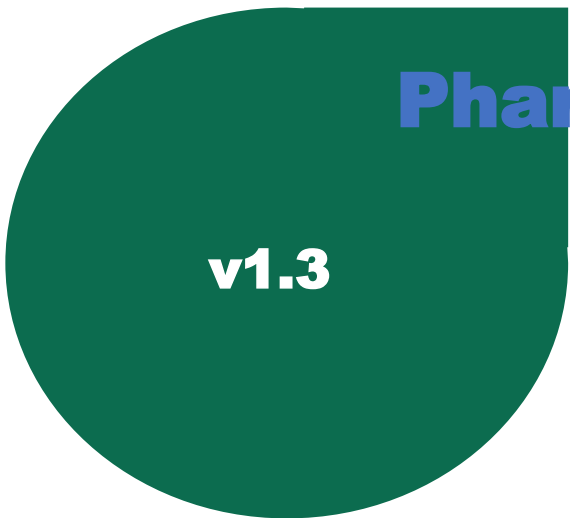
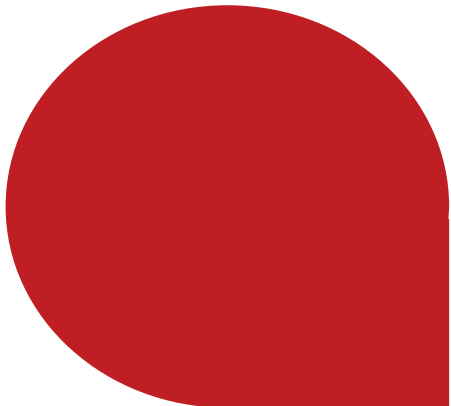




OHSC

Office of Health Standards Compliance
Ensuring quality and safety in health care



Pharmacy / Dispensary

v1.3

Regulatory CHC inspection tool

Facility:
Date:

- **Tool Name:** Regulatory CHC Inspection tool v1.3 - Final
- **HEs Type:** CHC **Sector:** Public
- **Specialization:** CHC
- **Created By:** Health Standards Development and Training

2 Pharmacy / Dispensary

Domain 2.1 USER RIGHTS

Sub Domain 2.1.1 4 User information

Standard 2.1.1.1 4(1) The health establishment must ensure that users are provided with adequate information about the health care services available at the health establishment and information about accessing those services.

Criterion 2.1.1.1.1 4(2)(a)(ii) The health establishment must provide users with information relating to service opening and closing times.

2.1.1.1.1.1 Legible signage at the entrance to the unit indicates the days and times when services are offered.

Assessment type: Observation - **Risk rating:** Essential measure

The opening and closing times must be displayed on a board or electronic screen at the entrance of the unit. All internal signs must as a minimum be laminated. Text on signs must be typed, no handwritten signs will be accepted. Signs do not need to be framed, but laminating must be in good condition with no turned corners or peeling. If frames are not used, posters must be neatly fastened to the wall.

Not applicable: Never

Score	Comment

Sub Domain 2.1.2 5 Access to care

Standard 2.1.2.1 5(1) The health establishment must ensure that users are attended to in a manner which is consistent with the nature and severity of their health condition.

Criterion 2.1.2.1.1 5(2)(a) The health establishment must implement a system of triage.

2.1.2.1.1.1 The process to fast-track very sick, frail and elderly users to the front of the queue is implemented.

Assessment type: Observation - **Risk rating:** Essential measure

It must be evident from observing the activities in the waiting area that there is a process of assessing and determining the order in which users should be seen, based on their need for care. The criteria used for this process must be explicitly stated either in a written or verbal manner to users. Evidence of adherence to these criteria must be observed by inspectors.

Not applicable: Where there were no very sick, frail and elderly care users during the time of inspection.

Score	Comment

Domain 2.2 CLINICAL GOVERNANCE AND CLINICAL CARE

Sub Domain 2.2.1 6 User health records and management

Standard 2.2.1.1 6(1) The health establishment must ensure that health records of health care users are protected, managed and kept confidential in line with section 14, 15 and 17 of the Act.

