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 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: A groundbreaking opportunity to increase contraceptive access and options”
   - “Key actions for advocates to advance subcutaneous DMPA”

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

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. 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.
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
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 provide guidelines for those services. They also may 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.

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.

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)
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.

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. 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.
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 providers and end users. You can also help ensure that these types of documents address WHO’s 2017 update on HIV risk and injectable contraception (for more information, see “DMPA and HIV: What advocates need to know”).

Where can you find more information?
▶ Tools for Sayana Press Introduction: Training and Communications (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
FP Costed Implementation Plans (CIPs)

What is the policy?
CIPs are multiyear, actionable road maps that help governments be strategic and efficient in investing limited resources to meet the growing demand for FP and achieve their FP goals, including FP2020 and Ouagadougou Partnership commitments.

Why does it matter?
Including DMPA-SC in your country’s CIP can be useful in maintaining commitment and mobilizing resources for scale-up.

Where can you find more information?
► FP2020 Costed Implementation Plan Resource Kit
Important policies

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—if any—that may need to be changed to enable women to self-inject. At minimum, the product must be registered for self-injection. If the product 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?
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 authorization will be required to permit self-injection, following regulatory approval.
- 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 or pharmacists 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)
- Sayana Press Home and Self-Injection Resources