EUnetHTA 21 – Stakeholder Meeting

Start: 8 September 2023
Friday 13:00-14:30 CET

1. **Welcome from the Chair of the Consortium Executive Board (CEB) and objective of the meeting**

Niklas Hedberg, TLV

Housekeeping of today's meeting

Juste Jurgutaviciute, ZIN

Information for attendees

Entering the meeting:

- Please ensure you have logged in with your **name, surname, organisation and country** *i.e. Juste Jurgutavičiūtė (ZIN, The Netherlands)*.
- Please note: you cannot switch on your camera or use your microphones.

Information for attendees

Questions:

- To ask questions, you may post them in the Q&A box.
- Responses to all questions will be coordinated by the Chair and will be taken at the **end of relevant presentations or during the Q&A item.**
- Please note: for internal purposes this meeting will be recorded.

Information for attendees

Technical issues:

- If you experience problems with Zoom during the meeting, please:

  1. Go to www.zoom.com and search for help.
  2. Contact eunethta@zinl.nl or call Juste Jurgutaviciute on **+31 6 43 47 04 69** for support (You may wish to take a picture of these contact details).

Today’s agenda

Niklas Hedberg, TLV

Agenda

ID		Description	Presenter/s
#1	13:00-13:10	Welcome from the Chair of the Consortium Executive Board (CEB) and objective of the meeting	Niklas Hedberg, TLV
#2	13:10-13:25	Update from the European Commission	Valentina Barbuto, DG SANTE
#3	13:25-14:05	Summing up the EUnetHTA 21 - Updates on Joint Scientific Consultations - Updates on Joint Clinical Assessments - Updates on Transversal activities - Results from Stakeholder evaluation	Antje Behring, G-BA Roisin Adams, NCPE Anne Willemsen, ZIN
#4	14:05-14:25	Q&A	Niklas Hedberg, TLV
#5	14:25-14:30	Closing remarks	Niklas Hedberg, TLV

2. **Update from the European Commission**

Valentina Barbuto, DG SANTE

Update on the implementation of the Regulation (EU) 2021/2282 on Health Technology Assessment

Valentina BARBUTO, Policy Officer

DG SANTE C2, Health Technology Assessment

Since the last EUnetHTA 21 Stakeholder meeting…

GOVERNANCE

- HTA Coordination Group (HTACG) 4th meeting -> 13 June 2023
- HTACG Subgroups: 2nd & 3rd meetings -> May-July 2023
- Stakeholder Network: 1st meeting -> 14 June 2023

IT PLATFORM

- 5th meeting of the IT users working group -> 25 May 2023
- 2nd & 3rd pilots of the IT Platform -> June 2023
- 6th meeting of the IT users working group -> 5 July 2023

Since the last EUnetHTA 21 Stakeholder meeting…

IMPLEMENTING ACTS

- 1st meeting of the HTA committee on the first implementing act on Joint Clinical Assessments (**JCAs**) **medicines** -> 15 September 2023.

PROJECTS

- Training of patients experts (**EU4Health**) – EUPATI & EUCAPA mid term -> September 2023
- HTA methodology research & training (**Horizon Europe**) awarded to SUSTAIN HTA - Utrecht University. Start -> September 2023
- 2nd HTA Infoday (**EU4Health**) -> Athens, 18 September 2023

European Commission

Next steps

- 2nd meeting of the Stakeholder Network -> 17 November 2023
- Engagement with local stakeholders through the HTA Information days (3rd Seville, 4th Utrecht, etc.)

