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COMMISSION IMPLEMENTING REGULATION (EU) 2024/2699

of 18 October 2024

laying down, pursuant to Regulation (EU) 2021/2282 of the European Parliament and of the Council, detailed procedural rules for the cooperation of the Member State Coordination Group on Health Technology Assessment and the Commission with the European Medicines Agency in the form of exchange of information as regards the joint clinical assessment of medicinal products and medical devices and *in vitro* diagnostic medical devices and as regards the joint scientific consultation on medicinal products and medical devices

(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 15(1), points (a) and (b), and Article 20(1), points (c) and (d), thereof,

Whereas:

- (1) Regulation (EU) 2021/2282 lays down a support framework and procedures for cooperation between Member States on certain health technologies and establishes the Member State Coordination Group on Health Technology Assessment ('the Coordination Group').
- (2) The Commission is to lay down rules for the implementation of Regulation (EU) 2021/2282 as regards the cooperation, in the form of exchange of information, of the Coordination Group and the Commission acting as secretariat of the Coordination Group ('the HTA secretariat') with the European Medicines Agency and with the expert panels designated in accordance with Article 106(1) of Regulation (EU) 2017/745 of the European Parliament and of the Council ⁽²⁾ relevant for the joint work referred to in Articles 7 to 21 of Regulation (EU) 2021/2282. Pursuant to Article 30 of Regulation (EU) 2022/123 of the European Parliament and of the Council ⁽³⁾, the European Medicines Agency is acting as secretariat for those expert panels. Therefore, the cooperation with the expert panels provided for in this Implementing Regulation should be conducted via the European Medicines Agency.
- (3) The exchange of information should include the exchange of information for the planning and forecast of the joint clinical assessments and joint scientific consultations. The exchange of that information is necessary for establishing and amending the annual work programme to be adopted by the Coordination Group that is to set out the planned number and type of joint clinical assessments and their updates and the planned number of joint scientific consultations. Pursuant to Article 6(3), points (a) and (b), of Regulation (EU) 2021/2282, in the preparation or amendments of the annual work programme, the Coordination Group is to take into account the reports on emerging health technologies referred to in Article 22 of Regulation (EU) 2021/2282 and information from the European Medicines Agency on the status of submitted and upcoming marketing authorisation applications for medicinal products referred to in Article 7 thereof. Pursuant to Article 22(2), point (b), of Regulation (EU) 2021/2282, the relevant sources for the preparation of the reports on emerging health technologies are to include information by the European Medicines Agency in relation to upcoming submissions of applications for marketing authorisation for medicinal products referred to in Article 7(1) thereof. The Commission should therefore set deadlines to ensure that the relevant information is provided by the European Medicines Agency to the

⁽¹⁾ OJ L 458, 22.12.2021, p. 1, ELI: <http://data.europa.eu/eli/reg/2021/2282/oj>.

⁽²⁾ Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1, ELI: <http://data.europa.eu/eli/reg/2017/745/oj>).

⁽³⁾ Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (OJ L 20, 31.1.2022, p. 1, ELI: <http://data.europa.eu/eli/reg/2022/123/oj>).

HTA secretariat in a timely manner for the preparation of the reports on emerging health technologies and the work programme. The Coordination Group should, via the HTA secretariat, receive from the European Medicines Agency other available information related to the forecast of the joint clinical assessments and joint scientific consultations necessary for the preparation of the reports on emerging health technologies in accordance with Article 22 of Regulation (EU) 2021/2282. The Commission should therefore specify which information and within which deadlines should be submitted by the European Medicines Agency.

