



On 12 January 2017, the CPME Executive Committee adopted the 'CPME response to public consultation on strengthening EU cooperation on Health Technology Assessment (HTA)' (CPME 2016/107 FINAL)

CPME response to public consultation on strengthening EU cooperation on
Health Technology Assessment (HTA)

CPME answers appear in blue font.

QUESTIONNAIRE FOR ADMINISTRATIONS, ASSOCIATIONS AND OTHER ORGANISATIONS

1. INFORMATION ABOUT THE RESPONDENT

Please provide the following data on your organisation/association/administration:

1.1. Please indicate the name of your organisation/association/administration

CPME – Standing committee of European Doctors

1.2. Please enter the country where your organisation/association/administration is based

Belgium

1.3. Please indicate whether your organisation/association/administration is listed in the Transparency Register?*

9276943405-41

2. IDENTIFICATION OF RESPONDENT

3. STATE OF PLAY

3.1. Please indicate your opinion on the following statements:

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	I don't know



<p>a) There are differences between HTA procedures among EU Member States (e.g. responsibilities of authorities, prioritisation /selection of health technologies to be assessed; duration of procedures; rights/obligations of sponsors during the procedure)</p>	X					
<p>b) There are differences between HTA methodologies for the clinical assessment (REA) among EU Member States (e.g. different data requirements for the submission dossier; choice of comparator; endpoints accepted; way of expressing added therapeutic value).</p>		X				
<p>c) There are differences between HTA methodologies for the economic assessment among EU Member States (e.g. different approaches for economic models, budget impact and health-related outcomes; importance of local economic context).</p>	X					

3.1.a. For a) please provide concrete examples of the differences you are aware of and their effects for your organisation:

3.1.b. For b) please provide concrete examples of the differences you are aware of and their effects for your organisation:

3.1.c. For c) please provide concrete examples of the differences you are aware of and their effects for your organisation:

3.2. In your opinion, differences among EU Member States regarding HTA procedures and/or



methodologies may contribute to (*one or more answers possible*):

- a) Duplication of work for your organisation
- b) Less work for your organisation
- c) High costs/expenses for your organisation
- d) No influence on costs/expenses for your organisation
- e) Diverging outcomes of HTA reports
- f) No influence on the outcomes of HTA reports
- g) Decrease in business predictability
- h) No influence on business predictability
- i) Incentive for innovation
- j) Disincentive for innovation
- k) No influence on innovation
- l) Other
- m) None of the above
- n) I don't know/No opinion

3.2.I. Please specify if 'Other':

3.3. In recent years EU-funded projects and two Joint Actions have been carried out which aimed at strengthening cooperation on HTA across the EU. Are you aware of these initiatives? (*one answer possible*):

- a) Yes, I have participated in one or more of these
- b) Yes, I am aware of them, but did not participate
- c) No, I am not aware

3.3.1. In general terms do you think the **EU cooperation on HTA (e.g. projects, joint actions)** has been

- a) Useful
- b) To some extent useful
- c) Not useful
- d) I don't know/No opinion

3.3.1.1. Please indicate which of the following factors concerning projects and Joint Actions were relevant for your reply (*more than one answer possible*)



- a) Allowed for sharing best practices
- b) Allowed for better knowledge of procedures and methodologies in other EU Member States
- c) Allowed for savings in your organisation
- d) Contributed to building trust between organisations and professionals involved
- e) Contributed to HTA capacity building
- f) Provided access to joint work
- g) Provided access to work done by other HTA bodies
- h) Provided access to expertise not available in my organisation
- i) Reduced workload for my organisation
- j) Contributed to increasing awareness and knowledge on HTA issues in my organisation
- k) Promoted involvement of patients' representatives in HTA activities
- l) Other

3.3.1.1.I. Please specify 'Other':

3.3.1.1.1. Please provide additional explanations and, if available, evidence supporting your answers to question 3.3.1.1. (please provide a link to supporting documents in English)

3.3.1.1.2. Please indicate to the best of your knowledge to which degree **joint work from EU-funded projects or Joint Actions was used by HTA bodies at national/regional level** as part of their decision-making process:

	To a great extent	To a limited extent	Not used	I don't know
a) Joint tools (templates, databases, etc)				<input checked="" type="checkbox"/>
b) Guidelines (e.g. for clinical and /or economic evaluations)				<input checked="" type="checkbox"/>
c) Early dialogues*				<input checked="" type="checkbox"/>
d) Joint reports on clinical assessments (REA)				<input checked="" type="checkbox"/>
e) Joint full HTA (clinical and economic assessment)				<input checked="" type="checkbox"/>
f) Other (please specify below)				

3.3.1.1.2.f. Please specify 'other':



3.3.1.1.3. Please indicate which shortcomings – if any - you identified in the EU-funded projects and/or Joint Actions

3.3.1.2. Please indicate which of the following factors concerning projects and Joint Actions were relevant for your reply (*more than one answer possible*)

- a) Provided for limited trust between organisations involved
- b) Provided limited added value for HTA priorities in my organisation
- c) There was a degree of uncertainty about the quality of the joint work
- d) Economic assessments cannot be carried out jointly due to specific socio-economic factors in each country
- e) Increased workload for my organisation
- f) Joint work is not recognised within Member States
- g) Accessing joint work and/or work done by other HTA bodies was difficult
- h) Joint work is not relevant for my organisation
- i) Other

3.3.1.2.i. Please specify 'Other':

3.3.1.2.1. Please provide additional explanations and, if available, evidence supporting your answers to question 3.3.1. (*free text field, possibility to upload supporting documents in English.*)

3.3.1.2.2. Please indicate which benefits – if any – you identified in the EU-funded projects and/or Joint Actions

4. EU COOPERATION ON HTA BEYOND 2020

4.1. In your opinion is there a need to continue EU cooperation on HTA after 2020 (when the EUnetHTA Joint Action 3 will end)?

