

## The Option of Providing Combined Oral Contraceptives (COCs) as Non-Dedicated Emergency Contraceptive Pills (ECPs)

### Objective

To guide decision making and program planning when provision of combined oral contraceptives for emergency contraception is being considered.

There are two types of ECPs: progestin-only pills containing levonorgestrel and COCs. This module briefly discusses issues to consider when looking at the option of providing COCs for emergency contraception. The following topics are discussed:

- Provision of COCs for Emergency Contraception
- Approaches for Providing COCs as Non-Dedicated ECPs
- Pros and Cons of Providing COCs as Non-Dedicated ECPs
- Planning for Product Supply

### Tools Provided at the End of This Module

- Prototype Package Format
- COCs for Emergency Contraception: Example of the Repackaging Format Used by the Family Guidance Association of Ethiopia
- Information to Include When Providing COCs for Emergency Contraception
- Provision of a One-Month Supply of COCs for Emergency Contraception

### Provision of COCs for Emergency Contraception

As described in the World Health Organization (WHO) publication *Emergency Contraception: A Guide for Service Delivery*, there are two kinds of products that can be used as emergency contraceptive pills: (1) progestin-only pills containing levonorgestrel and (2) COCs, containing progestin and estrogen, which are widely used for regular contraception.<sup>1</sup> The progestin-only pills have a higher effectiveness rate for emergency contraception and have fewer side effects than COCs when taken for emergency contraception.<sup>2</sup> In addition, progestin-only pills can be taken in one dose.<sup>3</sup> For these reasons, progestin-only pills are considered the preferred emergency contraceptive product for family planning programs.

In 2003, the WHO Model List of Essential Medicines was revised to include only the progestin-only pills for emergency contraception. There are two manufacturers that widely distribute a dedicated progestin-only ECP—that is, an ECP labeled and packaged specifically for emergency contraception.\*

In some countries, however, the option of providing a dedicated progestin-only ECP is not feasible or progestin-only pills may be registered but access may be limited. Family planning programs in this situation have found that providing COCs may be the only viable way to routinely offer emergency contraception to clients. They have done this by cutting up regular COC packets and repackaging the pills in the correct dosage for emergency contraception or by providing an entire cycle of pills with instructions for emergency contraceptive use. Although these approaches have been used successfully, there are trade-offs with regard to cost and quality. Most importantly, offering COCs means offering a less effective product. The table below shows the formulations and most common brand names of the COCs that are used for emergency contraception. Additional information about the availability of COC and ECP products, drawn from the International Planned Parenthood Federation 2002 Directory of Hormonal Contraceptives, is accessible on the website: <http://ec.princeton.edu/worldwide/default.asp>. This website provides a searchable database of oral contraceptives available worldwide—both COCs and progestin-only contraceptive pills—that can be used for emergency contraception. The database can be searched by country or by product.

<b>Combined Oral Contraceptives</b>			
<b>Formulation</b>	<b>Common Brand Names</b>	<b>First dose: Number of tablets</b>	<b>Second dose: Number of tablets</b>
EE 50 mcg + LNG 0.25 mg or EE 50 mcg + LNG 0.50 mg	Eugynon 50, Fertilan, Neogynon, Noral, Nordiol, Ovidon, Ovral, Ovran, PC-4, Preven	2	2
EE 30 mcg + LNG 0.15 mg or EE 30 mcg + NG 0.30 mg	Lo/Femenal, Microgynon 30, Nordette, Ovral L, Rigevidon	4	4
Abbreviations: EE = ethinyl estradiol    LNG = levonorgestrel    NG = norgestrel			
For all regimens, the first dose should be taken as soon as possible after intercourse, but optimally within 120 hours, and the second dose should be taken 12 hours after the first dose.			
Source: Adapted from Expanding Global Access to Emergency Contraception. International Consortium for Emergency Contraception (October 2000), p. 47.			

\*Gedeon Richter Ltd. and Laboratoire HRA Pharma. Contact information is provided in Module F: Regulation, Procurement, and Distribution of a Progestin-Only ECP.

