



## **INSTRUMENT FOR PRE-ACCESSION ASSISTANCE (IPA II) 2014-2020**

### **MULTI-COUNTRY**

### **EU4Health: Contribution to the availability and access to vaccines against COVID-19 in the Western Balkans**

#### **Action summary**

The Commission's communication on "Support to the Western Balkans in tackling COVID-19 and the post-pandemic recovery" of 29 April 2020, outlined substantial financial support to the Western Balkans also including, to the greatest possible extent, the Western Balkans in its own response to the pandemic. The EU has mobilised a package of over EUR 3.3 billion to the benefit of Western Balkans citizens including EUR 38 million of immediate support for the health sector, in particular through delivering essential supplies to save lives such as personal protective equipment, tests and ventilators.

This action provides further support to the Western Balkans in the health sector by contributing to the availability and access to COVID-19 vaccines to the Western Balkans at the same time as they are made available to EU Member States. Vaccines purchased through the EU-funded intervention will be administered especially to identified priority groups (e.g. healthcare workers, elderly, vulnerable and high-risk people) identified in the vaccination strategies of the Beneficiaries. Up to 15% may also be used for the purchase of equipment, medical devices, material and consumables necessary for the delivery of the vaccines.

<b>Action Identification</b>			
<b>Action Programme Title</b>	IPA II Multi-country Action Programme for Western Balkans Guarantee for the years 2019-2020		
<b>Action Title</b>	EU4Health: Contribution to the availability and access to vaccines against COVID-19 in the Western Balkans		
<b>Action ID</b>	IPA 2020/041-957.02/MC/EU4Health: vaccines		
<b>Sector Information</b>			
<b>IPA II Sector</b>	9. Regional and territorial cooperation		
<b>DAC Sector</b>	12250 (Infectious Disease Control)		
<b>Budget</b>			
<b>Total cost</b>	EUR 70 000 000		
<b>EU contribution</b>	IPA 2020: EUR 70 000 000		
<b>Budget line(s)</b>	22.020401 – Multi-country programmes, regional integration and territorial cooperation		
<b>Management and Implementation</b>			
<b>Method of implementation</b>	Direct management		
<i>Direct management:</i> <b>European Commission</b>	Directorate-General for Neighbourhood and Enlargement Negotiations, Unit D.5 Western Balkans Regional Cooperation and Programmes  EU Delegations in Albania, Bosnia and Herzegovina, Montenegro, North Macedonia and Serbia; EU Office in Kosovo*		
<b>Location</b>			
<b>Zone benefiting from the action</b>	Western Balkans		
<b>Specific implementation area(s)</b>	Republic of Albania, Bosnia and Herzegovina, Kosovo, Montenegro, Republic of North Macedonia, and Republic of Serbia		
<b>Timeline</b>			
<b>Final date for contracting including the conclusion of contribution/delegation agreements</b>	At the latest by 31 December 2021		
<b>Final date for operational implementation</b>	60 months from the adoption of this Financing Decision.		
<b>Policy objectives / Markers (DAC form)</b>			
<b>General policy objective</b>	<b>Not targeted</b>	<b>Significant objective</b>	<b>Main objective</b>
Participation development/good governance	X	<input type="checkbox"/>	<input type="checkbox"/>
Aid to environment	X	<input type="checkbox"/>	<input type="checkbox"/>
Gender equality (including Women In Development)	<input type="checkbox"/>	X	<input type="checkbox"/>

\* This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

Trade Development	X	<input type="checkbox"/>	<input type="checkbox"/>
Reproductive, Maternal, New born and child health	<input type="checkbox"/>	X	<input type="checkbox"/>
<b>RIO Convention markers</b>	<b>Not targeted</b>	<b>Significant objective</b>	<b>Main objective</b>
Biological diversity	X	<input type="checkbox"/>	<input type="checkbox"/>
Combat desertification	X	<input type="checkbox"/>	<input type="checkbox"/>
Climate change mitigation	X	<input type="checkbox"/>	<input type="checkbox"/>
Climate change adaptation	X	<input type="checkbox"/>	<input type="checkbox"/>
<b>Internal Markers</b>	<b>Not targeted</b>	<b>Significant objective</b>	<b>Main objective</b>
Digitalisation	X	<input type="checkbox"/>	<input type="checkbox"/>
COVID Response	<input type="checkbox"/>	<input type="checkbox"/>	X

# 1. RATIONALE

## PROBLEM AND STAKEHOLDER ANALYSIS

The COVID-19 pandemic, in addition to its immediate human health and life impact, is having a disruptive effect on the economies of the Western Balkans and on people's livelihoods. It represents an unprecedented burden on their health and social protection systems, as well as a severe setback to their economies. Thousands of citizens are at risk of losing their jobs, and temporary government support measures (unemployment benefits, deferrals/waivers to tax and social security contributions, etc.) represent a heavy fiscal burden. The governments are also under pressure to rapidly expand the coverage of social protection systems.

