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COMMISSION IMPLEMENTING REGULATION (EU) 2024/3169

of 18 December 2024

laying down rules for the application of Regulation (EU) 2021/2282 of the European Parliament and of the Council with regard to the procedures for joint scientific consultations on medicinal products for human use at Union level

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU [1], and in particular Article 20(1), points (a), (b) and (c), thereof,

Whereas:

(1) Regulation (EU) 2021/2282 lays down a support framework and procedures for cooperation between Member States on health technologies at Union level and establishes the Member State Coordination Group on Health Technology Assessment ('the Coordination Group').

(2) Pursuant to Article 16(1) of Regulation (EU) 2021/2282, the Coordination Group is to carry out joint scientific consultations in order to exchange information with health technology developers on their development plans for a medicinal product for human use ('medicinal product'). The aim of such consultations is to facilitate the process of preparing joint clinical assessments for medicinal products, as they will allow health technology developers to obtain guidance from the Coordination Group on the information, data, analyses and other evidence that are likely to be required from clinical studies for the joint clinical assessment of those medicinal products.

(3) In order to ensure sufficient predictability for health technology developers as to their opportunity to engage in joint scientific consultations on medicinal products with the Coordination Group, it is necessary to specify the deadline for the Coordination Group to set the dates of request periods for joint scientific consultation on medicinal products for the subsequent year, as well as the minimum number of such request periods per year. Under Article 6(2), point (b), of Regulation (EU) 2021/2282, the Coordination Group is to set out in its annual work programme the planned number of joint scientific consultations. To allow the health technology developers sufficient time to plan and prepare for joint scientific consultations on medicinal products, the Coordination Group should set the request periods for those consultations at the latest by the day on which it adopts its annual work programme, that is, by 30 November each year.

(4) Under Article 30(1) of Regulation (EU) 2021/2282, the Commission is to set up and maintain an IT platform consisting of, inter alia, a secure system for the exchange of information between the Coordination Group and its subgroups with health technology developers and experts participating in the joint work ('the HTA IT platform'). The health technology developers should therefore submit the requests for joint scientific consultation, the dossier of information, data, analyses and other evidence for joint scientific consultation on medicinal products including the list of questions ('the briefing package') and any further data through the HTA IT platform. Those requests and dossiers should be presented using the templates set out by the Coordination Group pursuant to Article 21, points (a) and (b), of Regulation (EU) 2021/2282.

[1] OJ L 458, 22.12.2021, p. 1, ELI: http://data.europa.eu/eli/reg/2021/2282/oj.

(5) Upon request from a health technology developer, joint scientific consultations on medicinal products may take place in parallel with the scientific advice on medicinal products by the European Medicines Agency pursuant to Article 57(1), point (n), of Regulation (EC) No 726/2004 of the European Parliament and of the Council [2] ('scientific advice'). In order for the subgroup on joint scientific consultations of the Coordination Group ('JSC Subgroup') to be able to identify the requests for joint scientific consultation to be conducted in parallel with the scientific advice, the health technology developer should indicate in the request for joint scientific consultation whether, in parallel, it is requesting scientific advice from the European Medicines Agency.

(6) Pursuant to Article 28, point (h), of Regulation (EU) 2021/2282, the Commission acting as secretariat of the Coordination Group ('HTA secretariat') is to facilitate the cooperation with the European Medicines Agency. The exchange of information with the European Medicines Agency relevant to joint scientific consultations on medicinal products should therefore take place through the HTA secretariat.

(7) The HTA secretariat should inform the European Medicines Agency of granted requests for joint scientific consultation on medicinal products to be conducted in parallel with the scientific advice. Where joint scientific consultations on medicinal products are conducted in parallel with the scientific advice, the HTA secretariat and the European Medicines Agency should exchange the appropriate information to ensure that the parallel consultations have synchronised timing.

(8) Where pursuant to Article 17(4) of Regulation (EU) 2021/2282, the Coordination Group, via the HTA secretariat, informs the health technology developer that it will engage in the joint scientific consultation on medicinal products, it should also inform the health technology developer of the timetable for the joint scientific consultation, including the deadline to submit the briefing package. To ensure that joint scientific consultations on medicinal products that are conducted in parallel with the scientific advice have synchronised timing, the timetable should be synchronised with the scientific advice process.

