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Check list for physical inspection of medicines to early detect and prevent Substandard and Falsified medical products

Dosage form: Syrup, Solution and Injectable

These checklists have been developed by Rwanda FDA, the tool is designed to help health care professionals to carry out physical inspection of medical products with signs of substandard and falsified during reception at pharmaceutical establishments.

All suspicious products should be reported to the Authority for further investigation using the suspected poor quality medicines reporting form.

1. Packaging

	Yes	NO	Other observation
1.1. Container and Closure system			
Does the container and closure protect the product from the outside environment; e.g.is the container properly sealed?			
Are the container and the closure appropriate for the product inside?			
1.2LABELLING The information written on the label is very important. The information can be printed on a label adhered to the container, or printed directly onto the container itself, but all information must be legible and indelible.			
If there is a carton protecting the container, does the label on the carton match the label on the bottles/Vials/Ampoules			
Is all information on the label legible and indelible?			
1.2.1 The trade(Brand)name	Yes	No	Other observation
Is the trade name spelled correctly?			
Does the symbol® follow the trade name?			
For bottles/Vials/Ampoules packed products, is the trade name indelibly impressed or imprinted onto bottles,vials and ampoule?			
1.2.2 The active ingredients name (Scientific name/generic name)			

Is the active ingredient name spelt correctly?			
1.2.3The manufacturer's name and logo			
Are the manufacturer's name and logo legible and indelible?			
1.2.4The manufacturer's full address:			
Is the manufacturer's full address legible and available?			
Has this company or its LTR registered the product in the country?			
1.2.5 The medicine strength(mg/Unit):			
Is the strength - the amount of active ingredient per unit clearly stated on the label?			
1.2.6 The dosage form (e.g., Syrup, Solution and injectable)			
Is the dosage form clearly indicated on the label?			
Does the dosage form stated on the label match the actual dosage form inside the container?			
1.2.7Dosage statement (if appropriate)			
Is the dosage clearly indicated on the label?			
1.2.8The batch (or lot) number:			
Does the Batch number on the outer package the same as the one on the inner package?			
Does the batch number on the outer package the same as the one on the bottle/vial/Ampoule packed products?			
For the bottle/vial/Ampoule packed medicines, is the batch number indelibly impressed or imprinted onto the bottles, vials and ampoules?			
1.2.9The date of manufacture and the expiry date: An expired product should not be sold under any circumstances.			
Is the manufacturing date clearly indicated on the label?			
Is the expiry dates clearly indicated on the label?			
Does the manufacture and expiry date on the outer package the same as the one on the inner package?			
Does the manufacture and expiry date on the outer package the same as the one bottle/vial/Ampoule packed products?			
1.2.10Storage information:	Yes	No	Other observation
Are the storage conditions indicated on the label?			
1.3 Leaflet or package insert: All product packs contain a leaflet explaining dosage, the medicine content, the adverse effects, the medicine's actions, and how the medicine should be taken. The only exceptions are where the packaging includes all the information that would otherwise be in the leaflet.			
Does the medicine has the leaflet inside?			
Is the information on leaflet written in at least one of official languages used in Rwanda?			
2.PHYSICAL CHARACTERISTICS OF SYRUP/SOLUTION/INJECTABLES			

2.1. Visual inspection of syrup, solution and injectable	NO	YES	Other Observation
Are the quantity in bottles/Vials/Ampoules the same as the one on the label?			
Does the syrup, solution and injectable medicine smell the same as the original (If available)? Does it smell peculiar?			
Are the colour of a syrup, solution and injectable the same as the one stated by certain Pharmacopoeia (USP, IP, BP...)?			
Are there any particulate matters in syrup, solution and injectable			
For the powder for suspension and injection, does the powder flow well in the bottles?			