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WORKING DOCUMENT

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

Delegations will find enclosed the revised Presidency proposal for rewording of Articles 12 to 18.

SECTION 2

JOINT SCIENTIFIC CONSULTATIONS

Article 11a
System of Joint Scientific Consultations

1. ***The Coordination Group shall establish a system of joint scientific consultations with a view to providing ~~advice~~ recommendations, in the form of ~~recommendations~~ a joint scientific consultation outcome document ~~report~~, on the design of clinical studies which generate data and evidence likely to be required as part of a joint clinical assessment~~s~~. Those recommendations shall in particular concern, but not be limited to, comparators, health outcomes, and patient populations.***

2. ***The ~~report~~ joint scientific consultation outcome document and any recommendations given ~~as part of~~ in the process of a joint scientific consultation~~s~~ shall not be binding on Member States, on the Coordination Group or on health technology developers.***[1]

Recital (20)

In order to facilitate ~~effective participation by health technology developers in~~ ***the process of*** joint clinical assessments, ~~such~~ ***health technology*** developers should, in appropriate cases, be afforded an opportunity to engage in joint scientific consultations with the Coordination Group to obtain guidance on the evidence and data that is likely to be required ~~for the purposes of clinical assessment~~ ***from clinical studies. Clinical studies comprise clinical trials of medicinal products, ~~and~~ clinical investigations required for clinical evaluations of medical devices and performance studies required for performance evaluations of in vitro diagnostic medical devices.***[2] Given the preliminary nature of the consultation, any guidance offered should not bind either the health technology developers or HTA authorities and bodies.

3. ***Where a Member State carries out a national consultation on a health technology that ~~is or~~ has been the subject of a joint scientific consultation, ~~that national consultation shall take into account the joint scientific consultation recommendation report and indicate deviations~~ it shall inform the Coordination Group thereof.***

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1 ***If the health technology has been subject to a Joint Scientific Consultation, the developer should explain any deviation from the recommendation when submitting for Joint Clinical Assessment. This could be included in Article 6.***

2 ***This recital is talking only about joint scientific consultations, not those done in parallel with expert panels. Developers of in-vitro diagnostic medical devices should have the opportunity to ask for a joint scientific consultation if they so wish.***

4. The system of joint scientific consultations established pursuant to paragraph 1 shall provide a possibility ~~for~~ to exchange information with the European Medicines Agency when such consultations on medicinal products ~~to~~ take place in parallel with the preparation of scientific advice from the European Medicines Agency pursuant to Article 57(1)(n) of Regulation (EC) No 726/2004. ~~The parallel nature shall refer to the exchange of information and the timing of the joint scientific consultation and scientific advice, with a view to achieving the objective of the respective systems, while the respective remits of the two systems shall remain separate.~~[3]

5. The system of joint scientific consultations established pursuant to paragraph 1 shall provide a possibility ~~for~~ to exchange information with the expert panels when such consultations on medical devices ~~and in-vitro diagnostic medical devices to~~ take place in parallel with ~~scientific advice from relevant Union bodies~~[4] ***consultations of expert panels pursuant to Article 61(2) of Regulation (EU) 2017/745.***

Recital (20a)

Where joint scientific consultations are carried out in parallel with the preparation of scientific advice on medicinal products provided for under Regulation (EC) No 726/2004 of the European Parliament and of the Council or consultation on medical devices provided for in Regulation (EU) 2017/745 of the European Parliament and of the Council, those parallel processes, including information exchange between the subgroup and the European Medicines Agency or the expert panel on medical devices, should be carried out with a view to ensure that the evidence generation fulfils the needs of the respective systems, while the remits should remain separate.[5]

6. The Coordination Group shall include anonymised***, aggregated, non-confidential*** summary information on the joint scientific consultations in its annual reports and the IT platform referred to in Article 27.