(9) To ensure the effective involvement of patients, clinical experts and other relevant experts ('individual experts') in joint scientific consultation on medicinal products, the HTA secretariat should start their identification as early as possible. Therefore, at the same time as the JSC Subgroup selects medicinal products that are to be subject to joint scientific consultation, the JSC Subgroup should also specify, for each joint scientific consultation, the disease, the therapeutic area concerned and other specific expertise, based on which the HTA secretariat is to identify individual experts to be consulted during that joint scientific consultation. To identify the individual experts, the HTA secretariat should consult the stakeholder network established pursuant to Article 29 of Regulation (EU) 2021/2282, the European reference networks for rare and complex diseases and other relevant sources, agencies and organisations. In making the final selection, the JSC Subgroup should give priority to individual experts who have expertise, across several Member States, in the disease or therapeutic area of the joint scientific consultation.

(10) The JSC Subgroup, via the HTA secretariat, should share with the selected individual experts the briefing package and should give them the opportunity to provide input on the joint scientific consultation. The HTA secretariat should invite the selected individual experts to the meeting for an exchange of views with the health technology developer referred to in Article 18(7) and (8) of Regulation (EU) 2021/2282. At any time during the joint scientific consultation, the JSC Subgroup should have the possibility to consult stakeholder organisations. In particular, such consultation should entail a more general input on the disease and therapeutic area from patient organisations, healthcare professional organisations or clinical and learned societies and should be conducted via the members of the stakeholder network. Such consultation must not disclose the actual medicinal product subject to the joint scientific consultation.

[2] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1, ELI: http://data.europa.eu/eli/reg/2004/726/oj).

(11) In order to ensure that individual experts take part in joint scientific consultation in an independent and transparent manner, free from conflict of interest, they should only be selected and involved in joint scientific consultations after the Commission has assessed their declared interests, in accordance with Article 5 of Regulation (EU) 2021/2282 and with Article 4 of Commission Implementing Regulation (EU) 2024/2745 ([3]).

(12) To reduce administrative burden and avoid duplication, where joint scientific consultations on medicinal products are conducted in parallel with the scientific advice, the health technology developer should submit the same documentation to the HTA secretariat and to the European Medicines Agency. For this purpose, before establishing the template of the briefing package pursuant to Article 21, point (b), of Regulation (EU) 2021/2282 to be used where the joint scientific consultation on medicinal products is carried out in parallel with the scientific advice, the Coordination Group should consult and reach agreement with the European Medicines Agency on the template.

(13) To ensure that joint scientific consultations on medicinal products that are conducted in parallel with the scientific advice have synchronised timing, the health technology developer should submit the relevant documentation for joint scientific consultation and scientific advice at the same time to the HTA secretariat and the European Medicines Agency. Moreover, the JSC Subgroup or the Coordination Group and the European Medicines Agency should, within the set timetable, approve, adopt and submit to the health technology developer the lists of issues, the joint scientific consultation outcome document and the advice letter.

(14) With the view of facilitating the discussion with the health technology developer and consultation of individual experts at the meeting referred to in Article 18(7) of Regulation (EU) 2021/2282, the JSC Subgroup, via the HTA secretariat, should share with the health technology developer the list of issues indicating the topics to be addressed at the meeting and where relevant the specific questions to be addressed only in writing before that meeting ('the list of issues'). The JSC Subgroup should give the health technology developer the opportunity to respond to the list of issues in writing in due time before the meeting.

(15) Where joint scientific consultations on medicinal products are conducted in parallel with the scientific advice, the HTA secretariat and the European Medicines Agency should exchange the respective lists of issues. The JSC Subgroup and the European Medicines Agency should discuss the lists of issues with the health technology developer in one single meeting. It should be specified which parties are to be invited to this joint meeting. The meeting should be held virtually and be co-chaired by the assessor or co-assessor for joint scientific consultation appointed pursuant to Article 18(3) of Regulation (EU) 2021/2282 ('the assessor and co-assessor') and one of the coordinators for scientific advice.

