DOCUMENT TITLE: SMPC REVIEW AND PUBLICATION		
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Strategic Plan for SmPC Review and Publication in Compliance with NAFDAC Template

This strategic plan outlines the process for reviewing existing Summary of Product Characteristics (SmPCs) for compliance with the NAFDAC SmPC template and ensuring consistent submission and timely publication of compliant SmPCs going forward. The purpose of the Strategic plan is to establish a robust and efficient system for SmPC management, ensuring public access to accurate and up-to-date product information. By this plan, the Agency also aims to review, standardize, and publish SmPCs for all registered medical products in Nigeria, adhering to NAFDAC guidelines and leveraging technology for efficient dissemination.

Current Status/Progress Made:

- An SmPC review team has been constituted, comprising members from Drug Registration & Regulatory Affairs and VBM Registration & Regulatory Affairs.
- Team members have received training on SmPC review.
- SmPC review has been removed from the SOP for Screening and Review of Dossiers, as recommended by the WHO Team.
- The SOP for Review and Publishing of SmPC on the NAFDAC Greenbook has been updated to include SmPC review.
- All Dossier Review Team members have been trained on the revised SOP.
- Hands-on training has been conducted for SmPC review team members.
- List of registered drugs and vaccine products published on the Greenbook without SmPC has been generated.
- Letters containing access link for upload of SmPC sent out to concerned Market Authorization Holders.
- Virtual meeting held with Indian manufacturers
- In-person meeting with local manufacturers
- Received SmPC have been, reviewed and Greenbook updated

Strategic Objectives:

1. **Review and update the Greenbook**: Ensure that all existing published drug products comply with the requirement for a published, compliant SmPC

2. **Establish a Standardized Submission Process:** Implement a mandatory SmPC template for all new product registrations.
3. **Integrate with NAPAMS v3 and Greenbook:** Enable seamless data transfer and automated publication.
4. **Ensure Ongoing Compliance:** Implement a system for monitoring and auditing SmPC compliance.

Strategic Actions:

Phase 1: Review and Update Greenbook (Target Completion: [Nov. 2024 – Jan. 2025])

- **Action 1.1:** Develop a list of registered drugs and vaccine products published on the Greenbook without SmPC.
- **Action 1.2:** Develop a process for communicating required changes to Marketing Authorization Holders (MAHs) and obtaining updated SmPCs.
- **Action 1.3:** Utilize the constituted SmPC review team to systematically review existing SmPCs against the NAFDAC template.
- **Action 1.4:** Establish a dedicated database/repository for storing reviewed and updated SmPCs.
- **Action 1.5:** Conduct regular progress reviews and report on the number of SmPCs reviewed, updated and published.
- **Action 1.6:** Integrate the online SmPC submission into the NAPAMS v3 platform.

Phase 2: Integrate with NAPAMS v3 and Greenbook (Target Completion: [December 2025])

- **Action 3.1:** Develop the necessary interfaces and data exchange protocols between NAPAMS v3 and the Greenbook platform.
- **Action 3.2:** Conduct thorough testing to ensure seamless data transfer and automated publication.
- **Action 3.3:** Implement automated publication of approved SmPCs on the Greenbook upon issuance of a certificate of registration.

Phase 4: Ensure Ongoing Compliance (Ongoing)

- **Action 4.1:** Establish a clear process for monitoring SmPC compliance, including regular audits of published SmPCs.
- **Action 4.2:** Develop a mechanism for addressing non-compliance, including communication with MAHs and potential regulatory action.

- **Action 4.3:** Regularly review and update the SmPC template and related guidelines to reflect evolving regulatory requirements and best practices.
- **Action 4.4:** Conduct periodic training for the SmPC review team and other relevant stakeholders.

Resources:

- Dedicated SmPC Review Team (Human Resources)
- NAPAMS v3 and Greenbook Platforms (IT Infrastructure)
- Budget for training, software development, and other related expenses.

Monitoring and Evaluation:

- Regular progress reports on SmPC review and publication.
- Key Performance Indicators (KPIs):
    - Number of SmPCs reviewed and updated.
    - Number of new product applications with compliant SmPCs.
    - Time taken for SmPC review and publication.
    - Number of non-compliance instances.
- Periodic audits of the SmPC management system.

Communication Plan:

- Regular communication with MAHs through workshops, emails, and other online resources.
- Public announcements on the NAFDAC website and other relevant channels.

This strategic plan provides a framework for improving SmPC management and ensuring public access to accurate and timely product information. By implementing these actions and monitoring progress, NAFDAC can strengthen its regulatory oversight and enhance public health.