Criterion 2.2.1.1.1 6(2)(b) The health establishment must ensure confidentiality of health records.

2.2.1.1.1.1 There is a 'No unauthorised entry' sign on the door of the pharmacy/dispensary.

Assessment type: Observation - **Risk rating:** Essential measure

Check if there is a sign that reads 'No unauthorised entry' on the pharmacy/dispensary door. All internal signs must as a minimum be laminated. Text on signs must be typed, no handwritten signs will be accepted. Signs do not need to be framed, but laminating must be in good condition with no turned corners or peeling. If frames are not used, posters must be neatly fastened to the wall. Any other sign, e.g., 'Staff only', will be scored non-compliant.

Not applicable: Never

Score	Comment

2.2.1.1.1.2 Access to the pharmacy/dispensary is controlled at all times.

Assessment type: Observation - **Risk rating:** Vital measure

The pharmacy/dispensary should have a lockable security gate or access-controlled door that only the pharmacy/dispensary personnel have access to. Those holding the keys/access cards/ access codes must keep it with them at all times and never leave it unattended.

Not applicable: Never

Score	Comment

Sub Domain 2.2.2 7 Clinical management

Standard 2.2.2.1 7(1) The health establishment must establish and maintain clinical management systems, structures and procedures that give effect to national policies and guidelines.

Criterion 2.2.2.1.1 7(2)(b) The health establishment must establish and maintain systems, structures and programmes to manage clinical risks.

2.2.2.1.1.1 Users are informed about their medicines.

Assessment type: Patient interview - **Risk rating:** Vital measure

Interview three users who have received medicines and verify whether they have been informed about the aspects listed. Score 1 if user was informed and 0 if not informed.

Score	Comment

Unit 1 User 1

Aspects	Score	Comment
1. The user is informed about what each medicine is for.		

2. The user is informed when to take the medicine.		
3. The user is informed whether to take the medicine with or without food.		
4. The user is informed about the most common side-effects they could expect from the medicine.		
5. The user is provided with an opportunity to ask any questions or discuss anything that worries them about their medicine.		

Unit 2 User 2

Aspects	Score	Comment
1. The user is informed about what each medicine is for.		
2. The user is informed when to take the medicine.		
3. The user is informed whether to take the medicine with or without food.		
4. The user is informed about the most common side-effects they could expect from the medicine.		
5. The user is provided with an opportunity to ask any questions or discuss anything that worries them about their medicine.		

Unit 3 User 3

Aspects	Score	Comment
1. The user is informed about what each medicine is for.		
2. The user is informed when to take the medicine.		
3. The user is informed whether to take the medicine with or without food.		
4. The user is informed about the most common side-effects they could expect from the medicine.		
5. The user is provided with an opportunity to ask any questions or discuss anything that worries them about their medicine.		

2.2.2.1.1.2 The licence for the pharmacy issued by the Director-General of the National Department of Health (NDoH) is available.

Assessment type: Document - **Risk rating:** Vital measure

This will promote user safety by ensuring that the unit meets all legal requirements. The licence issued by the Director-General of NDoH must be available and displayed. For a dispensary a copy of the Pharmacy license the dispensary is linked with must be available.

Not applicable: Never

Score	Comment

2.2.2.1.1.3 The current certificate of recording of a pharmacy or dispensary with the South African Pharmacy Council is displayed.

Assessment type: Document - **Risk rating:** Vital measure

The current certificate of registration of the health establishment's pharmacy with the South African Pharmacy Council displayed in the pharmacy.

Not applicable: To pre-May 2003 pharmacies. *Pre-May 2003 Pharmacies refers to all Pharmacies that were registered with SAPC on or before this date and they are deemed to be licensed* Reference: South African Pharmacy Council: Pharmacy Inspections and Guide to Compliance.

Score	Comment

2.2.2.1.1.4 The current certificate of registration of the responsible pharmacist for the health establishment with the South African Pharmacy Council is available.

