Supplement to EUnetHTA WP4 D4.10 Recommendations for Horizon Scanning, Topic Identification, Selection and Prioritisation for European Cooperation on Health Technology Assessment

External stakeholder input to Draft recommendations (EUnetHTA WP4 D4.8) and authors response

Stakeholders on the EUnetHTA stakeholder mailing list (see appendix 3, D4.10) were asked to provide input to Draft recommendations (D4.8). The Draft recommendations were considered an internal work document of EUnetHTA. The stakeholders input and authors response is shared in a transparent way.

The following organisations provided input:

Organisation	**Category**
International Association of Mutual Benefit Societies-AIM	PAYERS
European Institute of Womens Health-EIWH	PATIENTS
European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry-COCIR	INDUSTRY
European Federation of Pharmaceutical Industries and Associations-EFPIA	INDUSTRY
MedTech Europe (Eucomed)**	INDUSTRY

The table below provides an overview of General, Major and Minor comments (comments of linguistic nature not included)

Comment from	Page number	Line number	Comment and suggestion for rewording	Character of comment major =1 minor = 2	Author's response
AIM	General		We consider it strange that an international association of healthcare payers, which is a highly relevant stakeholder when dealing with international cooperation in the field of HTA, is only consulted at the very last stage of the preparation of such a document. AIM has indicated many many times that it wants to be more actively included in the work of EUnetHTA, but for some reason this is not happening, even when EUnetHTA	1	Stakeholder definition changed to be in line with EUnetHTA JA3 WP2 Deliverable 2.1 Stakeholder Analysis

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			staff and participants/partners continue to say that this indeed should happen.		
AIM	General		We consider it strange that an international association of healthcare payers, which is a highly relevant stakeholder when dealing with international cooperation in the field of HTA, is only consulted at the very last stage of the preparation of such a document. AIM has indicated many many times that it wants to be more actively included in the work of EUnetHTA, but for some reason this is not happening, even when EUnetHTA staff and participants/partners continue to say that this indeed should happen.	1	Payers are included in the stakeholder definition. Message on earlier involvement is reported to EUnetHTA Exceutive board
AIM	9	213	See also the comment above. Without healthcare payers involved, we need to rephrase "broad stakeholder involvement"	1	Payers are within the stakeholder definition.
AIM	9	226	A disruptive innovation can also be a totally new product (not only an improved product).	1	Disruptive innovation not used in the final version.
AIM	9	239	That a health technology is innovative, doesn't say anything about the benefits it generates for patients. An innovative health technology uses new ideas or methods, but it's not necessarily better or generates more benefits	1	Not changed. An innovation unlike an invention potentially provides added value. In the chosen definition of innovation, the public health perspective is choosen, and this implies per definition that value is for the patient or socieconomic domains.
AIM	10	257	We miss investors as stakeholders	1	Stakeholder definition changed to be in line with EUnetHTA JA3 WP2 Deliverable 2.1 Stakeholder Analysis

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AIM	10	265	It would be good to add here something about 'significant' or 'substantial' effect. When setting priorities for HTA, it is important to make a distinction between products that address unmet medical needs to a large extent and products that might have minor effect on the outcome of the disease or condition.	1	The term unmet need is not used in the final recommendations
AIM	11	296	It is clear that the patient needs are important, but what about potential financial impact?	1	See definition of transformative innovation and innovation. Financial impact (for health care systems) is covered by the definition of transformative
AIM	11	297	The term "minimal data-sets" is not described, can it be explained a bit, maybe also to be added to the glossary? (use words on page 23 around line 750)	1	Ammended: added to the glossay
AIM	23	716	Not sure if the criteria should be in line with the proposal or with the final version of the regulation.	1	The criterias have been revised to meet (amongst others) this comment
AIM	29	942	Why are stakeholders liminted to patients and health professional associations? Payers/decision makers could have a role too…?	1	Stakeholder definition changed to be in line with EUnetHTA JA3 WP2 Deliverable 2.1 Stakeholder Analysis
AIM	31	1010	Well, at least you are consistent…. But why no involvement of payers/decision makers too….?	1	Stakeholder definition changed to be in line with EUnetHTA JA3 WP2 Deliverable 2.1 Stakeholder Analysis
AIM	24	796-797	Stakeholder involvement should NOT be restricted to experts, patients and regulators. Decision makers/payers are the ultimate end users of HTA (HTA informs reimbursement decisions) and should be involved in the development of	1	Stakeholder definition changed to be in line with EUnetHTA JA3 WP2 Deliverable 2.1 Stakeholder Analysis

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			methodologies for Horizon scanning activities and those activities themselves.		
AIM	10	274	Add in this sentence the words in bold underlined: Relative effectiveness assessment can be defined as the assessment to measure the extent to which an intervention… etc	2	Definition in line with EUnetHTA definition of REA (see page 36)
AIM	11	290	What does this term "technology lifecycle perspective" mean? Explain in the text and add to the glossary?	2	Not ammended, clare enough from the context
AIM	12	325	Unclear figure. What do the orange, grey and blue line stand for?	2	Figure legend changed to explain
AIM	19	574	Was the document based on a stakeholder consultation process, or were stakeholders consulted after the document was ready in draft?	2	The draft recommendations were on a stakeholder consultation
AIM	19	594	Unclear what at QA approach is	2	QA=Question answer approach, abbreviation not used in the final text
AIM	21	653	Innovative or effective technologies? Highly innovative but ineffective new treatments should not be introduced. See also 9-236	2	Innovativeness depends on perspective. See defininion on innovation in health care.
AIM	21	664	What does that mean? The timeframe should be no later than when a product enters the lists… etc	2	Rephrased to three to six months before submission
AIM	22	697	Would it be an idea to add also something about the need to clarify the "direct contact with developers through regular	2	Table 1 is moved to background. This is shortly discussed in the discussion section

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			meetings" and its potential impact on independence of the assessor?		
AIM	23	743	Should patients do the ranking? I'm not sure how objective the ranking will be. Why only patients and "health care representatives" (what do you mean with this last group)? Why no role for decision makers/payers?	2	See recommendations on stakeholder involmenet: "5.3. If specialized selection or prioritisation committees are established, individual stakeholders without general conflict of interest in the technology/product should be recruited. In particular healthcare professionals (experts), payers and patie
AIM	25	807	Why at least once a year? And linked to which specific action does it need to be up to date in particular?	2	Recommendation changed se Rec 3.5.
AIM	25	808	Why particularly for pharmaceuticals?	2	Recommendation changed se Rec 3.5.
AIM	27	855	13 questions? Which questions?	2	Recommendations for the pilot- not part of the final recommendations. To clarify: The questions adapted from EuroScan described in methods.
AIM	34	1129	"Stakeholder contact has been a major focus of EUnetHTA as far as the regulators, EMA, developers, patients and health professionals are concerned…..	2	Recommendations for the pilot- not part of the final recommendations.
AIM	9	227-228	The part of the sentence "typically …. existing market (2)" should be deleted. This is a marketing strategy, and has no direct link with the term disruptive innovation.	1	Disruptive innovation not used in the final version.
AIM	13	351-360	It is unclear what the numbers in brackets refer to. Footnotes?	2	References

