CHILDREN'S INVESTMENT FUND FOUNDATION

Self-care & De-medicalisation Policy Impact Analysis

Building a supportive enabling environment

Final Deliverable (Updated) – October 29, 2020

- Process & methods
- Findings & key insights

DISCLAIMER

Please note that this work was carried out in a very short timeframe, and thus consists of a rapid and highly condensed assessment of the current state of policies. We rapidly reviewed relevant guideline documents, and spoke to a set of 2-3 key informants per country to validate our findings. The information included in this document and may not capture the most recent developments as the space continues to evolve in real time.

We also recognize that the illustrative guidelines selected for these purposes may not be indicative of the status of the broader self-care agenda in these policy areas and countries. ***Caution should be taken when interpreting results (an analysis taking into account a larger basket of policies will likely be required in the future in order to draw overarching conclusions or inform programmatic decisions).***

SCOPE | Rapid assessment focuses on four categories with the potential to accelerate a self-care agenda in three countries

Objective: Describe the state of key guidelines and regulations and assess the potential influence of policy and regulatory change on accelerating access to demedicalised and self-care products.

Policy Categories	Illustrative Guidelines
1 **Task-shifting to increase access through pharmacies, drug shops & CHWs**	Task shifting to pharmacists/CHWs
	PrEP initiation via pharmacies
2 **Promoting home-based & user-controlled access**	Opt out self-injection counselling
	Self managed/home-based MA
	Multi-month dispensation
3 **Telemedicine & remote counseling**	Online/telemedicine service provision
4 **Enabling OTC access to ease dispensation restrictions**	3rd party/age of consent removal
	OTC access/prescription removal

Priority Countries

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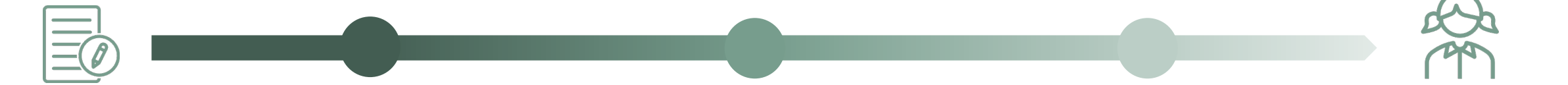
Note: *We recognize that illustrative guidelines selected for these purposes may not be indicative of the status of the broader self-care agenda in these policy areas and countries. An analysis taking into account a larger basket of policies will be required in the future in order to draw overarching conclusions.*

PRODUCT STATUS | We assessed a set of proxy products, determining where the guidelines for use fall along a spectrum

- Products on the right of the spectrum are likely already well positioned to contribute to the self-care agenda
- Product placement on the spectrum was based on formal documented policy (i.e. does not take into account provision through informal channels)



LEGAL & REGULATORY STATUS

PRODUCT REGISTRATION & PERMITTED USES

Product/service registered

Is the product or service registered?
**If so, what are its permitted uses?*

CHANNEL AVAILABILITY

Channels available

Is the product available in pharmacies & drug shops? Through community distribution programs?

Provider roles

What types of providers can provide or dispense the product or service?

PROVISION

Restrictions

Are users free from restrictions based on age, spousal consent, other?

Dispensation

Are dispensation requirements well crafted? E.g. is counseling required? Multi-month supplies?

OTC availability

Can the product be dispensed OTC (without a prescription)?
**applicable to certain products only*

CUSTOMER UPTAKE & USE

Selected proxy products & services

- OCPs
- EC
- DMPA-SC
- Mife/miso (MA)
- ARTs (PrEP)
- HIVST
- Telemedicine SRH

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Note: *This is a simplistic illustration of how products are registered, licensed and provided. We recognize that this process is not inherently linear. The selected proxy products and services may be expanded in the future for relevant illustrative guidelines.*

POLICY RATING FRAMEWORK | Our approach consisted of 3 steps, assessing: the current state of guidelines; the potential impact of various policy changes; and feasibility of future work in this space

