Report on the public consultation on
the modalities of stakeholder consultation
in the future Health Technology Assessment Network

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Contents

Background for the public consultation ................................................................. 3
Executive summary .................................................................................................. 3
Methodology ............................................................................................................ 4
Key findings when comparing stakeholder groups ................................................. 4
Citizen and patient organisations ........................................................................ 8
Input from industrial companies and associations .................................................. 10
Public healthcare payers ....................................................................................... 13
Health professionals ............................................................................................... 15
Individual and other responders .......................................................................... 18
National health authorities and HTA organisations ............................................. 18
Parties contributing to the consultation ............................................................... 23
Background for the public consultation

Article 15 of Directive 2011/24/EU on the application of patient rights in cross-border healthcare envisages the establishment of a permanent, voluntary Health Technology Assessment (HTA) network in the EU, connecting national authorities and bodies responsible for HTA appointed by the Member States.

The Directive specifies that stakeholder consultations on the Network’s activities should take place, and DG Health and Consumers held a public consultation from 2 May to 1 August 2012 to allow interested parties to express their view as to how the consultation of stakeholders in the HTA network’s activities could be facilitated.

Executive summary

The public consultation generated 52 contributions, of which 12 from national authorities or HTA institutions. Among the remaining 40, only 8 contributions come from EU associations who have been actively involved in previous and current HTA activities supported by the EU. This is positive, as a main purpose of the public consultation was to give also other interested parties the opportunity to provide input on how the future network could facilitate stakeholder consultation.

In general, the respondents expressed a clear interest in the HTA network but their capacity to actively engage differs; industry respondents in general reported better access to staff, experts and financial resources than other stakeholders, whereas citizen and patient organisations reported the lowest capacity.

The contributions illustrated that different stakeholder groups see their role in HTA differently. For example, EU organisations tended to be more interested in the overall governance of the HTA network, whereas individual companies and specialised stakeholder organisations showed more interest in activities related to the production of HTAs. Industry was in general much more interested in so-called "early advice" activities during the development phase of new health technologies than other stakeholders.

The future HTA network should recognise that different kinds of stakeholders are likely to engage in different parts of its work. The Network should therefore develop different ways of consulting stakeholders, and also accept that not all stakeholders will have the interest and capacity to engage in all activities initiated. The effective involvement of stakeholders with low resources would depend on the Network's ability to accommodate their needs.

1 The questionnaire is available on the European Commission's website; see http://ec.europa.eu/health/technology_assessment/consultations/index_en.htm
Methodology

This report outlines the main findings from the feedback received, distinguishing different stakeholder groups in the following way:

- Industrial companies and associations
- Patients' and citizens’ organisations
- Payer organisations and associations
- Health professionals' organisations
- Others (respondents not fitting into the other categories)
- National/regional health authorities and HTA organisations

The division of stakeholders into groups used in the report is based on work undertaken by European HTA organisations which are active in the European HTA network EUnetHTA², where the four groups Industry, Patients/Citizens, Payers and Health professionals constitute the Stakeholder Forum established as part of the Joint Action on HTA (2010-2012).

The summary of inputs is presented as a narrative text, and only main tendencies within each group are outlined. In cases where the questionnaire asks for rating of alternatives, averages have been calculated and are presented in the form of charts.

Given the low number of recipients in each group, the aggregated figures should be considered as tendencies and not as precise values. They do, however, illustrate differences and similarities in views/priorities within and between the groups. And, as there are only five – heterogeneous – respondents in the group individuals/others, only some general remarks are summarised from this group, mainly in the chapter Key findings.

Key findings when comparing stakeholder groups

The feedback from the different stakeholder groups are described more in detail in the following chapters. Some general trends can be seen, however, which are outlined here. It should be noted that input from national/regional health authorities and HTA bodies is – with one exception – not included in this chapter.

² www.eunethta.eu
Priority of HTA in the organisation

A first issue to look into is whether different stakeholder groups give different priority to HTA in their internal work plans and strategies. In that regard, respondents indicate the following (4=very high; 3=high; 2=somewhat; 1=low; 0=none):

![Priority of HTA in the organisation graph](image)

Overall, all groups are quite internally consistent in their response to this question.

