PATH/Will Boase

Important policies for advancing access to subcutaneous DMPA

One of the most exciting things about subcutaneous DMPA (DMPA-SC, or Sayana® Press*) is its potential to empower women and adolescent girls and dramatically increase contraceptive access. This promise can only be fulfilled if enabling policies are in place. Many countries, however, have policy restrictions that could hamper the provision of injectable contraceptives through key service delivery channels for DMPA-SC such as community-based distribution (CBD), private-sector provision, and self-injection.

How to use this tool: This tool provides an overview of key policies that affect introduction and scale-up of injectable contraceptives, including DMPA-SC. These policies are not meant to be exhaustive, but a starting point to direct your efforts.

1. Consult this tool when you conduct a mapping of your country's policy gaps, bottlenecks, and potential enablers to support expanded access to DMPA-SC for women and adolescent girls. It will help you identify the types of policies that may need to be changed or updated.
2. Use this tool—and the policies that are relevant to your country context—to help customize or inform the following materials in the Advocacy Pack for Subcutaneous DMPA:
   - "Policy brief template: scaling-up self-injection of DMPA-SC to increase contraceptive access and options"
   - "Key actions for advocates to advance subcutaneous DMPA"
   - "Advocacy strategy development template: planning to achieve DMPA-SC policy change"

Remember that policies are often interwoven—a change in one policy may require updates in guidelines, strategies, etc.—so it's important to map your country's family planning policies and strategically plan your policy advocacy efforts. Additionally, just because your government passes a policy does not mean it will be implemented. Policy advocacy must be coupled with accountability efforts to ensure resources are allocated.

*DMPA stands for depot medroxyprogesterone acetate. Sayana Press is a registered trademark of Pfizer, Inc.

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Product registration

What is the policy?

New contraceptive products typically must be registered with your country's national drug regulatory authority (NDRA) before they can be procured, imported, and used. Manufacturers are responsible for submitting registration applications. The decision to pursue registration of injectables in your country ultimately rests with the product manufacturer, who must see a market opportunity. In general, the NDRA decides whether to register a product based on a review of information submitted by the manufacturer, independent of advocates or implementing partners. Importation waivers may be an interim option for obtaining product in your country, as product registration can sometimes take a long time. Importation waivers may be more acceptable to ministries of health and subnational stakeholders in some countries than others. If DMPA-SC is already registered for administration by health workers but not for self-injection, the manufacturer will need to submit a product label update to the NDRA. If DMPA-SC is not yet registered in your country, any new registration application for the product overall is likely to include self-injection, based on stringent regulatory approval received in the United Kingdom in 2015.

Why does it matter?

Registration is the first step for countries that want to expand access to DMPA-SC. You can indirectly influence whether registration is pursued by getting your ministry of health (MOH) interested in DMPA-SC and/or the delivery option of self-injection. If your MOH is championing the product with donors and the manufacturer, then this can help advance registration and/or approval of self-injection. Once the registration application has been submitted, you can also check in with your MOH and/or NDRA to make sure the process is moving forward in a timely way.

Where can you find more information?

▶ Medicines regulatory support

Approval for self-injection of DMPA-SC:

In Uganda, for example, the National Drug Authority officially registered DMPA-SC (Sayana Press) in mid-2014. After a study examining the feasibility and acceptability of self-injection in Uganda, the product manufacturer submitted an application to the National Drug Authority for a label update to include self-injection, which was approved 2017.

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Essential Medicines List (EML)

What is the policy?

A national EML is a key policy that identifies safe, efficacious, and cost-effective health products needed for a country's population.

Why does it matter?

The national EML could be important for scaling up injectables in public-sector facilities in your country. In some countries, a new injectable must be included on the national EML (listed by type of medicine and dosage, not brand name) for the government to be able to purchase and distribute it through public-sector channels.

Where can you find more information?

- Essential Medicines for Reproductive Health: Guiding Principles for Their Inclusion on National Essential Medicines Lists
- World Health Organization (WHO) Model Lists of Essential Medicines

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Policies on community-based distribution (CBD) of injectable contraceptives

What is the policy?

These policies allow community health workers/volunteers/distributors to administer injectable contraceptives and train women to self-inject (where self-injection is approved). These policies provide guidelines for services and may also address other public or private sector workers, like pharmacists or drug shop operators. Types of policies may include:

- Policy guidelines and service delivery standards for reproductive health/family planning (FP).
- Community health worker policies.
- Task-shifting/sharing policies.
- Scope of work policies.
- Training curricula and accreditation bodies for community health workers and pharmacists that include injectable contraception administration.
- Circular, memo, or other policy authorization from the MOH allowing community health workers to train women to self-inject.

