



What information reaches the end user? Analysis of MA product labels collected globally.

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Today's panelists

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IPPF Medical Abortion Commodities Database

Catherine Kilfedder
IPPF



www.MedAb.org - launched September 2018

The screenshot displays the MedAb.org website interface. At the top left is the logo for the 'MEDICAL ABORTION COMMODITIES DATABASE'. At the top right is the logo for 'IPPF International Planned Parenthood Federation'. Below the header, there are three search filters: 'COUNTRY SEARCH', 'COMMODITY SEARCH', and 'BRAND SEARCH'. Each filter has a dropdown menu with the text 'Select Country', 'Select Commodity', and 'Select Brand' respectively. An orange 'Submit' button is located below the 'COUNTRY SEARCH' dropdown. In the center of the page is a world map where most countries are highlighted in blue, while some are in grey. On the left side, there is a vertical navigation menu with icons for 'About', 'Search', 'Summary Tables', 'External Resources', and 'Disclaimer'.



Why a medical abortion database?

- Review of cases of adverse events following medical abortion
- Independent testing of misoprostol from country programmes revealed quality issues
- Challenges in recommending appropriate commodities for country programmes
- No single source for this type of information



Quality

A misoprostol product is included if it:

- has met requirements and standards for **WHO prequalification**
- has been approved by a **Stringent Regulatory Authority (SRA)**
- has received a current positive risk-based assessment recommendation of category 1 or 2 from the **UNFPA Expert Review Panel (ERP) process**
- has **other sufficient evidence** on stability and clinical effectiveness from at least two of the following:
 - Stability testing data
 - Independent product testing
 - Data on clinical effectiveness



Availability

- Structured in-country data collection exercise in select countries
- Information from social marketing organizations, distributors, manufacturers and others



