



CONDOM REGULATORY PATHWAYS

LANDSCAPE OF REGULATORY PROCESSES REQUIRED TO REGISTER, IMPORT, AND SELL CONDOMS IN KENYA, ZAMBIA, NIGERIA, ZIMBABWE.

THIRD 20 BY 20 CONDOM INITIATIVE MEETING:
ACCELERATING COMMERCIAL ENGAGEMENT IN SUB-SAHARAN AFRICA

CHRIS JONES, SEPTEMBER 25, 2018



CONDOM REGULATORY PATHWAY

While different in each country, most Condom Regulatory Pathways to I consist of the below major steps



THE BIG PICTURE

- Most importers viewed regulatory process as manageable, albeit costly element of business.
- The devil is in the details
 - Quality facilitators that proactively manage process (pre-shipment, shipping, clearance) are key.
- Predictability of process is important
- Time is money for importers & commercial sector
- Taxes and fees all get transferred to the consumer
 - Except for suitcase importers (importing generally poor quality condoms illegally).
- Uneven regulatory costs imposed across 5 countries – from 0%-25%
- Non-regulatory barriers contribute to barriers (clogged ports, strikes, etc.)

COUNTRY COMPARISON

	Registration	Import permit	Clearance	Taxation	Total cost of \$50,000 shipment
Kenya	Long but somewhat similar process in cost and time	PVoC expedites process	Requirement to ship by rail creates delays, clogged ports.	16% VAT, 1.5% RDL, IMS, 2% duties	\$62,411 25% cumulative regulatory costs
Zambia		Pre-shipment in country testing sometimes required		No VAT, duties	\$50,107 0% cumulative regulatory costs
Nigeria		Fairly smooth process	Manageable regulatory process BUT port delays onerous	Low (5% VAT)	\$57,250 5% cumulative regulatory costs
Zimbabwe		No reported challenges	High post shipment testing cost	15% VAT & duty waiver/ exemption for NGOs	\$60,525 21% cumulative regulatory costs
South Africa		No requirements to register	One time registration to import.	3 days plus occasional inspections (~10% shipments)	15% VAT

Low cost Efficient process High predictability	Medium cost Mostly efficient process Somewhat predictable	High cost Long times Low predictability
POSITIVE	MODERATE	NEGATIVE



KENYA DEEP DIVE

UNPACKING THE REGULATORY PATHWAY



Kenya	1	2	3	4
	Registering Product	Securing Import Permit	Shipping	Clearing Customs
PROCESS	1.1 Submit dossier	2.1 Secure Certificate of Conformity 2.2 Apply for Import Permit/ Import Declaration Form (IDF)	3.1 Register Import Entry (customs docs)	4.1 Clearing Agent lodges 'Customs Entry' 4.2 Invoicing by KRA/KenTrade 4.3 Post - shipment Inspection from port of entry against BoL 4.4 Testing, Cert of Compliance from KEBS 4.5 Apply for Import Standardization Mark
KEY ISSUES	<u>Cost:</u> \$1,000 (\$100/year thereafter) <u>Time:</u> 180 days <u>Agencies:</u> PPB, KIPI <u>Facilitator:</u> Local Authorized Representative	<u>Cost:</u> 0.75% FOB + min of \$265 or 0.55% FOB (for CoC) (agent costs \$265/shpmnt < \$44k to 0.05% of FoB) <u>Time:</u> 2-3 weeks <u>Agencies:</u> KENTrade (KRA), PPB, KEBS <u>Facilitator:</u> PVOC agent	<u>Cost:</u> Variable <u>Time:</u> Variable (3-5 weeks) <u>Agencies:</u> NA <u>Facilitator:</u> Shipping Agent	<u>Cost:</u> 2% value FOB; 1.5% Railway Dvlpmt Levy; 16% VAT; .49KES Import Standardization Mark/package <u>Time:</u> 2-3 Weeks <u>Agencies:</u> KRA/KENTrade/KEBS/PPB <u>Facilitator:</u> Clearing Agent
OTHER INFO	Technical Documents required (PPB guidance on line here) i. Certificate of analysis from initial manufacturer (manufacturer can be different later on), ii. Leaflet/brochure, iii. Features of packaging iv. High quality photo of product/packaging	i. Importer license ii. Registration documents iii. Pro-forma invoice iv. Packing list v. Bill of Lading vi. Certificate of Origin vii. Certificate of Conformity: CoC agents can be backlogged		Bill of Lading & supporting documentation No cost for testing, but PPB can pull large quantities (up to 7,000)

KENYA CASE STUDY: KEY CONSTRAINTS (I)

- The unpredictability of timing for issuance of import permits – from 3 days to 2-3 weeks – adds uncertainty and cost to shipping.
- Pre-shipment scheduling with Pre-export Verification of Conformance (PVoC) agent requires coordination.
- Customs & KEBS are incentivized to finding discrepancies. The slightest error can create substantial fines, delays, and other challenges.
- It's possible to purchase the Import Standardization Mark (ISM) sticker only after the Certificate of Conformity (CoC) is issued
 - Existing processes prohibit stickers to be applied to packaging by manufacturer. This requires importers to unpack individual condom packages, apply sticker, and repack into dispenser – a considerable investment of time, money, and effort.
- Any cost (fees, taxes, etc.) to a low margin, low cost product are passed on directly to consumers through higher prices.

