Comments received from the Netherlands' delegation

Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU.

Comments from the Dutch Delegation on articles as proposed by the Croatian presidency

General remarks

The Netherlands highly values the efforts of the Croatian Presidency, especially in these difficult times, to collect all comments from Member States in order to conclude the progress made. The Netherlands sincerely hopes that upcoming presidencies will be able to continue the dialogue based on the Croatian effort, picking up from where Member States involuntarily halted at the outbreak of the COVID-19 pandemic in Europe.

This document highlights several technical comments in addition to the input given at the previous meetings. As there are several elements of the regulation, such as addressed in art. 8 et al. where no consensus exists and that still require a fundamental debate, we would welcome a joint report that focuses on the technical comments made by Member States.

In this light, we would support the Estonian appeal to the Presidency "to include in this report both the latest consolidated text on the full proposal of the regulation and an overview of where we stand and which questions still remain open. The overview of the state of play could point out in which parts of the text there is overall consensus and which are the open questions, including political, yet to be solved."

We feel that this will help to focus on these topics that require debate and fundamental choices in the next stage of the debate.

As the COVID-19 pandemic has radically changed our current way of working, The Netherlands feels that upcoming presidencies have an important, however challenging, responsibility to continue working towards a broadly supported, well regarded regulation. We remain open and committed to contributing to the dialogue, regardless of the technical forms in which communication will have to take place.

Article 5

- (ab)
    - In order to allow for the joint assessment of a product that already has market authorization for one indication, however has not undergone a joint clinical assessment for that indication and that is granted market authorization for an additional indication, the current text should be amended.

Article 6

- 6.1a
    - To prevent misunderstanding regarding "The (…) report shall be limited to (…) the relative effects":
        - A report is a relative effectiveness assessment (ie: one intervention compared to another intervention).
          An effect can be expressed in relative (yielding a ratio or percentage) or absolute terms (yielding a difference). In assessments, both relative and absolute effects are important.
    - Therefore the term relative effects should be replaced by relative effectiveness.

- 6.1b
    - As a scientific analysis of certainty of relative effects is not absolute, but rather requires an estimation of the *degree of* certainty with which the effects can be expected to occur, we suggest to retain *degree in* the wording of the paragraph.

- 6.2b (i) c&d
    - Both should be retained in the text.

- Recital 16c
    - The Netherlands supports the initial Swedish suggestion to accommodate for the potential use of Real World Evidence by adding the following text:

      For medicinal products, preferentially, randomized blinded controlled directly comparative studies whose methodology conforms to international standards of evidence based medicine, should be considered when conducting the joint clinical assessment. **This should not exclude observational studies, including those based on Real World Data, when needed and accessible.**

Article 9

- 2a
    - The practical implications of the addition of article 2a should be discussed. What is *expected of the member states to be made available to others?*
      Only full national (update) reports, or also small update reports in case it was part of a minor reconsideration?

Article 10 & 15

- It is unclear to us what the exact reason is to delete these two articles. Was this because the transitional arrangements were repositioned to a different article?

Recital 20

- We question the need to include this description of clinical studies. As far as the Netherlands is concerned the old text using "clinical assessment" made more sense as this term is used throughout the text.

Recital 25

- The part in between brackets should be deleted as the remit is now with the CG, rather than the European Commission.

Article 12

- We suggest not limiting it to "first in class", even though this is a criterion taken from EUnetHTA.

Article 13

- Para 8d
  - In the current EUnetHTa process diverging opinions are also part of the outcome document. This works well in practice and could be added here

Article 18

- 1a
  - In order to clarify the extent of the topic 'potential organizational and financial consequences, the text could be more precise by replacing with the following wording:
    "Potential treatment-related organizational consequences as well as the general financial consequences for payers based on the expected future pricing of products.

Council of the European Union
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Brussels, 14 June 2020

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WORKING PAPER

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WORKING DOCUMENT

From:	General Secretariat of the Council
To:	Working Party on Pharmaceuticals and Medical Devices (HTA)
N° prev. doc.:	WK 2577/2020
N° Cion doc.:	5844/18 PHARM 6 SAN 49 MI 61 COMPET 53 IA 43 CODEC 133 + ADD 1 + ADD 2 + ADD 3 + COR 1
Subject:	Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU - Comments received on Presidency texts

Delegations will find enclosed comments on the Presidency text set out in document WK 2577/2020 (from 5 March) and on the texts set out in the Presidency documents WK 689/2020 and WK 1661/2020 (from January and February). These comments were received in May 2020 from the Danish, French, Netherlands, Portuguese, Finnish and Swedish delegations.

Comments received from the Danish delegation

Comments received from the Finnish delegation

HTA; Comments from the Finnish delegation (18 May 2020)

Firstly, we would very much like to thank the Croatian colleagues for the constructive suggestions and collaboration under these very challenging circumstances. Thank you also for the opportunity to comment the following articles. At this point, we have only minor comments to send in writing.