Who the database is for and how it can be used

Service providers, programme managers, procurement personnel

Identify quality products that are available in country

Advocates, policy analysts

Define advocacy strategies, priorities and partnerships

Funders, fundraisers

Understand market and where to invest resources and target asks

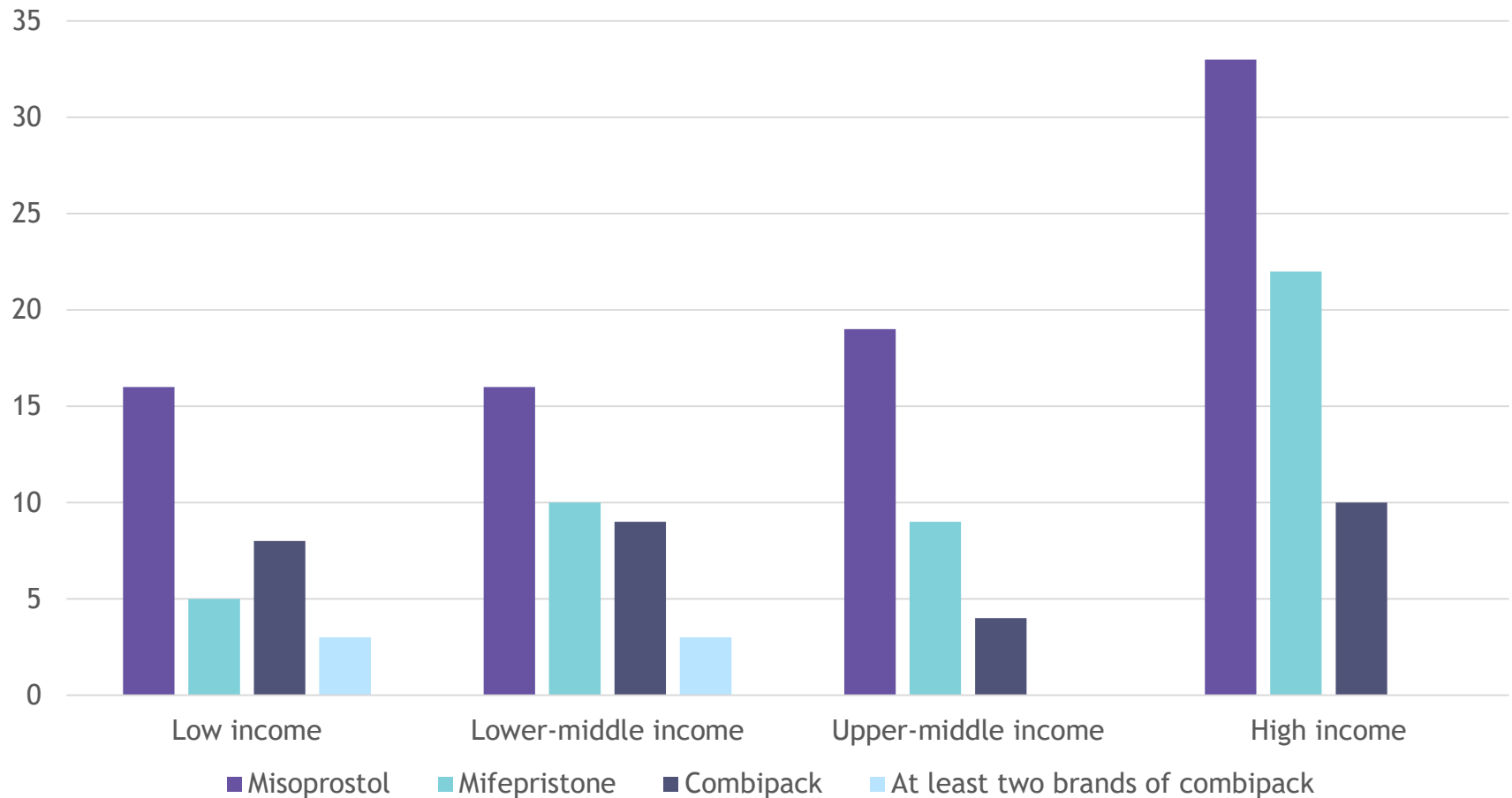


What the database is NOT

- A service providing website
- A complete market availability mapping for medical abortion commodities
- An endorsement or advertising by IPPF of certain brands
- A one-off project that is finished



Availability of medical abortion commodities, by income status





Moving forward

- Continued development and maintenance
- Continued focus on quality determination
- Data collection in additional countries
- Further analysis of secondary data



**MEDICAL ABORTION
COMMODITIES
DATABASE** —●—○—

info@MedAb.org



What information reaches the end user? Analysis of MA product labels collected globally.

Laura Frye, Gynuity Health Projects

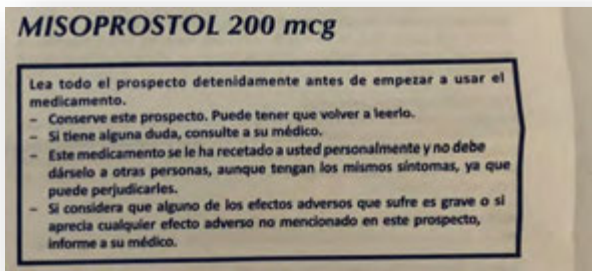


Background

- Purpose of an insert is to provide prescribing and safety information to health professionals

BUT

- May be the only information accessible to an end user



DRUG INTERACTIONS

- *Ketoconazole, Itraconazole, erythromycin, and grapefruit juice* may suppress the catabolism of mifepristone (raising its concentration in the serum).
- *Rifampicin, dexamethasone, St John's wort* and some anti-epilepsy drugs (*phenytoin, phenobarbital, carbamazepine*) may induce the metabolism of mifepristone (lowering the concentration in serum).
- *Non-steroid anti-inflammation drugs (NSAIDs)* including aspirin should be avoided to go along with mifepristone, for NSAIDs are normally anti-prostaglandin. Theoretically they would lower the effectiveness of mifepristone.