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3 ***Rephrased and included in Recital (20a)***

4 ***After checking the in-vitro diagnostic medical devices regulation, it has been clarified that IVD developers don't have the possibility to consult expert panels on performance evaluation plans - check Article 56 in regulation 746/2017;***

5 ***The exchange of information on procedural matters has been deleted from Article 13(1b) and inserted here.***

Article 12
Requests for Joint Scientific Consultations

~~2.~~ ***0.*** ~~In considering the requests for~~ ***whether to carry out a*** ~~joint scientific consultation, t~~***T***he Coordination Group shall ~~take into account the following criteria~~ ***base its decisions on*** ~~(a) the likelihood that the~~ ***carry out joint scientific consultations only for*** health technology***ies*** ~~under development~~[6] ~~will be~~ ***likely to be*** the subject of ~~a~~ joint clinical assessment***s*** in accordance with Article 5(1)~~;~~ ***and for which clinical studies are still in the planning stage.***[7]

00.[8] ***The Coordination Group shall establish criteria for selecting from*** ~~***eligible***~~ ***requests which are eligible pursuant to paragraph 0, based on***

~~(b) unmet medical needs;~~
~~(c)~~ ***the*** potential impact on patients, public health, or healthcare systems;
~~(d)~~ ***how*** significant ***the*** cross-border dimension ***is***;
~~(e) major Union-wide added value;~~
~~(f) the available resources.~~

and the need to ensure the equal treatment of requests ~~***addressing***~~ ***concerning health technologies*** ~~***the same***~~ ***similar intended indications. The criteria shall be made public on the IT platform referred to in Article 27.***

000. The Coordination Group shall publish the dates of ~~***set***~~ ***request periods and state the planned number of joint scientific consultations for*** ~~***the***~~ ***each of those request periods.***

1. ***Within the*** ~~***set***~~ ***request periods,*** health technology developers may request a joint scientific consultation with the Coordination Group ~~for the purposes of obtaining scientific advice concerning data and evidence likely to be required as part of a joint clinical assessment~~.

   Health technology developers of medicinal products may request that the joint scientific consultation takes place in parallel with the process of receiving scientific advice from the European Medicines Agency ~~pursuant to Article 57(1)(n) of Regulation (EC) No 726/2004~~. In such a case, it shall make ~~that~~ ***the request for scientific advice to the European Medicines Agency*** at the time of submitting ~~an application~~ ***the request*** for ***the joint*** scientific ***consultation*** ~~advice to the European Medicines Agency~~.

   Health technology developers of medical devices may request that the joint scientific consultation takes place in parallel with the consultation of an expert panel. In such a case, it shall make the request for a consultation with the expert panel at the time of submitting the request for the joint scientific consultation.

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6 ***Change made to address concerns related to updates of Joint Clinical Assessments.***
7 ***To be revisited in view of the discussion on updates of Joint Clinical Assessments***
8 ***This will need to be reflected in the tasks of the Coordination Group, Article 3(8).***

~~2. In considering the request for joint scientific consultation, the Coordination Group shall take into account the following criteria:~~

~~(a) the likelihood that the health technology under development will be the subject of a joint clinical assessment in accordance with Article 5(1);~~

~~(b) unmet medical needs;~~

~~(c) potential impact on patients, public health, or healthcare systems;~~

~~(d) significant cross-border dimension;~~

~~(e) major Union-wide added value;~~

~~(f) the available resources.~~

2a. At the end of each request period, where the number of eligible requests ~~outweigh~~ exceeds the number of planned joint scientific consultations, the Coordination Group, ~~based on the recommendation of~~ following a proposal from the designated sub-group[9], shall select ~~among requests eligible~~ ~~in accordance with paragraph 0 and~~ the joint scientific consultations to be carried out based on the criteria established pursuant to paragraph 00.

3. Within 15 working days after ***the end of each*** request ***period***, the Coordination Group shall inform the requesting health technology developer whether or not it will engage in the joint scientific consultation. Where the Coordination Group ~~refuses~~ ***rejects*** the request, it shall inform the health technology developer thereof and explain the reasons in accordance with paragraph***s*** ~~2~~ ***0 and 00***.