(16) Where the health technology developer amends the development plan of a medicinal product after the submission of the briefing package, it is necessary to set the deadline by which the health technology developer is to submit the relevant updates to the JSC Subgroup so that those updates can be considered in the joint scientific consultation outcome document.

(17) To ensure transparency, traceability and professional secrecy, the documentation related to joint scientific consultations on medicinal products should be sent in a digital format and should be exchanged with and between the Coordination Group, the JSC Subgroup, the HTA Secretariat, the health technology developer, and individual experts during joint scientific consultations on medicinal products through the HTA IT platform.

([3]) Commission Implementing Regulation (EU) 2024/2745 of 25 October 2024 laying down rules for the application of Regulation (EU) 2021/2282 of the European Parliament and of the Council as regards the management of conflicts of interest in the joint work of the Member State Coordination Group on Health Technology Assessment and its subgroups (OJ L, 2024/2745, 28.10.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/2745/oj).

(18) In accordance with Article 5(1), point (a), of Regulation (EU) 2018/1725 of the European Parliament and of the Council ([4]), it is necessary to lay down the rules for processing of personal data for the purposes of conducting joint scientific consultations on medicinal products. In particular, it is necessary to specify the personal data that may be processed, namely certain personal data relating to the individual experts involved in joint scientific consultations on medicinal products and certain personal data relating to the representatives appointed to the Coordination Group and the JSC Subgroup, the representatives of health technology developers and the representatives of the members of the stakeholder network. Where joint scientific consultations on medicinal products are conducted in parallel with the scientific advice, the Commission should receive from the European Medicines Agency the list of participants involved in the scientific advice that are invited to the meeting with the health technology developer.

(19) The Commission should be considered the controller of the processing of personal data within the meaning of Article 3, point (8), of Regulation (EU) 2018/1725. Any processing of personal data by the European Medicines Agency and by the members of the Coordination Group and the JSC Subgroup and their representatives outside of the HTA IT platform is to take place in accordance with, respectively, Regulation (EU) 2018/1725 and Regulation (EU) 2016/679 of the European Parliament and of the Council ([5]).

(20) To ensure the possibility to verify whether joint scientific consultations on medicinal products were conducted in an independent and impartial manner, for example, in the event of complaints or litigation, as well as to ensure the relevant in-depth specialised expertise in joint scientific consultation and to verify compliance with the requirement set out in Article 8(4) of Regulation (EU) 2021/2282 that the assessor and co-assessor for joint clinical assessment are to be different from the assessor and co-assessor for joint scientific consultation, it is necessary to provide for appropriate retention periods with regard to personal data and for their review at regular intervals.

(21) The identity of patients may reveal the patient's health status in relation to the subject matter of the joint scientific consultation and should therefore be considered a special category of personal data under Article 10 of Regulation (EU) 2018/1725. Such data should only be processed where the criteria set out in Article 10(2), point (i), of that Regulation are met. It is necessary to provide for suitable and specific measures to safeguard the rights and freedoms of the patient. In particular, patients should not be obliged to disclose their identity to the health technology developer. Under Article 5(6) of Regulation (EU) 2021/2282, the representatives appointed to the Coordination Group and the JSC Subgroup, as well as individual experts involved in joint scientific consultations, are subject to a requirement of professional secrecy, even after their duties have ceased. In order to ensure protection of personal data and of confidential information, it is necessary to provide that only individual experts who have signed confidentiality agreements may be involved in joint scientific consultations on medicinal products.

(22) The Coordination Group was consulted on these procedural rules on 10 June 2024 in accordance with Article 20(1) of Regulation (EU) 2021/2282.

(23) Regulation (EU) 2021/2282 starts to apply on 12 January 2025 and this Regulation should apply from the same date.

(24) The European Data Protection Supervisor was consulted in accordance with Article 42 of Regulation (EU) 2018/1725 and delivered an opinion on 6 November 2024.

([4]) Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39 ELI: http://data.europa.eu/eli/reg/2018/1725/oj).

