

**NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION
AND CONTROL (NAFDAC)**



**GUIDELINES FOR PROCUREMENT AND THE MANAGEMENT OF
THE MOBILE AUTHENTICATION SERVICE MAS SCHEME IN
NIGERIA**

2018

COMMENTS ARE WELCOMED FROM STAKEHOLDERS WITHIN 60 CALENDAR DAYS
(Ending 23rd September, 2018).
PLEASE SEND ALL INPUT TO pvpms@nafdac.gov.ng or pharmacovigilance@nafdac.gov.ng

© 2018 NAFDAC

This document is a publication of the National Agency for Food and Drug Administration and Control (NAFDAC), and all rights are reserved by the Agency. The document may, however, be freely reviewed, abstracted, reproduced and translated, in part or in whole, but not for sale nor for use in conjunction with commercial purposes.

For all enquiries or comments, write to:

The Director General,
Attention: The Director, PV/PMS Directorate,
National Agency for Food and Drug Administration and Control,
Plot 2032, Olusegun Obasanjo Way
Wuse Zone 7, Abuja, Nigeria

TABLE OF CONTENTS

FOREWORD	i
ACKNOWLEDGEMENTS	ii
ABBREVIATIONS	iii
1. BACKGROUND	4
2. SCOPE OF GUIDELINES	4
3. GENERAL OBJECTIVES	4
4. APPROVED MAS PROVIDERS AND THEIR CORRESPONDING SHORT CODES	4
5. ENROLLING ON REGISTERED PRODUCTS ON THE MAS SCHEME	5
5.1 Applicants Seeking to Deploy MAS on Registered Products:	5
5.2 Applicants Seeking To Renew Registration Status of Products on Approved Schedules	5
6. OPERATIONS	5
6.1 Switching to a new MAS Provider	5
6.2 Complaints	5
7. MINIMUM STANDARDS FOR QUALITY OF SERVICE FROM MAS PROVIDERS	6
7.1 Registration	6
7.2 Certifications	6
7.3 Short Messaging Service (SMS) Systems	6
7.4 Verification Channels	7
7.5 Market Intelligence	7
7.6 Database Management	7
8. STAKEHOLDER ROLES & RESPONSIBILITIES	7
8.1 Role of NAFDAC	7
8.2 Role of MAS providers	8
8.3 Role of HCRs	8
8.4 Role of Consumers and the Public	9
8.5 Role of Community Pharmacists	9
8.6 Role of Patent Proprietary Medicine Vendors (PPMVs)	9
9. PUBLIC ENLIGHTENMENT CAMPAIGNS	10
10. RISK MANAGEMENT PLAN	10
11. FUNDING	10

FOREWORD

In 2010, NAFDAC deployed the Mobile Authentication Service (MAS) scheme as one of the anti-counterfeiting strategies to detect substandard and falsified (SF) medical products. The scheme uses scratch codes and Short Messaging Service (SMS) to empower consumers to verify the authenticity of medicines at the point of purchase. The consumer scratches a panel on the product which reveals a unique, one-time use PIN which is sent toll-free to a short code using any of the GSM operators and the consumer receives a response in form of a text message (SMS) stating that the product is either genuine or suspected fake.

Following the success of the pilot, NAFDAC deployed the MAS Scheme in January 2012, across anti-malarials and antibiotic medicines imported or manufactured in Nigeria.

This document outlines procedures for the effective implementation of the MAS Scheme.

Currently, the following five (5) MAS providers offer MAS technology to Holders of Certificate of Registration (HCRs). The service providers and their corresponding codes are as follows:

LIST OF SERVICE PROVIDERS		
	Service Provider	Short Code
1	PharmaSecure	38351
2	Sproxil	38353
3	Savanté	38120
4	UBQ-t/Kezzler	20966
5	M-Pedigree	1393

All HCRs are to note that with effect from **January 1st, 2018**, the **MAS Standard Notification Form** will form part of the requirements for license renewal for all antibiotics and antimalarial medicines.

I implore all relevant stakeholders to study the guidelines and submit their comments to the Director, Pharmacovigilance and Post Marketing Surveillance through *mas@nafdac.gov.ng* to improve the content of the next edition of the guidelines.

Prof. Moji Christianah Adeyeye, PhD, FAAPS, FNAS, FNAPharm
Director-General
NAFDAC

ACKNOWLEDGEMENTS

The National Agency for Food and Drug Administration and Control (NAFDAC) appreciates the efforts, determination, support, and contributions from individuals and organizations that made the development of these guidelines possible.

The Agency is grateful to the Director-General (NAFDAC), Prof. Mojisola Christianah Adeyeye under whose leadership NAFDAC has entered a new and exciting era in the pharmaceutical regulation in Nigeria.

