AFRICLINIQUE
Capacity-Building Network for Research Regulatory Authorities in Central Africa

Organisation mondiale de la Santé

CANTAM
Central Africa Clinical Research Network

NEWS RELEASE

February 2021

ASSISTED SELF-ASSESSMENT OF THE NATIONAL REGULATORY AUTHORITY FROM THE REPUBLIC OF CONGO BY THE WORLD HEALTH ORGANIZATION

FEBRUARY 15-19, 2021

As part of the strengthening of health systems and in particular the regulation of drugs and health products, the headquarters of the World Health Organization (WHO), the WHO Regional Office for Africa (AFRO), and the WHO Country Office (PO) in the Republic of Congo provided technical assistance to support the Directorate of Pharmacy and Medicine (DPM) of Congo from February 15 to 19 2021 at « Le grand hôtel de Kintélé », in the north of Brazzaville.

The self-assessment of the Directorate of Pharmacy and Medicine (DPM) by the global benchmarking tool (GBT) of the NRAs was initiated at the regional workshop for the harmonization of drug regulation of the Economic and Monetary Community of Central Africa (CEMAC), in February 2020 in Libreville, Gabon. The GBT integrates the Maturity Level (ML) of the various drug regulatory functions in a computerized platform that facilitates its use and the ranking of maturity indicators. This self-assessment has enabled several countries in the sub-region to identify their ML as well as to put in place institutional development plans (IDPs) in order to access a ML which guarantees safety, quality and effectiveness of drugs in circulation

The self-assessment of Congo's DPM by the WHO Global Assessment Tool allowed to:

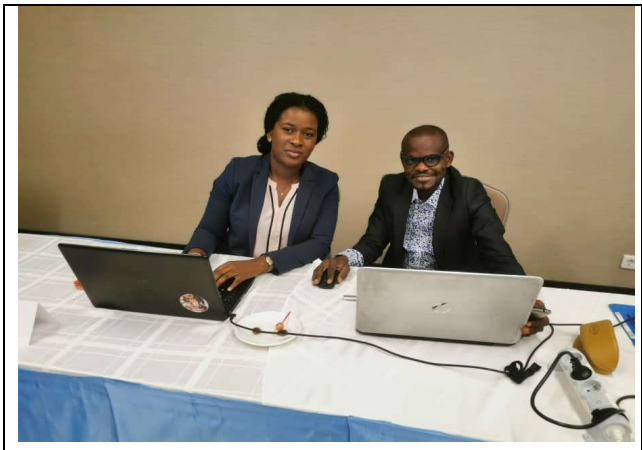
• Establish the current ML of the country's pharmaceutical regulation which is currently 1,

• Identify strengths and weaknesses,

• formulate an institutional development plan (IDP),

• formulate a roadmap leading to the formal assessment of the DPM to assess progress towards ML3.

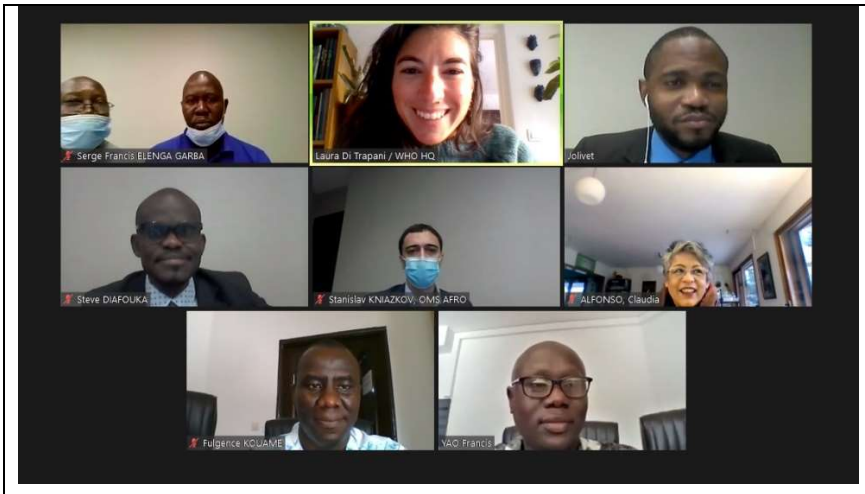
This action was led by WHO facilitator-DPM focal person peer for each of the eight functions assessed. Seven facilitators were mobilized by WHO (three on site in Brazzaville, two at headquarters in Geneva, and two others at the national regulatory agency of Côte-D'ivoire in Abidjan)



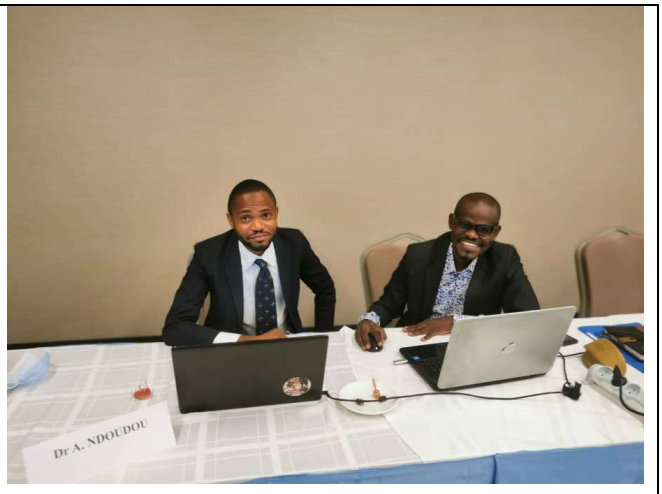
"Clinical trial supervision" evaluators

"Regulatory inspection" evaluators

As part of its interventions on capacity building for the regulation of clinical trials and pharmacovigilance for which it collaborates in particular with WHO and the Ministry of health of Congo, Fondation Congolaise pour la Recherche Médicale (FCRM) has provided to WHO, two facilitators, Mr. Jolivet MAYELA and Mr. Steve DIAFOUKA (both FCRM project managers) who respectively facilitated the "Vigilance" and "Supervision of clinical trials" functions.



WHO Facilitator Team



FCRM Representatives

This assessment revealed 207 recommendations as well as a roadmap to lead the Congo to maturity level3. The established institutional development plans will be integrated as soon as possible into the organizational plan of the DPM and communicated to the technical and financial partners.

It will allow the CANTAM and Africlinique projects coordinated by the FCRM to orient their actions to facilitate the achievement of the targeted objectives.

The Africlinique Congo team during the workshop

For further information:

Fondation Congolaise pour la Recherche Médicale: Villa D6, Cité OMS –Djoué – Brazzaville- République du Congo Tel : +242 06 997 79 80 www.cantam.org /www.africlinique.org

This project is part of the EDCTP2 programme supported by the European Union

EDCTP