MINUTES OF THE SECOND MEETING OF NIGERIAN HERBAL MEDICINAL PRODUCTS COMMITTEE (NHMPC) HELD ON THE 6TH SEPTEMBER, 2019 AT THE NAFDAC AUDITORIUM ISOLO LAGOS.

S/N	DISCUSSION/DELIBERATIONS	ACTIONS BY
1.0	**ATTENDANCE (Please see attached)**	
2.0	**OPENING**	
2.1 2.2 2.3 2.4 2..5	The meeting commenced at 09.50am with the national prayer followed by recognition of the Director-General (DG-NAFDAC), the Director Registration & Regulatory Affairs (R&R) and then self-introduction of everyone present.	DD (H&N)
3.0	**ADOPTION OF THE AGENDA**	
3.1 3.2	The agenda was adopted by Prof. Moses Akanmu and seconded by Dr. J. O. Idowu.	Secretariat
4.0 4.1	**READING AND ADOPTION OF LAST MINUTES**	
4.2 4.3 4.4 4.5 4.6 4.7 4.8 4.9 4.10 4.11 4.12	The following corrections were observed and effected on the minutes of the last meeting as follows: - Line 8.4 “unavoidably absent” to read “nominated in absentia” Line 8.3 “verifiaction “ to read “verification” Line 8.38 “Gimba” to read “Jimba” 8.39 To include “Dr. Uthman Abdulazeez” Include Loan & Grant committee as one of the sub committees. All names should be written in full Corrected minutes was adopted by Mr. Abdulazeez Uthman and seconded by Mr. Shola Jimba	
5.0 **5.1** 5.2	**GOODWILL MESSAGES**	

5.3 5.4 5.5 5.6 5.7 5.8 5.9 5.10 5.11 5.12 5.13 5.14 **6.0** 6.1 6.2 6.3 6.4 6.5 6.6 6.7 6.8 **7.0** 7.1 7.3 7.4 7.5 7.6 7.7 7.8 7.9 7.10 7.11 7.12 7.13 7.14	**PROF. ANTHONY ELUJOBA** In his goodwill message said he was happy to be present at the meeting and thanked God for the great progress made so far in the Agency since 1999. He noted that in the past, people have been apprehensive of Government approval of herbal medicines because of so many criticisms and the many dangers that people thought approval of herbal medicines will pose in the country but he is happy that till date there has been no phytovigilance report of death as a result of Herbal medicines. He however observed that we have not yet arrived at our destination because so much still needs to be done which requires our dedication and commitments. **ALHAJI AHMAD ABDULATEEF** In his remarks appreciated the effort of NAFDAC, the Nigerian government as whole and stakeholders in the development of traditional and herbal medicines. He said Nigeria has been looking for the way forward and believes the government is now ready to partner with practitioners and manufacturers, he therefore advised stakeholders to use this opportunity presented. **DIRECTOR TRADITIONAL, COMPLIMENTARY & ALTERNATIVE MEDICINE (TCAM) FEDERAL MINISTRY OF HEALTH (FMOH)** The D (TCAM) FMOH was represented by Pharm. Joseph Jiyah. In his remarks congratulated NAFDAC for this meeting, He went further to inform the committee that the TCAM Department was recently created and is passionate to see the development of traditional and complimentary medicines in Nigeria but believes they cannot do	

7.15 7.16 7.17 **8.0** 8.1 8.2 8.3 8.4 **9.0** 9.1 9.2 9.3 9.4 9.5 9.6 **10.0** 10.1 10.2 10.3 10.4 10.5 10.6 10.7 10.8 10.9 10.10 10.11 10.12 10.13 10.14 10.15 10.16 10.17	this alone and has therefore extended a hand to stakeholders particularly NAFDAC with whom they have already started collaboration. They are also extending a hand to other stakeholders like NIPRD and believe more stakeholders in Traditional Medicine (TM) industry will come together for the development of TM in the country. **DR S. O. FAFURE** He congratulated DG (NAFDAC) for organising this meeting and wants NAFDAC to increase Registration tempo of locally made Herbal Medicinal Products (HMP) so that more HMP will be listed in NAFDAC. **MR. MATTHEW AZOJI (MANAGING DIRECTOR NEIMETH)** The MD Neimeth congratulated the DG NAFDAC and expressed joy at the changes observed since her assumption in office and also for setting up this committee with aim of ensuring that quality herbal medicines for Nigeria. Finally he thanked the committee for inviting NEIMETH to the meeting. **WELCOME REMARKS BY DIRECTOR DRUG EVALUATION & RESEARCH D(DER)** The DDER was represented by Dr. Rametu Momodu Deputy Director (DER). She was particularly excited that the second edition of this meeting is holding with more people in attendance. She applauded the efforts of the DG NAFDAC for creating this platform (HMP manufacturers, Academia, Researchers, FMOH and NAFDAC to meet in order to bridge the gap in translating research to herbal products and advised members not to see this as any other meeting, rather they	All members

should ensure that all decisions taken are put in to action.