The Agency acknowledges Clinton Health Access Initiative (CHAI) for its support towards strengthening NAFDAC's regulatory capacity to combat substandard and falsified (SF) antimalarials and antibiotics medicines in Nigeria. CHAI specifically provided funds needed to develop these guidelines.

Finally, the tirelessness, hard-work, dedication, commitment, team spirit exhibited by the staff of Pharmacovigilance/Post Marketing Surveillance Directorate, Directorate Planning Research and Statistics and Technical Services of NAFDAC facilitated development of these guidelines. Their intellectual and vast experience enriched the content of these guidelines.

Pharm. Ali Ibrahim, fsi

Director,

Pharmacovigilance/Post Marketing surveillance Directorate

NAFDAC

LIST OF ABBREVIATIONS

NAFDAC	National Agency for Food & Drug Administration & Control
MAS	Mobile Authentication Service
HCR	Holder of Certificate of Registration
IEC	Information, Education & Communication
SMS	Short Messaging Service
M&E	Monitoring & Evaluation
PIN	Personal Identification Number
MoU	Memorandum of Understanding
NCC	National Communications Commission
SF	Substandard and Falsified (reference to medical products)
GSM	Global System of Mobile Communications
SMS	Short Messaging Service

1. BACKGROUND

In 2010, NAFDAC deployed the Mobile Authentication Service (MAS) scheme as one of its anti-counterfeit strategies to detect substandard and falsified (SF) medical products. The scheme uses scratch codes and Short Messaging Service (SMS) to empower consumers to verify the authenticity of medicines at the point of purchase. The consumer scratches a panel on the product, which reveals a unique, one-time use PIN. The PIN is sent toll-free to a short code using any of the GSM operators and the consumer receives a response in form of a text message (SMS) stating that the product is either genuine or suspected fake.

Following the success of the pilot, NAFDAC deployed the MAS scheme in January 2012, for all anti-malarials and antibiotic medicines imported into or manufactured in Nigeria.

This document outlines procedures for effective the enrolment and implementation of the MAS Scheme.

2. SCOPE OF GUIDELINES

The MAS Scheme currently covers antibiotics, anti-infective and anti-malarial medicines listed in the *“approved schedules”* within these guidelines as *Appendix I*.

3. GENERAL OBJECTIVES

This document serves to provide guidelines for:

1. Holders of Certificate of Registration (HCR)/“The Applicant” seeking to deploy MAS on their registered products.
2. Existing MAS providers deploying MAS technology; and MAS providers seeking entry as a NAFDAC approved service provider
3. Person(s) or Group(s) requesting Information, Education and Communication (IEC) materials on the MAS Scheme.

4. APPROVED MAS PROVIDERS AND THEIR CORRESPONDING SHORT CODES

NAFDAC has approved the following five (5) MAS Providers to offer MAS technology to Holders of Certificate of Registration (HCR). The MAS providers and their corresponding codes are as follows:

APPROVED LIST OF MAS PROVIDERS		
	MAS Provider	Short Code
1	PharmaSecure	38351
2	Sproxil	38353
3	Savanté	38120
4	UBQ-t/Kezzler	20966
5	M-Pedigree	1393

5. ENROLLING ON REGISTERED PRODUCTS ON THE MAS SCHEME

There are two scenarios to enrol registered products on the MAS scheme:

5.1 Applicants Seeking to Deploy MAS on Registered Products:

HCRs/ Holders of notification of registered products on approved schedules yet to enlist on the MAS scheme are required to approach any approved MAS provider of their choice to arrange for deployment of MAS on such product(s). The MAS provider is to verify the registration status of such product(s) from NAFDAC in writing, and immediately forward to the Agency, the standard notification form (**appendix II**) as completed by the HCRs/ Holders of Notification. The forms shall be signed by both parties..

5.2 Applicants Seeking To Renew Registration Status of Products on Approved Schedules

All HCRs are to note that with effect from January 1st, 2018, the MAS standard notification form (*see appendix II*) will form part of the requirements for license renewal for products listed in appendix 1.

6. OPERATIONS

6.1 Switching to a new MAS Provider

Any HCR intending to switch from one MAS Provider to another should notify the Agency in writing to the Director General, Attention: Director PV/PMS. The HCR shall in addition to this letter of intent, forward a detailed transition plan to the Agency. A switch from one MAS Provider to another will ONLY be approved after due consideration and implementation of the transition plan.

6.2 Complaints

Any complaint arising from agreements between MAS Providers and HCRs in the implementation of the MAS scheme shall be forwarded to the Agency via email to the following email address: mas@nafdac.gov.ng.