- a) Yes
- b) No
- c) I don't know / No opinion

4.1.a. If yes, please specify:

CPME shares the view that EU cooperation on HTA should be pursued beyond 2020 and a sustainable framework should be put in place at EU level. There is a need to capitalise on



experience gained through previous and ongoing joint actions, which have provided a common set of expertise, best-practices and HTA methodologies. **Principles of independence and transparency should guide the designing of the future EU framework on HTA.**

While EU collaboration on HTA can help Member states make better use of available resources and take evidence-based and equitable decisions (taking into account medical, social, economic and ethical factors), it can also help healthcare providers to have access to innovative treatments with added therapeutic value, based on a comprehensive assessment of clinical evidence available at a given time. In addition, it can also facilitate doctors' access to reliable, timely and objective information on medical technologies to take better informed decisions with their patients on the best treatment, provided that transparency and independence are guaranteed. Ultimately, it can help ensuring fairness and reducing inequalities in access to medical treatments between and within countries.

4.1.b. If no, please specify:

4.1.1. In your opinion, for which health technologies an EU cooperation on HTA would be more useful and respond to your needs?

	Very useful	To some extent useful	Not useful	I don't know
a) Pharmaceuticals	X			
b) Medical devices	X			
c) Other (please specify below)				

4.1.1.c. Please specify 'Other':

4.1.1.2. For which activities and if so to which degree do you consider that continuing EU cooperation on HTA beyond 2020 would respond to your needs?

	Responds very much to your needs	Responds to some extent to your needs	Does not respond to your needs	I don't know / No opinion
a) Joint tools (templates, databases, etc)		X		
b) Guidelines (e.g. for clinical or economic evaluations)	X			
c) Early dialogues	X			
d) Joint clinical assessment (REA)	X			



e) Joint full HTA (clinical and economic assessment)		X		
f) Other (please specify below)				

4.1.1.2.f. Please specify 'Other':

4.1.1.2.1. Please comment on the potential advantages and disadvantages of an EU initiative including the activities you consider useful for your organisation (e.g. workload, long-term sustainability of national healthcare systems, patients' accessibility to new technologies, business predictability, innovation)

CPME considers that an EU initiative on HTA, which would provide clinical and/or full assessment of new medicines and technologies, would enhance evidence-based decisions taken at both decision-makers and physicians level, while respecting the autonomy of healthcare providers to decide ultimately on what to use in the care process. It would also enhance coherence in the EU.

It should be ensured that final assessments are made public and easily accessible to national decision-maker, the medical profession and to the public. Transparency principles should not apply only to the results of the assessment but also to methodologies and processes. In addition, stringent set of rules on independence (e.g. management of conflicts of interest, recourse to internal and external expertise) should be put in place to ensure trust in the system.

4.1.1.3. In case EU cooperation on HTA will continue beyond 2020, in your opinion, what type of financing system should be envisaged? (*one possible answer*):

- a) EU budget
- b) Member States
- c) Industry fees
- d) A mix of A to C
- e) Other

4.1.1.3.1. Please explain your answer and comment on issues such as feasibility, advantages and disadvantages

If a European framework on HTA based on an EU budget would request a political commitment, this would ensure sustainability but also trust in the system by disconnecting industry fees from any assessment process. In this respect, option c) would not be acceptable in our view and could lead to question the result of the assessment performed within this framework.

4.1.1.4. In case EU cooperation on HTA will continue beyond 2020, in your opinion, the secretarial /organisation support should be ensured by (*one or more answers are possible*)



- a) European Commission
- b) Existing EU agency(ies)
- c) New EU agency
- d) Member States HTA bodies on rotational basis
- e) Other

4.1.1.4.1. Please explain your answer(s) and comment on issues such as feasibility, advantages and disadvantages

4.1.1.5. In your opinion, regarding an initiative on EU cooperation on HTA beyond 2020, which type of cooperation would respond to your needs? Please rank the following options from the most to the least preferable option).

	a) Most preferred option	b)	c)	d)	e) Least preferred option
a) Voluntary participation with voluntary uptake of joint work (i.e. as carried out by EUnetHTA Joint Actions)					<input checked="" type="checkbox"/>
b) Voluntary participation with mandatory uptake of joint work for the participants	<input checked="" type="checkbox"/>				
c) Mandatory participation with mandatory uptake of joint work			<input checked="" type="checkbox"/>		
d) Other (please specify below)					

4.1.1.5.d. Please specify 'Other':

4.1.1.5.1. Please explain your answer(s) and comment on issues such as feasibility, advantages and disadvantages

The option of 'voluntary participation with mandatory uptake' should not exclude all Member states and relevant parties from contributing to the assessment process.

5. Any other comments. Uploading relevant documents is also possible.