([5]) Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/679/oj).

(25) The measures provided for in this Regulation are in accordance with the opinion of the Committee on Health Technology Assessment,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down detailed procedural rules for joint scientific consultations carried out pursuant to Articles 16 to 21 of Regulation (EU) 2021/2282, as regards:

(a) submission of requests from health technology developers for joint scientific consultation on medicinal products for human use ('medicinal products');

(b) the selection and consultation of stakeholder organisations and patients, clinical experts and other relevant experts ('individual experts') in joint scientific consultation on medicinal products;

(c) cooperation, in particular by exchange of information, with the European Medicines Agency on joint scientific consultations on medicinal products where a health technology developer requests the consultation to be carried out in parallel with the scientific advice on medicinal products by the European Medicines Agency pursuant to Article 57(1), point (n), of Regulation (EC) No 726/2004 ('scientific advice').

Article 2

Setting of request periods for joint scientific consultation

1. By 30 November each year, the Coordination Group shall set the dates of request periods for joint scientific consultation on medicinal products for the subsequent year and the planned numbers of joint scientific consultations for each of those request periods.

2. The Coordination Group shall set at least three request periods for joint scientific consultation on medicinal products per year.

3. By way of derogation from paragraphs 1 and 2, by 31 March 2025, the Coordination Group shall set at least two request periods for joint scientific consultation on medicinal products for 2025.

Article 3

Submission of requests for joint scientific consultations

1. Any time during the request period published pursuant to Article 17(3) of Regulation (EU) 2021/2282, the health technology developer may submit a request for a joint scientific consultation on the medicinal product through the IT platform referred to in Article 30 of that Regulation ('the HTA IT platform').

The request shall follow the template established by the Coordination Group pursuant to Article 21, point (a), of Regulation (EU) 2021/2282.

2. When submitting the request referred to in paragraph 1, the health technology developer shall indicate whether, in parallel, it is requesting scientific advice from the European Medicines Agency.

3. By the end of a request period, the Commission acting as secretariat of the Coordination Group ('HTA secretariat') shall make available through the HTA IT platform the requests for joint scientific consultation on medicinal products complying with the requirements in paragraph 1, second subparagraph, to the subgroup on joint scientific consultations of the Coordination Group ('JSC Subgroup') and indicate for which of those requests scientific advice will be sought in parallel.

Article 4

Provision of information to the health technology developer on engagement in joint scientific consultations

1. With regard to joint scientific consultations on medicinal products, the information referred to in Article 17(4) of Regulation (EU) 2021/2282 shall be provided by the JSC Subgroup via the HTA secretariat and shall, where applicable, include a timetable for the joint scientific consultation.

2. Within 15 working days after the end of each request period, the HTA secretariat shall notify the European Medicines Agency of the list of the granted requests for joint scientific consultation on medicinal products to be carried out in parallel with the scientific advice.

3. Where the health technology developer requests the joint scientific consultation to be carried out in parallel with the scientific advice, the timetable referred to in paragraph 1 shall be agreed between the HTA secretariat, in consultation with the JSC Subgroup, and the European Medicines Agency and shall be synchronised with the timing of the process for scientific advice as specified in Article 7(5), points (a) and (c), Article 9(2), point (a), Article 12(2) and Article 13(2), point (b).

Article 5

Selection of individual experts for joint scientific consultations

1. When selecting the medicinal products that are to be subject to joint scientific consultations, the JSC Subgroup shall specify, for each medicinal product, the following:

(a) the disease;

(b) the therapeutic area;

(c) other specific expertise if needed for the joint scientific consultation.

2. On the basis of the information listed in paragraph 1, the HTA secretariat shall identify individual experts to be consulted during the joint scientific consultation and shall compile a list of relevant individual experts, in consultation with the JSC Subgroup and the assessor and co-assessor for joint scientific consultation appointed pursuant to Article 18(3) of Regulation (EU) 2021/2282 ('the assessor and co-assessor'). When compiling the list, the HTA secretariat may consult one or more of the following:

(a) the members of the stakeholder network established pursuant to Article 29 of Regulation (EU) 2021/2282;

(b) the European reference networks for rare and complex diseases and their respective European patient advocacy groups;

(c) the portal for rare diseases and orphan drugs;

(d) the national contact points designated in accordance with Article 83(1) of Regulation (EU) No 536/2014 of the European Parliament and of the Council ([6]);

(e) the European Medicines Agency.