Steps	1 Assessing current state of **guideline formulation & application**		2 Estimating **potential impact**	3 Assessing potential **feasibility**	
Approach	Assess if guidelines are *formulated*	Assess if guidelines are *implemented* nationally	Illustrate potential impact by estimating annual beneficiaries	Collect high-level indicators of where political will may be growing or contracting from key informants	Assess feasibility of work in different policy categories
Data sources	Desk review • National Guidelines & Strategies • Secondary reviews	Key informants **Nigeria:** JSI, SFH Nigeria & WHO **Kenya:** UNFPA Kenya & WHO **Ethiopia:** PSI Ethiopia, CIFF & WHO	Various • Literature review • Early program results • Key informants • Historical examples from other products	Key informants **Global:** CHAI, PATH, CIFF & WHO **Ethiopia:** CIFF **Kenya:** CIFF	Various • Inputs from key informants • Contextual current state information

Given the short timeframe, the process was condensed. The findings presented may not capture most recent developments as the space continues to evolve in real time. Results should not be used to make detailed programmatic decisions. This will require revision and a more comprehensive analysis over the coming months.

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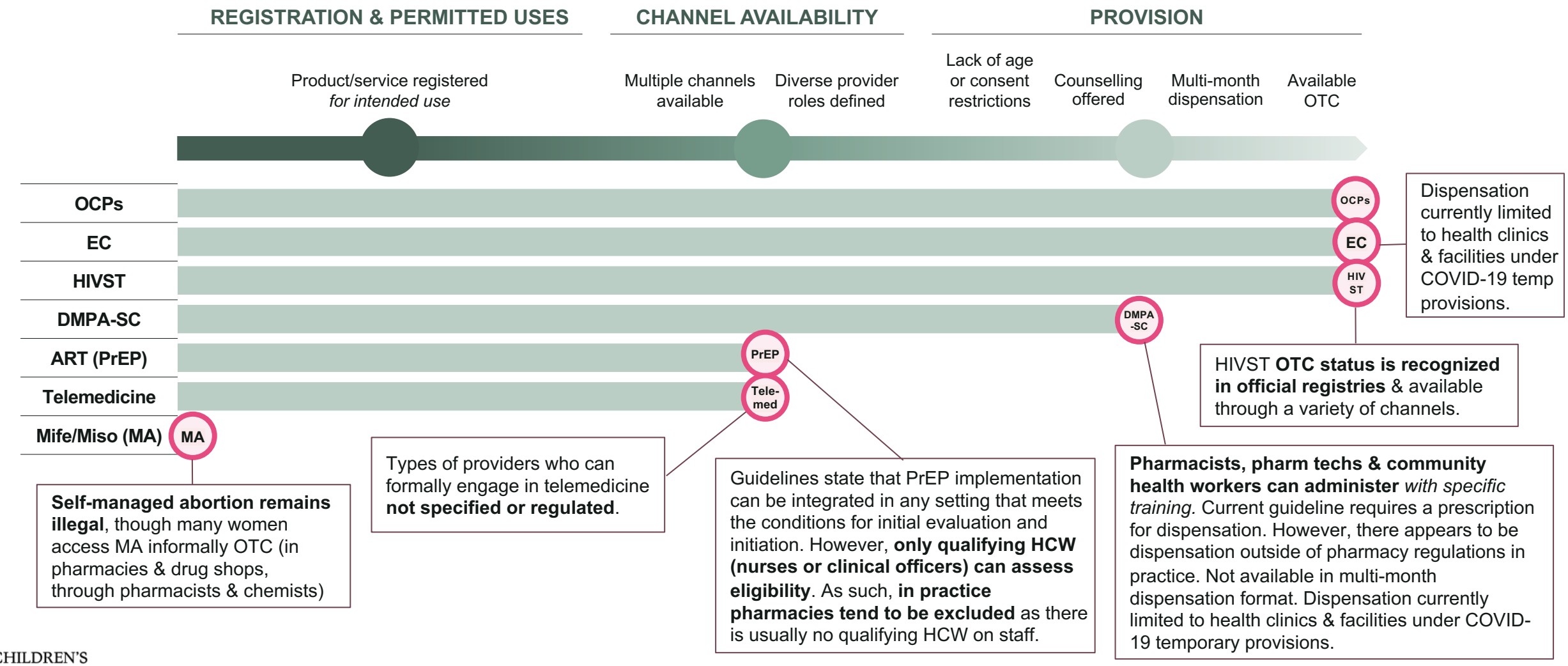
KENYA PRODUCT BACKGROUND | Overall, there appear to be few restrictions to access of key self-care products, with the exception of MA & certain COVID-19 channel closures (DMPA-SC, EC)

- OCPs, EC and HIVST are generally readily available without restrictions, laying the groundwork for uptake of these products by consumers



