MARIE STOPES INTERNATIONAL
Children by choice, not chance

# **Supporting self-management of medication abortion from pharmacies**: Evidence update and recommendations for practice




## Purpose of this brief

This evidence brief summarises recent learnings and practices that can help to create an enabling environment for the safe, supported self-management of medication abortion (MA) from pharmacies[1].

Self-management of MA is safe, effective, and can improve accessibility of abortion care. Both the combination-pack of mifepristone and misoprostol, or the less effective regimen of misoprostol-alone, can be purchased over the counter from pharmacies in many countries. The increasing access to MA through pharmacies over the past decade has helped reduce unsafe abortion and its associated morbidity and mortality globally. It has proved particularly important during the Covid-19 pandemic, when health facilities have been less accessible.

For supported and effective self-management, users of pharmacy-provided MA need:

- Quality products
- Adequate information about the medications
- Access to follow up support when needed

This brief summarises evidence and learning on improving access to quality information to users of pharmacy-provided MA through a range of communication channels, since published studies show that information provision through pharmacies can be inadequate for reaching end users.

[1]In this brief we use the term 'pharmacies' to refer to various types of pharmaceutical vendors including pharmacies, drug shops, and chemists, but acknowledge that these points of sale can range from trained pharmacists to informal drug stores with untrained staff, and that there are differing levels of regulatory oversight.

## Recommendations

**1. Ensure that MA users have direct access to information to support self-management and supplement information they may or may not receive from pharmacies.**

**Why?** Although pharmacy staff knowledge can be improved by training, improvements in knowledge do not necessarily improve pharmacy worker practice and can be limited by stigmatising attitudes, restrictive legal environments and high turnover of staff. Pharmacy worker training, detailing and information materials may result in some transfer of accurate information to MA users, but MA is often purchased on behalf of the user by a partner or family member, so verbal information provided by pharmacy staff may not reach the end-user.

Strengthening product packaging and links to health facilities, hotlines/contact centres or web-based information can ensure MA users are informed consumers, with better access to quality information and support. Social media, word of mouth, community mobilisers, accompaniment models and other forms of community engagement can ensure that MA users have an enabling environment to seek and access accurate and safe information about self-management.

**2. In line with national laws, product labelling can be improved or supplemented by including user-friendly, accurate product inserts. Ensure comprehensive user-testing and pictorial guidance for low literacy users.**

**Why?** Product inserts, which contain information for the approved indication in each country, often have inadequate or outdated information, and are not always designed with an end-user in mind. Label comprehension studies and formative research suggest that written and pictorial instructions are not always clear to end-users and are not always adapted to suit their contexts.

**3. Product packaging should link MA users to personalised support through hotlines, contact centres and secure digital platforms that can offer advice to clients and to pharmacy staff, and onward referral where needed**

**Why?** Product inserts have limitations or lack information to support self-management even when a combi-pack (combination regimen) is used. For instance, product packaging may be discarded by pharmacy staff or by users due to regulatory concerns. In legally restrictive settings, misoprostol products are often provided off-label, with product leaflets lacking information on how to administer misoprostol for MA.

Promotion of a contact number on product packaging and through other media and community-based activities can increase access to accurate information and support. Using hotlines or contact centres may not be appropriate to all settings, but web-based information or accompaniment programmes may be a more culturally acceptable way to consume information.

**4. Work with national health legislature to develop laws, policies and guidelines that enable pharmacy staff and MA users to access to high quality information (in line with WHO guidelines). This is especially critical for communities affected by pandemics or displacement, where access to self-managed MA is most needed.**

**Why?** The legal and regulatory environment in many countries constitutes a major barrier to the provision of information on self-managing MA. For example, despite the fact that most African countries have ratified the Maputo Protocol which calls on governments to authorize abortion in the event of sexual assault, rape, incest, or if a woman's health is in danger, national abortion laws do not include these legal indications in many settings. Legal restrictions on abortion, and the perception of abortion's illegality, create barriers for the availability of quality information as pharmacists and MA users can be nervous to speak about abortion or to carry information about MA self-use.

