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AGREEMENT

between the European Union, of the one part, and Montenegro, of the other part, on the association of Montenegro to the EU4Health Programme

The European Commission (hereinafter referred to as ‘the Commission’), on behalf of the European Union,

of the one part,

and

Montenegro (hereinafter referred to as ‘Montenegro’),

of the other part,

hereinafter referred to as ‘the Parties’

WHEREAS Protocol 8 to the Stabilisation and Association Agreement between the European Communities and their Member States, of the one part, and Montenegro, of the other part, on the general principles for the participation of Montenegro in Community programmes¹ (the ‘Protocol’) stipulates in its Article 5 that the specific terms and conditions regarding the participation of Montenegro in each particular programme, in particular the financial contribution payable, are to be determined by agreement, in the form of a Memorandum of Understanding between the Commission, acting on behalf of the Union, and Montenegro. This Agreement constitutes an agreement referred to in Article 5 of the Protocol;

WHEREAS the EU4Health Programme was established by Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union’s action in the field of health for the period 2021-2027, and repealing Regulation (EU) No 282/2014² (hereinafter referred to as ‘Regulation (EU) 2021/522’);

¹ OJ L 108, 29.4.2010, p. 3.

² OJ L107, 26.3.2021, p. 1, ELI: <http://data.europa.eu/eli/reg/2021/522/oj>.

CONSIDERING the European Union's efforts to lead the response by joining forces with its international partners to address global challenges in line with the plan of action for people, planet and prosperity in the United Nations Agenda 'Transforming our World: the 2030 Agenda for Sustainable Development', and acknowledging that health and wellbeing are essential elements for sustainable development;

WHEREAS the specific terms and conditions of the association should be determined by an agreement between the Union and the associated country;

RECOGNISING the general principles as set out in Regulation (EU) 2021/522;

SHARING the general objectives of the EU4Health Programme for improving and fostering health in the Union, supporting health promotion and disease prevention, protecting people in the Union from serious cross-border threats, improving the availability, accessibility and affordability of medicinal products and medical devices, and strengthening health systems by improving their resilience and resource efficiency;

CONSIDERING the common goals, values and strong links of the Parties in the field of health; and RECOGNISING the common desire of the Parties to develop, strengthen, stimulate and extend their relations and cooperation therein,

HAVE AGREED AS FOLLOWS:

Article 1

Scope of the association

Montenegro shall participate as associated country in and contribute to all parts of the EU4Health Programme established by Regulation (EU) 2021/522 in its most up to date version.

Article 2

Terms and conditions of participation in the EU4Health Programme

1. Montenegro shall participate in the EU4Health Programme in accordance with the conditions laid down in the Protocol, and under the terms and conditions set forth in this Agreement, in the legal act referred to in Article 1 of this Agreement, as well as in any other rules pertaining to the implementation of the EU4Health Programme, in its most up to date version.

2. Unless otherwise provided for in the terms and conditions referred to in paragraph 1 of this Article, legal entities established in Montenegro may participate in actions of the EU4Health Programme under conditions equivalent to those applicable to legal entities established in the

Union, including the respect of EU restrictive measures³.

3. Representatives of Montenegro shall have the right to participate as observers in the committee referred to in Article 23 of Regulation (EU) 2021/522, without voting rights and for points which concern Montenegro. The committee shall meet without the presence of the representatives of Montenegro at the time of voting. Montenegro shall be informed of the result.

4. Travel costs and subsistence expenses incurred by representatives and experts of Montenegro for the purposes of taking part as observers in the work of the committee as referred to Article 23 of Regulation (EU) 2021/522 or in other meetings related to the implementation of the EU4Health Programme, shall be reimbursed by the European Union on the same basis as and in accordance with the procedures in force for representatives and experts of the Member States of the European Union.

5. The Parties shall make every effort, within the framework of the existing provisions, to facilitate the free movement and residence of participants in the activities covered by this Agreement and to facilitate cross-border movement of goods and services intended for use in such activities.