KENYA POLICY ASSESSMENT | Building on task-shifting efforts & formulating guidelines for telemedicine may be promising areas to focus to advance the self-care agenda

Category	Guideline	Current state: Policy formulation	Current state: Policy application	Impact*: Total beneficiaries	Feasibility: Feasibility	Feasibility: Recent developments	Context
Task-shifting to increase access via pharmacies, drug shops & CHWs	Task-shifting Rx to pharm/CHWs (DMPA-SC)	🟢	🟡	🔴	🟢	↗	Trained pharmacists authorized to administer; negotiations re: training, quality of care ongoing for stakeholder buy-in. CHWs can distribute in hard-to-reach areas.
	Task-shifting assisted testing to pharm/CHWs (HIVST)	🟢	🟢	-	-	-	Policy appears well formulated & applied; no further policy work required
	PrEP initiation via pharmacies (ARTs)	🟡	🔴	🔴	🟡	-	PrEP can only be initiated by trained medical personnel who do not staff pharmacies and drug shops
Promoting home-based & user-controlled access	Self-injection is default for counselling (DMPA-SC)	🔴	🔴	🔴	🔴	↗	SI guidance is in the early stages of being developed (current practice and policy limits SI to implementation research)
	Self managed/home-based MA	🔴	🔴	🟡	🔴	↗	Exploring loopholes in current policy to allow providers to further consider women's needs for MA; legal barriers limit feasibility of self-managed MA
	Multi-month dispensing (OCPs)	🟢	🟢	-	-	-	Policy appears well formulated & applied; no further policy work required
Telemedicine & remote counseling	Online/telemedicine SRH services	🟡	🟡	🟢	🟢	↗	Integrated into guidelines for diff. health areas; e-health guideline to be updated to reflect ↑ role of telemed in COVID-19 context & beyond.
Enabling OTC access to ease dispensation restrictions	3rd party/age of consent removal (OCPs)	🟢	🟢	-	-	↘	New SRH bill may affect access for <18; work to remove age-related barriers may be needed to ensure adolescents can benefit from progress in other SRH areas
	OTC access/prescription removal (EC)	🟢	🟢	-	-	-	Policy appears well formulated & applied; no further policy work required
	OTC access/prescription removal (DMPA-SC)	🔴🟢	🔴🟢	🔴	🟡	↘	Despite recent authorization of trained pharmacists to dispense, status of SI limits OTC access; recent increase in scrutiny of online pharmacies dispensing OTC
	OTC access/prescription removal (HIVST)	🟢	🟢	-	-	-	Policy appears well formulated & applied; no further policy work required