HTA resources

The respondents' feedback demonstrates that some stakeholders have better HTA resources than others, as shown in the chart below (4=very high; 1=low):

![HTA resources graph](image)

Among the respondents in the groups payers and health professionals, the access to experts is higher than staff resources, which might be explained by the fact that European associations (which represent 2 of 5 payer respondents and 6 of 7 health prof. respondents) have limited staff resources in general, whereas their contact net provides a larger pool of available experts.
When to be consulted?

As regards when in an HTA process they would like to be consulted, stakeholders have the following view (priority one and two of each respondent group showed in the table):

Only the group "other" rank appraisal/verification of an HTA report among their top two priorities, all other respondents are more interested in the first two alternatives. Both the industry respondents and others clearly indicate that the scoping of a concrete HTA is their main interest. Both patients, payers and health professionals have as their first priority to be consulted on the identification of what areas for which to undertake an HTA.

If the view of stakeholders is compared to the reality in HTA organisations, we see that HTA bodies to a differing extent consult stakeholders in all these three areas:

Although appraisal activities also here have the lowest score, the differences are small and the average scores are low, which reflects the differing practices among the HTA agencies.
Areas of interest in the future HTA network

A comparison of the priorities of the different stakeholder groups (top three areas of interest) in the activities of the future HTA network illustrate that different stakeholder groups have different priorities:

Both patients/citizens and payers define governance of the network (rules of procedure, work plans etc.) as a major priority (together with others, all groups except payers see guidelines development as a major priority, and all groups except other give priority to relative effectiveness assessments (REA) for pharmaceuticals. In the case of relative effectiveness assessments for medical devices, payers and health professionals both outline this as a major priority, whereas no one points to HTA for complex health technologies. Industry and other are particularly interested in early advice issues.

Main needs in order to engage as a stakeholder

Finally, a summary of main needs of the stakeholders in order to engage in the future HTA network (top two priorities included in the table; the group individuals/others does not prioritise between the three categories):
Citizen and patient organisations

A total of 8 responses were given by this group (3 national and 5 EU organisations), of which two are general citizens'/consumer organisations and the remaining are patient organisations.

HTA knowledge and priority

Knowledge of HTA (where 0 = none and 3 = very high):
- National organisations: 2.25
- EU organisations: 2.00

As regards what aspects of HTA are of particular relevance, there is no clear pattern in this group. A majority seems to focus on issues like ethics, organisational and societal aspects of health technologies.

In this group, the average priority reported is "high"; 2 organisations indicate that HTA is given "very high" priority and 3 "somewhat".

When it comes to concrete experience with HTA's, 5 of 8 organisations have experienced no direct involvement in HTA processes. The remaining three have been involved "in some cases".

Two EU organisations have participated in EUnetHTA activities.

Resources available and expressed needs

As regards staff dedicated to HTA-related activities, 2 organisations report to have "high" staff resources available to work on HTA. The remaining organisations report to have "some" or "very little" capacity.

A similar pattern can be seen as regards access to experts; 2 organisations report to have expert access "to a large extent", and remaining organisations indicate that they have access to "some" or "very few" experts.

These organisations report lower participation in training than industry (average slightly above "in some cases").

As regards needs to participate effectively in HTA processes, 5 respondents point to a need for increased knowledge of methodologies, and 6 respondents indicate need for improved access to resources and time.

Modalities of stakeholder consultation

The feedback from the citizen/patient respondents rank possible HTA network activities in the following way (7 highest score possible – average score per sub-group and in total)

It seems clear that for these responders, governance of the HTA network as well as guideline development are clear priorities compared to the other types of activities.
When an HTA report is prepared and undertaken, citizen/patient respondents' have the following priorities (4 highest score possible):

The tendency is clear in this group; influencing in what areas an HTA should be undertaken and scoping (which aspects should be considered, how to measure outcome etc.) is more important than participating in appraisal and verification of a final report.

