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

Finnish Medicines Agency

*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).

pertti.happonen@fimea.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)

Pertti Happonen

*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):

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

There are differences in e.g.
• the structures within a MS that are responsible for HTA
• status of HTA results (e.g. how the information is used within the health system; how mandatory it is to follow the findings)
• stakeholder participation (industry, patients) and their role in the HTA process

See also:
http://www.sciencedirect.com/science/article/pii/S0168851016302111
https://www.cadth.ca/sites/default/files/pdf/ES0293_Single_Technology_Assessment_Processes.pdf

These have per se no effects on our organization; however, the effects become manifest in collaborative activities.

Fimea currently focuses its HTA activity on assessment of hospital-only pharmaceuticals. Assessments of out-patient medicines (as part of the pricing /reimbursement process) and of technologies other than pharmaceuticals are done elsewhere. Fimea's role is advisory and decisions are made elsewhere (by the hospital districts).

In many other MS, the same body assesses both pharmaceuticals and other technologies. Furthermore, decision making can be located at the same authority/body that conducts the assessments.

In the EUnetHTA context, this means that Fimea cannot participate in or implement an assessment performed within EUnetHTA, if it concerns health technologies other than pharmaceuticals. If the assessment concerns out-patient medicines, we cannot directly implement the assessment.

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

There are differences between the MS in the requirements for the submission dossier, and in how they handle for example indirect evidence: some consider it important, some do not use it at all.

Fimea has no formal requirements for the submission dossier, and an assessment can be carried out even without a submission by the marketing authorisation holder.

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

In some MS, the objectives of the decision maker and the theoretical background of the economic assessment are clearly defined and aligned, while in others it is more or less fuzzy.

The differences in economic assessment are more pronounced than those in the clinical assessment (http://www.eunethta.eu/sites/5026.fedimbo.belgium.be/files/Methods%20for%20health%20economic%20evaluations%20A%20guideline%20based%20on%20current%20practices%20in%20Europe_Guideline_Final%20May%202015.pdf). For this reason, sharing of an economic assessment with all MS does not seem possible. Nevertheless, it would be possible to co-operate between smaller groups of countries that have similar health systems and similar requirements for the economic evaluation. The co-operation could include e.g. sharing the technical check of an economic (cost-effectiveness or budget impact) model.

*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
- [ ] 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*)

- [ ] 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[*]
- [ ] g) Provided access to work done by other HTA bodies
- [ ] 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)

Joint methodology development has influenced national guidance on HTA
“Benchmarking” with regard to HTA expertise in 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

In the Joint actions, a key problem and "rate limiting step" was topic selection: the process was cumbersome and time-consuming, and the marketing authorisation holder could in practice prevent assessment of an otherwise highly relevant product (by not volunteering to provide the submission dossier). The overall process, too, was way too complicated with many back-and-forth project management steps that did not really add value. The general process could - and should - be much more streamlined and focus on the activities that actually add value to the output.

Not all agencies/bodies were 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.

The number of joint assessments produced remained low and their timing was not always optimal.

Low level of implementation of joint work.

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:

Optimally, EU level cooperation can enhance the possibilities of patients to access in a timely manner new treatments with added value and affordable costs.

EU level cooperation can lead to savings in workload required for assessment in the MS and that of technology providers. It also has potential for creating a better environment for health care innovation in the internal market. In addition, it will provide a framework for smaller groups of MS to seek deeper cooperation, possibly including economic evaluation or even procurement. Voluntary cooperation is expected to deepen over time.

Collaboration with the EMA is more efficiently organised by the cooperation mechanism than by individual agencies/bodies.

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':

E.g. various health care programs, surgical techniques etc.

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':

For pharmaceuticals, awareness of the timing of the regulatory process and availability of clinical study data (and subsequently accumulating efficacy and/or safety data) from the EMA.

For rational market introduction of a new health technology (a new pharmaceutical in particular), a joint rapid assessment of the therapeutic and economic value of a new technology that is available at the same time as the marketing authorisation is granted would be much more beneficial than a “classic” full HTA or a REA alone.

To save time and effort, the joint report could be a crude (rather than “polished”) version that serves as a template to be completed and finalised locally, taking into consideration any needs specific to the local decision making. A key prerequisite for the implementation of the joint report is its timely availability.

Later during the life-cycle of the product, the reassessment could be more comprehensive, provided that significant new evidence has emerged from clinical trials or real-world monitoring.

*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)

Joint work allows a more systematic and comprehensive evaluation of the relevant health technologies (than what could be covered by less coordinated evaluations carried out by the MS). Joint tools, for example databases and templates, will help to build cooperation and to share assessments. Guidelines are needed for the same purpose. However, differences among MS exist and it is not possible to fully harmonise e.g. the economic evaluation.

