Module F

Regulation, Procurement, and Distribution of a Progestin-Only ECP

Objective

To secure and distribute an adequate supply of a high-quality progestin-only emergency contraceptive pill (ECP) product.

The following topics are discussed in this module:

- Project Regulation
  - National regulatory authority (NRA)
  - Product registration
- Product Procurement
  - Estimating initial quantity of ECPs
  - Ongoing monitoring of ECP demand
  - Role of program staff in procurement cycle
  - Managing the procurement process
  - Ensuring product quality
  - Monitoring supplier performance
- Distribution
  - Distribution systems
  - Service delivery options

Tools Provided at the End of This Module

- Potential Market for ECPs: A Basic Demand Model
- lnformation to Include in a Levonorgestrel-Only ECP Package Insert
- Sample Procurement Specification: Levonorgestrel-Only ECPs
- Preferential Pricing for Public-Sector Agencies
- Procurement Through International Procurement Services

Progestin-only ECPs containing levonorgestrel are the preferred product for family planning programs because they are more effective, can be taken in one dose, and have fewer side effects than combined estrogen/progestin ECPs. In 2003, the World Health Organization (WHO) revised the Essential Drugs List to recommend a single dose of 1.5 mg levonorgestrel for emergency contraception instead of two doses of the combined oral contraceptive ethinyl estradiol/levonorgestrel.[1] This module provides information, as well as specific tools, to help a family planning program prepare for routine provision of a progestin-only ECPs. Regulation, procurement, and distribution are critical steps in the process of incorporating emergency contraception into a program. Program planners must understand and support these steps to ensure timely provision, adequate quantities, and high quality of the ECP product they plan to provide.

Progestin-Only Dedicated ECPs

Formulation (per pill)	Common Brand Names	Single Dose* (number of tablets)
LNG 0.75 mg	Levonelle-2, NorLevo, Plan B, Postinor-2, Vikela	2

*Manufacturers may introduce a single dose tablet for emergency contraception; in this event, the dose would be one 1.5 mg tablet.

Product Regulation

In most countries, all medicines, including contraceptives, are subject to national regulatory requirements. These requirements are based on national legislation that identifies the registration, licensing, market authorization, and inspection requirements with which products must comply. The overall purpose of regulatory requirements is to ensure the safety, efficacy, and quality of all medicines provided to the public. Following is a brief summary of the regulatory function, followed by a description of the registration process. What is presented here is the generally accepted model for these functions and processes; in any specific country they will vary, according to national policy and legislative requirements. In addition, the degree of oversight and enforcement depends on the resources available.

National regulatory authority (NRA)

In most countries, an NRA is established by national legislation to serve as an administrative agency, to ensure that regulatory requirements are properly implemented and enforced. In general, major NRA authority typically includes:

- Oversight of product manufacturer, importer, and distributor licenses.
- Registration of drugs, medicines, and other health products for use in country.
- Approval of product labeling, the package insert, and use instructions that accompany a product to ensure they are accurate, complete, and balanced.

- Determination of whether a product will be provided by physician prescription only, or will be widely available over-the-counter (i.e., with no prescription required).
- Postmarketing surveillance to monitor problems with adverse reactions and product quality.

Product registration

Product registration is one of the critical functions that almost all NRAs perform. The process of registering a product varies according to national requirements, but certain clinical, manufacturing, and distribution information is typically required. The most commonly required information is contained in the manufacturer's product dossier, which covers:

- Product formulation
- Manufacturing process
- Packaging requirements
- Clinical research results
- Product quality tests
- Other product-specific information

In most cases, the product manufacturer, working with its local distributor, is responsible for registering its product with the NRA and will submit the required documents to the NRA for product registration.

Facilitation of the Registration Process

Program planners interested in introducing a new ECP into a family planning program can help facilitate the registration process by:

- Contacting the manufacturer and its in-country distributor or helping to identify a distributor where none exists, to demonstrate that a market for the ECP product exists.
- Building support among those who influence policy, such as community leaders and medical providers and those who influence registration of new drugs—in particular, decision makers at the ministry of health and the NRA—by including them in initial advocacy and planning activities. Their participation is critical, as their advice and collaboration can help ensure timely progress through the registration process.
- Providing key information about ECPs to leaders and decision makers: for example, the role ECPs can play in preventing unintended pregnancy and abortion, the mechanism of action of ECPs, evidence-based information on the safety and efficacy of ECPs, and the fact that progestin-only ECPs are included in WHO's Essential Drugs List. This information is provided in Module A: Information for Policy Makers

Prescriptive or over-the-counter (OTC) status

The issue of whether a dedicated ECP product should be provided by prescription only or available OTC in pharmacies has been decided differently in various countries. Progestin-only ECPs are available without prescription in many countries in the European Union, including Belgium, France, Italy, Norway, and the United Kingdom. An application for OTC status—i.e., exemption from prescription-dispensing requirements—for a progestin-only dedicated ECP is currently under consideration by the U.S. Food and Drug Administration. The criteria that determine OTC status focus on safety—and the fact that ECPs have gained OTC status in many countries—speak to the safety of this contraceptive method, specifically in regard to the following key issues:

- ECPs are safe for self-medication, as there are no serious side effects[2] and an overdose or inappropriate use could not cause serious harm.[3]
- Studies have shown that women are able to follow the instructions and self-administer the treatment correctly.[4]
- Medical intervention is not necessary to ensure safe and correct use of ECPs because there are no documented medical contraindications for emergency contraception[5] and women can independently determine whether they need to use ECPs.[6]
- Contraindications relevant to frequent, long-term use listed in the package labeling of regular oral contraceptives are sometimes included on ECP packaging—but this is without justification, as ECP treatment is of short duration, ECPs are not toxic, and they have no important drug interactions. [2, 4]
- If a woman who was already pregnant took ECPs, it would not harm the fetus.[7]

Product labeling

Regulatory authorities require a product's primary package to be properly labeled before it can be approved for registration and in-country use. Product package labeling requirements will vary from country to country; however, for ECP products the most common labeling information required for the individual blister pack should include the following:

- Product/brand name
- Lot/batch number
- Expiration date (month and year)
- Date of manufacture
- Manufacturer's name or symbol
- Contents and quantity

Package insert sheet and client use instructions

Regulatory authorities require that drugs, medicines, and contraceptives packaged for consumer use contain printed materials with information about the product. The manufacturer therefore provides a package insert sheet with each consumer unit package. The insert sheet usually contains the following information:

- Active ingredient
- Other ingredients (excipients)
- Precautions and contraindications for use
- Use instructions
- Side effects
- Storage instructions

The package insert sheet should be easy for clients to read and understand. Information that should be included in a levonorgestrel-only ECP package insert is provided in the tools section of this module.

