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

Ministry of Social Affairs and Health

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

Finland

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

no

* 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).

taina.mantyranta@stm.fi

*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)

Taina Mäntyranta

*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

*2.1.a.Please specify the type of administration (one or more answers possible):

- [ ] a) HTA body
- [ ] b) Marketing authorisation body
- [ ] c) Pricing and reimbursement body
- [x] d) Ministry
- [ ] e) 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*):

- [x] a) Pharmaceuticals
- [x] 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.*

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:

- Organisational setting/location within public administration of HTA agency (e.g. research institute vs. university vs ministry vs hospital, or national vs. regional)
- Status of HTA results (how mandatory it is to follow the findings, how the information is used within the health system)
- Existence and role of stakeholder participation (industry, patients)

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

- Local variation of health care practice may have an important impact on the exact choice of health technologies to be assessed and the comparators used. The “same technology” may actually mean different things in two countries, e.g. antibiotics may be given for 5 days in one country and 10 days in another. Also the generation of technologies may vary so that somewhat newer version of the same technology is used in some countries.
- There are differences between MS in how they handle for example indirect evidence: some consider it important, some do not use it at all.

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

- Preferred analysis type may vary (e.g. cost-minimization vs. cost-effectiveness vs. cost-benefit vs. cost-utility, or cost-effectiveness vs. budget impact)
- Selected outcomes vary (e.g. total cost vs. QALY)
- Due to the variability, sharing economic assessments with all MS does not seem possible. Nevertheless, cooperation between smaller groups of countries that have similar health systems and requirements for the economic evaluation maybe feasible, and could be be encouraged. For example, technical checking of an economic (cost-effectiveness or budget impact) model could be carried out in collaboration
- Due to the variability in health systems, sharing economic assessments between Member States is challenging. One option would be to design in joint assessment a shared health economic model that would be made publicly available and that could be populated with local data in each country. The model could also be edited/revised if needed, if it would be published in suitable format. Such an approach has been researched relatively little within the EUnetHTA until now. Increased transparency in health economic evaluation would allow also external peer review of the model, contributing to better quality of assessments.

*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
- [ ] l) Other
- [ ] m) None of the above
- [ ] n) I don't know/No opinion

*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
- [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
- [x] i) Reduced workload for my organisation
- [ ] j) Contributed to increasing awareness and knowledge on HTA issues in my organisation
- [ ] k) Promoted involvement of patients' representatives in HTA activities
- [ ] l) Other

* *"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)

- HTA collaboration has been an important learning process for the HTA staff through developing, defining and learning new HTA methodologies and practices and working on joint assessments.
- New professional networks have provided an opportunity to collaborate and consult in practical projects, also beyond the actual joint work
- Both joint tools and assessment results have been utilized by national agency, which has assisted practical work and brought cost savings when unnecessary duplication has been avoided (e.g. national adaptation of a joint full HTA).
- Joint methodology development has also given direction to national guidance on HTA
- A certain kind of “benchmarking” with regard to HTA expertise in comparison with other agencies has been useful.

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

- Not all agencies fully committed to originally promised contributions (in terms of manpower and/or expertise)
- Originally planned timelines were often changed, which caused problems for having adequate expertise available just at the right time
- Continuously evolving needs and practical implementation of the HTA collaboration posed challenges to the tools development (that often were designed based on some initial assumptions of the needs)
- Implementation of results (both tools and joint assessments) not on a satisfactory level
- Too few pilot projects available still
- Timing of joint work not always optimal, e.g. joint work on themes where national assessment already existed.
- Topic selection process used in JA and JA2 emphasized topics that were ranked as “highest priority” by several agencies, but the other priority levels (e.g. “high priority” or “low priority”) was not taken into account at all. This led to selection of topics that were of very high relevance to some agencies and of little or no relevance to many others.
- Implementation of tools and the results of joint assessments in Member States’ health systems not considered enough
- In Joint Action 3 there is too much emphasis on drugs and devices only, although national health systems need HTA information of several other important themes too, e.g. on population screening, public health, mental health and new disruptive technologies.

*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
- [x] 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
- [x] e) Increased workload for my organisation
- [ ] f) Joint work is not recognised within Member States
- [ ] g) Accessing joint work and/or work done by other HTA bodies was difficult
- [ ] h) Joint work is not relevant for my organisation
- [ ] i) Other

*3.3.1.2.1. 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.)*

- Special attention should be given to the topic selection process so that the joint work addresses technologies that are relevant for the majority of participating Member States and that the assessment is done at the right time.
- Implementation of tools and results of joint assessments requires further work.
- From the point of view of pharmaceuticals, lack of economic evaluation limits usefulness of the cooperation, as (economic) value is a key driver in reimbursement and pricing decisions (in most MS). Consequently, joint EUnetHTA reports can only partially substitute local assessments, and local submissions from pharmaceutical companies are still needed. Because the economic assessment is often carried out simultaneously (or in parallel) with the clinical assessment, implementing a EUnetHTA report separately causes extra work and changes the local procedures. Furthermore, as the local "add-on" (economic) assessment can only start after the EUnetHTA report is finished, utilizing the EUnetHTA report may delay the local report and thus patients' access to treatment.
- Processes (including evidentiary requirements) for pharmaceuticals, both in MS and at the EU level, are much more developed and standardised than those for other technologies; i.e. the level of maturity of the process from development to patient access differs considerably between pharmaceuticals and other technologies. In particular for new pharmaceuticals, it would be possible to advance much more rapidly and benefit from synergy with the well-established marketing authorisation process at the European Medicines Agency (EMA). By developing the EMA processes further, it could be possible to eliminate the need for a separate Rapid Relative Effectiveness Assessment (REA) carried out subsequent to the regulatory assessment, by producing the REA alongside the regulatory assessment, and move directly to the local processes (with economic evaluation).