Potential areas of focus for future work

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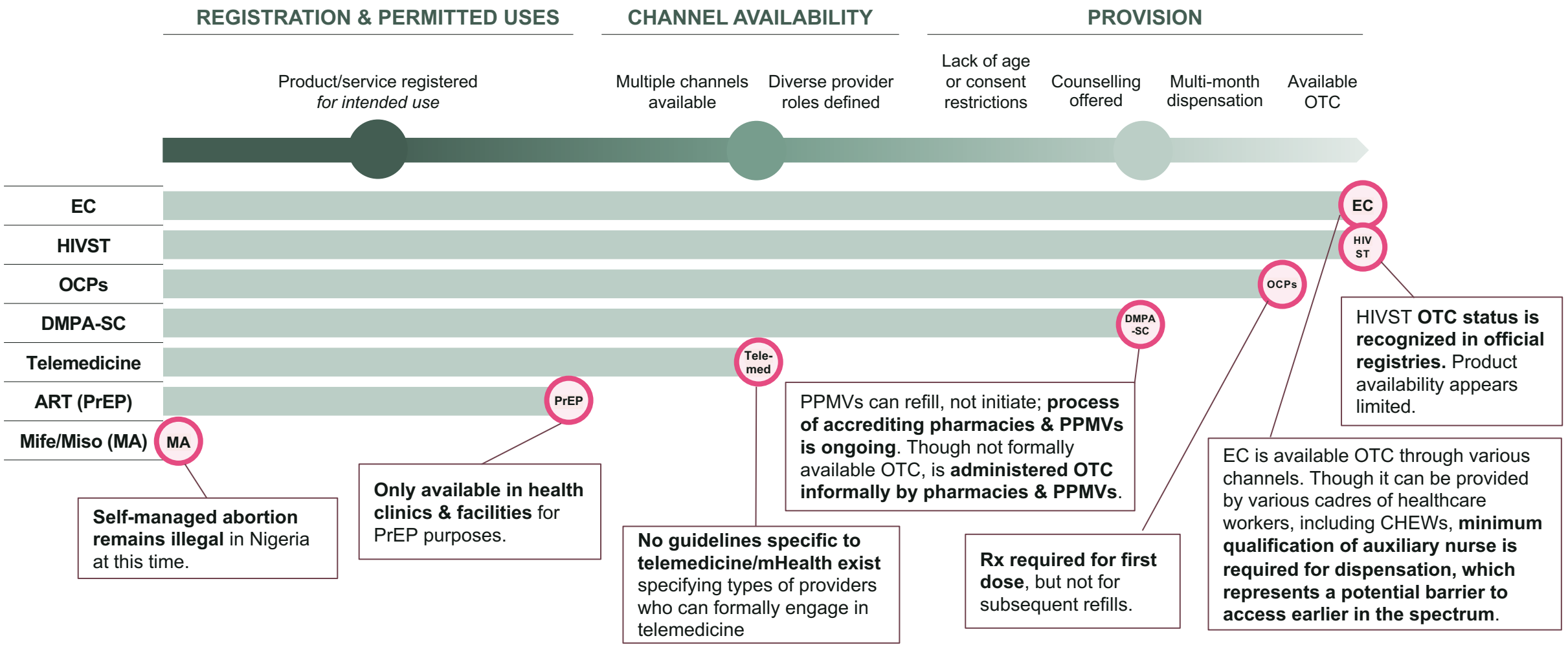
Efforts to increase availability through **different channels & providers for DMPA-SC** and **telemedicine** are underway & progress appears feasible, with the potential to generate a high impact on access in Kenya. However, work may be needed to ensure adolescents' access to SRH products & services amid potential new age restrictions.

🔴 Appears weak
🟡 Moderate
🟢 Appears strong

**Weak impact is defined as a total of <500K beneficiaries; moderate impact as ≥500K to <2M beneficiaries; strong impact as >2M beneficiaries*

NIGERIA PRODUCT BACKGROUND | The environment surrounding key products is slightly more restrictive; some limitations in provider roles continue to impede access (EC, ARTs)

- Key self-care products, including OCPs, pose difficulties for end user access due to restrictions around channel availability and provision.



NIGERIA POLICY ASSESSMENT | On-going efforts in task-shifting are a significant opportunity to advance self-care; policy formulation work in SI & telemedicine, and support for HIVST OTC may yield high impact

Category	Guideline	Current state		Impact*	Feasibility		Context
		Policy formulation	Policy application	Total beneficiaries	Feasibility	Recent developments	
Task-shifting to increase access via pharmacies, drug shops & CHWs	Task-shifting Rx to pharm/CHWs (DMPA-SC)	🟢	🟡	🟡	🟢	↗	20K providers trained over last 2 yrs under updated TSTS policy; state coverage uneven.
	Task-shifting assisted testing to pharm/CHWs (HIVST)	🟢	🟢	-	-	-	Policy appears well formulated & applied; no further policy work required
	PrEP initiation via pharmacies (ARTs)	🔴	🔴	🔴	🟡	↗	Pharmacists can screen & refer in 4/36 states (scale-up in Q4 2020) – policy change for initiation in discussion
Promoting home-based & user-controlled access	Self-injection is default for counselling (DMPA-SC)	🟢	🔴	🟡	🟡	↗	FMOH recently launched guideline for SI w/ dispensing protocol & counseling.
	Self managed/home-based MA	🔴	🔴	🟢	🔴	↗	National documentation developed last yr which stipulates safe ***provider-led termination;*** legal barriers limit feasibility of self-managed MA
	Multi-month dispensing (OCPs)	🟢	🟢	-	-	-	Policy appears well formulated & applied; no further policy work required
Telemedicine & remote counseling	Online/telemedicine SRH services	🟢	🟢	🟢	🟢	↗	No national documentation for telemedicine exists; currently **under discussion** w/ SFH engaged.
Enabling OTC access to ease dispensation restrictions	3rd party/age of consent removal (OCPs)	🟢	🟢	-	-	-	Policy appears well formulated & applied; no further policy work required
	OTC access/prescription removal (EC)	🟢	🟢	-	-	-	Policy appears well formulated & applied; no further policy work required
	OTC access/prescription removal (DMPA-SC)	🔴	🔴	🟡	🟡	↗	Lack of formal OTC status impedes DTC marketing & creates liabilities; potential to advocate with NAFDAC for formal OTC status amidst COVID
	OTC access/prescription removal (HIVST)	🟢	🟡	🟡	🟡	↗	Recent progress by certain states in rollout of OTC; Jan 2021 update to national HIV strategy will prioritize ST.

