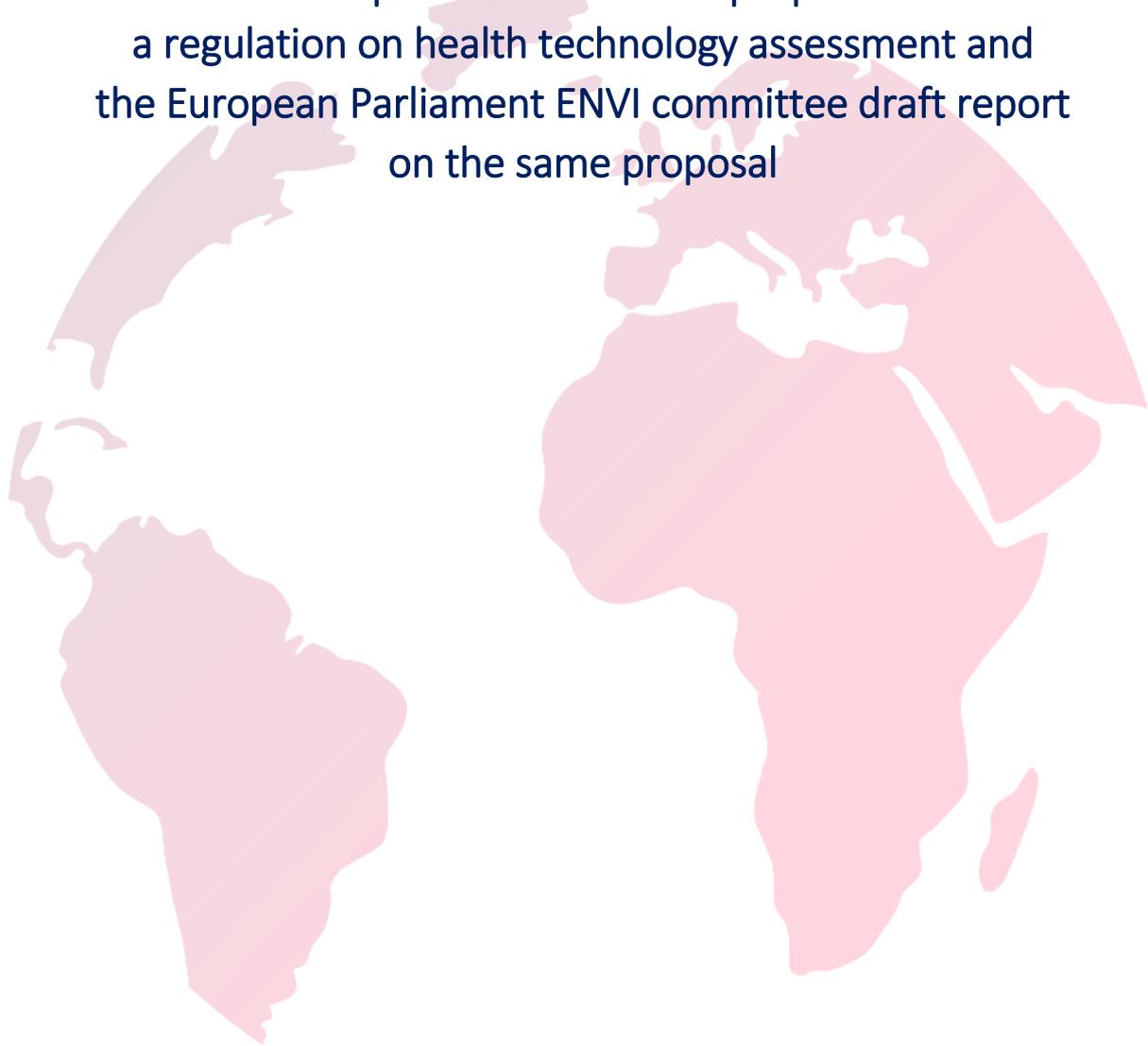