## Approaches for Providing COCs as Non-Dedicated ECPs

Because COCs generally come in one-month supply packets, providers distributing COCs for emergency contraception develop various approaches for delivering the pills to clients. Frequently used approaches for delivering COCs as nondedicated ECPs include the following:

- Providing a month's cycle of pills to the client with verbal instructions on how to take them.
- Cutting up cycles as needed and giving the pills to the clients with verbal instructions.
- Cutting up COCs in advance on site (at a health care facility) and inserting them in envelopes along with some form of written instructions.
- Repackaging COCs in a centralized, supervised facility and inserting printed instructions.

Although each of these approaches has advantages, there are also disadvantages, which means there is a trade-off as to safety/risk or cost savings/increased expense, as discussed below.

## Pros and Cons of Providing COCs as Non-Dedicated ECPs

There are several factors to address when considering whether provision of COCs as non-dedicated ECPs is an appropriate choice. These include the political situation regarding emergency contraception, regulatory requirements, the scale of the program, cost-saving opportunities, donor provision of appropriate COC products and possible donor restrictions on use of those products, and costs of repackaging and quality assurance. Program planners must evaluate all of these elements carefully before making a decision about repackaging COCs for EC.

### Reasons why programs would choose the option of providing COCs as nondedicated ECPs

1. **Potential opposition:** If there are sectors or groups in a country whose sensitivities toward emergency contraception might delay registration, procurement, and distribution of a progestin-only ECP, provision of COCs for emergency contraception—a low-profile approach—may be the best alternative, helping avoid controversy and making it possible to move ahead and incorporate emergency contraception into a program in a timely way. Provision of a month's cycle of pills, in particular, has the potential advantage of being more anonymous, in that no one will know how the client intends to use the pills.
2. **Availability:** Because COCs are widely used for regular contraception, they are registered and easily available in most countries.
3. **Access:** If COCs are donor-provided, it may be easier for a program to use some of the product for emergency contraception, rather than to procure an additional product.
4. **Cost:** Providing a month's cycle of pills or cutting up cycles as needed and giving them to the client with verbal instructions on how to take them would be a low-cost approach.

## Reasons why programs would not choose to provide COCs as nondedicated ECPs

1. Effectiveness: COCs are less effective for emergency contraception than progestin-only formulations, and they have more side effects.
2. Regulatory constraints: There may be regulatory barriers to cutting up COC packets and using the pills for any purpose other than that for which they were originally registered. A program considering this approach should be aware of the National Regulatory Authority (NRA) requirements. In the United States, for example, the Food and Drug Administration allows a repackaging/relabeling process when it is done on an individual basis for clients, but requires a manufacturer's license for large-scale repackaging. In many countries where there is not a dedicated emergency contraception product, however, family planning organizations informally cut up COC packets for emergency contraception, without seeking special NRA approval.
3. Quality control: The farther one gets from a centralized product quality control system, the greater the risks for error in packaging or in providing instructions for use. Possibilities for error include provision of the wrong product, the incorrect number of pills, and incorrect or incomplete instructions. Quality control can be difficult when cutting up pill packs by hand at multiple sites. A particular risk is that the integrity of the blister packs that protect each pill could be destroyed. Providing a month's cycle of pills or cutting up cycles as needed and giving them to the client with verbal instructions would entail greater risk of error and lack of quality control than cutting up COCs in advance on site and inserting them in envelopes along with written instructions or repackaging the COCs in a centralized, supervised facility and inserting printed instructions. Quality control problems could undermine an emergency contraception program.
4. Cost: The cost of cutting up COCs in advance and inserting them in envelopes along with some form of written instructions could, depending on the scale, be as high as the cost of providing a dedicated, levonorgestrel-only ECP.
5. Potential for incorrect administration: When providing a month's cycle of COCs with instructions on the number of pills to take for emergency contraception, the burden for correct administration is placed entirely on the client. The risk of error is high, especially for low-literate clients.
6. Mixing of different packets and batches: COC packets may not divide into the correct number of ECP doses, which means that pills from different packets and perhaps different manufacturing batches or lots could be repackaged together. This could result in an inaccurate expiry date or difficulty in tracing pills if a product recall were necessary.