Potential areas of focus for future work

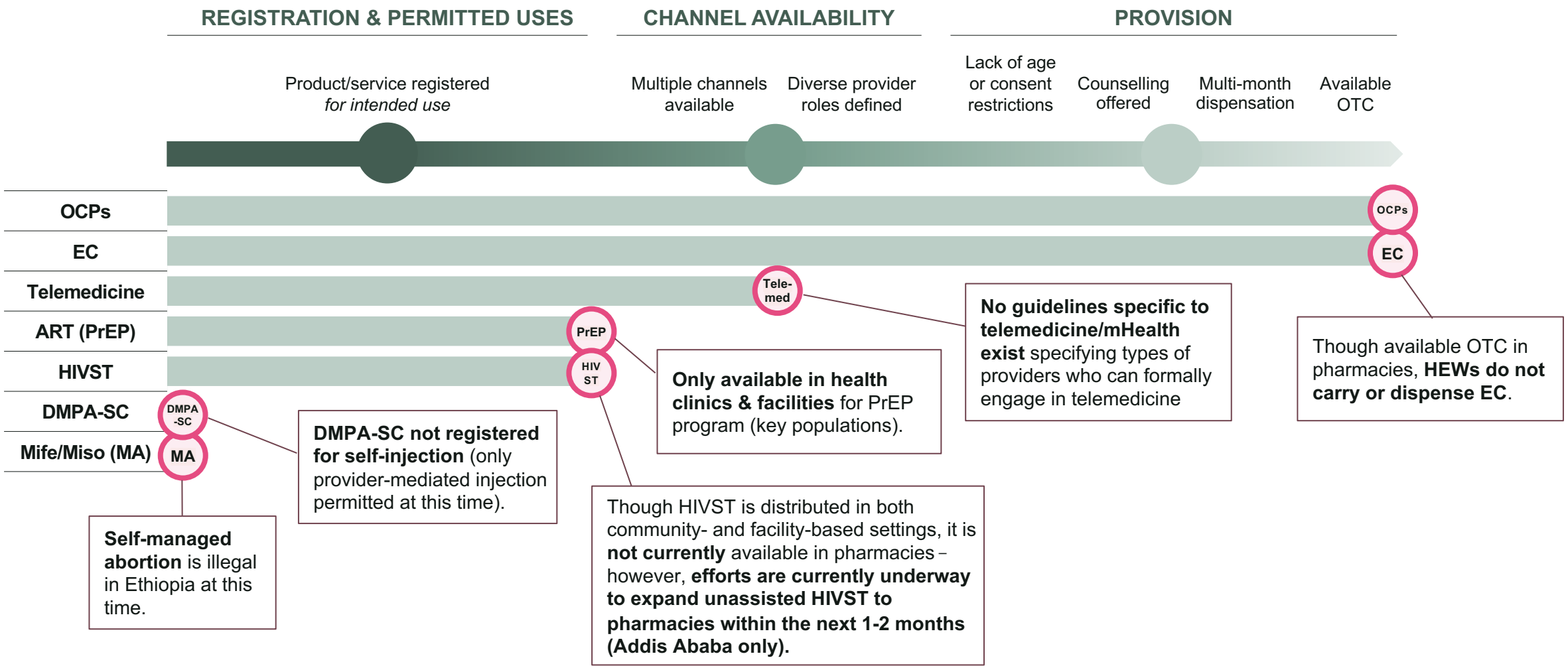
Efforts in **task-shifting DMPA-SC, removing policy & barriers to OTC access for HIVST**, and **telemedicine** are underway & further progress appears feasible. Stakeholder interest in establishing **SI as default** appears high, and potential impact is promising.

