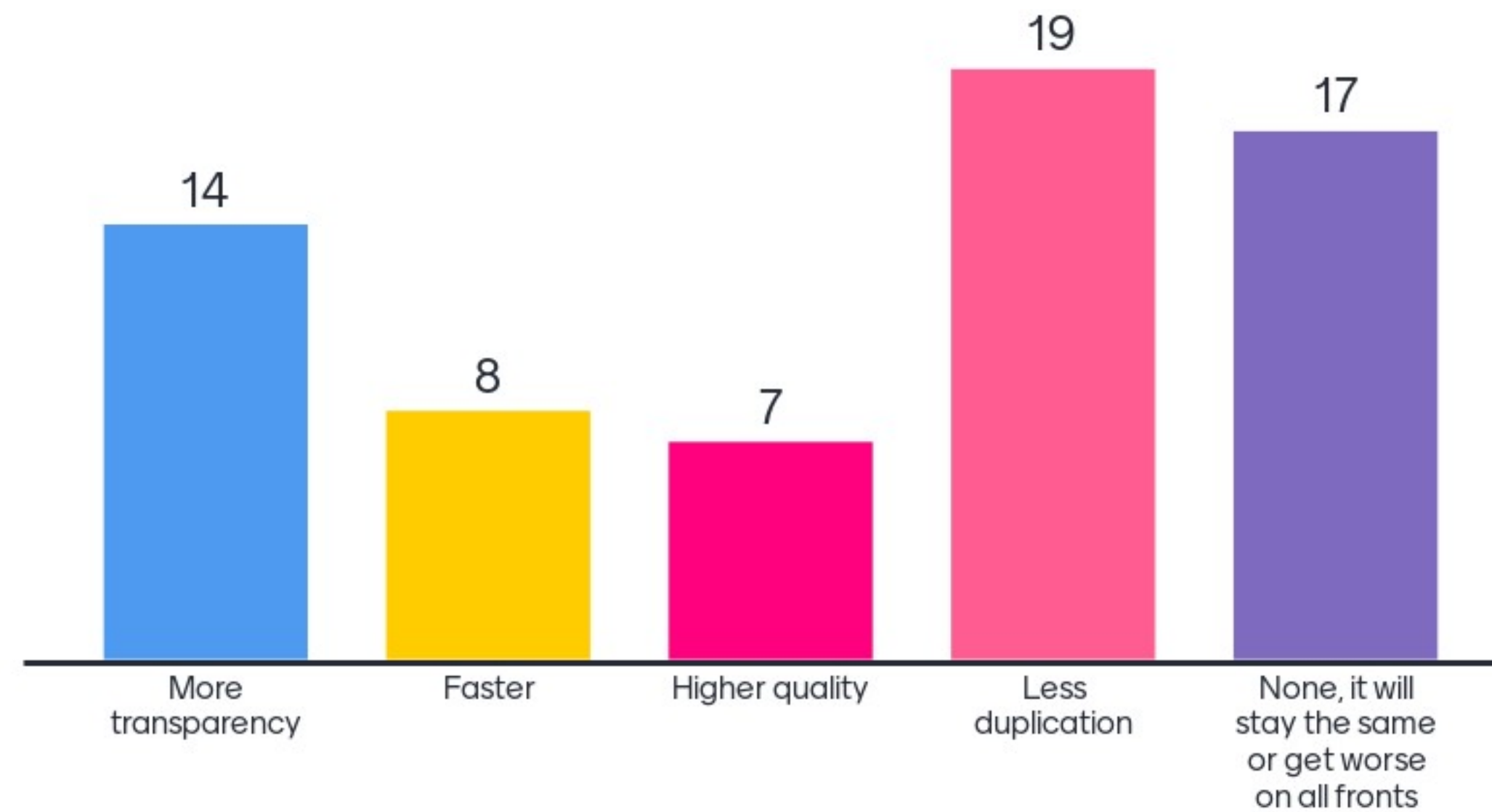
*NVTAG Symposium on EU HTA*

Rick Vreman, Patient