Assessment type: Document - **Risk rating:** Vital measure

A pharmacy managed by a qualified and registered person will promote the safety of users and staff, as the pharmacy will be supervised by a skilled and knowledgeable person. The current certificate of registration with the South African Pharmacy Council of the responsible pharmacist must be visibly displayed in the pharmacy. For a dispensary a current copy of the responsible pharmacist certificate the dispensary is linked with must be available.

Not applicable: Never

Score	Comment

2.2.2.1.1.5 Proof of registration with the South African Pharmacy Council for pharmacist(s) and pharmacist assistant(s) is available.

Assessment type: Document - **Risk rating:** Vital measure

The current certificate of registration with the South African Pharmacy Council of all pharmacist(s), pharmacist's assistant(s) must be available.

Not applicable: Never

Score	Comment

Standard 2.2.2.2 7(2) (b) A health establishment must establish and maintain systems, structures and programmes to manage clinical risk.

Criterion 2.2.2.2.1 7 The health establishment implements process to ensure environmental cleanliness.

2.2.2.2.1.1 The pharmacy/dispensary is observed to be clean.

Assessment type: Observation - **Risk rating:** Vital measure

Inspector to observe general cleanliness in all areas of the pharmacy/dispensary. Cleanliness could include but not limited to whether the area is free of dirt and dust.

Score	Comment

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Criterion 2.2.2.2.2 7 Practices for dispensing medicines must comply with the Pharmacy Act 53 of 1974, the Medicines and Related Substances Act 101 of 1965 and relevant regulations.

2.2.2.2.2.1 Medicines dispensed for users are labelled in accordance with applicable legislation.

Assessment type: Observation - **Risk rating:** Vital measure

Request permission from three users to assess the medicine that has been dispensed to them on day of the inspection. Check if medicine dispensed complies with the requirements below. Score 1 if the aspect is compliant and 0 if it is not compliant.

Score	Comment

Unit 1 User 1

Aspects	Score	Comment
1. The labels of dispensed medicines are clear and legible		
2. The label affixed to the medicine does not obstruct or cover the expiry date		
3. The label affixed to the medicine contains the name of the user		
4. The label affixed to the medicine contains the name of the medicine		
5. The label affixed to the medicine contains the dosage of medicine		
6. The label affixed to the medicine contains the route of administration.		
7. The label affixed to medicine contains the name and address of the health establishment where the medicine was dispensed.		
8. The label affixed to the medicine contains the date of dispensing.		
9. Reference number or prescription number (where applicable).		
10. Cautionary or advisory or instructions labels (where appropriate)		

Unit 2 User 2

Aspects	Score	Comment
1. The labels of dispensed medicines are clear and legible		
2. The label affixed to the medicine does not obstruct or cover the expiry date		

3. The label affixed to the medicine contains the name of the user		
4. The label affixed to the medicine contains the name of the medicine		
5. The label affixed to the medicine contains the dosage of medicine		
6. The label affixed to the medicine contains the route of administration.		
7. The label affixed to medicine contains the name and address of the health establishment where the medicine was dispensed.		
8. The label affixed to the medicine contains the date of dispensing.		
9. Reference number or prescription number (where applicable).		
10. Cautionary or advisory or instructions labels (where appropriate)		

Unit 3 User 3

Aspects	Score	Comment
1. The labels of dispensed medicines are clear and legible		
2. The label affixed to the medicine does not obstruct or cover the expiry date		
3. The label affixed to the medicine contains the name of the user		
4. The label affixed to the medicine contains the name of the medicine		
5. The label affixed to the medicine contains the dosage of medicine		
6. The label affixed to the medicine contains the route of administration.		
7. The label affixed to medicine contains the name and address of the health establishment where the medicine was dispensed.		
8. The label affixed to the medicine contains the date of dispensing.		
9. Reference number or prescription number (where applicable).		
10. Cautionary or advisory or instructions labels (where appropriate)		

Sub Domain 2.2.3 8 Infection prevention and control programmes

Standard 2.2.3.1 8(1) The health establishment must maintain an environment, which minimises the risk of disease outbreaks, the transmission of infection to users, health care personnel and visitors.