## Planning for Product Supply

When cutting up COC packets for emergency contraception, it will be necessary to determine how many packets of COCs will be needed to yield the desired number of EC cycles. In Zambia, where 21-pill packets of Microgynon are used, the practice is always to provide EC in segments of 4 pills, as smaller segments could too easily be lost. Since there are 2.5 EC cycles (of 8 pills each) in one packet of Microgynon, this practice means wasting 1 pill from each cycle. The wastage should be factored in when deciding on the number of packets to order.

## References

<sup>1</sup> World Health Organization. Emergency Contraception: A Guide for Service Delivery. WHO/FRH/FPP/98.19. Geneva:WHO (1998).

<sup>2</sup> WHO Task Force on Postovulatory Methods of Fertility Regulation. Randomized controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. *Lancet* 352:428-433 (1998).

<sup>3</sup> von Hertzen, H. et al. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a WHO multicentre randomised trial. *Lancet* 360(9348):1803-1810 (2002).



# Module G Tools List

- **Prototype Package Format**

A package format that can be adapted as needed.

- **COCs for Emergency Contraception: Example of the Repackaging Format Used by the Family Guidance Association of Ethiopia**

An illustration of a repackaging format used for repackaged COCs for emergency contraception.

- **Information to Include When Providing COCs for Emergency Contraception**

Essential information that should be provided either on the package or on a package insert and additional, optional information.

- **Provision of a One-Month Supply of COCs for Emergency Contraception**

Suggested instructions to provide when dispensing a month's supply of oral contraceptives for the indication of emergency contraception.