European Commission

Thank you

Contact of HTA team:

SANTE-HTA@ec.europa.eu

European Commission

3. **Summing up the EUnetHTA 21**

Antje Behring, G-BA
Roisin Adams, NCPE
Anne Willemsen, ZIN

Updates on Joint Scientific Consultations

Antje Behring, G-BA

D6 deliverables

https://www.eunethta.eu/jointhtawork/

	Title	
D6.1	D6.1.1 Production of 7 Joint Scientific Consultation (JSC)	The objective of this deliverable is to: • carry out six to eight JSCs under EUnetHTA 21, of which there were ultimately seven. A report was carried out for all seven JSC: Final Written Recommendation (confidential)
D6.2	D6.2.1 Briefing Document Template D6.2.2 Short Study Information	The objective of this deliverable is to: • update the Briefing document template following the experience of the joint productions and the public consultation • update related template for short study synopsis • improve the presentation of structured information and thereby improving assessability for HTA • improve the comprehensibility for HTD on required data when submitting information that is essential for the JSC
D6.3	D6.3.1 JSC Report Template	The objective of this deliverable is to: • update the template of the final output document, the JSC Final Written Recommendation • optimise structured and comprehensive presentation of the HTAbs' common position and national specificities to be delivered to the HTD

D6 deliverables

https://www.eunethta.eu/jointhtawork/

	Title	
D6.4	D6.4.1 Procedural guidance for JSC	The objective of this deliverable is to: • update the practical guideline for the JSC procedure together with EMA • improve transparency by providing detailed information on procedural steps and timelines as well as on scope, actors and responsibilities • gives insight to expert involvement (patient (representatives) and clinicals), for details on expert involvement, please refer to D7.2/3
	D6.4.2 Checklist for quality assurance in accordance with the Quality Management System	The objective of this deliverable is to: • develop a checklist for quality assurance in accordance with the Quality Management System to be used by the CSCQ JSC for its final validation of the JSC reports: JSC Final Written Recommendation • standardise the final quality check in order to achieve a high level of consistency and the highest quality of output

EUnetHTA 21 JSC

Summary:

- 7 JSC were carried out and completed, thereby fulfilling the service contract
- All JSC deliverables have been delivered according to the service contact as endorsed today
- Parallel JSCs have been established and further optimised in preparation of the JSC under the HTA Regulation: SG JSC is in charge

- Interim advice “EMA/HTAb Scientific Advice” had been officially announced on 3 July 2023

Status:

- Numerous questions received about general timelines, HTAb participation, fees and also MD advice
- Earliest possible applications until 11 September 2023 (interim advice starting in September and 3 months before draft briefing document submission via IRIS according to the guidance document)

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High involvement of European partners

ASR and CoASR – colleagues from 6 different HTAbs:

- Germany, Hungary, Norway, Portugal, Spain, Sweden

Participants – all of the CSCQ JSC members actively participated over the 7 JSC and also the CSCQ JSC validated all final output documents (JSC Final Written Recommendations):

- Belgium, France, Germany, Hungary, Ireland, Italy, Netherlands, Norway, Portugal, Spain, Sweden

HTAb participation in Hands-On-Groups (HOG) per JSC: 6 to 10 participating HTAbs formed the HOG

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EUnetHTA 21 JSC characteristics

- All of the products were First in Class
- 3 out of 7 products were orphan medicinal products
- 4 out of 7 products were oncology or oncology-related products
- 2 out of 7 products were ATMPs
- 2 of the 7 Applicants were SMEs
- In 6 out of 7 JSCs patient (representatives) and in 4 out of 7 JSCs clinical experts have been involved at European level

Publication on EUnetHTA 21 JSC analysis together with EMA planned for end of 2023

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EUnetHTA 21 JSC Final Report Recommendations