KENYA CASE STUDY: KEY CONSTRAINTS (II)

- Post shipment testing by KEBS often a delay; in past quality of testing variable.
- New in-country shipment law
 - Requires all shipments with Nairobi consignment address to be transported from Mombasa to NBO by rail, rather than truck. Rail lines currently aren't equipped to handle the load, creating logistical mess.
- Clogged ports.

KENYA CASE STUDY: ENABLING FACTORS

For a business supported by the right facilitators, the importation process is accepted as a cumbersome but relatively navigable part of doing business.

- Proactive action is important - engaging quality facilitators can expedite processes and eliminate unnecessary fees and penalties.
 - PVoC, shipping and clearing agents are key to support process. Be responsive to facilitators guidance.
- Important to know and understand the rules, processes, & standards.
 - Discrepancies in the process or documentation can be costly. Meticulously review documentation (15% penalties can be imposed for many products).
- PvOC to Standards is a significant enabler of expediting import process.
- There are 5 accredited agents in Kenya to support PVoC.

KENYA CASE STUDY: SUCCESS FACTORS

- Be Proactive – Engage quality facilitators.
 - PVoC, shipping and clearing agents are key to support process. Be responsive to facilitators guidance.
- Important to know and understand the rules, processes, & standards.
 - Discrepancies in the process or documentation can be costly. Meticulously review docs (15% penalties can be imposed for many products).
- For smaller importers, best bet is to work with consolidators - who are 'enhanced clearing agents'. The new "D" route on KEBS PVoC process is for consolidators that specifically support small traders/importers.

KENYA CASE STUDY: ROLE OF CLEARING AGENT

- Ensure security of goods on arrival to avoid pilfering.
- Get KRA details / invoice from government; help to facilitate payment (sometimes pre-paying on behalf of importer).
- Track & manage process from time goods are shipped to arrival (projecting impact of delays etc.). Will coordinate with KPA for space . KPA has created a 'VIP' zone for storage at port while awaiting inspection.
- Coordinate & manage shipment from manufacturer to warehouse. Facilitate payments and movement of goods, serve as advocate for shipper, etc.

REGULATORY PATHWAYS

- Zambia
- Nigeria
- Zimbabwe
- South Africa

ZAMBIA	1	2	3	4
	Registering Product	Securing Import Permit	Shipping	Clearing Customs
PROCESS	<p>1.1 Manufacturer/ Importer applies for Market Authorization (MA)</p> <p>1.2 ZAMRA reviews application</p>	<p>2.1 Apply for Permit / QA testing</p> <p>2.2 Obtain import Permit</p>	<p>3.1 Ship</p>	<p>4.1 Manufacturer/ Importer declares condoms at customs</p> <p>4.2 Inspection</p>
KEY ISSUES	<p><u>Cost</u>: \$500 / 5 years retention; \$200 annual fee, \$160.5 testing</p> <p><u>Time</u>: 5-9 months</p> <p><u>Agencies</u>: ZAMRA, PACRA</p> <p><u>Facilitator</u>: Registered agent (pharmaceutical wholesaler / importer w/PoA)</p>	<p><u>Cost</u>: \$10</p> <p><u>Time</u>: 14 days</p> <p><u>Agencies</u>: ZABS</p> <hr/>	<p><u>Cost</u>: Dependent</p> <p><u>Time</u>: Variable (but longer given no sea port)</p> <p><u>Agencies</u>:</p> <p><u>Facilitator</u>: Shipping Agent</p>	<p><u>Cost</u>: No taxes or tariffs imposed on taxes, including VAT</p> <p><u>Time</u>: Variable</p> <p><u>Agencies</u>: Zambia Compulsory Standards Agency (ZCSA)</p> <p><u>Facilitator</u>: Clearing Agent</p>
OTHER INFO	<p><u>ZAMRA condom Guidance</u></p> <p>Each variants such as color/scent or specific branding required to be individually registered.</p>	<p>Importer/ Manufacturer provides product samples (per ISO 4074 requirements) for testing prior to initiating any importation</p>		<p>ZCSA inspects condoms, issues invoice that covers Inspection and administrative costs.</p> <p>ZCSA may sample condoms (750 pieces per batch) and submits to Zambia Bureau of Standards (ZABS) for further testing.</p>

