QUESTIONNAIRE FOR ADMINISTRATIONS, ASSOCIATIONS AND OTHER ORGANISATIONS

Fields marked with * are mandatory.

INTRODUCTION

QUESTIONNAIRE FOR ADMINISTRATIONS[1], ASSOCIATIONS AND OTHER ORGANISATIONS [2]

GENERAL CONTEXT

In recent years a number of Member States have introduced so-called health technology assessments (HTA). Typically HTA measures the added value of a new technology in comparison with existing technologies. For the purpose of this survey, health technologies include, pharmaceuticals, medical devices, medical and surgical procedures and other measures for disease prevention, diagnosis or treatment used in healthcare. More information on health technologies is available at http://ec.europa.eu/health/technology_assessment/policy/index_en.htm.

HTA is a very useful tool, as it helps Member States to decide which health technology to favour at national/regional level. It also helps Member States to keep their health budgets under control, as products with no or limited added value cannot expect to be reimbursed or to obtain high prices. Last but not least HTA encourages industry to invest in innovation with substantial added benefits for patients.

Traditionally two types of assessments have been distinguished, namely (1) assessments focusing on clinical/medical benefits of the new technology (does a given technology work better than an exisiting one) and (2) assessments focusing on the economic benefits of the new technology (value for money). These assessments can be carried out jointly or consecutively, by dedicated HTA bodies or other organisations (e.g. regulators for pharmaceuticals).

At this stage, the vast majority of HTA are carried at national/regional level, i.e. EU Member States assess the new technology according to its national legislation. This leads to duplications of efforts for Member States and industry which translate in unnecessary costs throughout the HTA process. It can also lead to diverging results/outcomes (i.e. health technologies available earlier in some countries compared with others), which in turn can result in limited business predictability for industry and delayed access for patients.

Several projects funded by the EU have allowed Member States to share best practices on how HTA is carried out at national and/or regional and local level. Also a limited number of joint HTA reports have been prepared, but the use of these results is still decided at national level. In practice this has meant that the joint reports have not (yet) been used on a large scale.

There is consensus that HTA requires significant scientific, technical and economic expertise, and is costly. Currently not all Member States have such expertise at their disposal. Budget constraints also mean that even advanced Member States considered to be more advanced in this field cannot asess all new technologies. This has triggered the question whether there is a need to strengthen EU cooperation for HTA, in particular for the period beyond 2020 when the current financing of EU cooperation ends (so-called EUnetHTA Joint Action 3[3]).

For further details please refer to the Inception Impact Assessment on strengthening EU cooperation on Health Technology Assessment (HTA)[4].

OBJECTIVE OF THE CURRENT SURVEY

The aim of this public consultation is to gather detailed views and opinions regarding the future of the EU cooperation on HTA. The results of this public consultation will feed into the envisaged impact assessment which the Commission services are currently preparing on strengthening the EU cooperation on HTA.

This questionnaire is addressed to administrations, associations and other organisations. Citizens are asked to fill in a separate non-specialised questionnaire.

[1] For the purpose of this survey, administrations refer to both public administrations, as well as private administrations with public service obligation

[2] For the purpose of this survey, associations and other organisations refer to trade associations, professional associations, academia and scientific societies and organisations representing the interests of specific stakeholders

[3] European Network for Health Technology Assessment (EUnetHTA) is a Joint Action, co –funded by the Health Programme of the European Commissions (DG SANCO) and participating organisations. It gathers mainly national and regional HTA bodies. Its scope of activities is on scientific and technical issues. www.EUnetHTA.eu

[4] http://ec.europa.eu/smart-regulation/roadmaps/docs
/2016_sante_144_health_technology_assessments_en.pdf

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

European Cancer Patient Coalition

*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?

57929627082-79

* In the interest of transparency, organisations and associations have been invited to provide the public with relevant information about themselves by registering in Transparency Register and subscribing to its Code of Conduct. If the organisation or association is not registered, the submission will be published separately from the registered organisations/associations.

*1.4. Please enter your e-mail address (this data will not be made public).

francesco.florindi@ecpc.org

*1.5. The name of a contact person (please note that the name will not be made public and is meant for follow-up clarification only)

Francesco Florindi

*1.6. Do you consent to the Commission publishing your replies?

- (●) a) Yes (*On behalf of my organisation/association/administration I consent to the publication of our replies and any other information provided, and declare that none of it is subject to copyright restrictions that prevent publication*)
- ( ) b) Yes, only anonymously (*The replies of my organisation/association/administration can be published, but not any information identifying it as respondent*)
- ( ) c) No (*The replies provided by my of my organisation/association/administration will not be published but may be used internally within the Commission. Note that even if this option is chosen, your contribution may still be subject to 'access to documents' requests.*)*

* As set out in Regulation (EC) No 1049/2001, any EU citizen, natural, or legal person has a right of access to documents of the EU institutions, including those which they receive, subject to the principles, conditions and limits defined in this Regulation.