Topic	Recommendation
JSC procedure	• Shorter intervals between Open Calls for applications / increased number of calls for applications and increased flexibility between the acceptance and the start of the consultation are preferable by HTDs to improve plannability.
	• Further explanations of the prioritisation criteria and further communication of the selection process is needed to encourage applications, e.g. the Applicant's needs to present their argumentation on the HTAR selection criteria at the timepoint of application which is especially crucial to be aware of for the criteria "First in class".
	• Specific rules and/or requirements are needed for the assignment of ASR and CoASR. Capacity building activities and training is crucial to ensure resources are available on the HTA side as required under the HTAR.
	• Kick-off meeting and training before the start of the joint production under the HTAR is highly recommended, also at the start of every JSC.
	• A process for joint scientific advice on Medical Devices (MDs) needs to be developed. Hence, exchange and cooperation with the MD Coordination Group and the expert panels (EMA Secretariat of expert panels) needs to be implemented.
Expert involvement	• Guidance on expert involvement is needed with a clear approach and contact points for identification and recruitment taking into account MS demands on COI. A common database development with EMA would be beneficial in this regard.
	• Further work should be done on how to effectively share contact information on experts between HTA and EMA. Although the aim should be to involve experts from both sides independently, a GDPR-compliant standard procedure for contact and information exchange is key.

Updates on Joint Clinical Assessments

Roisin Adams, NCPE

D4 – methodological and practical guidelines

Roisin Adams

D4 deliverables

https://www.eunethta.eu/jointhtawork/

	Title	
D4.2	Practical Guideline – Scoping Process	• Define the concept of PICO, the process on how to derive MS requirements and how to consolidate this. • Based on MD JCA and mock PICOs on medicinal products, the process is refined • a suggestion is made for a dedicated working group
D4.3.1	Practical Guideline Direct & Indirect Comparisons	Produced a practical guideline on how to deal in practice with indirect comparisons in reports (and which data/documents should then be requested from the HTD). Based on the updated methodological guideline (D4.3.1) • Will describe possible approaches and specific instructions for assessing the results of direct and indirect comparisons • Will include check lists for different data situations
D4.3.2	Methodological Guideline Direct & Indirect Comparisons	• Addition of new approaches for random-effects meta-analyses • Discussion of the problematic situation of a meta-analysis with very few studies • Addition of new approaches for network meta-analysis • Addition of population-adjusted methods for indirect comparisons • Comparisons of non-randomised evidence
D4.4	Practical Guideline on Endpoints	• Common definition of meaningful clinical endpoints when drafting the PICO; • Definition of requirements for safety endpoints; • Identification of determinant endpoints for some therapeutic areas or clinical contexts, if applicable; • Guidance how to consider and assess surrogate/intermediate endpoints; • Patient-reported Outcome Measures, validity of scales and information needed for interpretation of the results in term of clinical relevance, and place of external recommendations and guidelines for the choice of endpoints.

D4 deliverables

https://www.eunethta.eu/jointhtawork/

	Title	
D4.5	Practical Guideline Applicability of Evidence	• How to consider complementary analysis (e.g. subgroup analysis, post hoc analysis, sensitivity analysis); • How to handle multiplicity issues resulting from multiple testing, e.g. due to multiple subgroup analyses, comparisons across multiple treatment arms and analyses of multiple outcomes?
D4.6	Practical Guideline Validity of Clinical Studies	• how to consider, classify and label various types of evidence in the assessment reports, including real world data and data from basket trials. • general principles which determine the certainty of results (e.g. internal validity, external validity, and statistical precision).
D4.7.1, 4.7.2	Framework for JCA of high risk MD	Guidance for JCA of individual high-risk MD and IVD after CE marking : • general principles • details on processes • work step tasks & responsibilities, • timing & points of interaction with stakeholders, • and information requirements from HTD + take national constraints into account
D4.7.3, 4.7.4	EUDAMED data reporting template/Guidance for EUDAMED-based TISP process	Define a EUDAMED-based process for TISP: define the process steps and its participants, frequency and time needed, pilot and evaluate the process