🔴 Appears weak
🟡 Moderate
🟢 Appears strong

**Weak impact is defined as a total of <500K beneficiaries; moderate impact as ≥500K to <2M beneficiaries; strong impact as >2M beneficiaries*

ETHIOPIA PRODUCT BACKGROUND | Higher number of restrictions at the level of registration & permitted uses for certain products, while others (OCPs, EC) are more accessible

- OCPs and EC are readily available without restrictions, laying the groundwork for uptake of these products by consumers



ETHIOPIA POLICY ASSESSMENT | Agenda may benefit from a focus on policy formulation & implementation work in self-managed MA & telemedicine

Category	Guideline	Current state: Policy formulation	Current state: Policy application	Impact*: Total beneficiaries	Feasibility: Feasibility	Feasibility: Recent developments	Context
Task-shifting to increase access via pharmacies, drug shops & CHWs	Task-shifting Rx to pharm/CHWs (DMPA-SC)	🔴	🔴	🔴	🔴	↗	Currently developing national self-care guidelines with strong task-shifting focus; low feasibility for DMPA-SC due to structure of procurement & distr.
	Task-shifting assisted testing to pharm/CHWs (HIVST)	🟢	🟢	-	-	-	Policy appears well formulated & applied; no further policy work required
	PrEP initiation via pharmacies (ARTs)	🔴	🔴	🔴	🔴	↗	New USAID-funded PrEP program has led to the establishment of community ART groups; strict provider requirements for initiation remain
Promoting home-based & user-controlled access	Self-injection is default for counselling (DMPA-SC)	🔴	🔴	🔴	🔴	-	Expanding permitted uses of DMPA-SC to include SI is currently not a gov. priority. Pushing further on this is not recommended.
	Self managed/home-based MA	🔴	🔴	🟡	🟡	↗	New self-care guidelines allow for self-managed MA; feasibility will increase once adopted & clinical guidelines developed.
	Multi-month dispensing (OCPs)	🟢	🟢	-	-	-	Policy appears well formulated & applied; no further policy work required
Telemedicine & remote counseling	Online/telemedicine SRH services	🔴🟢	🔴🟢	🟡	🟡	↗	Conversation evolving in light of COVID-19; feasibility limited due to infrastructural & technological barriers to access.
Enabling OTC access to ease dispensation restrictions	3rd party/age of consent removal (OCPs)	🟢	🟢	-	-	-	In practice, unmarried girls and women may face barriers to access due to high degree of stigmatization.
	OTC access/prescription removal (EC)	🟢	🟢	-	-	-	Pharmacy availability limited in rural settings. HEWs don't carry EC.
	OTC access/prescription removal (DMPA-SC)	🔴	🔴	🔴	🔴	-	Legal and regulatory barriers to self-injection render OTC status infeasible.
	OTC access/prescription removal (HIVST)	🟢	🟡	🔴	🟢	↗	Temp. COVID-19 guidelines recognize benefits of ST; preparatory work underway for expansion to pharmacies (Addis Ababa) within 1-2 months

Potential areas of focus for future work

Recent development of national consolidated self-care guidelines is a key opportunity to engage and multiply wins, particularly for **self-managed MA** and in **broader task-shifting efforts.** Though impact is lower, regional policy application efforts could help **expand OTC access to HIVST** in pharmacies outside the capital.

🔴 Appears weak
🟡 Moderate
🟢 Appears strong

**Weak impact is defined as a total of <500K beneficiaries; moderate impact as ≥500K to <2M beneficiaries; strong impact as >2M beneficiaries*

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SUMMARY | Across countries, work to advance task-shifting & telemedicine appears promising. Targeted work to secure HIVST OTC access & support MA in specific geographies is also of interest.

- We examined the current state of policies, estimated the potential impact of future policy work and rated these opportunities based on feasibility.
- Assessment revealed key opportunities in each policy category: **1) investment in task-shifting to increase access through different channels**; **2) securing OTC access for HIVST in Nigeria & Ethiopia; 3) supporting self-managed MA in Ethiopia; & 4) investment in telemedicine**.

Task-shifting to increase channel availability

Requires different approaches based on context:

1. Nigeria & Kenya: DMPA-SC introduction can be leveraged to pave the way for broader task-shifting efforts for other key self-care products.
2. Ethiopia: focus on DMPA-SC may be harmful to overall efforts to advance the self-care agenda. A broader approach to task-shifting (with a focus on products with a less politically contentious nature) is recommended, and a window of opportunity may be opening.

Securing OTC access for HIVST in Nigeria & Ethiopia

Literature suggests high price sensitivity. Further market research is required.

Nigeria: This is likely to represent a near-term opportunity to build on current efforts and contribute to a wide-scale rollout of HIVST.