6. Montenegro shall take all necessary measures, as appropriate, to ensure that goods and services, purchased in Montenegro or imported into Montenegro, which are partially or entirely financed pursuant to the grant agreements and/or contracts concluded for the realisation of the activities in accordance with this Agreement, are exempted from customs duties, import duties and other fiscal charges, including the VAT, that are applicable in Montenegro.

7. English shall be used for the procedures related to requests, contracts and reports, as well as for other administrative aspects of the EU4Health Programme.

Article 3

Financial contribution

1. Participation of Montenegro or legal entities established in Montenegro in the EU4Health Programme shall be subject to Montenegro contributing financially to the EU4Health Programme and the related management, execution and operation costs under the general budget of the Union (hereinafter referred to as the ‘Union budget’).

2. The financial contribution shall take the form of the sum of:

- a) an operational contribution; and
- b) a participation fee.

³ The EU restrictive measures are adopted pursuant to the Treaty on the European Union or the Treaty on the Functioning of the European Union.

3. The financial contribution shall take the form of an annual payment made in one instalment, and shall be due at the latest in May.
4. The operational contribution shall cover operational and support expenditure of the Programme and be additional both in commitment and payment appropriations to the amounts entered in the Union budget definitively adopted for the EU4Health Programme.
5. The operational contribution shall be based on a contribution key defined as the ratio of the Gross Domestic Product (GDP) of Montenegro at market prices to the GDP of the Union at market prices. The GDPs at market prices to be applied shall be determined by the dedicated Commission services based on the most recent statistical data available for budget calculations in the year prior to the year in which the annual payment is due. Adjustments to this contribution key are laid down in Annex I.
6. The operational contribution shall be calculated applying the contribution key, as adjusted, to the commitment appropriations entered in the Union budget definitively adopted for the applicable year for financing the EU4Health Programme.
7. The participation fee shall be 4% of the annual initial operational contribution as calculated in accordance with paragraphs 5 and 6 and shall be phased in as set out in Annex I. The participation fee shall not be subject to retrospective adjustments or corrections.
8. The Union shall provide Montenegro with information in relation to its financial participation as included in the budgetary, accounting, performance and evaluation related information provided to the Union budgetary and discharge authorities concerning the EU4Health Programme. That information shall be provided having due regard to the Union's and Montenegro's confidentiality and data protection rules and shall be without prejudice to the information which Montenegro is entitled to receive under Annex II.
9. All contributions of Montenegro or payments from the Union, and the calculation of amounts due or to be received shall be made in euro.

Article 4

Monitoring, Evaluation and Reporting

1. Without prejudice to the responsibilities of the Commission, the European Anti-Fraud Office (OLAF) and the Court of Auditors of the European Union in relation to monitoring and evaluation of the EU4Health Programme, the participation of Montenegro in that Programme shall be continuously monitored on a partnership basis involving the Commission and

Montenegro.

2. The rules concerning sound financial management, including the financial control, recovery and other antifraud measures in relation to Union funding under this Agreement are laid down in Annex II.

Article 5

Final provisions

1. This Agreement shall enter into force on the date on which the Parties have notified each other of the completion of their internal procedures necessary for that purpose.

2. This Agreement shall apply retroactively from 1 January 2024. It shall remain in force for as long as is necessary for all the projects, actions, activities or parts thereof financed from the EU4Health Programme, all the actions necessary to protect the financial interests of the European Union and all the financial obligations stemming from the implementation of this Agreement between the Parties to be completed.

3. The Union and Montenegro may apply this Agreement provisionally in accordance with their respective internal procedures and legislation. The provisional application shall begin on the date on which the Parties have notified each other of the completion of their internal procedures necessary for that purpose.

4. Should Montenegro notify the Commission acting on behalf of the European Union that it will not complete its internal procedures necessary for the entry into force of this Agreement, this Agreement shall cease to apply provisionally on the date of receipt of this notification by the Commission, which shall constitute the cessation date for the purposes of this Agreement.