D5 – Joint Clinical Assessment

Roisin Adams

D5 deliverables

https://www.eunethta.eu/jointhtawork/

	Title	
D5.1	Submission Dossier Template* & Guidance **will be published in the coming weeks*	Guidance on the template & an actual template are produced • For MP JCA • For MD JCA, a set of recommendations is developed
D5.2	JCA report template & Guidance	Guidance on the JCA report template, the actual template & summary report template developed
D5.3.1	Selection criteria (co-)assessor JCA	A list of selection criteria for the appointment of JCA selection criteria, to ensure appropriate expertise is available
D5.3.2	HTA body technical expert working groups	A suggestions is made for HTAb expert working groups on information retrieval and statistical expertise, to support JCA assessors when needed.
D5.4	Production 2 MD JCA	JCAMD001: The Optilume® Urethral DCB Catheter for men ≥18 years of age with bothersome urinary symptoms associated with recurrent anterior urethral stricture. JCAMD002: Saluda Medical Evoke® Spinal Cord Stimulation System as an aid in the management of chronic intractable pain of the trunk and/ or limbs
	Production 3 MP JCA without HTD submission **will be published in the comin weeks*	No compounds were submitted by HTDs for a JCA. To allow testing guidelines and templates, 3 PICO exercises were conducted on products (with positive CHMP opinion, to avoid confidentiality aspects): 1. oncology 2. ATMP 3. orphan
	Timelines for MP JCA production	Not an official deliverable Created to ensure feasible timeline for the JCA given the newly developed guidelines Focus on MP, initial marketing authorisations. No process developed for dealing with change in indication

EUnetHTA 21 JCA Final Report Recommendations

Topic	Recommendation

JCA procedure	• Conducting the JCA
	  • >1 individual per organisation conducting the JCA should be involved in the JCA production
	  • Two dedicated Project Managers have to be appointed to the JCA, and it proved crucial that the PM keeps the JCA team informed about information exchange with the HTD and their responses to questions
	  • A checklist for the submission dossier completeness check should be created for the assessors, as well as a guidance on consequences for incompleteness of this dossier for the HTD.
	  • Procedural fairness and predictability of the process should be guaranteed and therefore production process, templates and guidelines should not be changed once a JCA is started.
	• The Review process
	  • Reviewers do not comment on grammar and typo's – unless it changes the meaning of the sentence – as the JCA will undergo medical editing
	  • Sufficient time should be planned for the complex reviewing and validation process
	• Kick-off meeting and training before the start of the joint production under the HTAR is highly recommended, also at the start of every JCA.
	  • Training on how to submit data according to PICO is required

Expert involvement	• Guidance on expert involvement is needed with a clear approach and contact points for identification and recruitment. • A common database development with EMA would be beneficial in this regard. • A dedicated stakeholder/external expert team is recommended