access manager & policy lead

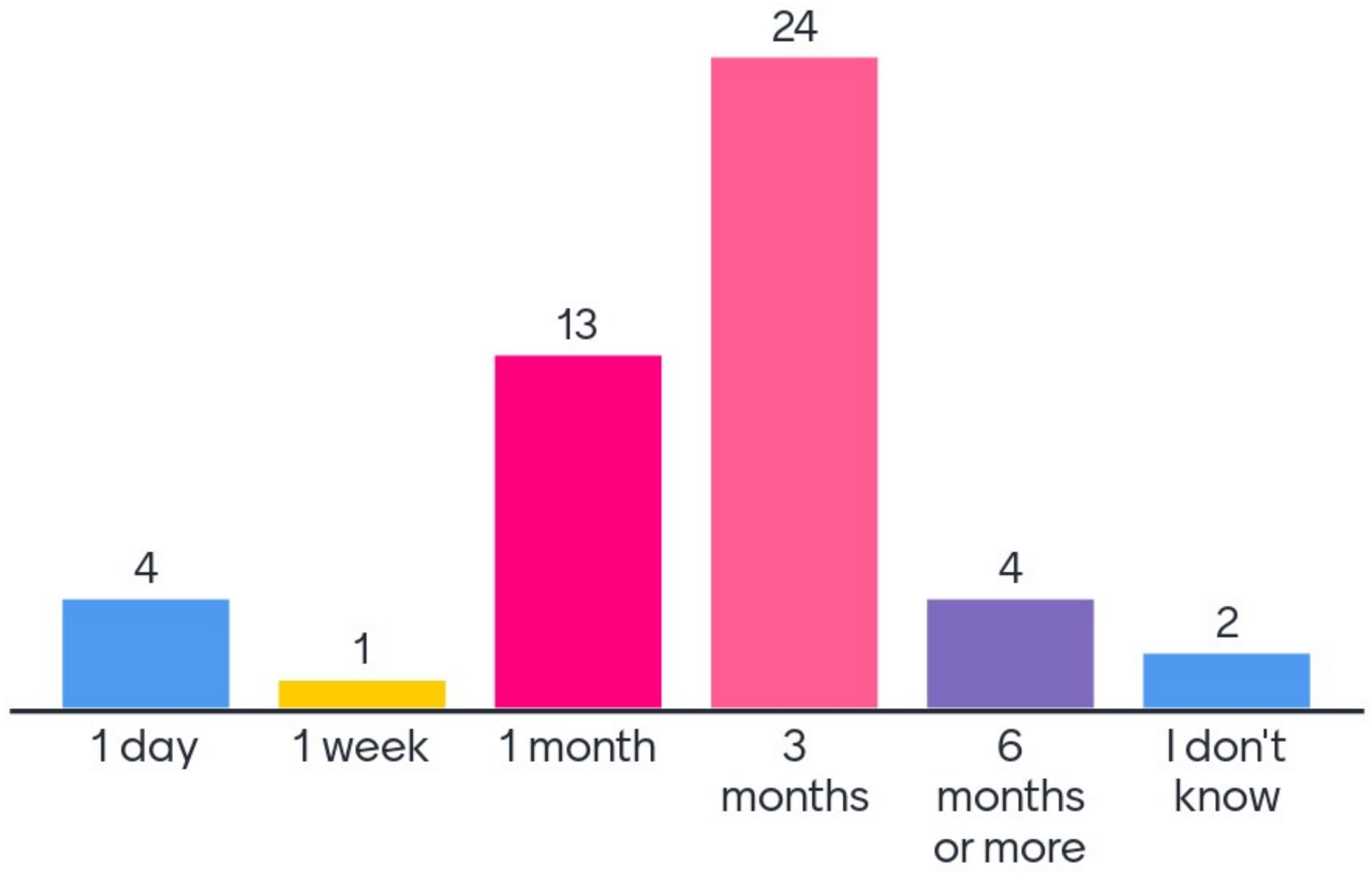
Roche Netherlands B.V.