5. The application of this Agreement may be suspended by the European Union in case of non-payment of the financial or operational contribution due by Montenegro in accordance with point II of paragraph 3 of Annex I.

Suspension of the application of this Agreement shall be notified by the European Union to Montenegro by a formal letter of notification which shall take effect 15 days following the receipt of this notification by Montenegro.

In case the application of this Agreement is suspended, legal entities established in Montenegro shall not be eligible to participate in award procedures not yet completed when the suspension takes effect. An award procedure shall be considered completed when legal commitments have been entered into as a result of that procedure.

The suspension does not affect the legal commitments entered into with the legal entities established in Montenegro before the suspension took effect. This Agreement shall continue to apply to such legal commitments.

The European Union shall immediately notify Montenegro once the entire amount of the

financial or operational contribution due has been received by it. The suspension shall be lifted with an immediate effect upon this notification.

As of the date when the suspension is lifted, legal entities of Montenegro shall be again eligible in award procedures launched after this date and in award procedures launched before this date, for which the deadlines for submission of applications have not expired.

6. Either Party may terminate this Agreement at any time by a written notification informing of the intent to terminate it.

The termination shall take effect three calendar months after the date on which the written notification reaches its addressee. The date on which the termination takes effect shall constitute the termination date for the purposes of this Agreement.

7. Where this Agreement ceases to apply provisionally in accordance with paragraph (4) or is terminated in accordance with paragraph (6), the Parties agree that:

a) projects or actions, activities or parts thereof in respect of which legal commitments have been entered into during the provisional application and/or after the entry into force of this Agreement, and before this Agreement ceases to apply or is terminated shall continue until their completions under the conditions laid down in this Agreement;

(b) the annual financial contribution of the year N during which this Agreement ceases to apply provisionally or is terminated shall be paid entirely in accordance with Article 3.

The Parties shall settle by common consent any other consequences of termination or cessation of provisional application of this Agreement.

8. This Agreement may only be amended in writing by common consent of the Parties. The entry into force of the amendments will follow the same procedure as that applicable for the entry into force of this Agreement.

9. The Annexes to this Agreement shall form an integral part of this Agreement. This Agreement shall be drawn up in duplicate in English.

Done atonin the year two thousand twenty-four.

FOR THE EUROPEAN UNION

FOR MONTENEGRO

Stella KYRIAKIDES
European Commissioner for Health and
Food safety

Dr. Vojislav ŠIMUN
Minister of Health

ANNEX I: Rules governing the financial contribution of Montenegro to the EU4Health Programme (2021-2027)

ANNEX II: Sound Financial Management

Annex I

Rules governing the financial contribution of Montenegro to the EU4Health Programme (2021-2027)

I. Calculation of Montenegro's financial contribution

1. The financial contribution of Montenegro to the EU4Health Programme shall be established on a yearly basis in proportion to, and in addition to, the amount available each year in the Union budget for commitment appropriations needed for the management, execution and operation of the EU4Health Programme.
2. The participation fee referred to in Article 3(7) of this Agreement shall be phased in as follows:
 - 2024: 2%;
 - 2025: 2,5%;
 - 2026: 3%;
 - 2027: 4%.
3. In accordance with Article 3(5) of this Agreement, the initial operational contribution to be paid by Montenegro for its participation in the EU4Health Programme will be calculated for the respective financial years by applying an adjustment to the contribution key.

The adjustment to the contribution key shall be:

$$\text{Contribution Key Adjusted} = \text{Contribution Key} \times \textit{Coefficient}$$

The coefficient used for the above calculation to adjust the contribution key shall be 0.5 for 2024-2027.

II. Payment of Montenegro's financial contribution

1. The Commission shall communicate to Montenegro, as soon as possible and at the latest when issuing the first call for funds of the financial year, the following information:
 - a. the amounts in commitment appropriations in the Union budget definitively adopted for the year in question for the budget lines covering participation of Montenegro, in EU4Health Programme;
 - b. the amount of the participation fee referred to in Article 3(7) of this Agreement.