While the EU itself is heavily affected by the pandemic, it has a particular responsibility and interest to lead the global response and assist partners in need, especially in its immediate neighbourhood and among pre-accession partners. As part of its international efforts, the EU has been providing unparalleled support to the Western Balkans of more than EUR 3.3 billion to address the immediate health crisis and resulting humanitarian needs, as well as longer term structural impact on their societies and economies. This includes delivery of medical devices and material, (protective equipment, tests, ventilators, ambulances, ICU beds)

Given their European perspective, the EU has also been granting the Western Balkans privileged access to EU initiatives and instruments. This has included associating the region with joint procurement of medical equipment, exempting the Western Balkans from the EU's export authorisation scheme for personal protective equipment and the supply by the EU of test calibration material. Stakeholders across the region are fully integrated in European COVID-19 research and innovation efforts. The whole region is also benefitting from technical assistance and information exchange facilitated by the European Centre for Disease Prevention and Control (ECDC), while the candidate countries in the Western Balkans have been invited as observers to the EU Health Security Committee and are given access to the related Early Warning and Response System.

A vaccine will be key to the resolution of the COVID-19 crisis. Immunisation is one of the most effective public health interventions – both in terms of lives saved and in terms of economic benefits. Large-scale inoculation will allow the Western Balkans to rebuild and continue to work towards meeting the Copenhagen criteria, alongside significant re-investment. Access to vaccines is therefore of primary importance. The EU has been at the forefront of the creation of the *Access to Covid-19 Tools Accelerator* (ACT-A) at the end of April, to ensure equitable access to tests, treatments and vaccines around the globe. The “vaccine pillar” of ACT-A, COVAX, was set up following these principles. COVAX, the global alliance to purchase vaccines now gathers 189 country members, including the 27 EU Member States. The EU has encouraged the Western Balkans partners to join COVAX as the key source of vaccines for third countries, and all of them have done so (all as self-paying countries with the exception of Kosovo). These vaccines are likely to become available in the second half of 2021.

In parallel, through its Joint Vaccine Strategy, the EU has supported the ramp up of the development and the production, and secured doses of several promising vaccines. The European Commission has concluded six legally binding agreements on behalf of the 27 EU Member States reserving around 1.3 billion doses to be delivered throughout 2021. Some of these vaccines are due to become available by the end of 2020, after the European Medicines Agency's (EMA) approval and the European Commission market authorisation. This means that European Member States will - in the coming weeks - have access to vaccines considered safe and efficient to be able to start a vaccination campaign for their priority groups.

It would be essential that our partners in the Western Balkans are also given access to a limited stock of the vaccines as early as possible to enable them to start their vaccination campaigns at the same time as the EU,

based on vaccination strategies and plans. Our economies and people are closely linked and vaccinations in the Western Balkans will be an important health security measure for the EU, as well as a sign of strong solidarity and EU's continuous commitment vis-à-vis the region. It will also help promote the most efficacious and safest vaccines (on the basis of EMA authorisation) available on the market to be used in the region and to avoid any potential health risks related with the use of insufficiently verified alternatives.

To be effective in terms of quantities, logistics and timing, the provision of the vaccines to the region will have to be based on a mix of donations from the Member States and EU funding support, accompanied by possible assistance to the region in the deployment of the vaccine.

## **OUTLINE OF IPA II ASSISTANCE**

The overall objective of the IPA II assistance is to mitigate the social and economic impact of COVID-19 in the Western Balkans, through providing early access of the region to reliable and effective - EU authorised - vaccines for the vaccination of priority groups (primarily medical staff, and elderly groups, primarily with pre-existing conditions and other high risk and vulnerable groups).

