

**ORGANISATION DE COORDINATION POUR LA LUTTE CONTRE LES ENDEMIES
EN AFRIQUE CENTRALE**

Secrétariat Exécutif

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**SUBREGIONAL PROGRAM FOR THE HARMONISATION OF NATIONAL
PHARMACEUTICAL POLICIES (HPPN) IN CENTRAL AFRICA (CEMAC)**

**4th CALL FOR EXPRESSIONS OF INTEREST (CEI) FOR THE JOINT
REGIONAL ASSESSMENT OF MEDICINES IN THE CEMAC REGION**

As part of the Harmonisation of National Pharmaceutical Policies (HPPN) process in Central Africa, the member states of the Central African Economic and Monetary Community (CEMAC)—Cameroon, Central African Republic, Congo, Gabon, Equatorial Guinea, and Chad, have agreed to conduct joint assessment of applications for Marketing Authorisation (MA) for medicines.

This program intends to improve the quality of drug registrations in the region while also promoting integrated pharmaceutical regulation.

This call for expressions of interest, published in accordance with the document "Framework for Joint Assessment in the CEMAC Region" available on the official OCEAC website (www.oceac.org), is addressed to any applicant wishing to submit an application for harmonised registration in the member states.

The assessments will be conducted in accordance with Regulation No. 5/13-UEAC-OCEAC-CM-SE-2, which establishes the harmonised framework for the approval procedures of medicinal products for human use within the CEMAC region. This Regulation is also available on the OCEAC website. The detailed evaluation procedure is attached to this call for proposals.

◆ Scope and Implications of the Joint assessment

Any application that receives a positive recommendation from the Expert Committee established under this program will be considered eligible for registration in the six Member States.

- The applicant must then contact the competent authorities of the relevant country or countries and pay the registration fees in accordance with national regulations.
- The application must be submitted to the National Pharmaceutical Regulatory Authority (ANRP) within ninety (90) days of the regional recommendation. After this period, the recommendation will be deemed void.

○ Eligibility criteria of medicinal products through

The pharmaceutical products eligible for this procedure are categorised as follows:

Category 1 :

- New chemical or biological entities (brand-name drugs);
- Complex generic products (i.e., products whose active ingredients, formulations, dosage forms, or routes of administration are complex, or drug-device combination products and liposomal formulations) and vaccines and other biological products such as biologics and biosimilars, including gene therapies and advanced gene therapies.

- **Biosimilars for chronic local conditions:** biosimilars for kidney disease (EPO) or diabetes (insulin analogs)
- **Complex generic drugs for sickle cell disease:** Hydroxyurea (pediatric formulation) and iron chelators (Deferasirox)
- **Vaccines against specific epidemics:** Yellow Fever, Monkeypox, or Cholera
- **Combined drug-device medical products:** Epinephrine auto-injectors or insulin pens adapted for humid tropical regions (heat and humidity resistance).

Category 2 :

- Medicines intended to treat priority diseases identified among African populations, such as noncommunicable diseases (NCDs), metabolic diseases, anticancer drugs, etc.
- **Neglected Tropical Diseases (NTDs):** Compounds targeting onchocerciasis, African human trypanosomiasis, Yaws, etc.
- **Oncology and Metabolic Diseases:** Essential anticancer drugs (pediatric protocols, cervical and breast cancer) and diabetes/hypertension treatments suitable for primary care
- **Critical Anti-infectives:** New therapeutic combinations for drug-resistant malaria and antibiotics on the WHO's "Watch" and "Reserve" lists (AWaRe).

Category 3: Narcotics and Psychotropic Substances.

- Molecules essential for palliative care and mental health

Note: Priority will be given to applications in which the applicant demonstrates that the product has not undergone a centralized evaluation by the EMP TC within the last 24 months, AND/OR applications requiring specific validation of Zone IV climate stability data, in accordance with the specific requirements of the CEMAC subregion.

◆ Submission Guidelines

The submission process is as follows:

- Preparation of the dossier in CTD format, in accordance with the aforementioned Regulation
- Submission of the dossier in a sealed envelope marked "CEMAC Joint Assessment Application" to the registration department of one of the ANRP/DPMs of the member states, no later than July 5, 2026
- The envelope must include an electronic version of the dossier on a USB drive
- Samples of products and reference substances must be submitted simultaneously, in accordance with the specifications of the regulation.

◆ Following the preliminary selection

The OCEAC Executive Secretariat will notify applicants of the acceptance or rejection of their applications no later than July 14, 2026, following a preliminary screening conducted by the Technical Secretariat responsible for joint reviews.

Shortlisted applicants will have fifteen (15) days to pay the non-refundable joint evaluation fees, to be deposited into the OCEAC bank account:

- Laboratories in the CEMAC/CEEAC region: **2.000.000 XAF / per application**
- Laboratories in other African countries: **3.500.000 XAF / per application**
- Laboratories outside Africa: **4.000.000 XAF / per application**

BANK : SOCIETE COMMERCIALE DE BANQUE CAMEROUN (SCB CAMEROUN)
ACCOUNT NAME : HPPN / REGLEMENTATION CEMAC
BANK CODE : 10002
TELLER CODE : 00069
ACCOUNT NUMBER : 90001728553
CLE RIB : 19
IBAN : CM2110002000699000172855319
B .I.C. : BCMACMCX

Note: As previously indicated, registration fees will be paid at the national level, in accordance with the regulations in effect in each member country.

◆ **Cases of Inadmissibility**

If the application is deemed ineligible, the applicant may submit a new application during a future call for expressions of interest.

For further information, please contact one of the following addresses:

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Done at Yaoundé, on 02 AVR 2026

The Chief Executive Officer (CEO)




Dr KHADIDJA GUIRSIMI YOUSOUF