PHARMACOVIGILANCE/POST MARKETING SURVEILLANCE NEWSLETTER

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NEW DEVELOPMENTS AND ACTIVITIES OF THE NATIONAL PHARMACOVIGILANCE CENTRE IN THE YEAR 2020 AND 2021

Content

EDITOR'S NOTE...

We wish to thank all our numerous stakeholders who have been working tirelessly with the National Pharmacovigilance Centre (NPC) to ensure the safe use of medicines in Nigeria. The NPC is committed to sending out the quarterly newsletter to its stakeholders. The objectives of the Newsletter are to disseminate information on Pharmacovigilance activities nationally and globally, to educate stakeholders on medicine safety issues, to promote rational use of drugs and to promote reporting of Adverse Drugs Reactions (ADRs). This edition of the newsletter focuses on **New Developments and Activities of the National Pharmacovigilance Centre in the year 2020 and 2021.**

We encourage Health care Professionals and other stakeholders to continue to report all adverse drug reactions. Your valued comments and acknowledgement of receipt of this issue through our email addresses (nafdac_npc@yahoo.com; pharmacovigilance@nafdac.gov.ng, fdic@nafdac.gov.ng) would be most appreciated.

You may also send us email if there are areas of interest that you would want addressed in subsequent issues of the newsletter

Thank you for your relentless efforts in strengthening the Pharmacovigilance System in Nigeria.

Introduction

The National Pharmacovigilance Centre (NPC) is domiciled in the PV Division of the Pharmacovigilance/Post Marketing Surveillance Directorate and is responsible drug events. Activities of the National centre have been sustained even in the face of the pandemic.

Pharmacovigilance is the practice of detecting, assessing, understanding, reporting, and preventing adverse drug reactions, including reactions to vaccines. The challenges associated with drug safety surveillance include underreporting of adverse drug events (ADEs) and inability to identify and transmit ADE Reports. Reporting systems are in place for institution-based surveillance to assist healthcare professionals (HCPs) in their responsibility of reporting ADEs observed and comply with NAFDAC Good Pharmacovigilance Practices Guidelines 2020. How much information is gathered and duly reported largely depends on the awareness and assertiveness of the professionals. In a study at Johannesburg South Africa, the attitudes of healthcare professionals were measured by the factors that encouraged and discouraged them, as well as the circumstances in which they were most likely to report ADRs. The reasons for the underreporting of ADRs by healthcare professionals discovered include inability to recognize ADRs, ignorance of the reporting requirements, lack of reporting forms, feeling of guilt following the occurrence of adverse effects and fear of litigation. These, prevent HCPs from adhering fully to the reporting requirements, resulting to inadequate or incomplete data (Gordhon & Padayachee, 2020). The range of factors found to discourage respondents from reporting ADRs include the perception that it is more important to prioritize managing the patient and lack of knowledge about the reporting system.

It is crucial for ADEs experienced by patients to be promptly reported to the Pharmacovigilance centre to take adequate measures in response to the frequency and severity of these ADEs. A systematic review of underreporting of ADEs revealed that the median underreporting rate across 37 studies from 12 different countries was a staggering 94% (Hazell and Shakir, 2006). A timely and relevant area of concern for this underreporting is its implications on the current COVID-19 pandemic (Albani, et al., 2021). Underreporting of ADEs is a major challenge in the epidemiological track and tracing as it reduces our ability to accurately estimate morbidity and mortality rates. These, all have impacts on vaccination strategies and other important clinical implications that rely on accurate epidemiology practices. Underreporting of adverse drug events (ADEs) by Health Care Workers (HCWs) is an international health concern and still a global problem.

Launch of Med Safety App

In our stride to promote spontaneous reporting of ADEs, the Med safety app, a mobile app for reporting of adverse drug reactions was launched on 4th November

2020 in the Director-General's Conference room, Abuja. The African Union Development Agency – NEPAD, (AU-3S) team and the MHRA facilitated the development of a vaccine reporting form for use in the Med Safety App. This enables e-reporting of adverse events following immunization (AEFIs) by both healthcare professionals and the public. While this form was initially only rolled-out to the four AU-3S pilot countries, it has since been made available to all other countries using the Med Safety App.