## What practices are currently used to support self-management of MA from pharmacies?

Many practices are already used by governments, non-governmental organisations and civil society to support self-management of MA from pharmacies, though limited evidence exists about the effectiveness of most of these mechanisms. These routes of communication to clients vary due to local legal frameworks and regulatory contexts, but can involve support to pharmacy staff, efforts to communicate directly with MA users, and signposts to further information from contact centres or online platforms:

1. Written and pictorial information for clients and pharmacist/pharmacy workers on how to safely take MA products, spot warning signs and seek follow up care.
2. Product inserts can provide understandable client-facing information about how to use the medications for a range of literacy levels, where approved by regulatory bodies.
3. Combi-packs contain the correct dosages of mifepristone and misoprostol needed to induce an abortion in one packet, and have instructions in the packaging about how to use these medications.
4. Hotlines/contact centres staffed by trained professionals offer support to users of MA from pharmacies and the pharmacy staff themselves.
5. Websites, instructional videos, e-learning courses and apps have been developed to provide interactive audio-visual information on how to take MA products and signpost users to hotlines.
6. Training of pharmacy workers Face to face training has commonly been used in harm reduction frameworks to try to ensure that MA users receive accurate information about self-management.
7. Pharmacy detailing In-person visits to pharmacy staff are commonly used by pharmaceutical salespeople to distribute and sell medications. During these visits, information and materials can be provided to improve pharmacist knowledge and access to hotlines.
8. In-pharmacy informational materials These can be used to refer users to accurate sources of information about MA or to directly provide information about MA.
9. Accompaniment models and other grass-root peer support networks can provide the information and support needed to safely self-manage MA, whether it is purchased from a pharmacy or directly provided by the accompaniment network or distribution network.
10. Harm minimisation models ensure MA users can receive information from a clinic-based medical provider before and after self-managing MA from a pharmacy, in restrictive policy environments.

# Existing resources that can support safe self-management of medication abortion

### Written and pictorial information

- MSI's pictorial information for MA administration
- Women on Waves low literacy online materials for safe medical abortion, including aftercare, and short summaries for printing as stickers.
- MAMA network information materials for mifepristone and misoprostol, or misoprostol alone
- Gynuity Health Projects Image bank: can support development of MA information materials.
- Written guidance on how to use MA products in 16 languages from How To Use Abortion Pill
- Ipas MA self-use materials for humanitarian settings
- Ipas training materials for accompaniment persons for support of MA self-care.

### Hotlines

- MSI contact centres
- Women Help Women hotlines
- Women on Web helpdesk

### Websites

- How to use abortion pill website (with interactive chatbot)
- Mariprist and Misoclear product websites
- Safe2choose.org website, chat function, Facebook site, and email address

### E-Learning courses

- E-learning courses for pharmacists and pharmacy workers from How To Use Abortion Pill

### Apps

- Hesperian Safe Abortion App
- Euki App
- Women on Waves App

### Digital resources

- IPPF Video on how MA pills work.
- Marie Stopes Cambodia's videos on how to take MA pills (in Khmer only), developed in collaboration with LSHTM.
- Ipas video on how to use misoprostol for MA (in Spanish with English subtitles)

### What do MA users need to know to safely self-manage?

1. The options available for MA (mifepristone-misoprostol regimen, if available, or misoprostol-alone regimen) and what to have on hand for pain management.
2. How to assess gestational age and who is eligible to use MA (understanding the contraindications).
3. How and when to take the pills (number of pills that should be taken, route of administration and timing intervals).
4. What to expect (e.g. pain, bleeding and other possible side effects) and how long the process and bleeding that follow could last.
5. Warning signs for potential complications, and where to seek additional support or urgent medical care.
6. When contraception can be started (almost all methods can be started immediately), and that fertility returns rapidly.
7. When normal activities can be resumed, including sexual intercourse.

*Source: WHO Medical management of abortion (2018)*

### What role can pharmacists play in safe self-management of MA:

1. Provide information about safe abortion.
2. Ensure quality MA products are stocked and stored appropriately.
3. Sell MA and analgesics to clients according to local legal frameworks.
4. Provide contraception along with MA to those interested in quick start of methods with MA, including oral contraceptives, condoms, self-injectables or emergency contraception.
5. In the context of rigorous research, the WHO recommended in 2015 that qualified pharmacists can assess eligibility for MA, administer the medications and assess completion and the need for further clinic-based follow up.