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COCIR	9	226	Glossary: Definition Disruptive Innovation: COCIR suggest to use the term of Disruptive innovation, for consistency reasons, as identified by the Expert Panel on Effective ways of Investing in Health which is as follows: "disruptive innovation" in health care [is understood] as a type of innovation that creates new networks and new organisational cultures involving new players, and that has the potential to improve health outcomes and the value of health care. This innovation displaces older systems and ways of doing things.[1]"	1	The term disruptiv innovation is not used in the final recommendations. The term has been removed from the glossary.
COCIR	9	235	Glossary : Definition of Horizon Scanning: COCIR believes that the definition of Horizon Scanning should include transformative technologies since it is a criterion in the selection process (line 719 – 720) and the prioritization criteria tested in the pilot (line: 986), and the pilot project (Line: 1163). COCIR suggests the following as definition "Horizon scanning is the systematic identification of health technologies that are transformative, emerging or becoming obsolete and that have the potential to effect health, health services and/or societies"	1	We do not support changing the cited definition of Horizon scanning. We do recognise the importance of focusing on transformative technologies in the recommendations for widening the scope of horizon scanning beyond the initial phase.
COCIR	22	710 – 748	Prioritization: COCIR agrees with the identified selection criteria (lines 718 – 724) in the EUnetHTA recommendations and that are the unmet medical need and the potential impact on patients, public health, or healthcare systems.	1	The recommendations have been modified according to several inputs.

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COCIR	13	388-390	The EU Commission's proposal for a regulation on HTA, (published on January 31st, 2018) is still not finalized and the legislative process is still ongoing between the EU Commission, the EU Parliament and the Council of the EU. Therefore, COCIR believes that it is too early for the proposed recommendations for HSS to be integrated in a draft legislation that is still under discussion. As such, COCIR suggest deleting the following sentence: "The recommendations for a HSS in this document are for an HSS integrated with the EU proposal for joint assessment as well as continued voluntary collaboration in areas not covered by the joint assessments".	1	The wording has been changed. Opposing views regarding the EU proposal on regulation of HTA amongst stakeholders have been shortly referred to in the discussion.
COCIR	21	675-697	Information sources: The proposition to allow the developers to enter information in a data base, as the primary sources for topic identification, is welcomed by COCIR. Nonetheless, any Data Platform set for this purpose should ensure the data is reliable and secure. Provided the confidentiality of the data is guaranteed, the creation of database can be considered. However, there are currently no actions that secures the research in-confidence or commercial in confidence data access for the developers. This is well mentioned in the sentence (line 695): "Special arrangements with developers and regulators, on how to deal with confidential information might be needed". COCIR believes that this should be the starting point before developing the databases.	1	The recommendations have been modified to accomodate confidentiality arrangements: See recommendation 1

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COCIR	22	698-709	Selection: COCIR believes it is of utmost importance Use clear and predictable criteria for the choice of technologies undergoing an evaluation and use a horizon scanning approach.	1	We agree. Hopefully clear enough now.
COCIR	23	740-743	Selection: COCIR agrees that the ranking should be done by carefully selected and trained committees including patients and health care representatives. However, the selection criteria of these experts should be transparent and unambiguous, and the selection process should be done in a spirit of mutual trust. Industry should not be regarded as "biased" in this context.	1	Industry should contribute to identification, selection and preparation of data sets needed for prioritisation. Industry should not be involved in prioritisation.
COCIR	24	776-803	Stakeholders Involvement : While COCIR support the involvement of all relevant stakeholders, we recommend that it should be done at an early stage and in a timely way. Therefore, COCIR recommends specifying the timing of the stakeholders involvement given it is not described in the draft recommendations. This is an important gap as it provides insight for degree of opportunity of cooperation and by which stakeholders.	1	Stakeholder definition changed to be in line with EUnetHTA JA3 WP2 Deliverable 2.1 Stakeholder Analysis. Involvement at different stages are now described.
COCIR	35		Conclusions: COCIR believes the process of Horizon Scanning as laid out in the document should not be dependent on EUnetHTA being active after 2020 or not.	1	The recommendations are not restricted to EUnetHTA being active
COCIR	General		Timing: COCIR believes that a timely and enhanced stakeholder involvement is needed. Under JA1 and JA2, the representatives of the EUnetHTA Stakeholder Platform were consulted on the basis of clear Terms of Reference that defined the modalities of interaction, with clear and transparent criteria for involvement. COCIR believes such a dedicated platform for stakeholders is indeed needed, in order to ensure more inclusive approach for interactions such as this consultation, between the EUnetHTA and the stakeholders. This point is supported by MedTech Europe.	1	Stakeholder definition changed to be in line with EUnetHTA JA3 WP2 Deliverable 2.1 Stakeholder Analysis. Involvement in all stages described

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			Moreover, the summer time given to consult stakeholders on the report is not optimal, and which may have an impact on the quality of contributions sent.		
COCIR & MedTech Europe	20	616-628	Purpose of the Horizon Scanning: Horizon Scanning is not systematically used by all healthcare systems. For example, Germany and France do not use such approach; however, UK, Norway, Sweden use Horizon Scanning to initiate early dialogues, for planning purposes and to identify the technologies that have the potential to impact the public health system. Moreover, COCIR observes there is currently a weak alignment between the process and the expectations from Horizon Scanning Systems. In the countries where HS is used, the usefulness is not very certain (example: England, Norway). HS should not be used systematically for HTA or for early assessment or early price negotiations. COCIR believes Horizon Scanning should be used from a broad perspective focusing on disease or care pathways rather than on products. This would help identify general trends, gaps and set healthcare priorities and shape policies.	1	The purpose of HS in this context is to inform the initiation of HTA cooperation. The purpose of HTA varies, in some cases related to reimbursement of individual new products (single technology assessments), in other cases reassessment involving a broader perspective.The point made by COCIR with regard to broad perspectives rather than products is related to the scope and outcome of the HTA process rather then the purpose of HS. Due to uncertainties regarding future models for cooperation and legislative regulation, we (the TISP group) were not able to do provide recommendations on the ownership and financial responsibilities for horizon scanning and the TISP process, nor detailed criteria for selection and prioritisation. These are important areas that remain to be defined.
COCIR, MedTech Europe	10	270	Glossary : Transformative Technologies Definition: COCIR observes inconsistency in using the term of transformative technology in the EUnetHTA Draft recommendations on HSS and TPIS, therefore COCIR suggest using the following definition: "Transformative technology are those technologies that have the potential to address high unmet patient/citizen and/or societal and health care systems needs and that require significant structural and/or organisational change to deliver their benefits. These technologies have the potential to significantly transform and improve clinical pathways, the organisation of healthcare service delivery, and/or healthcare	1	Consistency checked, definition not changed.

