



PHARMACY AND MEDICINES REGULATORY AUTHORITY

Quality Medicines for Malawi

PROMOTION OF DIRECT REPORTING OF INDIVIDUAL CASE SAFETY REPORTS (ICSRs) BY PATIENTS USING MEDSAFE-360 USSD PLATFORM



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In reply please
refer to:

Your reference:

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Area 5
PO Box 30241
Lilongwe, 3
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22 March 2018

Dear Mr Kumpalume,

I have pleasure in informing you that the World Health Organization (WHO) Collaborating Centre for International Drug Monitoring has advised us that working relations have been established with the National Pharmacovigilance Centre, Malawi. We can thus confirm that Malawi is the 135th full member of the WHO Programme for International Drug Monitoring with immediate effect. WHO considers this Programme a vital network in promoting pharmacovigilance throughout the world. I confirm that you, as the designated contact person at the National Pharmacovigilance Centre, will continue to receive WHO relevant publications.



DATA IN VIGIFLOW

Number of case reports in VigiBase

1 043

Malawi

31 756 989

Globally

Versions

- Low reporting rates attributable to:
 - Reliance on one reporting tool (Paper based reporting)
 - Low patient involvement

PROPOSED WAY FORWARD

- Introduction of Medsafe-360
 - Alternative reporting tool
 - Direct patient reporting



MEDSAFE-360

- USD based platform
- Dial *360# to access
- It is free
- Available on TNM and Airtel
- In English and Chichewa (Local Language)
- Respond to questions – Mirror paper based form
- Able to continue where you left
- SMS feedback – Automated
- Takes 4 to 7 minutes to complete (typing speed and familiarity with USSD platforms)



DATA RECEIVED IN MEDSAFE-360 (June 2021 to May 2022)

Total Entries Reports = 22, 203

Complete = 509

Valid = 240



CHALLENGES

- Large number of incomplete reports
- Challenges in naming medicines and side effects

Way forward

- Pilot Study before country wide promotion
 - Evaluate usability of Medsafe-360 as a reporting tool and the efficiency of the promotion strategy

Study Objectives

- Understand the:
 - The feasibility of the strategy in promoting use of Medsafe-360 for direct ICSRs reporting by patients
 - Acceptability of the strategy in promoting use of Medsafe-360 for direct ICSR reporting by patients
 - How the promotion strategy modify barriers or enhance enablers of direct patient reporting.
 - Acceptability of Medsafe-360 as a tool for direct reporting of ICSRs by patients.
 - Comparability of the quality of data between the Medsafe-360 and the paper based report.



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THANK YOU

