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COMMISSION IMPLEMENTING DECISION

of 19.10.2023

**on the financing of the Special measure to enhance manufacturing capacities and access
to vaccines, medicines and health technologies in Africa for 2023**

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THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012¹, and in particular Article 110 thereof,

Having regard to Regulation (EU) 2021/947 of the European Parliament and of the Council of 9 June 2021 establishing the Neighbourhood, Development and International Cooperation Instrument – Global Europe, amending and repealing Decision No 466/2014/EU and repealing Regulation (EU) 2017/1601 and Council Regulation (EC, Euratom) No 480/2009², and in particular Article 23(4) thereof,

Whereas:

- (1) In order to ensure the implementation of the Special measure to enhance manufacturing capacities and access to vaccines, medicines and health technologies in Africa for 2023, it is necessary to adopt an annual financing decision, which constitutes the annual work programme, for 2023. Article 110 of Regulation (EU, Euratom) 2018/1046 ('the Financial Regulation') establishes detailed rules on financing decisions.
- (2) The envisaged assistance is to comply with the conditions and procedures set out by the restrictive measures adopted pursuant to Article 215 TFEU³.
- (3) This special measure contributes to the implementation of the Global Gateway strategy⁴ and the EU Global Health Strategy⁵, aiming to strengthen strategic autonomy to produce health products in Africa that has emerged as priority during the COVID-19 pandemic. The Commission has made available funding from the NDICI - Global Europe geographic programme 'Sub-Saharan Africa' to support the Team Europe Initiative on manufacturing and access to vaccines, medicines and health technologies (TEI MAV+) (Commission Decisions C(2021)9814 and C(2022)9783) in addition to funding mobilised by European Financing Institutions and the EU Member States.

¹ OJ L 193, 30.7.2018, p.1.

² OJ L 209, 14.6.2021, p.1.

³ www.sanctionsmap.eu. Note that the sanctions map is an IT tool for identifying the sanctions regimes. The source of the sanctions stems from legal acts published in the Official Journal (OJ). In case of discrepancy, the OJ prevails.

⁴ https://commission.europa.eu/strategy-and-policy/priorities-2019-2024/stronger-europe-world/global-gateway_en

⁵ https://ec.europa.eu/commission/presscorner/detail/en/statement_22_3128

However, further funding is needed across several countries to deliver transformational impact and ensure long-term sustainability which requires the adoption of this special measure. To this end, EUR 134 000 000 from the emergency challenges and priorities cushion laid down in Article 17 of the NDICI – Global Europe is mobilised to reinforce the three Sub-Saharan Africa regional budget lines (West Africa, East and Central Africa, and Southern Africa and Indian Ocean) and the Southern Neighbourhood budget line. The objectives pursued by the special measure should support the advancement of country level interventions in Africa deemed critical for reinforcing local manufacturing capacities and creating an improved access to health products in Africa and are aligned with those of the annual measure to be financed under ‘Sub-Saharan Africa’ and ‘Neighbourhood’ geographic programmes of the Regulation (EU) 2021/947. The TEI MAV+ complements a range of other health related interventions supported at national, regional and global level by the Commission that relate to health systems strengthening and advancing universal health coverage.

- (4) The action entitled “Special measure to enhance manufacturing capacities and access to vaccines, medicines and health technologies in Africa for 2023” will support the development of an enabling environment for pharmaceutical products and health technologies in Senegal, Rwanda, Ghana, South Africa, Nigeria and Egypt, with a primary focus on responding to the concrete needs identified at country level, notably skills development through higher education and vocational training, research and innovation, support to the regulatory authority, business development, digitalisation, supply chains, technology transfers, and ensuring demand for locally produced goods complementing continental and regional level actions. It will also reinforce the dialogue established between EU, Member States and/or European financing institutions in a Team Europe approach and these beneficiary countries’ Governments on this matter.
- (5) Countries benefiting from this action are either considered being front-runners of the TEI MAV+ or have demonstrated that production of vaccines, essential medicines and health technologies is their national priority, with strong commitment to consolidate national pharmaceutical industries and have concrete national plans to implement policy priorities.
- (6) This action relates to the priority area of Public Health of the African Union-European Union Innovation Agenda and will contribute to its implementation. The AU-EU Innovation Agenda, adopted by the African Union and the European Union in July 2023, as one of the flagship initiatives of the Global Gateway, aims to transform and increase the innovative capacities and achievements of European and African researchers and innovators into tangible outputs, such as products, services, businesses and jobs.
- (7) It is appropriate to authorise the award of grants without a call for proposals and to provide for the conditions for awarding those grants.
- (8) Pursuant to Article 26 (1) of the NDICI - Global Europe Regulation (EU 2021/947) indirect management is to be used of the implementation of the action.
- (9) The Commission is to ensure a level of protection of the financial interests of the Union with regards to entities and persons entrusted with the implementation of Union funds by indirect management as provided for in Article 154(3) of the Financial Regulation. To this end, such entities and persons are to be subject to an assessment of their system and procedures in accordance with Article 154(4) of the Financial