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			systems systems and require investment to implement these changes. "		
EFPIA	General		Given that the aim of the document is "to serve the European HTA network beyond 2020", EFPIA considers that any recommendations should be established against the framework established by the Commission Proposal for a Regulation on HTA. In EFPIA's view, for pharmaceuticals, the Commission Proposal focuses on the delivery of joint scientific consultation (JSC) and joint clinical assessments (JCA).	1	Our mandate was not restricted by the EU proposal. In addition, the EU proposal has listed 4 areas of focus: " 1. joint clinical assessments (JCA); 2. joint scientific consultations (JCS) whereby developers can seek advice from HTA authorities; 3.early identification of promising emerging health technologies (Emerging technologies); 4.continuing voluntary cooperation (VC) in areas not covered by joint clinical assessments ." To emphasize this further, we have added JCA and JCS to the acronyms, and JCA, JCS, VC have been added to the list of defined terms (emeging technologies was already defined in the draft).
EFPIA	General		EFPIA considers it is not necessary to establish a complex HSS for the purpose of JSC and JCA but rather, that a sound topic identification mechanism managed by the Member State Coordination Group (CG) needs to be foreseen. o By definition, JSC is an offer open to pharmaceutical companies when developing a candidate product. EFPIA considers that all candidate products should have the opportunity to request JSC and is calling for the permanent system to have sufficient resources available to respond to all demands, similarly to what is currently done at the EMA. o Given that the Commission Proposal foresees that all centrally authorised medicinal products will be subject to JCA, there will be no need to select nor prioritise pharmaceutical products beyond the transition period. There will solely be the need to identify all product	1	The definitions stated by EFPIA are taken from the EU proposal on HTA regulation. The purpose of the recommended HS service(s) is not only to prepare and make room for the JCA, but also national HTA planning and uptake of products produced by a cooperative network on HTA. It should be noted that developers and EMA currently do not provide systematically available information corresponding to an HS. However, we agree that collaboration with developers and EMA for the purpose of mandatory initial JCA (as defined by the EU proposal) may reduce costs of this part of an HS service. - We agree, if all identified and selected technologies within a predefined scope are to be assessed, a prioritisation step will not be needed. However, prioritisation will at least be needed in a transition phase before there is room for assessment of all pharmaceuticals.

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			candidates and their authorisation timelines, in order to manage workload of the Coordination Group, similarly to what is currently done by the EMA in business pipeline review meetings which is about "anticipating in a timely manner the quantitative and qualitative impact of pharmaceutical pipelines on the operations of the Agency"[1]. It will be important to ensure that the CG has sufficient resources available to deliver this work. During the transition period, when the CG will gradually expand its capacity, it should be in the remit of the CG to prioritise topics on the basis of agreed criteria.		
EFPIA	General		EFPIA also wants to underline that industry is the primary source of information on candidate products in development (before marketing authorisation) and is the only party that can provide valid data on timelines, so that any system aiming the anticipate the impact of pharmaceutical pipelines on the operations of the HTA network needs to build on data provided by the manufacturers.	1	The question on commercially sensitive data has been discussed several times by the TISP group. The following was agreed on: "1.3 The horizon scanning service should be a legal entity with an appropriate confidentiality framework to allow developers of technology (including manufacturers and prospective marked authorisation holders) to share information at an early stage." and in the discussion "Several existing horizon scanning services have confidentiality frameworks that allow for early identification and timeliness, and are still able to provide transparent datasets for prioritisation. As a rule of the thumb, we consider information that may be cited from a publicly available source to be non-confidential. Thus, confidentiality issues can be overcome by citing sources of information. If accurate information cannot be shared, best guess estimates regarding level of impact (e.g. high-, medium-, low impact) and approximate time frames (e.g. year quarter of the year) should be included."
EFPIA	General		The system needs to be lean and efficient in order to ensure that it does not lead to delays in assessment and therefore no delays in access for patients. It must be predictable for companies, and free of	1	We agree, encaptured by: " 1.2 One or more horizon scanning services with transparent, unbiased and efficient

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			any discrimination in favour or against a specific innovative health technology or sector of the industry.		processes should inform prioritisation of European cooperation on HTA."
EFPIA	General		EFPIA considers that any EU level or supra-national horizon scanning system should aim to complement work done at national level and focus on elements which are not country or region specific, including product information, clinical properties and timelines for regulatory approval. Elements relating to assessing the impact on national health systems, including on budgets, organisation and healthcare delivery, are best handled at national level. o We have concerns about the lack of specific details and also how the proposed HSS would interact with other existing and established supranational or national HSS. The document stated several times that this was out of scope, but in another section would say that there should be collaboration or the need to not create duplication. o In general, a proposed HSS system should focus on domains that offer the most efficiencies for member states. This is outlined in Section 8 (starting at Line 749)- it says what should be included in the produced output/datasets, but does not go as far as saying what should not be included. The proposed HHS should not include costs and economic evaluations, ethical analysis, organizations aspects, patient and social aspects, or legal aspects as these are country-specific and varying amongst member states similar to the Rapid REA which does not include these elements. And as stated on Lines 692-693, only non-confidential information should be included in data sets which again strengthens the argument for limited domains relevant to inform resource planning for upcoming JSC and JCA. Throughout the document there are various reference to the need to	1	We have read the principles described by EFPIA carefully and have taken these into acount when formulating the final recommendations. The HS output is not an assessment, potential impact on any field including costs, ethics and organisation may influence the prioritisation of joint or collaborative REAs

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			collect pricing information for the HSS. This is highly concerning to EFPIA as it is clearly a national competence which remains out of scope of European HTA cooperation. EFPIA has developed principles on horizon scanning which are attached for information.		
EFPIA	16	488-491	In half of the countries, it says the HTA does not have a role in topic selection/prioritization since they carry out work either by request of a decision maker or through industry submission. This raises the question about if HS will create more reviews which may then stretch or be beyond the capacity of MS agencies. As previously suggested, it seems like there are less complex and burdensome ways to select and limit the number of products as was demonstrated by the EMA when it was established.	General comment	The aim of the HS/TISP process is not to restrict the number of HTAs, but to assure that the most relevant topics for cooperation on HTA in Europe are identified in a timely manner.
EFPIA	13	354	we are concerned about the reference to support procurement processes which is not an objective of the EC HTA proposal and therefore should not be a valid objective here.	1	Our mandate was not restricted by the EU proposal. Notably, this is stated as factual information on how HS and HTA is used in the background chapter.
EFPIA	21	665	no later than when a pharmaceutical enters the lists of medicines under evaluation in EMA: A medicine appears in the EMA list only after the validation phase which is approx. 1 month after MAA submission. "This list only includes information for medicines whose applications have been validated at the time the report was compiled."	1	See: Rec 3.2 "To assure timeliness of the REAs, pharmaceuticals should be identified early enough to allow selection approximately three to six months before the technology/products enter the lists of medicines under evaluation in EMA. MDs and IVDs should be identified early enough to be selected around the time when a CE mark is provided. The time frames need to be adjusted based on experience gained once the system is established.
EFPIA	21	667	no later than six months before the time when pivotal trial data are anticipated to become available: Not clear what timepoint is considered – study completion date or CSR availability date? At this	1	See: Rec 3.2