On the basis of its Draft Budget, the Commission shall provide an estimate of information for the following year under points (a) and (b) as soon as possible, and, at the latest, by 1 September of the financial year.

2. The Commission shall issue, at the latest in April of each financial year, a call for funds to Montenegro corresponding to its contribution under this Agreement.

Each call for funds shall provide for the payment of Montenegro's contribution not later than 30 days after the call for funds is issued.

For the first year of implementation of this Agreement, the Commission shall issue the call for funds within 60 days of the signature of this Agreement.

3. Montenegro shall pay its financial contribution under this Agreement in accordance with point II of this Annex. In the absence of payment by Montenegro by the due date, the Commission shall send a formal letter of reminder.

Any delay in the payment of the financial contribution shall give rise to the payment of default interest by Montenegro on the outstanding amount from the due date.

The interest rate for amounts receivable not paid on the due date shall be the rate applied by the European Central Bank to its principal refinancing operations, as published in the C series of *the Official Journal of the European Union*, in force on the first calendar day of the month in which the due date falls, increased by three and half percentage points.

In case the delay in the payment of the contribution is such that it may significantly jeopardise the implementation and management of the EU4Health Programme, participation of Montenegro in the EU4Health Programme will be suspended by the Commission following the absence of payment 20 working days after a formal letter of reminder, without prejudice to the Union's obligations according to grant agreements and/or contracts already concluded pertaining to the implementation of the indirect actions for which Montenegro was selected.

Annex II

Sound Financial Management

Protection of financial interests and recovery

Article 1

Reviews and audits

1. The European Union shall have the right to conduct, in accordance with the applicable acts of one or more Union institutions or bodies and as provided in relevant agreements and/or contracts, technical, scientific, financial, or other types of reviews and audits on the premises of any natural person residing in or any legal entity established in Montenegro and receiving European Union funding, as well as any third party involved in the implementation of Union funds residing or established in Montenegro. Such review and audits may be carried out by the agents of the institutions and bodies of the European Union, in particular of the European Commission and the European Court of Auditors, or by other persons mandated by the European Commission.
2. The agents of the institutions and bodies of the European Union, in particular of the Commission and the European Court of Auditors, and the other persons mandated by the Commission, shall have appropriate access to sites, works and documents (both in electronic and paper versions) and to all the information required in order to carry out such audits, including the right of obtaining a physical/electronic copy of, and extracts from, any document or the contents of any data medium held by the audited natural or legal person, or by the audited third party.
3. Montenegro shall not prevent or raise any particular obstacle to the right of entrance in Montenegro and to the access to the premises of the agents and other persons referred to in paragraph 2 on the grounds of the exercise of their duties referred to in this Article.
4. The reviews and audits may be carried out, also after the suspension of application of this Agreement pursuant to its Article 5(3), the cessation of provisional application or its termination, on the terms laid down in the applicable acts of one or more European Union institutions or bodies and as provided in relevant agreements and/or contracts in relation to any legal commitment implementing the European Union budget entered into by the European Union before the date on which the suspension of application of this Agreement pursuant to its Article 5(3), the cessation of provisional application or termination of this Agreement takes effect.

Article 2
**Fight against irregularities, fraud and other criminal offences
affecting the financial interests of the Union**