Under most of the EU Advance Purchase Agreements with vaccine producers, the EU Member States (as well as European Economic Area (EEA) countries and Switzerland to whom the doses will be resold) have the option of donating or reselling part of their allocation to third countries subject to certain conditions, including the agreement of the manufacturers. The IPA II financing will be used to provide grants to the Western Balkans - according to their population size or based on identified needs - to cover the amount paid by the Western Balkans partners for the vaccines but not more than the purchase price negotiated by the EU in the Advance Purchase Agreements to purchase the vaccines doses that will be made available to Western Balkans partners.

A part of the assistance (maximum 15%) may also be used for the purchase of equipment, medical devices, material and consumables necessary for the delivery of the vaccines.

## **RELEVANCE WITH THE IPA II MULTI-COUNTRY INDICATIVE STRATEGY PAPER AND OTHER KEY REFERENCES**

Enhancing access to affordable, sustainable and high quality services, such as health care is among the thematic priorities set out in Annex II – thematic priorities for assistance of the IPA II Regulation (EU) No 231/2014<sup>1</sup>.

The Multi-country Indicative Strategy Paper 2014-20 (MCISP)<sup>2</sup> indicates that as regards promoting competitiveness and growth a priority for support includes “ *Investing in education, employment and social policies, to increase access to education and training systems, improve their quality and relevance, activate people on the labour markets, align and improve the skills base to meet labour market needs, promote gender equality, the rights of the child, and foster social inclusion as well as **investing in health** – across these areas, a special focus is required to reach the most marginalised groups including Roma*”.

The Zagreb Declaration, adopted on 6 May 2020, indicates that: “*Once we exit the immediate measures to contain the COVID-19 pandemic, a new phase of close cooperation to tackle the significant socio-economic impact of the crisis will follow....The focus should also be put on social development, and in particular on measures in the areas of **health**, education, social policy, and creating further opportunities for the youth.*”

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<sup>1</sup> Regulation (EU) No 231/2014 of the European Parliament and of the Council of 11 March 2014 establishing an Instrument for Pre-accession Assistance (OJ L 77, 15.03.2014, p. 11).

<sup>2</sup> C(2014) 4293 final: Commission Implementing Decision of 30.6.2014 adopting a Multi-country Indicative Strategy Paper for the period 2014-2020

The Economic and Investment Plan for the Western Balkans<sup>3</sup> stress the need for **health systems reform**, strengthened health insurance and support to the **resilience of public health systems**. *“There is a need to reduce costs and ensure all citizens have access to better treatment. Regional cooperation needs to be reinforced to tackle cross-border threats to health security. Continued support to strengthen the Western Balkans public health systems preparedness and resilience will therefore be ensured.”*

The EU global response to the COVID-19 pandemic is spelled out in the Joint Communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the Global EU response to COVID-19<sup>4</sup>, and foresees support to the health sector.

## LESSONS LEARNED AND LINK TO PREVIOUS FINANCIAL ASSISTANCE

The European Centre for Disease Prevention and Control (ECDC) has been developing its cooperation with the Western Balkans and Turkey since 2008, gradually involving their representatives in its work, financed by funding agreements with the European Commission. Since 2008, ECDC has implemented five IPA funded projects for this purpose. Currently two contribution agreements are being implemented for beneficiaries from the Western Balkans<sup>5</sup>. As a result of the gradual involvement of representatives from Western Balkans and Turkey in the work of ECDC, when the COVID-19 pandemic broke out, IPA II beneficiaries were able to benefit from the guidance and advice of the Centre.

Support to the health sector in the Western Balkans has been stepped in the wake of the COVID-19 pandemic. The EUR 3.3 billion COVID-19 response for the Western Balkans developed at the beginning of the pandemic included reallocations from IPA II of EUR 38 million of immediate support for the health sector, in particular through delivering essential supplies such as personal protective equipment, tests and ventilators. Most of this assistance has been delivered. The key problem encountered in the delivery of this type of assistance was the scarcity of supply of certain types of medical equipment (e.g. Personal Protection Equipment, ventilators). Therefore ensuring a secure supply chain is essential for timely delivery of the assistance. This is being done through negotiations with Member States that will share their allocations with the Western Balkans.