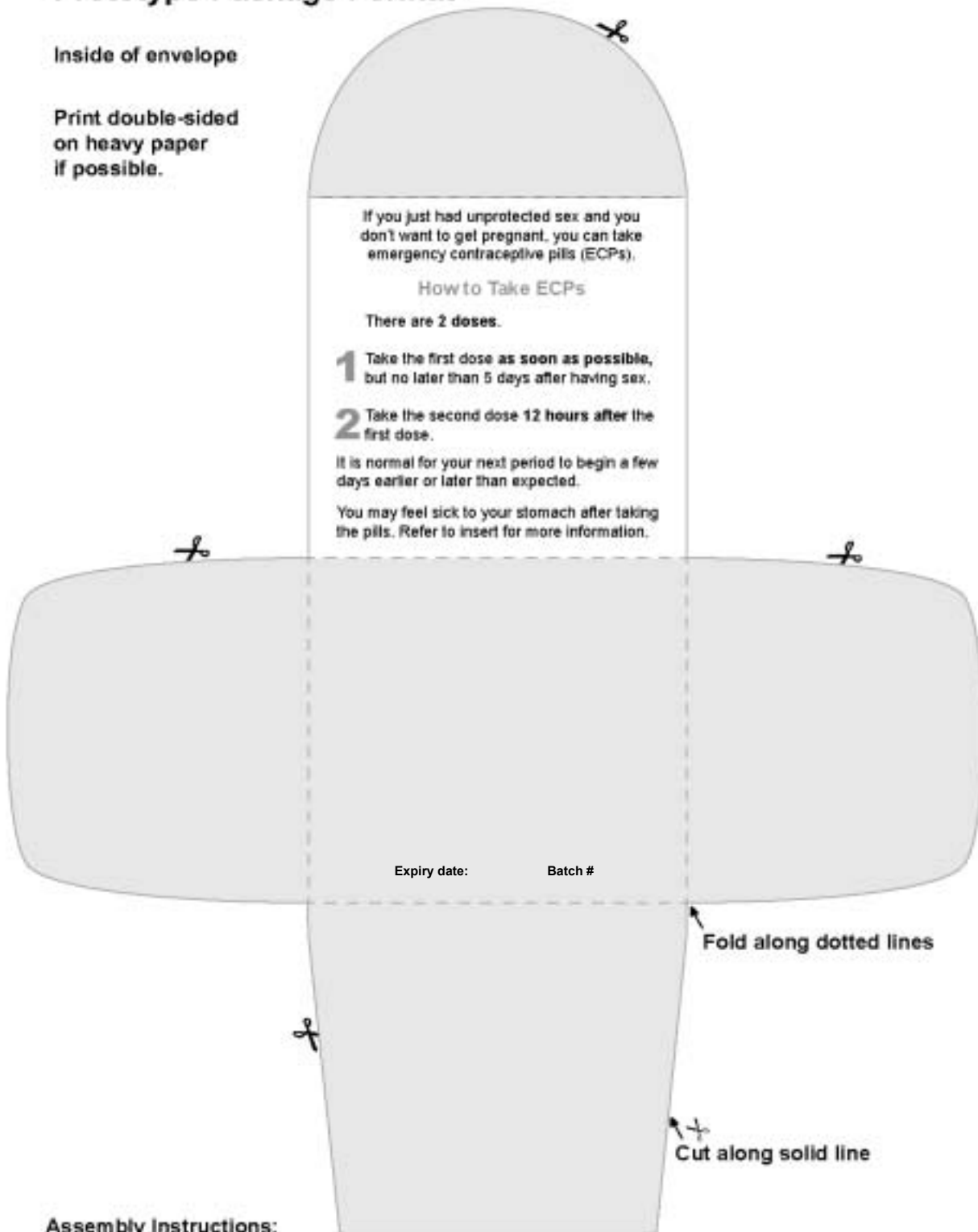




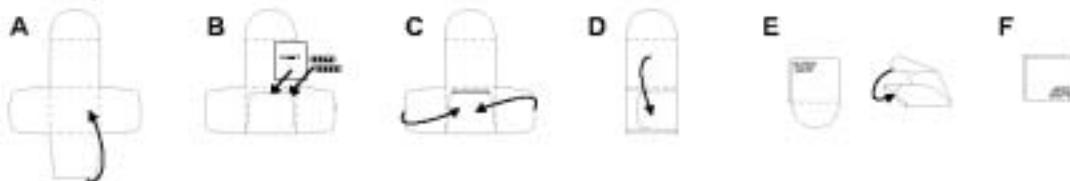
## Prototype Package Format