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			timepoint it is not clear whether the trial will be successful or not. Is this not too early? What will be the source for this information ClinicalTrial.gov?		
EFPIA	22	694	Information related to pricing: The initial assessment (REA) on a European level is about the clinical efficacy. Cost-effectiveness for which prices are required is national competency and should be handled on a national level. Pricing should be deleted. it is highly concerning that pricing information would be considered in scope of HSS. This is a national matter that remains out of scope of any European exercise.	1	If prioritisation criteria are implemented, potential budget impact (high unit price/large volume) may be an important criteria for prioritisation. We consider that an anticipated level of budget impact may be identified and shared without sharing commersially senistive data.
EFPIA	23	720	budget impact should not be a criterion for European HSS as it is a context-specific issue	1	We consider that budget impact can be within the criteria, but special arrangements are needed. The need for this is reflected in Rec 1.3. "
EFPIA	23	729	….For cooperation on PLEG, prioritisation could in addition to the general criteria, contain additional criteria such as those described by EUnetHTA JA2 WP7(23): For any cooperation on PLEG a third filter is suggested. How many medicines would have a chance to pass all three hurdles?	1	Recommendations on PLEG removed, However, see Rec 3.3. "Additional HTA activities are anticipated to benefit from horizon scanning, this should be integrated into plans of European cooperation on HTA. Focus should be on transformative technologies and patient needs. For extension of horizon scanning to support additional activities, pilots on relevant TISP processes should be conducted to define the scope and criteria exemplified by cases."
EFPIA	23	758	or the scope is reassessment a more comprehensive data-set may be needed. The aim of a more comprehensive data-set is to provide sufficient information to allow for prioritization and ensure transparency of the prioritisation process. : Why should a medicine considered relevant for a reassessment be sorted out via a prioritization process?	1	If not all medicines are to be re-assessed on a regular basis, prioritisation will be needed

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EFPIA	24	786	healthcare professionals, payers and patients should be involved in the prioritisation process: Why should payers be involved and which payers – national – regional- individual payers?	1	Stakeholder definition changed to be in line with EUnetHTA JA3 WP2 Deliverable 2.1 Stakeholder Analysis. Involvement in all stages described. See Rec 5.
EFPIA	24	787	developers should not participate in the prioritisation process: If developers nevertheless wish to propose their product for joint assessment and have not been prioritized, would they be excluded?	1	Yes, if not prioritised for joint/cooperative REA there will be no joint/cooperative REA. However, it will be transparent that they have been proposed, and national HTA may be planned.
EFPIA	24	799	…For pharmaceuticals, regulator involvement should include agreements with EMA to provide structured information.: EMA receive the information by developers (industry). Therefore industry should be the primary source for information on HS.	1	See "1.3 The horizon scanning service should be a legal entity with an appropriate confidentiality framework to allow developers of technology (including manufacturers and prospective marked authorisation holders) to share information at an early stage." AND " 2.1 The horizon scanning service should use both proactive and reactive approaches for topic identification. This implies that a range of predefined sources should be systematically searched for information, stakeholders should be proactively consulted and the identification step should be open to public proposals."
EFPIA	25	811	In cases were prioritisation is needed……: There is no rationale provided why a prioritization is needed. According to the Commission proposal beyond 2020 (at the latest after the transition period) no prioritization is necessary. Every medicines with a centralized MA should be within the scope of the joint assessments.	1	Prioritisartion will be needed also for pharmaceuticals until full amendment of the regulation, including during a transition phase also for pharmaceuticals
EFPIA	28	892	Timeframe TISP relative to EMA process and Joint Assessment process: Defining a time to start with the TISP process is missing Based on company experience with EUnetHTA pilots, it is critical that the scoping meeting with the pMAH should take place prior to the authoring team developing PICO. A subsequent submission review meeting could also be envisaged.	1	Comments to recommendations on the pilot, further improvement of details are needed

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EFPIA	28	904	There are currently no resources available for establishing an extensive HSS within EUnetHTA JA3: What is considered by EUnetHTA as an extensive HSS? Is Figure 4 an outline of an extensive HSS or simplified HSS? States no resources available to establish a HSS in JA3 – this proposal therefore seems redundant	1	"The recommendations are from the perspective of HTA assessors involved in EUnetHTA relative effectiveness assessments (REAs). The recommendations are generic in the sense that they are valid for different models of European cooperation on HTA. The main conclusion is that transparent, unbiased and efficient horizon scanning services should inform prioritisation of European cooperation on HTA. Due to uncertainties regarding future models for cooperation and legislative regulation, we (the TISP group) were not able to provide recommendations on the ownership and financial responsibilities for horizon scanning and the TISP process, nor detailed criteria for selection and prioritisation. These are important areas that remain to be defined. "
EFPIA	29	921	this does not take into account the proposed Commission Regulation	1	Comments to recommendations on the pilot, further improvement of details are needed
EFPIA	29	931	Feedback from developers can be used as an early indication on the ability/interest of the developer to submit a documentation file.: Voluntary participation by industry?	1	Comments to recommendations on the pilot, further improvement of details are needed
EFPIA	29	936	…prioritisation committees (PCs, one for pharmaceuticals…: Who are members of the proposed PCs, HTAB only?	1	Comments to recommendations on the pilot, No PCs were used in the pilots. Further improvement of details are needed.
EFPIA	30	976	Per comments above, cost or economic information should not be in scope as it varies from country to country.	1	Comments to recommendations on the pilot, information on costs not included in the minimal data-set used in the pilot
EFPIA	33	1105	as mentioned above information on pricing should be out of scope	1	Comments to recommendations on the pilot, information on costs not included in the minimal data-set used in the pilot
EFPIA	35	1157	there is no need for a separate coordinating secretariat if the objective is to support the core joint work of JSC and JCA	1	Comments to recommendations on the pilot, See pilot evaluation report

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EFPIA	33	1079-1081	the proposals are indeed ambitious and we would argue they go far beyond what is necessary for the purpose of European collaboration on HTA. We would propose to recenter on priorities to be able to deliver something meaningful and in line with expectations as established in the draft Regulation.	1	The EU proposal suggests an annual study to be performed on emerging technologies. This would in our minds be HS. We do beliew that HS is needed to be initiated more often than annualy to timely initiate HTAs. See "3.2. To assure timeliness of the REAs, pharmaceuticals should be identified early enough to allow selection approximately three to six months before the technology/products enter the lists of medicines under evaluation in EMA. MDs and IVDs should be identified early enough to be selected around the time when a CE mark is provided. The time frames need to be adjusted based on experience gained once the system is established."
EFPIA	34	1114-1116	In EUnetHTA JA3 WP4 prioritisation is the responsibility of the individual agencies. In the recommendations for stakeholder involvement (Recommendation 10) we have stated that developers should not be involved in prioritisation.: In order to raise interest why are developers in the three month pilot excluded from the prioritization step.	1	Comments to recommendations on the pilot, - changed to prioritisation by interest of EUnetHTA partners only. Developers were asked to submit topics.
EFPIA	33	1128-1131	see comments above on stakeholder involvement	1	Comments to recommendations on the pilot, Stakeholder contribution/involvement in the pilot was limited -see pilot evaluation report
EFPIA	34	1136-1137	Timely and structured information from EMA on this items and sharing this 1136 information with EUnetHTA partners is valuable for planning of HTA activities within EUnetHTA.: Primary source of information should be the developer (e.g. industry).	1	Comments to recommendations on the pilot, See pilot evaluation report
EFPIA	34	1150-1151	Likewise, identification of obsolete technologies does depend on monitoring.: obsolete technologies is a value judgement that cannot	1	Commented on in the discussion