~~***Recital (20b)***~~

~~***In view of the legally non-binding nature of joint scientific consultations, the decision by the Coordination Group to accept or refuse a request for joint scientific consultation should be final.***~~[10]

[9] ***To be revisited after the discussion on the structure of the Coordination Group, also in relation to Article 13.***

[10] ***Taken out as not lawful.***

Article 13

*Joint Scientific Consultation ~~Recommendations~~ ~~Reports~~ **Outcome Documents***

1. Following the acceptance of a request for a joint scientific consultation in accordance with Article 12 and on the basis of its annual work programme, the Coordination Group shall designate a sub-group to oversee the preparation of the joint scientific consultation ~~report~~ ~~***recommendation***~~ ***outcome document*** on behalf of the Coordination Group.

1a. The joint scientific consultation ~~report~~ ~~***recommendation***~~ ***outcome document*** shall be prepared in accordance with the requirements in this Article and in accordance with the ***guidance and*** procedural rules ~~and documentation~~ established pursuant to Articles ***3 and*** 16 ~~and 17~~.

~~10.~~ ***1b.*** Where the joint scientific consultation is carried out in parallel with ***the preparation of*** scientific advice given by the European Medicines Agency ***or consultations of expert panels***, the ~~assessor~~ ***designated sub-group*** shall ***exchange appropriate information*** ~~***and***~~ ~~seek to coordinate with the Agency~~ ~~***or the expert panel***~~ ~~as regards~~ ~~the consistency of the conclusions of the joint scientific consultation report with those of the scientific advice~~ ~~***procedural matters***~~.[11]

2. ***Upon request by*** ~~T~~the designated sub-group***,*** ~~shall request~~ the health technology developer ~~to~~ ***shall*** submit the documentation containing the information~~, data and evidence~~ necessary for the joint scientific consultation.

2a. The joint scientific consultation shall start when all necessary information has been received from the health technology developer.

3. The designated sub-group shall appoint from among its members, an assessor and a co-assessor, with responsibility for conducting the joint scientific consultation. The appointments shall take into account the scientific expertise necessary for the consultations.

4. The assessor, with the assistance of the co-assessor, shall prepare the draft joint scientific consultation ~~report~~ ~~***recommendation***~~ ***outcome document***.

[11] ***The exchange of information on procedural matters was inserted in Recital 20.***

4a. At relevant points in the preparation of the joint scientific consultation ~~*recommendation*~~ ~~*report*~~ *outcome document,*

- ~~6.~~ the members of the designated sub-group shall ***have the opportunity to*** provide comments ~~during the preparation of the draft joint scientific consultation recommendations~~;
- ~~8. The designated sub-group shall ensure that~~ patients~~, and~~ clinical experts***, and other relevant experts*** ~~are given an~~ ***shall have the*** opportunity to provide ~~comments during the preparation of the draft joint scientific consultation report and set a time-frame in which they may submit comments~~ ***input***;
- ***the designated subgroup shall organise an exchange of views with the health technology developer and relevant experts;***

  Where the joint scientific consultation is carried out in parallel with the preparation of scientific advice given by the European Medicines Agency or consultations of expert panels, representatives of the Agency or those panels shall also ~~***be invited to***~~ ***participate in the exchange of views.***

5. ~~Where, at any stage in the preparation of the draft joint scientific consultation report, the assessor considers that additional evidence from a health technology developer is necessary in order to complete the report, it may request the designated sub-group to suspend the time period set for the preparation of the report and to request the additional evidence from the health technology developer. Having consulted the health technology developer on the time needed to prepare the necessary additional evidence, the request from the assessor shall specify the number of working days for which the preparation shall be suspended.~~

~~6. The members of the designated sub-group shall provide their comments during the preparation of the draft joint scientific consultation recommendations.~~

7. ~~The assessor shall provide the draft joint scientific consultation report to the submitting health technology developer and set a time-frame in which the developer may submit comments.~~

~~8. The designated sub-group shall ensure that patients, clinical experts, and, where appropriate, other relevant experts are given an opportunity to provide comments during the preparation of the draft joint scientific consultation recommendations.~~

9. Following receipt and consideration of any comments ***and input*** provided in accordance with paragraph~~s~~ ***4a*** ~~6, 7 and 8~~, the assessor, with the assistance of the co-assessor, shall finalise the draft joint scientific consultation ~~report~~ ~~***recommendation***~~ ***outcome document*** and submit the draft joint scientific consultation ~~report~~ ~~***recommendation***~~ ***outcome document*** to the designated sub-group ~~for comments~~.