In order to improve resilience of the health system, support will also be provided as part of the COVID-19 response to enable the World Health Organisation (WHO) to provide support to the Western Balkans. In line with the WHO European Region Resolution EUR/RC68/R7 and its Action Plan to Improve Public Health Preparedness and Response, WHO/Europe led work in the development of health security capacity in the region across three pillars. These are to build, strengthen and maintain core capacities in line with the core requirement set in the International Health Regulation (IHR) (2005); strengthen event management and compliance with the IHR requirements; and measure progress and promote accountability. The new programme will develop these elements as well as support the Western Balkans in the development of their vaccination strategies and plans.

The EU support to the Western Balkans to handle the COVID-19 pandemic represents – together with the substantial assistance to health services and recovery - an unprecedented opportunity for economic development and job creation in the region, based on the EU criteria and values. The envisaged assistance will be effectively explained and strategically communicated across the region, using the most advanced communication practices including the Team Europe approach.

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<sup>3</sup> COM (2020) 641 final of 6.10.2020 Commission Communication on An Economic and Investment Plan for the Western Balkans

<sup>4</sup> JOIN(2020) 11 final of 8.4 2020. Joint Communication to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on the Global EU response to COVID-19

<sup>5</sup> ECDC-IPA6/2019/409-781 “Preparatory measures for the participation of the Western Balkans and Turkey in the European Centre for Disease Prevention and Control with special focus on One-Health against AMR, 2020 — 2022” and ENI-2020-415-420 EU Initiative on Health Security starting 1 April 2020 until 2024

## 2. INTERVENTION LOGIC

### LOGICAL FRAMEWORK MATRIX

OVERALL OBJECTIVE(S) / (IMPACT(S))	OBJECTIVELY VERIFIABLE INDICATORS Quantitative and/or qualitative variables providing a simple and reliable mean to measure the achievement of the corresponding expected result (i.e. outputs, outcomes, impacts). Indicators should have a clear measurement unit and be formulated in a neutral way.	BASELINES (INCL. VALUE & REFERENCE YEAR <sup>6</sup> )	TARGETS (INCL. VALUE & REFERENCE YEAR)	SOURCES & MEANS OF VERIFICATION	
SPECIFIC OBJECTIVE(S) / OUTCOME(S)	OBJECTIVELY VERIFIABLE INDICATORS (*)	BASELINES	TARGETS	SOURCES OF VERIFICATION	ASSUMPTIONS
To mitigate the social and economic impact of COVID-19 in the Western Balkans	UN Human Development Index (HDI)	0 (2020)	TBC	WHO and country reporting on COVID cases	
<b>Specific Objective 1:</b> To ensure that vaccines purchased through the EU-funded intervention are administered in Western Balkans, especially to identified priority groups (e.g. healthcare workers, elderly, vulnerable and high-risk people).	Number of COVID-19 vaccines administered (disaggregated by Western Balkans partner, priority group targeted, sex)	0 (2020)	Depending on price of vaccine available there are two scenarios: 1) vaccination of medical and care staff as well as people over 79 years of age; 2) vaccination of medical and care staff as well as people over 70 years of age.	WHO reports Grant beneficiaries reports	Logistical and supply chain barriers addressed Partner governments are fully supportive and take full responsibility and act to ensure deployment of delivered vaccines Target population accepts to be vaccinated
OUTPUTS	OBJECTIVELY VERIFIABLE INDICATORS (*)	BASELINES	TARGETS	SOURCES OF VERIFICATION	ASSUMPTIONS
<b>Output 1:</b> COVID-19 vaccines are procured for Western Balkans	Number of COVID-19 vaccine doses procured per Western Balkans partner	0 (2020)	TBC	Grant beneficiaries reports	Effective and safe vaccines are available on the market in a timely manner and in the appropriate quantity
<b>Output 2:</b> Provision of equipment, medical devices, material and consumables necessary for the delivery of the vaccines	Number of units of equipment, medical devices, material and consumables necessary for the delivery of the vaccines				EU Member States are willing to sell COVID-19 doses to the Western Balkans

<sup>6</sup> Targets are indicative as dependent on which vaccine EU Members States would be ready to sell to the Western Balkans and its price. These two important variables are not yet known.

## **DESCRIPTION OF ACTIVITIES**

The action consists in the delivery of COVID-19 vaccines to the Western Balkans to be made available at the same as the EU Member States in early 2021.