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			be done at the HSS stage, it needs to be based on a proper assessment		
EFPIA	10	253-260	it is very concerning to see Wikipedia used as a source, especially when EUnetHTA has established its own stakeholder SOP as part of the EUnetHTA JA2.	1	Stakeholder definition changed to be in line with EUnetHTA JA3 WP2 Deliverable 2.1 Stakeholder Analysis. Involvement in all stages described
EFPIA	11	294-295	It is unclear what the process would be for further expansion to high impact (innovative), transformative, or disruptive technologies. There is little discussion about this in the document, including who would determine/recommend the need for expansion and what criteria would be used, although it should be commended that the focus would be beyond medicines, devices, and diagnostics (as outlined in Lines 649-652).	1	This has been clarified
EFPIA	12	387/616	Prioritisation of pharmaceuticals would not be needed if the scope as envisaged in the EC proposal is carried forward.	1	The follwoing is stated under 3. Topic selection and scope: If all identified or selected topics are to be assessed, there is no need for prioritisation. In such case, the output of selection should be used to initiate HTA.
EFPIA	16	482-485	It is mentioned that currently some countries using HS limit the scope of topic selection (e.g. inpatient products). However, the methods section (starting at Line 636) for the proposed HSS under this document does not adequately outline the scope for topics beyond pharmaceuticals, medical devices, and IVDs. Does this mean all medicines would be included? Or will the scope be further limited to only a subset of medicines? That aspect is important to understand.	1	This is stated as factual information in the background chapter.
EFPIA	17	506-508 & 568-570	How national HS information will be utilized for activities of a permanent HTA is critical to know. It is necessary to understand the organisation of the proposed HSS - will it be truly centralized as the	1	This section is changed with a reference to the Pilot endpoint evaluation report.

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			document seems to imply or more decentralized in nature, working more like a patchwork of networks which include existing HSS? It is concerning that there is no clarity here.		
EFPIA	20	629-635	This section was lacking sufficient details for clarity of what the organisation of the HSS would be when established. Furthermore, it again outlines collaboration with existing HHS, which was earlier said to be out of scope. The process envisaged seems overly complex for a European cooperation that focuses on clear deliverables with a prioritization of products which should be relatively straightforward.	1	The following is stated: "Due to uncertainties regarding future models for cooperation and legislative regulation, we (the TISP group) were not able to provide recommendations on the ownership and financial responsibilities for horizon scanning and the TISP process, nor detailed criteria for selection and prioritisation. These are important areas that remain to be defined."
EFPIA	22	695-696	industry is the primary source of information on candidate products in development (before marketing authorisation) and is the only party that can provide valid data. Any system aiming the anticipate the impact of pharmaceutical pipelines on the operations of the HTA network needs to build on data provided by the manufacturers. Regulatory authorities may not pass on information they received to HTA authorities without the consent of manufacturers.	1	Not all development of new technology is industry sponsored, but we agree that for medicinal products: industry is the most important source of valid information. All information that is public available and not provided to the regulator as commersially sensitive may be shared in more structured ways than to day. This kind of information may also be found in for instance clinical trial registries etc. See general comment on sensitive information
EFPIA	22	698 + 710	6. Selection + 7. Prioritisation . Prioritisation describes the process in which specific criteria are applied to the selected/filtered technologies with the purpose of retaining for assessment (or any other HTA activity) the technologies with greater impact depending on the system's/network's capacity for assessment: According to the Commission proposal after a transition period all centrally approved drugs should undergo a joint clinical assessment. The EUnetHTA draft goes against this approach as it recommends two filters to be applied: 1. Selection followed by 2. Prioritisation and	1	The follwoing is stated under 3. Topic selection and scope: " If all identified or selected topics are to be assessed, there is no need for prioritisation. In such case, the output of selection should be used to initiate HTA. "

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			it is not clear what does this mean for all medicines which are not selected & not prioritized?		
EFPIA	22	699-700 & 711 & 738	These sections are highly complex and unclear. The proposed Regulation establishes that all centralized products are in scope, with prioritization based on set criteria during the transition phase. This should be the guiding principle for any HSS established by EUnetHTA. If EUnetHTA is to pilot the criteria established by the Regulation, a public comment period should be available to allow all stakeholders to weigh-in on the criteria/ranking utilized in order to ensure the system is predictable for companies, and that there is no discrimination in favour or against specific technologies or a specific sector of the industry.	1	EUnetHTA has no funding for piloting the criteria of the EU-proposal. The pilots were for a simpler model based on voluntary collaboration. The need to pilot the criteria is included in the final recommendation.
EFPIA	24	776-803	This section outlines stakeholder involvement without keeping in mind the objective of the European collaboration, which is to ensure high quality, timely clinical assessments are available to feed into national HTA that support national P&R decisions. Stakeholder involvement is not an objective per se, but should be there to support the overall objective of the European collaboration. As the assessments are there to support national activities, those that conduct those activities should be the primary responsible for prioritization where this is necessary. Concretely, this takes place during the transition period in the foreseen Regulation and the Coordination Group can take up this role. There is no need to include further stakeholders for prioritization. However stakeholders will have a key role to play to provide data (industry is the primary source of information on candidate products in development (before marketing authorisation) and a key role to play in the assessments (patient experts, clinical experts, etc).	1	For prioritisation according to criteria involving subjective judgements, we argue that there is a need for patients, expert and payers involvement. For voluntary collaboration, based on the sole prioritisation criteria being interest in the topic we agree.

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EFPIA	25	806-807	Updating the minimal data-sets with emerging technologies (identified before initiation of pivotal trials) should at least be performed once a year, preferentially more often in particular for pharmaceuticals: The definition of emerging technologies provided line 229 – 231 is too vague because it refers only on the development status.	1	NIPHNO -ammended to definition derived from glossary
EFPIA	24	821-829	this section seems to completely ignore that the proposed Regulation is establishing a Coordination Group composed of Member State representatives that will conduct all joint work.	1	"The recommendations are from the perspective of HTA assessors involved in EUnetHTA relative effectiveness assessments (REAs). The recommendations are generic in the sense that they are valid for different models of European cooperation on HTA. The main conclusion is that transparent, unbiased and efficient horizon scanning services should inform prioritisation of European cooperation on HTA. Due to uncertainties regarding future models for cooperation and legislative regulation, we (the TISP group) were not able to do provide recommendations on the ownership and financial responsibilities for horizon scanning and the TISP process, nor detailed criteria for selection and prioritisation. These are important areas that remain to be defined. "
EFPIA	29	916-918	…the scope of the pilot will be restricted to initial joint assessment of new medicines as outlined by the EU proposal. Selection of identified topics in accordance with the scope will be performed by the WP4 authors based on the identification list.: In the proposal, joint clinical assessments are limited to: medicinal products undergoing the central marketing authorisation procedure, new active substances and existing products for which the marketing authorisation is extended to a new therapeutic indication (line extensions).	1	Comments to recommendations on the pilot, -We do not know if the EU regulation will be amended