- (4) Under Article 7(4) of Regulation (EU) 2021/2282, the Commission, after seeking a recommendation from the Coordination Group, is to adopt a decision, by means of an implementing act and at least every 2 years, selecting the medical devices and *in vitro* diagnostic medical devices referred to in Article 7(1), points (c) and (d), of Regulation (EU) 2021/2282 for joint clinical assessment. For the purposes of such selection, it is necessary to ensure that the HTA secretariat regularly receives from the European Medicines Agency the list of those medical devices and *in vitro* diagnostic medical devices.
- (5) In order to ensure the preparation of the reports on emerging health technologies referred to in Article 22 of Regulation (EU) 2021/2282, the preparation of the annual work programme of the Coordination Group, its adoption and the adoption of its amendments and to enable the Coordination Group to provide the recommendation referred to in Article 7(4) of Regulation (EU) 2021/2282, the HTA secretariat should share the information provided by the European Medicines Agency related to the planning and forecast of the joint clinical assessments and joint scientific consultations, as well as the information on the medical devices and *in vitro* diagnostic medical devices referred to in Article 7(1), points (c) and (d), of Regulation (EU) 2021/2282 as appropriate with the Coordination Group and/or its relevant subgroups established by the Coordination Group on 28 November 2022 pursuant to Article 3(7), point (k), of Regulation (EU) 2021/2282, that is the subgroup on the identification of emerging health technologies ('the EHT Subgroup') or the subgroup on joint clinical assessments ('the JCA Subgroup').
- (6) The information on upcoming marketing authorisation applications, as well as certain other available information related to the planning and forecast of the joint clinical assessments and joint scientific consultations, is based, *inter alia*, on the information shared by health technology developers with the European Medicines Agency on a voluntary basis and it may contain commercially confidential data. In addition to the requirements of Article 5(6) and Article 30(3), point (m), of Regulation (EU) 2021/2282, appropriate and specific measures to protect adequately this and other confidential information received by the HTA secretariat from the European Medicines Agency within the context of joint clinical assessment and joint scientific consultation should be set out in this Implementing Regulation. This is necessary in order to ensure that such information is protected not only at the level of the Coordination Group or its subgroups, but also at the level of their members, including where the access to that information is given to other individuals who might be involved in joint clinical assessment and joint scientific consultation by the members of the Coordination Group and its subgroups. Moreover, in order to safeguard the appropriate protection of confidential information shared by the European Medicines Agency within the context of joint clinical assessment and joint scientific consultation, it is appropriate to specify the purposes for which the information received from the European Medicines Agency may be used and set out the rules on how the level of protection is attributed. Without prejudice to any legal or criminal proceedings by the competent national authorities of the Member States in accordance with their laws and regulations and to contractual remedies, in case of breaches or failure to respect the obligations of professional secrecy, appropriate measures should be taken.