# On which aspect do you think EU HTA can help us do better regarding reimbursement decision making in the Netherlands?



# How long do you believe a Dutch assessment should take after the JCA report is available?





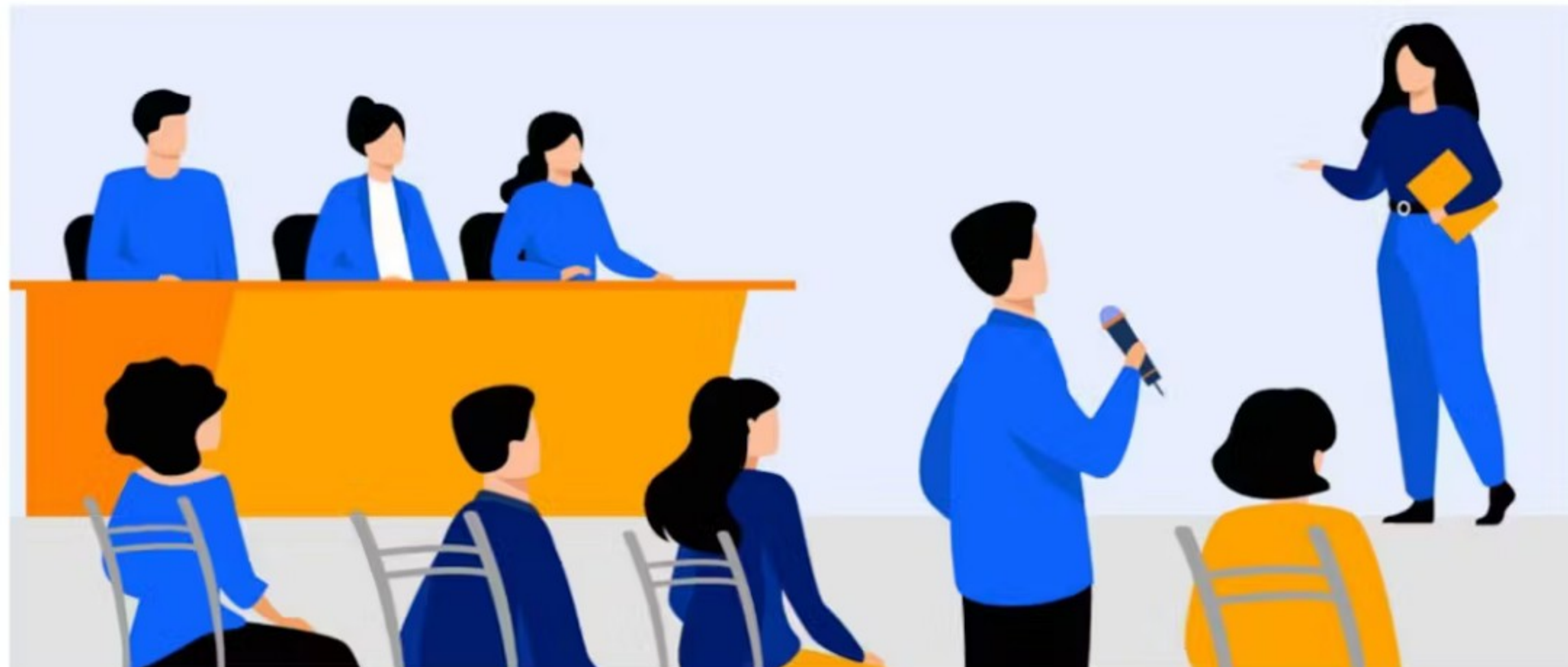
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# Panel Discussion

**Maurice Driessen, NVTAG board member**



# Do you have questions for the panel?

7 responses

What will be the biggest challenge for implementing the EU HTA regulation?

The statement was made we just have to start and try, but on the other hand the statement was made of dossier is deemed incomplete you get only one chance...is that realistic in the 1st period?

CEA and BIA are left at the responsibility of the local authorities but are not missing there an opportunity to harmonize across MS? Eg use of R

To what extend is there collaboration with the EMA?  
Especially given that the EMA has become more lenient for surrogate outcomes and single arm trials for ultra orphan drugs?

I have rarely seen all stakeholders (regulators, pharma, consultancy) in such positive harmony. What am I missing?

What is the most important question regarding methods that needs to be answered to increase the success of implementing the regulation?

Would it be possible to include (like the EMA process) one or two moments of questions and answers from assessors to pharmaceutical company?



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