2. IDENTIFICATION OF RESPONDENT

*2.1. Main field of work of the responding organisation/association/administration (*one answer possible*):

- ○ a) Public administration (other than payers)
- ◉ b) Patients and consumers
- ○ c) Healthcare provider
- ○ d) Payer (irrespective of status i.e. public or private)
- ○ e) Industry or service provider
- ○ f) Academia or scientific society
- ○ g) Other

** Small and medium-sized enterprises (SMEs) are defined in the Commission Recommendation 2003/361. The category of micro, small and medium-sized enterprises is made up of enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million.*

*2.2. Please specify the geographic coverage of your organisation/association/administration (*one answer possible*):

- ◉ International/European
- ○ National
- ○ Regional/local

*2.3. Are you an organisation/association/administration representing the interests of the stakeholders mentioned in question 2.1 (*one answer possible*):

- ◉ Yes
- ○ No

*2.4. Please specify which health technologies are of interest for your organisation/association /administration (*one or more answers possible*):

- ☑ a) Pharmaceuticals
- ☑ b) Medical devices[*]
- ☑ c) Other

** "Medical device" means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means (Council Directive 93/42/EEC of 14 June 1993 concerning medical devices). Please note that the current legislation has been revised and the new requirements will be published soon.*

*2.4.c. Please specify 'Other':

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medical procedures, organisation of care.
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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)	◉	○	○	○	○	○

*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).	◉	○	○	○	○	○

*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).	◉	○	○	○	○	○

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

While HTA is increasingly being performed by Member States, it is also true that not all EU countries perform HTA, or do perform it in comparable ways to other countries. In this respect, we are aware of the incredible variety and differences of HTA procedures across Europe, and the difficulty to compare considerably differing procedures in many different languages. We often receive complaints from our members but it is difficult for a patient organisation to check the legality of procedures in legislation and regulations in so many languages. While the EU has adopted a common procedure for granting market authorisation to cancer medicines through the European Medicines Agency (EMA), pricing and reimbursement decisions reside with national governments/agencies. In many countries, pricing and reimbursement decisions including the impact of HTA's recommendations are not fully transparent nor easily accessible to citizens. We share the assessment of the European Commission expressed in issue 2.
In particular, regarding the nature of the report produced by HTA agencies, we strongly believe that non-binding reports undermine the principle of evidence-based policymaking. As a consequence, economic factors impact decisions on pricing and reimbursement more than health-related factors. ECPC believes that HTA at the national level must be taken into consideration within the pricing and reimbursement decision. The extent of the legally binding value of the HTA reports should vary in relation to the specific set up of each healthcare system.
Regarding the duration of the assessment, the vast difference in HTA procedures creates unacceptable differences in the timeframe of production of HTA evaluation across Member States. Despite an EU Directive on pricing and reimbursement that specifies a 180-day limit post EMA authorisation for national implementation, adherence/compliance with this deadline is extremely variable. The same medicine can be reimbursed in one country few days after the EMA market authorisation, but it might take years to be reimbursed in a

bordering country.
Thus, for a drug like trastuzumab (included in the WHO list of essential medicines in 2015) and which targets the ERB2 receptor and has led to a new standard of care for this aggressive form of breast cancer, there are marked differences in time to approval/reimbursement across EU members. For metastatic disease for example, variations within Western Europe were significant; while countries like Germany, the Netherlands and Spain had rapid approvals, in the UK (+564 days), Belgium (+1160 days) and Denmark (+1891 days), delays were significant. Disparities were even more pronounced in Eastern Europe, with all countries but the Czech Republic exceeding the 180 day limit, while for certain countries e.g. Hungary (+2713 days), Romania (+2878 days), Slovakia (+3686 days) and Latvia (+4660 days), delays were even more striking and were associated with concomitant reductions in breast cancer survival.
The two-stage process for registration of new therapeutics, involving both EMA approval and in many countries, a HTA, allied to the pricing/ reimbursement issues outlined above, can lead to significant differences in time-to-access for new therapeutic interventions.
Finally, medical devices and procedures are not uniformly assessed and reviewed across Member States. While we do have pan-European guidelines of organization of care and care pathways for many cancers, those are not uniformly assessed from an HTA perspective. In cancer, the cost of medicines accounts for approx. 15-20% of the overall cancer budget, while the rest is spent on other healthcare services. To ensure sustainability of cancer care, we believe that a cost-effectiveness evaluation of medical devices, cancer screening, radiotherapy services, surgeries and pathways of care should be performed to identify inefficiencies in the system and properly evaluate innovative treatment modalities in order to decrease inefficiencies and evaluate investment plans.