PREGNANCY AND LACTATION

- Women using this method to have abortion should be told in advance that if the method does fail, other than that the pregnancy may go on, and there is a risk to deliver a deformed baby later. In case this method does fail, it is a must to use another method to terminate the pregnancy in the next follow-up visit the hospital.
- There is no kinetic data to prove or disprove that mifepristone can be secreted in mother's milk. Nevertheless, to play it safe, it is recommended that after taking mifepristone, the patient should stop nursing for 3-4 days.

ADVERSE REACTIONS

Urogenital system:

- + **Bleeding:** All women using this drug will have bleeding situation, and it is more or less proportional to the length of pregnancy in days that the amount of bleeding increases. Some will have heavier bleeding than others.
- + During the next few hours after taking prostaglandin, it is quite often to have uterus contraction or spasm phenomena.

Gastrointestinal system: After using prostaglandin, the patient often feels stomach sick, displays vomiting, and diarrhoea symptoms.

Cardiovascular diseases: A few cases had hypotension phenomenon.

Others: In very few cases there were: skin rash, headache, body discomfort, hot flash, dizziness, feeling cold and rare fever.

OVERDOSAGE

Research in dosage pointed out that a single dose of mifepristone up to a total of 2 g would not cause apparent side effects. For all acute poisoning, it is recommended that the patient should be hospitalized for further observation and treatment under special environment.

During the next few hours after taking prostaglandin, it is quite often to have uterus contraction or spasm phenomena.

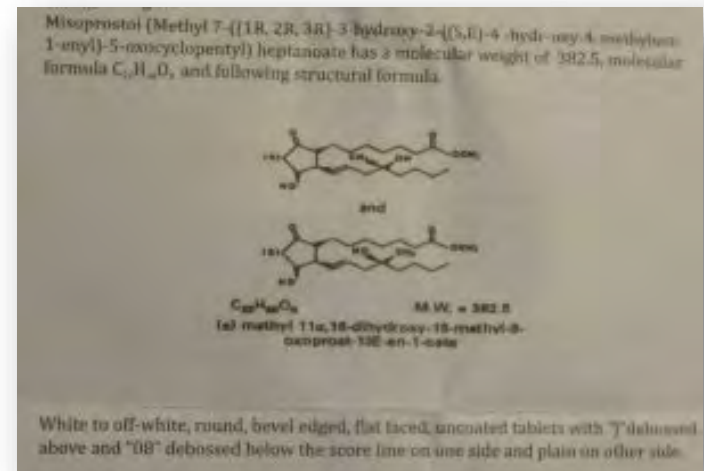
STORAGE : Store in a well-closed container, in a dry place, protect from light. Do not store above 30°C.

SHELF-LIFE : 36 months from the date of manufacturing.

PACKAGING : Blister of 1 tablet. Box of 1 blister.

SPECIFICATION : Manufacturer's specification.