*Source: WHO Health Worker Roles in Safe Abortion*

MARIE STOPES INTERNATIONAL
Children by choice, not chance



## Pharmacy provision of MA is safe and effective

A growing body of evidence has found that MA users can have safe, complete abortions with medications provided by pharmacy staff. In Nepal, a study by CREPHA and PSI found that trained pharmacy workers can provide MA with safe and effective outcomes, long after the training is completed. The Guttmacher Institute have similarly conducted research in Nigeria which suggests high abortion completion rates (94%) after self-administering misoprostol from pharmacies.

A previous MSI study in Bangladesh also found similarly high completion rates among combi-pack users who purchased from pharmacies. Two forthcoming studies from Ipas in Cambodia and Ghana compare clinical outcomes of MA sourced from pharmacies with MA sourced from clinics, which also support non-inferiority of pharmacy-sourced MA.

However, studies have also documented challenges when using medication abortion products without adequate guidance and support. For example, a qualitative study in Madagascar found that misoprostol was accessed formally or informally, but often used incorrectly due to a lack of reliable information and this could result in incomplete abortions and complications. The MSI Bangladesh study found nearly half of all users received no information from pharmacists on how to safely take the pills, and most misoprostol users were not sold the correct regimen. High completion rates may therefore reflect the safety of the regimen itself rather than the quality of pharmacy workers' practice.

## Key learnings on pharmacy provision of MA

- MA is safe and effective, so users can safely self-manage their abortion after buying drugs from pharmacies, despite the lack of information generally provided by pharmacy staff .
- People living in poorer countries with more restrictive abortion laws, however, are most likely to face challenges surrounding access to accurate information (as well as quality products), so pharmacy interventions must be improved.

# Product inserts often lack adequate information and careful piloting is needed to ensure understanding and accessibility

A recent multi-country review of 41 MA product inserts from outlets in 20 low and middle income countries found that instructions often had inadequate or conflicting storage instructions, outdated or missing gestational age limits and outdated regimen instructions. A third of inserts used language that was directed at the end user while the remainder were aimed at prescribers. Instructions were poorly worded, translated with errors and conflicting in many of the inserts.

Two recently published studies have also explored how MA users interpret and respond to written and pictorial information about the medications:

A label comprehension study in South Africa assessed how easily women of different literacy levels could understand a non-pictorial combi-pack product label (see image). MA purchasers' understanding of the instructions was mixed: the highest comprehension scores were for contraindications (80%) and lowest for how to follow up with a pregnancy test (60%) and the timing of drugs (57%). Low-literacy women were 86% more likely to answer questions about indications incorrectly, and 91% more likely to answer questions on the appropriate gestational age incorrectly.

Formative, qualitative research with garment factory workers in Cambodia, which aimed to inform an MA digital intervention, asked respondents about their preferences for receiving information on MA. Findings show that illustrations in pictorial instructions could be improved by removing emotions from people's faces which could be distracting, by indicating timing more clearly, and by ensuring illustrations reflect the type of environment clients take the products in (e.g. at home). Information about mode of administration was often confusing and could be contradictory in different materials. The researchers highlighted that MA product materials should put the most important component first, which is usually a contact phone number, and try to print this on the foil of the blister pack as product packaging is often discarded to maintain secrecy.

## Key learnings on product inserts

- Comprehension of written product labels can be low, particularly among low-literacy groups, and certain pieces of guidance (timing and mode of administration) are particularly confusing. Label comprehension pilots are important for instructional materials.
- Illustrations and accessible language should make information understandable for a range of literacy levels.
- Information materials should be responsive to the context that pharmacies operate in, and the ways that clients consume other forms of medical information.
- Hotline / contact centre phone numbers should be prioritised on MA product packaging, but phone numbers should be printed on product foil as well as outer packaging, as packaging is sometimes discarded.

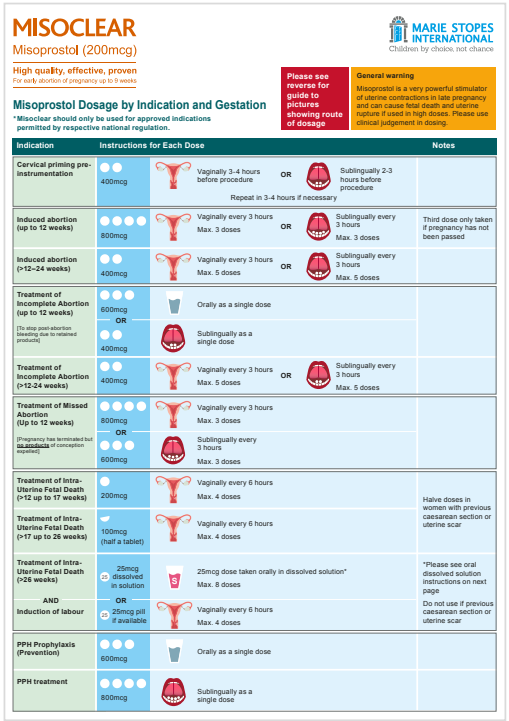
# Improvements in pharmacist knowledge do not always increase access to information, but hotlines give information directly to MA users