Product Procurement

Procurement is the process by which ECP products are requested and obtained from manufacturers and distributors. Regardless of whether the requesting institution is a nongovernmental organization or a government agency, the standard procurement process is traditionally managed by dedicated procurement personnel and includes:

1. Confirming the quantity required.
2. Managing the procurement process.
3. Ensuring product quality.
4. Monitoring supplier performance.

Program planners support this process by providing information on program requirements, such as quantities, delivery schedule, and other specific program needs. This module provides extensive information about procurement. Much of this information will actually be used only by those involved in the procurement process. However, this information also can be useful as an overview for decision makers of what is involved in supplying a program with this contraceptive method, which differs from other methods due to its irregular use by clients.

Estimating initial quantity of ECPs

Because ECPs are not intended for regular use, traditional techniques for estimating demand are likely not to be appropriate. There currently does not appear to be a consistently used method for forecasting demand, partly due to the fact that dedicated ECP products have only recently begun to be widely available.

When initiating provision of ECPs, the experience of a social marketing organization has indicated that a simple calculation can be useful. The organization purchases initial supplies of ECPs based on an estimate of 5 to 10 percent of the volume of oral contraceptives regularly sold in the country—adjusting toward the low or high end, depending on how well-known ECPs are in the country and the country's statistics on contraceptive prevalence by method. As this initial supply of ECPs is used, staff record data on the number of clinics or pharmacies supplied and the number of ECP packets in the dispensers sold to these locations. These sales data are then used for forecasting future demand.

Initial demand estimation

A spreadsheet for estimating the quantity of ECPs a program should initially purchase is included in the tools section of this module (Potential Market for ECPs: A Basic Demand Model). The spreadsheet enables the user to calculate an estimated maximum that could be needed and then to refine this first estimate to produce a more realistic estimate of ECP supply required for an initial order.

Ongoing monitoring of ECP demand

Once an initial supply of ECPs has been received, it is important to monitor use and stock depletion over time. Careful monitoring is critical for both avoiding stockouts and compiling data that can be used to forecast future demand. Funding cycles may make reordering before the next procurement cycle difficult; however, if it is feasible, ECP product should be reordered even before the next cycle if monitoring indicates that the initial supply was inadequate and a stockout is possible. Monitoring and recording use over one year will establish demand data that can be used in forecasting future requirements. Monitoring use should include noting trends, such as increased use due to campaigns for increased awareness of the method; these trends should be quantified and factored into the resupply process. Projections can be based on the patterns of ECP consumption and extrapolations of those patterns for the time period covered by the next procurement cycle. As the procurement unit plans for the next procurement cycle, program managers are responsible for providing them with a forecast of ECP product needed.

Role of program staff in procurement cycle

Program staff play an important role in the procurement cycle. In addition to identifying program requirements and delivery schedule needs, they also serve as a technical resource in assisting procurement staff to promptly respond to product and delivery schedule changes requested by the supplier. Program staff also provide information on product problems encountered in the field. The procurement unit will document this information and use it in evaluating supplier performance as they consider suppliers for the next cycle of procurement. For these reasons, it is important for program staff to establish and maintain a continuous, collaborative working relationship with procurement personnel responsible for ECP procurement.

Managing the procurement process

The procurement process a family planning program will use to ensure an ECP product supply depends on several factors, including the funding source and relevant requests governing use of funds (e.g., whether it is donor-provided or government funded), the number of manufacturers, and the program delivery schedule requirements (when the product is needed). These factors also affect the length of time it will take to complete the entire procurement cycle, from initial identification of requirements to final delivery of product. It is therefore important, for planning purposes, for program staff to work closely with procurement personnel to obtain accurate estimates of the procurement cycle time. Some of the key factors that determine the procurement method to be used are briefly discussed below.

Funding source

Donor-provided: When EC products are directly provided by a donor, the procurement process is shortened, because several steps in the process are eliminated (requesting quotes, negotiating contracts with suppliers, etc.). If the donor provides direct funding to the responsible government procurement agency, these steps will have to be included, the process will take more time, and any special procurement requirements imposed by the donor must be complied with. Donor agencies vary in their approach to emergency contraception, as seen in the policies of two of the major contraceptive donor agencies, the United States Agency for International Development (USAID) and the United Nations Population Fund (UNFPA). Both USAID and UNFPA endorse country programs' routine provision of ECPs as one of the contraceptive options offered in the method mix. Through 2003, USAID, however, has not provided a dedicated progestin-only ECP product to country programs. UNFPA provides dedicated ECPs to requesting countries. Module A: Information for Policy Makers discusses the ECP support available through these agencies. UNFPA also offers a service under which they procure and ship dedicated ECPs to support a country program for a fee. Information on UNFPA procurement services is provided in the tools section of this module.

Government-funded: Government-funded procurement must comply with national procurement requirements, which in most cases follow a traditional public-sector process that includes: identifying requirements; obtaining budget approval; preparing bidding documents (which include specifications, quality assurance and inspection requirements, proposed terms and conditions); requesting bids or quotes; evaluating bids or quotes; negotiating and awarding contract; arranging for shipment; and product inspection. As mentioned above, program planners support this process by providing procurement managers with specific information on program requirements.

Number of product manufacturers

When there are multiple manufacturers of a product, there is a competitive environment—which can result in a lower price. In a competitive environment, as is the case for combined oral contraceptives, donors' and national procurement policy often will require open or limited international bidding—a formal process requiring a lead time of several months. In the case of progestin-only dedicated ECP products, the number of suppliers currently is limited. The two pharmaceutical companies that are the dominant suppliers of dedicated, progestin-only ECP products (i.e., products packaged and labeled specifically for emergency contraception) are Gedeon Richter Ltd. and Laboratoire HRA Pharma. Their ECP products, Postinor-2 (Gedeon Richter Ltd.) and NorLevo (Laboratoire HRA Pharma) are registered in many countries. There are other manufacturers of levonorgestrel, principally in China and India, that have significant local market shares and that could become suppliers of a dedicated levonorgestrel-only ECP in the future. Product and contact information of additional suppliers will be made accessible on the website of the International Consortium for Emergency Contraception, when they enter the international market. As of 2003, however, because Gedeon Richter Ltd. and Laboratoire HRA Pharma are the only two major suppliers, the procurement agency can issue a request for quote directly to each manufacturer, rather than requesting bids from multiple manufacturers, which will streamline the procurement process and shorten the procurement cycle. Contact information for both Gedeon Richter Ltd. and Laboratoire HRA Pharma is contained in the tools section of this module.

