World Health Organization

Review of product information for selected antiretroviral medicines circulating in five African countries

World Health Organization

Review of product information for selected antiretroviral medicines circulating in five African countries

Review of product information for selected antiretroviral medicines circulating in five African countries

ISBN 978-92-4-005088-4 (electronic version)
ISBN 978-92-4-005089-1 (print version)

Suggested citation. Review of product information for selected antiretroviral medicines circulating in five African countries. Geneva: World Health Organization; 2022. Licence: Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://apps.who.int/iris.

Layout by Harri Aittasalo / Acreativeproductions

Contents

1 Acknowledgements

The survey was organized by the Regulation and Safety (WHO REG) and Prequalification Units (WHO-PQT) of the World Health Organization, Regulation and Prequalification Department. The survey was developed by Mr Rutendo Kuwana of the Incidents and Substandard/Falsified medical products team (WHO ISF) with principal support from Mr Wondiyfraw Zeleke Worku (WHO PQTm) and Dr Regine Lehnert (External expert to WHO PQTm). The survey data collation and major evaluation was conducted by Dr Stephanie Buchholz (Independent expert) with assistance from Mrs Carol Gray (consultant) who provided editing services.

The survey was carried out by WHO in cooperation with the Ministries of Health and National Medicines Regulatory Authorities of Burkina Faso, Democratic Republic of the Congo, Nigeria, Rwanda and Zambia. WHO thanks these Ministries of Health and National Medicines Regulatory Authorities for their important cooperation and assistance. Acknowledgement is due to the country teams and to individuals who developed the national sampling plans and organized collection and dispatch of samples, in particular to:

Nerwaya Eve Ramata Ouedraogo, Responsible for the Post-marketing Quality Control of Health Products, Direction générale de la pharmacie du médicament et des laboratoires, Ministère de la Santé, Burkina Faso;

Paul Kombuma Ndobe, Inspector, Direction de la Pharmacie et du Médicament, Democratic Republic of the Congo;

Ibrahim Otulukpe Ali, Ag. Director, Pharmacovigilance & Post Marketing Surveillance, National Agency for Food Administration and Control, Nigeria;

Alex Gisagara, National Medicines Regulation Officer, Pharmaceutical Services of the Ministry of Health, Rwanda;

Felix P Chizu, Assistant Director, Inspection and Surveillance, Zambia Medicines Regulatory Authority, Zambia; and **Kelvin Mujelemani**, Inspector, Zambia Medicines Regulatory Authority, Zambia.

WHO also thanks staff members from WHO offices in participating countries and WHO regional office for Africa who provided invaluable assistance in preparing the survey in the various countries.

Thanks to the following staff of Ministries of Health and National Medicines Regulatory Authorities in the participating countries for their valuable cooperation during the results analysis and review meeting:

Professor Moji Christiana Adeyeye, Director General, National Agency for Food and Drug Control, Nigeria;

Kenneth Nkemakolam Onu, Principal Regulatory Officer, Technical Services/Baseline Study Project Office, National Agency for Food Administration and Control, Nigeria;

Alex Gisagara, National Medicines Regulation Officer, Pharmaceutical Services of the Ministry of Health, Rwanda; and

Makomani Siyanga, Inspection and Surveillance, Zambia Medicines Regulatory Authority, Zambia.

Thanks are also due to the following manufacturers who provided comments and representatives to the report review meeting:

- Cipla Ltd, Macleods Pharma Ltd, Micro Labs Ltd, Mylan Laboratories Ltd and Strides Shasun Ltd.

The survey has been organized and this document has been produced with the kind financial assistance of the Bill & Melinda Gates Foundation and UNITAID. The views expressed herein are those of the authors and can in no way be taken to reflect the official opinion of the Bill & Melinda Gates Foundation or UNITAID.

2 Abbreviations

3TC	Lamivudine
3TC/NVP/AZT	Lamivudine/nevirapine/zidovudine
3TC/AZT	Lamivudine/zidovudine
ART	antiretroviral treatment
ARV	antiretroviral
AZT	Zidovudine
BALD	Baker Able Leaflet Design
BNF	British National Formulary
CMIT	Le Collège des Universitaires des Maladies Infectieuses et Tropicales
Disp.	dispersible
EFV	Efavirenz
EFV/FTC/TDF	Efavirenz/emtricitabine/tenofovir disoproxil fumarate
EMA	European Medicines Agency
EML	Essential Medicines List
EPAR	European Public Assessment Report
EQIP	Ensuring Quality Information for Patients
FDC	fixed-dose combination
FTC	Emtricitabine
HIV	Human Immunodeficiency Virus
IP	Intellectual Property Watch
MOH	Ministry of Health
MSF	Medicines sans Frontiers
NRA	national regulatory authority
NVP	Nevirapine
OI	opportunistic infections
PAR	public assessment report
PEPFAR	President's Emergency Plan for AIDS Relief
PI	product information
PIL	patient information leaflet
PQ	prequalified
PQT	Prequalification Unit
PQTm	Prequalification Unit - medicines assessment team
QC	quality control
RSS	Regulatory Systems Strengthening Team
SmPC	summary of product characteristics
TDF	Tenofovir disoproxil fumarate
UN	United Nations
USAID	United States Agency for International Development
US FDA	United States Food and Drug Administration