Criterion 2.2.3.1.1 8(2)(a) The health establishment must ensure that there are hand washing facilities in every service area.

2.2.3.1.1.1 Hand washing facilities are available.

Assessment type: Observation - **Risk rating:** Vital measure

Use the checklist below to check whether the items listed below are available. Score 1 if the aspect is available and 0 if it is not available.

Score	Comment	
Aspects	Score	Comment
1. Functional hand wash basin. Explanatory note: The basin should not be blocked, broken, or have cracks.		
2. Taps are functional and not broken.		
3. Plain liquid soap		
4. Wall mounted soap dispenser		
5. Paper towel dispenser with disposable hand paper towels.		
6. General waste container. Explanatory note: This could be a wall mounted or a disposable or reusable vessel placed at the point of waste generation for the purpose of receiving waste. It may include but not limited to a bin, bucket, box, etc. The container must be lined with the appropriate colour coded liner.		

2.2.3.1.1.2 Alcohol based hand rub is available.

Assessment type: Observation - **Risk rating:** Vital measure

Observe whether alcohol-based hand rub is available in the service areas.

Not applicable: Never

Score	Comment

2.2.3.1.1.3 Posters on hand hygiene are displayed.

Assessment type: Observation - **Risk rating:** Essential measure

Observe whether posters on hand hygiene are displayed. This could be a single hand hygiene poster or individual posters for hand washing or correct use of alcohol-based hand rub.

Not applicable: Never

Score	Comment

Sub Domain 2.2.4 9 Waste management

Standard 2.2.4.1 9(1) The health establishment must ensure that waste is handled, stored, and disposed of safely in accordance with the law.

Criterion 2.2.4.1.1 9(2)(a) The health establishment must have appropriate waste containers at the point of waste generation.

2.2.4.1.1.1 Appropriate containers for disposal of pharmaceutical waste are available.

Assessment type: Observation - **Risk rating:** Vital measure

A dark green container marked with the words 'Pharmaceutical waste liquid or solid' must be available in the pharmacy or dispensary.

Not applicable: Never

Score	Comment

Criterion 2.2.4.1.2 9(2)(b) The health establishment must implement procedures for the collection, handling, storage and disposal of waste.

2.2.4.1.2.1 Waste is segregated as required by the waste management practices.

Assessment type: Observation - **Risk rating:** Essential measure

Use the checklist below to check if waste is segregated as required by the waste management practices stipulated in the National Environmental Health Norms and Standards. Score 1 if the aspect is compliant and 0 if it is not compliant.

Score	Comment	
Aspects	Score	Comment
1. General waste is discarded separately in a black or white or transparent plastic bag		
2. Pharmaceutical waste is discarded separately in a green container		

2.2.4.1.2.2 Sharps are safely managed and discarded in the pharmacy or dispensary.

Assessment type: Observation - **Risk rating:** Vital measure

Use the checklist below to check whether sharps are safely managed and discarded. Score 1 if the aspect is compliant and 0 if it is not compliant.

Score	Comment	
Aspects	Score	Comment
1. Waste is properly segregated Explanatory note: Only sharps and vials are discarded into the container; no other waste is observed in the container.		

2. Sharps containers are discarded when they reach the limit mark		
3. Sharps containers are placed on a work surface or in wall mounted brackets		
4. Sharps containers have correctly fitting lids		
5. Needles are not recapped before disposal		
Explanatory note: This is not applicable for safety needles and syringes		

2.2.4.1.2.3 Expired or obsolete medicine is discarded according to prescribed procedures.

Assessment type: Observation - **Risk rating:** Vital measure

Observe if the health establishment complies with the procedure for discarding expired or obsolete medicine. Score 1 if the aspect is compliant and 0 if it is not compliant.