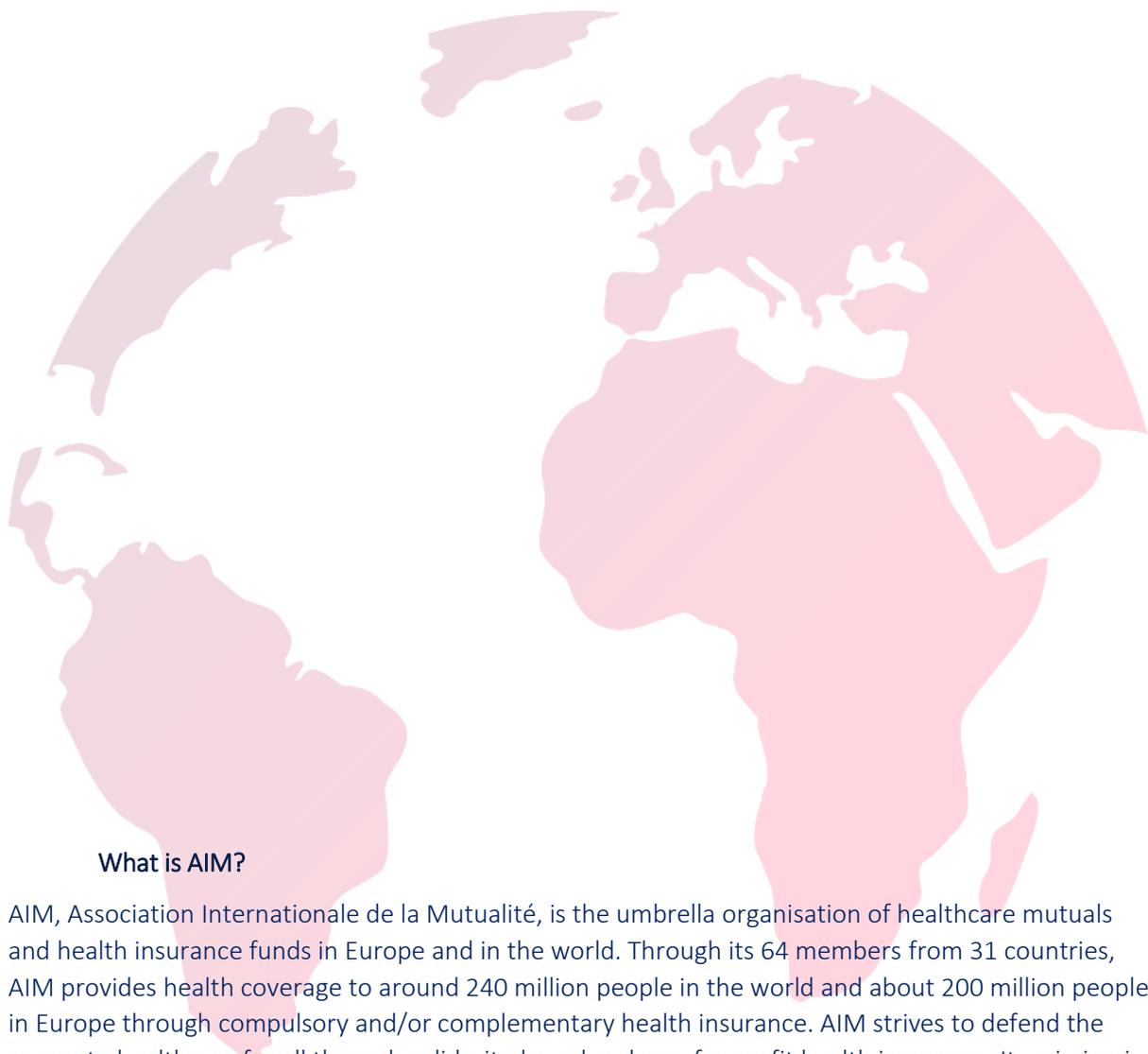


