ORGANISATION DE COORDINATION POUR LA LUTTE CONTRE LES ENDEMIES EN AFRIQUE CENTRALE
Secrétariat Exécutif
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SUB-REGIONAL PROGRAM FOR THE HARMONIZATION OF NATIONAL PHARMACEUTICAL POLICIES (HPPN) IN CENTRAL AFRICA (CEMAC)

CALL FOR EXPRESSIONS OF INTEREST (EOI) FOR THE SELECTION OF CANDIDATE FILES FOR THE JOINT EVALUATION OF MARKETING AUTHORIZATION (MA) APPLICATION FILES FOR MEDICINES IN THE CENTRAL AFRICA (CEMAC) REGION

As part of the Harmonization of National Pharmaceutical Policies (HPPN) in Central Africa (CEMAC), member states (Cameroon, Central African Republic, Congo, Gabon, Equatorial Guinea, Chad) have adopted the principle of organizing joint evaluations of Marketing Authorization (MA) application files to improve the quality of medicine registrations in the region.

This call, published in accordance with the document entitled "Framework for the joint evaluations of MA application files in the CEMAC region" available on the OCEAC website www.oceac.org, is addressed to any MA applicant who wishes to submit their file to the CEMAC joint evaluation procedure for registration purposes in the member countries.

The evaluation of candidate files for this call will be carried out in accordance with REGULATION No. 5/13-UEAC-OCEAC-CM-SE-2 Establishing the Reference Framework for the Harmonization of Human Medicine Registration Procedures in the CEMAC area, also available on the website www.oceac.org . The evaluation procedure is attached to this call.

A favorable evaluation of a candidate file by the expert committee for the joint evaluations of MA application files in the CEMAC region indicates that the said file is eligible for registration in the six (06) member countries of CEMAC. For this, the applicant will approach the country(ies) of their choice and proceed with the payment of registration fees to meet the administrative and legal requirements in accordance with the national regulations in force.

The submission of the registration file to the National Pharmaceutical Regulatory Authority must be made within ninety (90) days following the issuance of the regional recommendation, failing which the evaluation will be considered null and void.

The categories of medicines concerned by this call are as follows:

Category 1:

- New chemical or biological entities (innovative medicines), including Improved Traditional Medicines (ITM);
- Complex generic products (i.e., products with complex active ingredients, formulations, dosage forms, or routes of administration, or combined drug-device products and liposomal forms) and vaccines and other biological products such as biotherapeutic products and similar biotherapeutic products (biosimilars), including gene therapies and advanced gene therapies.

Vu le DAE

Category 2:

- Medicines intended to treat priority diseases identified within African populations, such as Non-Communicable Diseases (NCDs), Neglected Tropical Diseases (NTDs), and metabolic diseases.

HOW TO RESPOND TO THIS CALL FOR EXPRESSIONS OF INTEREST

The process for submitting a candidate file to this call is as follows:

1. The applicant will compile their candidate file, according to the CTD format contained in CEMAC Regulation No. 5/13-UEAC-OCEAC-CM-SE-2 Establishing the Reference Framework for the Harmonization of Human Medicine Registration Procedures in the CEMAC area previously indicated and available on the OCEAC website : www.oceac.org .
2. Applications must be submitted in a sealed envelope with the mention **"CEMAC Joint Evaluation Application"** to the registration service of one of the NRAs / DPMs of the CEMAC countries, no later **than March 15, 2025, at 14:30 GMT.**

NB: The envelope must also contain the electronic version of the candidate file on a USB key.

3. The samples of the products and reference substances must be submitted at the same time as the candidate file. Details on the sample size are recorded in CEMAC Regulation No. 5/13-UEAC-OCEAC-CM-SE-2 establishing the Reference Framework for the Harmonization of Human Medicine Registration Procedures in the CEMAC area, available on the website www.oceac.org .

After the pre-selection, a notification of acceptability or non-acceptability will be sent to the applicant, no later than **March 28, 2025,** by the technical secretariat in charge of joint reviews of MA applications in the CEMAC area.

The submitter of the pre-selected file will have a period of fifteen (15) days to pay the non-refundable joint evaluation fees into the OCEAC bank account, the details of which are indicated below:

BANK: SOCIETE COMMERCIALE DE BANQUE CAMEROUN (SCB CAMEROUN)

ACCOUNT NAME: HPPN / CEMAC REGULATION

BANK CODE: 10002

BRANCH CODE: 00069

ACCOUNT NUMBER: 90001728553

RIB KEY: 19

IBAN: CM2110002000699000172855319

BIC: BCMACMCX

Vu le DAF

The joint evaluation fees for pre-selected files are as follows:

- Pharmaceutical laboratories in the CEMAC / CEEAC area: 1,000,000 FCFA / file;
- Pharmaceutical laboratories from other African countries: 1,500,000 FCFA / file;
- Pharmaceutical laboratories outside Africa: 2,500,000 FCFA / file.

NB: As previously indicated, the payment of registration fees will be made at the national level, in accordance with the regulations in force.

If an applicant receives a notification of non-acceptability, they may resubmit another marketing authorization (MA) application file for pre-selection in a future call.

For any additional information, please contact one of the following addresses:

- **OCEAC:** Dr. Aimé DJITAFO FAH, contact@oceac.org / aime.djitafo@oceac.org
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- **Equatorial Guinea**: Don Gaspar ESONO, gasparesonomicha@yahoo.es
- **Chad:** Dr. ALKALI LAOKISSAM: alkalilaokissam@gmail.com

Done in Yaoundé, on 15 DEC 2024.

The Chief Executive Officer

ORGANISATION DE COORDINATION pour la Lutte Contre les Endémies en Afrique Centrale
Le Secrétaire Exécutif
O.C.E.A.C

Dr. KHADIDJA GUIRSIMI YOUSSOUF

Vu le DAE