

# 5 BASIC STEPS

## To institutionalize the FC2 Female Condom within your country



### The 5 steps

What will follow is a detailed description of each of the 5 steps to institutionalize the FC2 Female Condom:

#### 1 Registration

Most of the times, essential documents such as a Certificate of Country of Origin / Free Sale Certificate / Regulatory Approvals / Labelling / Quality Assurance tests, are required by the MoH / in-country regulatory agencies. It is important to request a list of all required documents, identifying the ones that need to be notarized and translated. Usually registration can be held by the MoH itself or by an in-country distributor. In some countries, UNFPA can request special permission to import FC2 for the MoH, while registration is not (yet) in place. In few cases, acquisitions via UNFPA are exempt from in-country registration when MoH makes use of international quality assurance approvals (WHO/FDA). Female Health Company can be contacted by the MoH, in-country distributor or UNFPA to provide the necessary documents for registration. Please do note that registration can take between 6 months to 1,5 year based on the country and its rules. Take this into account when planning the other steps, as it will determine how long it will take before the product can be imported into the country.

#### 2 Institutionalization

Male and female condoms play an important role in the prevention of STIs and unplanned pregnancies, and therefore should have a dedicated budget line that avoids stock-outs. It is important to sensitise policy and decision makers about the importance of making both male and female condoms available, using concrete evidence, such as: FC2 increases the number of protected sex acts, it prevents a mother with Zika from infecting her baby, it is more cost effective to prevent any STI than to treat them, among many other reasons. According to the publication *“The Business Case for Female Condoms”* (S.Thurston and A. Forbes, Global Health Visions, 2014) the economic gains to be realized from investment in female condoms far outweigh the costs of programming, especially in high HIV prevalence countries. Female condoms further offer a competitive cost per DALY (Disability Adjusted Life Year) against WHO-CHOICE (CHOosing Interventions that are Cost Effective) thresholds and in comparison with alternative interventions.

In countries where a national condom policy / guideline already exists, it facilitates the integration of the female condom. To institutionalize a female condom program within a country and make it sustainable, it needs to be included in the following areas of a country's policy:

- FC2 is included on the national essential medicine list
- FC2 is included on the national procurement list
- FC2 is included in the national health strategy
- FC2 has an assigned budget line within the MoH budget
- FC2 is included in the MoH standard training
- FC2 is registered in (the) country (through a distributor)

#### 3 Procurement

Like creating a budget line for the acquisition of male and female condoms, procurement is also a complex task, as it encompasses the following steps:

- Sending a quote inquiry to manufacturer Female Health Company
- Receiving a quote
- Production / testing
- Shipping (from Malaysia to country port) (from 2 to 3 months)
- Product clearance
- In-country logistics

The FHC team has the expertise to support the MoH during the procurement process.

### *“The Business Case for Female Condoms”*

(Global Health Visions, 2014)

Return on investment of female condom procurement for governments in 2 ways:

- Cost savings to the health system, by focussing on prevention instead of treatment.
- Economic productivity losses averted, as more women are able to join the workforce.

The Business Case for Female Condoms found that for every \$1 invested in female condoms in Kenya a return of \$1.94 is made. For every \$1 invested in Nigeria, they found a return of \$3.20.

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### 4 Training

While working on the prior 3 steps mentioned, it is key to develop a framework that will guide the implementation of condom activities in a country. It is crucial that male and

female condoms are promoted by a well-trained and skilled network of health care providers / outreach workers / peer educators.

In general terms, the framework should comprise:

- Communication & demand generation (informative materials, training materials)
- Capacity building & training (training of key stakeholders / pelvic models / samples / flip charts)

Female Health Company has developed service packages that fulfil the country's needs in terms of materials and training. The services are attached to the number of FC2 procured and are financed by the company. All training materials are freely available online. From training manuals to how to use animations, posters, leaflets and a variety of studies/publications, everything can be found on FHC's website: [www.fc2femalecondom.com](http://www.fc2femalecondom.com).

### 5 Monitoring and evaluation

An important component of male and female condom programs that reveals best practice and offers direction for learning and improvement. Lessons learned can be

incorporated in policies and practices. Besides that, M&E is a tool to assess the link between implementers, beneficiaries on the ground and decision makers.

In parallel, it is also important to consider developing a plan to share the lessons learned, which should draw on both positive experiences (ideas to improve the program's efficiency) and negative experiences. All documented lessons learned should contain at least four general elements:

1. Program information
2. A clear statement of the lesson
3. A background summary of how the lesson was learned
4. Benefits of using the lesson and suggestion how the lesson may be used in the future.

### Background

Over the last few years the second generation of the female condom, FC2, has gained presence in countries worldwide. FC2 institutionalization is in different stages in various countries. Brazil and South Africa have the most extensive long-term distribution programs in the public sector and have institutionalized the FC2 Female Condom. This means that:

- FC2 is registered with the regulatory agency
- FC2 has a budget line within the MoH's overall budget (national treasury funds)
- FC2 is included in the annual national procurement list
- FC2 is part of the MoH's communication strategy

### Objective

To provide Ministries of Health with a document that describes the 5 basic steps to successfully introduce and institutionalize FC2 in their respective countries' STI prevention and family planning programs.

### Output

Knowledge about the 5 basic steps to successfully introduce and institutionalize the FC2 Female Condom and introduction to Female Health Company service packages.

### Duration

The duration of the steps varies from country to country, depending mainly on each country's functioning structure. Even though specific tasks are needed to accomplish each of the five steps, most of them can be carried out in parallel. For example, while working on registration, meetings with decision makers can be arranged to discuss the creation of a budget line to procure the commodity, as well as planning allocation of funds.

### Beneficiaries

MoH officials, NGOs, social marketing organizations and other key stakeholders.



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