Under most of the EU Advance Purchase Agreements with vaccine producers, the EU Member States have the option of donating or reselling part of their allocation to third countries, subject to certain conditions, including the agreement of the manufactures. The IPA II financing will be used to provide grants to the Western Balkans according to their population size to cover the amount paid by the Western Balkans partners for the vaccines but not more than the purchase price paid by the Member States to purchase the vaccines doses that they will make available to Western Balkans partners.

Vaccines purchased through the EU-funded intervention will be administered especially to identified priority groups (e.g. healthcare workers, elderly, vulnerable and high-risk people) identified in the vaccination strategies of the Beneficiaries. Up to 15% may also be used for the purchase of equipment, medical devices, material and consumables necessary for the delivery of the COVID-19 vaccines.

The delivery of COVID-19 vaccines to the priority groups is a matter of urgency, therefore a number of preparatory actions will have to take place by the time the grant agreements are signed (see Conditions for Implementation section below). The actions under the projects will then be implemented in two stages as follows:

### **Preparatory phase – by 20 February 2021:**

- (1) Emergency procurement of any missing equipment/supplies for the vaccination campaign by the Western Balkans partners
- (2) Signature of the resale/donation agreements with the Member States and the producers
- (3) Delivery of the first batches of vaccines under the agreements
- (4) Launch of the vaccination campaign

### **Vaccination phase: 20 February – 31 May 2021:**

- (5) Implementation of the vaccination campaign based on two doses, registration and monitoring as required by regulators
- (6) Completion of the vaccination campaign (based on a two-dose schedule) for the targeted priority groups and possible extension to other groups.

The delivery of the vaccines via the EU Member States allocation under the EU Advance Purchase Agreements with producers will be possible under three financial arrangements:

- (a) Donation by the Member State of a part of their allocated doses to the Western Balkans.
- (b) Resale by the Member State of a part of their allocation of doses and its reimbursement to the Western Balkans through the EU grant financed from IPA II under the present action.
- (c) Resale by the Member State of a part of their allocation of doses without reimbursement (e.g. where the grant would not cover the required number of doses for a specific priority group.

The total available funds under this IPA II action (EUR 70 million) would be allocated to the Western Balkans according to the size of their population (rounded) according to Eurostat data or according to identified needs.

The key target groups are expected to be medical and social care staff plus senior citizens (65+ or a specific subgroup thereof). In terms of the size of these priority groups, the Western Balkans have an estimated 250,000 medical and care workers, which would translate into 500,000 vaccine doses based on a two-dose schedule. The estimated population over 65 years of age is 3,450,000, which would require the procurement of 6,900,000 doses. The population of people of 70 years of age and over is about 2,150,000 (4,300,000 doses needed) while the population of people over 79 years of age is about 950,000, (1,900,000 doses needed).

There are two vaccines, which are likely to be available under the Advance Purchase Agreements as of January 2021. Depending on which of these vaccines would be made available by each of the Member States that wish to participate in this scheme, funding under action could be sufficient 1) to cover medical and care staff as well as people over 79 years of age in one case and 2) medical and care staff as well as people over 70 years of age, in the other. As other vaccines are likely to become available in the meantime, these combinations may further change. Therefore these figures are indicative as definite prices are also not yet available.

## **RISKS**

This action takes place in the unprecedented circumstances of a global emergency. The key risks include:

- (a) **Lack of Member States' willing to engage with this scheme** – while this risk would have a critical impact on the whole operation, this risk is unlikely to materialise, based on informal discussions with Member States, as a number of them are interested in participating in the scheme.
- (b) **Actual price of authorised vaccines is higher than anticipated** – the number of vaccine doses that will be financed will ultimately depend on the unit price, which varies significantly (and is not officially known due to commercial secret); the choice of the vaccines in the first months of 2021 is very limited and achieving the objective will require using any option under which an allocation is still available, which may be the more expensive one; a very high price may, however, affect reaching the target in terms of population vaccinated, a lower price may enable more vaccinations.
- (c) **Wastage of vaccine doses as a result of lack of capacities of the Western Balkans to handle and deliver them** – this risk will be mitigated by development by the Beneficiaries of vaccination plans, identifying the technical gaps and procurement needs; the grants will also allow for use of a small part of the funding for the procurement of medical equipment.
- (d) **Liability issues related to side effects or malfunctions of the vaccine** – while this risk is usually transferred on the producer, in this case, because of the urgency of the development of the vaccines, part of the liability will lie with the country purchasing the vaccines. The liability clauses will be clearly spelled out in the agreements with the producers and the Member States.
- (e) **Lack of market authorisation of the vaccines by the relevant authorities in the Western Balkans partners** – the vaccines available under the Advance Purchase Agreements will have the EU market authorisation granted by the European Medicines Agency (EMA), which has no jurisdiction over non-EU countries. Therefore, the Western Balkans will need to carry out an express authorisation process based on the EMA assessment. Any delays will cause delays in the delivery of the vaccines to the target groups.