Members of the designated sub-group may, as appropriate, provide additional recommendations specific to their individual Member State.

~~10. Where the joint scientific consultation is carried out in parallel with scientific advice given by the European Medicines Agency, the assessor shall seek to coordinate with the Agency as regards the consistency of the conclusions of the joint scientific consultation report with those of the scientific advice.~~

11. The assessor, with the assistance of the co-assessor, shall ~~take into account the comments of the members of the designated sub-group and~~ submit the final draft joint scientific consultation ~~report~~ ~~***recommendation***~~ ***outcome document, including any recommendations specific to individual Member States,*** to the Coordination Group.

12. The ~~***chair of the***~~ Coordination Group shall ~~approve~~ ***ensure that additional recommendations specific to individual Member States are included***~~, wherever possible by consensus or, where necessary, by a two-thirds majority of Member States, at the latest 100 days following the start of the preparation of the report referred to in paragraph 4~~ ***and finalise the joint scientific consultation*** ~~***recommendation***~~ ~~***report***~~ ***outcome document at the latest after a maximum number of days set by the Coordination Group in accordance with the guidance developed pursuant to Article 3(8)(ba).***[12]

~~1.~~ ***13.*** The Coordination Group shall ~~communicate the approved~~ ***send the final*** joint scientific consultation ~~report~~ ~~***recommendation***~~ ***outcome document*** to the requesting health technology developer at the latest 10 working days ~~following their approval~~ ***after it has been finalised***.

[12] ***Guidance, which should include the set period for joint scientific consultations, will be included in Article 3(8)***.

~~*Article 14*~~

~~*Joint Scientific Consultation Reports*~~

~~1. The Coordination Group shall communicate the approved joint scientific consultation report to the requesting health technology developer at the latest 10 working days following its approval.~~

~~2. The Coordination Group shall include aggregated information on the joint scientific consultations in its annual reports and the IT platform referred to in Article 27.~~

~~3. Member States shall not carry out a scientific consultation or an equivalent consultation on a health technology for which a joint scientific consultation has been initiated and where the contents of the request are the same as those covered by the joint scientific consultation.~~

[Article 15

Transitional Arrangements for Joint Scientific Consultations[13]

During the transitional period referred to in Article 33(1):

(a) the Coordination Group shall base the annual number of planned joint scientific consultations on the number of Member States participating and the resources available to it;

(b) members of the Coordination Group from Member States not participating in joint scientific consultations shall not:

(i) be appointed as assessors or co-assessors;

(ii) comment on the draft joint scientific consultation reports;

(iii) take part in the approval process of the final joint scientific consultation reports;

(iv) take part in the preparation and approval process on the parts of the annual work programmes on joint scientific consultations.]

[13] ***This will be discussed together with transitional provisions in Article 33***

Article 16

Adoption of Detailed Procedural Rules for Joint Scientific Consultations[14]

1. ***After consulting the Coordination Group,*** the Commission shall develop, by means of implementing acts, procedural rules for:

   (a) submissions of requests from health technology developers ~~and their involvement in the preparation of~~ ***for*** joint scientific consultation***s*** ~~report~~ ~~***recommendation***~~;

   ~~(b) the appointment of assessors and co-assessors;~~

   ~~(c) determining the detailed procedural steps and their timing;~~

   (d) the ***selection and*** consultation of patients, clinical experts and other relevant ~~stakeholders~~ ***experts***;

   (e) ~~cooperation with the European Medicines Agency on~~ the ***exchange of information with the European Medicines Agency for*** joint scientific consultations on medicinal products where a health technology developer requests the consultation to be carried out in parallel with a process for scientific advice from the Agency;

   (f) ~~cooperation~~ ***the exchange of information*** with the expert panels referred to in Article 106(1) of Regulation (EU) 2017/745 ~~on the~~ ~~***exchange of information***~~ ***for*** joint scientific consultations on medical devices ***where a health technology developer requests the consultation to be carried out in parallel with the consultation of those expert panels***.

2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).

