

**THE NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION &
CONTROL (NAFDAC) MOBILE AUTHENTICATION SERVICE SCHEME**

**GUIDELINES FOR THE PROCUREMENT AND MANAGEMENT OF THE NAFDAC
MOBILE AUTHENTICATION SERVICE (MAS) SCHEME**

A. GENERAL:

These guidelines are for the interest of the public and in particular:

1. Person(s) or Group (s) requesting for information, Education and Communication (IEC) materials on the Mobile Authentication Service (MAS) Scheme.
2. Marketing Authorization Holders (MAHs) seeking to deploy MAS on their registered products.

B. REGULATED PRODUCTS COVERED IN THE MAS SCHEME

All NAFDAC regulated products are to be covered under the scheme, but phase-I covers anti-biotics, anti-infectives and anti-malarial pharmaceutical products (listed in Schedule-I of this guidelines)

C. APPROVED SERVICE PROVIDERS FOR THE MAS SCHEME

	<u>Service Provider</u>	<u>Shot Code</u>
1	PharmaSecure	38351
2	Sproxil	38353
3	Savanté	38120
4	UBQ-t/Kezzler	20966
5	M-Pedigree	1393

D. How to Implement the MAS for registered products

There are three possible scenarios for applicants seeking to obtain approval for implementation of the MAS on their regulated products:

1. Applicants seeking to Register New Products on Schedule-I:

An applicant can contact any service provider of their choice ONLY after they have obtained notification from the Agency communicating that the products has been approved for registration. The service provider is to

verify from the Agency that all products applying for the MAS deployment have been duly registered or at least approved for registration. After proper MAS deployment, the service provider is to immediately forward to the Agency standard notification form as completed by the MAH and signed by both parties.

2. Applicants Seeking to Deploy the MAS on Registered Products:

MAHs with registered products on Schedule-I yet on the MAS scheme by July 1st 2014, are to approach any service provider of their choice to arrange the deployment of the MAS on such products. The service provider is to verify from the Agency the registration status of such products. After proper MAS deployment, the service provider is to immediately forward to the Agency standard notification form as completed by the MAH and signed by both parties.

3. Applicants Seeking to Renew Registration Status of Products on Schedule-I:

All MAHs are to note that with effect from July 1st 2014, the MAS Standard Notification Form (see Schedule-II) will form part of the requirement for license renewal for regulated products in Schedule-I.

E. HOW TO SWITCH SERVICE PROVIDERS FOR THE MAS

In the event that an MAH wishes to switch service provider for any particular product, both the MAH and the new service provider will notify NAFDAC through the MAS Secretariat. The MAH is also to forward a comprehensive Risk Management Plan (RMP) to the Agency. The RMP is to conform to provisions of the RMP as in Schedule-III. Approval for a switch will ONLY be approved after due consideration and implementation of the RMP.

F. CONSUMER COMPLAINTS

Any complaint arising from implementation of the MAS scheme could be forwarded to the MAS secretariat via mas@nafdac.gov.ng

G. DATABASE MANAGEMENT

1. MAH/Service Providers should provide NAFDAC with data/information on all products under the MAS scheme. The content/format of data/information will be agreed by all partners.
2. NAFDAC will manage and maintain the data/information provided in 1 above.

3. NAFDAC in collaboration with the MAS Service Providers will develop a framework for data model and monitoring & Evaluation (M&E) mechanism for the scheme.

H. ROLE OF NAFDAC

1. Maintain the oversight function of the MAS scheme.
2. Maintain appropriate data base on the MAS scheme
3. Provide advice to the service provider on the registration status of the product(s) of the company intending to subscribe to the service
4. Handle complaints arising from the implementation of the service.
5. Coordinate the promotion of the service through public enlightenment campaigns
6. Coordinate the monitoring, evaluation and enforcement mechanism of the scheme.
7. Utilise data from the implementation of the scheme for appropriate decision making
8. The PV/PMS directorate of the Agency will in collaborate with other relevant directorates of the agency will develop a framework for appropriate monitoring and evaluation mechanism, this will leverage information in the database as well as input from the R & R directorate.

I. ROLE OF A SERVICE PROVIDER

1. Provide the necessary tools for effective implementation of the technology
2. Support and maintain the service for efficiency
3. Provide safe and secure data to NAFDAC
4. Undertake public enlightenment campaigns to promote awareness on implementation of the scheme.

J. ROLE OF MARKETING AUTHORIZATION HOLDERS (MAHs)

1. MAH of products on schedule 1 should ensure deployment on their products.
2. MAH should ensure compliance with requirement
3. MAH should educate and equip their supply chain with the right information and necessary tools
4. The Marketing Authorization Holders (MAHs) are to liberty to highlight the MAS scheme within approved advertorials on their products.

K. ROLE OF CONSUMERS AND THE GENERAL PUBLIC

1. Ensure that they scratch and text at the point of purchase
2. Ensure they text the right pin to the right code
3. Ensure the buy drugs from only registered pharmacies and patent medicines outlets

4. Ensure they obtained and retained receipts of payment for items purchased in case there is an issue
5. Report all cases of counterfeit products to NAFDAC's anticounterfeit desk in Pharmacovigilance and Post Marketing Surveillance Directorate
6. Report other complaints relating to the scheme through a free text message to the PRASCOR number 20543
7. Always call the call centre number provided for verification and further information

L. ROLE OF ACPN

1. The community pharmacists have a role to play in creating awareness amongst the patrons of the shops and the general public on the need to activate the pincode on the products through scratching and texting.
2. Pharmacists are to authenticate the outer packs of medicines before the consumer will scratch and text from the primary packaging to authenticate the purchased product.
3. Association of Community Pharmacist of Nigeria (ACPN) will collaborate with the NAFDAC in promoting the extensive adoption of the MAS scheme as anticounterfeiting device.
4. ACPN should contribute to the success of the service by embarking on point of sale advertisements and promotion.

M. PUBLIC ENLIGHTENMENT CAMPAIGN

1. There should be a unified singular advertisement and other public enlightenment campaigns on the NAFDAC MAS Scheme.
2. These adverts/ public enlightenment campaigns are to be solely financed by all the five approved MAS service providers.
3. The advertisement is to be created under the supervision and ultimate approval of the Agency.
4. The Special Duties Directorate as well as the Regulation and Registration Directorate are to supervise the advert and public enlightenment campaigns.

N. RISK MANAGEMENT PLAN

Risks associated with the implementation of the MAS service will be mitigated by appropriate Risk Management Plan applied as required such as the process of switching service providers on a particular product or inadequate data management.

O. CALL CENTRE

The protocol being implemented for the call center by the various service providers will be harmonized to be more effective in addressing issues arising from implementation. A more appropriate design call center will be addressed in subsequent Phases of the service.

P. FUNDING

NAFDAC will coordinate the funding arrangement to enable all stakeholders key into the service scheme especially in the area of creating public awareness on the scheme.