Requests for a quote can be based on procurement specifications or the manufacturer's brand name. If using procurement specifications to request quotes, a sample generic procurement specification for levonorgestrel-only ECPs can be found in the tools section at the end of this module. The procurement agency can use this sample to develop its own product specification.

The procurement agency should always ensure that only products registered through the NRA are purchased for use in country. This is traditionally addressed in the request for bid documents by including a requirement that the supplier be responsible for registering its product in-country before it can be considered for a contract award.

Product availability

Information about the availability of ECP products, drawn from the International Planned Parenthood Federation (IPPF) 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 combined oral contraceptive pills and progestin-only contraceptive pills—that can be used for emergency contraception. The database can be searched by country or by product. In addition, the International Consortium for Emergency Contraception website provides a list of countries in Africa, Asia, and Latin America with information about the status of dedicated ECP products. The list, which is updated annually, can be accessed at: http://www.cecinfo.org/files/ecstatusavailability.pdf.

Factors that affect the procurement price of a product

Cost impact on the supplier: The purchaser can improve the chances of obtaining favorable prices by trying to minimize the costs incurred by the supplier in filling the order. A program can realize savings by:

- Maximizing the volume of a single order. The volume of product ordered is a factor that most manufacturers will consider when determining the price they will charge a customer. The greater the volume of product ordered, the greater savings a manufacturer may be able to achieve through such measures as bulk procurement of raw materials. These savings are often then passed on to the purchaser by offering a lower price for the product.
- Limiting special requests. Any time a manufacturer has to change or adapt a standard process to accommodate a purchaser's special request, an additional cost is incurred. For example, if a purchaser requests special packaging requirements (for example, requesting four products per box when the norm is six per box) the manufacturer must order different size boxes and adjust its standard packaging process. The additional costs incurred are most often passed on as higher prices to the purchaser.
- Minimizing the number of shipments for the order. The more frequent the number of shipments the purchaser requests, the greater the administrative cost incurred by the purchaser. This increase in administrative costs can be passed on to the purchaser in the form of higher prices.

Preferential pricing: If a governmental or public-sector agency is conducting the procurement, it is possible to request preferential public sector pricing directly from the manufacturer. Both Gedeon Richter Ltd. and Laboratoire HRA Pharma offer public-sector pricing (see Preferential Pricing for Public Sector Agencies in the tools section for these manufacturers' contact information and more details.)

Ensuring product quality

As mentioned in the section above on product regulation, the NRA has the responsibility of ensuring the quality of drugs and medicines by establishing inspection and quality assurance testing requirements. However, it is the responsibility of the procurement unit to ensure compliance with these requirements. This is traditionally accomplished by including appropriate certification, inspection, and testing requirements in the technical specifications and special conditions of contracts issued to suppliers.

Commonly requested certification requirements for pharmaceutical contraceptives can be found in sections 1.3 through 1.7 of the Sample Procurement Specification: Levonorgestrel-Only ECPs contained in the Tools section of this module. Common inspection and testing requirements are also included in this sample procurement specification.

Monitoring supplier performance

Once the elements described above have been considered and the process for procuring an emergency contraception product has been determined, the procurement process can be set in motion. Managing this process involves preparing appropriate documents, establishing contract terms that ensure product quality, arranging for product shipment, ensuring adherence to contract terms, and monitoring the supplier's performance. Information that will help in carrying out this process is found in the Sample Procurement Specification: Levonorgestrel-Only ECPs in the tools section of this module. This document is provided to illustrate the level of detail that is required for a specification that addresses product quality, inspection, and testing issues. The procurement specification is an important component of managing the process because, along with appropriate contract terms and conditions, it helps to ensure that products provided to the program are of acceptable quality.

Distribution

Because ECPs are most effective when taken as soon as possible after unprotected sex, and should be taken within 120 hours, easy access to this method is of particular importance.

Barriers to ECP access have included:

- Client embarrassment in requesting ECPs (because they have to admit that they had sex without protection).
- Provider biases against ECPs or certain users.
- Restrictive hours of service delivery.

Distribution systems

The table below describes some of the advantages and disadvantages associated with three broad categories of distribution systems: public sector, family planning nongovernmental organizations, commercial pharmacies, and social marketing or franchising.

Distribution System	Advantages	Disadvantages
Public sector (clinics, hospitals, special services for sexual assault or sexually transmitted infections)	• Large clientele • Organizational structure may provide for effective quality control of services and counseling • Potential for linking clients to other reproductive health services • Low or no cost to clients	• May have restricted hours • May not have the flexibility to respond quickly to ECP needs • Locations may not be easily accessible to clients • May present challenges for youth or unmarried women or couples requesting ECPs • May be difficult to incorporate ECPs into programs that have not traditionally provided family planning
Family planning NGOs	• Specialized family planning services may make it easier to integrate ECPs into systems • Organizational structure may provide for effective quality control of services and counseling • Potential for linking clients to other reproductive health services • May provide low-cost services to clients	• May have restricted hours • Locations may not be easily accessible to clients
Commercial pharmacies	• Easy access, open long hours, weekends • Attractive to youth and other populations less comfortable with clinics • Can make ECP distribution self-sustaining	• Pricing generally higher than through public distribution mechanisms and therefore less accessible to low-income clients • Pharmacy staff providing ECPs to clients may not have correct information about indications for use or dosage • Pharmacies that lack separate counseling setting may be intimidating to some potential users • Do not always provide a link to other needed services
Social marketing/ social franchising	• Potential for low cost to client • Includes advertising and awareness-raising • Typically uses training to improve service quality • Can make ECP distribution self-sustaining	• Often requires ongoing subsidy for product and/or advertising • Distribution staff may not have correct information about indications for use or dosage • Does not always provide a link to other needed services

Service delivery options

Given the time-sensitive nature of ECP use, program planners should develop awareness-raising systems to ensure that women know about ECPs and where to access them. Information about ECPs can be delivered in a variety of venues, including public-sector clinics, where providers can routinely mention ECPs during family planning visits, and social service and other public-sector or NGO nonclinical service points. Mass media campaigns are another mechanism for raising awareness. (See Module C: Raising Public Awareness for more detailed discussion of these issues.) One approach for ensuring timely access to ECPs is to provide women with an advance supply (along with instructions for use) or an advance prescription that can be filled if needed. Advance provision of ECPs has been found to reduce unintended pregnancies without increasing repeated use or encouraging women to abandon other methods of contraception.[8]

It may be possible to integrate ECP products, as well as information and counseling, into specialized service delivery options beyond the categories described above. These might include:

- Community-based distribution programs
- School nurses
- University health centers
- NGO programs
- Social services
- Factories with many young female workers
- Private-sector medical providers
- Sexual assault services

Regardless of the distribution system implemented, it is important to ensure a consistent supply of the ECP product.