1. The European Commission and the European Anti-Fraud Office (OLAF) shall be authorised to carry out administrative investigations, including on-the-spot checks and inspections, on the territory of Montenegro. These investigations shall be carried out in accordance with the terms and conditions established by applicable acts of one or more Union institutions.
2. The Montenegro's competent authorities shall inform the European Commission or OLAF within reasonable time of any fact or suspicion which has come to their notice relating to an irregularity, fraud or other illegal activity affecting the financial interests of the Union.
3. On-the-spot checks and inspections may be carried out on the premises of any natural person residing in or legal entity established in Montenegro and receiving Union funds, as well as of any third party involved in the implementation of Union funds residing or established in Montenegro.
4. On-the-spot checks and inspections shall be prepared and conducted by the Commission or OLAF in close collaboration with the competent Montenegro's authority designated by Montenegro. The designated authority shall be notified a reasonable time in advance of the object, purpose and legal basis of the checks and inspections, so that it can provide assistance. To that end, the officials of the competent Montenegro's authorities may participate in the on-the-spot checks and inspections.
5. Upon request by Montenegro's authorities, the on-the-spot checks and inspections may be carried out jointly with the Commission or OLAF.
6. Commission agents and OLAF staff shall have access to all the information and documentation, including computer data, on the operations concerned, which are required for the proper conduct of the on-the-spot checks and inspections. They may, in particular, copy relevant documents.
7. Where the person, entity or another third party resists an on-the-spot check or inspection, Montenegro's authorities, acting in accordance with national rules and regulations, shall assist the Commission or OLAF, to allow them to fulfil their duty in carrying out an on-the-spot check or inspection. This assistance shall include taking the appropriate precautionary measures under national law, in particular in order to safeguard evidence.
8. The Commission or OLAF shall inform the Montenegro's authorities of the result of such checks and inspections. In particular, the Commission or OLAF shall report as soon as possible to the competent Montenegro's authority any fact or suspicion relating to an irregularity which has come to their notice in the course of the on-the-spot check or inspection.

9. Without prejudice to application of Montenegro's criminal law, the Commission may impose administrative measures and penalties on legal or natural persons of Montenegro participating in the implementation of a programme or activity in accordance with European Union legislation.
10. For the purposes of proper implementation of this Article, the Commission or OLAF and Montenegro's competent authorities shall regularly exchange information and, at the request of one of the parties to this Agreement, consult each other.
11. In order to facilitate effective cooperation and exchange of information with OLAF, Montenegro shall designate a contact point.
12. Information exchanged between the Commission or OLAF and Montenegro's competent authorities shall take place having due regard to the confidentiality requirements. Personal data included in the exchange of information shall be protected in accordance with applicable rules.
13. Montenegro's authorities shall cooperate with the European Public Prosecutor's Office to allow it to fulfil its duty to investigate, prosecute and bring to judgment the perpetrators of, and accomplices to, criminal offences affecting the financial interests of the European Union in accordance with the applicable legislation.

Article 3

Recovery and enforcement

1. Decisions adopted by the Commission imposing a pecuniary obligation on legal or natural persons other than States in relation to any claims stemming from the EU4Health Programme shall be enforceable in Montenegro. The order for enforcement shall be appended to the decision, without any other formality than a verification of the authenticity of the decision by the national authority designated for this purpose by Montenegro. Montenegro shall make known its designated national authority to the Commission and the Court of Justice of the European Union. In accordance with Article 4 of this Annex, the European Commission shall be entitled to notify such enforceable decisions directly to persons residing and legal entities established in Montenegro. Enforcement shall take place in accordance with the Montenegro law and rules of procedure.
2. Judgments and orders of the Court of Justice of the European Union delivered in application of an arbitration clause contained in a contract or agreement in relation to Union programmes, activities, actions or projects shall be enforceable in Montenegro in the same manner as Commission decisions referred to in paragraph 1.
3. The Court of Justice of the European Union shall have jurisdiction to review the legality of the decision of the Commission referred to in paragraph 1 and to suspend its enforcement. However, the Courts of Montenegro shall have jurisdiction over complaints that enforcement is being carried out in an irregular manner.

Article 4

Communication and exchange of information

The European Union institutions and bodies involved in the implementation of the EU4Health Programme, or in controls over that programme, shall be entitled to communicate directly, including through electronic exchange systems, with any natural person residing in or legal entity established in Montenegro and receiving Union funds, as well as any third party involved in the implementation of Union funds residing or established in Montenegro. Such persons, entities and parties may submit directly to the European Union institutions and bodies all relevant information and documentation which they are required to submit on the basis of the European Union legislation applicable to the EU4Health Programme and of the contracts or agreements concluded to implement that programme.