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

Concrete examples are scarce, not because patients are not interested in HTA but because their participation is in HTA procedures is limited, not sought, not facilitated by the HTA Agencies and often are not reported.
The involvement of patients in the HTA process is patchy and overall insufficient in those countries where HTA is performed. During a recent survey among the participants to the ECPC Annual General Meeting (Europe's largest gathering of cancer patients, Brussels, June 2016), none of the approx. 120 participants representing our 408-strong membership was involved in any way in health technology assessments at the national level.
At the same time, patients' organisations' understanding of the role HTA plays in the decisions on pricing and reimbursement is insufficient or simply non-existent. This is exacerbated by the fact that the HTA procedures vary enormously from one country to the other, de facto undermining any attempt by umbrella patient organisations to provide actionable information and tools to national patients' organisations on how to fruitfully contribute to the HTA process.
In general, ECPC questions the role that national medicines agencies play in the production of HTA (Italy, for example). We strongly believe that a body independent from medicines agencies and national ministries should be in charge of producing HTA reports, to avoid any possible conflict of interests and/or exploitation of HTA for political or economic reasons. In this respect, we believe that NICE remains the reference model in Europe, from both patient-representation and independence perspectives.
There are a few possibilities in Europe for patients and patient organizations interested in learning about HTA and those are available so far only in English language, from various organizations, (EMA, LSE, HTAi, ACN, ISPOR, etc.) but not from national HTA agencies, thus making language an additional barrier.

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

EU cooperation on health technology assessment and a more efficient implementation of the Transparency directive can effectively cut delay in access to innovative medicines. However, the broader issue of affordability of new cancer medicines relates to larger economic and financial situation at the Member State level.
The official list prices of anticancer medicines vary widely across Europe, while the actual prices paid are unclear owing to confidential discounting [Vogler et al. 2016A]. Most EU Member States negotiate a national price for new medicines using 'international reference pricing', i.e. based on the price in other countries. This leads to inefficiencies in the way prices are negotiated, leaving smaller and poorer EU countries with little negotiation leverage and therefore hampering these countries' capacity to access new

medicines. Furthermore, national healthcare budgets rarely match the burden of cancer: the national expenses on cancer in many EU countries have stagnated or decreased, often due to austerity measures and overall poor economic performance, thereby curtailing the budget available for new medicines. This means that the few resources available must be equitably divided between these modalities (surgery, radiotherapy, medicines, etc) to provide the best value for patients. As a result, decisions on pricing and reimbursement (and ultimately access) are often driven by financial considerations more than by considerations regarding the overall value of the overall services brought to patients, therefore increasing the existing inequalities in access to healthcare.
Over-bureaucratisation of HTA, and duplication of assessment done at the national level contributes to the unfavourable state of the art, by creating delays in the pricing and reimbursement decision.
For this reason, ECPC welcomes the introduction of pay-for-outcome schemes that would facilitate the evaluation of the effective value of new medicines. Such schemes must collect patient-reported outcome measures (PROMs) as well as other clinical, economic and legal/ethical information, in order to provide a comprehensive picture of the real impact of drugs within national healthcare systems. The preconditions to achieve actionable and effective new pricing models are: closer collaboration among EU countries on improving patients' access, better coordinated value assessment, horizon scanning, more consistent investments in health and, at the practical level, a well-functioning and interoperable eHealth infrastructure in each EU country.
Given the magnitude and the complexity of developing effective models for pay-for-outcome schemes, ECPC strongly believes that the best approach would be via a pan-European collaboration on the economics of cancer. To do this in an efficient manner, ECPC strongly encourages the European Commission, Member States and academia to work together towards the identification of pay-for-outcome models that would be implementable at the national level
ECPC supports the principle of outcomes-based pricing for new anticancer medicines. Outcomes-based pricing rewards improved outcomes for patients and healthcare systems rather than volume of usage - thereby representing a form of payment for performance. The wider application of outcomes-based pricing will require the integration of an agreed definition of how to measure appropriate outcomes and the establishment of suitable means to collect real-world patient-level data. Pricing should also be flexible over time, reflecting changes in assessed outcomes and cost-effectiveness during the lifetime of the medicine in question [Jonsson IHE 2016]. Research is required to evaluate the link between price and therapeutic value for new cancer medicines in Europe [Jonsson IHE 2016].
The first step towards such model would be the creation and implementation of pan-European full HTA assessment. We are aware that including cost-effectiveness evaluations in the European full-HTA evaluation would need to overcome important technical and political barriers. At the same time, we respect Member States ultimate competence in deciding on pricing and reimbursement of new drugs. However, we strongly believe that reference cost-effectiveness evaluations, that can be weighted by each countries' financial capabilities would lead to substantially fairer and more sustainable pricing negotiations.
Most importantly, it is necessary to routinely and systematically involve