Score	Comment	
Aspects	Score	Comment
1. Expired or obsolete medicine is put in a dark green container marked with the words 'Pharmaceutical waste liquid or solid'		
2. The required documentation is attached to the container or available on request. Explanatory note: This includes but is not limited to the name of the health establishment, the date, expired or obsolete medicine, strength, dosage form, quantity, expiry date for expired items and signature of the responsible person.		

Domain 2.3 CLINICAL SUPPORT SERVICES

Sub Domain 2.3.1 10 Medicines and medical supplies

Standard 2.3.1.1 10(1) The health establishment must comply with the provisions of the Pharmacy Act, 1974 and the Medicines and Related Substances Act, 1965.

Criterion 2.3.1.1.1 10(2)(a) The health establishment must implement and maintain a stock control system for medicine and medical supplies.

2.3.1.1.1.1 The electronic network system for monitoring the availability of medicines is used effectively.

Assessment type: Observation - **Risk rating:** Essential measure

Use the checklist to check whether the electronic network system for monitoring the availability of medicines is used effectively. The electronic systems can include but are not limited to Stock Visibility System (SVS), RX Solutions and JAC. To determine whether the health establishment has reported the availability of medicines as required, visit the website used to view captured medicine availability data, and the Primary Health Care Health Establishment Dashboard associated with it. Score 1 if the aspect is compliant and score 0 if it is not compliant.

Score	Comment	
Aspects	Score	Comment

1. The health establishment has a functional electronic network system for monitoring the availability of medicines		
2. The approved list of medicines to be updated is visible in the electronic network system		
3. The capturing device and accessories are in working order		
4. The capturing device is stored in a lockable unit (only applicable to SVS)		
5. Accessories for the device, i.e., batteries and charger, are stored in a lockable unit (only applicable to SVS)		
6. In the last seven working days or more this health establishment has not been marked as non-reporting at the point of assessment. Explanatory note: The source for the information will be the website used to view the availability of captured medicine data and the associated Primary Health Care health establishment dashboard. The SVS cell phone will show last reporting date (only applicable to SVS).		

2.3.1.1.1.2 Re-ordering stock levels (minimum/maximum and/or reorder levels) are determined for each item.

Assessment type: Document - **Risk rating:** Vital measure

Randomly sample five items held as stock and verify whether minimum, maximum and/or reorder levels are documented. The levels must be recorded on the bin cards or equivalent. The system may be manual or electronic. Score 1 if compliant and 0 if not compliant.

Score	Comment	
Aspects	Score	Comment
1. Item 1		
2. Item 2		
3. Item 3		
4. Item 4		
5. Item 5		

2.3.1.1.1.3 Stock take of medicine was done in the last 12 months.

Assessment type: Document - **Risk rating:** Vital measure

Documented evidence of a formal stock take will be required, i.e., a report indicating that the stock take has been completed in the last 12 months. Report should detail amongst others-expired medicine and its monetary value.

Not applicable: Never

Score	Comment

2.3.1.1.1.4 Schedule 6 medicines in stock correspond with the balance recorded in the register.

Assessment type: Observation - **Risk rating:** Vital measure

Select three medicines from the schedule 6 medicine cupboard and verify whether the quantity available corresponds with the balance recorded in the register. Score 1 if there is correspondence 0 if not.

Score	Comment		
Aspects	Score	Comment	
1. Medicine 1			
2. Medicine 2			
3. Medicine 3			

2.3.1.1.1.5 The register for Schedule 6 medicines is completed correctly.

Assessment type: Document - **Risk rating:** Vital measure

Accurate, comprehensive recording of dispensing of Schedule 6 medicines is a legal requirement and must be done in accordance with the applicable legislation. All columns in the registers must be comprehensively completed. Any omitted information noted during the review of the register will result in a non-compliant score. The inspector must confirm that all sections of the register have been completed correctly. If any of the columns have not been completed, this measure will be scored 0.

Not applicable: Where schedule 6 medicines are not held at the health establishment.

Score	Comment		

Criterion 2.3.1.1.2 10(2)(b) The health establishment must ensure the availability of medicines and medical supplies for the delivery of services.