References

1 http://www.who.int/medicines/organization/par/edl/expcom13/mem_reprod.doc.

2 WHO Task Force on Postovulatory Methods of Fertility Regulation. Randomised controlled trial of levonorgestrel versus the Yuzpe regimen of combined oral contraceptives for emergency contraception. *Lancet* 352:428-33 (1998).

3 Grimes, D.A., Raymond, E.G., and Scott Jones, B. Emergency contraception over-the-counter: the medical and legal imperatives. *Obstetrics and Gynecology* 98:151-155 (2001).

4 Augeny, E. Can hormonal emergency contraception (EC) be available without medical prescription? *European Journal of Contraception and Reproductive Health Care* 5 Suppl 1:41, abstract (2000).

5 World Health Organization. Improving Access to Quality Care in Family Planning: Medical Eligibility Criteria for Contraceptive Use. 2nd edition. WHO/FRH/FPP/96.9. Geneva:WHO (2000).

6 Grimes, D.A. Switching emergency contraception to over-the-counter status. *New England Journal of Medicine* 347:846-850 (2002).

7 Bracken, M.B. Oral contraception and congenital malformations in offspring: a review and meta-analysis of the prospective studies. *Obstetrics and Gynecology* 76:552-557 (1990).

8. Glasier A and Baird D. The effects of self-administering emergency contracpetion. *NEJM* 1998;339(1): 1-4.

Module F Tools List

Potential Market for ECPs: A Basic Demand Model

Because ECPs are used on an irregular and unexpected basis, forecasting the need and planning the supply process will differ from regular contraceptive pills. This tool will help program managers plan for an initial supply of ECPs.

Information to Include in a Levonorgestrel-Only ECP Package Insert

Regulatory authorities require that drugs, medicines, and contraceptives packaged for consumer use contain printed materials with information about the product. It is important to ensure that this information sheet uses clear language and is easy for clients to understand. The package insert should be designed to meet regulatory requirements and provide clients with key information that they will need for using the pills. This tool provides essential information for pill users as well as optional additional information that can be considered, if space permits.

Sample Procurement Specification: Levonorgestrel-Only ECPs

Procurement units can use this sample format as a guide, adding country-specific information where appropriate. The sample specification is designed to be used in conjunction with bidding and contract documents. The specification also can be useful as an overview of the kind of information that will be needed for procurement purposes.

Preferential Pricing for Public-Sector Agencies

Contact information is provided for two manufacturers of a dedicated levonorgestrel-only ECP who offer public-sector pricing.

Procurement Through International Procurement Services

Organizations with limited procurement capacity or wanting to procure small quantities of ECPs may find that ordering through a reputable international procurement agency is advantageous. Information about this option is provided.

Potential Market for ECPs: A Basic Demand Model

This model is a tool to help program managers use generally available statistics and data to define the potential market for ECPs in their service area—both the maximum demand per year and the realistic demand per year. The maximum demand is the total number of ECPs that could potentially be needed by the target population based on estimates of unprotected sex acts. The realistic demand reduces this estimate by taking into account issues of ECP knowledge, accessibility, and women's ability to pay for the pills.

In the beginning, when ECPs are just being introduced, the maximum demand will be much higher than the realistic demand. But over time, by increasing client awareness and provider training, the total realistic demand will grow because of increased knowledge and increased access, and will therefore more closely match the maximum demand.

Model Description, Data, and Assumption

Maximum demand per year

The first section of the model estimates the maximum demand per year for ECPs. This is calculated by combining estimates of the maximum number of coital acts that could require ECPs for women using contraceptives and women not using any contraception. The estimate for women using contraception is calculated by computing the total number of women of reproductive age using traditional methods, male condoms, and oral contraceptive pills; estimating the total number of theoretically protected coital acts per year; and then, based on observed departure from effective use of contraception, calculating the number of coital acts that require pregnancy prevention.

Traditional methods, condoms, and pills are the only contraceptives included in the model because they are the methods for which a woman would be aware of a departure from effective use and would perceive the need for ECPs (sexual relations outside of the safe period, partner failing to withdraw, inconsistent condom use, or missed oral contraceptive pills). Users of other methods of contraception such as sterilization and intrauterine devices are not likely to need ECPs. To calculate the total number of coital acts in this population, the model uses the world average of 106 coital acts per year.[1] The observed departure from effective use of contraception is included in the model as a fixed rate of 20 percent, based on estimates of observed departure from effective use of contraception (the percentage of coital acts that contraceptive users would **know** they did not actually use their contraception effectively). The 20 percent estimate is based on data indicating that an average of 22 percent of women knowingly miss more than 2 pills per cycle;[2] approximately 19 percent of coital acts by condom users are knowingly unprotected;[3] and failure rates of withdrawal and rhythm methods are 20 percent and 19 percent, respectively.[4] While the failure rate of traditional methods is not parallel to the data for condoms or pills, the assumption is that most failure of traditional methods would be clearly observed (either because women following their cycle had intercourse during their fertile period or their partner did not withdraw in time). Furthermore, since unprotected acts do not always lead to pregnancy, the observed rate would not be any lower than actual failure rate.

The estimate for women not using any contraception is calculated by computing the total number of sexually active women of reproductive age not using contraception, estimating the total number of unprotected coital acts per year, and then—based on the estimate of the proportion of women who would prefer to avoid a pregnancy—calculating the total number of coital acts among women not using any contraception that would require pregnancy prevention.

The proportion of women not using contraception who would prefer to avoid pregnancy is based on data indicating that about 17 percent of married women in the developing world would prefer to avoid a pregnancy but are not using any form of contraception.[5]

Realistic demand per year

The second section of the model estimates a more realistic demand for ECPs by calculating a subset of the maximum demand by determining the number of those women who would have knowledge of ECPs, live in an area where ECPs are accessible, and have the ability to pay. These percentages are estimated based on local knowledge of the population and will vary by country.

References

[1] MacKay, J. *The Penguin Atlas of Human Sexual Behavior*. New York: Penguin Reference (2000).