Article 9 para 2a on updates

- If national updates are not forbidden, do we need a para allowing the MS to update?
- It is important that also the new data of the updates would be shared. Just sharing assessments (perhaps with a country specific methodology) may not be so useful. The final wording should be considered together with possible requirements for data sharing in article 8.
- The word "with" is missing in the sentence "Such updates shall be shared **with** the members of the Coordination Group via the IT platform".

Article 11a

- In our view, the suggested wording "establish a system" to "carry out" changes the meaning slightly. We understand this in such a way that external experts or companies could be used in the assessment. This needs to be discussed and drafted so that it would be understood by all in the same way.
- Para 1a. It might be good to have the possibility to expand JSCs to a wider range of technologies than only those defined in the scope of the JCA. Could a stepwise approach be possible, i.e. starting with those technologies that go to a JCA and extending further to other technologies, especially if the pharmaceutical companies shall pay for the JSC? This needs to be discussed.
- Para 2. We would like to change the word "recommendation" to "advice", which better describes the nature of the consultation. Giving recommendations actively may lead to situation in which the CG takes responsibility of the trial design. For comparison, SA in EMA works by answering specific questions from the company e.g. on whether a certain procedure can be acceptable. The role of the JSC is to help to improve the possibilities that the study can answer to the question "is it worth it?"

Article 12

- 2b add d) high risk of uncertainty in therapeutic value

Article 13

- The rules for transferring confidential information between EMA and CG should be clarified and they should be included in the Regulation.

Article 13b

- There is no timeframe for the JSC. In our view, it should be included in the Regulation (like for JCA).

SUNDHEDS-
OG ÆLDREMINISTERIET

Sundheds- og Ældreministeriet

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Written comments on WK 1661/2020 and WK 2577/2020

Health Technology Assessment

Article 6, paragraph 0b:

- In regards to medical devices, the time measurement should be calculated as X number of days after the Notified Body has provided the manufacturer with a certificate.

- It is important, that the timeframe is laid down in a way, that is realistic for both pharmaceuticals and medical devices.

Article 6, paragraph 1a

- "*to conduct the joint clinical assessment*" should be amended to "*to prepare the joint clinical assessment*".

- The rapporteurs shall prepare the JCA and thereby the draft reports, cf. article 6a, 1 and then send it to the coordination group, cf. article 6a, 10.

Article 6, paragraph 1b

- This article states, that: *"The scoping process shall also take into account input received from patients and clinical experts".*

- It is uncertain how this will work in practice. Thus, the legal provision may need to be supported by Rules of Procedure with regard to the more precise involvement of patients and clinical experts..

NEW Article 6, paragraph 1c

- We propose to add the following clarification in a recital (or a wording along the same lines) : *"1c. If a Member State deems that the assessment scope is not suitable in a national context it may decide not to participate in the joint clinical assessment and conduct its own clinical assessment. The Member State shall justify its reasons for non-participation in the joint clinical assessment."*
- We deem it of importance to clarify Member States' room for maneuver in case they deem the PICO unsuitable/unworkable in a national context.

- We suggest that it equally follows from a recital that Member States do not need to await the result of the JCA before they initiate a national process.

Article 6, 1 indent b

- It is unclear to us why "degree of" has been deleted. . As it seems relevant to focus on the degree of certainty of the relative effects.

- The Presidency uses the wording "*scientific uncertainty*" in recital 15b – we propose to amend this to *"scientific certainty*in order to align with the wording used in the article that reads "a scientific analysis" "of the certainty of the relative effects".

Article 6.2, paragraph 2a

- It follows from para 2a, that the developer must submit the dossier no later than 60 days prior to the envisaged CHMP opinion. We are wondering whether this is a sensible approach to the JCA process as it seems to be a very early point in time. The Committee for Medicinal Products for Human Use might give a negative review afterwards – or recommend substantial modifications to the applied indication(s).

Article 6.2 paragraph 2a, litra (ii)

- It appears from footnote 22, that the list of obligations in terms of the dossier for medical devices will be completed at a later date after a discussion with EUnetHTA.
- We deem it of importance with a more indebt discussion on medical devices, including on dossier requirements and this in particular in view of the scope once we have a better overview of what that may look like.
- It is our immediate response that the dossier for medical devices should at least include the clinical evaluation, the clinical evaluation assessment report and, if applicable, the scientific opinion provided by the relevant expert panel in the framework of the clinical evaluation procedure.

Article 6.2, paragraph 2e

- The Presidency proposal reads: "*If the health technology developer fails to comply with obligations set out under this Article, Member States shall impose penalties as set in Article 34a.*"

- We propose to amend "shall" to "may" as this leaves Member States room for maneuver in their decisions on potential sanctions.

- In the PRES paper it is suggested to sanction companies that do not submit the necessary data.

- As communicated previously Denmark takes the view that the most effective incentive is an agile and well-functioning system. On this basis we find it of importance that Art 28 leaves room for evaluation as to whether this overall objective has been achieved.