3. Where the consultation of the sources referred to in paragraph 2 has not yielded a sufficient number of relevant individual experts, the HTA secretariat may consult the following for compiling a list of individual experts:

(a) other databases or directories than the ones listed in paragraph 2;

(b) members of the Coordination Group and its subgroups;

(c) relevant Union and international agencies and organisations.

([6]) Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1, ELI: http://data.europa.eu/eli/reg/2014/536/oj).

4. After the Commission, in accordance with the rules set out in Article 5 of Regulation (EU) 2021/2282 and Article 4 of Implementing Regulation (EU) 2024/2745, has assessed the declared interests of individual experts in the list compiled by the HTA secretariat in accordance with paragraphs 1 to 3 of this Article, the HTA secretariat shall provide the JSC Subgroup with a list of available individual experts.

5. The JSC Subgroup shall make the final selection of individual experts to be consulted during the joint scientific consultation from the list of individual experts provided by the HTA Secretariat in accordance with paragraph 4. In making the final selection, the JSC Subgroup shall give priority to individual experts who have expertise across a number of Member States in the disease or the therapeutic area of the joint scientific consultation.

Article 6

Professional secrecy obligations of individual experts

The HTA secretariat shall ensure that only individual experts who have signed a confidentiality agreement are involved in joint scientific consultations on medicinal products.

Article 7

Briefing package and further data for joint scientific consultations

1. The health technology developer shall submit the dossier of information, data, analyses and other evidence for joint scientific consultation on medicinal products pursuant to Article 21, point (b), of Regulation (EU) 2021/2282 including the list of questions ('the briefing package') by means of the template established by the Coordination Group pursuant to Article 21, point (b), of Regulation (EU) 2021/2282 or pursuant to Article 8 of this Regulation through the HTA IT platform.

2. The deadline to submit the briefing package shall be set in the timetable referred to in Article 4(1). The HTA secretariat shall make available through the HTA IT platform the briefing package complying with the requirements in paragraph 1 to the assessor and co-assessor and the JSC Subgroup.

3. Where the assessor or the co-assessor considers that further specifications or clarifications or additional information, data, analyses or other evidence are necessary in the briefing package, or that one or several questions submitted by the health technology developer are out of scope of joint scientific consultation, the HTA secretariat shall request the health technology developer to submit an amended briefing package within the deadline set in the timetable referred to in Article 4(1).

4. Where the assessor or the co-assessor, at any time during the preparation of the draft joint scientific consultation outcome document considers that further specifications or clarifications or additional information, data, analyses or other evidence are necessary, the HTA secretariat shall request the health technology developer to provide such information, data, analyses or evidence within the deadline set by the assessor and co-assessor.

5. In addition to the rules set out in paragraphs 1 to 4, where the joint scientific consultation on medicinal products is carried out in parallel with the scientific advice, the following shall apply:

(a) the health technology developer shall submit the briefing package containing the information necessary for the joint scientific consultation on medicinal products and for scientific advice at the same time to the HTA secretariat and the European Medicines Agency, by the deadline set in the timetable referred to in Article 4(1);

(b) the HTA secretariat and the European Medicines Agency shall exchange their respective requests to submit an amended briefing package, if any, at the same time as they send these requests to the health technology developer;

(c) the health technology developer shall submit the amended briefing package at the same time to the HTA secretariat and the European Medicines Agency, by the deadline set in the timetable referred to in Article 4(1);

(d) the HTA secretariat and the European Medicines Agency shall exchange with each other confirmation of receipt of the briefing package referred to in points (a) and (c) at the same time as they send confirmation of receipt to the health technology developer;

(e) the European Medicines Agency shall notify the HTA secretariat of the validation of the application for scientific advice;

(f) the HTA secretariat shall notify the European Medicines Agency of the acceptance of the briefing package for joint scientific consultation by the JSC Subgroup;

(g) the health technology developer shall submit the information, data, analyses or other evidence referred to in paragraph 4 at the same time to the HTA secretariat and the European Medicines Agency.