[2] Rosenberg, M.J., Waugh, M.S., and Burnhill, M.S. Compliance, counseling and satisfaction with oral contraceptives: a prospective evaluation. *Family Planning Perspectives* 30(2):89-92, 104 (1998).

[3] Myer, L., Mathews, C., and Little, F. Condom use and sexual behaviors among individuals procuring free male condoms in South Africa: a prospective study. *Sexually Transmitted Diseases* 29(4):239-241 (2002).

[4] Hatcher, R.A., Trussell, J., Steward, F., et al. *Contraceptive Technology*, 16th revised edition. New York: Irvington Publishers (1994).

[5] Ross, J.A. and Winfrey, W.L. Unmet need for contraception in the developing world and the former Soviet Union: an updated estimate. *International Family Planning Perspectives* 28(3): 138-143 (2002).

Content and format for this tool were adapted from a forecasting model developed by AltaCare. PATH greatly appreciates contributions made to the model by the Deliver Project at John Snow, Inc. and Population Services International.

Potential Market for ECPs: A Basic Demand Model

MAXIMUM DEMAND PER YEAR

(Maximum number of coital acts for which women may question their pregnancy status immediately after intercourse)

Women Using Contraception

(a) Total population	
(b) Percentage of women of reproductive age	
(c) Total number of women of reproductive age = (a)x(b)	-
(d) Contraceptive prevalence rate—traditional methods (withdrawal, rhythm) (%)	
(e) Contraceptive prevalence rate—male condoms (%)	
(f) Contraceptive prevalence rate—oral contraceptive pills (%)	
(g) Total contraceptive prevalence rate of traditional methods, condoms and pills (%) = (d)+(e)+(f)	-
(h) **Total number of women of reproductive age using traditional methods, condoms, or pills** = (c)x(g)	-
(i) Average number of coital acts per year	106
(j) **Total number of theoretically PROTECTED coital acts/year** = (h)x(i)	-
(k) Observed departure from effective use of contraception (%)i.e., missed oral contraceptive pills, unprotected coital acts by condom users)	20%
(l) **Total number of coital acts among women using traditional methods, condoms, and pills requiring pregnancy prevention/year** = (j)x(k)	-

Women NOT Using Any Contraception

(m) Total number of sexually active women of reproductive age	
(n) Rate of non-contraceptive use (%)	
(o) **Total number of sexually active women of reproductive age not using contraception** = (m)x(n)	-
(p) Average number of coital acts per year	106
(q) **Total number of theoretically UNPROTECTED coital acts / year** = (o)x(p)	-
(r) Proportion of women not using any contraception who prefer to avoid pregnancy (%)	17%
(s) **Total number of coital acts among women not using any contraception requiring pregnancy prevention/year** = (q)x(r) (Maximum opportunity)	-
(t) TOTAL MAXIMUM DEMAND PER YEAR = (l)+(s)	**-**

REALISTIC DEMAND PER YEAR

(Subset of coital acts from maximum opportunity of women that have knowledge of ECPs, live in area where ECPs are accessible, and have ability to pay)

(u) Total number of coital acts requiring pregnancy prevention per year =(total maximum demand from (t) above)	-
(v) % of women with knowledge of ECPs	
(w)% of women who live in areas where ECPs are accessible	
(x) % of women who have ability to pay for ECPs	
(y) **Total % of women who may seek ECPs** = (v)x(w)x(x)	-
(z) TOTAL REALISTIC DEMAND PER YEAR **Number of coital acts for which women may seek ECPs = (u)x(y)**	-

The shaded boxes are calculated automatically in the electronic version of this document.

References included in model description.

Instructions for Using the Basic Demand Model to Assess the Potential Market for ECPs

Maximum Demand per Year

Women using contraception

(a) Enter the total number of women in the population. Individual country data is available online from the Population Reference Bureau website http://www.worldpop.org/datafinder.htm, the United Nations World Contraceptive Use 1998 website http://www.un.org/esa/population/pubsarchive/wcu/wcu.htm, and the Measure Demographic and Health Surveys website http://www.measuredhs.com/countries/start.cfm.

(b) Enter the percentage of women of reproductive age. Country-specific data may be available on the websites described in (a) above.

(c) Multiply (a)x(b) to find the total number of women of reproductive age.

(d) Enter the contraceptive prevalence rates for traditional methods (i.e., withdrawal and rhythm) as a percentage (%). Country specific data may be available on the websites described in (a) above.

(e) Enter the contraceptive prevalence rates for male condoms as a percentage (%). Country-specific data may be available on the websites described in (a) above.

(f) Enter the contraceptive prevalence rates for oral contraceptive pills as a percentage (%). Country-specific data may be available on the websites described in (a) above.

(g) Add (d)+(e)+(f) for the total contraceptive prevalence rate of traditional methods, condoms, and pills.

(h) Multiply (c)x(g) to find the total number of women of reproductive age using traditional methods, condoms, or pills as their contraceptive method.

(i) There is no need to enter anything here. The average number of coital acts per year around the world is estimated to be 106. This is a fixed number. However, it can be substituted with a number more reflective of local conditions, if local data are available.

(j) Multiply (h)x(i) for the total number of theoretically PROTECTED coital acts per year for traditional methods, condoms, and pills.

(k) There is no need to enter anything here. This is a fixed rate of 20 percent based on estimates of observed departure from effective use of contraception (the percentage of coital acts that contraceptive users would KNOW they did not actually use their contraception effectively).

(l) Multiply (j)x(k) for the total number of coital acts using traditional methods, condoms, and pills requiring pregnancy prevention per year.

Women NOT using any contraception

(m) Enter the total number of sexually active women of reproductive age. Country-specific data may be available on the websites described in (a) above.

(n) Enter the rate of noncontraceptive use. Find this rate by subtracting the total percent of contraceptive use from 100 to get the noncontraceptive use rate. The total contraceptive use rate can be found at the Population Reference Bureau, the United Nations World Contraceptive Use 1998, or the Measure Demographic and Health Surveys websites described in (a) above.

(o) Multiply (m)x(n) for the total number of women not using contraception.

(p) There is no need to enter anything here. The average number of coital acts per year around the world is estimated to be 106. This is a fixed number. However, it can be substituted with a number more reflective of local conditions, if local data are available.

(q) Multiply (o)x(p) for the total number of theoretically UNPROTECTED coital acts per year.

(r) There is no need to enter anything here. This number is based on the estimate that 17 percent of married women in the developing world would prefer to avoid a pregnancy but are not using any form of contraception. This is a fixed number.

(s) Multiply (q)x(r) for the total number of coital acts requiring pregnancy prevention per year.