Article 6a, paragraph 7a

- The Presidency have replaced "*stakeholders*" with "*The sub-group shall ensure that specified experts on the assessment topic, including patients, and other relevant experts, are given an opportunity to provide input on the draft reports*."

- We propose to reinsert "*stakeholders*", since patients are not encompassed by the term "*experts*".

Article 6a, paragraph 8

- The developer only has five working days to comment on the draft report, which seems to be very little time. High quality reports are in everybody's interest and we therefore believe that a few more days could add value to this part of the process.

Article 6a.1, paragraph 14

- We propose to set a deadline for notification of the developer.

Article 9, paragraph 2a

- We propose to insert paragraph 2a as a new paragraph 3a and make it clear that the provision is without prejudice to paragraphs 1-3.
- When is it possible for Member States to carry out updates of joint clinical assessments on national level? We assume that national updates could be replaced by European updates carried out by the Coordination Group afterwards.

Article 12, paragraph 2b

- It is (still) our opinion that developers of health technologies which are likely to be part of a joint scientific assessment should have the possibility to get a joint scientific consultation, and these developers should receive equal treatment. It could be very difficult to prepare for a joint scientific assessment if a request for a joint scientific consultation is denied. We are not convinced that the proposal with the selection criteria will be a suitable solution.

Article 13b, paragraph 12

- The timeframe (10 working days after the joint scientific outcome document has been finalised) is quite long. Maybe we could consider a shorter timeframe, e.g. 5 working days.

Comments received from the Swedish delegation

Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU.

We would like to refer to our previous written comments on Presidency paper WK 1661/2020 and Presidency paper WK 689/2020. Regarding Presidency paper WK 2577/2020 Sweden has the following comments:

Article 9 2 a

- SE supports the clarification that MS may perform updates as needed. This may include, for example, the need to make national evaluations for additional sub populations, comparators, or upcoming nationally relevant scientific information.

Article 11 a

- With current wording, JSC is to be implemented to provide input to the manufacturers regarding their clinical studies. We believe that in some cases it may also be relevant to provide consultation on the generation of evidence *after* the marketing approval, so-called post launch evidence generation (PLEG). This is possible today within EUnetHTA. The possibility of PLEG consultations enables follow-up of products with limited evidence upon approval. SE therefore proposes to consider wording stating that JSC can also be conducted for PLEG.

Article 12

- As regards the requests for parallel advice in Article 12 (1), it is stated that the request for a joint JSC shall be made at the time of submitting the request for scientific consultation to the EMA / expert panels. We suggest that it should be stated in the application to the EMA / expert panels that it is a request for parallel advice. This could be added either in Art 12.1, in Art 16, or in implementing acts.
- We also wonder if a developer who's application for a JSC gets rejected has the opportunity to apply again in the next application period?

Article 13 b 12

- Article 6a (1) states that "after any reasoned divergent scientific views have been annexed, the CG will endorse those reports by consensus ..." We propose a similar wording in this article. For example: "The final draft joint scientific consultation outcome document shall be endorsed by the CG by consensus."

Comments received from the French delegation

(French original)

Commentaires des autorités françaises portant sur le règlement relatif à l'évaluation des technologies en santé (HTA).

Réf. : Documents CM 1454/2020, WK 1661/2020 et WK 1683/2020.

Commentaire général.

Les autorités françaises remercient la présidence Croate pour ses efforts et le travail réalisé concernant ce projet de règlement dans le contexte actuel. Les discussions ont été constructives et ont permis de faire progresser le texte. Pour autant, sur l'ensemble des articles travaillés, les autorités françaises maintiennent leurs propos et les réserves liées à deux points majeurs déjà précisés :

- Le règlement HTA doit être plus explicite sur le fait que les EM ne sont pas contraints dans leur propre processus national d'évaluation ; des évolutions du texte sont à poursuivre dans ce sens.
- Le règlement HTA doit également être un processus décidé et piloté entièrement par les EM. Sur ce point également, les travaux sont à poursuivre.

Au regard de ces éléments qui ont fait l'objet de commentaires lors des différentes réunions de travail, et considérant également que les différentes parties du texte sont liées les unes aux autres, les autorités françaises considèrent qu'aucun texte ou extrait de texte de compromis ne peut être validé à ce stade et que les travaux doivent se poursuivre.

Vous trouverez ci-dessous les remarques, propositions et commentaires préparés pour la réunion du 10 mars 2020 et que nous n'avions pas pu porter à votre connaissance. Ils se composent d'un commentaire général sur l'ensemble du texte et de commentaires plus détaillés sur les articles 9, 10, 11a à 16.. Les commentaires et remarques portant sur les autres articles du texte examinés sous présidence Croate ont déjà été formulés lors des réunions en présentiel et ne sont pas intégrés au document par souci de.

Commentaires sur les articles 9, 10, 11a à 16

1. Commentaire général

Les autorités françaises soutiennent une coopération européenne en matière d'évaluation des technologies de santé, qui permette d'avoir une réelle valeur ajoutée, de qualité et qui soit pilotée par les Etats-membres. Les consultations scientifiques communes (JSC) devraient permettre de faire mieux correspondre les études réalisées avec les attentes des Etats-membres et ainsi améliorer la qualité attendue. Elles constituent un point important du règlement mais ne sont pas au cœur du texte, contrairement aux évaluations cliniques communes.