Inside of envelope

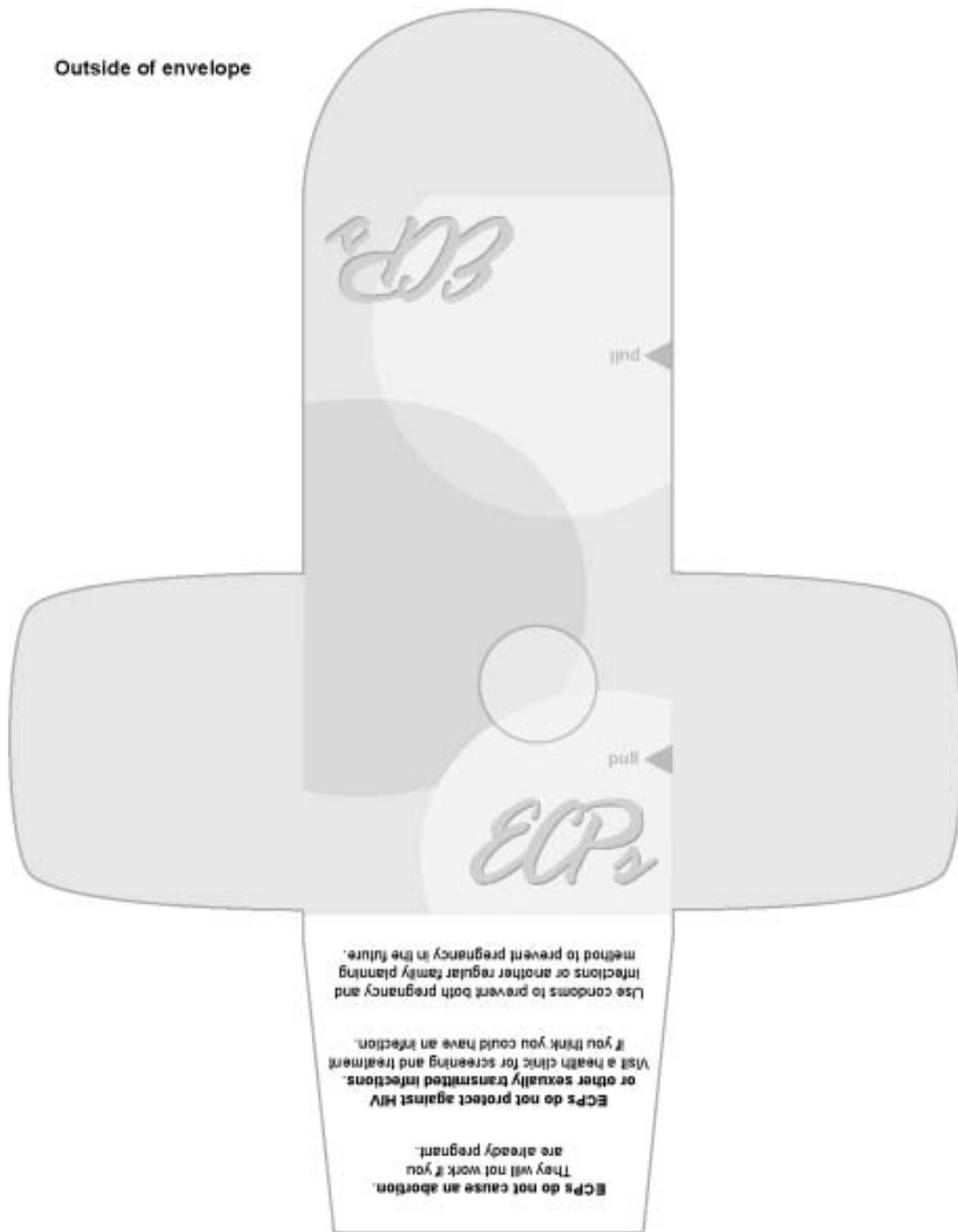
Print double-sided  
on heavy paper  
if possible.