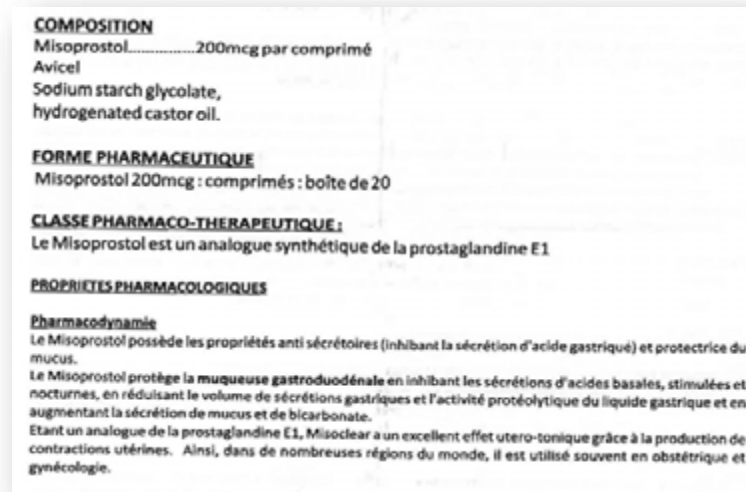
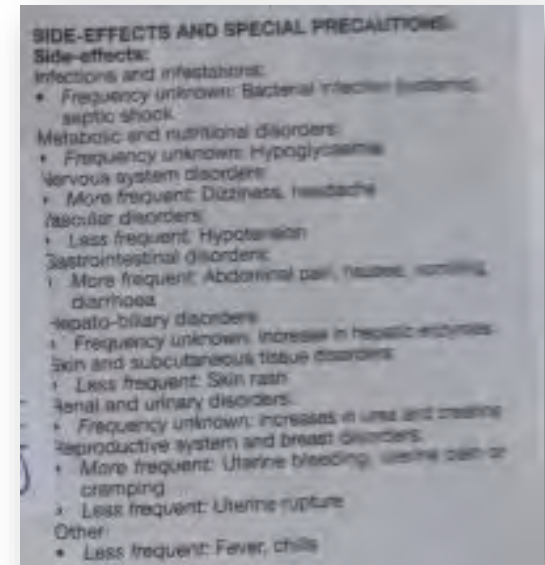
THIS DRUG SHOULD BE USED ONLY BY QUALIFIED GYNAECOLOGIST





Methods

- Secondary analysis of data from medical abortion database
- Not representative, meant to explore issues
- Analyzed “unique” inserts in English, Spanish, French, Portuguese
 - 37 Inserts
 - 24 Miso
 - 7 Mife
 - 6 Combipacks
 - 19 Countries





What's Missing

STORAGE

Store below 30°C. Keep away from direct sunlight. Keep out of reach of children.

STORAGE : Store in a well-closed container, in a dry place, protect from light. Do not store above 30°C.

STORAGE INSTRUCTIONS:

Store below 25°C.
KEEP OUT OF REACH OF CHILDREN.

- ❖ Storage instructions *
 - ❖ 84% of inserts mentioned how to store the drug

DESCRIPTION

White, round-shaped tablet, quadrisected on both sides.

- ❖ Appearance
 - ❖ 43% of inserts described the pill

DESCRIPTION

Light yellow, round - shaped, biconvex tablet, fracture line on one side.

- ❖ Date
 - ❖ 35% of inserts listed the date it was updated
 - ❖ Dates ranged from 1991 to 2018

January 1991

along with p...
Last revision done on: September 2012

Date of Revision: November 2016.



Translation

From awkward, to wrong, to problematic

...for patients of young age type diabetes...

...long lasting vaginal bleeding phenomenon...

...Grapefruit juice...

...fruit juice (grape)...

...jugo de uva...

...Dos días después de la prostaglandina se administra Usted debe quedarse y descansar durante 3 horas después de la prostaglandina...



Misoprostol Indications

- *Most common indication was gastric ulcer*
- *Four products labeled for medical abortion*
- *No products listed all evidence-based indications*

Product Number	Indication: Med Ab	Indication: PPH	Indication: Ulcer	Indication: PAC
1	Yes	Yes	Yes	No
2	Yes	No	No	No
3	Yes	No	Yes	No
4	Yes	No	Yes	Yes
5	No	Yes	No	Yes
6	No	Yes	No	Yes
7	No	Yes	No	Yes
8	No	Yes	No	Yes
9	No	Yes	Yes	Yes
10	No	Yes	Yes	Yes
11	No	Yes	Yes	Yes
12	No	Yes	Yes	Yes
13	No	No	Yes	No
14	No	No	Yes	No
15	No	No	Yes	No
16	No	No	Yes	No
17	No	No	Yes	No
18	No	No	Yes	No
19	No	No	Yes	No
20	No	No	Yes	No
21	No	No	Yes	No
22	No	No	Yes	No
23	No	No	Yes	No
24	No	No	Yes	No