- (7) Regulation (EU) 2021/2282 provides for the involvement of patients, clinical experts and other relevant experts ('individual experts') having expertise in the therapeutic area concerned in joint clinical assessments and joint scientific consultations. Similarly, individual patients and healthcare professionals having expertise in the therapeutic area concerned are being engaged by the European Medicines Agency in the context of the evaluation of medicinal products. Joint clinical assessments and joint scientific consultations under Regulation (EU) 2021/2282 are conducted on the health technologies that are subject to the centralised procedure provided for under Regulation (EC) No 726/2004 of the European Parliament and of the Council ⁽⁴⁾, the clinical evaluation consultation procedure pursuant to Article 54 of Regulation (EU) 2017/745 and the performance evaluation consultation procedure pursuant to Article 48(6) of Regulation (EU) 2017/746 of the European Parliament and of the Council ⁽⁵⁾. Under Regulation (EU) 2021/2282, the joint clinical assessments are to be conducted in parallel with the centralised procedure and in close cooperation with the European Medicines Agency and joint scientific consultations may be conducted in parallel with the preparation of scientific advice pursuant to Article 57(1), point (n), of Regulation (EC) No 726/2004 and with the consultation with an expert panel pursuant to Article 61(2) of Regulation (EU) 2017/745 and in close cooperation with the European Medicines Agency. Therefore, the HTA secretariat and the European Medicines Agency should cooperate to identify individual experts to be engaged in the respective procedures.
- (8) The specific rights and responsibilities of the individual experts are different during the assessments of health technologies performed by the Coordination Group and the evaluation of medicinal products and consultation procedures on medical devices and *in vitro* diagnostic medical devices performed by the European Medicines Agency and the expert panels. Therefore, an individual expert should not be prevented from being engaged in the context of the evaluation of health technologies during the centralised procedure or during the procedures pursuant to Article 54 of Regulation (EU) 2017/745 and Article 48(6) of Regulation (EU) 2017/746, on the one hand, and in a joint clinical assessment or joint scientific consultation of the same health technology, on the other hand. However, the transparency of such engagement should be ensured.
- (9) The cooperation between the HTA secretariat and the European Medicines Agency on the identification of individual experts should include the exchange of personal data, namely the names, contact details and areas of expertise of individual experts. Such processing is necessary within the meaning of Article 5(1), point (a), and Article 10(2), point (i), of Regulation (EU) 2018/1725 of the European Parliament and of the Council ⁽⁶⁾ for the performance by the Commission of its tasks laid down in Article 28 of Regulation (EU) 2021/2282. This Implementing Regulation should determine that the Commission is the controller within the meaning of Article 3, point 8, of Regulation (EU) 2018/1725 for the processing of the personal data received from the European Medicines Agency. In order to ensure the relevant in-depth specialized expertise in the joint work, for example, in the event where the selected individual experts step down from their roles and responsibilities, it is appropriate to provide for a retention period of personal data of individual experts not selected to take part in a joint clinical assessment or a joint scientific consultation.
- (10) The identity of the patient may reveal the patient's health status in relation to the subject-matter of the joint clinical assessment or the joint scientific consultation. Therefore, that type of data should be considered a special category of personal data under Article 10 of Regulation (EU) 2018/1725, and the processing of such data should be made conditional on the fulfilment of the criteria laid down in Article 10(2), point (i), of that Regulation, including the set-up of suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy. Personal data of patients involved in joint clinical assessments and joint scientific consultations should not be published.

⁽⁴⁾ 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 and veterinary 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>).

⁽⁵⁾ Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176, ELI: <http://data.europa.eu/eli/reg/2017/746/oj>).

⁽⁶⁾ 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>).

- (11) In order to allow for a more informative decision making and for exchange of information and pooling of knowledge, the Coordination Group, with the facilitation of the HTA secretariat, should ensure appropriate exchange of information with the European Medicines Agency on horizontal issues of scientific or technical nature related to joint clinical assessment and joint scientific consultation, such as methodological issues following international standards of evidence-based medicine. In order to preserve the separation of the respective remits of the Coordination Group and the European Medicines Agency, these exchanges should not relate to the assessment of individual health technologies. The Coordination Group should also be able to involve in this exchange of information the stakeholder network established pursuant to Article 29 of Regulation (EU) 2021/2282 ('the HTA stakeholder network').
- (12) Under Article 30(1) of Regulation (EU) 2021/2282, the Commission is to set up and maintain an IT platform consisting of a secure system for the exchange of information on the joint work, including the exchange of information with the European Medicines Agency ('the HTA IT platform'). The Commission and the European Medicines Agency will be working towards the interoperability of the HTA IT platform and the IT systems of the European Medicines Agency, which will however not be in place by the date of application of Regulation (EU) 2021/2282, that is 12 January 2025. It is therefore necessary to specify that the HTA secretariat and the European Medicines Agency should exchange the information within the context of joint clinical assessment and joint scientific consultation as appropriate through the HTA IT platform.
- (13) As Regulation (EU) 2021/2282 applies with effect from 12 January 2025, this Regulation should also apply from that date.
- (14) The European Data Protection Supervisor was consulted in accordance with Article 42 of Regulation (EU) 2018/1725 and delivered an opinion on 27 August 2024.
- (15) 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 concerning cooperation, in the form of exchange of information, of the Member State Coordination Group on Health Technology Assessment ('Coordination Group'), with the facilitation of the secretariat of the Coordination Group ('the HTA secretariat'), with the European Medicines Agency on the joint clinical assessment and joint scientific consultation referred to in Articles 7 to 21 of Regulation (EU) 2021/2282 as regards:

- (a) planning and forecast of the joint clinical assessments and joint scientific consultations;
- (b) identification of patients, clinical experts and other relevant experts ('individual experts') to be involved in joint clinical assessments and joint scientific consultations;
- (c) horizontal scientific and technical matters related to joint clinical assessment and joint scientific consultation;
- (d) security of sharing and protection of confidential information exchanged between the European Medicines Agency and the HTA secretariat and then shared by the HTA secretariat with the Coordination Group or its subgroups and their members within the context of joint clinical assessment and joint scientific consultation.

*Article 2***Information exchange related to the planning and forecast of the joint clinical assessments and joint scientific consultations**

1. At the latest by 30 April each year, the European Medicines Agency shall provide the HTA secretariat with the following information concerning medicinal products:

- (a) information on upcoming submissions of initial applications for marketing authorisation for medicinal products;
- (b) information, where available, about the variations to the terms of existing marketing authorisations which correspond to a new therapeutic indication planned by marketing authorisation holders;
- (c) estimated number of advice procedures for undertakings pursuant to Article 57(1), point (n), of Regulation (EC) No 726/2004.

The information referred to in the first subparagraph, point (a), shall cover the period of the current year and at least the following year and include the following elements, where available:

- (i) the international non-proprietary name for the active substance;
- (ii) the name of the health technology developer;
- (iii) the therapeutic indication summary;
- (iv) the eligibility basis for the centralised procedure provided for in Regulation (EC) No 726/2004;
- (v) the eligibility for a priority (PRIME) scheme;
- (vi) the expected submission date of the application for marketing authorisation.

2. At the latest by 30 April each year, the European Medicines Agency shall provide the HTA secretariat with the following information concerning medical devices likely to be the subject of joint clinical assessment:

- (a) number of ongoing and finalised advice procedures initiated by manufacturers in accordance with Article 61(2) of Regulation (EU) 2017/745 and information on medical devices subject to the advice for the period of last 12 months;
- (b) where available estimated number of future requests for advice by manufacturers from the expert panels pursuant to Article 61(2) of Regulation (EU) 2017/745 and information on medical devices subject to the future advice.

The information referred to in the first subparagraph shall include the following elements, where available:

- (i) the type of device;
- (ii) the intended purpose, including any medical indication(s), contraindication(s) and target population(s);
- (iii) the development phase of the device.

3. The European Medicines Agency shall provide the HTA secretariat with available updates of the information referred to in paragraphs 1 and 2, identified together with the EHT Subgroup as relevant for the preparation of the report on emerging health technologies referred to in Article 22 of Regulation (EU) 2021/2282.

Article 3

Information exchange related to the selection of medical devices and *in vitro* diagnostic medical devices for joint clinical assessment

1. The European Medicines Agency shall provide the HTA secretariat with:
 - (a) information on all medical devices for which the expert panels designated in accordance with Article 106(1) of Regulation (EU) 2017/745 have provided or have decided to provide a scientific opinion in the framework of the clinical evaluation consultation procedure pursuant to Article 54 of that Regulation;
 - (b) information on all *in vitro* diagnostic medical devices for which the expert panel has provided or has been asked to provide its views in the framework of the procedure pursuant to Article 48(6) of Regulation (EU) 2017/746.

The information referred to in the first subparagraph, point (a), shall include the following elements:

- (i) the name and type of the device;
- (ii) the name of the manufacturer;
- (iii) the name of the notified body;
- (iv) the expert panel decision regarding the intention to provide a scientific opinion referred to in Section 5.1, point (c), of Annex IX to Regulation (EU) 2017/745;
- (v) where available, the scientific opinion of the expert panel.