### Assembly Instructions:



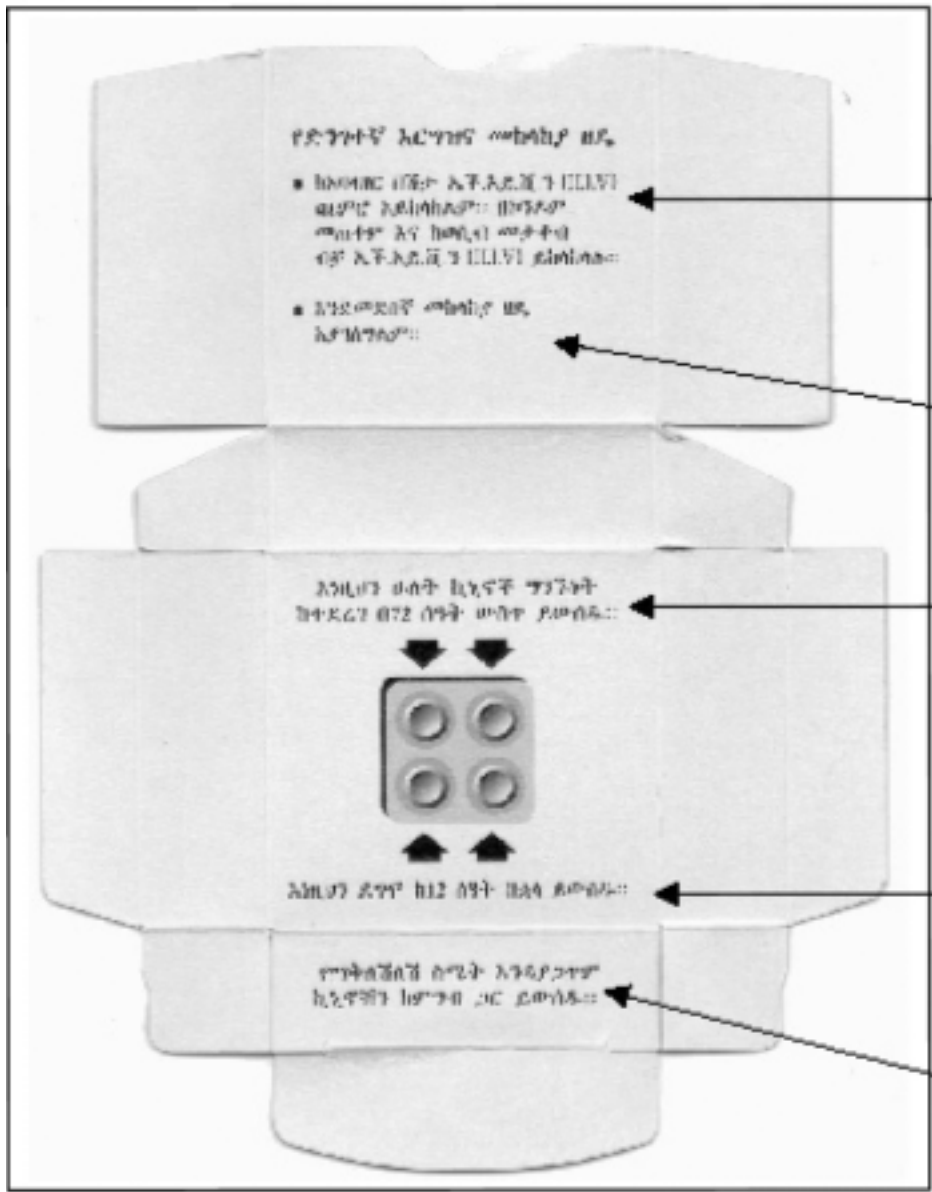
Outside of envelope



This format was developed by PATH

# COCs for Emergency Contraception: Example of the Repackaging Format Used by the Family Guidance Association of Ethiopia

For emergency contraception



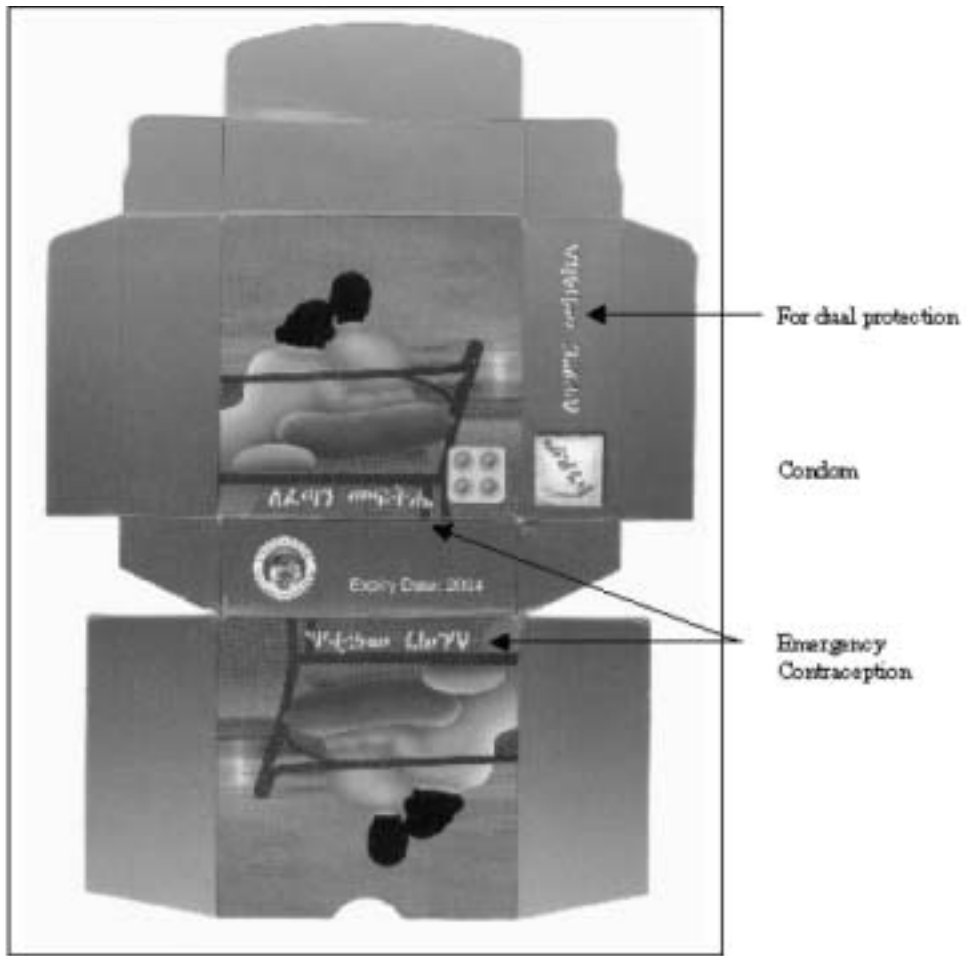
This method does not protect against sexually transmitted infections, including HIV. Only abstinence and condoms can do that.