In 2018, a systematic review found there were very few evaluations of interventions to improve the quality of pharmacy worker MA practices. Most studies on this topic had evaluated training interventions for pharmacy staff, and although some studies documented improvements in knowledge, these improvements did not always result in pharmacy staff changing their practices.

Since 2018, several new studies have been conducted. A study led by UCSF in Uttar Pradesh in 2018 evaluated whether provision of an infographic handout about MA to pharmacists would improve their knowledge, and clients' access to information. The infographic contained guidance about directions, indications, contraindications, side-effects, signs of completed abortion, signs of complications, and advice on contraception. The study found that pharmacy worker knowledge of the correct combination regimen improved significantly (from 21% to 36%), and pharmacy workers provided positive feedback on the infographic leaflets. Mystery clients were more likely to be shown instructions in the intervention pharmacies, but there was little change in any other pharmacist behaviour; they were not more likely to ask about gestational age, provide information on warning signs or how to take the MA product. These findings again suggest that pharmacy training and informational interventions may improve knowledge, but they do not positively impact pharmacy worker behaviours and quality of care.

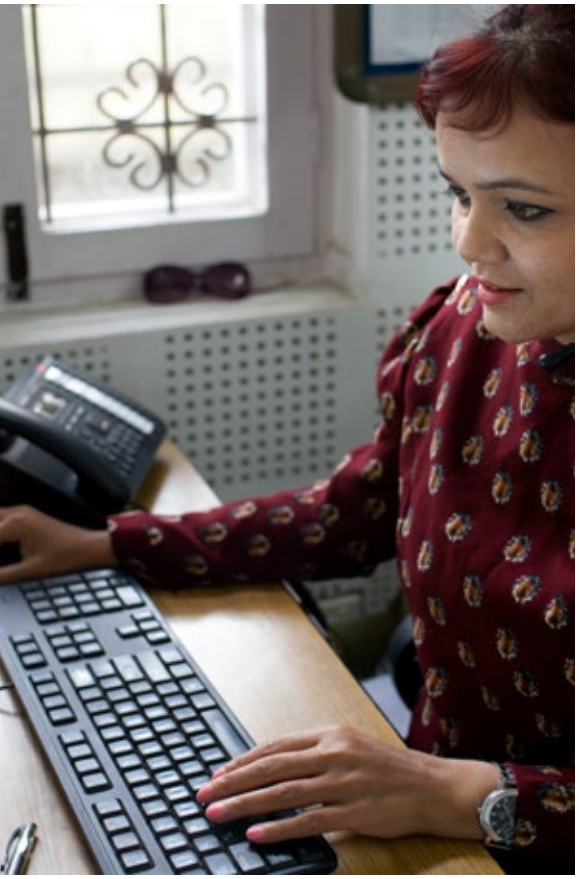
MSI conducted a study in Zambia in 2018 to evaluate whether provision of promotional materials to pharmacies (stickers on MA products, banners, posters, table talkers, pocket cards and t-shirts / lab coats for pharmacy staff), could increase access to information and support for MA self-management, by raising awareness of the Marie Stopes Zambia contact centre. The study did not see an increase in contact centre use associated with the intervention, and qualitative research suggested that although the promotional materials were acceptable to pharmacy staff, space is at a premium and smaller materials are preferred. High staff turnover, the need for reduced branding and stronger user-testing also impacted the intervention. Importantly, calling a stranger on a hotline to speak about personal issues was considered culturally unusual but also intimidating in the context of low knowledge about abortion's legal status. The value of the combi-pack for supporting self-management was also highlighted by pharmacy staff.