Finally, responders point to the following to exemplify how well-functioning stakeholder consultations could be facilitated:

- Netherlands: National hearings concerning the reimbursement of individual medicinal products.
- Italy: Patient/citizens' organisations have been consulted regarding the introduction of new drugs at national level, and also at regional level.
- EU level: The European Medicines Agency Patients and Consumers Working Party (PCWP) can be considered as a good example of stakeholders’ involvement and consultation, including on specific scientific issues.
- General remark: Stakeholders should be involved throughout all stages of the HTA process for a comprehensive assessment of a technology. Patients, professionals, hospitals, academics and industry all have a unique perspective to offer on the practical impact of a particular technology. Consultation with stakeholders provides important input into the real value of a technology for the health system and the permanent network for HTA should include a mechanism for continued stakeholder consultation on each assessment. When stakeholders do not have sufficient input into an HTA, there should also be an appeal process for HTA with decisions taken by a body independent of the original assessor.
- General remark: Alongside the consultation, there must also be clear rules of procedure and transparency regarding the information available throughout the assessment process. Without greater transparency, assessments lack validity. A high level of transparency within HTA processes and during consultation with stakeholders is of great importance to the overall value of HTA.
Input from industrial companies and associations

A total of 17 responses were given by this group (8 companies and 9 associations), representing both the pharmaceutical industry and medical technology industries.

HTA knowledge and priority

Knowledge of HTA (where 0 = none and 3 = very high):
- EU associations: 2.57
- Individual companies: 2.43
- National associations: 1.33

As regards what aspects of HTA are of particular relevance, there is a division between actors representing medicinal products and medical devices. Pharmaceutical associations and companies consider many aspects of health technologies, whereas the focus of medical devices companies and associations is somewhat more limited.

With two exceptions, all respondents indicate "very high" or "high" priority given to HTA work. This applies both to associations and individual companies. National associations give the lowest average priority.

When it comes to concrete experience with HTA's, associations report "none" or "very little" involvement in concrete HTA's, whereas 4 individual companies report "many times", 1 "in some cases" and 2 never.

A majority of the responders have been involved in EUnetHTA activities; 4 of 7 individual companies, 0 national associations and 6 of 7 EU associations.

Resources available and expressed needs

As regards staff dedicated to HTA-related activities, individual companies report the highest use of resources (average between "high" and "very high"), EU associations somewhat less (between "some" and "high"), national associations the least (between "little" and "some").

Also when it comes to the access to experts who can be consulted, national associations report the lowest figure (ranging from "very few" to "to some extent"). Here, EU associations give the highest average score, with individual companies slightly below (both ranging between "to a large extent" and "to some extent").

This pattern is repeated on participation in training activities, where EU associations give the highest average score. individual companies slightly lower (both leaning towards "many times"), with national associations ranging between "one or two cases" and "in some cases".

As regards needs to participate effectively in HTA processes, there is no clear pattern dividing the respondents in this group. 7 respondents express a need for increased knowledge of methodologies, and 10 respondents see a need for improved access to resources and time.

One individual company commented more specifically that "… clear and transparent systems, supported by appropriate financial and organisational means need to be established to allow for more effective involvement from our end."
Modalities of stakeholder consultation

The industry respondents rank possible HTA network activities in the following way (7 highest score possible – average score per sub-group and in total).

The higher number of replies from pharmaceutical sector/integrated companies may partly explain why rapid assessments of medical devices has a significantly lower score than relative effectiveness assessments (REA) for pharmaceuticals. It is also evident that EU associations have a particular interest in HTA network governance, whereas this is considered less relevant for individual companies.

When an HTA report is prepared and undertaken, industry respondents’ have the following priorities (4 highest score possible):
Finally, responders point to the following to exemplify how well-functioning stakeholder consultations could be facilitated:

- General remark: The HTA process should be transparent and encourage the involvement of relevant stakeholders including healthcare practitioners, healthcare planners/payers, patients and technology manufacturers at all stages of the process.

- General remark: The process including the selection of topics, appraisal criteria, process timelines, consideration of evidence, development of recommendations must be transparent and supported by a clear audit trail. Analyses should be independent of policy decision making and be conducted within a recognised process framework to ensure transparency, quality and stakeholder involvement. Conflicts of interest should be declared by all stakeholders including HTA assessors.

- General remark: Reference to Key principles for the improved conduct of HTA for resource allocation decisions by M.F. Drummond, J.S. Schwartz, B. Jonsson et al. International Journal of Technology Assessment in Health Care, 24:3 (2008), 244-258.

- European level: Joint Scientific Advice meetings with the EMA and representative HTA organisations. The model was piloted in 2011 and worked well, particularly for drugs in phase II clinical trial development. The challenge however is that most of the EU HTAs are insufficiently staffed to do this sort of scientific advice procedure. NICE has a fee-for-service model; other HTAs should adopt something similar to help support the scientific advice model in their country. There should be openness to doing this cross-border and together with the regulatory authorities.