Article 8

Establishment of the template of the briefing package where the joint scientific consultation is carried out in parallel with the scientific advice

The Coordination Group shall, after consulting and reaching agreement with the European Medicines Agency, establish a specific template of the briefing package to be used where the joint scientific consultation on medicinal products is carried out in parallel with the scientific advice.

Article 9

List of issues to be discussed in the meeting for an exchange of views

1. After having assessed the briefing package and where applicable the documentation referred to in Article 7(4), the JSC Subgroup, via the HTA secretariat, shall share with the health technology developer the list of issues indicating the topics to be addressed at the meeting referred to in Article 18(7) of Regulation (EU) 2021/2282 and where relevant the specific questions to be addressed only in writing before that meeting ('the list of issues'). The health technology developer shall provide the JSC Subgroup, via the HTA secretariat, with written responses, if any, to the list of issues as well as any necessary materials or presentations for the meeting at the latest 10 days before that meeting.

2. In addition to the rules set out in paragraph 1, where the joint scientific consultation on medicinal products is carried out in parallel with the scientific advice, the following shall apply:

(a) the JSC Subgroup, via the HTA secretariat, and the European Medicines Agency shall send their respective lists of issues to the health technology developer within the deadline set in the timetable referred to in Article 4(1);

(b) the HTA secretariat and the European Medicines Agency shall exchange with each other the lists of issues on the same day as sending them to the health technology developer;

(c) the health technology developer shall send to the JSC Subgroup, via the HTA secretariat, a copy of their written responses, if any, to the list of issues provided by the European Medicines Agency at the same time as it sends those responses to the European Medicines Agency;

(d) the health technology developer shall send to the European Medicines Agency a copy of their written responses, if any, to the list of issues provided by the JSC Subgroup at the same time as it sends those responses to the JSC Subgroup, via the HTA secretariat.

Article 10

Input of individual experts on joint scientific consultation

No later than 30 days after the submission of the amended briefing package referred to in Article 7(3) or, where the joint scientific consultation on medicinal products is carried out in parallel with the scientific advice, no later than 30 days after the validation of the application referred to in Article 7(5), point (e), the JSC Subgroup, via the HTA secretariat, shall share the briefing package with the individual experts selected in accordance with Article 5 and give them the opportunity to provide input on the joint scientific consultation.

Article 11

Consultation of stakeholder organisations during joint scientific consultation

1. At any time during the joint scientific consultation on medicinal products, the JSC Subgroup, via the HTA secretariat, may seek input on the disease and therapeutic area relevant for the medicinal product from patient organisations, healthcare professional organisations or clinical and learned societies via the members of the stakeholder network established pursuant to Article 29 of Regulation (EU) 2021/2282, whilst respecting the confidential nature of the request for joint scientific consultation.

2. Where the joint scientific consultation on medicinal products is carried out in parallel with the scientific advice, the HTA secretariat shall share the input referred to in paragraph 1 with the European Medicines Agency at the same time as sharing it with the JSC Subgroup.

Article 12

Meeting with the health technology developer

1. The following participants shall be invited to the meeting referred to in Article 18(7) of Regulation (EU) 2021/2282:

(a) the representatives of the health technology developer;

(b) the assessor and co-assessor;

(c) individual experts selected in accordance with Article 5;

(d) other representatives of the JSC Subgroup than the ones listed in point (b);

(e) the staff members of the HTA secretariat responsible for providing secretariat support to the JSC Subgroup.

2. In addition to the participants listed in paragraph 1, where the joint scientific consultation on medicinal products is carried out in parallel with the scientific advice, the following participants shall be invited to the meeting referred to in Article 18(8) of Regulation (EU) 2021/2282:

(a) the coordinators for scientific advice;

(b) other members of the scientific advice working party of the Committee for Medicinal Products for Human Use than the ones listed in point (a);

(c) the staff members of the European Medicines Agency responsible for providing secretariat support to the scientific advice working party.