Updates on Transversal Activities

Roisin Adams, NCPE

D7 deliverables

https://www.eunethta.eu/jointhtawork/

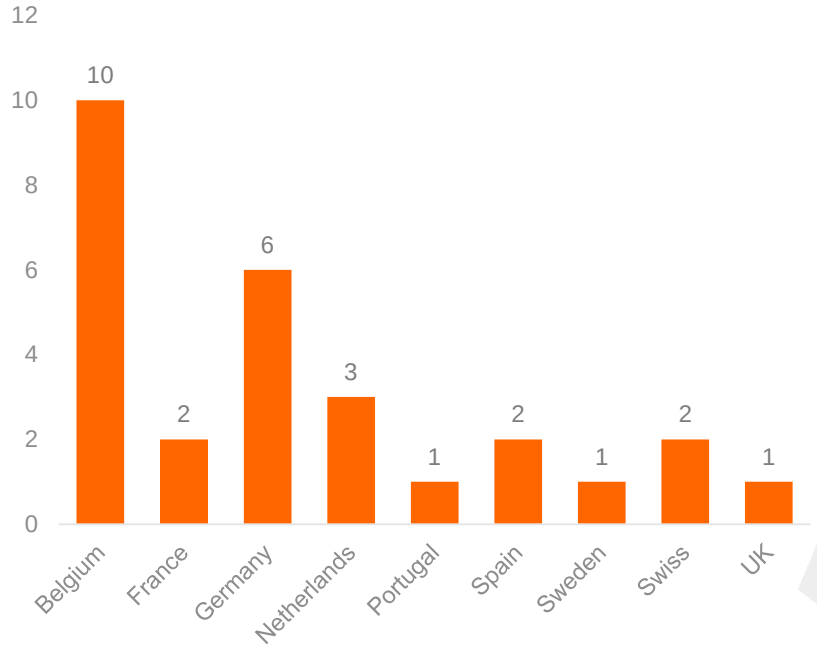
	Title	
D7.1	Practical Guidelines HTD and HTA interaction	Guideline on: • General interaction process throughout JSC and JCA production • Guidance on the factual accuracy check by HTD in the JCA • Procedure for confidential information and citation • only focus on commercially sensitive information. Academic in confidence is not accepted.
D7.2/7.3	Patient and HCP guidance & templates for interaction	Developed a process for selection, recruitment, involvement and evaluation of patient experts, clinical experts, patient organisations and healthcare professional organisations for JSC and JCA. Guidance does not describe how this can be done in national process, but does encourage the national involvement. Templates for each of the interactions are developed.
D7.4.1	Collaboration with MP regulator (EMA)	A joint work plan between EMA and EUnetHTA 21 has been developed, under which 4 bilaterals have taken place
D7.4.2	Collaboration with MD regulator	• Meetings with representatives from the MDCG and expert panel took place • A wishlist is developed for a TISP process in collaboration with EMA • A work plan was developed for interaction with EMA on the TISP process. This has been included in the published work plan under D7.4.1
D7.5	Guidance and templates for Declaration of Interest and confidentiality	Conflict of Interect Committee set up to continue central management of DOI forms via bi-weekly meetings and a DOI database, evaluate procedures and DOI/ECA forms Major COI for methodological development were also created

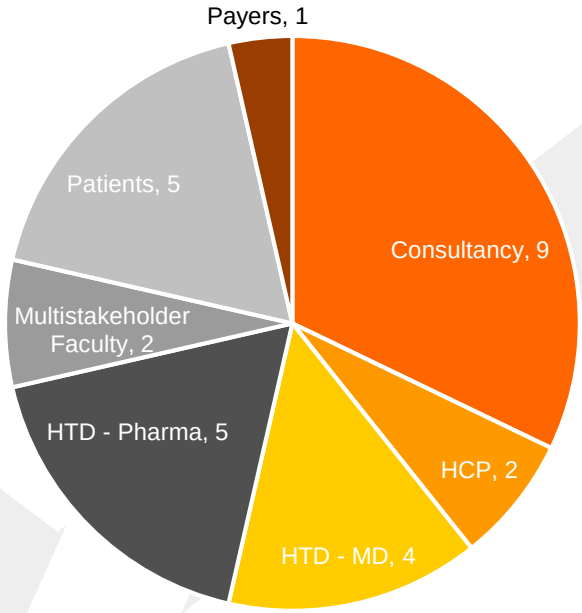
Results from Stakeholder evaluation

Anne Willemsen, ZIN

Feedback survey (July 2023)

- Survey was online for a month, in July 2023
- 28 stakeholder organisations responded





Feedback – Stakeholder meetings

The responses indicated that stakeholders highly appreciated the meetings.

- *“they have been instrumental in enhancing the understanding of the project's current status (…) in particular primarily focussing on the overall process”*

To improve the effectiveness, it was mentioned:

- Adding more specificity of medical device technologies would greatly benefit the meetings.
- Moreover stakeholders expressed the wish for a follow up with meeting minutes as well as more tailored meetings rather than following a ‘’generic’’ approach.