(t) Add (l)+(s) for the total maximum demand per year.

Realistic demand per year

(u) Enter the total number of coital acts requiring pregnancy prevention per year. This is the total maximum demand per year from (t) above.

(v) Estimate the percentage (%) of women with knowledge of ECPs. Knowledge, attitudes, and practices studies about ECPs performed locally may provide this information.

(w) Estimate the percentage (%) of women who live in areas where ECPs are (or will be) accessible. For example if ECPs are only available in urban areas, use the percentage of the population living in urban settings.

(x) Estimate the percentage (%) of women with the ability to pay for ECPs. This estimate may depend on whether ECPs are available at a subsidized price

(y) Multiply (v)x(w)x(x) for the total percentage (%) of women who may seek ECPs.

(z) Multiply (u)x(y) for the total number of coital acts for which women may seek ECPs. **This is the realistic demand per year.**

Content and format for this tool were adapted from a forecasting model developed by AltaCare. PATH greatly appreciates contributions made to the model by the Deliver Project at John Snow, Inc. and Population Services International.

Information to Include in a Levonorgestrel-Only ECP Package Insert

Essential information for clients

- Brief instructions:
  - ECPs are medicine to prevent pregnancy after unprotected sexual intercourse. Use ECPs if you do not want to become pregnant, if you think your contraceptive method failed, or if you were raped.
  - Take a single dose of 1.5 mg levonorgestrel as soon as possible within 120 hours after unprotected sex. ECPs are more effective the sooner they are taken.
  - ECPs can be used anytime in the menstrual cycle.
- Brief information about side effects:
  - Most women do not feel anything after taking ECPs. Some women have sore breasts and headaches. Some women have their period a little later or a little earlier than usual. Some women feel sick to their stomach, and some women even vomit after taking ECPs.
  - If you vomit within 1 hour after taking ECPs (it may mean you have vomited up the ECPs), you should try to take another dose immediately.
  - If you vomit more than one hour after taking ECPs, you do not need to take extra pills.
  - These ECP side effects 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 STIs or HIV. If you think you may have contracted an STI or HIV, visit your health or STI clinic.

Optional additional information

- 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 birth control 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 oral contraceptive pills.

Sample Procurement Specification: Levonorgestrel-Only ECPs

The following sample format can be used in developing procurement specifications for emergency contraceptives. In developing a procurement specification it is important to thoroughly review national regulatory and registration requirements for the product to ensure that appropriate product requirements are incorporated into the specification. In this sample, examples of product specifications are in italics: when preparing a procurement specification, appropriate product specifications can be substituted for the italicized examples. The sample procurement specification is designed to be used in conjunction with bidding and contract documents.

Notes (for submission of sample of product):

The sample emergency contraceptives pills submitted by the bidder in response to this solicitation must be exactly the same as would be supplied if a contract were awarded to the bidder. In other words, samples should have same tablet shape, color, weight, ingredients, and identification imprint; same blister pack size, material, text, and identification markings; same inner box size, material, text, and identification markings.

1. Requirements

1.1 Emergency Contraceptive Tablets in Accordance with the Following Specifications:

Two-tablet package consisting of two emergency contraceptive levonorgestrel-only tablets.

Each tablet shall contain 0.75 milligrams of levonorgestrel.

Product and Brand Names:

Product Name: _____

Brand Names: _____

1.2 Raw Materials

Emergency contraceptives offered under this purchase description shall be produced from validated raw materials obtained from a licensed manufacturer or its authorized distributor. A typical validation includes, but is not limited to, these areas.[1]

- Manufacturing records and procedures for the raw material synthesis, processing, packing, and storage.
- Quality control records and procedures for the raw material, in-process, and final product.
- Plant certification by local regulatory authorities (such as Commerce, Industry, Health, Environment) as required.

[1] Because the raw materials that make up both active and inactive ingredients are of great importance for final product bioavailability and stability, good manufacturing practices require that manufacturers validate vendors for all raw materials.

- Certification of workers' training in good manufacturing practices and safety protection.
- Records demonstrating raw materials with the required physical and chemical characteristics.

1.3 Registration Requirements

Emergency contraceptives offered under this purchase description shall be currently registered in the country of destination and approved by _____ (local regulatory authority).

1.4 Certificate of Licensing Status

Emergency contraceptives offered under this purchase description shall be licensed for marketing by the drug regulatory authority of the country of origin. Prior to award of the Contract, the successful offeror(s) may be required to submit a "statement of licensing status of pharmaceutical product(s)" as provided under the World Health Organization (WHO) Certification Scheme.[2]

1.5 No Objection Certificate

In the case of goods of foreign origin, emergency contraceptives offered under this purchase description shall have been awarded a No Objection Certificate by _____(local regulatory authority) on behalf of any local manufacturer(s) of the importing country.

1.6 Compliance with Good Manufacturing Practices

The Supplier must be able to provide certification that the emergency contraceptives are manufactured according to WHO good manufacturing practices (GMP). Such certification can be found in the WHO Certification Scheme "Certificate of a Pharmaceutical Product." Supplier also must be able to provide copies of its annual GMP audit reports.

1.7 WHO Certification—Movement in International Commerce

The Supplier must be able to provide documentation indicating manufacturer of the product has received confirmation from the Ministry of Health of the country of manufacture that the pharmaceutical meets the requirements in the WHO Certification Scheme.

1.8 Shape and Dimensions

Tablets shall be of the shape and dimensions of the Bidder's normal, standard commercial tablet.

1.9 Colors

Emergency contraceptive tablets shall be similar to Bidder's normal, standard commercial tablets.

[2] WHO Certification Scheme for the Quality of Pharmaceutical Products Moving in International Commerce. For additional information see www.who.int/medicines/library/qsm/who-edm-qsm-2000-2/certifscheme.shtml.

1.10 Tablet Marking

Each tablet shall bear the identifying imprint of its manufacturer if such imprint is provided on the Bidder's normal, standard commercial tablet.

1.11 Packaging

1.11.1 Presentation

Each individual tablet shall be enclosed in a transparent blister pack of thermoformed polymer with a foil backing. The supplier shall be able to provide to the satisfaction of the registration/national quality control authorities the manufacturer's stability test data to validate the product's stated shelf life at ambient temperature 32 degrees C or above and relative humidity of 85 percent. Variations must be proven scientifically comparable by means of stability data.

The size of the package shall not be less than 65 mm (2.6 inches) x 27 mm (1.08 inches). Thicker polymer or foil or the addition of a card to either the front or back of the package (in addition to the minimum polymer or foil) is acceptable.