The Med Safety Mobile App is a customized platform for reporting ADRs to NAFDAC by using smartphones. Along with enabling a quick and easy submission of ADR reports, the mobile application allows users to view and submit updates of previously submitted reports, create a watchlist of medications for signal detection & management, receive drug safety information, news and alerts and keep track of the number of ADR reports in VigiBase®. Anyone who wants to report an ADR can download the application from the app store of Google Play®, install it on the smartphone, select "Nigeria" as home country, create an account and follow the instructions for reporting the ADR. Records available to the office show that over 600 smart phone users had downloaded the app by 30th November 2020. The Benefits of the Med Safety App include the following:

- it is convenient for ADR reporting
- it promotes awareness & increased ADR reporting
- it gives instant access to stakeholders via NAFDAC social media platforms
- it is free to download & use on Android and iOS devices
- it gives NRAs news feed
- Summaries of ADR data are available in graphical form and
- It can be used in 3 languages: English, Russian or Armenian.

The use of the Med Safety App has increased significantly in Nigeria, driven by NAFDAC's practical training sessions with healthcare professionals, and a strong communication plan developed in collaboration with the National Primary Health Care Development Agency (NPHCDA).

"Previously, we only had paper forms to report AEFIs. The Med Safety App improved our visibility and gave us real-time access to AEFI reports to inform our regulatory decisions. AU-3S provided us with multiple materials to help us with our national communications about safety surveillance."

- Prof. Moji Adeyeye, Director General of NAFDAC

Pharmacovigilance Assessment of Facilities

NAFDAC in collaboration with the Management Sciences for Health (MSH) implemented few activities approved under the Global Fund Resilient and Sustainable Systems for Health (GF-RSSH) grant 2020. One of the activities implemented under the grant was quarterly assessment of pharmacovigilance systems in selected health facilities towards future active safety monitoring of new medicines used for HIV-AIDS, Tuberculosis and Malaria (ATM) interventions across the country. The main

objective of this exercise is to evaluate the level of participation of healthcare institutions across the country in the Pharmacovigilance system preparatory to monitoring drug safety problems of new molecules used in HIV-AIDS, Tuberculosis and Malaria in patients using the modified Indicator-Based PV Assessment Tools (I-PAT). The assessment continued in 2021 with support from the National Agency for the Control of AIDS (NACA) as Principal Recipient of Global Fund Resilient and Sustainable Systems for Health (GF-RSSH 2) grant for 2021-2023. During the period under review, there was a PV Assessment of Facilities in Twenty-four states of the federation and in each state, Ten (10) healthcare facilities were visited.

African Union Smart Safety Surveillance (AU 3S) Programme

The Head of Pharmacovigilance Division represents NAFDAC at the African Union Smart Safety Surveillance (AU 3S) Programme which is ongoing in four African Countries namely Nigeria, Ghana, Ethiopia and South Africa. The programme which is being coordinated by AUDA-NEPAD is focused on conducting safety surveillance for COVID-19 Vaccine introduction so that all safety concerns related to the use of the vaccine in country can be monitored, tracked and documented. The programme is hinged on the need for strengthened safety surveillance on the continent.

Olson demonstrated that drugs whose approval was fast-tracked were associated with higher numbers of ADRs. In addition, shorter U.S. launch lags and more novel drugs have also been found to be associated with a larger number of ADEs (Olson,2008). The COVID-19 pandemic and COVID-19 vaccines rollout, by their unprecedented nature and record timelines respectively, further point to the need for a more fulsome understanding of the safety of these products. The COVID-19 vaccines were ready for rollout less than a year after the COVID-19 outbreak started in January 2020, even though it usually takes several years to develop a vaccine. Due to urgency, regulators are shortening the time and path to market, notably through emergency use authorisations (EUAs), to enable the products to be made available in a timely manner. The scale of exposure of patients to the COVID-19 vaccines is unprecedented, since the objective is to vaccinate several billion people soon (African Union Development Agency – NEPAD, 2021). There is an inherent conflict between expedited drug approval (for life-saving drugs to reach the public) and assurance of drug safety which requires time to complete. The safety of new drugs cannot be fully ascertained until the drug has been marketed for many years (Chen et al, 2013).