2.3.1.1.2.1 Medicines on the current national tracer medicine list is available.

Assessment type: Observation - **Risk rating:** Vital measure

Request the current national tracer medicine list and randomly sample 3 items from each category/group of medicine listed below. Check whether the selected items are available and not expired. Score 0 if the selected item is not available or expired or if there is no tracer medicine list available. Sampled items to be recorded in the comment section. Should medicines be out of stock, substitutions will only be accepted if documented evidence of the recommended substitute from the district pharmacist is available. Alternatively, where tracer medicine list recommends several medicines as equivalent for treatment, substitutions from this list of recommended medicines will be acceptable without a letter from the district pharmacist.

Score	Comment		
Aspects	Score	Comment	
Antibiotics			
1. Sampled medicine 1			

2. Sampled medicine 2		
3. Sampled medicine 3		
Analgesic		
4. Sampled medicine 1		
5. Sampled medicine 2		
6. Sampled medicine 3		
Gastrointestinal		
7. Sampled medicine 1		
8. Sampled medicine 2		

9. Sampled medicine 3		
TB medicines		
10. Sampled medicine 1		
11. Sampled medicine 2		
12. Sampled medicine 3		
Antiretrovirals		
13. Sampled medicine 1		
14. Sampled medicine 2		
15. Sampled medicine 3		
Medicine for Non-Communicable Diseases (e.g., Diabetes, Hypertension)		
16. Sampled medicine 1		
17. Sampled medicine 2		
18. Sampled medicine 3		
Emergency medicine (e.g., Adrenaline)		
19. Sampled medicine 1		
20. Sampled medicine 2		
21. Sampled medicine 3		
Topical treatments		
22. Sampled medicine 1		

23. Sampled medicine 2		
24. Sampled medicine 3		
Contraceptives		
25. Sampled medicine 1		
26. Sampled medicine 2		
27. Sampled medicine 3		
Vaccines		
28. Sampled medicine 1		
29. Sampled medicine 2		
30. Sampled medicine 3		

2.3.1.1.2.2 The temperature of the pharmacy or dispensary is maintained within the safety range.

Assessment type: Document - **Risk rating:** Vital measure

Use the checklist below to check whether the temperature in the pharmacy/dispensary is maintained between 15 and 25 degrees Celsius. Score 1 if the aspect is compliant and 0 if it is not compliant.

Score	Comment	
Aspects	Score	Comment
1. The temperature of the pharmacy or dispensary is recorded daily. Explanatory note: This is to assess if the health establishment consistently monitors the room temperature. Request temperature monitoring sheets from the previous three months.		
2. The temperature of the pharmacy/dispensary is maintained between 15 and 25 degrees Celsius		

2.3.1.1.2.3 Procedures to maintain the cold chain for vaccines are implemented.

Assessment type: Observation - **Risk rating:** Vital measure

Use the checklist below to check whether the cold chain for vaccines is maintained. Score 1 if compliant with the aspect below and score 0 if not compliant.

Score	Comment	
Aspects	Score	Comment

1. The pharmacy or dispensary has a vaccine or medicine refrigerator with a thermometer. Explanatory note: The vaccine or medicine refrigerator can be located in any space in the CHC, a domestic refrigerator will be scored non-compliant.		
2. The temperature of the refrigerator is recorded twice daily, seven hours apart (check three months records)		
3. The temperature of the refrigerator is maintained between 2 and 8 degrees Celsius (check three months records)		
4. There is a cooler box for storage of vaccines		
5. Ice packs are available for use		
6. There is a functional thermometer for use in the cooler box		

2.3.1.1.2.4 The scripts in the pharmacy or dispensary are correlated with the medicines dispensed to ensure that all medicines were received as prescribed.

Assessment type: Patient record audit - **Risk rating:** Vital measure

Select three user scripts in the pharmacy/dispensary and check whether medicines were dispensed against this script. If all medicines as prescribed were dispensed, score 1. If a user has not received all the medicines as prescribed, score 0. Document the unique identifier of the sampled scripts in the comment column.

