QUALITY OF ACTIVE PHARMACEUTICAL INGREDIENTS (APIs) USED IN THE MANUFACTURE OF FINISHED PHARMACEUTICAL PRODUCTS (FPPs) FOR THE NIGERIAN MARKET

The quality of Active Pharmaceutical Ingredients (APIs) used in Finished Pharmaceutical Products (FPPs) manufacturing directly impacts the safety, efficacy, quality, regulatory compliance, consistency, supply chain, reputation, and cost-effectiveness of pharmaceutical products. Pharmaceutical companies and manufacturers must prioritize sourcing APIs from reputable suppliers while adhering to stringent quality control measures to ensure the highest standards in their products.

To this end, NAFDAC wishes to inform all stakeholders intending to submit dossiers for product registration starting from January 2024, that only applications supported by APIs or FPPs sourced from any of the underlisted approved sources will be accepted for review. These are:

1. WHO Prequalified APIs
2. APIs with certificates of suitability to the monographs of the European Pharmacopoeia (CEP)
3. APIs and FPPs sourced from facilities certified by PIC/S. participating Authorities.
4. APIs sourced from facilities certified by Stringent Regulatory Authorities (SRA) or WHO Listed Authorities (WLA)
5. APIs certified by accredited quality control laboratories.

Furthermore, all excipients to be used in the manufacture of finished pharmaceutical products must be of pharmacopoeia grade, and must be from an ISO-9001:2015 or EXCiPACT-certified facility.

Companies with registered FPPs who have not sourced their APIs or Excipients from any of the listed sources, must provide evidence by January 2027 of a change of source to another manufacturer that satisfies any of the provisions listed above. The evidence must be submitted to the agency as a variation or post-approval change before the last day of January 2027. This directive takes immediate effect. Please note that failure to comply will attract very stiff penalties. Thank you.

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