patients in pricing decision-making process. In the scenario described, which requires a very efficient management of scarce resources, patients have little involvement in pricing decision-making. This may reflect a lack of will among authorities and appropriate forums and processes for patient input, together with a lack of knowledge and expertise in this area among patients.

*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 organisation
- [ ] b) Less work for your organisation
- [x] 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
- [x] g) Decrease in business predictability
- [ ] h) No influence on business predictability
- [ ] i) Incentive for innovation
- [x] j) Disincentive for innovation
- [ ] k) No influence on innovation
- [x] l) Other
- [ ] m) None of the above
- [ ] n) I don't know/No opinion

*3.2.l. Please specify if 'Other':

Unacceptable delays in access to innovative treatments.
Unacceptable differences in the time frame for access to treatments across EU countries.

*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*)

- [x] a) Allowed for sharing best practices
- [x] b) Allowed for better knowledge of procedures and methodologies in other EU Member States
- [ ] 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)*

*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)

During the ECPC Annual General Meeting 2016 (3-5 June 2016), both the European Commission Deputy Director General Martin Seychell and the EUnetHTA coordinator Wim Goettsch took part to the event, addressing the audience with key messages on HTA harmonisation at the EU level.

In particular, Goettsch presentation was key to increase our Membership's undertanding of HTA at both national and European level.
More details on the event can be found here: http://ecpc.org/about-us/annual-general-meetings/372-agm-2016

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)	○	◉	○	○
*b) Guidelines (e.g. for clinical and /or economic evaluations)	○	◉	○	○
c) Early dialogues	○	◉	○	○
*d) Joint reports on clinical assessments (REA)	○	◉	○	○
*e) Joint full HTA (clinical and economic assessment)	○	◉	○	○
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)

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

The deliverables of EUnetHTA 1 and 2 are key in the definition of the scenarios for an effective and actionable implementation of a pan-European HTA framework.
However, the Joint Action did not address the issue of patients involvement in HTA evaluations sufficiently. During a recent survey among the participants to the ECPC Annual General Meeting (Europe's largest gathering of cancer patients, Brussels, June 2016), none of the approx 120 participants representing our 408-strong membership was involved in any way in health technology assessments at the national level.
The Joint Actions do not provide a consolidated methodology to substantially and consistently involve patients and their organisations within the process of health technology assessment. Overall, the involvement of patient organizations in the JAs was sub-optimal. We acknowledge that the Core Model identifies specific assessment elements to include the perspective of patients. However, neither the Core Model nor the other EUnetHTA tools identify a stable table for discussion with patients organisations, nor does it specify how patient organisations can be empowered to be a true partner within the HTA evaluation.
This lack of focus on patients' and their role and perspective, and the lack of adoption of the Core Model undermines the otherwise great work done by the 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:

The important achievements of EUnetHTA must be fixed in a reliable EU regulatory framework that would facilitate the implementation of the EUnetHTA tools. We fully recognise Member States prerogative related to the decisions on pricing and reimbursement of healthcare services. At the same time, it is undeniable that EUnetHTA has provided much needed guidance on the harmonisation of a field of EU competence such as HTA. EU cooperation on HTA is perfectly in line and within the spirit of the EU Treaties

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	◉	○	○	○
*b) Medical devices	◉	○	○	○
c) Other (please specify below)	◉	○	○	○

*4.1.1.c. Please specify 'Other':

Considering that digital technologies have found their way in health care and that the European Commission recognizes their role (WG on mhealth guidelines assessment, ehealth stakeholder group, etc,) mhealth apps and ehealth systems should also be included in HTA. Mobile health applications use mobile devices to assist in disease prevention and improve treatment adherence or offer patient support. There are currently EU funded projects that study the use of mhealth apps in the clinical setting, and health systems that already use them. When assessing the value of mobile health applications, importance should be given to reliability, validity, stability, transparency, usability, safety, effectiveness, and security. The Commission already works on voluntary guidelines for the assessment of mhealth apps for mhealth developers, meaning that sooner or later mhealth apps will be accepted as another medical intervention.
Sustainability is also in line with the recommendations included in the policy paper on disinvestment produced within the Joint Action on Cancer Control (CanCon). The document, to be published in February 2017, and written with the contribution of several EU ministries, calls for a better economic and clinical evaluation of existing and innovative health technology, with the objective to phase out inefficient health services and to promote new or more cost-effective ones, fully respecting the right of all EU citizens to access essential and quality cancer care.
In our opinion, the best way to ensure that disinvestment policies are undertaken in respect of patients' rights is by assessing all health technologies, including, for example medical devices, medical interventions, digital technologies in cancer care, care organisation models, pharmaceutical products etc. using a harmonised HTA model.