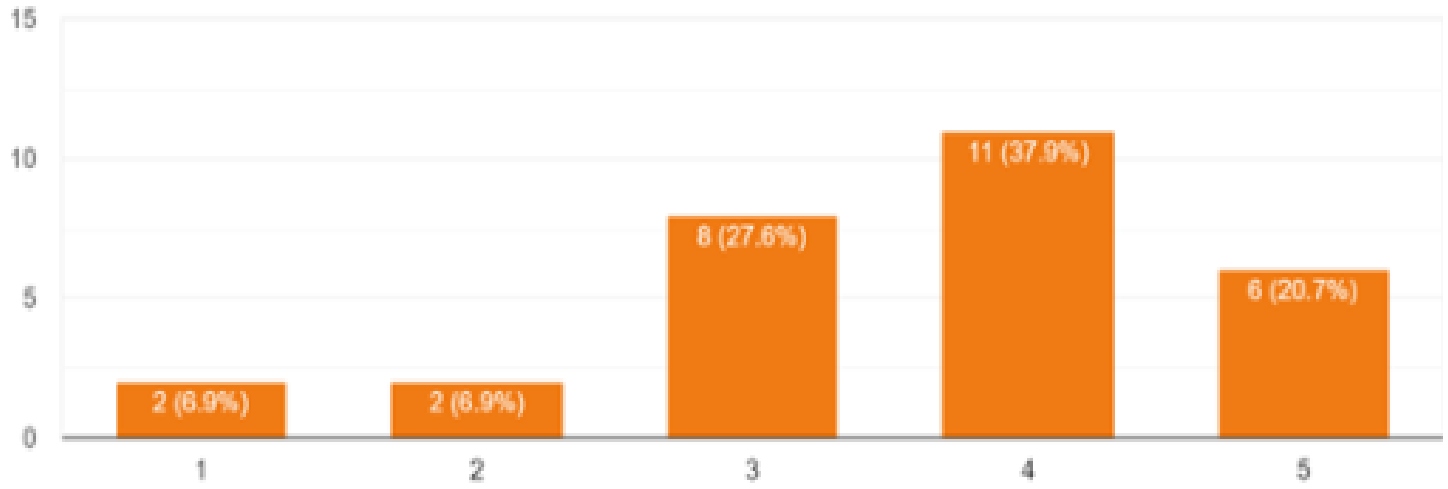
Feedback – Public consultations

Generally, the process was rated well. Stakeholders feedback:

- Personalized feedback on the comments is requested
- Website structure for accessing information and the status could have been clearer
- Concerns on timelines have been raised, e.g. multiple consultations at the same time summer period, and short duration
- It was recommended to explore alternative mechanisms for public consultations
- More transparency was requested on how comments were incorporated in the final documents, e.g. by track changes

How would you rate the overall process of the public consultation?