Recital (25)

In order to ensure a uniform approach to the joint work provided for in this Regulation, implementing powers should be conferred on the Commission to establish ***[***a common procedural and methodological framework for clinical assessments, procedures for joint clinical assessments and***]***[15] procedures for joint scientific consultations.Where appropriate, distinct rules should be developed for medicinal products and medical devices. In the development of such rules, ***the Commission should consult the Coordination Group and*** take into account the results of the work already undertaken in the EUnetHTA Joint Actions. It should also take into account initiatives on HTA funded through the Horizon 2020 research programme, as well as regional initiatives on HTA such as the Beneluxa and Valletta Declaration initiatives. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council.

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14 ***Scrutiny reservation***: BG, DE, ES, FR;

15 ***Issues that are not directly related to the Articles now under discussion occur in square brackets.***

~~*Article 17*~~

~~*Documentation and Rules for Selecting Stakeholders for Joint Scientific Consultations*~~[16]

~~The Commission shall be empowered to adopt delegated acts in accordance with Article 31 concerning:~~

~~(a) the contents of:~~

~~(i) requests from health technology developers for joint scientific consultations;~~

~~(ii) dossiers of information, to be submitted by health technology developers for joint scientific consultations;~~

~~(iii) joint scientific consultation reports.~~

~~(b) the rules for determining the stakeholders to be consulted for the purpose of this Section.~~

16 ***The Coordination Group shall develop detailed procedures and guidance. This will be included in Article 3.***

Article 18

Identification of Emerging Health Technologies

1. The Coordination Group shall ~~annually prepare a study~~ ***~~provide~~ ensure the preparation of reports*** on emerging health technologies ***~~before they reach the market that are~~*** expected to have a major impact on patients, public health or healthcare systems.

Recital 22

In order to ensure the efficient use of available resources, it is appropriate to provide for "horizon scanning", to allow the early identification of emerging health technologies that are likely to have ~~the most~~ ***a major*** impact on patients, public health and healthcare systems. Such scanning ~~should facilitate the prioritisation of technologies that are to be selected for joint clinical assessment.~~ ***~~Such reports shall~~ could be used to support the Coordination Group in planning its work in particular in relation to joint clinical assessments and joint scientific consultations and can also provide information for long term planning purposes on both EU and national level.***

1a. The ~~following~~ topics ~~are to~~ addressed shall ~~be addressed~~ include:

(a) Estimated clinical impact;

(b) Potential organisational and financial consequences.

2. ~~In ***Activities*** t~~***T***he preparation ~~of the study, the Coordination Group shall consult:~~ ***of the reports referred to in paragraph 1 shall ~~rely~~ be based on existing scientific reports or initiatives on emerging health technologies and relevant sources including, but not limited to:***

(0a) Clinical study registers and scientific reports;

(~~d~~ ***0b***) the European Medicines Agency ~~including on the pre-notification of medicinal products prior to marketing authorisation applications~~ ***in relation to upcoming submissions of applications for medicinal products referred to in Article 5(1)***;[17]

(~~e~~ ***0c***) the Medical Devices Coordination Group established in Article 103 of Regulation (EU) 2017/745;

(a) ***~~Individual~~*** health technology developers ***~~on products that are identified~~ on products they are developing***;

~~(c~~ ***ab)~~~~relevant~~*** clinical ***and other relevant*** experts;

(b) ~~patient organisations~~ ***the Stakeholder Network***;

~~(c)~~ ***~~relevant~~*** clinical ***~~and other relevant~~*** ~~experts;~~

~~(d) the European Medicines Agency including on the pre-notification of medicinal products prior to marketing authorisation applications;~~

~~(e) the Medical Devices Coordination Group established in Article 103 of Regulation (EU) 2017/745;~~

3. ~~The conclusions of the study~~ ***The Coordination Group shall include anonymised, aggregated, non-confidential information from the reports referred to in paragraph 1*** ~~shall be summarised~~ in ~~the Coordination Group's~~ ***its*** annual report ***and make that information available on the IT platform referred to in Article 27***. ***The reports referred to in paragraph 1*** shall be taken into account in the preparation of its annual work programme~~s~~.

4. The reports and underlying non-confidential information shall be made available to Member States.

[17] ***Changed after consulting EMA on the correct terminology, as "pre-notification" is not a term used in pharma legislation for the centralised procedure.***