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			Given that the EC proposal foresees a JCA for all centralized approved drugs (at the latest after the transition period) why is selection and a priorization filter considered?		
EFPIA	26		Under Identification within the figure, National TSIP lists is included twice. It is unclear is this was simply an error or if another source should have been listed instead for one of those buckets where it is duplicated. The process seems overly complicated in an environment which aims to identify those products which are in development and which are likely to be soon authorized by the EMA. This information is readily available from manufacturers and a process of interaction should be envisaged rather than a complex set of review of various sources. It is in the interest of manufacturers to provide the relevant information to ensure timely assessment of their product, in order to ensure their timely availability.	1	We agree, but due to resource restrictions and time-lines agreements were not included in the pilot plans. For pharmaceuticals, a list was sent to EFPIA. Based on expersience from the pilot we recommend involvement of developers at an early stage.
EFPIA	General		Given that the aim of the document is "to serve the European HTA network beyond 2020", EFPIA considers that any recommendations should be established against the framework established by the Commission Proposal for a Regulation on HTA. In EFPIA's view, for pharmaceuticals, the Commission Proposal focuses on the delivery of joint scientific consultation (JSC) and joint clinical assessments (JCA).	1	The EU proposal has listed 4 areas of focus: " 1. joint clinical assessments (JCA); 2. joint scientific consultations (JCS) whereby developers can seek advice from HTA authorities; 3.early identification of promising emerging health technologies (Emerging technologies); 4.continuing voluntary cooperation (VC) in areas not covered by joint clinical assessments ." To emphasize this further, we have added JCA and JCS to the acronyms, and JCA, JCS, VC have been added to the list of defined terms (emerging technologies was already defined in the draft).
EFPIA	9	236	….or becoming obsolete: Obsolete Health Technologies are a new topic which is not covered by the Commission proposal towards Horizon scanning. It is not defined in the EUnetHTA draft document who will make the decision by when a medicine is considered as	2	Obsolete technology is wording used in the cited definition of HS. Obsolete technology was defined as: "A health technology that is no longer at the standard of care or clinical benefit, safety or cost-effectiveness that has been

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			"obsolete" throughout Europe. A decision whether a medicine is obsolete (throughout Europe?) could only be made after an evaluation and not at the time point of HS.		superseded by available alternative technologies [34]." We were not restricted in our mandate to the EU proposal. Introduction of new and effective technologies will potentially make existing technologies obsolete. There are several sources of information for obsolete technologies: assessments of new technologies; variations in use; inapropriate use (not in line with guidelines).
EFPIA	9	244	…Obsolete technology: Lacking explanation who will decide by when a health technology is obsolete	2	This is wording used in the cited definition of Horizon scannig, see comment above.
EFPIA	9	295	the reference to obsolete technologies is confusing as it will not be possible upfront to determine what is and what is not an obsolete technology (prior to assessment)	2	See comments above.
EFPIA	21	655	…HTA activities should not delay the introduction of innovative technologies and should contribute to timely withdrawal of obsolete technologies.: Withdrawal of the marketing authorization? Not clear what is meant by timely withdrawal.	2	No, replacement by new technology through change of practice or withdrawal of reimbursement (not regulation)- sentence has been rephrased to avoid confusion
EFPIA	21	672	… (goal: inform a possible need to increase uptake of innovative technology/possible need to disinvest obsolete technologies): The statement underlined requires more explanation	2	Rephrased, hopefully more clear
EFPIA	21	680	Table 1industry is the primary source of information on candidate products in development (before marketing authorisation) and is the only party that can provide valid data on timelines, so that any system aiming to anticipate the impact of pharmaceutical pipelines on the operations of the HTA network needs to build on data provided by the manufacturers. Any other information should be	2	Table 1 moved to background. Industry should be a primary source of information, but not the only source of candidates for HTA.

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			based on publicly available information, including information from regulatory bodies.		
EFPIA	23	756	….In cases were no prioritisation is needed, e.g. if all new pharmaceuticals are to be assessed,: No information provided by when this will be the case – no priorization?	2	Changed to explain: In cases were no prioritisation is needed, e.g. if as according to the proposed EC regulation on HTA all new pharmaceuticals are to be assessed
EFPIA	24	777	Stakeholders to a European cooperative HSS include … payers: Who are these "payers" - for example in Germany the GKV-SV or the individual statutory health insurance like AOK. In Germany there are 110 individual statutory health insurance organisations.	2	Stakeholder definition changed: see Recommendation 5.1-5.5. Proactive contact on umbrella organisational level for identification. Individuals with the payers perspective could be recruited for committees if needed.
EFPIA	24	778	developers (industry, researchers and any other commercial or non-commercial developers of health technology), those holding or applying for marketing authorisation: What is the difference between developers and those holding or applying for marketing authorization?	2	Those applying for MAH may have purchased personal rights, company rights, or companies etc and are not necessarily developers. -see glossary
EFPIA	24	785	any stakeholder could be contacted upon need to populate and verify the data-sets: upon need to populate and verify – information about the potential interval is missing	2	Rephrased (see rec 2.3) iterative is said, but due to uncertainty with regard to funding no recommendation could be made, but see rec 3.2 with regard to timeliness of identification.
EFPIA	26	843	Workflow for TISP EUnetHTA JA3 WP4 (draft): EUnetHTA suggested applying two filters to identify products for a joint assessment.	2	Pilot recommendations, see pilot plans and pilot evaluation (available at https://eunethta.eu/services/horizon-scanning/)
EFPIA	31	1020	The pilot will be conducted in the period October to December 2018 with preparation starting in August.: The proposed timeframe for the pilot of three months appears to be very short.	2	Comments to recommendations to the pilot. The pilots were delayed, short time-frame and delay was due to ressource restrictions.

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EFPIA	9	226-228	it is unclear whether this definition is widely accepted and it would be interesting to have a more thorough discussion on this concept.	2	The term disruptive interventions is not used in the final recommendation, the definition is removed.
EFPIA	13	385-389	The document outlines that HS activities will "facilitate the prioritization of technologies that are to be retained for joint activities." However, will developers (i.e. manufacturers) still be eligible for joint activities if desired even if HS does not dictate such? If not, it seems like manufacturers could miss out on benefiting from the efficiencies gained via joint processes.	2	We recommend both pro-active and reactive identification- the HS should not exclude topics within the scope - developers should be able to propose topics, but should not be able to dictate prioritisation.
EFPIA	25	817 - 818	If prioritisation for initial assessment is to be performed after the technology has entered the regulatory process…..	2	Comments to recommendations to the pilot.
EIWH	30	955	Recommedations for the pilot: Indication(s) (anticipated) by age and sex	1	Comment to recommendations for the pilot, Indication (including age and sex) was used. See pilot plans and pilot evaluation (available at https://eunethta.eu/services/horizon-scanning/)
EIWH	30	986	8. Type of output: impact on patients by age and sex (burden of disease, transformative technology potential impact	1	Comment to recommendations for the pilot, Indication (including age and sex) was used. See pilot plans and pilot evaluation (available at https://eunethta.eu/services/horizon-scanning/)
EIWH	32	1043	12. Implementation: Joint clinical assessment includes a focus on unmet need, it is important to consider an age and sex perspective to improve date , outcomes and equity	1	Comment to recommendations for the pilot, Indication (including age and sex)- in the final recommendation this is covered by: Indication and target population.
EIWH	32	1047	13. How can the pilot be evaluated: Availability of data from different sources by age and sex	1	Needs to be further explored, there was no funding for detailed evaluation of the pilot
EIWH	32	1050	13. How can the pilot be evaluated: relevance of critera by age and sexi	1	Needs to be further explored, there was no funding for detailed evaluation of the pilot