Les autorités françaises remercient la Présidence pour le travail réalisé sur ces 2 sujets dans le contexte actuel particulier et difficile.

Le projet relatif aux consultations scientifiques communes présente moins de difficultés que les évaluations cliniques conjointes (joint clinical assessments - JCA). La proposition de règlement devrait malgré tout encore évoluer, notamment concernant :

- l'articulation des travaux entre les consultations scientifiques communes (JSC) et les JCA au sein du groupe de coordination – et notamment 1° la charge de travail relative entre les consultations et les rapports, ainsi que 2° la composition du sous-groupe relative aux consultations ;

- la liberté clairement exprimée pour les Etats-membres de conduire des dialogues précoces ou consultations scientifiques au niveau national, indépendamment des travaux communs ;
- la compétence donnée au groupe de coordination de décider des modalités pratiques de réalisation de ces JSC – dès lors, les « implementing acts » relatifs à ce sujet (cf. article 16) doivent être supprimés ;
- les éléments de calendrier qui ne sont actuellement pas du tout définis dans le règlement et renvoyés à un « *implenting act* » de la Commission, ce qui est contraire à notre position.

L'actualisation des évaluations cliniques communes n'est pas suffisamment travaillée, notamment car nous n'avons pas encore pu suffisamment avancer sur les évaluations cliniques initiales. Nous proposons de supprimer la possibilité de réaliser des actualisations, pour se concentrer sur les évaluations initiales.

2. Commentaires par article

Article 9 : Updates of Joint Clinical Assessments

1. et 2. A ce stade, les réévaluations ne sont pas suffisamment précises dans le texte du règlement. Il n'y a pas de procédure détaillée pour réaliser ces réévaluations, ni de calendrier pour pouvoir les réaliser.

Compte tenu des difficultés relatives aux discussions sur les évaluations initiales, nous sommes en faveur de la **suppression des paragraphes 1 et 2**. (Pas de réévaluation au niveau européen).

2a. Supprimer « *such updates shall be shared the members of the Coordination Group via the IT platform* » pour éviter d'alourdir la charge de travail des MS.

Article 10 : Transitional Arrangements for Joint Clinical Assessments

Remarque : pourquoi supprimer cet article 10 ?

Recital (20)

Les modalités d'accès aux consultations scientifiques ne sont pas suffisamment précisées. Il faut davantage souligner qu'il s'agit d'une possibilité pour les développeurs de technologies de santé (HTD) de demander de telles consultations mais que le groupe de coordination doit conserver le droit d'instruire ou non ces demandes. En effet le règlement précise déjà les règles à respecter concernant la soumission.

Nous pourrons rappeler qu'à ce stade des travaux du texte, le service est offert gracieusement aux HTD. Dès lors, il faut faire attention à ce que le travail européen ne soit pas uniquement embolisé par de telles consultations scientifiques.

Recital (20a)

Il est important que le respect des missions respectives du groupe de coordination et de l'EMA dans le cadre des JSC soit présent dans le règlement. Une phrase du type « the JCS shall respect the different remits of HTA and regulatory processus » (cf. FR-DE) pourrait être introduite dans le règlement.

Recital (20b)

Ce point est repris dans l'article 12, mais il semble important de mentionner clairement dans le règlement que le groupe de coordination peut ou non accepter une JSC. (cf proposition à l'article 12).

Recital (25) – Point important

Ce point a déjà été précisé : nous ne souhaitons pas d'acte d'exécution portant sur la définition de la méthodologie d'analyse et les JSC. C'est au groupe de coordination d'effectuer ce travail, et non à la Commission. Ce point fera l'objet d'un commentaire similaire lors de l'instruction de l'article 16.

La référence aux initiatives existantes (Horizon 2020, Beneluxa and Valletta Declaration initiatives) n'est pas appropriée. Ces initiatives, qui influencent la décision de prix / remboursement dans les Etats concernés, vont bien au-delà du cadre proposé par le règlement HTA. Nous proposons de ne pas les mentionner.

Nous souhaitons la suppression de l'ensemble de ce recital 25.

Article 11a : System Principles of Joint Scientific Consultations

1. S'agissant d'un article général de présentation et non pas d'un article définissant les missions du groupe de coordination, une formulation du type suivant serait plus adaptée: « *the JSC are carried out by the CG with the view to…. » (au lieu de « the CG shall carry out… »).*

Nous souhaitons également que le « shall » de la dernière phrase (« those recommandations shall in particular concern ») soit remplacé par un « may » : en effet, on ne veut pas forcément donner des recommandations sur l'ensemble de ces éléments à chaque fois. Par ailleurs, nous apprécions l'ajout réalisé par la Présidence (« all relevant clinical study design aspects ») – dans ce contexte, il serait utile de supprimer « but not limited to ». En effet, en conjonction avec le « shall », ce segment sous entendrait qu'il faut systématiquement aller plus loin dans le contenu du rapport, ce qui n'est pas toujours souhaitable.