This should not be used as a regular family planning method.

Take these two pills within 72 hours of intercourse.

Take these two pills 12 hours later.

To prevent nausea, take pills with food.



The Family Guidance Association of Ethiopia developed this package format in collaboration with the Modern Center for Business Services in Dubai and with the Population Council. It was reprinted with permission.

# Information to Include When Providing COCs for Emergency Contraception

## Essential Information

There are two kinds of essential information: product information and information for the user. This information should be provided either on the package or on a package insert.

### Product information

- Label: Emergency Contraceptive Pills (or ECPs).
- Expiry date of pills, including month, day, and year.
- Manufacturer's batch or lot number.
- Locally mandated information (required by government agencies).

### Information for the user

- Brief instructions:
  - ECPs can **prevent** pregnancy after unprotected sexual intercourse. Use ECPs if you do not want to become pregnant, if you think your contraceptive method has failed, or if you were raped.
  - The first dose should be taken as soon as possible after sex, but can be taken up to 5 days (120 hours) after sex. ECPs are more effective the sooner they are taken.
  - The second dose should be taken 12 hours after the first dose.
  - Try to take the first dose so that the timing of the second dose (12 hours later) is practical for you (i.e., during waking hours).
  - ECPs can be used anytime in the menstrual cycle.
- Brief information about side effects:
  - Some women have sore breasts, headaches, or feel nauseous. Some women even vomit after taking ECPs.
  - If you vomit within one hour after taking ECPs, take another dose immediately.
  - If you vomit more than one hour after taking ECPs, you do not need to repeat the dose.
  - The side effects of ECPs may be uncomfortable, but they are not harmful and usually last for only one day or less.
  - It is normal for your next period to begin a few days earlier or later than expected.
- Sexually transmitted infections (STIs): ECPs do not protect against STIs or HIV. If you think you may have contracted an STI or HIV, visit your health or STI clinic.
- Locally mandated information (required by government agencies).

## Optional Additional Information

If the program is providing a package insert, the following additional information could be included.

- ECPs do not work if you are already pregnant.
- ECPs are effective contraception, but they do not work every time. If your period does not start within 3 weeks after taking ECPs, you may be pregnant. Have a pregnancy test to know for sure.
- As soon as possible, begin using a birth control method you will be able to use on an ongoing basis. ECPs are intended for emergency protection. They are not as effective as other forms of birth control.
- After using ECPs
  - Use a barrier method, like a condom, each time you have sex until you begin your next menstrual period. After that time you may continue using your contraceptive method or begin a new one; or
  - If you were using oral contraceptives pills, you should continue taking the tablets starting on the day after you took the ECPs until the end of the cycle. You should then use a condom or other barrier contraceptive method for at least seven days after restarting contraceptive pills.

### ECPs and Condoms: Packaging for Dual Protection

ECPs are sometimes packaged with condoms as dual protection, since ECPs do not protect against STIs, including HIV/AIDS. In such cases, there will be two expiry dates—one for the pills and one for the condom. It will be important, when planning distribution, to use the earlier of the two expiry dates. There also may be some additional client information provided with the package when two products are provided.

# Provision of a One-Month Supply of COCs for Emergency Contraception

In a few countries, programs have chosen to distribute the entire one-month supply of COCs, along with instructions on the number of pills to take for EC. While it may be easier to dispense EC using this approach, of the four approaches outlined in this module, this one entails the most risk because it places the burden for correct dosage squarely on the client. The risk of incorrect dosage is greatly enhanced if literacy is low, if there is no way to confirm that the client thoroughly understands the instructions she has been given, if multiple pill brands are available in the country, and/or if the pack contains iron pills or placebos in addition to the birth control pills. The following instructions could be given to clients when providing them with a month's supply for EC, in addition to providing use instructions such as those printed on the prototype package in the tools section of this module.

- For emergency contraception, pills can be taken from a whole packet of regular oral contraceptive pills. Do not mix brands. Take the two doses from the same packet.
- If you have a complete packet of 28 regular oral contraceptive pills, the last 7 pills should not be used. EC doses should be taken using pills from the first 21 pills in the packet.