7. MINIMUM STANDARDS FOR QUALITY OF SERVICE FROM MAS PROVIDERS

The following minimum standards must be fulfilled by every NAFDAC approved MAS provider. NAFDAC shall audit all MAS providers periodically to ensure adherence to set minimum quality standards.

7.1 Registration

The MAS provider must be a registered company in Nigeria, subject to applicable Nigerian laws.

7.2 Certifications

MAS providers shall have an established data quality management and data security system, which is verifiable.

7.3 Short Messaging Service (SMS) Systems

7.3.1 Response message for product verification status:

All MAS providers shall use the following unified response messages as feedback on the status of request to consumers:

Status	Definition	Response Message
Unconfirmed product / unregistered / suspected counterfeit	This refers to product whose PIN cannot be found on the database after PIN is entered correctly at the time of request	Product not verifiable, Please call contact centre on product pack
Confirmed product	This refers to products for which the status can be verified	Genuine product. include : defined minimum information listed below in "7.3.2"

7.3.2 Content of SMS feedback:

SMS responses for confirmed products shall contain the following minimum information:

- Product name
- NAFDAC registration number of the product
- Product expiry date
- Product batch number
- Helpline for further information and/or reports of suspected

counterfeits (i.e. non-verifiable products)

7.3.3 Confirming accurate entry of MAS PIN:

When a PIN is entered and a product is not confirmed “Genuine” at first attempt, the response message shall read “INCORRECT PIN” try again.

7.4 Verification Channels

MAS providers shall offer verification via SMS, and must provide 24-hour call services as a backup verification channel in addition to SMS, using a local phone number for ease of access.

7.5 Market Intelligence

MAS providers shall provide NAFDAC access to information on locations of potentially counterfeit products, and any other information relevant to the regulatory activities of the Agency.

7.6 Database Management

- a. HCRs and MAS providers shall provide the Agency with data and/or information on all products under the MAS scheme. The content and data format shall be agreed upon by relevant parties.
- b. NAFDAC will manage and maintain the data and/or information provided in “a” above.
- c. NAFDAC in collaboration with the MAS providers will maintain the framework for Monitoring & Evaluation (M&E) of the scheme.

8. STAKEHOLDER ROLES & RESPONSIBILITIES

8.1 Role of NAFDAC

NAFDAC Shall:

- 8.1.1. Maintain oversight function of the MAS scheme.
- 8.1.2. Collect and maintain appropriate data and information on the MAS scheme.
- 8.1.3. Confirm to the MAS providers the registration status of the product(s) the HCRs intending to enrol on the service.
- 8.1.4. Deal with consumers’ complaints arising from the use of the MAS and share feedback with MAS providers to ensure improved quality of service.
- 8.1.5. Coordinate promotion of the scheme through public enlightenment campaigns.
- 8.1.6. Develop a framework for monitoring and evaluation of the scheme.

- 8.1.7. Coordinate the monitoring, evaluation and enforcement of the scheme.
- 8.1.8. Develop guidelines for the MAS providers for periodic reporting.
- 8.1.9. Establish restricted access to database where Service Providers can check the current registration status of companies applying for the service.
- 8.1.10. Establish and maintain a MAS helpdesk where stakeholders can contact to make enquiries.
- 8.1.11. Conduct surveillance in collaboration with MAS Providers to determine compliance with the scheme.
- 8.1.12. Check the authorization status of MAS providers with relevant authorities.
- 8.1.13. Supervise and approve all advertisements and public enlightenment campaigns before release to the public.

8.2 Role of MASproviders

MAS Providers Shall:

- 8.2.1. Support and maintain MAS for efficiency and effectiveness.
- 8.2.2. Provide timely and complete report to the Agency based on the reporting template as specified in the MoU
- 8.2.3. Forward a monthly report of the preceding month on all MAS related activities by **15th of the next month** to the Agency through the designated reporting channel.
- 8.2.4. Undertake and finance sensitization programmes and public enlightenment campaigns to promote awareness on the implementation of the scheme among HCRs and the public.
- 8.2.5. Ensure that it has a subsisting and valid licence with the National Communications Commission (NCC) and all relevant bodies to provide and ensure quality service.
- 8.2.6. Renew all relevant licences as at when due to avoid any disruption of service.
- 8.2.7. Establish and maintain a functional call centre to address issues arising from the implementation of MAS.
- 8.2.8. Pay an annual subscription fee of Two Hundred and Fifty Thousand (**250,000**) Naira only to NAFDAC, upfront within the first quarter of the year.