2. Nous supportons pleinement la note de bas de page 4 tendant à modifier l'article 6, pour que les déviations par rapport aux JSC soient explicitées par les HTD.

3. Nous proposons de supprimer la fin de ce paragraphe (« shall inform the CG »), tout en conservant la possibilité de faire des consultations scientifiques au niveau national. Sur de telles données très précoces, il existe un doute certain sur le respect du secret industriel.

Article 12 : Requests for Joint Scientific Consultations

0. Le texte se doit d'être plus précis sur les points suivants :

- le groupe de coordination doit pouvoir accepter ou non une demande de JSC faite par l'HTD ; Une phrase ainsi rédigée pourrait être ajoutée à cet article pour clarifier ce point : « The CG remains free to accept or decline any request of JSC from a HTD ».
- le groupe de coordination doit pouvoir refuser cette demande de JSC selon sa charge de travail et sur la base de critères objectifs (et pas uniquement avoir recours aux critères lorsque que le nombre de demandes apparaît trop élevé). En effet, l'écriture actuelle du règlement laisse penser que si les quotas sont respectés, le groupe de coordination doit instruire toutes les demandes sans prendre en compte les critères, ce qui n'est pas souhaitable.

2b. Concernant les critères objectifs permettant de sélectionner les demander des HTD. Actuellement, dans le process EunetHTA on en compte trois :

- « A new mode of action for the indication;
- AND targeting a life-threatening or chronically debilitating disease;
- AND responding to unmet need (no treatment or only unsatisfactory treatment available) ».

Nous proposons de reprendre ces critères de la façon suivante afin de donner plus de flexibilité au groupe de coordination lors de l'instruction de demandes :

« *Criterias for selecting from eligible requests, for medicinal products and medical devices are based on:*

- *A new mode of action for the indication;*
- *AND targeting a life-threatening or chronically debilitating disease;*
- *AND responding to unmet need (no treatment or only unsatisfactory treatment available)* ».

Cette rédaction permet en outre d'avoir des critères de sélection qui sont indépendants des quotas, de sorte qu'une double sélection s'opère, à la fois sur la base des critères (intérêt de l'analyse) ET sur la base des quotas (charge de travail).

3. Nous ne souhaitons pas d'encadrement de délai pour les JSC dans le règlement s'il s'agit d'un « service » offert aux HTD (suppression de « within 15 working days after the end of each request period »). Par ailleurs, pour clarifier, nous proposons l'ajout de « *for rejection* » après « *shall explain the reasons* ».

Article 13 Preparation of the Joint Scientific Consultation Outcome Document

1. Le règlement doit préciser les modalités (procédures, règles de déontologie et articulation avec les JCA) permettant de désigner le sous-groupe en charge d'effectuer les JSC.

La rédaction actuelle donne l'impression d'un groupe différent pour chaque produit, ce qui n'est pas le cas pour EunetHTA aujourd'hui (un groupe de travail), ni pour l'EMA sur ce sujet (groupe SWAP).

Il serait préférable de laisser de la flexibilité en indiquant que le sous-groupe en charge des JSC « *shall oversee the preparation and the conduct of the Joint Scientific Consultation on behalf of the Coordination Group »* sur le produit concerné.

2. Comme nous l'avions proposé fin 2018, nous soutenons la nécessité d'une grande flexibilité pour cette activité, par conséquent la nature du dossier doit être fixée par le groupe de coordination. Les consultations scientifiques ne sont pas liantes et n'ont pas d'impact juridique, mais elles sont importantes car elles ont un lien direct avec la qualité des études qui seront fournies plus tard.

Nous souhaitons en outre la suppression de la référence au calendrier défini avec l'Article 16.

Article 13a : Procedure of drafting joint scientific consultation outcome documents

4a. De la flexibilité est requise pour cette activité dont le produit n'est pas liant. Aussi, nous demandons la suppression de ce paragraphe.

8. Nous nous interrogeons sur la description, dans le règlement, de l'étape faisant intervenir les patients ou des experts puisqu'il s'agit à ce stade de formuler des recommandations méthodologiques aux HTD.

8b. Il faut préciser que les « *(early) joint scientific consultations shall respect remits of HTA and regulatory process »*. Cette disposition doit se trouver dans le règlement et pas uniquement dans les considérants.

9. Nous proposons de supprimer la phrase suivante : « *Members of the designated sub-group may, as appropriate, provide additional recommendations specific to their individual Member State ».* L'intérêt de recommandations spécifiques nationales est contraire au process HTA européen. Par ailleurs, il n'est pas prévu que l'ensemble des EM soient représentés au sein du sous-groupe.

Nous soutenons en revanche pleinement le fait que les Etats membres du sous-groupe, puissent, à ce stade de la procédure (c'est-à-dire après une première révision du document par l'assesseur et le co assesseur), commenter à nouveau sur le JSC.