She recalled that at the first meeting seven committees were setup and were expected to come up with documents that can be implemented in the course of our work.

She went further to remind the members that the aim of the meeting was to ensure that knowledge of traditional medicines with the practitioners who may not be literate is not wasted. Finally she hopes that the meeting will change our mindset and perception about herbal medicinal products. She charged the manufacturers to talk with academia and researchers to help develop and formulate these products so that they can be registered by NAFDAC.

OPENING REMARKS BY DG NAFDAC

Thanked members for attending the meeting which is a unique one comprising professors who are recognized internationally meeting with practitioners and as such wants this meeting to yield outcomes and recognition of the effectiveness of HMP. She explained that although orthodox medicines are effective, Nigerians still prefer to use herbal medicines rather than orthodox medicines maybe because of poor accessibility to doctors, issue of no money etc. She believes that the plants around us are not there by accident rather for our use just like in the Garden of Eden.

She informed the house that NAFDAC has already started creating awareness on the usefulness of herbal medicine and recently was on NTA, Brekete FM 101.1 in collaboration with FMOH, NIPRD and Prof. Maurice Iwu.

She recalled that she had been involved in herbal Herbal Medicine research even before joining NAFDAC and observed that some plants in Nigeria

11.27 11.28 11.29 11.30 11.31 11.32 11.33 11.34 11.35 11.36 11.37 11.38 11.39 **12.0** 12.1 12.2 12.3 12.4 12.5 12.6 12.7 12.8 12.9 12.10 12.11 12.12 12.13 12.14 12.15 12.16 12.17 12.18 12.19 12.20 12.21 12.22 12.23	may be a sub species to plants in the other parts of the world, for example a plant in America did not have the bioactives for management of sickle cell whereas the one in Nigeria had contained the bioactives. She said NAFDAC has well over1000 listed Herbal medicines (both local and imported) however NAFDAC plans to stepdown on the registration of imported herbal medicines where we have local production of similar products. DG NAFDAC advised the Academia to look into TETFUND to obtain funds since such funds are usually available to university. She also advised practitioners/manufacturers to be open to academia/researchers on what they are working on. Finally she stated that NAFDAC is working to create a confidentiality agreement document to be used by the academia and herbal practitioners to ensure trust and that the rights of all parties involved are protected. **PRESENTATION BY THE COMMITTEES** **PHARMACOVIGILANCE (PVG)** presentation was by Dr. Charles Iheanacho on Herbal Pharmacovigilance process in Nigeria. Highlight of presentation includes: - • overview of Pharmacovigilance • Aim of pharmacovigilance • Services that will enhance Herbal Vigilance activities • Criteria for ADR reporting. **COMMENTS** • There is an existing pharmacovigilance policy by FGN and we need to anchor on the already existing policy. • The PVG committee may need to build on the existing policy, see if there are gaps and close such gaps.	PVG committee members

12.24 12.25 12.26 12.27 12.28 12.29 **13.0** 13.1 13.2 13.3 13.4 13.5 13.6 13.7 13.8 13.9 13.10 13.11 13.12 13.13 13.14 13.15 13.16 13.17 13.18 13.19 13.20 13.21 13.22 13.23 13.24 13.25 13.26 13.27 13.28 13.29	• The house suggested the developing computer software Applications for dissemination of information , use of different colours (i.e. yellow. Green & Red) on product labels to report adverse drug reactions and inclusion of emergency telephone numbers on insert leaflets for ADR reporting. • The committee needs to look at Herbal Pharmacovigilance as it is done in other countries like China, India, and Germany and come up with workable herbalvigilance guidelines. • The DG informed the meeting that NAFDAC has started herbalvigilance in her Drug safety monitoring activities **HERBAL MEDICINE FORMULATION** presentation by Prof Martins Emeje Highlights of presentation • Manufacture of HM • Good practices in production • Good practices in Quality Control • Packaging/Labelling Information • Claims/Therapeutic Indications • Pharmacokinetics • Side Effects, Adverse Effects &Stability profile **QUESTION/ANSWER SESSION** Q1. The Herbal practitioner wants a guarantee that intellectual property will be protected if they expose the HMP formulation to researchers? A1. In order to protect the practitioners, both parties will sign • Non-disclosure Agreement • Material transfer agreement Q2. How can manufacturers be close to researcher in one click? A2. NNMDA has Intellectual Property Technology Transfer office (IPTTO) and works in collaboration	