1.11.2 Mounting

Tablets shall be mounted two (2) tablets per package.

1.12 Identification Markings on Individual Blister Packs

1.12.1 Each individual blister pack shall have the following information:

- Product/brand name
- Lot/batch number
- Expiration date (month and year)
- Date of manufacture
- Manufacturer's name or symbol
- Contents and quantity
- Product use and storage instructions (accompanying the blister pack)

1.12.2 Printing and layout

On the back of each blister package the trade or brand name of the product shall be printed in precision full registration.

The month and year of expiration, and the lot/batch control number shall be shown on each individual blister pack. Debossing is acceptable for these numbers.

The tablet formulation and/or the international nonproprietary name shall be printed on the individual packet and may be printed on the reverse side (smallest type no less than one mm high).

1.13 Workmanship

Products and packaging shall be free of defects that impair their serviceability, affect their durability, or detract from their appearance.

1.14 Lots Per Order

The Supplier shall fill the order using the fewest number of manufacturing lots possible.

1.15 Shelf Life

The shelf life of the product provided under this solicitation shall be ___ (_) years from the date of manufacture when stored under tropical conditions such as those prevailing in _____*(recipient country name).* The Supplier shall be able to provide to the satisfaction of registration/national quality control authorities manufacturer's stability test data substantiating this ___year shelf life at ambient temperatures 32 degrees C or above and relative humidity of 85 percent in the proposed blister package.

At the time of inspection or acceptance for delivery to the country of destination, no more than ___ (__) months shall have expired since the date of manufacture shown on the batch release or Certificate of Analysis.

1.16 Test Data

Chemical and physical test data for raw materials, components, in-process, and finished product testing must be on record for each lot shipped and must be available to Purchaser's representatives when requested.

2. Quality Assurance Provisions

2.1 Compliance

The Supplier shall guarantee that the products as packed for shipment comply with all provisions of the specification and related documents.

2.2 Documentation

2.2.1.

The Supplier shall provide evidence[3] of the satisfaction of the technical specification requirements for which specific inspection instructions or protocols have not been provided. Such evidence is contained in the "Manufacturer's Batch Certificate" under the WHO Certification Scheme.

[3] Including quality control and manufacturing records, in-process control records, and final product certificate of analysis.

2.2.2.

The Supplier shall provide a copy of the manufacturing record and procedures to the Purchaser for each lot intended for shipment.

2.2.3.

The Supplier shall provide a copy of the Certificate of Analysis to the Purchaser for each lot intended for shipment.

2.2.4.

The Supplier shall provide to the Purchaser a copy of the approval of each component for each lot intended for shipment.

2.3 Inspection by the Purchaser

The Purchaser reserves the right to perform or cause to be performed any of the inspections and tests set forth in the Specification and Special Conditions of Contract to ensure that the goods conform to prescribed requirements. The Purchaser reserves the right, and/or may assign the right to a representative, to enter and inspect the production facility prior to shipment of the goods and to draw samples from the Supplier's factory and/or warehouse. Except as otherwise specified in the contract or purchase order, prior to shipment the Purchaser will sample or cause to be sampled the product as packed in inner boxes preparatory to packing in exterior shipping cartons. The sampling shall be according to recognized standards.[5]

The Purchaser may have some or all of the tests specified in Section _____of the contract performed by a laboratory suitably equipped and qualified to conduct quality assurance tests on pharmaceutical products according to _____Pharmacopoeia.

2.4 Sampling Procedures

The Purchaser or the Purchaser's representative shall select the required samples from the lot according to Section ____ of the Special Conditions of Contract. If the order is to be filled using more than one production lot, each production lot shall be separately sampled and tested.

Where an inspection lot is smaller than 10,001 units, it will be deemed to be 10,001 for determination of sample sizes.

The normal, tightened, and reduced inspection provisions of ISO 2859 (Inspection by Attributes) may be used for visual inspection. Sampling for analytical testing shall be done in accordance with pharmacopoeial requirements.

All sampled boxes and shipping cartons shall be so marked and shall include the date and initials of sampler.

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[4] In some cases, Special Conditions of Contract are added to the governing contract. These terms accommodate any special needs not otherwise covered, such as requirements to remedy non-conforming product, time limitations on inspections, or the use of specific inspection agencies.

[5] Depending on the tests required, sampling may be conducted according to the standards of the International Organization for Standardization (ISO 2859: Inspection by Attributes), or as dictated by local or international pharmacopoeiae. Following recognized sampling procedures helps to ensure that the products tested are representative of the whole. For information on obtaining ISO 2859: Inspection by Attibutes, see www.iso.ch/iso/en/CatalogueDetailPage.

2.5 Sample Retention

The Supplier shall retain a sample of ten blister packages, or the equivalent required to perform three complete chemical assays, from each lot shipped, for a period of one year after the printed expiration date.

3. Packing

3.1 Inner Boxes

3.1.1

Products sealed in individual packages as specified in Section 1.11 shall be packed in inner boxes of ___ (__) *packages* per inner box. Inner boxes shall be made of *light fiberboard (white)* of a size sufficient to contain the specified number of packages. The overall dimensions should be such that the product does not get damaged during transportation and storage.

3.1.2

For inner boxes, the Bidder shall fill in the blanks provided below:

The products in each inner box will be ___ (__) individual *packages;* the overall dimension of a box will be ___cm x ___cm x ___cm.

3.2 Exterior Shipping Cartons

3.2.1.

Product and printed materials, packaged and packed as specified above, shall be contained in exterior shipping cartons of strong, export quality material able to withstand rough handling and the prevailing climatic conditions during transport and storage.

3.2.2

The Bidder shall fill in the following blanks:

The exterior shipping carton will contain ____ inner boxes; the overall dimensions of a carton will be _ cm, x __ cm x __ cm and the gross weight of one shipping carton will be ___ kg.

A standard 20 foot (6.096 meter) container will accommodate _____ exterior shipping cartons.

4. Markings

4.1 Inner Boxes

The inner boxes shall be marked with the following information in a clearly legible manner that is acceptable to the Purchaser.[6]

[6] The smallest type shall be no less than 1 mm high, unless otherwise specified by the commercial laws of the country if importation.

