

Supplemental materials

1) Rating system for local private pharmaceutical distributors.

The rating system includes 5 quality assurance criteria, regrouping the 12 Model Quality Assurance System-activities. Each of the 12 activities is evaluated with a score ranging from 0-4, using an ordinal scale. For each of the 5 criteria, the MQAS-compliance is calculated as the average of the scores of its activities. Copied from Van Assche (unpublished 2016-2017).

Rating system for local private pharmaceutical distributors												
Selection of Sources	Good Distribution Practices						Cold Chain Management	General Quality Requirements				Quality Control
	Organisation of warehouse	Physical storage conditions	Stock control	Control at reception	Distribution	Cold Chain Management		Documents system	Recall and complaints handling	Human resources	Self inspection	
Selection of sources							Cold Chain Management					Quality control
4 Low risk	Same as level 3 + pest control	Same as level 3 + evidence of mapping	Same as level 3 + handling of discrepancies (with CAPA)	SOP in place + correct control + QA supervision + conformity to qualified dossier	Dedicated area for order preparation, organized + SOP in place + QA supervision	Same as level 3 + evidence of mapping	Same as level 3 + evidence of mapping	SOPs in place + system + quality manual + change control	Recall SOP + complaints handling SOP + CAPA linked to complaints and recall	Same as level 3 + GDP training	Internal + external audit, follow up of corrective actions + indicators	QC in place + coherent sampling plan + correct selection of laboratory + CoA reviewed by QA
3	Same as level 2 + good management of flows	Temperature and humidity are controlled and monitored	Level 2 + evidence of periodic stock reconciliations	SOP in place + correct control + QA supervision	Dedicated area for order preparation, organized + SOP in place	Same as level 2 + consistent SOPs for cold chain management incl. deliveries	Same as level 2 + consistent SOPs for cold chain management incl. deliveries	SOPs in place + system + quality manual	Recall SOP + complaints handling SOP	QA pharmacist + job description	Internal audit with corrective actions follow up - no indicators	QC in place + coherent sampling plan + correct selection of laboratory
2 Medium risk	All key zones are clearly identified and compliant with WHO guidelines	Temperature is controlled and monitored	Stock control system: consistent documentation Evidence of FEO (control obsolete/expired)	SOP in place but weak control	Dedicated area for order preparation, organized but no SOP	Same as level 1 but "cold rooms" or fridges are controlled	Same as level 1 but "cold rooms" or fridges are controlled	SOPs in place + system but no quality manual	Recall & complaints handling	Pharmacist with some QA tasks/profile	Internal audit but no follow up of corrective actions	QC in place + coherent sampling plan but no laboratory selection criteria
1	Warehouse is organized but not compliant with WHO guidelines	Physical conditions are controlled but weakly	Stock control in place but poorly documented	No SOP but organized	Defined area for order preparation but no organization	"Cold rooms" or fridges are available but conditions are poorly controlled	"Cold rooms" or fridges are available but conditions are poorly controlled	Some documents in place but no real system	Recall or complaints handling	At least one pharmacist	Concept is known but no real system formalised	QC possible but no coherence - no sampling plan
0 High risk	Not organized	No control and/or physical conditions can harm the products	No evidence of consistent stock control system	No SOP - unclear organization	Unorganized order preparation	The cold chain is poorly managed (upstream and/or internally and/or downstream)	The cold chain is poorly managed (upstream and/or internally and/or downstream)	Non existing	Non existing or non documented	No pharmacist	Unknown concept/Non existing	Non existing
						Not applicable	Not applicable					

2) Compliance of each local private distributor with the 5 quality assurance criteria: Sub-Saharan African countries.¹

The levels of MQAS-compliance range from a minimum of 0 to a maximum of 4. LIC: Low-income country, MIC: Middle-income country.

Distributor	Country	Income group	Quality Assurance criteria		
			General Quality Requirements	Good Distribution Practices	Cold Chain management
#1	A	LIC	0,25	0,60	-
#2	B	LIC	0,75	0,40	0
#3	B	LIC	0,75	0,80	0
#4	B	LIC	0,25	0,80	0
#5	B	LIC	0,50	1,00	-
#6	B	LIC	0,25	1,00	-
#7	B	LIC	1,25	1,20	1
#8	B	LIC	0,25	0,40	0
#9	C	LIC	0,25	0,60	-
#10	C	LIC	1,25	1,80	0
#11	C	LIC	0,25	1,00	2
#12	C	LIC	0,75	1,60	1
#13	C	LIC	0,50	0,40	-
#14	C	LIC	2,00	2,60	-
#15	C	LIC	1,75	1,80	1
#16	C	LIC	1,00	2,20	2
#17	C	LIC	2,00	2,60	3
#18	C	LIC	1,25	2,20	2
#19	D	LIC	1,00	0,80	1
#20	D	LIC	0,25	0,00	-
#21	D	LIC	0,75	0,80	2
#22	D	LIC	0,50	0,20	-
#23	E	LIC	1,25	1,20	2
#24	E	LIC	0,50	1,40	0
#25	E	LIC	0,50	0,80	0
#26	F	MIC	1,25	0,60	0
#27	G	MIC	1,50	2,20	-
#28	G	MIC	2,25	2,40	4
#29	G	MIC	0,25	0,60	-
#30	H	MIC	3,00	2,60	2

¹ Coded data. Motivated request to access data by country should be addressed to the corresponding author.

3) Compliance of each local private distributor with the 5 quality assurance criteria: non-Sub-Saharan African.²

The levels of MQAS-compliance range from a minimum of 0 to a maximum of 4. LIC: Low-income country, MIC: Middle-income country.

Distributor	Country	Income group	Quality Assurance criteria		
			<i>General Quality Requirements</i>	<i>Good Distribution Practices</i>	<i>Cold Chain management</i>
#31	I	LIC	1,25	2,00	2
#32	I	LIC	1,50	1,40	1
#33	I	LIC	0,25	0,60	-
#34	I	LIC	0,25	1,40	0
#35	J	MIC	0,25	0,00	-
#36	J	MIC	0,50	0,60	-
#37	J	MIC	1,25	2,40	2
#38	J	MIC	2,25	3,60	4
#39	J	MIC	2,50	3,60	3
#40	J	MIC	2,50	2,00	1
#41	J	MIC	2,75	3,40	4
#42	J	MIC	2,50	3,40	4
#43	J	MIC	2,75	3,40	4
#44	J	MIC	1,00	1,40	2
#45	J	MIC	1,50	1,60	2
#46	K	MIC	1,00	1,80	2
#47	K	MIC	0,75	2,20	1
#48	K	MIC	2,00	2,00	-
#49	K	MIC	2,25	2,40	2
#50	K	MIC	0,25	1,40	-
#51	K	MIC	3,25	3,40	4
#52	K	MIC	0,75	0,80	0
#53	K	MIC	0,25	0,80	2
#54	K	MIC	2,00	2,40	1
#55	L	MIC	2,50	3,00	3
#56	L	MIC	2,50	2,00	3
#57	L	MIC	2,50	2,00	3
#58	L	MIC	2,25	1,60	2
#59	L	MIC	0,50	0,20	-
#60	M	MIC	1,50	2,80	3

² Coded data. Motivated request to access data by country should be addressed to the corresponding author