*Promotional materials used in the research in Zambia*




*MSI's pictorial information for MA administration*

> "…because of the way it has been packaged, it's easier to use for both health care providers like ourselves and clients, because for us we have to give that information on how to use the medication. So, if the medication has not come nicely packaged it becomes a little bit of a challenge when it comes to dispensing the medication but with the one that comes as a combination yeah its easier."
>
> Pharmacy worker speaking about the combi-pack in Zambia (2018)




*Promotional materials used in Bangladesh*

In contrast, in Bangladesh, the Marie Stopes contact centre has been made visible through promotional stickers, wallet-sized cards, and posters in pharmacies and village doctors since 2010, and has also been printed on the packaging of various combi-pack and misoprostol products available market. The printing of this phone number on different branded product packaging has resulted in increases in calls from users of those products and brands. The contact centre receives calls from pharmacy staff (23%) as well as market. The printing of this phone number on different branded product packaging has resulted in increases in calls from users of those products and brands. The contact centre receives calls from pharmacy staff (23%) as well as Menstrual Regulation (MR) users, and their friends and relatives (57%) and village doctors (20%). A survey of pharmacy workers in 2013 found that pharmacy workers who had used a contact centre had higher knowledge of a correct medical MR regimen.

Future research could assess how hotlines and contact centres impact the experiences of self-management for MA users, but one study from Indonesia has already highlighted that hotline-supported abortions can be safe and effective.

## Key learnings on information provision through hotlines

- Pharmacy staff can respond positively to informational and promotional materials, and these types of materials in pharmacies may increase access to information for MA users.
- Pharmacist knowledge does not necessarily result in improved counselling or practices for information provision and interventions that focus on increasing pharmacy worker knowledge through training are unlikely to improve quality of care.
- Materials that directly promote a helpline to MA users in pharmacies may not be adequately targeted, but inclusion of a helpline on product packaging can increase use of this source of information.
- Pocket cards inside product packaging that do not mention MA, reproductive health, or other sensitive content, but encourage users to call a helpline if needed, might be subtle enough to be acceptable for pharmacy staff and clients in contexts where the packaging is usually thrown away.
- Whether using a contact centre or hotline feels appropriate to clients will vary in different contexts, and digital, written or pictorial information may be more culturally acceptable in some settings.
- Training pharmacy workers at scale is unlikely to be sustainable as it needs to be periodic, particularly in the context of high pharmacy staff turnover, negative attitudes and restrictive legal environments. Unlike for health workers, pharmacy workers lack common training and accreditation schemes.

# Keep digital content short, accessible and secure and include a link to a phoneline

Formative qualitative research in Cambodia with garment workers found that participants were reluctant to use and keep written instructions on self-management of MA, but signposting clients to digital resources, and using video content with written words as well as voiceover could improve the accessibility of information about MA.

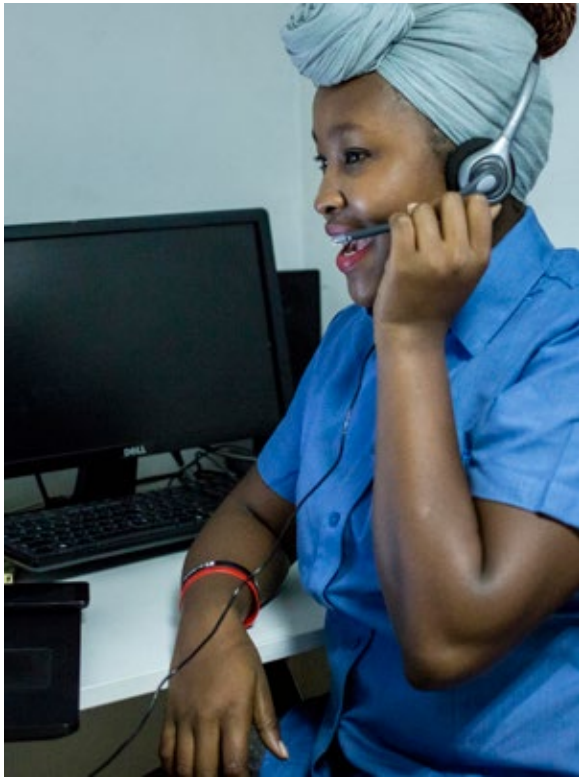
The study found that YouTube was often used as a search engine to get information about MA, and Facebook as a platform for sharing these videos. Marie Stopes Cambodia developed a short, informational YouTube video, informed by the research findings, which was posted on Facebook in March 2020. It had received 40,000 views by July 2020 and resulted in many private messages to Marie Stopes Cambodia. Short video animations were also found to be an acceptable way of providing MA information in a multicentre randomised control trial comparing MA information delivered by animation versus face-to-face consultation. The trial found that recall was as high in the group who received information by video as the group who had face-to-face consultations, and acceptability of the video animations was high. Short videos that explain MA are available through IPPF's video on how MA pills work, Ipas' video on how to use misoprostol for MA and a set of videos that form an e-learning courses for pharmacists and pharmacy workers from How To Use Abortion Pill.

