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20, AVENUE APPIA - CH-1211 GENEVA 27 - SWITZERLAND - TEL CENTRAL +41 22 791 2111 - FAX CENTRAL +41 22 791 3111 - WWW.WHO.INT

Tel. direct: +41 22 791 2486 Professor Moji Christianah Adeyeye

Fax direct: +41 22 791 4856 Director General

E-mail:

National Agency for Food and Drug

Administration and Control (NAFDAC)

Plot 2032 Olusegun Obasanjo Way,

Wyse Zone 7

Wuse Zone 7

Abuja Nigeria

Your reference:

In reply please

refer to:

25 March 2022

Dear Professor Adeyeye,

I have the honour to inform you of the outcome of the World Health Organization (WHO) rebenchmarking of the national regulatory system of Nigeria, represented by the National Agency for Food and Drug Administration and Control (NAFDAC).

The WHO Regulatory Systems Strengthening (RSS) Team of the Regulation and Safety (REG) Unit in the Department of Regulation and Prequalification (RPQ), led a team of international experts to conduct the re-benchmarking of NAFDAC and other relevant regulatory institutions of Nigeria, in particular, the Pharmacists Council of Nigeria (PCN). The re-benchmarking was conducted in the area of regulation of medicines and vaccines (non-producing) from 21 to 25 February 2022 in close collaboration with the WHO Regional Office for Africa (AFRO) under the coordination of the WHO Country Office

The re-benchmarking is part of the WHO programme for regulatory system strengthening. This re-benchmarking was aimed to evaluate and document the status of NAFDAC in the area of regulation of medicines and imported vaccines .

WHO has previously conducted a formal benchmarking of NAFDAC from 17 to 21 June 2019 and an institutional development plan (IDP) follow-up virtual meeting from 5 to 9 July 2021 to follow-up on the outcome of the aforementioned benchmarking and the implementation status of the provided recommendations, as well as corrective and preventive actions.

In view of this, I have the pleasure to announce that the regulatory system of Nigeria has achieved maturity level three (ML3) effective **from 22 March 2022** following the implementation of all critical recommendations. The full benchmarking report is available at the following link: https://worldhealthorg.sharepoint.com/sites/ws-att/nra_nigeria/benchmarking_2019/SitePages/Benchmarking-2022.aspx

cc: The Registrar, Pharmacists Council of Nigeria, Abuja

This represents a significant milestone for Nigeria, as NAFDAC reached the level of a regulatory system operating as a stable, well-functioning and integrated system for regulation of medicines and imported vaccines. This achievement is the result of investment by the Government of Nigeria in the strengthening of the regulatory system for medical products and reaffirms the collaboration between WHO and the Government of Nigeria towards realizing the targets of universal health coverage and sustainable development goals.

I believe this achievement should serve to promote confidence, trust and further reliance on authorities attaining this level of maturity. It is expected that NAFDAC, PCN and the Government of Nigeria will sustain this achievement.

Please accept, Sir, the assurance of my highest consideration.

Dr Mariângela Simão Assistant Director-General

Access to Medicines and Health Products