



The Status of Labelling Harmonization - ECOWAS

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Introduction

- The Economic Community of West African States (ECOWAS) was formed in **May, 1975**. It is made up of Fifteen (15) member countries - Benin, Burkina Faso, Cape Verde, Cote d' Ivoire, The Gambia, Ghana, Guinea, Guinea Bissau, Liberia, Mali, Niger, Nigeria, Sierra Leone, Senegal and Togo.
- In 1987, West African Health Organization (WAHO) was formed when the Heads of State and Government from all fifteen (15) countries in the ECOWAS adopted the protocol in creating the organization.



Introduction – cont.

- **Objective** 'WAHO shall be the attainment of the highest possible standard and protection of health of the people in the region through the harmonisation of the policies of the Member States, pooling of resources, and cooperation with one another and with others for a collective and strategic combat against the health problems of the sub-region.'
- In 2010 WAHO started the development of the Common Technical Document (CTD) on Medicines Registration Harmonization for ECOWAS and it's draft validated in December 2016. **1st Joint Assessment was in June 2018.**



Introduction – cont.



- **Western Africa Population - 429,079,551 (World Population, 2022)**



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General Requirement for Submission (Joint Evaluation)



All applications shall be submitted in **English language**



Documentation must be submitted in the CTD format (standardised Module 2-5)



Module 1 – contains the following;

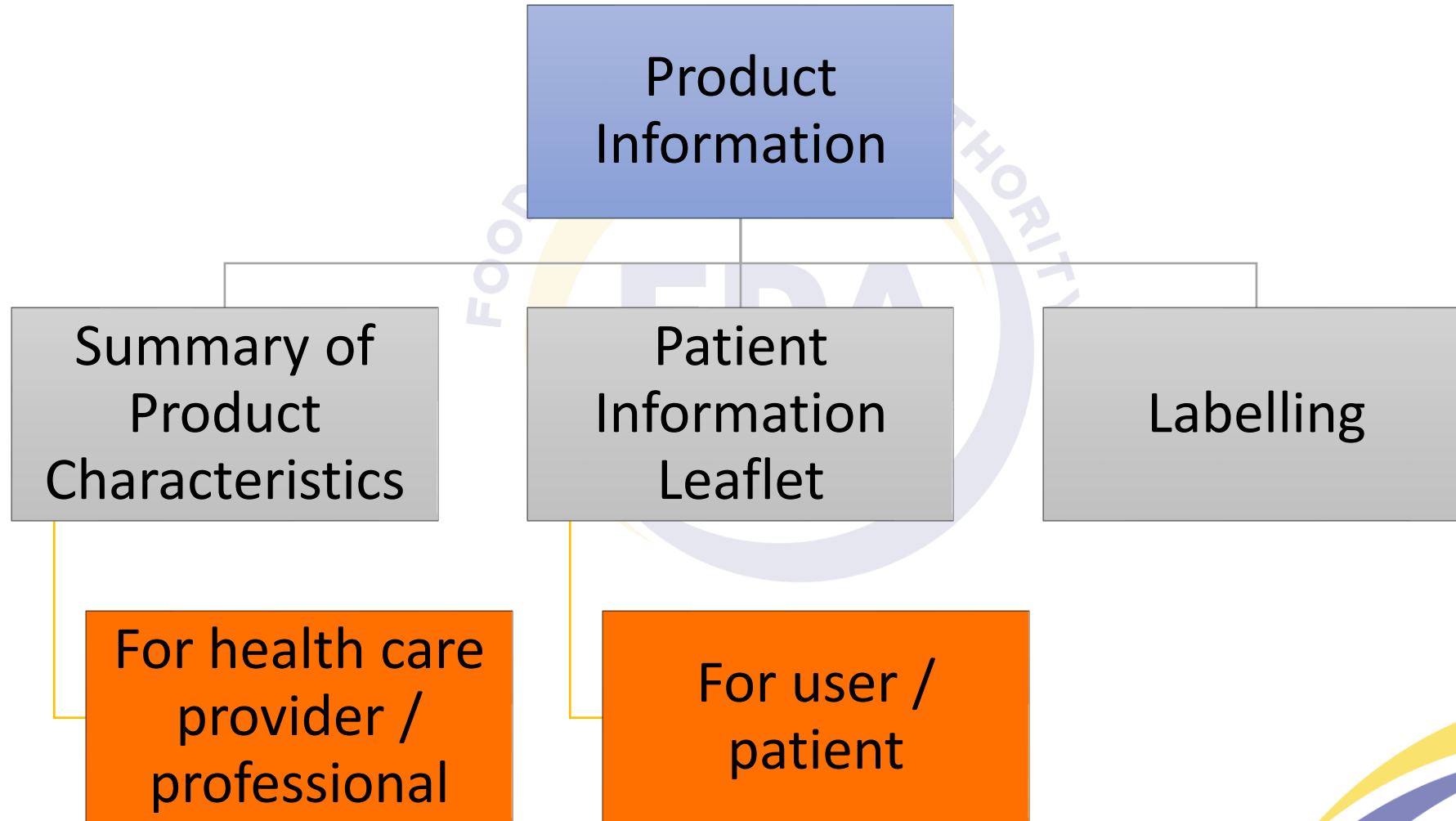
- 1.0 Table of content Modules 1 to 5
- 1.1 Correspondence
- 1.2 Administrative Information

1.3 Product information

- 1.4 Regional Summaries
- 1.5 Electronic Documents



1.3 Product Information Format and content





1.3 Product Information

- The content of the Summary Product Characteristics (SmPC), labels and Patient Information Leaflet (PIL) shall be submitted in **all the three** official languages in the region
 - English
 - French
 - Portuguese.
- The technical content and presentation of the SmPC and PIL are the same for all three languages
- With regards to the product labelling, some differences in the requirement currently exist between requirement for the Francophone countries and the other countries.



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The benefits of harmonizing labelling across the region

- It saves cost and time to the applicant since the same product information is required by all 15 countries
- Reduces duplication of work and time used to assess product labels
- Helps to identify counterfeiting or sub-standard products on the market
- Consistency of products information on labels across the subregion



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The challenges that regulators face to arrive at a harmonized label

- Some regulators (Francophones) do not accept some labels of products that are classified as Over-the Counter Medicines to have of pictorial diagrams (no pictures of mosquitoes on antimalarial medications)
- However, other countries within the region accept these diagrams for OTC medicines
- Thus, requirements are not harmonized for certain product labels



Progress being made in the ECOWAS region with respect to harmonizing labelling

- There are currently harmonized requirements for SmPC and PILs
- Templates have been developed and published by WAHO to guide all applicants
- The current templates follow the pattern of that of WHO and EMA which makes it's adoption by applicant easy and friendly



Progress being made in the ECOWAS region with respect to harmonizing labelling

- Adoption of the developed ECOWAS CTD format dossier is ongoing within the member countries.
- Training of the dossier assessors on the current regulatory requirements (eg. Product information) are ongoing
- WAHO is engaging the Francophone Countries on the need for harmonizing product labels



Conclusion

Countries within the sub-region recognize the importance for harmonizing production information across the region.

Efforts have been made over the years to harmonize the content for PILs, SMPC and labels

Guidelines and templates published by WAHO are being adopted by countries across the region

There are still more work to be done especially regarding product labels

Training for the regulators within the region to ensure effective implementation of the harmonized requirements is essential



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Thank you



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