Position of AIM on  
the European Commission's proposal for  
a regulation on health technology assessment and  
the European Parliament ENVI committee draft report  
on the same proposal



Brussels, 8 June 2018



### **What is AIM?**

AIM, Association Internationale de la Mutualité, is the umbrella organisation of healthcare mutuals and health insurance funds in Europe and in the world. Through its 64 members from 31 countries, AIM provides health coverage to around 240 million people in the world and about 200 million people in Europe through compulsory and/or complementary health insurance. AIM strives to defend the access to healthcare for all through solidarity-based and non-for profit health insurance. Its mission is to provide a platform for members to exchange on common issues and to represent their interests and values towards the European and international Institutions.

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## Summary

AIM supports the overall objective of the EC proposal on HTA and calls upon the Council of the European Union and the European Parliament to ensure a compromise text that will bring EU collaboration in the field of HTA further.

- AIM would only be able to support an obligatory system for joint clinical assessments (as described in article 8 of the proposal) if
  - more clarity is created in the regulation about the timing of joint clinical assessments,
  - the methodological framework to be used is described in the regulation,
  - the transparency of assessment outcomes and the data used is ensured
  - Member States have the possibility to do context-specific additional clinical assessments
- Decision maker involvement in HTA is crucial. The regulation should foresee in consultation mechanisms between the coordination group and pricing and reimbursement authorities and payers.

## Introduction

Health technology assessments are an important tool to support pricing and reimbursement decisions and to ensure sustainable access to healthcare for all. AIM therefore has a keen interest in the European Commission Proposal on HTA<sup>1</sup>. As rightly stated in the draft ENVI committee report on that proposal<sup>2</sup>, *“we need more and better clinical evidence as the basis for determining the relative efficacy and therapeutic benefits of medicines”*. At the same time it must be mentioned that to ensure access to effective medicines much more than HTA collaboration at EU level alone is required.

AIM has followed EU collaboration in the field of HTA with a lot of interest. It is convinced that only through joint efforts at EU level, real progress in this field can be made. We are of the opinion that continuation with EU funded joint actions like EUnetHTA would at this point in time not be the best way forward. AIM therefore welcomes with much enthusiasm the Commission’s proposal for a more permanent structure for HTA collaboration<sup>3</sup>. It sees nevertheless some possibilities for further strengthening of the proposal, which will be described in this document. This position will also reflect on the amendments proposed in the draft report on the proposal, published by the European Parliament ENVI Committee on May 4<sup>th</sup> of this year.

### 1. Why an EU Regulation on HTA?

Under “Reasons for and objectives of the proposal”, the European Commission presents three problems which would justify this regulation. AIM is not denying that these problems exist, but would like to see another element have a more prominent position in the narrative, being that joint efforts would lead to higher quality assessments. **AIM welcomes amendment 5 in the Cabezón draft report**, which highlights the many barriers to access to medicines and innovative technologies in the Union of which fragmented HTA is only one.

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<sup>1</sup> The Commission proposal for a regulation on HTA can be found [here](#)

<sup>2</sup> The draft report of the ENVI Committee (rapporteur Soledad Cabezón Ruiz) can be found [here](#)

<sup>3</sup> See also AIM’s [first general reaction](#) to the EC proposal for a Regulation on HTA

Under the same heading, the European Commission should emphasize that the general objective of the current proposal would (also) be to facilitate Member States to ensure financially sustainable health systems and broad access to a high level of human health protection.

## 2. What is the legal base for this proposal?

Article 114 TFEU, on the functioning of the internal market, should according to AIM not be the only legal base for this regulation. The lack of an EU wide clinical health technology assessments is not the only factor to impede the functioning of the internal market. Pricing and reimbursement decisions, based on clinical and non-clinical assessments have nothing to do with market access per se. Pharmaceutical companies have access to the entire EU market after EU marketing authorization through the European Medicines Agency and ultimately the European Commission. Article 168 TFEU would be an appropriate additional legal base. **AIM therefore welcomes amendment 1 in the Cabezón report.**

## 3. Dialogue at EU level about cost-effectiveness studies should not stop.

AIM agrees with the Commission that the economic part of assessments should remain the sole responsibility of the Member States. At the same time, we would like to underline the importance of continuous dialogue among Member States about this part of the assessment. AIM sees great added value in technical collaboration in this field. Non-clinical assessments remain difficult to make for individual Member States and inscrutable for the general public. It is important that countries are being supported in the strengthening of this part of the HTA process too. Member States should, within the frame of this regulation, be given the possibility to continue to give priority to a dialogue with other EU member states about this part of the assessment, to strengthen their own methodologies for (relative) cost-effectiveness studies.