13.30 13.31 13.32 13.33 13.34 13.35 13.36 13.40 **14.0** 14.1 14.2 14.3 14.4 14.5 14.6 14.7 14.8 14.9 14.10 14.11 14.12 14.13 **15.0** 15.1 15.2 15.3 15.4 15.5 15.6 15.7 15.8 15.9 15.10 15.11 15.12	with National Office for Technology Acquisition and Promotion (NOTAP) • Members can liaise with NNMDA to translate claims into intellectual property and later forward it to NOTAP to patent. • Members were also advised to apply stepwise approach to registering product i.e. a product with one phytomedicinal plant at a time. Q3. How simple is registration of HM. Because we don't want NAFDAC to discourage listing of HM. A3. NAFDAC has always been and is still encouraging listing registration of HMP • FMOH is also working on to stakeholders with researchers. • The DG NAFDAC explained that for transparency NAFDAC will allow practitioners to choose researchers of their choice to work with. **PROTOCOL FOR CLINICAL TRIALS (CT)** presentation by Prof Adefule Oshitelu Highlights of the presentation • They need to be educated / literate/ may need translation. • They should be duly registered either with state Traditional Medicine Board and/or Approved National Body with duly signed identity cards. • All practitioners should be encouraged to register their product with NAFDAC at affordable cost. **COMMENTS** The house wants the committee to come up with a draft protocol for CT that can be adopted.	Clinical Trials committee members D(R&R)

15.13 15.14 15.15 15.16 15.17 15.18 15.19 15.20 15.21 15.22 15.23 15.24 15.25 15.26 15.27 15.28 15.29 15.30 **16.0** 16.1 16.2 16.3 16.4 16.5 16.6 16.7 16.8 16.9 **17.0** 17.1 17.2 17.3 17.4	**IDENTIFICATION AND STANDARDIZATION** presented by Professor Iwu Highlights of his presentations • Need for expert identification of herbal medicinal plants • Need to have retention sample for every batch • Method of identification e.g- Microscopic and macroscopic profiling • Methods of standardization • Guidelines for standardization of HM • The Herbal Pharmacopeia available include: - • Nigeria Herbal Pharmacopeia • West African Herbal Pharmacopeia • African Herbal Pharmacopeia **COMMENTS** • DG NAFDAC requested the D(R&R) to come up with an abridged guideline for listing/Full registration of HMP and communicate to the committee through the WhatsApp group. Member should come up with a list of commonly used products of plant origin so that members can borrow from if they want to standardize their product. • African Union has a list of twelve (12) standardized plant materials and Nigeria is proposing 15 more, making a total of 27 standards for herbal medicinal plants. • Suggestions on identification and standardization by committee is welcome. • Manufacturers should be adequately trained so they can standardize their products and also identify marker substances etc. **GUIDELINES FOR CLAIMS VERIFICATION** Presented by Prof Elujoba.	Identification and standardization committee Train manufacturers

17.5 17.6 17.7 17.8 **18.0** 18.1 18.2 18.3 18.4 18.5 18.6 18.7 18.8 18.9 18.10 18.11 18.12 18.13 18.14 18.15 18.16 18.17 18.18 18.19 18.20 18.21 18.22 18.23 18.24 18.25 18.26 18.27	• Presented a few of NAFDAC listed products 2014 • The NAFDAC Laboratories should be empowered to carry out with strict confidentiality agreement the certification of Herbal medicines • They can liaise with NIPRD or may wish to commission individual private laboratories. **GUIDELINES FOR HAVESTING AND HANDLING OF HERBAL MEDICINAL RAW MATERIALS** Presented by Dr. Isaac Odeyemi, Highlights: • Meeting with Herbal Medicinal plant sellers. • Meeting and interactions with harvesters of herbal medicinal plants. • Meeting with farmers of herbal medicinal plants. **LOANS AND GRANT COMMITTEE** Presented by Dr Idowu Johnson • Major difficulty in accessing loans/grants • NAFDAC should facilitate the inclusion of HMP in Primary Health Care (PHC) system moving forward **COMMENTS** • NAFDAC cannot recommend introduction of HMP into National or Primary Health Care system unless such products have undergone clinical trials and has full registration status. • The house wants NAFDAC to give incentives to manufacturers whose products have been listed	NAFDAC Legal Dr. R. O. Momodu