- England/Wales: In the EU, the NICE processes potentially have the best processes and positive experiences for stakeholder engagement. The definition of stakeholders is broad, the opportunities for stakeholder engagement are clearly defined, and stakeholders are engaged at every step of the process from scoping the review, submitting evidence, to commenting on interpretation and final guidance. This best practice model of engagement should be strongly considered by EUnetHTA.

- Switzerland, USA, Ontario (Canada), Scotland, England/Wales: Good examples of overall agency governance

- Sweden: Data gathering and pre-submission discussion between agency and the company

- Germany, England/Wales: Decision-making process to assess a given technology and its application
- England/Wales, Australia: Assessment of evidence and production of recommendations
- England/Wales: In the field of diagnostics, the stakeholder consultations of the Diagnostics Assessment Programme of NICE³

**Public healthcare payers**

A total of 4 responses were given by this group (2 national and 2 EU organisations).

**HTA knowledge and priority**

Knowledge of HTA (0 = none; 3 = very high):
- Average: 2.2

There is no clear pattern in this group as regards what aspects of HTA are of particular relevance. However, all four respondents include "Health problem and current use" and "Clinical effectiveness", and none include "Ethical analysis".

They all indicate that HTA is a priority within their organisations; 3 of 4 respondents indicate "very high" and the last one "high".

All national but none EU organisations have experienced direct involvement in HTA processes, and all 4 respondents have participated in EUnetHTA activities.

**Resources available and expressed needs**

As regards staff dedicated to HTA-related activities, national organisations report to have somewhat higher staff capacity than EU organisations, answers range from "very few" to "high" in the group as a whole.

A similar pattern can be seen as regards access to experts ("some" is the most used answer); but here EU organisations are closer to the feedback of national organisations.

All respondents indicate that they staff has participated in trainings "in some cases".

As regards needs in the organisation to more effectively get involved in HTA processes, the respondents indicate need of increased knowledge of methodologies as well as of improved access to resources and time.

³ [http://www.nice.org.uk/getinvolved/sh/diagnostictechnologiesstakeholderregistration.jsp](http://www.nice.org.uk/getinvolved/sh/diagnostictechnologiesstakeholderregistration.jsp)
Modalities of stakeholder consultation

The feedback from the payer respondents ranks possible HTA network activities in the following way (7 highest score possible – average score per sub-group and in total):

Also in this group, the preferences differ between national and international level. At international level, governance issues and guideline development are top priorities, whereas for national organisations, relative effectiveness assessments (REA) for both medicinal products and medical devices get the highest score.

Similarly to the patient/citizen responders, also payers consider appraisal/verification of draft HTA reports as far less important than identifying areas for HTA and scoping.
When it comes to needs to participate as a stakeholder in the future HTA network activities, payer responders have the following priorities (4 highest score possible):

Finally, responders point to the following to exemplify how well-functioning stakeholder consultations could be facilitated:

- Belgium: Stakeholders are consulted in the Reimbursement Committee of pharmaceuticals as well as in the Consensus meetings through Delphi rounds, written comments, interviews, distribution of drafts documents, a meeting in order to finalise reports and proposals, and a 2nd discussion on open issues.
- General remark: Timelines for consultation on lengthy final documents need to be adequate to allow organisations with few resources to respond meaningfully. Consultation earlier in the process and along the process would be preferred, via e-mail and perhaps e-conferencing to avoid the costs of displacement. Biannual face-to-face meetings to review overarching governance and organisational issues and the deliverables should be foreseen, with suitable financial support for non-profit organisations.

Health professionals

A total of 7 responses were given by this group (all EU organisations).

HTA knowledge and priority

Knowledge of HTA (0 = none; 3 = very high):
Average: 2 (=high)

Health professionals include a high number of aspects of HTA as relevant in their answers, with a notable exception for "legal aspects", which only one organisation includes.

As regards the priority given to HTA in their own organisation, answers range from "somewhat" to "very high"; four respondents indicating "somewhat".

3 of the organisations have experienced direct involvement in HTA processes, two of them "many times", but only 1 organisation has participated in EUnetHTA activities.
**Resources available and expressed needs**

As regards staff dedicated to HTA-related activities, answers range from "very little" to "high", the average between "some" and "very little."

