POSITION

Hauptverband der österreichischen Sozialversicherungsträger

Strengthening EU Cooperation on Health Technology Assessment (HTA)

Comments to the European Commission's Public Consultation

4 January 2017

Hauptverband der österreichischen Sozialversicherungsträger
Main Association of Austrian Social Security Institutions
1031 Wien, Kundmanngasse 21
+43 1 71132-0
posteingang.allgemein@hvb.sozvers.at

HVB/2017

Content

I. Introduction

The Austrian social insurance system comprises health, accident and pension insurance. It is based on the principles of compulsory insurance, solidarity and self-governance. Responsibility for social security is delegated to independent bodies – the insurance/social security institutions. There are 22 statutory social security institutions – 15 providing health insurance and 7 general insurance institutions – some of which are not only responsible for one but for two or even all three types of insurance. For historical reasons the system is structured both geographically and professionally.

The umbrella organisation of all social security institutions is the **Main Association of Austrian Social Security Institutions** (*Hauptverband der österreichischen Sozialversicherungsträger (HVB)*). The *HVB* is responsible for safeguarding general social security interests and for representing the social security institutions in matters of common concern (e.g. concluding contracts with doctors, hospitals, etc.). It also represents the Austrian social security system in dealings with similar organisations abroad and, in an international context, acts as an access point and liaison body in matters of health, accident and pension insurance. The *HVB* is a member of the European Social Insurance Platform (ESIP) and is listed in the European Union's transparency register (ID-number 685141118619-24).

In the framework of the ongoing consultation it has to be highlighted that the *HVB* acts both as a **pricing and reimbursement authority** for pharmaceuticals (i.e. „payer") in outpatient care and as a **HTA body for pharmaceuticals and non-pharmaceutical interventions including medical devices**.

II. Comments to the consultation

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
*a) There are differences between **HTA procedures** among EU Member States (e.g. responsibilities of authorities, including advisory vs decision-making role and product scope; prioritisation/selection of health technologies to be assessed; duration of procedures; rights/obligations of sponsors during the procedure)	X	○	○	○	○	○
*b) There are differences between **HTA methodologies for the clinical assessment (REA [= relative effectiveness assessment])** among EU Member States (e.g. different data requirements for the submission dossier; choice of comparator; endpoints accepted; way of expressing added therapeutic value).	X Out patient pharma	X Medical devices	○	○	○	○
*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).	X Out-patient pharma	○	X Medical devices	○	○	○

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

Pharmaceuticals for outpatient use

There are several observed differences between the Austrian procedure according to the Erstattungskodex (i.e. code of reimbursement which is a positive list) and other countries.

Just a few examples:

In Austria the assessment and the reimbursement and pricing-decision for outpatient-pharmaceuticals are conducted in parallel by the HVB; in other countries they are sometimes conducted sequentially and even by different institutions. Also assessment and appraisal are often seen as two distinct processes in the European context.

In Austria, the HVB usually performs single-technology assessments. In England, for example, also multi-technology assessments can be conducted.

While the HVB is only in charge of the assessment of outpatient pharmaceuticals, in other countries both outpatient and inpatient pharmaceuticals are assessed.

The timeframe differs between countries because in some countries like in the Netherlands there are pre-submission meetings to discuss the pre-submission dossier, whereas in Austria the timeframe is 180 days from the time of submission (excluding possible clock-stops of max. 60 days due to clarifying questions or requests for additional data).

Unlike in other countries (e.g. Germany – all assessments are publicly available, Belgium – assessments are published/made available upon request) all assessments are confidential.

Recently, managed entry agreements have become an option particularly for very expensive pharmaceuticals. These are, however, also confidential. In some countries standard contracts for managed entry agreements exist whereas in others these agreements are tailored to the specific circumstances of individual products.

Non-pharmaceutical interventions including medical devices

Usually the health service and not the single medical device is the object of reimbursement. An assessment will therefore include the functional category of devices and/or services. Usually it is assessed in the view of social security system to be reimbursed in case of effectiveness and necessity in curing the disease.

Joint assessments are used for decision support, and if necessary adapted for national specialities. The reimbursement decisions for the outpatient health care sector are done by the sickness funds, the reimbursement decisions for the inpatient health care sector are done by the counties (*Bundesländer*), the ministry of health and the social insurance in a common process using HTA assessments as a decision support.

The decision support using HTA assessments is mainly done for interventions which are currently not covered by statutory health insurance (i.e. new interventions). There is no common procedure for re-assessing particular devices or services using HTA assessments. HTA assessments are done internally (in HVB), contracted with other Austrian HTA institutions (i.e. LBI HTA) or conducted within the framework of EUnetHTA. The decision on the level of reimbursement is taken separately.

