



KINGDOM OF BELGIUM
Federal Public Service
**Foreign Affairs,
Foreign Trade and
Development Cooperation**

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your communication of	your reference	our reference	date
		D2.5/TR/DEV.04.06/2023/11257/1	

To be quoted in all correspondence

ORGANISATION – contribution to project “Support to regulatory harmonization and operationalization for the African Medicines Agency (AMA)”, - **BA 14.54.16.35.60.49– 2023 – engage 4,000,000 EUR – NN 4927**
BA54 16 35 60 49

Dear Mrs. Nardos Bekele-Thomas,

I have the pleasure to inform you that the Government of Belgium, through its Federal Public Service Foreign Affairs – Directorate-General for development Cooperation (DGD) has decided to make available to the African Union Development Agency – New Partnership for Africa’s Development (AUDA-NEPAD) a financial contribution of an amount of 4,000,000 EUR, for the project “Support to regulatory harmonization and operationalization for the African Medicines Agency (AMA)”.

This contribution is to be used under the Terms and Conditions as stated in the financial contribution agreement attached to this letter.

Please find enclosed a copy of the Royal Decree awarding 4,000,000 EUR to AUDA-NEPAD.

FINANCIAL CONTRIBUTION AGREEMENT

In execution of the decision taken by the Belgian Government, the following agreement is signed between:

The Donor: The Federal Government of Belgium, represented by the Minister of Development Cooperation, Rue des Petits Carmes 15, PO Box 1000 Brussels, Belgium

And

The Beneficiary: African Union Development Agency-New Partnership for Africa's Development (AUDA-NEPAD) (Support to the African Medicines Regulatory Harmonization (AMRH) programme]
Represented by Chief Executive Officer, Ms. Nardos Bekele-Thomas
230 15th Road Midrand, Johannesburg, South Africa

Article 1

1.1. The donor provides the beneficiary with a grant of four million 4,000,000 EUR for the project « support to regulatory harmonization and operationalization for the African Medicines Agency (AMA) ».

1.2. The project duration is 15 months. The present agreement shall come into force on the date of its signature by both Parties and shall expire as soon as all mutual obligations are fulfilled.

A no-cost extension or a change within the program can be allowed by the donor, provided that reasonable motivation is given and that the overall objective is maintained. The request and the approval will be produced via an exchange of letters. The letter and the answer will constitute an additional clause to this agreement.

1.3. The project consists of the following activities:

General objective: The overall goal of the project is to improve access to safe, efficacious and quality-assured medical products for responding to the priority health needs of the African continent. The goals of the continent include:

1. To improve the availability and quality of medical products by regulatory experts in Africa.
2. To strengthen regulatory systems for medical products at the continental, regional and national levels.
3. To facilitate harmonization and capacity building for the regulation of in-vitro diagnostics (IVDs).
4. To strengthen the capacity of the AUDA-NEPAD to facilitate regulatory harmonization and technical operationalization of the Africa Medicines Agency (AMA).

Specific objectives: The specific objectives of the project are captured in the following work-packages:



1. Regulatory Capacity Development, capacity build of (4) newly established Regional Centres of Regulatory Excellence (RCOREs) as platforms for advancing regulatory science on the continent.
2. Regulation of medical devices and in-vitro diagnostics, capacity strengthened of African Medical Devices Forum (AMDF), including having undertaken (2) continental joint assessments and operationalized (2) designated RCOREs for IVDs.
3. Strengthening the capacity of the AUDA-NEPAD to facilitate regulatory harmonization and technical operationalization of the Africa Medicines Agency (AMA), and advocate for AMA Treaty ratification in five countries.

Further information on the project is provided in the attached project proposal, detailed budget breakdown and result indicators, which form an integral part of this agreement.

Article 2

2.1. The grant shall be used within the limits of the following estimated budget: 4,000,000 EUR.

Article 3

3.1. The contribution will be transferred in 2 instalments to the following account:

Account Name: AUDA-NEPAD DONORS EURO
Account No: 7927364219
Currency: EUR
Branch Code: 198765
Swift Code: NEDSZAJJ

The first installment of 2,000,000 EUR will be paid after the receipt of the request for payment. The second installment of a maximum of 2,000,000 EUR will be paid after the receipt of narrative and financial reports covering the budget spent and proving that at least 70% of the previous installment has effectively been spent, a list of the costs and expenses already taken place, and the request for payment.