29 responses



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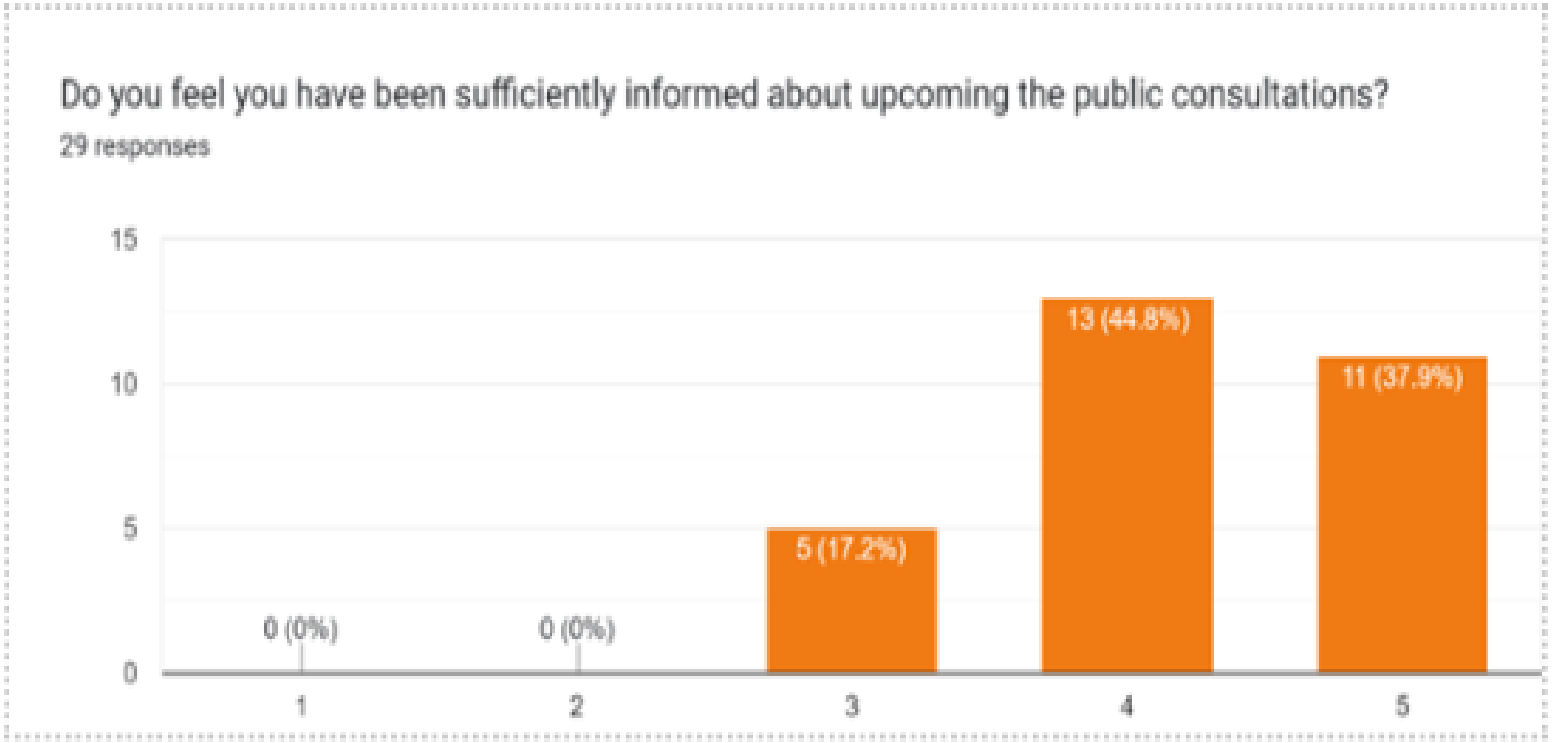