For the pharmaceutical sector, early dialogues and close collaboration with the EMA throughout the lifecycle of a pharmaceutical are important for both timely introduction and rational use of medicines over their life cycle. Incorporating the HTA process deeper into the EMA process would streamline patients' access to new treatments. Consequently, an additional joint clinical assessment (REA) after the EMA process would be no longer needed, resulting in reduced workload for all parties involved.

Joint full HTA, including the economic evaluation, does not seem possible at the EU level. However, smaller groups of MS could benefit from cooperation in the economic assessments. (Some initiatives in this direction already exist outside of the EUnetHTA context.) To facilitate this development, the EU should provide the platform and tools for cooperation but let the MS decide the nature and level of cooperation and how it is organized to fit into the local processes.

A well-functioning cooperation between the MS would decrease workload, increase business predictability for technology developers and support innovation in the EU. The possibility to better select the treatments that are used, based on increased knowledge of harmonised quality, would contribute to the sustainability of national health systems. The possibility for deeper cooperation, including economic evaluation and procurement, could lead to direct savings in health system budgets.

In summary, such cooperation would increase patients' timely access to new technologies that provide added value. Regarding new medicinal products, however, the cooperation should focus on actions before the marketing authorization (early dialogues, parallel regulatory-HTA work) and evidence generation over the product's life cycle that fulfills both regulatory and HTA needs after the marketing authorisation. By itself, without alignment to the regulatory process, a separate joint REA following marketing authorisation provides little added value in terms of reduced workload or health system sustainability and may cause delays in patients' access to new treatments.

*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

Preferably, joint work should be financially independent from industry funding. (Industry fees are not likely to save the eventual costs borne by health systems, as the industry will pass the costs to the payer in any case.) For early dialogues, however, a fee to industry could be considered, similar to which currently exists for regulatory scientific advice.

With regard to the extent that the REA assessment would be integrated with regulatory assessment, the standard EMA fees (adapted according to work load) and funding would apply, and only those activities that are carried out in addition to the regulatory steps would need to be funded separately.

*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.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 maximal benefits from synergy between regulatory and HTA processes, and thus 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

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, as the regulatory and HTA processes are closely linked to each other and this connection is even expected to strengthen in the future. Already now, the regulatory agencies, HTA bodies, and the pricing authorities are facing the situation where marketing authorisation and the initial prices are based on very limited evidence (e.g. conditional approval, orphan drugs), and there is the need to re-evaluate the benefit-risk and the relative effectiveness /therapeutic value, when further evidence (phase III studies, registries etc.) is provided. The evolution of the concept of adaptive pathways to patients will further enforce this trend.

Another manifestation of regulatory-HTA synergy that already exists is parallel scientific advice. This activity needs to be further promoted, as it has the potential to bring about major efficiencies in product development and thus to support innovation. This in turn may result in more timely patient access to therapeutic advances, as well as savings to the health system.

The EMA has an established track record as a platform for managing a pan-European cooperation network towards a common goal. Thus, there is no need to reinvent the wheel but learn from the experiences that have accumulated over the years. The recent concept of multinational assessment teams, for example, is a promising initiative to make more efficient use of the capacity available collectively.

In case there are reservations on broadening the role of the EMA in HTA that cannot be overcome, it might be necessary to divide the secretarial support into two:
...continued / the answer in full is provided in the uploaded file.

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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The REA is aligned with the regulatory assessment (throughout the life cycle
of the medicinal product) and as such it becomes mandatory for all MS.

Participation in the economic assessment should be voluntary, and most likely
collaboration in the economic assessment would be among selected groups of MS
(or regions) rather than across the board of all MS.
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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

Integration of the REA with regulatory assessments maximises the synergies throughout the life cycle of the medicinal product and thus makes the overall process from development to patient and that of supporting rational use most efficient.

As long as decision making remains local and cost is a consideration, uptake of joint assessments should be voluntary. A common process does not fit the decision-making processes of all of the MS (or regions), and making the uptake mandatory might lead to loss of efficiency. For example, the current process for new medicinal products includes a rapid REA after marketing authorisation, followed by a local report possibly including economic evaluation produced afterwards. In many cases this sequential approach, if made mandatory, would make patient access to new technologies less timely compared with local parallel clinical and economic assessments.

To increase the uptake of joint work, more emphasis should be placed on supporting groups of MS that are voluntarily cooperating on HTA. EU level cooperation should give organisational support, e.g. intranet for data exchange and a common repository of assessments, but allow the cooperating MS to decide what kind of processes best fit their local decision-making needs.

EU legislation could focus on supporting the production of assessments that are implemented. See 4.1.1.2.1. for details.

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

2000 character(s) maximum

Sections 3.3.1.2., 3.3.1.2.1. and 3.3.1.2.2. are missing in this web form.
Our answers to those are provided in the uploaded file.
Due to the space limitation, our answer to question 4.1.1.4.1. did not fully fit the box. The complete answer is also provided in the uploaded file.

Please upload your file (2Mb max)

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/Additions_to_Finnish_Medicines_Agency_s_response_to_HTA_consultation_170113.pdf

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