- Product/brand name
- Lot/batch number
- Expiration date (month and year)
- Date of manufacture
- Manufacturer's name, address
- Contents and quantity
- Drug registration numbers (if applicable)
- Instructions for storage and handling

4.2 Exterior Shipping Cartons

The following information shall be stenciled or labeled on the exterior shipping cartons on two opposing sides in bold letters at least __ mm high with waterproof ink in a clearly legible manner that is acceptable to the Purchaser:[7]

Regulatory Information (on two opposing sides of carton)

- Product/brand name
- Lot/batch number
- Expiration date (month and year)
- Date of manufacture
- Manufacturer's name, address
- Contents and quantity
- Drug registration numbers (if applicable)
- Instructions and symbols (see below) for storage and handling
- Notice of need to protect from exposure to water and extreme heat or extreme cold

Customs/Shipping Information (on two opposing sides of carton)

- Made in _____
- Supplier's name and address (if different from manufacturer)
- Consignee's address in full
- Gross weight of each carton (in kg)
- Port of entry
- Contract number
- Quantity of goods
- Carton ___ of ___

[7] The smallest type shall be no less than ten mm high, unless otherwise specified by the commercial laws of the country of importation.

5. Printed Materials—Product Information Sheets

5.1 Consumer information and directions for use shall be printed in English and/or in _____ and provided as package inserts, one copy for each consumer unit.

5.2 Information for Physicians' Use shall be printed in English and/or in _____. Two copies of such information shall be provided for each 100 blister packages and shall be placed in each exterior shipping carton.

Preferential Pricing for Public-Sector Agencies

In consideration of the need and the public good, manufacturers may decide to offer a preferential price to public-sector or nonprofit programs.

Gedeon Richter Ltd. (Postinor-2) and Laboratoire HRA Pharma (Norlevo), the two major international pharmaceutical companies that currently manufacture and distribute levonorgestrel-only products packaged and labeled specifically for emergency contraception, have both indicated a willingness to provide their product to qualified governmental organizations and public-sector agencies at preferential prices. Requests for preferential public-sector pricing should be issued directly to the companies at the following addresses:

Gedeon Richter Ltd.
1103 Budapest
Gyomroiu. 19-21
Hungary
Attention:
Ms. Agnes Hazslinszky, Area Manager, International, Dosage Form Products (a.hazslinszky@richter.hu)
Tel: 36-1-431-4406 Fax: 36-1-261-9641

AltaCare, on behalf of Laboratoire HRA Pharma
19, rue Frederick Lemaitre
75020 Paris, France
Attention:
Mr. Saad Harti, Managing Director (saad.harti@altacare.fr)
Mrs. Sophie Godefroy, Brand Manager (godefroy@altacare.fr)
Tel: 33-143-49-6133 Fax: 33-143-49-6179

The companies may request information that confirms the organization is a bona fide governmental organization or public-sector agency. They may request information on the plans for successfully introducing emergency contraception into the existing family planning/ reproductive health program. Other information that the companies may request includes:

- Quantity of ECP dosages required.
- Delivery date for shipment.
- Shipping instructions and shipping document requirements.
- Inspection or testing requirements.
- Registration, licensing, and quality assurance documentation required to register and import product.
- Name and contact information for follow-up questions.

Since procurement personnel are traditionally responsible for contacting manufacturers and suppliers to request pricing and detailed product information, program planners should work closely with their procurement staff to provide the information that the manufacturers may request.

Procurement Through International Procurement Services

An organization would want to use the services of a reputable international procurement agency to obtain levonorgestrel-only emergency contraceptive pills if the organization has limited procurement capacity or the value of an order is small. Two international agencies with experience in procuring and providing levonorgestrel-only ECPs are UNFPA and IPPF, which have provided the general ordering and contact information below.

UNFPA

UNFPA has considerable experience in the international procurement and shipment of dedicated ECPs and its procurement services are available to government ministries, multilateral and bilateral agencies, and NGOs. General ordering requirements for UNFPA procurement services are as follows.

For orders of 20,000 packs or more of levonorgestrel-only ECP, delivery time is an average of two to three months after the purchase order is issued.

UNPFA is currently able to fill orders of fewer than 20,000 packs. The delivery time for small orders is a period of several days.

UNFPA payment terms are net 30 days and there is a service fee charge of 5 percent of the cost of insurance and freight value of the goods to cover UNFPA expenses to process the order.

Requests for UNFPA procurement services and general inquiries should be issued directly to UNFPA at the following address:

Ms. Nana Essah, Sr. Procurement Officer
Procurement Services Section
United Nations Population Fund (UNFPA)
220 East 42nd Street
New York, New York 10017, USA
Tel: 212-297-5384
Fax: 212-296-4916
Email: essah@unfpa.org

*For planning purposes, the approximate order value of 20,000 packs is US$5,000 at a current price of US$0.25 per pack of two tablets. The gross weight of a shipment of 20,000 packs of Postinor 2 is approximately 137 kilograms

International Planned Parenthood Federation (IPPF)

IPPF, working through a subsidiary, ENET, provides international procurement and shipment of dedicated levonorgestrel-only ECPs to its member associations and third-party customers.

Organizations placing orders through IPPF must guarantee that their levonorgestrel-only ECP products (examples of which are Postinor-2 and Norlevo) will be exclusively distributed through family planning clinics and youth centers, where the end users will receive the ECPs either free of charge or for a minimal fee to cover costs. Member associations and third party customers who can comply with this requirement must submit an official letter to IPPF confirming that the product will be distributed through the public sector or an NGO. The letter should also identify the annual quantity of ECPs required. Within two weeks of receipt of the above letter, IPPF will study the possibilities of supplying within that country and a decision will be taken. IPPF's ability to supply the product is conditioned by several factors, including whether or not the product is registered in a country and IPPF's agreement with ECP manufacturers. IPPF will notify the requesting party of its ability to supply product, including information on any conditions of provision that would be required.

For those requests for ECP that have been approved, IPPF currently has a minimum order quantity requirement of 10,000 packs of levonorgestrel-only ECPs. The approximate price for ECP ranges from US$0.25 to US$0.60, depending upon the manufacturer supplying the product. The time required to process an order for ECPs is approximately 2 to 3 months after the purchase order has been received by IPPF. IPPF payment terms are 30 days and there is a service fee charge of 4.5% of the CIF (cost of insurance and freight) value of the goods to cover IPPF expenses to process the order.

Requests for IPPF procurement services should be issued directly to IPPF at the following address:

Mrs. Vanessa Gerbron, Services Provider
E-mail: vgerbron@ippf.org
or
Carl Foissey, Business Analyst
E-mail: cfoissey@ippf.org
International Planned Parenthood Federation (IPPF)
Regent's College
Inner Circle, Regent's Park
London NW1 4NS
United Kingdom
Telephone: +44 (0)20 7487 7926
Fax: +44 (0)20 7487 7950

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