3.2. An **original statement of money owed on an organisation stationery with an official header duly dated and signed** must be produced by the beneficiary, with reference to this agreement and stating the bank details mentioned in article 3.1., which can be formulated as follows:

"STATEMENT OF MONEY OWED:

The undersigned Nardos Bekele-Thomas, who represents the African Union Development Agency-New Partnership for Africa's Development (AUDA-NEPAD), declares that the Belgian State owes the aforementioned association the amount of 4,000,000 EUR, as the subsidy granted for the implementation of the project support to regulatory harmonization and operationalization for the African Medicines Agency (AMA)". This amount can be paid into account:

Bank Name: **Nedbank Limited**
Account Name: **AUDA-NEPAD DONORS EURO**
Account No: **7927364219**
Currency: **EUR.**



Branch Code: **198765**
Swift Code: **NEDSZAJJ**

3.3. A final narrative and financial report (including expenditure of final installment) has to be produced by the beneficiary within 3 months after the end of the implementation of the granted project. Once approved by the donor, the project will be definitely closed.

Article 4

4.1. The financial report consists of a certified financial statement regarding the (un)spent balances, and a list of the costs and expenses already taken place. The donor is entitled to ask for additional elements.

4.2. The accounts and receipts and invoices will be kept available during at least seven years after the end of this project. Certified copies (on digital supports as CD-Rom or USB sticks) have to be delivered to the donor for control purposes.

4.3. During the period of this agreement, the beneficiary will allow representatives of the donor to verify and assess the implementation of the project including the accounts and original receipts and invoices at the beneficiary's office, provided that reasonable advance notice is given.

4.4. The donor can also undertake or ask the beneficiary to undertake an external evaluation and/or an external audit to assess the program.

Article 5

5.1. Unspent parts of the grant will be reported and must be reimbursed to the Belgian government on the account mentioned in the established entitlements.

Article 6

6.1. If there is any doubt about the interpretation of this agreement, the beneficiary will consult the donor. Each decision will be subject to an exchange of letters.

6.2. Legal conflicts regarding this agreement are subject to the jurisdiction of the Belgian Courts.

Article 7

7.1 The Donor and the beneficiary have a zero tolerance for inaction approach to tackling sexual exploitation and abuse ("SEA")¹ and sexual harassment (SH)². This means the beneficiary and its implementing partners will take all reasonable steps to prevent SEA or SH by both its employees and any implementing partner and respond appropriately when reports of SEA or SH arise, in accordance with their regulations, rules, policies and procedures.

7.2 The donor and the beneficiary agree that it is important to take all necessary precautions to avoid corrupt practices. To this end, the beneficiary shall maintain standards of conduct to govern the performance of its staff, including of corrupt practices in connection with the award and administration of contracts, grants, or other benefits, in accordance with their regulations, rules, policies and procedures. Where appropriate and in line with its financial regulations, rules and procedures, the beneficiary will provide as soon as possible information and corrective measures to the Donor relating to any instances of credible allegation of fraud or corruption with regards to the contribution.



Article 8

8.1. All correspondence between the donor and the beneficiary will pass to the following donor agency directly.

The Directorate General for Development Cooperation & Humanitarian Aid – D2.5
Federal Public Service of Foreign Affairs, Foreign Trade and Development Cooperation
Rue des Petits Carmes 15
1000 Brussels
Belgium

Article 9

9.1. The visibility of Belgian development cooperation will be ensured through the inclusion on all written and audiovisual promotional documents (website, invitations, brochures, etc.) of the following indications, in proportion to the importance of the subsidy:

- 1° With the support of Belgian Development Cooperation - DGD, Federal Public Service Foreign Affairs, Foreign Trade and Development Cooperation" accompanied by the official logo and the website address of Belgian Development Cooperation;
- 2° In case of lack of space, the official logo of the Belgian Development Cooperation.

Article 10

10.1. The present Agreement will be put into application on the date of its official notification by the donor.

Done in duplicate on _____,

On behalf of the donor

On behalf of the beneficiary

Caroline Gennez,

Minister of Development Cooperation
and Major Cities Policy,

Nardos Bekele-Thomas

Chief Executive Officer

African Union Development Agency
(AUDA-NEPAD)