Africa faces a unique context and specific challenges related to safety surveillance. Many African countries have constrained resources including financial, human, and technical. Particularly for National Regulatory Authorities (NRAs), there is often a lack of sustainable funding and a shortage of qualified staff and operational resources resulting in a limited PV capacity. Vaccine adverse event reporting has been historically low in Africa, and in fact, less than 1% of all Adverse Events Following immunisation (AEFIs) contained in the global database

(VigiBase) were generated in African countries. This is a major concern as the African population accounts for ~17% of the world's population and many large immunisation campaigns have been conducted on the continent. Within this small portion of African reports, >95% were generated by only 10 out of a total of 55 African countries (African Union Development Agency – NEPAD, 2021).

Report on Adverse Drug Reaction Case Reports received in 2020

During the period under review, the National Pharmacovigilance Centre (NPC) received Adverse Drug Reactions (ADR) reports from various stakeholders including patients, health care professionals, health institutions and Marketing Authorization Holders (MAHs) across the country. Individual case safety reports (ICSRs) were sent to the NPC via different sources; CIOMS, NPC ADR Forms, e-Reporting and Med Safety App. The reports, irrespective of the source, were transcribed and entered on VigiFlow which can further be transmitted to the VigiBase, the WHO International Drug Safety Monitoring Program database domiciled in Uppsala Monitoring Centre, Sweden after causality assessment. As of 31st December 2020, a total of Fifteen thousand, six hundred and eighty-six (15, 686) ICSRs/AEFIs were documented on the Vigiflow and as of 31st December 2021, a total of thirty-six thousand seven hundred and ninety-seven (36,797) ICSRs/AEFIs were documented on the Vigiflow. The reports received in 2021 from different reporting platforms are summarily presented as follows:

Report Source	Year 2021
Med Safety App	18,845
e-Reporting	223
CIOMs	996
NPC ADR forms	257
AEFI Forms	646

Table 1. Number of reports received in 2021

Monitoring of Covid-19 Vaccination Activities

Nationwide monitoring of COVID-19 Vaccination Activities was carried out from 17th to 26th March 2021 in respect of the roll out of the first dose of Covishield AstraZeneca vaccine. Deployment of pharmacovigilance officers to the field in all the States of the Federation for monitoring of safety of the COVID-19 Covishield vaccination during the 2nd dose roll out commenced on 25th May 2021. Staff were also deployed for monitoring in August/September 2021 in respect of roll out of Moderna COVID 19 vaccines.

The National Agency for food and drug administration and control (NAFDAC) in collaboration with the University of Maryland Baltimore (UMB) through funding from United States Centre for Disease Control and Prevention (US-CDC) is conducting a Cohort Event Monitoring (CEM) Evaluation following COVID-19 vaccination in selected tertiary health facilities and other high volume vaccination centers across the six geopolitical zones of

Nigeria. The CEM is a multi-regional prospective cohort evaluation that aims to monitor and ensure COVID-19 vaccine safety in the country. The preparatory activities for the CEM included a three-day tool development workshop and was followed immediately by a four-day training of trainers which held from 23rd to 25th and 26th to 29th August respectively in Nasarawa State. Subsequently, various teams were deployed to the zones to conduct step down trainings for proposed data entrants and follow-up clinicians from 1st to 4th September 2021, requisite to their deployment to selected facilities for the evaluation. Data collection for the CEM commenced on 9th September 2021. Consequently, staff of the Directorate, have been to the various sites for monthly monitoring/supervisory visits. Also, as part of the CEM activity, the weekly meetings are held with UMB and Site/Project coordinators, every Wednesday. The preliminary report of the CEM is being developed. As part of the CEM activity, staff of the Directorate participated in supervisory visits to the following Teaching hospitals: UNTH Enugu, UBTH Edo, ATBUTH Bauchi, LSUTH Lagos, ABUTH Zaria and UATH Gwagwalada. Currently, Causality Assessment of the AEFIs are ongoing.

Conclusion

The National Pharmacovigilance Centre (NPC) sustained its activities even in the face of the pandemic. An integral part of a medication's life cycle is the post market evaluation which ensures that a medication remains safe and effective after market approval. This makes it crucial for Adverse Drug Events experienced by patients to be promptly reported to the Pharmacovigilance centre so that we can take proper measures in response to the frequency and severity of these ADEs. Underreporting ADEs is a major challenge in the epidemiological track and tracing as it reduces our ability to accurately estimate morbidity and mortality rates; these all have impacts on vaccination strategies and other important clinical implications that rely on accurate epidemiology practices.

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