In general, we do not observe many differences between Austria and other EU countries for the HTA supported decision process for the reimbursement of non-pharmaceutical interventions.

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

Pharmaceuticals for outpatient use

In Austria, the Market Authorisation Holder (MAH) submits a number of key documents, including the Summary of Product Characteristics, the European Public Assessment Report, European prices and a maximum of three clinical “key” studies. These documents may be supported by additional documents, such as systematic reviews, etc. Any type of study design has to be considered in the assessments – ranging from RCTs (randomized clinical trials) to expert opinions. Other countries have stricter rules.

Neither the assessments nor the documents submitted by the MAH are published in Austria. Other countries publish their assessments and also the submitted dossiers.

If relevant and possible, the comparators are identified based on the 4th level of the ATC Code. If this is not feasible, further levels of the ATC code are used or the standard of care for the respective indication is used. Off-label use of potential comparators cannot be considered as treatment alternative.

The results of the HVB’s evaluations are explicit classifications in terms of pharmacologic, therapeutic and economic value. During the pharmacological evaluation the aim is to determine one of eight degrees of innovation (from 1. generic product, that is containing the same active substance, the same strength and the same mode of administration to 8. the substance allows the treatment of a specific disease for the first time). The aim of the medical-therapeutic evaluation is to determine and quantify the benefit of a drug in relation to its treatment alternatives on a scale from 1 to 6. Divergent classifications are used in countries.

Even though patient relevant outcomes (morbidity, mortality, quality of life) are preferred there is no legal definition of “patient relevant”. If patient relevant outcomes are not available, surrogate endpoints are accepted but no guidelines exist how the validity should/has to be assessed.

In terms of recommendations for reimbursement, the Drug Evaluation Committee assists the HVB in elaborating an ultimate decision. The members of this committee are representatives of the Social Insurance System, the Austrian Chamber of Commerce, independent pharmacologists/physicians, Federal Labour Board, the Austrian Medical Association and the Chamber of Pharmacists. Comparable advisory boards in other countries include different stakeholders.

Non-pharmaceutical interventions including medical devices

We do not observe many differences between Austria and other EU countries for the HTA supported decision process for the reimbursement of non-pharmaceutical interventions.

Sometimes the national timeframe for an assessment does not allow conducting joint assessment with other Members States risking to be too time-consuming

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

Pharmaceuticals for outpatient use

In Austria, QALYs or ICERs are not used for cost-assessment or pricing. Cost-effectiveness models deviate and in some countries these models have to be part of the submission dossier.

However, since HVB would favour joint assessments in terms of RAPID REAs over full assessments, eliciting differences for economic methods might be less relevant.

Non-pharmaceutical interventions including medical devices

In Austria we do not use QALY or ICER for cost-assessment or pricing.

3.2 In your opinion, differences among EU Member States regarding HTA procedures and/or methodologies may contribute to (one or more answers possible):

x a) Duplication of work for your organization

☐ b) Less work for your organisation

☐ c) High costs/expenses for your organisation

☐ d) No influence on costs/expenses for your organisation

x 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

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):

X a) Yes, HVB has 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

X 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)

X a) Allowed for sharing best practices

X b) Allowed for better knowledge of procedures and methodologies in other EU Member States

X c) Allowed for savings in your organisation

X d) Contributed to building trust between organisations and professionals involved

X e) Contributed to HTA capacity building

X f) Provided access to joint work[*]

X g) Provided access to work done by other HTA bodies

X h) Provided access to expertise not available in my organisation

☐ i) Reduced workload for my organisation

X j) Contributed to increasing awareness and knowledge on HTA issues in my organisation

☐ k) Promoted involvement of patients' representatives in HTA activities

☐ l) Other

* "Joint Work" refers to activities in which countries and/or organisations work together in order to prepare shared products or agreed outcomes. These may include, for example, literature reviews, structured information for rapid or full HTAs, early dialogues or scientific advice on R&D planning and study design. Joint work aims at supporting Member States in providing objective, reliable, timely, transparent, comparable and transferable information and enable an effective exchange of this information (according to HTA Network's "Strategy for EU Cooperation on Health Technology Assessment" adopted in October 2014)" (according to HTA Network's "Strategy for EU Cooperation on Health Technology Assessment" adopted in October 2014)

For l) 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)

Up to date, HVB has mostly been involved in the assessment of non-pharmaceutical interventions and to a lesser extent in the assessment of outpatient pharmaceuticals. The answers therefore mainly account for non-pharmaceutical assessments and for common methods and tools from EUnetHTA. The common methodology (i.e. Core Model, templates for rapid assessments) creates comparable results and increases trust into the results of others.

