Dear Stakeholders and international partners,

**January 2025 Mandatory Inclusion of Bioequivalence Data in Dossier Submissions for Drug Products that do not Qualify for Biowaivers**

It has been discussed and made public at different meetings of manufacturers that the inclusion of Bioequivalence data in Dossier submissions will be mandatory from January 2025.

Multisource pharmaceutical products (generic products) are required to conform to the same standards as those of the innovator products, as well as provide assurance of clinical interchangeability with the innovator products. Bioequivalence (BE) studies have been shown to be the most appropriate method of demonstrating interchangeability, and these requirements are expected to be met by any product submitted to the agency for marketing authorization approval.

Please recall that at several engagements with stakeholders, the importance of bioequivalence (BE) studies for multisource pharmaceuticals presented for registration has always been highlighted by the Agency. Therefore, in keeping with our resolve for continuous improvement and strengthening of the Agency's regulatory systems for market authorization, **submission of bioequivalence data in a dossier will become mandatory from January 2025.**

Stakeholders and our international partners are hereby implored to note and ensure strict compliance with this directive.

**Prof Mojisola Christianah Adeyeye PhD, FAS**
**Director-General**

**November 29, 2023**