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EIWH	32	1051	13. How can the pilot be evaluated: interrater reliability/variation of priority scoring by age and sex	1	Needs to be further explored, there was no funding for detailed evaluation of the pilot
EIWH	24	775	9. Review of output: sources and any other predefined criteria for quality assurance by age and sex	1	Covered by indication and target population
EIWH	30	977	8. Type of output: More extensive information about the disease, indication (population) including age and sex	1	Comment to recommendations for the pilot, Indication (including age and sex) was used. See pilot plans and pilot evaluation (available at https://eunethta.eu/services/horizon-scanning/)
EIWH	15		Early dialogue (ED) within EUnetHTA JA3 WP5 452 · : unmet need, high disease burden (life-threatening/chronic disabling disease, including an age and sex / gender perspective	1	Part of the background chapter. This is a description of the current criteria for ED not a recommendation. The Background chapter has been moved to after the recommendations to not confuse the reader.
EIWH	24	763	8. Type of output to be produce: treatment strategies (comparator(s)), potential areas of impact on male and female patients. European Commission. 2015. Advancing the case for gender-based medicine. https://ec.europa.eu/programmes/horizon2020/en/news/advancing-case-gender-based-medicine	2	This is not instructions for trial design: but in HTA this should of course be considered
EIWH	32	1048	13. How can the pilot be evaluated: regulatory status of data when entering the minimal data-set by age and sex	2	No resources for this in the pilot, needs to be further evaluated after initiation
EIWH	33	1093	Discussion: WP5 post launch evidence generation including sex and age (PLEG)/additional evidence generation (AEG)	2	Comments to recommendation on the pilots, not further commented on

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EIWH	23	753	8 Type of output to be produced: authorisation holder (MAH) or applicant (pMAH), the intended indication for use , male or female specific	2	Generally covered by indication and target population. In HTA this should of course be considered
EIWH	24	768	8. Type of output to be produced: publicly available. The database should give a clear, but easy overview of data by age and sex	2	Generally covered by indication and target population. In HTA this should of course be considered.
EIWH	24	770	8. Type of output to be produced: Additional outputs like reports on selected therapeutic areas describing in more detail unmet need by age and sex.	2	Additional output deleted from recommendations
EIWH	23	718	7. Prioritisation: unmet medical need by age , sex and gender ENGENDER Project. 2011. Gendered Exposures and Vulnerabilities. https://eurohealth.ie/gender-exposures-and-vulnerabilities/	1	"The recommendations are from the perspective of HTA assessors involved in EUnetHTA relative effectiveness assessments (REAs). The recommendations are generic in the sense that they are valid for different models of European cooperation on HTA. The main conclusion is that transparent, unbiased and efficient horizon scanning services should inform prioritisation of European cooperation on HTA. Due to uncertainties regarding future models for cooperation and legislative regulation, we (the TISP group) were not able to provide recommendations on the ownership and financial responsibilities for horizon scanning and the TISP process, nor detailed criteria for selection and prioritisation. These are important areas that remain to be defined. "
MedTech Europe	General		MedTech Europe calls for a separate Horizon Scanning System for medical technologies and pharmaceuticals. Major differences should be made as regards 1. the selection and 2. the point-in-time. 1. HSS for medtech should not be limited to the identification of emerging technologies but should rather focus on transformative technologies, i.e. a subset of disruptive technologies, namely those that can address high unmet needs, would lead to significant changes in	1	Should be covered by the recommendations : "1.2 One or more horizon scanning services with transparent, unbiased and efficient processes should inform prioritisation of European cooperation on HTA." With regard to the mentioned recommendations on NICE MedScan initiatives, they are currently not public available and we can not provide recommendations for any specific collaboration. A common

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			healthcare delivery and need significant investment. 2. As regards the point-in-time, HSS should not necessarily take place very early in the development process to be ready before marketing authorization; instead a timely HSS for medtech would give sufficient time to allow for an initial use of the technology into practice. These two conditions would make a major difference in making sure horizon scanning serves a purpose and would eventually be of value for a future potential HTA cooperation on the selected technology. The Accelerated Access Review of NICE and Medscan should be used for an EU medtech Horizon Scanning.		overall workflow for TISP has been recommended. Details for different scopes need to be outlined. See Disclaimer: "The recommendations are from the perspective of HTA assessors involved in EUnetHTA relative effectiveness assessments (REAs). The recommendations are generic in the sense that they are valid for different models of European cooperation on HTA. The main conclusion is that transparent, unbiased and efficient horizon scanning services should inform prioritisation of European cooperation on HTA. Due to uncertainties regarding future models for cooperation and legislative regulation, we (the TISP group) were not able to provide recommendations on the ownership and financial responsibilities for horizon scanning and the TISP process, nor detailed criteria for selection and prioritisation. These are important areas that remain to be defined."
MedTech Europe	General		Confidentiality is crucial. At the moment a technology, pharmaceutical or device is "detected" by HSS this is an information for the competition what is coming up in the pipeline. If the manufacturer reveals the pipeline for HSS there should be an incentive, e.g. a link to reimbursement after EU HTA in the case of a positive assessment. Predictability is also key. What are the criteria of selection? Which evidence is needed? What is the link to a possible EU HTA after 2020?	1	confidentiality discussed an aknowledged through : "1.3 The horizon scanning service should be a legal entity with an appropriate confidentiality framework to allow developers of technology (including manufacturers and prospective marked authorisation holders) to share information at an early stage." Reimbursement decisions are national, and also it is out of scope for the recommendations on HS and TISP to provide recommendations reimbursement.
MedTech Europe	13	358	On the question of mandatory and voluntary cooperation, we believe that for HTA cooperation on medtech to be meaningful, cooperation should be initiated and led with a collaborative approach around groups of Member States' common needs. The mandatory cooperation would lead to unintended consequences, such as delays	1	This is a statement from MedTech Europe concerning the EU proposal and not the HS/TISP recommendations.

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			in access and limited options available for the benefits of patients and healthcare systems.		
MedTech Europe	20	622	Due to the stronger market exclusivity and patent protection for pharmaceuticals and the lack of data exclusivity period, we suggest the following rephrasing: "HTA activities to be supported should reflect technology lifecycle, patent protection, data exclusivity period and do include: …"	1	No change based on this comment. We consider these aspects to be within the term life-cycle perspective.
MedTech Europe	20	629	Considering synergies between HTA and HSS, are there discussions on combining the planned HS secretariat with the one of the planned HTA secretariat?	1	We agree that the role of the Coordination group of the EU proposal has to be clarified. Changes have been made to distinguish between different roles, but it is out of our mandate to define the role of the Coordinating group described in the EU proposal on regulation of HTA.
MedTech Europe	22	707	Further clarification on the designation of the panels of experts would be needed.	1	See: "5.3. If specialized selection or prioritisation committees are established, individual stakeholders without general conflict of interest in the technology/product should be recruited. In particular healthcare professionals (experts), payers and patients, should be members of the committees. Declarations of interests should be provided as described in the EUnetHTA Declaration of Interest and Confidentiality agreement procedures [5]. AND "3.5. As far as possible, criteria that can be objectively measured should be used. If selection criteria involve judgements on impact, specialized selection committees should be appointed by the horizon scanning service in collaboration with a central acting coordination group of the HTA network." AND "4.3. If prioritisation criteria involve judgment on impact and evidence level, carefully selected and trained committees should perform the ranking. "

