REPORT OF THE REGIONAL WORKSHOP ON ICH Q1 GUIDELINES WHICH WAS HELD ON 23RD – 26TH JULY, 2024 AT MARRIOTT HOTEL, IKEJA, LAGOS.

The workshop started with the opening speech by Professor Mojisola Adeyeye, Director General of NAFDAC, emphasising the importance of harmonising pharmaceutical stability guidelines across different jurisdictions. In her opening remarks, she stated that the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) was established in 1990 to harmonize scientific and technical aspects of pharmaceuticals and that ICH guidelines are applied globally by numerous regulatory authorities. In her remark, she opined the goal of the workshop is to ensure pharmaceutical products remain stable throughout their lifecycle, despite varying guidelines in different regions.

Professor Adeyeye stated further that she was introduced to ICH through late Mr. Lou Blecher, a founding industry member, highlighting the formation of the International Pharmaceutical Excipients Council (IPEC) to harmonise excipient standards.

In her remarks, she highlighted the role of NAFDAC in ICH, that:

i. NAFDAC holds an Observer status with ICH and aims for full membership.
ii. The Agency has integrated ICH guidelines into its regulatory processes and is participating in expert working groups on Stability Principles, Quality Risk Management, and Bioequivalence.

She concluded by urging active participation at the workshop noting the importance of achieving globally accepted harmonized standards to ensure the quality, safety, and efficacy of medicines.

SUMMARY OF PRESENTATIONS DURING THE WORKSHOP

1.0. Day 1 (23rd July 2024): Introduction to ICH and Overview of ICHQ1

The presentation provides a comprehensive overview of the importance of stability in pharmaceuticals, Stability Testing of New Drug Substances and Products Q1A(R2), Stability

Testing for New Dosage Forms, Evaluation of Stability Data, Bracketing and Matrixing Designs for Stability Testing of New Drug Substances and Products and Photostability Testing of New Drug Substances and Products.

It concludes with the benefits of harmonizing stability practices, such as streamlining regulatory processes, accelerating product access to patients, and reducing unnecessary testing.

The day's presentations included Mrs. Abisola Ayodele's introduction to Stability and Stability Testing for New Dosage Form. Dr. Arit Onwisah's presentation focused on Stability Testing of New Drug Substances and Products Q1A(R2) while Dr. Ken Miller's presentation emphasized the Evaluation of Stability Data. Dr. Ken Miller concluded the day by explaining the importance of Bracketing and Matrixing Designs for the Stability Testing of New Drug Substances and Products.

2.0 Day 2 (24th July 2024): Quality of Biotechnology Product: Stability Testing of Biotechnology/Biological Products (ICHQ5C)

The second day focused on the ICHQ5C guideline on the stability testing of biotechnological/biological products. It emphasises the unique stability considerations for biologics, compared to synthetic drugs, and outlines the necessary components of stability programs to ensure product quality and safety.

The Science and Risk-Based Approaches, Product Knowledge to Specification, and utilization of stability data to build production knowledge, inform primary and ongoing stability program design and set specifications formed the major discussion.

The day featured presentations on Stability Testing of Biotechnology/Biological Products and the introduction to ICH Q5C by Dr. Ken Miller. Dr. Joseph McCulloh's presentation focused on Science and Risk-Based Approaches – Product Knowledge to Specification while Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management (Relationship to Stability) with emphasis on ICH Q12 was presented by Mr. Roydon Mesquita. Also, Dr Jared Auclair presentation on the day highlighted WHO Technical Report Series 1010 Annex 10 and Dr. Ken Miller wrapped up the day with his presentation based on In-use Stability Study to ensure that product quality is maintained under normal conditions and intended period of use.

3.0 Day 3 (25th July 2024): Case Studies and Guided Discussions on Product through its Lifecycle and Interactive Questions

Day three began with Dr Jared Auclair's presentation on the Case Study and Guided Discussion on a Product through its Lifecycle and followed by Interactive Questions. His second presentation focused on the application of ICH Principles with Interactive Case Studies. Some of the Cases highlighted During the Interactive Session include:

- Process Scale & Site-Specific Stability
- New Product Submission with Reduced Stability Data – Tablets
- Drug Substance Process Change + New Drug Product Site

This interactive session encapsulates the essence of applying ICH principles in stability training through case studies, highlighting the importance of science and risk-based decisions focusing on patient benefits.

4.0 Conclusion

The workshop covers the importance of stability on drug substances (APIs) and drug products, light on product stability, and methods for testing excipients, and APIs.

It emphasizes the need to apply ICH guidelines for stability studies to ensure medicines remain safe, efficacious, and high-quality throughout their shelf life. This is because, stability impacts patient safety and the integrity of the drug product throughout its lifecycle, from manufacturing to distribution. The commitment of National Regulatory Authorities (NRAs), and pharmaceutical sectors to follow ICH guidelines will contribute to high-quality drug products throughout their lifecycle.

The workshop justified the importance of collaboration, adherence to best global practices, and continuous learning to ensure the safety and efficacy of medicines.

As Nigeria and Africa advance toward medicines security through the African Medicines Regulatory Harmonization Initiative (AMRH), the knowledge and expertise gained from this workshop will play a pivotal role in achieving Regional regulatory harmonization initiatives and networks.