Ethiopia: Opportunity to build on ongoing policy application efforts in Addis Ababa by focusing resources to expand HIVST access & social marketing to pharmacies in other regions.

Supporting self-managed MA in Ethiopia

The adoption of consolidated self-care guidelines in Ethiopia provides strong impetus for the advancement of a broader self-care agenda. In particular, upcoming changes in self-managed MA regulation and policy may be key to generating support for further advances in user-controlled methods.

Telemedicine

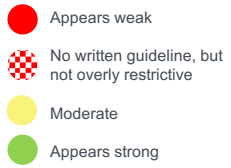
Appears attractive across all 3 countries and with high potential impact, based on country-specific context and population data combined with usage data for SRH in European contexts.

More work is needed to better understand feasibility, the potential for this to be a pro-poor solution, and to formalize the policy context.

Appendix

CURRENT STATUS OF POLICY | Assessments indicate that some of these areas currently have strong policies, while others may require efforts to strengthen policy formulation & application

- Task-shifting & increasing availability through different channels likely requires a mix of efforts in policy formulation (PrEP initiation) & policy application, especially sub-nationally (DMPA-SC); despite broader implementation challenges, task-shifting for HIVST is underway and requires no further policy work.
- With the exception of multi-month dispensation, enhancing home-based access likely requires efforts in policy formulation and legal work to allow for specific uses.
- Telemedicine & remote counselling is an emerging area of focus where efforts in policy formulation are required to formalize the practice.
- Work in policy formulation & application is likely required to ensure formal OTC access for both DMPA-SC & HIVST (except for Kenya for HIVST)



Policy work Category	Policy guideline	KENYA		NIGERIA		ETHIOPIA	
		Policy formulation	Policy application	Policy formulation	Policy application	Policy formulation	Policy application
Task-shifting to increase access via pharmacies, drug shops & CHWs	Task-shifting Rx to pharm/CHWs (DMPA-SC)						
	Task-shifting assisted testing to pharm/CHWs (HIVST)						
	PrEP initiation via pharmacies (ARTs)						
Promoting home-based & user-controlled access	Self-injection is default for counselling (DMPA-SC)						
	Self managed/home-based MA						
	Multi-month dispensing (OCPs)						
Telemedicine & remote counseling	Online/telemedicine SRH services						
Enabling OTC access to ease dispensation restrictions	3rd party/age of consent removal (OCPs)						
	OTC access/prescription removal (EC)						
	OTC access/prescription removal (DMPA-SC)						
	OTC access/prescription removal (HIVST)						

Mix of efforts in policy formulation (particularly in Ethiopia) & application required, with the exception of task-shifting for HIVST.

Likely requires **efforts in policy formulation and legal work** (particularly in Ethiopia)

Efforts in policy formulation required to formalize the practice.

Further work in OCPs & EC not anticipated to generate measurable changes in access; work in **policy formulation** required to formalize DMPA-SC access, and **policy application** for wide-scale rollout of HIVST.

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PRODUCT BACKGROUND | Overall, Kenya had few restrictions to access of key self-care products, with the exception of MA & certain COVID-19 channel closures (DMPA-SC, EC)

KENYA

PRODUCT BACKGROUND

	Product/ service registered	Multiple channels available	Diverse provider roles defined	Lack of age or consent restrictions	Counselling offered	Multi-month dispensation	Available OTC	*Notes*
DMPA-SC	✓*	✓	✓	✓	✓	✗	✗	• *Though approved for SI, policy currently limits the practice to implementation research • Pharmacists, pharm techs & community health workers can administer *with specific training* • Sometimes administered by untrained providers; channels + restricted under COVID-19
OCPs	✓	✓	✓	✓	✓	✓	✓	• Community health workers can formally administer but *require specific training*
EC	✓	✓	✓	✓	✓	N/A	✓	• Channels more restricted under COVID-19
ART (PrEP)	✓	✓	✗	✓	✓	✓	✗	• In practice pharmacies largely excluded as requires qualifying HCW on staff to dispense • 1-month supply offered at 1st visit; multi-month supplies dispensed thereafter (under COVID, 3-month supplies dispensed at each visit)
HIVST	✓	✓	✓	✗	N/A	N/A	✓	• All distributing outlets require private & dedicated space to accommodate assisted testing • Nurses cannot administer rapid diagnostic tests in facilities • Adolescents aged 15-17 require assisted testing
Mife/Miso (MA)	✓*	✓*	✗	✗	✗	N/A	✗	• *Not permitted for self-managed MA • Informally women access OTC from drug shops & pharmacies, and pharmaicists & chemists
Telemedicine & remote counselling	✓	N/A	✗	✓	✓	N/A	N/A	• Types of providers who can formally engage in telemedicine not specified