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)	◉	○	○	○
*b) Guidelines (e.g. for clinical or economic evaluations)	◉	○	○	○
*c) Early dialogues	◉	○	○	○
*d) Joint clinical assessment (REA)	◉	○	○	○
*e) Joint full HTA (clinical and economic assessment)	◉	○	○	○
f) Other (please specify below)	○	◉	○	○

*4.1.1.2.f. Please specify 'Other':

Generally, the options 1 and 2 presented in the Commission's impact assessment maintain broadly the current state of fact. From this point of view, the shortcomings identified so far are not addressed therefore the ECPC considers that the options 1 and 2 do not provide any noticeable improvements. We consider option 3 to be the basic requirement for a successful implementation of the only two options providing real added value at the EU level: option 4 and 5.
ECPC strongly encourages the European Commission to propose legislation in line with scenario 5, therefore proposing full harmonisation of HTA at the EU level, including cost effectiveness, ethical and organisational aspects, but most importantly renewed and more inclusive patient and social aspects. ECPC recognises the complexity of implementing scenario 5, first and foremost in relation to the level of implementation of possible future joint HTA evaluation at the local level. Nonetheless, we call the Commission to propose a courageous plan for action, confident that the technical details can be worked out in collaboration with civil society, medical associations and other stakeholders in the coming years.
Finally, the impact assessment does not take into consideration how to harmonise patients' involvement in HTA. A possible solution would be to include in future legislative proposal the outcome of the IMI-PREFER project: http://imi-prefer.eu/ since it will produce results as to patient preferences regarding treatment. (IMI PREFER is only about medicinal products not the whole array of products, services and equipment entering HTA procedures).

*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)

ECPC strongly believes that any future HTA collaboration which would harmonise HTA evaluation below the level set by scenario 4 will be a failure. In this respect, we strongly believe that scenario 5 will provide EU Member States, industry and patients the greatest advantages, namely:

- Cut costs and duplication of efforts across HTA bodies: we agree with the Commission's evaluation ("Likely economic impact, Option 4 and 5"), but we believe that reduction of administrative and economic burden of HTA agencies at the national level will also be dramatically decreased, both in countries with established HTA bodies and in countries with emerging or no dedicated HTA agencies;
- Decrease the delay in access to innovative health technologies: option 5 guarantees that the best HTA possible is provided to Member States within a well-defined time limit, which will speed up the decision on pricing and reimbursement. This is crucial achievement for all patients, particularly for those from EU Member States having less established HTA bodies. In this respect, scenario 5 fulfils best the objectives of article 114 TFEU;
- Facilitate participation of patients in the HTA decision making process: having one, binding, European HTA evaluation for all health technologies will facilitate the contribution of European patients to the HTA decision making process, by providing one table of discussion on HTA, instead of the current 50+ HTA discussion tables. A selected number of expert patients can be easily involved in the assessment of new technologies, ensuring that the voice of patients is taken into due consideration. For scenario 5 to successfully fulfil such objective, it is necessary to identify a solid methodology, including patient education in HTA, institutionalized patient involvement in HTA decision making;
- Facilitate access to the market to healthcare companies: by having only one HTA body, industry will be able to create more reliable and solid collaboration with a competent, European actor, responsible for the HTA evaluation of new product. This will also cut costs for industry, since they will be able to dismantle/decrease national market access departments, in favour of a more solid and concentrated work at the European level. One HTA for all Europe means also that SMEs working in health will have the real capacity to access the whole of the EU market, without having to spend prohibitive resources in the establishment of national market access branches.

*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.e. Please specify 'Other':

Scenario 5 of the impact assessment should be supported by:
- EU funds
- In-kind contributions from existing national HTA bodies

To guarantee full independence of the future HTA evaluation, ECPC believes that industry should not be required to pay a fee to have their products assessed.

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

2000 character(s) maximum

See document attached

*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

2000 character(s) maximum

See document attached

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

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

2000 character(s) maximum

See document attached

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

2000 character(s) maximum

Please upload your file (2Mb max)

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