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, Core model)		X medical devices	X outpatient pharma	
*b) Guidelines (e.g. for clinical and/or economic evaluations)		X medical devices	X outpatient pharma	
c) Early dialogues			x	
*d) Joint reports on clinical assessments (REA)	X medical devices		X outpatient pharma	
*e) Joint full HTA (clinical and organisational/social/legal/ethical assessment)	X medical devices		X outpatient pharma	
f) Other (please specify below)				

* Early Dialogue (ED or early scientific advice) aims to provide prospective, transparent and timely advice by regulators or HTA body/bodies (multi-HTA) or both (parallel) to product' sponsors so that they may integrate their specific needs in the product development and generate evidence appropriate for HTA purposes (definition proposed by the EU-funded study SEED)

For 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

General shortcomings:

- difficulties in terms of producing joint assessments in time
- difficulties in terms of topic selection (i.e. relevance of the assessed pharmaceutical)
- open questions concerning quality assurance within the joint assessments
- resources needed; i.e. participation in joint assessments in addition to daily work-load
- internal lack of communication between WPs
- lack of common rules on necessary/supportive data provision from companies for joint assessments (especially for pharmaceuticals)
- lack of clear common wording and definitions (e.g. for use/ re-use; impact; decision support; etc.)

Shortcomings regarding EUnetHTA tools:

- lack of particularly relevant features (i.e. exchangeability for single issues/ domains within the Core model online tool; REA frame in Core Model online tool; possibility to write the national assessment directly in the online tool; export as a pdf – function)
- lack of a common database of HTAs resting on EUnetHTA joint assessments (i.e. results from POP Db which are published)

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

X f) Joint work is not recognised within Member States

X g) Accessing joint work and/or work done by other HTA bodies was difficult

☐ h) Joint work is not relevant for my organisation

X i) Other

For i) Please specify 'Other':

As laid out in the consultation document, current challenges that health care systems are facing are manifold necessitating a joint response from payers/HTAs. In addition, joint assessments save resources by sharing expertise and therefore allow the evaluation of a larger number of technologies. This contributes to sustainable health care systems and to timely patient access to safe and effective technologies.

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

- reducing work-load by re-using EUnetHTA assessments of JA1 and JA2 (in the field of medical devices)
- using common methods (in the field of medical devices)
- using the commonly developed REA/RA assessment template for medical devices (word format)
- knowledge transfer with experts from other organisations/ countries

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)?

X a) Yes

○ b) No

○ c) I don't know / No opinion

For a) If yes, please specify:

A sustainable high-quality health care system needs a structured and methodologically sound evaluation for deriving reimbursement decisions**.** The development of guidelines and templates which could and should serve as commonly accepted tools in Europe foster comparability across individual Member States assessments (MS) potentially reducing duplication. In addition, joint assessments can save resources by sharing expertise and therefore allow the evaluation of a larger number of technologies.

Generally, a strong HTA network on a European level is of utmost importance to strengthen payers/HTAs. Since considerable resources have already been invested in European HTA collaboration and different stakeholders have expressed their support for a strengthened cooperation, **risking an end of the cooperation should be avoided under all circumstances.**

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)	X			

For c) Please specify 'Other':

For non-pharmaceutical interventions with or without using medical devices.

4.1.2 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 (RA)	X (medical devices)	X (outpatient pharma)		
*e) Joint full HTA (clinical and economic assessment)		X (Health system interventions)		
f) Other (please specify below)				

For f) Please specify 'Other':

/

4.1.2.1 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)

- Especially larger countries with well-established HTA systems might be reluctant to adopt new methods and to engage in the production and reuse of jointly developed HTAs. Participation of these countries, with a high purchasing power, is fundamental for a truly functioning internal market and a streamlined system for assessments/data generation.

- Legal obstacles can hamper adoption of new methods.
- Workload: Depending on the type of the joint assessment (single vs multi-technology assessment; joint vs collaborative assessment) the additional work-load of producing joint assessments can be substantial. Also, familiarisation with EUnetHTA tools and templates as well as the underlying processes of the joint assessments requires staff time. On the other hand, time savings can be accrued if re-use of joint assessments is possible on a large scale.

4.1.3 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

X e) Other

For e) Please specify 'Other':

Monetary EU-contributions for those member states that actively produce HTA assessments for the network could be reduced. This would **not require any fixed budget** and **incentivizes contributions**. Alternatively the HVB would prefer option d).