The access to experts is a different matter, here 3 organisations report "to a large extent" and 3 "to some extent".

3 of 7 organisations report to have sent representatives to HTA-related training (2 many times, 1 in some cases).

As regards needs in the organisation to more effectively get involved in HTA processes, 5 respondents indicate need of increased knowledge of methodologies, and 5 need of improved access to resources and time.

**Modalities of stakeholder consultation**

The feedback from the payer respondents ranks possible HTA network activities in the following way (7 highest score possible – average score per sub-group and in total):

![Bar chart showing network activities](chart.png)

For this group, all activities are of interest, but work related to concrete HTA's seems to be the major priority.
When an HTA report is prepared and undertaken, health professional respondents' have the following priorities (4 highest score possible):

![Bar chart]

When it comes to needs to participate as a stakeholder in the future HTA network activities, health professional responders have the following priorities (4 highest score possible):

![Bar chart]

Finally, responders point to the following to exemplify how well-functioning stakeholder consultations could be facilitated:

- England/Wales: Some responders point to good experiences with the consultation processes of NICE, in which they have participated.
- Finland: The strategic use of a variety of tools (particularly ICT tools) to communicate, educate and consult stakeholders on both the overall activities in the field of HTA, particularly targeting health professionals.
- General remark: Effective stakeholder consultations could be carried out through focussed questionnaires, which are adaptable to the various stakeholders’ expertise and allow for nuanced input. Expert meetings or eMeetings can complement written consultations and elaborate specific issues in greater depth. It would be useful to share the outcomes of the consultations with all stakeholders for the benefit of transparency and further discussion.
Individual and other responders

As only five respondents belong to this group, and they have no common characteristics (one think-tank, two multi-stakeholder networks, one academic institution and one individual), no further analysis will be provided in this chapter (see aggregated figures in the Key findings chapter).

However, they point to the following suggestions as to how well-functioning stakeholder consultations could be facilitated:

- Suggestions for the future HTA network: In order for all stakeholders to have an informed voice when being consulted in a network such as that being prepared, it is imperative that they are not only educated to the right degree to be able to provide usable evidence to the HTA agencies, but also that each stakeholder group can interact with one another at European as well as national and local level.
- Different types of organisation have a role to play – so long as there is clarity of inter-relationships and structures.
- There might be a need to move away from the conventional focus on only health actors, but to take a more holistic societal value approach. This means a matrix interaction at regional, national and European levels.

National health authorities and HTA organisations

- On an ad hoc basis: 2 respondents
- To a limited extent: 6 respondents
- Extensively: 4 respondents

As to why stakeholder consultation is used, respondents report different reasons. The overall pattern is nevertheless (average values; answers ranging from 1 to 5 with 5 as highest priority):

Respondents differ in their feedback on when in the HTA process stakeholders are consulted (average values, answers ranging from 1 to 4 with 4 as highest priority):
Respondents' feedback regarding when stakeholders should be consulted in the future HTA network differs from what is reported to take place in national settings:
When it comes to needs to participate as a stakeholders in the future HTA network activities, citizen/patient responders have the following priorities (4 highest score possible):

![Graph showing priorities of citizen/patient responders](chart1.png)

When it comes to needs to participate as a stakeholder in the future HTA network activities, industry responders have the following priorities (4 highest score possible):

![Graph showing priorities of industry responders](chart2.png)
When an HTA report is prepared and undertaken, payer respondents' have the following priorities (4 highest score possible):

Also within this group, appraisal/verification has a lower priority than the other two alternatives.

There are 12 respondents in this group, of which 8 produce HTA reports regularly/often. All but two respondents are responsible for medicinal products, and many of them have responsibilities related to medical devices, hospital interventions and/or preventive actions.

As regards the extent to which stakeholders are consulted, practice among countries varies:

The large majority of respondents has a similar approach to which stakeholder groups are consulted, including at least three of the four groups in the questionnaire. Only two respondents diverge (both using consultations to a limited extent), one only consulting patient organisations and the other only industrial companies.

This might reflect the experiences of some of the respondents with past and current activities in EUnetHTA. In any case, responders' divergent views are reflected in the relatively small differences in scores.
One responder points to the fact that the future HTA network not necessarily will have as its core business to carry out HTA assessments, and that capacity building both within HTA organisations and in stakeholder organisations might be just as important.