In the Cabezón report it is suggested to delete voluntary cooperation that facilitates synergies with initiatives under the digital single market strategy in relevant digital and data-driven areas relevant digital and data-driven areas of health and care (with a view to the provision of additional real world evidence relevant for HTA out of the scope for voluntary cooperation. AIM is of the opinion that this is a relevant piece of collaboration that should be included in the regulation as an option for voluntary cooperation and **would therefore not support amendment 31 in the draft Cabezón report.**

## 4. Who should pay for all this?

With enormous economic interests, the health technology sector is prone to conflicts of interest. It is for AIM very important that HTA is organized in an objective, independent and transparent manner. That means that the financing of assessments, but also joint scientific consultations, should not include direct contributions from the pharmaceutical industry. **AIM welcomes the general idea brought forward in amendments 36 and 144 in the Cabezón report**, which would change recital 27 and article 24 and would allow the Commission to establish a system of charges for developers, but would also ensure that these fees may under no condition be used to directly fund the joint work provided for in the Regulation.

## 5. Is a mandatory joint clinical assessment the best way forward?

The European Commission proposes a mandatory joint clinical assessment (art 8). The Regulation in its current form and with its current level of detail is according to AIM not fit for the creation of such an obligation. AIM therefore suggests further clarification and substantiation of some of the articles.

## 6. Which aspects need further clarification?

Before AIM can support an obligatory system, more clarity needs to be created in the draft regulation about:

- The timing of the joint clinical assessments: AIM is not yet convinced whether the deadlines suggested in Amendment 81 of the Cabezón Report would be most appropriate.

### Amendment 81

#### Article 6 – paragraph 14 a (new)

<i>Text proposed by the Commission</i>	<i>Amendment by Rapporteur</i>	<i>New Amendment by AIM</i>
	14a. The joint clinical assessment report and the summary report must be ready in not less than 80 days and not more than 210 days, except in justified cases where, owing to clinical necessity the process needs to be accelerated or delayed.	14a. The joint clinical assessment report and the summary report must be ready in not less than 80 days and not more than 210 days <b>after the submission for marketing authorisation by the sponsor of the application file and the clinical relative efficacy assessment</b> , except in justified cases where, owing to clinical necessity the process needs to be accelerated or delayed.

- Member States should have the possibility to involve in some parts of the process pricing and reimbursement decision makers to participate in the work of the coordination group, for example when priorities are being set or when discussions about additional evidence collection from clinical practise are taking place.

**AIM welcomes amendment 50 of the Cabezón report**, which would introduce a required two third majority for decisions by the coordination group, instead of simple majority.

- **AIM does not support amendment 71 of the Cabezón report**, as clinical assessments should not necessarily be limited to clinical (relative) efficacy. Where appropriate clinical (relative) effectiveness should be taken into account too, preferably including patient-relevant health outcomes, especially when re-assessments are carried out.

- In the Cabezón report it is proposed through Amendments 34, 39 and 139 that the methodology should be decided upon by the Coordination Group. **AIM members support amendments 34, 39 and 139.**

AIM proposes to add in amendment 139 under (b) that the assessment of relative effectiveness shall be based on end-points **according to international standards of evidence based medicine.**

### **Amendment 139**

#### **Article 22 – paragraph 1 a (new)**

<i>Text proposed by the Commission</i>	<i>Amendment by Rapporteur</i>	<i>New Amendment by AIM</i>
	(b) the assessment of relative effectiveness shall be based on end-points which are relevant to the patient with useful, relevant, tangible and specific criteria suited to the clinical situation concerned;	(b) the assessment of relative effectiveness shall be based on end-points <b>according to international standards of evidence based medicine</b> , which are relevant to the patient with useful, relevant, tangible and specific criteria suited to the clinical situation concerned;

The Cabezón report proposes through amendment 41 to introduce a new recital 28d, that would ensure definitions for the concepts ‘high-quality innovation’ and ‘therapeutic added value’. AIM does not see the need for such definitions, nor does it expect agreement or consensus of all parties on these concepts. The current methodological framework for HTA as used in EUnetHTA does not require definitions for these concepts. **AIM does therefor not support amendment 41**

-Transparency, public availability of information about the outcome of the assessment, the process followed, the people involved and the data used are extremely important to our association. **AIM therefore particularly welcomes amendment 29, 68 and 105 in the Cabezón report**, which ask for the highest possible level of public openness for the scientific data used and the actual assessment.