Nigeria

1

2

3

4

Registering Product

Securing Import Permit

Shipping

Clearing Customs

PROCESS

1.1 Submit product dossier following Common Technical Document.
1.2 Submit Comprehensive Cert of analysis, cert of business incorporation, cert of brand.
1.3 Quality Assurance inspection of facility of product registered may be required

2.1 Complete Form M
2.2 The importer activates the cert on the [online single window](#).
2.3 Combined Certificate of Value & Origin (**CCVO**)
2.4 Pre-Arrival Assessment Report approved by NCS
2.5 Quality Assurance

3.1 Ship on receipt of Form M

4.1 importer activates the SONCAP Certificate and applies for Pre-Arrival Assessment Report (PAAR) issuance on the Nigeria Single Window for Trade.
4.2 PAAR approved by NCS is required
4.3 Appropriate documentation provided
4.4 Testing product

KEY ISSUES

Cost: 346,950 Naira, variants: 205,875; 346,950 renewal fee
Time: 3-12 months
Agencies: NAFDAC
Facilitator: Local Agent with PoA

Cost:
Time: varies
Agencies: Fed MoF, the Central Bank of Nigeria (CBN), NAFDAC, Standards Org of Nigeria (SON)

Cost: varies
Time: varies
Facilitator: shipping agent

Cost: 5% VAT, 10% duties but NGO exempt
Time: only one port of entry creates frequent backlog at port
Agencies:
Facilitator: Clearing agent

OTHER INFO

Forms can be found [here](#) and [here](#)
Certificate of Analysis from manufacturer required
i. The brand name of the product.
ii. The batch number of the product.
iii. The manufacturing and expiry dates.
iv. The name, designation and signature of the analyst.

An e-**Form M** is a mandatory documentation process put in place by the the MoF & CBN, to monitor goods that are imported into the country & collect import duties where applicable.

GMP inspection of facility abroad – cert of analysis required.

CCVO; Transport document and Packing list to the relevant bank, plus invoice, BoL.

Users report process not overly onerous, but can be unpredictable due to port delays.
SMers able to secure exemption.

Zimbabwe	1	2	3	4
	Registering Product	Securing Import Permit	Shipping	Clearing Customs
PROCESS	1.1 Submit forms (MC.Con 1&2) 1.2 Submit 1,400 condoms for testing	22.1 Submit application w/required documentation	3.1 3.1 Ship on approval of import permit	4.1 notify the DG of using Form I.E 6, BoL lodged 4.2 testing 4.3 Documents processed; delivery Release Order issued
KEY ISSUES	<u>Cost:</u> \$690 <u>Time:</u> 60 days (brand ext) - 1 year <u>Agencies:</u> Medicines Control Authority of Zimbabwe (MCAZ) and Zim Intellectual Property Office (ZIPO) for trademarks	<u>Cost:</u> <u>Time:</u> <u>Agencies:</u> ZIMRA, MCAZ <u>Facilitator:</u> Local Agent	<u>Cost:</u> varies <u>Time:</u> varies <u>Facilitator:</u> Shipping Agent	<u>Cost:</u> 15% VAT; import duty 5%, \$350 / variant test (NGO exempt), verification fee of 0.05% <u>Time:</u> 4-5 days, ~10-14 days testing <u>Agencies:</u> Zim Revenue Authority (ZIMRA) MCAZ <u>Facilitator:</u> Clearing agent
OTHER INFO	Registration committee meetings once/month MCAZ Guidance can be found here , and here .	MCAZ guidance can be found here ,	NA	Import guidance from ZIMRA here

South Africa

1

Registering Product

2

Securing Import Permit

3

Shipping

4

Clearing Customs

PROCESS

1.1 Currently no requirement to register condoms, although expectation of shift soon.

Importer/Manuf applies for a blanket import permit (license medical device establishments for brand. Permit becomes good for 5 years and allows unlimited import.

4.1 straightforward process lead by clearing agent

KEY ISSUES

Cost:
Time: 1—12 months
Agencies: SABS, Medicines Control Council (MCC)
Facilitator: Local agent

Cost: Distributor's Licence Fee – R13 000, Manufacturers fee: 21,000 R
Time: varies.
Agencies: MCC, SAPHORA

Cost: varies
Time: 4-6 weeks
Facilitator: Shipping agent

Cost: 15% VAT, no duties
Time: ~3 days
Agencies: South Africa Revenue Service (SARS), SABS, port health, customs
Facilitator: Clearing agent

OTHER INFO

Guidance on registration [here](#)

<http://www.sahpra.org.za/>
<http://www.samed.org.za/>
<https://www.sabs.co.za/>

Condoms are Medical Device Licensed by medical controls council

Once registered, the license must be modified to reflect any changes (to condom manufacturer, variants). Guidance on import [here](#) with essential documents included. Once condoms by variants are registered, easy to import and distribute

Post Shipment testing not required. Occasionally (10% time) shipment will be audited by port health. Cost ~5,000 rand/day.