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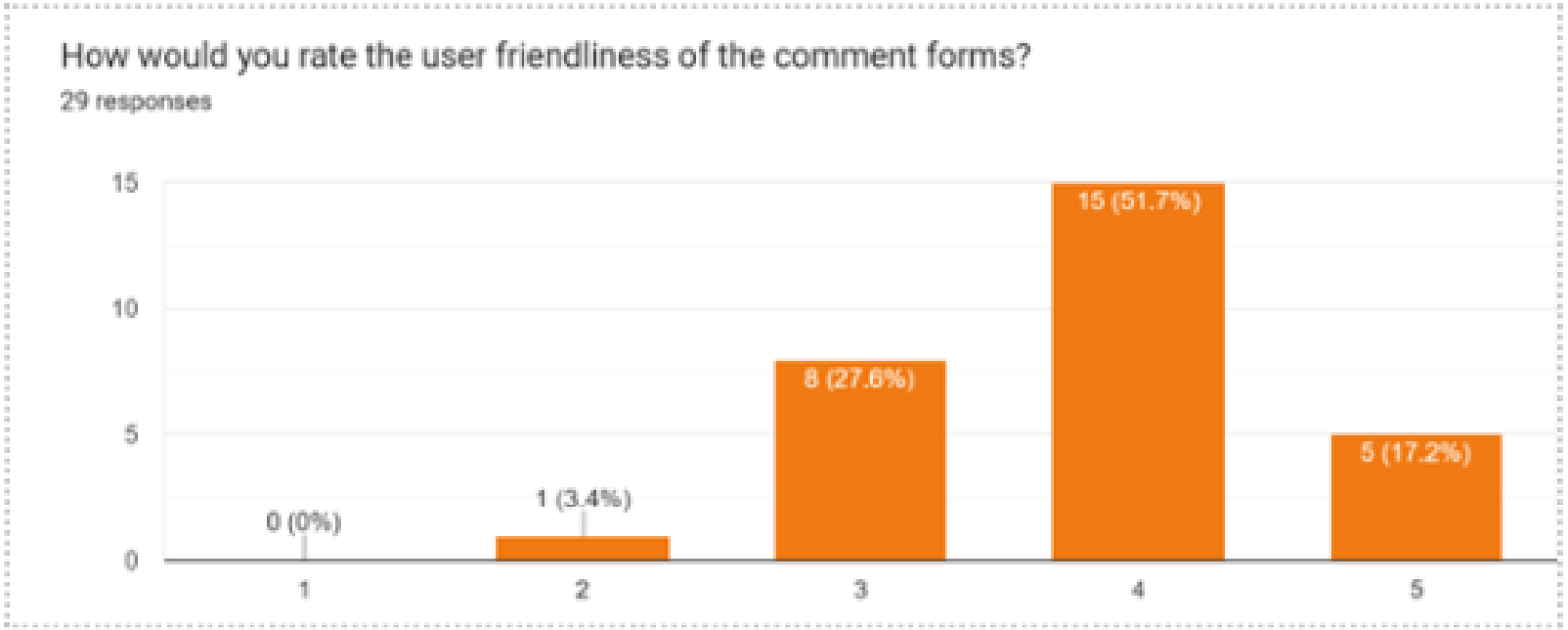

(1=very poor, 5=very good)

Feedback – Recommendations

Stakeholder recommendations:

- Maintain the public consultation
  - but consider alternative approaches, especially to gain earlier stakeholder engagement
  - refine timelines, instructions and website design
- Maintain stakeholder meetings
  - Consider tailored stakeholder meetings, not only general stakeholder events
  - Record meeting minutes and gather questions & answers
  - Facilitate face-to-face meetings
- Transparent communication

4. **Q&A**

Niklas Hedberg, TLV

5. **Closing remarks**

Niklas Hedberg, TLV

EUnetHTA 21 stakeholder meetings recap

slides: https://www.eunethta.eu/ja3events/

Meeting date	Objective
25 March 2022	HTD & Consultancy (Pharma & MD) - Focus on production process JCA & high level overview Submission Dossier Template
29 April 2022	2n General EUnetHTA 21 Stakeholder Meeting
25 May 2022	Patient and Healthcare Professional (HCP) roundtable - Discuss proposed methods for involvement in JSC and JCA
July 2022	EMA/EUnetHTA 21 bilateral in accordance to work plan
13 July 2022 (instead of 15th of July)	3rd General EUnetHTA 21 Stakeholder Meeting
October 2022	EMA/EUnetHTA 21 bilateral in accordance to work plan
18 November 2022	4th General EUnetHTA 21 Stakeholder Meeting
February 2022	EMA/EUnetHTA 21 bilateral in accordance to work plan
12 May 2023	5th General EUnetHTA 21 Stakeholder Meeting
25 May 2022	HTD specific meeting to discuss JCA production timelines and submission dossier template
8 September 2023	6th & final General EUnetHTA 21 Stakeholder Meeting
September 2023	EMA/EUnetHTA 21 bilateral in accordance to work plan

For further questions

- EUnetHTA 21 website is going to be closed down by the end of the year, therefore please download all relevant information before that time.
- For further questions or advice please contact: SANTE-HTA@ec.europa.eu
- Thank you very much for your involvement and input!

EUnetHTA 21 – Stakeholder Meeting

End: 12 May 2023
Friday 10:00-12:00 CET