- **AIM welcomes the general idea of amendment 53, 54, 56, 57 and 103** to specify, register and publish (conflicts of) interests.

-The timeline for possible updates of joint clinical assessments is important for our members. **AIM welcomes therefore amendments 11 and 19 of the Cabezón report** which state that HTA can help in decision-making on divestment in cases where a technology becomes obsolete and unsuitable in comparison to other, better, available options. If these updates of assessments do not take place at EU level within a reasonable time frame, Member States should have the possibility to carry out these assessments independently. **We welcome amendment 95 and 96 in the Cabezón report on this matter.**

## Amendment 95

### Article 9 – paragraph 1 – point ba (new)

<i>Text proposed by the Commission</i>	<i>Amendment by Rapporteur</i>	<i>New Amendment by AIM</i>
	(ba) five years after the assessment or earlier when new evidence or clinical data emerges.	(ba) five years after the assessment or earlier when new evidence or clinical data emerges. <b>If the Coordination Group does not carry out the requested updates the requesting members / Member States have the possibility to carry out these updates independently.</b>

#### 7. More flexibility for member states to do additional research

AIM fully supports the proposal of the Commission not to allow for duplication of work. Where appropriate, Member States should have the possibility to do context-specific assessments, also taking into account national decision-making processes and timing. **AIM supports amendment 133 and 134. AIM also supports the general aim of the amendments 42 and 89-92 in the Cabezón report. Amendment 92 is for AIM members absolutely crucial.**

#### 8. In which cases should a Joint Scientific consultation take place?

Joint scientific consultations can be of added value for both the developer and the assessment agency, but should only take place in very specific circumstances. Too intimate relations between sponsor and assessor are a breeding ground for conflict of interest. Where it is on the basis of the standard methodology of HTAs and data requirement unclear what these mean for this specific technology, joint scientific consultations could be considered.

#### 9. Stakeholder involvement in HTA

AIM considers the involvement of stakeholders in HTA crucial. At the same time, it is important that the actual assessment is carried out independently from stakeholder interest. Where appropriate stakeholders should be involved in joint scientific consultations and identification of emerging technologies, discussions about the general HTA methodology to be used, the timing, the data requirements, etc. After the scientific assessment has been carried out, stakeholders should have the possibility to express their opinion about the end result, before the final decision about the assessment will be drawn. We consider it similarly important to involve stakeholder in the further development of the implementing acts, which means that not only HTA bodies should be involved, but also pricing and reimbursement authorities and healthcare payers should be formally consulted<sup>4</sup>.

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<sup>4</sup> Read [this AIM publication](#) to get a better understanding of involvement of our members in HTA and pricing and reimbursement at national level.

Amendments 33, 34, 35, 39, 116, 136, 149 and 158 of the Cabezón report should include healthcare payers as members of the network of to be consulted stakeholders.

### Amendment 33

#### Recital 24 a (new)

<i>Text proposed by the Commission</i>	<i>Amendment by Rapporteur</i>	<i>New Amendment by AIM</i>
	(24a) Dialogue with patient organisations, consumer organisations, health NGOs and health experts and professionals must be ensured via a network of stakeholders (etc)	(24a) Dialogue with patient organisations, consumer organisations, <b>payer associations</b> , health NGOs and health experts and professionals must be ensured via a network of stakeholders (etc)
<i>Justification:</i>		
Healthcare payers should be involved in EU collaboration in the field of HTA, to ensure that the joint clinical assessments are addressing the needs of the ultimate end users.		

### Amendment 116

#### Article 16 – paragraph 1 – point d

<i>Text proposed by the Commission</i>	<i>Amendment by Rapporteur</i>	<i>New Amendment by AIM</i>
d) the <b>consultation</b> of patients, clinical experts and other relevant stakeholders	d) the <b>submission of comments by patients, healthcare professionals</b> , clinical experts and other relevant stakeholders	d) the submission of comments by patients, healthcare professionals, <b>healthcare payers</b> , clinical experts and other relevant stakeholders
<i>Justification:</i>		
Healthcare payers should be involved in EU collaboration in the field of HTA, to ensure that the joint clinical assessments are addressing the needs of the ultimate end users.		