Note: *In some cases, product policies do not correspond to ways the products can be accessed informally (OTC, unregulated channels, etc.)*

PRODUCT BACKGROUND | Similarly, the environment surrounding key self-care products in Nigeria is not highly prohibitive, though in some cases limitations in provider roles continue to impede access (DMPA-SC, EC, ARTs)

NIGERIA

PRODUCT BACKGROUND

	Product/ service registered	Multiple channels available	Diverse provider roles defined	Lack of age or consent restrictions	Counselling offered	Multi-month dispensation	Available OTC	*Notes*
DMPA-SC	✓	✓	✓	✓	✓	✓	✗	• PPMVs can refill, not initiate; process of accrediting pharmacies & PPMVs not complete • Upon 2nd visit & demonstrated competency to self-inject, patient can be provided 2 doses • In practice women access OTC (informally)
OCPs	✓	✓	✓	✓	✓	✓	✗	• Rx required for 1st dose, not required for refills • PPMVs can only refill, not initiate
EC	✓	✓	✗	✓	✓	N/A	✓	• Minimum qualification of aux nurse required for dispensation
ART (PrEP)	✓	✗	✗	✓	✓	✓	✗	• CHEWs can maintain/refill but not for PrEP • Pharmacists cannot initiate but can screen & refer; policy change anticipated for Q4 2020 • Providers recommended to issue 90-day prescription/refill authorizations
HIVST	✓	✓	✓	✗	N/A	N/A	✓	• Regulatory processes to ensure accessibility through the national program not yet fully established; kits available OTC are not WHO pre-qualified • Policy specifies that minors require consent; implies those <18
Mife/Miso (MA)	✓*	✓*	✓*		✗	N/A	✓*	• *Not permitted for self-managed MA • Pharmacies, PPMVs and community-based distribution of miso only; permitted uses unclear
Telemedicine & remote counselling	✓	N/A	✗	✓	✓	N/A	N/A	• No national guidelines specific to telemedicine/mHealth exist, but environment does not appear to be prohibitively restrictive

Note: *In some cases, product policies do not correspond to ways the products can be accessed informally (OTC, unregulated channels, etc.)*

PRODUCT BACKGROUND | Ethiopia had a higher number of restrictions at the level of product registration & permitted uses, while others (OCPs, EC) remain more accessible

ETHIOPIA

PRODUCT BACKGROUND

	Product/ service registered	Multiple channels available	Diverse provider roles defined	Lack of age or consent restrictions	Counselling offered	Multi-month dispensation	Available OTC	*Notes*
DMPA-SC	✓*	✗	✗	✓*	✓*	N/A	✗	• *Not permitted for self-injection (only approved for provider-mediated injection) • At a functional level, there is no community-level access. HEWs are not trained to administer, nor is it available in pharmacies and for private sector distribution
OCPs	✓	✓	✓	✓	✓	✓	✓	• Widely distributed by HEWs
EC	✓	✓	✓	✓	✓	N/A	✓	• Social marketing programs (DKT-Ethiopia) largely responsible for distribution in the commercial sector • Pharm & pharm techs can dispense; however, HEWs cannot carry or dispense
ART (PrEP)	✓	✗	✗	✓	✓	✓	✗	• PrEP available for key populations only • ART for PrEP provided by primary care providers, in clinics & facilities only • 3-month MMD & 6-month MMD guidelines exist for eligible patients
HIVST	✓	✗	✓	✗	N/A	N/A	✗	• Assisted ST for some key & priority pops; recent approval of unassisted ST for wider population • Currently not available in pharmacies, but preparatory work underway for social marketing & OTC • Age restrictions currently under discussion to make unassisted HIVST available to youth <15
Mife/Miso (MA)	✓*	✓*	✓*	✓*	✗	N/A	✗	• *Not permitted for self-managed MA • In practice women access OTC (informally)
Telemedicine & remote counselling	✓	N/A				N/A	N/A	• No national guidelines specific to telemedicine/mHealth exist

Note: *In some cases, product policies do not correspond to ways the products can be accessed informally (OTC, unregulated channels, etc.)*