Medicines Control Authority of Zimbabwe

The status of labelling harmonisation in SADC

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Outline

- Labelling requirements in Zimbabwe
- Benefits of harmonized labelling in SADC
- Progress towards harmonized labelling
- Challenges regulators face to arrive at a harmonized label

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https://www.resourcelabel.com/resources/demand-these-6-things-from-your-pharmaceutical-label-supplier

Labelling requirements in Zimbabwe

- Requirements are stated in the Medicines and Allied Substances Control (General) Regulations
- Section 37 state requirements for labels and section 38 state the requirements for package inserts
- MCAZ guideline on submission of generic medicines also explains the labelling requirements

Zimbabwe specific requirements

- Generic name should be more prominent than the trade name on labels
- Inclusion of registration number
- Inclusion of category for distribution
- Name and address of manufacturer on product information
- Pharmacological classification on package insert vs ATC

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Benefits of harmonised labelling

- Improve patient access to medicines
- Improve affordability of medicines
- Use of reliance/harmonised regulatory assessment procedures in product information assessment

Labelling harmonisation in SADC

- Guidelines developed through Zazibona
- A TWG which included representatives from the different NRAs in SADC produced the first draft in March 2018
- The guideline was circulated by NRA to their stakeholders and by Zazibona to different stakeholder associations
- Physical meeting with stakeholders
- Final draft as at February 2020

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GUIDELINE ON PRODUCT INFORMATION AND LABELLING

Version 0: Initial draft produced by the NMRA Technical Working Group	March 2018
Version 1: Draft incorporating Stakeholder comments	June 2018
Version 2: Draft incorporating Stakeholder comments	November 2018
Version 3: Draft produced incorporating Stakeholder comments	March 2019
Version 4: Draft produced incorporating SADC Regulators Forum comments	June 2019
Version 5: Draft produced incorporating Stakeholders comments	September 2019 December 2019
Version 6: Final Draft	February 2020

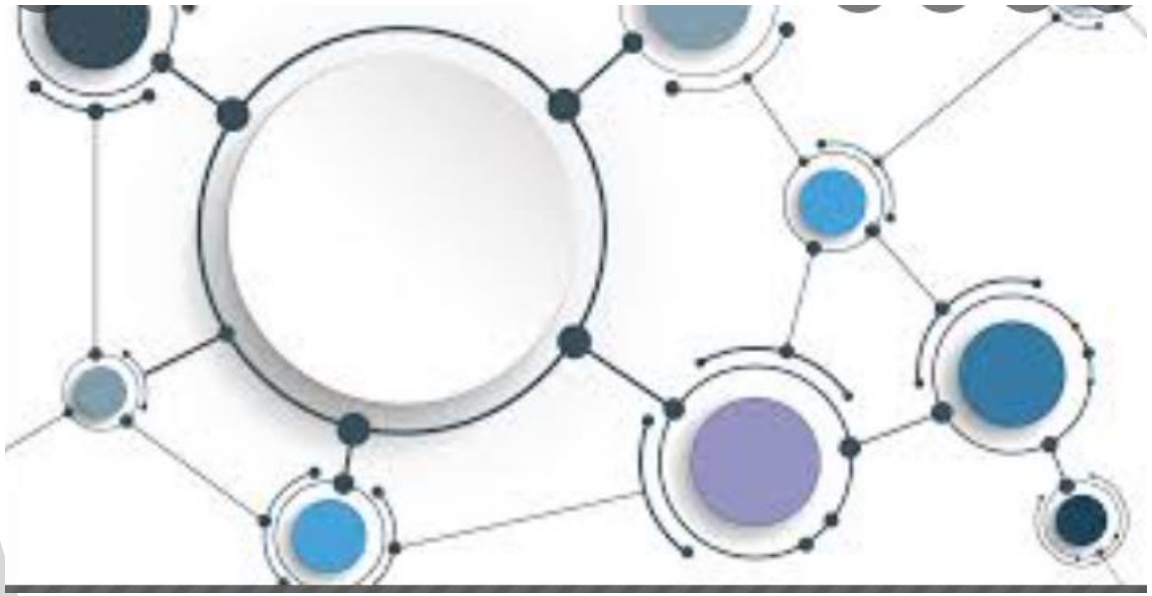
SOUTHERN AFRICAN DEVELOPMENT COMMUNITY

GUIDELINE ON EXCIPIENTS IN THE LABELLING, SUMMARY OF PRODUCT CHARACTERISTICS AND PATIENT INFORMATION LEAFLET OF MEDICINAL PRODUCTS FOR HUMAN USE

Version 0: Initial draft produced by the NMRA Technical Working Group	September 2019
Version 1: Final Draft	February 2020

Structure of the Guideline on Product Information and Labelling

- Dissemination and Accessibility of Product Information
- Summary of Product Characteristics
- Patient Information Leaflet
- Product Labelling



https://martech.org/marketing-operations-2-0-defining-new-organizational-structure/

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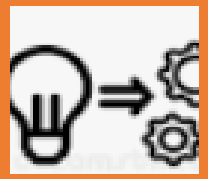
Next Steps



Zazibona to ascertain the level of implementation of the guideline by the SADC NRAs.

Proposed meeting with stakeholders

Goal _ harmonised labelling requirements in the SADC region

Challenges faced by SADC

http://motivive.com/2019/08/12/challenges-a-fun-way-to-complete-daily-tasks/

- Harmonisation of country specific requirements
- a. Pharmacological classification
- b. Category for distribution/scheduling
- c. Registration number
- Differences in maturity levels of regulatory authorities
- Differences in social and economic status of different countries
- Legislation

"One part at a time, one day at a time, we can accomplish any goal we set for ourselves"-— Karen Casey

Questions

https://www.goconqr.com/es/p/15878979?for_copy=true

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