The information referred to in the first subparagraph, point (b), shall include the following elements:

- (i) the name and type of the *in vitro* diagnostic medical device;
- (ii) the name of the manufacturer;
- (iii) the name of the notified body;
- (iv) where available, the views of the expert panel.

2. The European Medicines Agency shall provide the information referred to in paragraph 1 no later than 15 days after the end of each quarter, pertaining to that quarter. For the first reporting period, the European Medicines Agency shall provide the information referred to in paragraph 1 covering the period from 1 January 2024.

Article 4

Information exchange with the Coordination Group and its EHT Subgroup and JCA Subgroup

1. Once the HTA secretariat receives the information from the European Medicines Agency pursuant to Article 2, it shall make that information available as appropriate to the EHT Subgroup or to the Coordination Group, or both, for further analysis in the preparation of the reports on emerging health technologies referred to in Article 22 of Regulation (EU) 2021/2282 and for the preparation and amendment of the annual work programme of the Coordination Group.

The EHT Subgroup may, via the HTA secretariat, consult the European Medicines Agency in the context of preparing the reports on emerging health technologies referred to in Article 22 of Regulation (EU) 2021/2282.

2. Once the HTA secretariat receives the information from the European Medicines Agency pursuant to Article 3, it shall make that information available for further analysis in the preparation of the recommendation referred to in Article 7(4) of Regulation (EU) 2021/2282 to the following:

- (a) the Coordination Group;

- (b) the EHT Subgroup or the JCA Subgroup, based on the decision of the Coordination Group; or
- (c) the Coordination Group and the EHT Subgroup or the JCA Subgroup, based on the decision of the Coordination Group.

Article 5

Information exchange related to the identification of individual experts in the context of joint clinical assessments and joint scientific consultations

1. On request and where that information is available, the European Medicines Agency shall provide the HTA secretariat with information on potentially suitable individual experts for its consideration to be proposed to the relevant subgroup as a patient, clinical expert or other relevant expert in a joint clinical assessment or joint scientific consultation. Personal data that may be provided are limited to names, contact details and areas of expertise of individual experts.
2. The summary minutes of the meeting of the Coordination Group and its subgroups as well as joint clinical assessment reports or joint scientific consultation outcome documents shall record whether an individual expert was engaged in the context of the evaluation of the same medicinal product or comparator medicinal product during the centralised procedure or the same medical device or *in vitro* diagnostic medical device or comparator device during the procedures pursuant to Article 54 of Regulation (EU) 2017/745 and Article 48(6) of Regulation (EU) 2017/746. Personal data of patients involved in joint clinical assessments and joint scientific consultations shall not be published.
3. The processing of personal data referred to in paragraph 1 shall be based on Article 5(1), point (a), of Regulation (EU) 2018/1725, and Article 10(2), point (i), thereof for data concerning health. The Commission shall be controller of the processing of the personal data received from the European Medicines Agency. The Commission shall take specific safeguards for the data processed in the context of Article 10(2), point (i), of Regulation (EU) 2018/1725, such as pseudonymisation, prevention of unauthorised access, prevention of unauthorised reading, copying, modification or deletion of personal data, as well as organisational measures ensuring that personnel authorised to process data have access only to data covered by their access authorisation, and that it is possible to verify and establish what data have been accessed, by which member of the personnel and at what time.
4. The Commission shall keep the personal data of individual experts not selected to take part in a joint clinical assessment or a joint scientific consultation only for as long as necessary in order to ensure the relevant in-depth specialised expertise in the joint work and no longer than 3 years after the date on which the European Medicines Agency provided the HTA secretariat with this data.