Mifepristone and Combipack Indications

- All combipacks (n=6) listed a single indication, medical abortion
 - 3 specified <63 days
 - 2 specified <9 weeks
 - 1 specified first trimester
- Mifepristone (n=7) products had more variety
 - 1 did not list an indication (though instructions for MedAb <63 days)
 - 3 listed MedAb <49 days
 - 3 listed four indications
 - Early MedAb
 - 63 days or 56 days
 - Cervical ripening prior to surgical termination
 - Pre-treatment before prostaglandin for later MedAb for medical reasons
 - 13-20 weeks
 - After first trimester
 - Beyond 3 months
 - Labor induction for IUFD
 - 2 specify when prostaglandin or oxytocin not possible



Medical Abortion Regimens

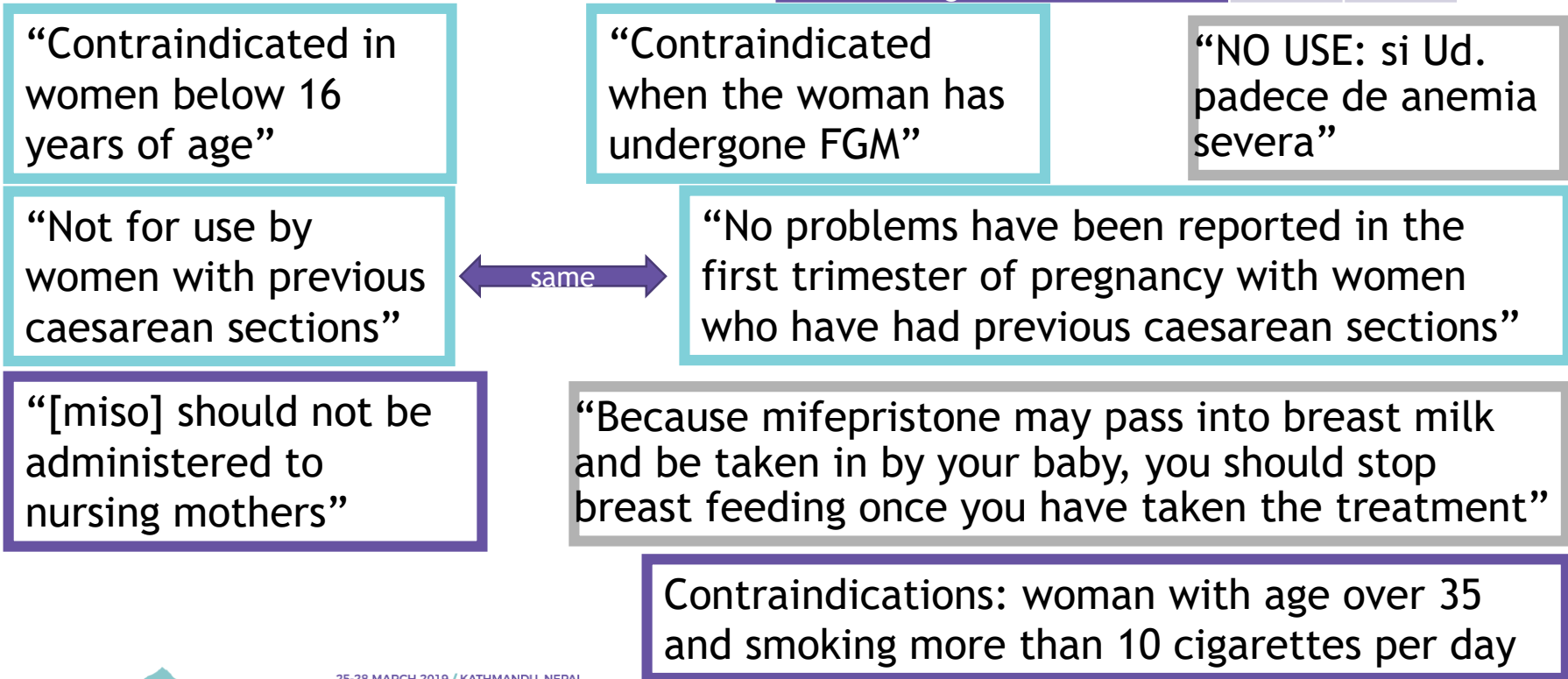
- ❖ Two products labeled for gastric ulcer and medical abortion only had ulcer regimens
 - ❖ Potentially dangerous
- ❖ Some products had different regimens by gestational age, representing the era of research
- ❖ Some listed medical abortion regimens maintained 600 mg mife, cost implications
- ❖ Wide range of miso doses (400-800mcg) and routes (oral, vaginal, sublingual, buccal, sublingual/buccal)