Why does it matter?

Many countries have community workers/volunteers/distributors who provide contraceptive counseling and methods (standard days method, male and female condoms, pills) to reach remote populations. CBD policies that address injectable contraception are often needed for the product to be introduced or scaled at the community level. Ensuring that your country has policies and guidelines supporting CBD of injectables is critical for reaching underserved women and adolescent girls, including those in remote areas and new users of contraception.

If your country already has a policy on CBD of injectables, it may need to be updated to permit CBD of DMPA-SC products, such as Sayana Press.

Once your NDRA has approved DMPA-SC for self-injection, the MOH may need to give additional approval through a policy statement, such a circular or memo.

Where can you find more information?

- **Community Health Worker Provision of Injectable Contraceptives: An Effective CBA2I Strategy (Advocacy Toolkit)**
- **Community-Based Health Workers Can Safely and Effectively Administer Injectable Contraceptives: Conclusions from a Technical Consultation**
- **Optimizing Health Worker Roles to Improve Access to Key Maternal and Newborn Health Interventions through Task Shifting**
- **Community Health Workers: Bringing Family Planning Services to Where People Live and Work** (Family Planning High Impact Practices)

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Policies on private-sector provision of contraceptives

What is the policy?

These include a range of laws, regulations, and policies that affect private-sector participation, including pharmacies and accredited drug shops, in the contraceptive market. For example, these may impact:

- Whether and which types of businesses or cadres of health workers can stock/sell injectables.
- Whether and which types of private providers can administer injectables.
- Whether and which types of private providers can train women to self-inject.

Why does it matter?

Private retail outlets—such as pharmacies and drug shops—are often an important source of contraceptives, especially for adolescents and young people. However, many countries have policy barriers that hinder private-sector provision of contraceptives. For example, some countries have laws that exclude certain types of providers (such as pharmacists) from administering any type of injection or from stocking injectable contraceptives. Ensuring your country has policies that are favorable to private-sector distribution of injectable contraceptives can help create more sustainable access and potentially reach more young people, as well as new users of contraception.

It is also important to note that some providers may play roles in both the private and public sectors. Explore whether this is common practice in your country, and if so, look into the policy implications. For example, if a provider is authorized to provide injectable contraceptives through community health initiatives, does that authorization also extend to his/her ability to provide injectables through pharmacies and accredited drug shops? Different policies may be needed to allow provision through different service delivery points.

If your NDRA has approved DMPA-SC for self-injection, private providers may be a key outlet for providing the product and training women to self-inject. Explore with your MOH whether additional policy authorization is needed to enable this.

Where can you find more information?

- **Meeting Demand for Modern Contraception: Role of the Private Sector**
- **Reaching Youth with Modern Contraception**
- **Health Worker Roles in Providing Safe Abortion and Post-Abortion Contraception** (WHO guidance that recommends pharmacists can administer injectable contraceptives)
- **Drug Shops and Pharmacies: Sources for Family Planning Commodities and Information** (Family Planning High Impact Practices)
- **Toolkit: Expanding Access to Injectable Contraceptives through Pharmacies** (SHOPS Plus advocacy toolkit for pharmacy associations)

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Policies on use: Guidelines, training materials, and job aids (including for self-injection)

What is the policy?

These policies provide guidance and instruction on DMPA-SC. Materials and training should be customized by target audience: health professionals, community health workers, and/or women and young people (for self-injection).

Why does it matter?

Guidelines, training materials, and job aids are foundational resources that support introduction and scale-up. Such materials have already been developed and pre-tested, and can be adapted for your country's use.

You can play a key role by advocating with your MOH to develop and widely disseminate the resources and ensure their availability among providersand end users. You can also help ensure that these types of documents address WHO's 2019 guidance on HIV risk and injectable contraception, which states that women at high risk of acquiring HIV can use progestin-only injectables (including DMPA) with no restrictions (for more information, see "DMPA and HIV: What advocates need to know").

Where can you find more information?

- **DMPA-SC (Sayana Press) Training Materials** (includes training materials, job aids, and resources on self-injection in both English and French)
- **How to Introduce and Scale Up Sayana Press: Practical Guidance From PATH Based on Lessons Learned During Pilot Introduction**

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FP Costed Implementation Plans (CIPs)

What is the policy?