Regulation⁶ and, if necessary, to appropriate supervisory measures in accordance with article 154(4) thereof before a contribution agreement can be signed.

- (10) It is necessary to allow for the payment of interest due for late payment on the basis of Article 116(5) of the Financial Regulation.
- (11) In order to allow for flexibility in the implementation of the measure, it is appropriate to determine the changes which should not be considered substantial for the purposes of Article 110(5) of the Financial Regulation.
- (12) The measure provided for in this Decision is in accordance with the opinion of the NDICI - Global Europe Committee established under Article 45 of Regulation (EU) 2021/947,

HAS DECIDED AS FOLLOWS:

Article 1 *The measure*

The annual financing decision, constituting the measure for the implementation of the Special measure to enhance manufacturing capacities and access to vaccines, medicines and health technologies in Africa for 2023, as set out in the Annex, is adopted.

The measure shall include the following Action:

“Special measure to enhance manufacturing capacities and access to vaccines, medicines and health technologies in Africa for 2023” set out in Annex.

Article 2 *Union contribution*

The maximum Union contribution for the implementation of the measure for 2023 is set at EUR 134 000 000, and shall be financed from the appropriations entered in the following line of the general budget of the Union:

- (a) budget line: 14.020110: EUR 3 000 000;
- (b) budget line: 14.020120: EUR 75 000 000;
- (c) budget line: 14.020121: EUR 40 000 000;
- (d) budget line: 14.020122: EUR 16 000 000.

The appropriations provided for in the first paragraph may also cover interest due for late payment.

Article 3 *Methods of implementation and entrusted entities or persons*

The implementation of the actions carried out by way of indirect management, as set out in the Annex, may be entrusted to the entities or persons referred to or selected in accordance with the criteria laid down in point 4.3.3 of the Annex.

⁶ Except for the cases referred to in Article 154(6) of the Financial Regulation, where the Commission may decide not to require the assessment.

Article 4
Flexibility clause

Increases or decreases of up to EUR 10 000 000 not exceeding 20% of the contribution set in the first paragraph of Article 2, or cumulated changes to the allocations of specific actions not exceeding 20% of that contribution as well as extensions of the implementation period shall not be considered substantial for the purposes of Article 110(5) of the Financial Regulation provided that these changes do not significantly affect the nature and objectives of the actions.

The authorising officer responsible may apply the changes referred to in the first paragraph. Those changes shall be applied in accordance with the principles of sound financial management and proportionality.

Article 5
Grants

Grants may be awarded without a call for proposals in accordance with the conditions set out in the Annex. Grants may be awarded to the bodies referred to in the Annex, selected in accordance with point 4.3.1 of the Annex.

Article 6
Financial instruments

The provision of financial support by means of the Africa investment Platform⁷, that is already established, for the amount set in the Annex, may be entrusted to the entities referred to or selected in accordance with the criteria laid down in point 4.3.4 of the Annex.

Done at Brussels, 19.10.2023

For the Commission
Jutta URPILAINEN
Member of the Commission

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[Regulation \(EU\) 2021/947 of the European Parliament and of the Council of 9 June 2021 establishing the Neighbourhood, Development and International Cooperation Instrument \(europa.eu\)](#)