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MedTech Europe	23	717	As a minimum and for consistency purposes, the listed prioritization criteria should be updated when the final EU Proposal is adopted.	1	Due to uncertainties regarding future organisation of HTA coooperation, no detailed prioritisation criteria are given. See recommendation 4 Prioritisation
MedTech Europe	23	750	We would like the content of the minimal data set for MD and IVD to be reconsidered with regards to the above comment.	1	
MedTech Europe	13	388-390	MedTech Europe suggests changing the sentence into: "The recommendations for a HSS in this document are for an HSS integrated with the EU proposal for joint assessments as well as voluntary collaboration for technologies with significant impact".	1	See Executive summary: "This report provides recommendations for horizon scanning and topic identification, selection and prioritisation (TISP) processes to support European cooperation on Health technology assessment (HTA). " AND Disclaimer provided there
MedTech Europe	20	646-648	The Commission's proposal defines Horizon Scanning as the 'Identification of Emerging Technologies'. We believe Horizon Scanning should not be limited to the identification of technologies that are in the pipeline. Instead MedTech Europe supports a HSS based on the identification of transformative technologies or solutions which 1. address high unmet patient/citizen or societal and health care systems' needs and 2. require significant structural or organization change to deliver their benefits and investments for change.	1	We agree, this is also reflected by the definition of HS used by us: "Horizon scanning: The systematic identification of health technologies that are new, emerging or becoming obsolete and that have the potential to effect health, health services and/or society. Related terms include early awareness and alert system [25, 34]". We consider this to be a comment to the EU proposal not the recommendations.
MedTech Europe	21	664-666, 896 – 901	"To allow prioritization of initial assessments the timeframe for identification should be: no later than when a device or IVD is anticipated to enter the CE marking process." "The timeframe for identification of MDs and IVDs will be one of the following depending on technology and available information: · around the time of CE mark · when pivotal trial data are anticipated to become available · when a CE marked product is anticipated to be available for use outside clinical trials"	1	A general and in the same time precise statement of time frame for identification can not be provided. Identification should not delay HTA relative to regulation, in this case the CE mark. Not all MDS and IVDs will be prioritised, however there is a need to identify all selectable MDS/IVDs, this can be done based on information from regulators or developers. See Rec 3.2. "To assure timeliness of the REAs, pharmaceuticals should be identified early enough to allow selection approximately three to six months before the

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			These two different formulations may lead to misunderstandings. In addition, the timeframes for the regulatory process of medical devices vary considerably, as also pointed out in the text; and depending on the risk classification and type of device, the "sufficient evidence for assessment or action (row 659)", i.e. the data required for the prioritisation process may well be available during the actual CE marking process. Therefore, we propose to change the wording to reflect the medtech model reality.		technology/products enter the lists of medicines under evaluation in EMA. MDs and IVDs should be identified early enough to be selected around the time when a CE mark is provided. The time frames need to be adjusted based on experience gained once the system is established."
MedTech Europe	22	690 - 691	"Collaboration between the HSS and regulatory bodies should be explored to assure timely and regular access to structured information". While the output of the regulatory process might be used a source of information for the HSS, it would be advisable to keep the two processes separate as they play different roles. Through the regulatory approval, safety, performance and a clinical benefit are demonstrated before market entry and monitored when the technologies are on the market while the HTA aim to inform a decision, for example on funding and coverage, after market entry at an appropriate point in time when effectiveness data are available.	1	The information needed from the regulatory process might not be as detailed as indicated by this comment. The most time consuming part of populating the minimal dataset of the pilot was information to wether the product was CE marked and, in case yes, what class. This information is currently not available in a structured way. See Rec 2.2." Regulatory authorities and developers should be consulted to keep all records as up-dated as possible. In particular, information from EMA should be used as explored by the TISP pilot on pharmaceuticals [1]. Cooperation with regulatory authorities on MDs and IVDs needs to be further explored, in particular the planned EUDAMED database to be available in 2022 [2], should provide means for structured data to be available. "
MedTech Europe	22	691 – 693	"Issues of confidentiality should be clarified. Preferentially, to ensure that the HSS is as transparent as possible, only non-confidential information should be used to populate the data-sets" Linked to this is the statement on row 1096 that "EUnetHTA JA3 WP4 has experienced a lack of commitment from developers of technologies to suggest topics for HTA". In our experience developers are hesitant to submit any information	1	This has been overcome by existing HS systems. The section is changed, but we do recommend transparency. See Rec 1.2 " One or more horizon scanning services with transparent, unbiased and efficient processes should inform prioritisation of European cooperation on HTA. 1.3 The horizon scanning service should be a legal entity with an appropriate confidentiality framework to allow developers

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			(not only "information related to timelines and pricing" as stated in line 1104) prior to market launch unless confidentiality can be guaranteed. There may not be an existing patent protection and patents are easier to work around for medical devices than for pharmaceuticals. We have similar considerations with the development of EUDAMED.		of technology (including manufacturers and prospective marked authorisation holders) to share information at an early stage.
MedTech Europe	24	783-784 &1006	"regulators should be involved in the process of topic identification and the populating and updating of data-sets" – "involving regulators in topic identification" The two processes of the regulatory approval and the horizon scanning in view of a potential HTA have separate and specific roles and purposes. The regulatory process leading to the CE marking aims to demonstrate safety, performance and a clinical benefit whereas the HTA aims to assess the added-value of an innovation compared to the current standard of care. While the output of the regulatory process may be used for horizon scanning purposes, multiple stakeholders other than regulators might be better suited to be involved in the process of topic identification.	1	This is covered. See Rec 5 Stakeholder involvement
MedTech Europe	24	787 & 1013	"developers should not participate in the prioritization process" – "developers of technology should not be involved in the selection or prioritization processes" It would be more insightful to have all the relevant stakeholders involved in the selection or prioritization process, including technology developers. EUnetHTA should aim for a "collaborative approach instead of reiterating classical models.	1	A collaborative approach is assured by inviting developers to participate in other steps, but developers can not be part of the prioritisation process as they will have commercial interest in the topics.
MedTech Europe	29	928-932	"Stakeholders may be approached with the lists of selected topics and reveal their interest […] to provide input before a pre-specified	1	See above and Rec 1.3

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			deadline. Feedback from developers can be used as an early indication [..] on the ability/interest of the developer to submit a documentation file". Line 1007 invites "commercial developers to verify content of prioritisation lists and provide letters". We are concerned that for many medical device companies this means disclosing market secrets. It would be interesting to know more about who is invited to take part in submitting information and how the stakeholders are identified. We also welcome the wording in line 1108 that special arrangements with developers and regulators, on how to deal with confidential information might be needed for a cooperative European HSS.		
MedTech Europe	24	782	We welcome the suggestion that "any stakeholder should be able to suggest a topic to the HS identification process"	2	noted -no change
MedTech Europe	24	788	We welcome the suggestion that "any stakeholder should be able to provide feedback and be informed on status of HTA activities within the network."	2	noted -no change
MedTech Europe	25	807	The reason for updating the minimal datasets more often for pharmaceuticals specifically is not clear. The development times and life cycle time for technologies are generally shorter than for pharmaceuticals.	2	Exact timelines could not be provided. The minimal data-sets should be updated iteratively based on continous scanning for changes in regulatory status and availability of data from pre-selected clinical trials and stakeholder input. Pharmaceuticals follow more predictable regulatory processes then MDs and IVDs. In particular for pharmaceuticals, an HTA process should not delay possible introduction and updates from EMA on regulatory status of pharmaceuticals could be close to monthly based on mutual agreements. Similarly, when the EUDAMED database becomes available, updates on regulatory status on MDs and IVDs could also be on a regular basis.