19.0 19.1 19.2 19.3 19.4 19.5 19.6 19.7 19.8 19.9 19.10 19.11 19.12 19.13 19.14 19.15 19.16 19.17 19.18 19.19 19.20 19.21 19.22 19.23 19.24 19.25 19.26 19.27 19.28 19.29 19.30 19.31 19.32 19.33 19.34 19.35 19.36	• Manufacturers with listed products were advised to work closely with researchers /academia • We can start by looking at classical plant products that their CT has been carried out in other countries. • There has not been much collaboration amongst HM practitioners even after the last meeting. • Confidentiality Agreement to be created so that any linkage developed will signed by both parties. • Dr. R.O. Momodu to send confidentiality agreement to the linkage groups developed after this meeting. **ROUND TABLE MEETING** Members defined the objectives of NHMPC as follows: • To promote HM product • To collate data for CT • To initiate & encourage collaboration amongst Manufacturers, Researchers and Academia. • To mainstream herb medicinal product into National Healthcare system. **Expectations and questions by the members** • To be able to link with researcher(s) • The committee to develop draft Guidelines for clinical trials of HMP • Who will fund the research • How much will it cost manufacturers to carry out CT **COMMENTS/SUGGESTIONS** • Phytoplants that have been used routinely over the centuries and have not been found to be harmful in any way may not need to pass through full CT e.g. Bitter leaf which has been	All subcommittee members Manufacturers/practitioners Academia/Researchers

19.37 19.38 19.39 19.40 19.41 19.42 19.43 19.45 19.46 19.47 19.48 19.49 19.51 19.52 19.53 19.54 19.55 19.56 19.57 19.58 19.59 19.60 19.61 19.62 19.63 19.64 19.65 19.66 19.67 19.68 19.69 19.70 19.71 19.72 19.73	used over the years is not likely to be hazardous. • There is need for documentation of use to have evidence of use e.g. Chinese which has at least 5000 years history of use for certain phytomedicinal plants like Artemisia annual that has been used as tea in China • Herbal products are treated in NAFDAC as Medicinal products irrespective of the size of the facility (whether micro, small, medium or large scale) • NAFDAC has observed that most production managers do not have good knowledge of GMP for Herbal medicinal products. • Committees should come up with relevant documents/guidelines for NAFDAC and these documents will be binding on members • Manufacturers/practitioners were advised to link up with at least one researcher either through phone/internet calls or by sending SMS. find below contact details of Academia/researchers • Researchers were advised to find ways to reduce research cost as much as possible • Research is not clinical trial, so before commencing CT manufacturers are advised to visit NAFDAC to apply for CT. • Already published research work in journals cannot be used for product development and should not be patented. • You are advised to only publish only after you have filed for protection (patented). All patents are publications and are available for downloading. • Practitioners were advised to respect the researchers' opinion on Investigated Claims especially when the findings are not in concordance with theirs. • Practitioners were also advised to follow due process while the researchers should try to	Manufacturers NAFDAC DER

19.74 19.75 19.76 19.77 19.78 19.79 19.80 19.81 19.82 19.83 19.84 19.85 19.86 19.87 **20.0** 20.1 20.2 20.3 20.4 20.5 20.6	collaborate as much as possible with little or no finances • Companies who wish to carry out CT were advised to come to NAFDAC for proper guidance before they commence. • One of the challenges facing practitioners is lack of GMP Knowledge, so NAFDAC plans to organize quarterly GMP trainings for our stakeholders which will be paid for by them. • Practitioners were encouraged to do team work (when 2 or more companies partner to get a facility that will be accepted by NAFDAC.) Contract manufacturing arrangement can also be explored by facilities manufacturing similar product lines. Practitioners were challenged to go beyond Nigeria and even Africa to attend International conferences etc. E.g. The World Congress on Integrative Medicine will be holding November 2019. • Finally the academia was advised to work on offering into offer undergraduate courses on African Traditional medicines as is done by other countries e.g. Ghana, Ghana, China, India. **CLOSING** Dr. Momodu gave the vote of thanks. She thanked everyone for their active participation and passion displayed all through the meeting. Finally she said those interested in joining any of subcommittees were welcome to do so. The meeting came to a close at 4.55PM.	

NAMES OF RESEARCHERS AND AREAS OF SPECIALIZATION

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