Nous souhaiterions donc que :

- cette deuxième phase de commentaire soit plus large (pas uniquement les recommandations nationales), et qu'elle s'applique ainsi à l'ensemble du rapport ;

- Que l'assesseur et le co assesseur soient obligés de reprendre les commentaires des Etats membres à ce stade.

Ce point (double phase de commentaires, avec reprise obligatoire des commentaires de la deuxième phase) est très important pour garantir un document de qualité reflétant les ajouts de tous les Etats-membres présents.

Cette deuxième phase de commentaires par les Etats-membres pourrait utilement être effectuée au niveau du Groupe de coordination (plutôt qu'au sein du sous-groupe).

11. Idem

Article 13b : Procedure at Coordination Group

12. Comme pour les JCA, le document, scientifique par nature, n'a pas à être approuvé. La terminologie doit être modifiée et homogénéisée dans le règlement.

13. Nous ne souhaitons pas d'encadrement de délai pour les JSC dans le règlement puisque s'il s'agit d'un « service offert » aux développeurs de technologies de santé (Health Technology Developpers – HTD).

Article 16 : Adoption of Detailed Procedural Rules for Joint Scientific Consultations

1. Les consultations scientifiques ne sont pas liantes, ni au niveau des HTD, ni au niveau des agences HTA nationales et du groupe de coordination. D'ailleurs, elles sont destinées à apporter des conseils aux HTD pour construire leurs études dont les résultats serviront à au dossier d'HTA clinique conjointe. Les résultats de cette évaluation clinique conjointe ne sont pas non plus liants au niveau des agences nationales HTA et des HTD.

Par conséquent, les autorités françaises ne souhaitent pas figer le dispositif et souhaitent donc la <u>suppression des actes d'exécution</u> prévus à cet article. Ce point est majeur.

Nous avons besoin de flexibilité pour ce type d'activité. Les avis scientifiques sont assez peu détaillés dans le règlement 726/20014 (Mandate, objectives and rules of procedure of the Scientific Advice Working Party : https://www.ema.europa.eu/en/documents/other/mandate-objectives-rules-procedure-scientific-advice-working-party-sawp_en.pdf).

Comments received from the French delegation

(English courtesy translation)

General comment

France would like to thank the Croatian presidency for the work done on this draft regulation in the current context. The discussions have been positive and have made it possible to move the text in the right direction. However, France maintains its position on all the articles discussed and still expresses its reservations on two major points that have already been made, namely:

- The HTA regulation must be more explicit on the fact that the Member States are not constrained in their own national evaluation process; developments are to be pursued in this direction.

- The HTA Regulation must also be a process decided and steered entirely by the MS. Here too, work needs to continue.

In light of these elements, already communicated at each previous working party, and considering the fact that the different parts of the text are linked to each other, France considers that no text or excerpt can be subject to a compromise at this stage.

Here are the remarks, proposals and comments prepared for the WP of March the 10th that we were unable to bring to your attention with a general comment on the entire text and comments more detailed for the articles 9, 10, 11a to 16..

Comments and remarks on the other articles discussed under the Croatian Presidency have already been made during the previous meetings and are not included in the document for the sake of readability and to focus our remarks on exchanges that could not take place.

Comments on articles 9, 10, 11a to 16

1. General comment

France supports a European cooperation in the field of HTA, which allows to have a real added value, quality and which is managed by the Member States. Joint scientific consultations should make it possible to better match the studies carried out by HTD with the expectations of MS and thus improve the expected quality. Consultations represent an important part of the regulation but they are not at the heart of the text, like the joint clinical assessments.

The proposal for the joint scientific consultation (JSC) has fewer challenges than the JCA. The proposal for a regulation should nevertheless continue to evolve, in particular as regards:

- the articulation of work between JSC and JCA within the GC : including 1° the relative workload between consultations and reports, and 2° the composition of the consultations sub-group;
- The clear freedom of MS to conduct early dialogues or scientific consultations at national level, independent of joint work;
- The authority given to the GC to decide on the practical arrangements for carrying out these JSC. Therefore, the « *implementing acts* » on this subject (see Article 16) must be deleted;
- Calendar elements that are not currently defined at all in the regulations and referred to an « *implenting act* » by the commission, which is contrary to our position.

Finally, the updating of the JCA is not sufficiently worked out, in particular because we have not yet been able to make enough progress on the initial clinical assessments. We propose to remove the possibility of updating, to focus on the initial assessments.

2. Comments by article

Article 9: Updates of Joint Clinical Assessments

- **§1/2**: at this stage, re-evaluations are not sufficiently precise in the text of the regulation. There is no detailed procedure for carrying out these re-evaluations, nor is there a time frame for carrying them out. Given the difficulties in discussing the initial assessments, we support the deletion of paragraphs 1 and 2. (No reassessment at European level.)
- **§2a:** we are in favor of the deletion of « *such updates shall be shared the members of the Coordination Group via the IT platform* » to avoid increasing MS workload.