Article 6

Information exchange on horizontal scientific and technical matters related to joint clinical assessment and joint scientific consultation

1. The Coordination Group and its subgroups shall ensure an appropriate exchange of information with the European Medicines Agency on horizontal issues of scientific or technical nature related to joint clinical assessment and joint scientific consultation. These exchanges shall occur via the HTA secretariat and shall not relate to the assessment of individual health technologies.
2. The Coordination Group may involve the stakeholder network established pursuant to Article 29 of Regulation (EU) 2021/2282 ('the HTA stakeholder network') in the exchange of information referred to in paragraph 1.

*Article 7***Secure exchange of information**

1. The HTA secretariat and the European Medicines Agency shall exchange the information within the context of joint clinical assessment and joint scientific consultation as appropriate through the IT platform referred to in Article 30 of Regulation (EU) 2021/2282, consisting of a secure system for the exchange of information on the joint work, including the exchange of information with the European Medicines Agency ('the HTA IT platform').
2. The exchange of information through the HTA IT platform shall be based on its technical specifications containing provisions on effective technical and security measures for interfacing, access to information and data processing.

*Article 8***Protection of confidential information**

1. The information received from the European Medicines Agency within the context of joint clinical assessment and joint scientific consultation shall be used exclusively for the purposes of planning and conducting the joint clinical assessments and joint scientific consultations referred to in Articles 7-21 of Regulation (EU) 2021/2282.
2. The European Medicines Agency shall clearly indicate the level of protection that it attributes to the information shared with the HTA secretariat within the context of joint clinical assessment and joint scientific consultation. Before providing the information received from the European Medicines Agency to the Coordination Group and to its relevant subgroups, the HTA secretariat shall attribute to this information at least an equivalent level of protection.
3. The members of the Coordination Group or its subgroups shall implement necessary and appropriate technical and organisational measures to ensure and protect within their organisation the confidentiality of the information received from the European Medicines Agency within the context of joint clinical assessment and joint scientific consultation. In particular, the members of the Coordination Group or its subgroups shall ensure that only their representatives appointed to the Coordination Group or its subgroups and other individuals bound by the professional secrecy obligations who have a 'need-to-know' may access this information.
4. The members of the Coordination Group or its subgroups shall immediately report to the HTA secretariat any breach or suspected breach of protection of the information received from the European Medicines Agency within the context of joint clinical assessment and joint scientific consultation.

*Article 9***Failure to respect the obligations of professional secrecy**

1. If the Commission becomes aware that a representative of the member of the Coordination Group or its subgroups or an individual expert failed to respect the obligations of professional secrecy as laid down by Article 339 of the Treaty on the Functioning of the European Union and Article 5(6) of Regulation (EU) 2021/2282, as well as by the Commission's rules on security regarding the protection of EU classified information and sensitive non-classified information, as laid down in Commission Decisions (EU, Euratom) 2015/443 ⁽⁷⁾ and (EU, Euratom) 2015/444 ⁽⁸⁾, it shall inform the representative or individual expert in writing and request a clarification of the situation. The representative or the individual expert shall provide the requested clarification within 14 days from the day of the notification of the request.

⁽⁷⁾ Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41, ELI: <http://data.europa.eu/eli/dec/2015/443/oj>).

⁽⁸⁾ Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53, ELI: <http://data.europa.eu/eli/dec/2015/444/oj>).

2. If the representative or the individual expert does not provide the requested clarification within the period referred to in paragraph 1, the Commission may decide to exclude the representative or the individual expert from participation in the joint work until the clarification is provided and assessed by the Commission.
3. If the requested clarification is provided, the Commission may exclude the representative or the individual expert from the joint work for a period up to 2 years, if the representative or the individual expert failed to respect the obligations of professional secrecy intentionally or by gross negligence.
4. The HTA secretariat shall inform the representative, the individual expert and, as appropriate, the member of the Coordination Group or its subgroup, the Coordination Group or its subgroups of the decisions of the Commission referred to in paragraph 3 and shall ensure the enforcement of the measures imposed in those decisions.

Article 10

Entry into force

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 October 2024.

For the Commission
The President
Ursula VON DER LEYEN