Medical Abortion Eligibility

- Many of the eligibility criteria did not align with WHO guidelines, potentially over restricting access

Medical Abortion Eligibility	n	%
Gestational age: none	4	24%
Gestational age: ≤49	4	24%
Gestational age: ≤56	1	6%
Gestational age: ≤63	8	47%
Gestational age: ≤70	0	0%





Protocols

Some labels went beyond the WHO guidelines to put additional restrictions on medical abortion protocols

“El uso de [mife] require que se tomen medidas para evitar que el factor Rhesus sensibilizacion (si usted es Rh negative)”

“Right after taking misoprostol, the patient should stay at the hospital for 3 hours for observation”

“Rhesus-negative women who have not been rhesus immunized will require protection with anti-D immunoglobulin”

“Consulte a su medico especialista en ginecologia”

“it is recommended that after taking mifepristone the patient should stop nursing for 3-4 days”

“The trained health care provider must...be able to assure the Client access to medical facilities equipped to provide blood transfusions”

“Oxytocin should not be used after 6 hours of administration of the last dose of misoprostol”

“Avalez les comprimés entiers avec un verre d'eau en présence d'un médecin ou d'un member de l'équipe médicale”



Values come through in the absence of evidence

“Los datos disponibles sobre el riesgo potencial de anomalías fetales después de un aborto sin éxito son limitados e inconcluyentes; por lo tanto, si una mujer desea continuar con un embarazo expuesto, no es necesario insistir en finalizarlo”

“In case this method does fail, it is a must to use another method to terminate the pregnancy in the next follow-up visit the hospital”

“En cas d' échec de l' interruption de grossesse, le risque encouru par le foetus est inconnu, si vous décidez de poursuivre la grossesse, un suivi prénatal attentif et des échographies répétées, avec une attention particulière portée aux extrémités, devront avoir leur dans un centre spécialisé.”



Implications

- ❖ Evidence on medical abortion procedures are evolving
- ❖ The initiative and cost of changing an insert to reflect new evidence usually falls to a manufacturer
- ❖ How can the reproductive health community help to ensure accurate information is provided to people seeking abortion?

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Within Reach

Expanding Access to Safe Abortion

The videos in this presentation were developed by Population Reference Bureau with guidance from a global Technical Advisory Group of researchers, advocates, and medical professionals. We thank the members of that group for their time and dedication, including:

- Akinrinola Bankole, Ph.D., MA, M.Sc., Guttmacher Institute
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- John Townsend, Ph.D., Population Council

Within Reach: Expanding Access to Safe Abortion

For more information, or to download the full presentation,
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Question and Answer



KATHMANDU

25-28 MARCH 2019 / KATHMANDU, NEPAL

19TH GENERAL MEMBERSHIP MEETING OF THE REPRODUCTIVE HEALTH SUPPLIES COALITION



Thank you

On behalf of Gynuity Health Projects and IPPF