Smart phone applications are also increasingly being developed to support MA self-management. Ibis Reproductive Health developed the 'Euki' app in partnership with Women Help Women, and have used formative research to assess the needs and preferences of app users. The research highlighted the importance of offering comprehensive sexual and reproductive health information (not only abortion), offering emotionally and medically supportive information (including testimonials, information and reminders) and providing an interactive and customisable experience. Most importantly, apps need to offer privacy by design, for example by not collecting back end data or sending any data to cloud servers so that the user can remove all trace of the app if needed; by using discrete logos, unassuming names, discrete notifications and icons; and by offering password protected access, security measures that display a fake screen in case an alternative password is entered, and a quick exit button.

A literature review on self-use of MA after online access found that users were as satisfied with interactive services as those offered in-person by healthcare staff, and that clinical outcomes were similar. However, some users of non-interactive online abortion services and information reported feelings of anxiety, vulnerability, and fears about lack of provider guidance, so ensuring the availability of interaction with an informed provider can support confident MA self-management from pharmacies.

## Key learnings on digital resources for MA information

- Short, accessible and localised video content on social media (e.g. Facebook, YouTube) may be preferred to and more effective than pharmacy interaction in some contexts.
- Audio-visual animations are an acceptable and effective way of providing key MA information.
- Apps and websites need to offer privacy by design and respond to user feedback to ensure relevant content.
- Digital resources should always offer an option for interaction, for example through a connection to a hotline or contact centre, or an interactive Chatbot – see the How to Use website for an example.



## Accompaniment models and other grassroots networks can improve access to information and support after MA is purchased from pharmacies

Accompaniment models and other grass-roots networks can provide information and support for individuals self-managing MA from pharmacies, and can create an enabling environment outside of formal health systems. A study on the Socorrista network in Argentina, found that accompaniments can offer supportive, person-centred guidance for second-trimester MA and post-abortion care through in-person and telephone support. A pilot study of accompaniment models across three continents by Ibis Reproductive Health in 2019 found these models to be safe and effective. In Nepal, a study on female community health volunteers and their provision of MA information found that training low cadres of staff can increase the awareness of safe services and referral options.

### Key learnings on accompaniment models

- Accompaniment has been used to provide acceptable and supportive information on first and second trimester self-managed MA in settings where abortion access is restricted and can improve the safety of pharmacy-purchased MA.
- Lower level cadres of staff can be trained to provide safe information, MA products and referrals.
- Lessons so far show that accompaniment models should be adapted based on the needs of the local community, recruit male as well as female agents, and equip agents with training, resources and MA products so that they can provide accurate information on the self-management of MA.

### **In summary**: how we can make self-use of MA safer

Evidence shows that MA provided by pharmacies can be self-managed safely and effectively. Improved access to quality information ensures that MA users have an enabling environment for supported self-management of MA. Information can be provided through developing user-friendly product labelling, by signposting users to contact centres, digital resources, health facilities or accompaniment networks, and by working with national health legislature to enable pharmacy staff and MA users access to high quality information. With these components in place, MA users are able to safely self-manage MA from pharmacies using information they can easily access and understand, and seek support if they need or want follow-up care.

MARIE STOPES INTERNATIONAL
Children by choice, not chance

Acknowledgements

Thank you to our partners at Ipas, DKT, IPPF and Options for their review and inputs to this brief.

This brief was produced with financial support from the Women's Integrated Sexual Health (WISH) Lot 1 – a joint programme delivered by Marie Stopes International, IPPF, Ipas, DKT, Options, ThinkPlace and Leonard Cheshire, and funded by UKAID from the UK Government.



For more information, please contact evidence@mariestopes.org.

UKaid from the British people

dkt INTERNATIONAL

Ipas

Options

IPPF International Planned Parenthood Federation