Article 10: Transitional Arrangements for Joint Clinical Assessments

Question : Why delete this article ?

Recital (20)

The terms of access to scientific consultations are not sufficiently specified. It should be further clarified that this is an opportunity for HTD to request such consultations but that the GC must retain the right to hear or not hear such requests. Indeed, the regulations already specify the rules to be followed regarding the submission.

We can recall that at this stage of the work of the text, the service is offered free of charge to HTD. We must therefore be careful that the European work is not only emboldened by such scientific consultations.

Recital (20a)

It is important that the respect for the respective missions of the GC and the EMA in the context of the JSC be placed in the regulation itself. A sentence such as « *the JSC shall respect the different remits of HTA and regulatory process* » (see DE/FR proposal) could be introduced into the regulation.

Recital (20b)

This is repeated in article 12, but it seems important to mention clearly in the regulation that the GC may or may not accept a JSC (see proposal in Article 12).

Recital (25)

Important point (this has already been clarified) : we do not want an implementation act concerning the definition of the analysis methodology and the JSC. It is up to the GC to do that task and not the commission. This point will be subject of a similar comment (see Article 16)

Also, the reference to existing initiatives (Horizon 2020, Beneluxa and Valletta Declaration initiatives) is not appropriate. These initiatives, that influence the price/reimbursement decision in the states concerned, go well beyond the framework proposed by this HTA regulation. We propose not to mention them.

We would like to delete all of this recital 25.

Article 11a: System Principles of Joint Scientific Consultations

- **§1** : because this is a general introductory article and not an article that aim to define the missions of the GC, the following formulation would be more appropriate: « *the JSC are carried out by the CG with the view to….* » (instead of « *the CG shall carry out… »)* ;

We also want the « *shall* » in the last sentence (« *those recommendations shall in particular concern* ») to be replaced by a « *may* », because we don't necessarily want to give recommendations on all of these elements each time. We also appreciate the addition by the Presidency (« *all relevant clinical study design aspects* ») – in this context, it would be useful to delete « *but not limited to* ». Indeed, in conjunction with the « *shall* », this would imply that the content of the report must be systematically expanded, which is not what we are in favor of

- **§2** : we fully support the footnote on page 4 that amend article 6 so that deviations from the JSC are explained by the HTD.
- **§3** : we propose to delete the end of this paragraph (« *shall inform the CG* »), while maintaining the possibility of national scientific consultations. On such very early data, there is some doubt about the respect of industrial secrecy.

Article 12: Requests for Joint Scientific Consultations

- **§0** : the text should be more precise on the following points:
    - the GC must be able to accept or not a JSC request made by the HTD : a sentence could be added to this article to clarify this point: « *The CG remains free to accept or decline any request of JSC from a HTD* » ;
    - The GC must be able to refuse this JSC request based on its workload and objective criteria (and not only use the criteria when the number of requests appears to be too high). Indeed, the current wording of the regulations suggests that if quotas are met, the GC must consider all applications without taking into account the criteria, which is not what we are in favor of.
- **§2b**: regarding the objective criteria for selecting HTD applications. Currently, in the Eunethta process, there are three:
    - « *A new mode of action for the indication;*
    - *AND targeting a life-threatening or chronically debilitating disease;*
    - *AND responding to unmet need (no treatment or only unsatisfactory treatment available)* »

We propose to resume those criteria as follows in order to give the GC more flexibility when processing applications:

« *Criterias for selecting from eligible requests, for medicinal products and medical devices are based on:*

- *A new mode of action for the indication;*
- *AND targeting a life-threatening or chronically debilitating disease;*
- *AND responding to unmet need (no treatment or only unsatisfactory treatment available) ».*

This drafting also makes it possible to have selection criteria that are independent of quotas, so that a double selection takes place, both on the basis of criteria (interest of the analysis) AND on the basis of quotas (workload).

- **§3**: we do not want a time frame for JSC in the regulation if it is a « service » offered to HTD (removal of « *within 15 working days after the end of each request period* »). In addition, to clarify, we propose adding « *for rejection* » after « *shall explain the reasons* ».

Article 13: Preparation of the Joint Scientific Consultation Outcome Document

- **§1**: the rules shall specify the procedures (procedures, rules of ethics and articulation with the Jcas) for designating the subgroup responsible for carrying out the JSC. The current drafting gives the impression of a different group for each product, which is not the case actually for Eunethta (a working group), nor for the EMA on this subject (SWAP group). It would be preferable to give flexibility by indicating that the JSC sub-group « *shall oversee the preparation and the conduct of the Joint Scientific Consultation on behalf of the Coordination Group* » on the relevant product.
- **§2**: as we proposed at the end of 2018, we support the need for a high degree of flexibility for this activity, therefore the nature of the file must be determined by the GC. Scientific consultations are not binding and have no legal impact, but they are important because they are directly related to the quality of the studies that will be provided later. We would also like to delete the reference to the timetable defined in Article 16

Article 13a: Procedure of drafting joint scientific consultation outcome documents