4.1.3.1 Please explain your answer and comment on issues such as feasibility, advantages and disadvantages *(2000 character(s) maximum)*

/

4.1.4 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

x e) Other

For e) Please specify 'Other':

A strong cooperation with existing EU agencies (EMA) and the HTA Network should be envisaged. However, under any circumstance there should be a clear distinction between market authorization (i.e. EMA) and reimbursement decisions. This should also be visible in terms of the affiliation of the secretariat. Preferably, the coordination stays within the HTA bodies. However, a rotation of the secretariat will not contribute to a secure and consistent management of the large network which requires substantial organizational expertise as well as human resources.

4.1.4.1 Please explain your answer(s) and comment on issues such as feasibility, advantages and disadvantages *(2000 character(s) maximum)*

See above.

4.1.5 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)	○	○	○	○	**X**
*b) Voluntary participation with mandatory uptake of joint work for the participants	**X**	○	○	○	○
*c) Mandatory participation with mandatory uptake of joint work	○	○	○	**X**	○
d) Other (please specify below)	○	○	○	○	○

For d) Please specify 'Other':

/

4.1.5.1 Please explain your answer(s) and comment on issues such as feasibility, advantages and disadvantages *(2000 character(s) maximum)*

The document (Strengthening of the EU cooperation on HTA) highlights the most distinct options of pursuing collaboration. However, several issues remain unclear, making a definite answer difficult.

1. We acknowledge that options which require **legislative changes are more difficult to implement**. However, the previous Joint Actions relied upon a voluntary system and resulted in modest reuse of joint assessments. Similarly, the introduction of commonly developed tools as standard procedure in national systems has been slow.

2. (Re-)use: In order to increase the acceptance and the uptake of any outputs of the HTA cooperation by the MS its necessary to define the terms (i.e. definition of (re-)use of common tools/assessments, compulsory for the results etc.) in a standardized way so that the MS can estimate the consequences and/or the obligations of a closer cooperation on the national systems of pricing and reimbursement. Re-use could range from just considering the results of the joint assessment over a mandatory incorporation/translation of the results for national assessments to a complete replacement of nationally conducted assessments. If the results were seen as an additional document (in addition to the submission dossier) which will be

considered in the national evaluation, this would (currently) not pose a difficulty. It should be emphasised though that reimbursement decisions should stay national responsibilities and that re-use should under no circumstances be mandatory when active participation in the joint assessments has not taken place.

3. It is also necessary to establish a legal framework for EUnetHTA: e.g. the authorities of pricing and reimbursement should have access to all documents submitted by the MAH for the joint assessments. Furthermore, pricing and reimbursement decisions based upon joint assessment are time-consuming, thus also requiring an extension of current the deadlines as set out in the Transparency Directive (89/105/EEC). The legal framework which sets out how data is collected, shared and used has to comply with national legal requirements, especially with data protection to ensure a transparent process.

4. Types of assessments: it might be advisable to not clearly distinguish between options 4 and 5 (rapid vs full assessments) but to use a more general approach. As a mandatory requirement, the domains of the rapid model have to be addressed in all joint assessments, but if time allows it should be up to the authors to also include elements from the full model.

5. Topics & timing: if voluntary participation is to be successful, differences in scope (e.g. in-vs outpatient drugs) have to be taken into account. Also, in Austria the MAH has to submit an application. If they do not, (re-)use is not possible. Therefore, the topics selected should cover all MS needs. Also, the timely production of the joint assessments is key to allow potential use of the results which are in line with legal national requirements.

4. Any other comments. Uploading relevant documents is also possible. (2000 character(s) maximum)

On the operative level the *methods development* should be **balanced** with the *production of HTA reports*, especially in the view of uptake of available reports and reduction of single national HTA production. It has to be taken into account that **only a published report can be taken for decision making and create impact**. There is still no common understanding about the definition of “impact”.

The uptake and impact of already collaboratively produced EUnetHTA reports was measured within the evaluation work package (WP3) in Joint Action 2 and provides additional and detailed information to the referred sources (footnote 54, 55 and 56 in the strategy document), done by a mixed method approach of qualitative, quantitative and modelling parts for estimated costs.

We suggest **not to use costs in €** terms due to a high variety of salaries and pricing among the EU member states, **but to use person days/ person months for** a more valid **comparison**.

The results of the evaluation of Joint Action 2 show, that the uptake will probably increase

- with more existing assessments from EUnetHTA addressing more different topics (currently it is only 4 from JA1, and 15 from JA2)
- by trust in the good quality
- by improved consistency and shared results within the HTA Core Model online tool

The relatively low uptake within Joint Action 2 was due to the high production rate of joint assessment by the end of the project.

As evaluated within the survey(s) there was a higher uptake planned after the finalisation of Joint Action 2.