On request from the European Medicines Agency, other experts selected in accordance with the relevant rules of the European Medicines Agency to participate during the scientific advice may be invited to the meeting for an exchange of views.

3. The meeting referred to in paragraph 2 shall be held virtually. It shall be co-chaired by the assessor or co-assessor for the joint scientific consultation and one of the coordinators for scientific advice.

4. Before the meeting referred to in paragraph 2, the European Medicines Agency shall send to the HTA secretariat the list of meeting participants who are to be invited to the meeting in accordance with paragraph 2.

Article 13

Joint scientific consultation outcome document

1. Where, after the submission of the amended briefing package, the health technology developer submits updates related to the amended development plan for the relevant medicinal product, the JSC Subgroup shall ensure that those updates are considered in the outcome document, provided that it receives them no later than 10 days before the meeting referred to in Article 18(7) of Regulation (EU) 2021/2282.

2. In addition to the rules set out in paragraph 1, where the joint scientific consultation on medicinal products is carried out in parallel with the scientific advice, the following shall apply:

(a) the health technology developer shall submit the amended development plan referred to in paragraph 1 at the same time to the HTA secretariat and the European Medicines Agency;

(b) the Coordination Group shall approve the joint scientific consultation outcome document and the Committee for Medicinal Products for Human Use of the European Medicines Agency shall adopt the advice letter to the health technology developer within the deadline set in the timetable referred to in Article 4(1);

(c) the HTA secretariat and the European Medicines Agency shall exchange with each other the outcome document approved by the Coordination Group and the advice letter adopted by the Committee for Medicinal Products for Human Use on the same day as sending them to the health technology developer.

Article 14

Correspondence during joint scientific consultations

Any documentation referred to in Regulation (EU) 2021/2282 and in this Regulation shall be sent in a digital format and shall be exchanged with and between the Coordination Group, the JSC Subgroup, the HTA Secretariat, the health technology developer and individual experts during joint scientific consultations on medicinal products through the HTA IT platform.

Article 15

Personal data processing

1. The Commission shall be the controller of the processing of personal data collected for the purpose of conducting joint scientific consultations on medicinal products under this Regulation.

2. The categories of personal data necessary for the purpose referred to in paragraph 1 are:

(a) the identity, email address and affiliation of the representatives appointed to the Coordination Group and the JSC Subgroup;

(b) the identity and email address of individual experts in any of the following cases:

  (i) they are identified as relevant for joint scientific consultation;

  (ii) they are selected to be consulted in a joint scientific consultation;

  (iii) they are consulted in a joint scientific consultation;

(c) the identity, email address and affiliation of the representatives of health technology developers;

(d) the identity, email address and affiliation of the representatives of the members of the stakeholder network established pursuant to Article 29 of Regulation (EU) 2021/2282;

(e) the identity, email address and affiliation of participants involved in the scientific advice referred to in Article 12(2) that are to be invited to the meeting with the health technology developer.

3. The representatives appointed to the Coordination Group and the JSC Subgroup shall have access only to the parts of the secure system of the HTA IT platform that are relevant for the performance of their tasks. Representatives may collaborate, through the HTA IT platform, with other representatives appointed to the Coordination Group, or the JSC Subgroup to which they belong, for the purposes of conducting joint scientific consultations on medicinal products.

4. During the meeting referred to in Article 12, patients shall not be obliged to disclose their identity to the health technology developer.

5. The Commission shall keep the personal data referred to in paragraph 2 only for as long as necessary for the purpose referred to in paragraph 1 and no longer than 15 years after the date on which the data subject no longer participates in joint scientific consultation. The Commission shall review the necessity of storing the personal data every 2 years.

The Commission shall keep the personal data of individual experts not selected to be consulted in a joint scientific consultation only for as long as necessary in order to ensure the relevant in-depth specialised expertise in joint scientific consultation and no longer than 3 years after the date on which the Commission received this data.

Article 16

Entry into force and date of application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 12 January 2025.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 18 December 2024.

For the Commission
The President
Ursula VON DER LEYEN