Score	Comment	
Aspects	Score	Comment
1. User 1		
2. User 2		
3. User 3		

2.3.1.1.2.5 There is at least one functional room thermometer.

Assessment type: Observation - **Risk rating:** Vital measure

A functional thermometer is available.

Not applicable: Never

Score	Comment

Domain 2.5 FACILITIES AND INFRASTRUCTURE

Sub Domain 2.5.1 14 Management of buildings and grounds

Standard 2.5.1.1 14(1) The health establishment and their grounds must meet the requirements of the building regulations.

Criterion 2.5.1.1.1 14(2)(d) The health establishment must as appropriate for the type of buildings and grounds of the establishment have ventilation systems that maintain the inflow of fresh air, temperature, humidity and purity of the air within specified limits set for different service areas such as theatres, kitchen and isolation units.

2.5.1.1.1.1 The pharmacy or dispensary has a functional air conditioner.

Assessment type: Observation - **Risk rating:** Vital measure

Check if the air conditioner switches on and off and provides cold/cool air to the room in accordance with the temperature setting.

Not applicable: Never

Score	Comment



Official Sign-Off

The National Health Act, 2003 (Act No. 61 of 2003) provides for quality requirements and standards in respect of health services provided by health establishments to the public. The main objective is to promote and protect the health and safety of the users of health services and contribute to improved outcomes and improved population health.

To achieve this mandate standardised inspection tools aligned to Norms and Standards Regulations applicable to different categories of health establishments promulgated by the Minister of Health in 2018 have been developed for Community Health Centres (CHC).

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- The internal OHSC teams (Compliance Inspectorate, for their contribution during the update of the CHC inspection tools).
- National Department of Health for their input and commenting on the inspection tools.

It is hereby certified that the Regulatory CHC Inspection tools version 1.3 was updated by the Office of Health Standards Compliance.

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MS. WINNIE MOLEKO

EXECUTIVE MANAGER: HEALTH STANDARDS, DEVELOPMENT ANALYSIS AND SUPPORT

DATE: 10/07/2023

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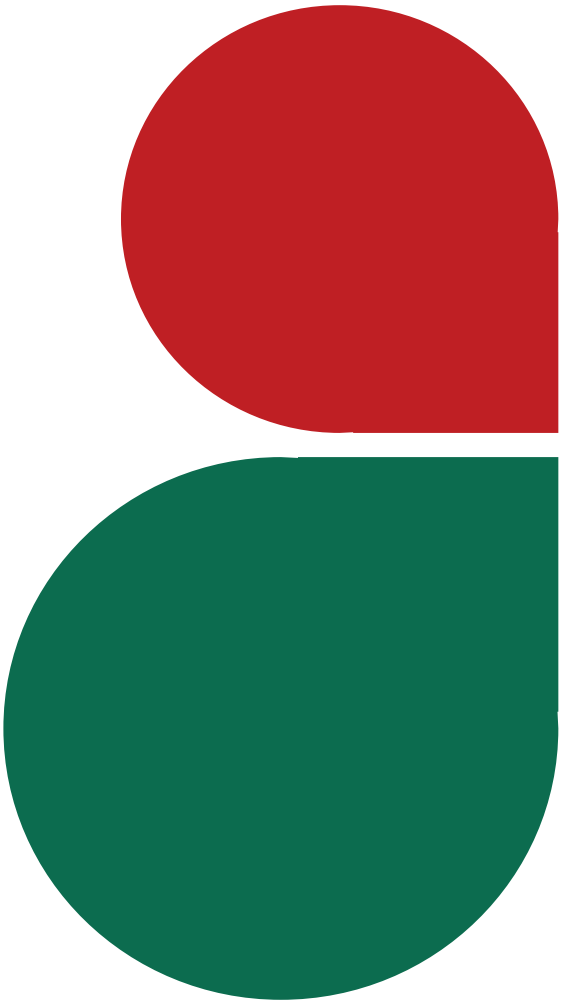
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