- **§4a:** flexibility is required for this activity, the product of which is not binding. We also ask that this paragraph to be deleted.
- **8**. We wonder about the description, in the Regulation, of the step involving patients or experts, since at this stage it is a question of making methodological recommendations to HTDs.
- **§8b**: it should be noted that the « *(early) joint scientific consultations shall respect remits of HTA and regulatory process* ». This provision must be found in the Regulation and not only in the recitals.
- **§9:** we propose to delete the following sentence « *members of the designated sub-group may, as appropriate, provide additional recommendations specific to their individual Member State* ». The interest of specific national recommendations is contrary to the European HTA process. In addition, it is not expected that all MS will be represented in the sub-group. On the other hand, we fully support the fact that the MS of the subgroup may, at this stage of the procedure (that is, after an initial revision of the document by the assessor and the co-assessor), comment again on the JSC.

We would therefore prefer that:

- this second stage of comment be broader (not only national recommendations), and that it applies thus to the whole report;
- That the assessor and the co assessor are obliged to take up the comments of the MS at this stage.

This point (double stage of comments, with obligatory repetition of the comments of the second phase) is very important to ensure a quality document reflecting the inputs of all the MS present.

This second stage of comments by the MS could usefully be done at the level of the Coordination Group (rather than within the sub-group).

- **§11 :** same as previously.

Article 13b: Procedure at Coordination Group

- **§12:** as for JCA, the document, scientific by nature, does not need to be approved. The terminology must be modified and homogenized in the regulation.
- **§13:** we do not want a time frame for JSC in the regulations as this is a « *service provided* » to HTD.

Article 16: Adoption of Detailed Procedural Rules for Joint Scientific Consultations

- **§1:** scientific consultations are not binding, either at the HTD level or at the level of national HTA agencies and the GC. Moreover, they are intended to provide advice to HTD to build their studies whose results will be used for the joint clinical HTA file. The results of this joint clinical evaluation are also not binding at the national HTA and HTD agencies level.

Consequently, the French authorities do not want to freeze the system: we therefore would like to abolish the implementing acts provided for in this article. This is a major point.

We need flexibility for this type of activity. The scientific opinions are not very detailed in Regulation 726/20014 (Mandate, objectives and rules of procedure of the Scientific Advice Working Party: https://www.ema.europa.eu/en/documents/other/mandate-objectives-rules-procedure-scientific-advice-working-party-sawp_en.pdf).

Comments received from the Portuguese delegation

PT comments regarding the documents proposed by Croatian Presidency on a Regulation on Health Technology Assessment

General Comments

The Portuguese delegation thanks and welcomes the compromise proposals put forward by the Croatian presidency. We regret it was not possible to progress with the negotiation on this very file considering its relevance for the HTA landscape in Europe.

In our view, the existence of a clear and robust HTA assessment system should be emphasized. One that brings predictability for all involved, clarifies requirements and provides scientific guidance and alignment of HTA processes. On the other hand, it is important to develop maintain and update methodological guidance, documents, tools and establish standard operating procedures that guarantee transparency and quality of assessments.

Moreover, the COVID-19 pandemic is also leading to a reflexion on our regulatory system that may also make go bring back to the discussion of the initial premises upon which the HTA regulation was proposed.

In these exceptional circumstances, everyone involved needs to consider how collectively, we can simplify, harmonize and accelerate procedures in order to ensure the long-term sustainability of EU HTA cooperation.

Specific comments

Health Technologies subject to Joint Clinical Assessments and the list of Assessed Health Tecnhologies

We consider the proposed approach by the Presidency a good step forward as it seems to reflect the desired predictability.

We would like to see included a date to start the medical devices assessment under this Regulation.

Our delegation consider that the elimination of article 7 must be carefully weighed up.

Annual Work Programme and Annual Report

The proposed text takes into account not only the planned number of joint clinical assessments and planned number of updates to joint clinical assessments but also the planed number of assessments in the area of voluntary cooperation.

We consider that the Presidency proposal to establish the necessary cooperation to draft the Annual Work Programme, should not only take into account the cooperation with the European Medicines Agency, but also with the Medical Devices Coordination Group (MDCG) recognising the relevance that medical devices will have in health technology assessment .

Joint Scientific Consultations

The framework on joint scientific consultations suggested by the Presidency takes into account the general principles stablished on EUnetHTA when a health technology developer seek the advice of HTA authorities and bodies on the data and evidence likely to be required as part of a potential future joint clinical assessment.

We consider that the adoption of detailed procedural rules text for joint scientific consultation balances well what the European Commission and the Coordination Group will have to do.

Review (of the Regulation)

The foreseen review proposed a report carried out by the European Commission, which should be supported by reports on emerging health technologies and after consulting the Coordination Group, as well as, the reviewing non-duplication of the provision of information for joint clinical assessment in terms of reducing administrative burden for Member States and health technology developers.

The principle here established seems to be a possible approach. However, it is still a preliminary discussion as it depends on the outcome of other articles.