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:

- Good tools and networks available and those should be utilized and developed further
- If no collaboration exists, a great amount of unnecessary duplication of work is done in Member States and only a fraction of all new technologies can be assessed.
- Ideally, EU level cooperation can enhance patients' timely and equitable access to new treatments with added value and affordable costs.
- EU level cooperation can lead to savings in the workload required for assessments in the MS, as well as the workload of technology providers. In addition, it has the potential to create a better environment for health technology innovation in the internal market.
- EU level cooperation provides a framework for smaller groups of MS (with similar health systems, cost structures) to seek a deeper level of cooperation among themselves, including cooperation in the economic evaluation.

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':

- Screening
- Medical and surgical procedures
- eHealth/mHealth
- Public health
- Disruptive technologies (e.g. nanotechnology, personalized medicine and genomic medicine)

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':

Awareness of the timing of the regulatory process and availability of clinical study data from the EMA.

*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)

ADVANTAGES

- Reduction of redundant work
- Availability of expertise in clinical and methodological aspects
- A larger share of new technologies can be assessed, leading to better long-term sustainability of healthcare system and better accessibility for patients to new technologies
- Shared methodologies and processes contribute to better quality of HTA information and more predictable and trustworthy knowledge base
- A well-functioning cooperation between MS would increase business predictability for technology developers and support innovation in the EU.
- For pharmaceuticals, early dialogues -- together with the EMA -- are important for speeding up the development process and thus timely patient access. Collaboration in evidence generation throughout the lifecycle of a medical product supports rational use of medicines.
- The EU initiative can facilitate collaboration among smaller groups of MS
- Cooperation in economic evaluation, and possibly procurement, could lead to direct savings in health care budgets.

DISADVANTAGES

- Too rigid system particularly in prohibiting national adaptation work may lead to reduced applicability of joint work and use of outdated information
- For pharmaceuticals, joint REA following marketing authorisation may cause delays in patients' access to new treatments, if the regulatory and HTA processes, including economic assessment, are not aligned.
- If the HTA collaboration is only about REA, the usefulness of available information is greatly reduced. Several technologies require a wider spectrum of analysis, including e.g. economic, organizational and social analysis (+all other HTA Core Model domains). Although the assessment results of non-clinical domain may require further work in a local setting, the joint work bears a good potential in assisting this work.
- HTA collaboration should not be limited to drugs and devices only, but instead should consider all types of technologies that have an impact on public health problems.

*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':

- A mix of A and B.

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

2000 character(s) maximum

- The basic funding of HTA should be from public sources.
- Funding for Early Dialogues should come from the industry, but great care should be taken to ensure that the funding does not compromise objectivity of assessments.

*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
- [x] b) Existing EU agency(ies)
- [x] c) New EU agency
- [x] d) Member States HTA bodies on rotational basis
- [x] e) Other

*4.1.1.4.e. Please specify 'Other':

The remit of the EMA could be broadened and the Agency developed into a European Health Technology Agency (EHTA). This would allow reaping of maximal benefits from synergy between regulatory and HTA processes, and support health technology innovation in Europe.

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

2000 character(s) maximum

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•	If there’s a rotation of HTA bodies, the period should be long enough (e.g. 4 years) and extra care should be taken that the transition period from one agency to another goes smoothly.
•	For pharmaceuticals, synergies between HTA and regulatory matters (including evidence generation throughout the lifecycle of a medicinal product) are much greater than those between HTA of pharmaceuticals and other technologies .
•	It is important to have similar HTA process for pharmaceuticals and other tehnologies.
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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.d. Please specify 'Other':

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•	Voluntary participation and mandatory uptake should be accompanied with the possibility (or obligation) to make a national adaptation of the joint work.
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*4.1.1.5.1. Please explain your answer(s) and comment on issues such as feasibility, advantages and disadvantages

2000 character(s) maximum

• The current policy options indicated in the Inception Impact Analysis do not include the concept of national adaptations of joint work – which has been a very central EUnetHTA concept particularly in the context of full assessments. Building mechanisms to avoid redundant duplication of work is a good idea, but such mechanisms should not prevent HTA agencies in Member States from making national adaptations by e.g. interpreting the results of joint work or amending them with local data (if needed because of local circumstances).
• Due to the continuous evolvement of health technologies and availability of new (primary) research results, HTAs are valid for a specific period only. Therefore it is important that national agencies are allowed to update and reanalyse the joint work or parts of it whenever needed.

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

2000 character(s) maximum

Please upload your file (2Mb max)

Contact

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