## Amendment 136

### Article 22 – paragraph 1 a (new)

<i>Text proposed by the Commission</i>	<i>Amendment by Rapporteur</i>	<i>New Amendment by AIM</i>
iii) <b>the consultation</b> of patients, clinical experts, and other stakeholders in clinical assessments.	iii) <b>comments</b> of patients, <b>healthcare professionals</b> , clinical experts and other stakeholders in clinical assessment <b>and the duly justified replies</b> ;	iii) comments of patients, healthcare professionals, <b>healthcare payers</b> , clinical experts and other stakeholders in clinical assessment and the duly justified replies;
<i>Justification:</i>		
Healthcare payers should be involved in EU collaboration in the field of HTA, to ensure that the joint clinical assessments are addressing the needs of the ultimate end users.		

## Amendment 149

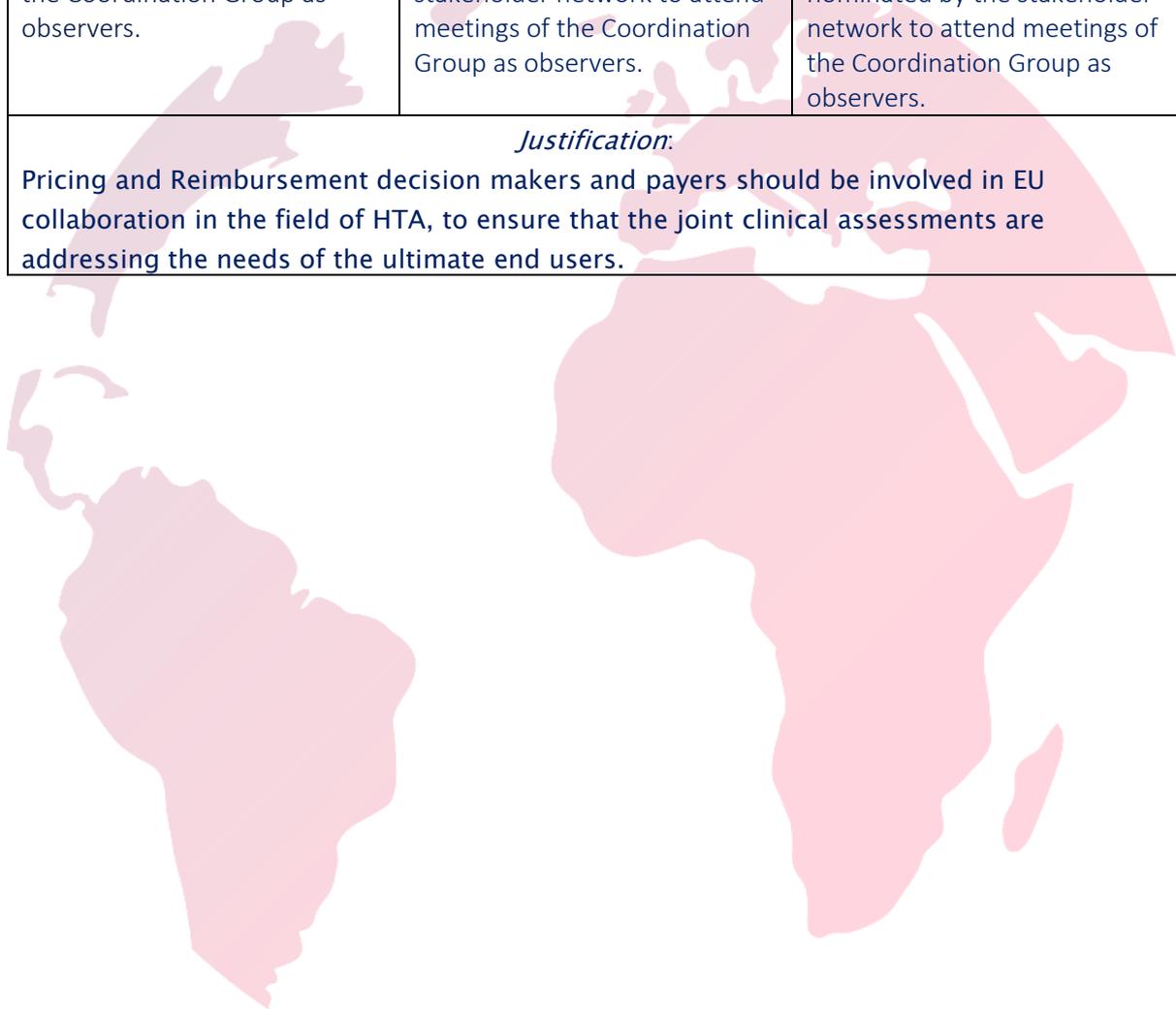
### Article 26 – paragraph 1

<i>Text proposed by the Commission</i>	<i>Amendment by Rapporteur</i>	<i>New Amendment by AIM</i>
1. The Commission shall establish a stakeholder network through an open call for applications and a selection of suitable stakeholder organisations based on selection criteria established in the open call for applications.	1. The Commission shall establish a stakeholder network through an open call for applications and a selection of suitable stakeholder organisations based on selection criteria established in the open call for applications. <b>The organisations to be addressed by the call shall be patient associations, consumer organisations, non-governmental organisations in the field of health and healthcare professionals.</b> The European Parliament shall have two representatives in the stakeholder network.	1. The Commission shall establish a stakeholder network through an open call for applications and a selection of suitable stakeholder organisations based on selection criteria established in the open call for applications. The organisations to be addressed by the call shall be patient associations, consumer organisations, <b>healthcare payer associations</b> , non-governmental organisations in the field of health and healthcare professionals. The European Parliament shall have two representatives in the stakeholder network.
<i>Justification:</i>		
Healthcare payers should be involved in EU collaboration in the field of HTA, to ensure that the joint clinical assessments are addressing the needs of the ultimate end users.		