## **CONDITIONS FOR IMPLEMENTATION**

The following actions will have to take place in parallel in order to implement the action:

(1) preparation of vaccination plans, including effective information campaigns to the public, by the relevant authorities of each of the Western Balkans partners to the extent possible aligned with the methodology recommended by the European Commission to the Member States; as a minimum, the plans will have to include the identification and size of the priority groups, as well as a self-assessment of the fulfilment of technical conditions for the delivery of the vaccines, in particular the ultra-cold and cold chain availability.

(2) identification of Member State(s) willing to provide the required doses and negotiation of agreements between each of the Western Balkans, the Member State involved and the manufacturer of the vaccine offered.

(3) identification of gaps in terms of equipment or medical consumables needs that will have to be procured for a successful vaccination campaign.

These actions will have to be carried out in parallel with the adoption of the financing decision and preparation of the grant agreements.

## **3. IMPLEMENTATION ARRANGEMENTS**

### **ROLES AND RESPONSIBILITIES**

The implementation of the action will require close coordination between several stakeholders, in particular:

- The EU Member States (Ministers of Health) participating in the donation/resale scheme will have to come forward and identify the number of doses that they wish to donate or resell and engage in negotiating an agreement with the manufacturer and the Western Balkans partner; the EU Vaccine Steering Board, made up of the European Commission and the Member States, established under the EU Vaccine Strategy will be involved in the donation/resale discussions;
- The vaccine producers will be party to these agreements and will be responsible for delivering the vaccines and any other items as stipulated in the agreements between the EU Member States and the Western Balkans partners;
- The relevant Western Balkans Ministries will be responsible for preparing a vaccine plan, including effective information campaigns to the public, identifying critical equipment gaps, procuring the missing equipment and entering into agreements with the Member States and the vaccine producers. They will also be responsible for the implementation of the vaccination plan for the priority groups;
- The European Commission will sign grant contracts with relevant ministries of the Western Balkans partners and will monitor the overall implementation of these grants contracts.

### **METHOD(S) OF IMPLEMENTATION AND TYPE(S) OF FINANCING (SEE ANNEX IMPLEMENTATION – BUDGET)**

This action will be implemented in direct management through award of grants without a call for proposals to the following line ministries having the overall responsibility for COVID-19 vaccination campaigns:

- The Ministry of Health and Social Protection in Albania;
- The Ministry of Civil Affairs in Bosnia and Herzegovina;
- The Ministry of Health in Kosovo;
- The Ministry of Health in Montenegro;
- The Ministry of Health in North Macedonia;
- The Ministry of Health in Serbia.

## **4. PERFORMANCE MEASUREMENT**

### **METHODOLOGY FOR MONITORING (AND EVALUATION)**

The European Commission may carry out a mid-term, a final or an ex-post evaluation for this action or its components via independent consultants, through a joint mission or via an implementing partner.

In case a mid-term or final evaluation is not foreseen, the European Commission may, during implementation, decide to undertake such an evaluation for duly justified reasons either on its own decision or on the initiative of the partner. Where an evaluation is to be contracted by the European Commission: The European Commission shall inform the implementing partner in advance of the dates foreseen for the evaluation missions. The implementing partner shall collaborate efficiently and effectively with the evaluation experts, and inter alia provide them with all necessary information and documentation, as well as access to the project premises and activities.

The evaluation reports shall be shared with the Western Balkans partners and other key stakeholders. The implementing partner and the European Commission shall analyse the conclusions and recommendations of the evaluations and, where appropriate, in agreement with the Western Balkans partners, jointly decide on the follow-up actions to be taken and any adjustments necessary, including, if indicated, the reorientation of the action.

