



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

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)

© World Health Organization 2022

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization (<http://www.wipo.int/amc/en/mediation/rules/>).

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

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

Sales, rights and licensing. To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests for commercial use and queries on rights and licensing, see <https://www.who.int/copyright>.

Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

Layout by Harri Aittasalo / Acreativeproductions

Contents

1	Acknowledgements	v
2	Abbreviations	vi
3	Executive summary	vii
4	Introduction	1
5	Rationale for the survey	3
6	Scope of the survey	4
6.1	Objectives of the survey	4
7	Methodology	5
7.1	Main activities	5
7.2	Sample collection	5
7.3	Review of product information	5
7.3.1	Review of product information for the healthcare provider	5
7.3.2	Review of product information for the patient	6
7.4	Evaluation of the format of the product information	6
7.5	Evaluation of the readability, layout and design of patient information leaflets	6
7.5.1	Evaluation tool: EQIP Score	6
7.5.2	Baker Able Leaflet Design (BALD) criteria	7
7.6	Evaluation questionnaire on healthcare providers' awareness, perceptions of quality and use of WHOPARs	7
7.7	Evaluation questionnaire on the acceptance of dispersible tablets for paediatrics	8
8	Results	9
8.1	Overview of the samples collected	9
8.2	Compliance of product information with WHOPAR or Innovator PI	10
8.2.1	Sample eligibility	10
8.2.2	Overall compliance with published WHOPAR information	11
8.2.4	Compliance of medical information in provided SmPCs with WHOPAR SmPCs	13
8.2.5	Collected samples' format compliance with WHOPAR format	15
8.2.6	Compliance of medical information in provided PIL with WHOPAR PIL	17
8.3	Quality, readability, layout and design of the PILs	20
8.3.1	Sample eligibility	20
8.3.2	Language	20
8.3.3	Readability of the PILs	20
8.3.4	Baker Able Leaflet Design (BALD) assessment of the PILs	20
8.3.5	Ensuring Quality Information for Patients (EQIP) evaluation of PILs	21
8.4	Evaluation of the awareness, usage and perceived value of WHO PQTm-website and WHOPARs among healthcare providers in the surveyed African countries	23
8.4.1	Experiences of healthcare professionals in the surveyed countries in accessing PQTm-website product information (WHOPARs) and ARV product information	23
8.4.2	Awareness and use of WHOPARs	23
8.4.3	Review by healthcare providers of the quality of product information	25
8.4.4	Review by healthcare providers of the quality of PILs	25
8.4.5	Dispensing staff	25
8.5	Evaluation of acceptance levels of selected dispersible paediatric ARV products in the surveyed African countries	27
8.5.1	Healthcare providers' experience relating to acceptance levels of selected dispersible paediatric tablets in the surveyed countries	27
8.5.2	Complaints about taste, flavour, sweetness or bitterness	27

9 Discussion	28
9.1 Objectives, achievements and limitations of the study	28
9.1.1 Objectives	28
9.1.2 Strengths and limitations of methodology	28
9.2 Overall findings	29
9.3 Objective 1: Evaluation of the compliance of sampled product information with WHO norms, standards and approved PQT information	29
9.3.1 Overall compliance of collected ARV products with WHOPARs	29
9.3.2 Overall manufacturer compliance with WHOPAR or innovator information	29
9.3.3 Overall country compliance with WHOPARs	30
9.3.4 Overall product compliance with WHOPARs	30
9.3.5 Compliance of SmPC medical content with WHOPAR SmPC	30
9.3.6 Compliance of PIL medical content with WHOPAR PIL	31
9.3.7 Overall format compliance with WHOPARs and layout and design of the evaluated ARV product information	31
9.4 Objective 2: Evaluation of the readability, format, layout and design of the collected PILs	32
9.4.1 Manufacturer practice of providing a PIL	32
9.4.2 Language	32
9.4.3 Readability of the evaluated PILs	32
9.4.4 Format of the evaluated PILs	32
9.4.5 BALD criteria of the evaluated PILs	32
9.4.6 EQIP score of the evaluated PILs	32
9.5 Objective 3: Evaluation of the value of PQTm-website product information (WHOPARs) and ARV product information for healthcare providers in the surveyed African countries	33
9.5.1 Review by healthcare providers of the SmPCs of market ARV products	33
9.5.2 Review by healthcare providers of the PIL of market ARV products	33
9.6 Objective 3: Evaluation of the acceptance of selected ARV paediatric dispersible tablets in the surveyed African countries	34
9.7 Comments from surveyed countries	34
9.8 Comments from manufacturers	35
9.9 Comments from WHO	35
10 Proposals for WHO-PQTm on future improvements	37
10.1 Improvement of WHOPAR compliance	37
10.1.1 Consultation with manufacturers	37
10.1.2 Consultation with and involvement of NRAs	37
10.2 Improvement of WHOPAR awareness and usage	37
10.3 Improvements to the readability, quality of information, structure and layout of the PILs	37
10.4 Avoidance of stigmatisation	37
10.5 Product-related PI improvements	38
10.6 WHOPAR and PQTm-related recommendations	38
11 Conclusions	39
12 References	40
13 Annexes	42
13.1 Annex 1: Questionnaire WHOPAR	42
13.2 Annex 2: Questionnaire on acceptance levels of dispersible tablets	45
13.3 Annex 3: BALD scores of the evaluated 28 PILs	47
13.4 Annex 4: Individual EQIP scores of the 28 evaluated PILs	48
List of tables	49
List of figures	50

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 PQM) and Dr Regine Lehnert (External expert to WHO PQM). 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

预览已结束，完整报告链接和二维码如下：

https://www.yunbaogao.cn/report/index/report?reportId=5_31279