In this group, respondents point to the following examples of well-functioning stakeholder consultation approaches at national level in the field of HTA:

One respondent reflects on this issue in detail:

*Stakeholder involvement is necessary for increasing quality, relevance and acceptance of HTA-research, not for “democratic” reasons alone. It has to be organised wisely, otherwise it can be very time-consuming. Therefore: the more focused and project-specific the better the gain/benefit in increasing quality, relevance and acceptance.*

*Generalists (“meta”-representatives of stakeholder-institutions: EU-patient organisations, EFPIA, etc.) should ONLY be involved in public consultation of methodology issues (e.g. REA-guidelines), but when a drug is actually assessed (guided by REA-guidelines) the respective company, the respective patient group, the respective provider-group concerned should/might be consulted (if a gain/benefit in increasing quality, relevance and acceptance is to be expected).*

- **Sweden:** Patient and user organisations are offered the opportunity the give opinions on the investigation file and suggested decision on the reimbursement of medicinal products. During the consultation, neither the suggested decisions nor the opinions given are public.

- **Austria:** Stakeholders are involved in three stages of HTA projects: a) industry is consulted to identify unpublished studies/ongoing trials in the beginning, b) identifying unpublished studies by peer review of (clinical) experts (providers) in the end (appraisal/verification of the draft report), c) Scoping for increasing relevancy of research (providers: organisational problems that hinder, patient relevant outcomes, “acceptable” risks/ adverse events, standard practice. Regulators: hidden agenda, policy question)

- **Belgium:** See KCE-report 174c, January 2012

- **England/Wales:** The process guides for the development of HTA guidance of NICE

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5 Available at [http://www.nice.org.uk](http://www.nice.org.uk)
Parties contributing to the consultation

The following have contributed with input to the consultation (geographical location is not indicated for multi-/pan-European parties).

Patient and citizen organisations:
- Active Citizen Network, Italy
- BEUC, the European Consumers' Organisation
- Dutch Association for Neuromuscular Diseases, Netherlands
- EURORDIS
- European Genetic Alliances' Network
- Foundation for Christianity, Hungary
- GAMIAN Europe
- Pain Alliance Europe

Industrial companies and associations:
- Association of the European Self-Medication Industry
- Baxter
- Bundesverband Medizintechnologie, Germany
- COCIR
- EUCOMED
- EuropaBio
- European Diagnostics Manufacturers Association (EDMA)
- European Federation of Pharmaceutical Industries and Associations (EFPIA)
- Ferring Arzneimittel GmbH, Switzerland
- Ferring SPA, Switzerland
- Ferring International Center SA, Switzerland
- Johnson & Johnson
- Novartis
- Pfizer
- Plasma Protein Therapeutics Association
- Roche
- Vibrant MED-EL, Austria

Payer organisations and associations:
- Association Internationale de la Mutualité (AIM)
- European Social Insurance Platform (ESIP)
- IKK e.V., Germany
- Union Nationale des Mutualités Libres, Belgium
Health professionals' associations:

- Comité Permanent des Médecins Européens (CPME)
- European Association for the Study of the Liver
- European Association of Neurology
- European Glaucoma Society
- European Nurse Directors’ Association (ENDA)
- European Society of Cardiology
- National Society of Statutory Health Insurance Physicians, Germany

Other:

- EPPOSI
- Health First Europe
- HTAi Patient and Citizen Involvement in HTA Interest Sub-Group (PCISG)
- Institute for Economic Research, Slovenia
- Jose Manuel Cebrian Gregorio, Spain

National/regional authorities and HTA organisations:

- AHTAPol, Poland
- College voor zorgverzekeringen (CVZ), Netherlands
- Dental and Pharmaceutical Benefits Agency (TLV), Sweden
- INAMI, Belgium
- Ludwig Boltzmann Institute, Austria
- Ministry of Health, Council for HTA, Czech Republic
- Ministry of Health, Malta
- National Institute for Health and Clinical Excellence (NICE), United Kingdom
- National Institute for Quality and Organizational Development in Healthcare and Medicines, Hungary
- National School of Public Health, Management and Professional Development, Bulgaria
- State Health Accreditation Agency, Lithuania
- Veneto Region, Italy