8.3 Role of HCRs

HCRs of products on approved schedules shall:

- 8.3.1. Deploy MAS on their products, ensuring that MAS labels are affixed

- on outer packs of all products for verification
- 8.3.2. Ensure that engaged MAS provider complies with minimum MAS requirements as specified within the guidelines
- 8.3.3. Ensure they provide the MAS provider relevant information about their products as requested.
- 8.3.4. Educate and equip their supply chain in line with **NAFDAC GOOD DISTRIBUTION PRACTICES GUIDELINES FOR PHARMACEUTICAL PRODUCTS.**
- 8.3.5. HCRs that wish to affix the MAS code in the country shall obtain approval from the Agency and notify the Ports Inspection Directorate (PID) prior to entry of the products.
- 8.3.6. HCRs are at liberty to highlight the MAS scheme within approved advertorials on their products.

8.4 Role of Consumers and the Public

The Public shall:

- 8.4.1. Ensure to scratch and text at the point of purchase
- 8.4.2. Ensure to text the right PIN to the right code provided
- 8.4.3. Purchase medicines from only registered pharmacies and patent medicines outlets
- 8.4.4. Obtain and retain receipts of payment for items purchased for reference to address any issues that may arise from sales or purchasing the product
- 8.4.5. Report all cases of suspected sub-standard and falsified (SF) medical products to NAFDAC by calling the helpdesk/call centre affixed to the packaging of the product.

8.5 Role of Community Pharmacists

All proprietors of pharmacy shops and medicine retail outlets shall:

- 8.5.1. Authenticate outer packs of medicines before purchase, via scratch and text.
- 8.5.2. Collaborate with NAFDAC in promoting the extensive deployment of the MAS scheme as an anti-counterfeiting tool.
- 8.5.3. Collaborate and support the awareness of sales advertisements and promotion to create awareness amongst consumers.

8.6 Role of Patent Proprietary Medicine Vendors (PPMVVs)

All patent and proprietary medicine vendors shall:

- 8.6.1. Authenticate outer packs of medicines before purchase, via

scratch and text

8.6.2. Collaborate with NAFDAC in promoting the extensive deployment of the MAS scheme as an anti-counterfeiting tool.

8.6.3. Collaborate and support the awareness of sales advertisements and promotion to create awareness amongst consumers

9. PUBLIC ENLIGHTENMENT CAMPAIGNS

9.1. There must be a unified singular advertisement and other public enlightenment campaigns on the NAFDAC MAS Scheme.

9.2. Adverts and public enlightenment campaigns shall be undertaken and financed by MAS providers under the supervision and ultimate approval of the Agency.

10. RISK MANAGEMENT PLAN

Risks associated with implementation of the MAS scheme shall be mitigated by applying the appropriate mitigation plan as may be required. Such risks may include the process of switching MAS providers on a product or inadequate data management.

11. FUNDING

NAFDAC shall coordinate funding arrangements for all activities related to the MAS scheme.

APPENDIX

Appendix I: Approved List of Medicines on the Scheme.

The following are regulated products covered in the implementation of the MAS Scheme

(ANTI INFECTIVES):

1. Antiprotozoal Drugs

- a. Antimalaria drugs (All antimalarial drugs including sulphadoxine-pyrimethamine (SP) and injectables)
- b. Antiamoebic, antigiardial and antitrichomonal drugs (metronidazole formulations only infusions, tablets and suspensions)

2. Antibacterial Drugs

- a. Beta-lactam drugs
- b. Penicillins
- c. Cephalosporins
- d. Other beta-lactam antibacterials

3. Other antibacterials

- a. Chloramphenicol
- b. Quinolones
- c. Tetracyclines
- d. Macrolides
- e. Aminoglycosides
- f. Metronidazole
- g. Sulfonamides and trimethoprim

Appendix II: Letter of Notification

Name and Complete Address of Service Provider (Letter headed paper)

The Director-General
NAFDAC

Attention:

Director R&R
NAFDAC

Sir/Ma

LETTER OF NOTIFICATION

This is to certify that the Holder of Certificate of Registration (HCR) stated below has deployed Mobile Authentication Service on the under listed product(s)

Name of HCR.....

Name and details of Product(s)

- i.
- ii.
- iii.

Duration of Contract Agreement.....

Name and Signature of Service Provider

Name and Signature of HCR

.....

.....

Date.....

Date.....



National Agency For Food And Drug Administration And Control (NAFDAC)

Mobile Authentication Service (MAS)

Putting the power of detecting counterfeit medicine in the hands of the consumers.

How to Use

- ▣ Scratch Card to Reveal **PIN**
- ▣ Text **PIN** to **Code Provided**
- ▣ Wait for an **SMS response**
- ▣ Text **PIN** only **once**



Service Providers	GSM CODE
PharmaSecure	38351
Sproxil	38353
Savante	38120
UBQ-t/Kezzler	20966
M-Pedigree	1393

Text Message
is FREE



Contact:

Email: info@nafdac.gov.ng
Website: www.nafdac.gov.ng

NAFDAC ...Safeguarding the Health of the Nation