The evaluations should be carried out following the Directorate-General for Neighbourhood and Enlargement Negotiations guidelines on linking planning/programming, monitoring and evaluation. It is recommended that a Reference Group comprising the key stakeholders of this action be set up to steer the evaluation process and ensure the required quality level of the evaluation outputs as well as the proper follow-up of the recommendations of the evaluation.

IPA II monitoring process is to be organised and led by the EU Delegations. The monitoring process is aimed to improve programming, implementation and sustainability as well as timely identification, remedying and alleviation of potential issues in the process of programming and implementation of the interventions.

In addition, the action might be subject to external monitoring in line with the European Commission rules and procedures.

## **5. CROSS-CUTTING ISSUES**

### **GENDER MAINSTREAMING**

The action will address gender considerations directly. Gender is an important factor influencing demand, access and use of health services including immunisation services. Likewise, women are a significant majority among first line healthcare workers that are involved in the fight against COVID-19 pandemic. As such, they will be the first to profit from the vaccination once available, which will both protect them personally from getting sick and allow to continue with their duties to care about other patients. Outreach and social mobilisation of both women and men could lead to higher rates of immunisation.

## **EQUAL OPPORTUNITIES**

Human health is a fundamental value and an investment in economic growth and social cohesion. Healthy individuals are more likely to be employed and less likely to be socially excluded. A healthy workforce is more productive, and healthcare services and health industries (pharmaceuticals, medical devices, and health research) are an important knowledge-intensive economic sector that enables people to maintain and improve their health and creates a steady demand for workers. Finally, COVID-19 represents an opportunity to build new and better, more resilient health systems.

## **MINORITIES AND VULNERABLE GROUPS**

Vaccines purchased through the EU-funded intervention will be administered especially to identified priority groups (e.g. healthcare workers, elderly, vulnerable and high-risk people).

Climate action relevant budget allocation: EUR 0
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## **6. SUSTAINABILITY**

The COVID-19 pandemic, in addition to its immediate human health and life impact, is having a disruptive effect on the economies of the Western Balkans and on people's livelihoods. It represents an unprecedented burden on their health and social protection systems, as well as a severe setback to their economies. A vaccine will be key to the resolution of the COVID-19 crisis.

Sustainability of the action is affected by the unknown regarding the COVID-19. It is the first time that mass scale vaccination will be done with vaccines developed in a very short time. The action will only provide support for the vaccination of part of the population. In order to fully address the impact of the COVID-19 pandemic, a higher share of the population will have to be vaccinated through other means.

## **7. COMMUNICATION AND VISIBILITY**

Communication and visibility will be given high importance during the implementation of the action. The implementation of the communication activities shall be funded from the amounts allocated to the action. The envisaged assistance will be effectively explained and strategically communicated across the region, using the most advanced communication practices including the Team Europe approach.

All necessary measures will be taken to publicise the fact that the action has received funding from the EU. Communication and visibility activities shall be implemented in accordance with the EU communication and visibility requirements in force. All stakeholders and implementing partners shall ensure the visibility of EU financial assistance provided through IPA II throughout all phases of the programme cycle.

Visibility and communication actions shall demonstrate how the intervention contributes to the agreed programme objectives and the accession process, as well as the benefits of the action for the general public. Actions shall be aimed at strengthening general public awareness and support of interventions financed and the objectives pursued. The actions shall aim at highlighting to the relevant target audiences the added value and impact of the EU's interventions and will promote transparency and accountability on the use of funds.

Visibility and communication aspects shall be complementary to the activities implemented by the Directorate-General for Neighbourhood and Enlargement Negotiations and the EU Delegations/Office in the field.

It is the responsibility of the implementing partners to keep the EU Delegations/Office and the European Commission fully informed of the planning and implementation of the specific visibility and communication activities. The Commission, and where applicable, the relevant EU Delegation(s) will be consulted in advance on the planned communication activities around key milestones as well as on country-specific EU visibility and communication activities before work starts, in order to ensure greater outreach and impact.

The implementing partners shall provide any information requested by the concerned Delegations as input to their own communication activities, including by giving full access to relevant audio, photo and video material. The implementing partners shall coordinate communication activities with regional and bilateral communication initiatives funded by the European Union, to the extent possible. To enhance the effectiveness of communication activities, the implementing partners shall nominate contacts points responsible for communication. Monitoring and reporting of the activities will be provided on a regular basis.

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