**Amendment 158**

**Article 26 – paragraph 4**

<i>Text proposed by the Commission</i>	<i>Amendment by Rapporteur</i>	<i>New Amendment by AIM</i>
4. On the request of the Coordination Group, the Commission shall invite patients and clinical experts nominated by the stakeholder network to attend meetings of the Coordination Group as observers.	4. On the request of the Coordination Group, the Commission shall invite patients, <b>healthcare professionals</b> and clinical experts nominated by the stakeholder network to attend meetings of the Coordination Group as observers.	4. On the request of the Coordination Group, the Commission shall invite patients, healthcare professionals and <b>payers, as well as</b> clinical experts nominated by the stakeholder network to attend meetings of the Coordination Group as observers.
<p style="text-align: center;"><i>Justification:</i></p> <p>Pricing and Reimbursement decision makers and payers should be involved in EU collaboration in the field of HTA, to ensure that the joint clinical assessments are addressing the needs of the ultimate end users.</p>		



AIM's mentions in this position paper a specific opinion about the following amendments:

AIM welcomes amendment 1

AIM welcomes amendment 5

AIM welcomes amendment 11

AIM welcomes amendment 19

AIM welcomes amendment 29

AIM does not support amendment 31

AIM members proposes changes to amendment 33

AIM welcomes amendment 36

AIM does not support amendment 41

AIM welcomes amendment 42

AIM welcomes amendment 50

AIM welcomes amendment 53,

AIM welcomes amendment 54

AIM welcomes amendment 56

AIM welcomes amendment 57

AIM welcomes amendment 68

AIM does not support amendment 71

AIM proposes changes to amendment 81

AIM welcomes amendment 89

AIM welcomes amendment 90

AIM welcomes amendment 91

AIM particularly welcomes amendment 92

AIM welcomes amendment 95 and proposes additional improvements

AIM welcomes amendment 96

AIM welcomes amendment 103

AIM welcomes amendment 105

AIM proposes changes to amendment 116

AIM welcomes amendment 133

AIM welcomes amendment 134

AIM proposes changes to amendment 136

AIM members welcome amendment 139 but also proposes changes to it

AIM welcomes amendment 144

AIM proposes changes to amendment 149

AIM proposes changes to amendment 158