CIPs are multiyear, actionable road maps that help governments strategically and efficiently invest limited resources to meet the growing demand for FP and achieve their FP goals, including **FP2020** and **Ouagadougou Partnership** commitments. According to FP2020, comprehensive CIPs address demand creation, service delivery, commodity security, an enabling policy environment, and management and accountability.

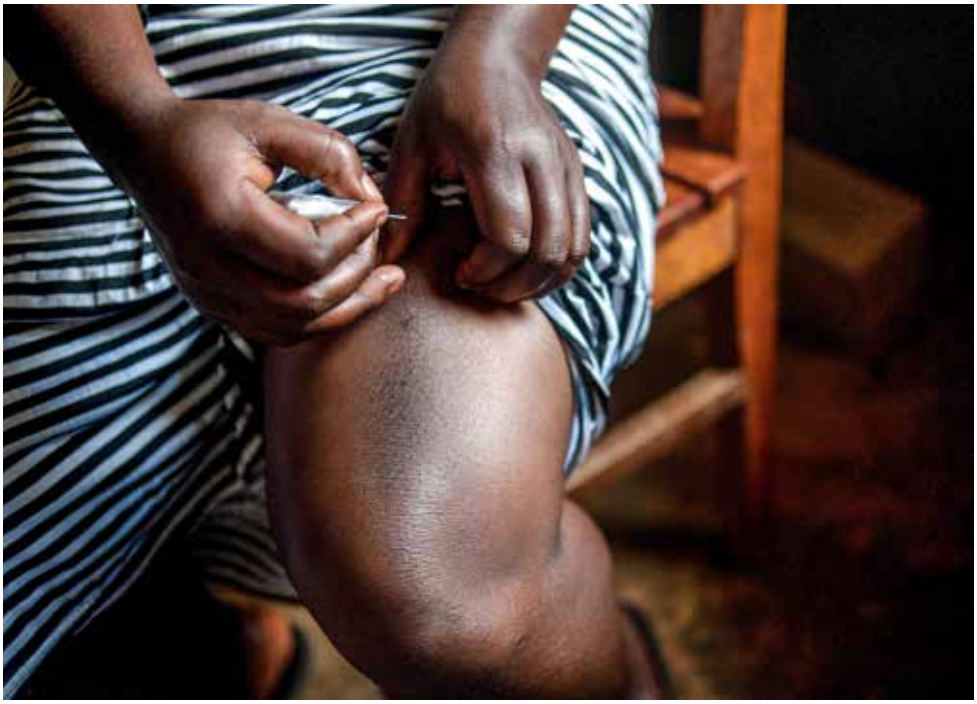
Why does it matter?

CIP development often includes multiple government ministries, development partners, the private sector, youth, and sub-national leaders, who come to consensus on strategic FP priorities and develop a roadmap for implementation. CIPs can also mobilize resources by estimating the impact of interventions and forecasting costs. Including DMPA-SC in your country's CIP can be useful in maintaining commitment and mobilizing resources for scale-up.

If your country is decentralized and sub-national governments are responsible for health service delivery, it may also be important for district/provinces/states to develop their own CIPs.

Where can you find more information?

- **FP2020 Costed Implementation Plan Resource Kit**



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Policies affecting self-injection

What is the policy?

Because self-injection is such a new approach, there is little country experience with the types of policies that may need to be changed to enable women to self-inject. At minimum, the product must be registered for self-injection by the NDRA.

Why does it matter?

Your government may need to have certain policies or guidelines in place to permit scale-up of self-injection of DMPA-SC. To help figure this out, you can:

- Explore with FP leaders in your country whether any type of formal policy authorization will be required to permit self-injection, following regulatory approval (e.g. policy memo, circular, or inclusion in clinical guidelines).
- Determine whether your country will need to have policies that support advance provision of DMPA-SC to women (for example, through facility providers or CBD agents, or through pharmacy and drug shop sales).
- Consider whether community health workers, pharmacists, or drug shop operators might be well positioned to teach clients to self-inject in your context, and what policy revisions might be required to support that.

Where can you find more information?

- **Health Worker Roles in Providing Safe Abortion Care and Post-Abortion Contraception** (WHO guidance that recommends self-administration of products like DMPA-SC in circumstances where FP clients have training and support)
- **DMPA-SC Self-Injection Resources**

This is not an exhaustive list of all the policies that impact DMPA-SC scale-up. Also consider the broader health environment, such as primary health care policies, integration with HIV/AIDS programs, and guidelines for waste disposal.