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An update on access to emergency contraception in European Union countries

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Emergency contraception (EC) methods have been available in most European Union (EU) countries¹ for more than 15 years. However, information on equality of access to EC methods within the region is scarce. Timely access to EC is an important component of the contraceptive mix offered to women, in order to ensure their reproductive health and rights.

In 2012-13, the European Consortium for Emergency Contraception (ECEC) conducted a survey to learn more about EC accessibility in the EU countries. The expert-based survey assessed the legal status of different EC methods; prescribers and places of delivery; costs and reimbursement policies; availability of data on estimated frequency of use and of clinical and service delivery guidelines; and common practices at the country level. The main findings are summarized in the factsheet *Access to emergency contraception in the European Union countries*, published in October 2014. In 2015, and with the valuable collaboration of local experts, ECEC updated the available data, in order to capture the changes on accessibility.

This factsheet provides a summary of the main changes in access to EC in the EU countries, up to October 2015, and refers only to EU member states. If subnational policies apply for specific regions, these have not been captured in this factsheet. For more detailed information on a specific country or to know more about EC access in other European countries, please visit the *Country-by-Country* information section of the ECEC website.

If you believe that information presented here is inaccurate or outdated, please contact us at info@ec-ec.org. This factsheet can be found online at www.ec-ec.org/resources/publications.

1. What is emergency contraception?

Emergency contraception, also known as *postcoital contraception* or *the morning after pill* refers to contraceptive methods that women can use to prevent pregnancy after unprotected or inadequately protected sexual intercourse.

Currently, there are three main types of EC methods available in EU countries:

- Levonorgestrel emergency contraceptive pills (LNG ECPs)
- Ulipristal acetate emergency contraceptive pills (UPA ECPs)
- Insertion of a copper intrauterine device (Cu IUD).

1. Currently, the EU consists of 28 member states: Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, the United Kingdom.

Other emergency contraceptive pills (ECPs), containing a low dose of mifepristone (30 mcg), are available in Armenia, Russia, Republic of Moldova and Ukraine, as well as in China and Vietnam, but these are currently not found on EU markets. An older ECPs regime, called Yuzpe, consists of a higher dose of regular combined progestin and estrogen contraceptive pills. The use of this regimen has become marginal in Western countries, however, because more effective methods are readily available.

2. Where is EC available?

Both LNG and UPA ECPs are available in all EU countries, except Malta, where ECPs are not registered. Cu IUDs are also available throughout the EU, but in Malta, they are not allowed for EC use. Distribution of UPA ECPs for sale without prescription commenced in 2015 in all EU member states except in Hungary, where prescription remains obligatory to obtain any type of EC. In the Baltic countries (Latvia, Estonia, and Lithuania), due to distribution issues by the end of 2015 UPA EC could not be found in the local markets, but was expected to be available in 2016. In Cyprus, where no ECPs were available since 2013, UPA ECPs are now available but not LNG ECPs.

3. Prescription requirements

Since 2015, at least one brand of LNG ECPs can be obtained directly from a pharmacy without a doctor's prescription in all EU countries except for Malta, Hungary and Poland. In Hungary a prescription is still required for both UPA and LNG ECPs, and in Poland for the time being, only for LNG ECPs. In Malta, no emergency contraceptive pills are available. Croatia, Germany and Italy have witnessed major changes in 2015, and now allow the sale of LNG ECPs and UPA ECPs without prescription. A provider prescription and insertion is required to fit a Cu IUD in all countries.

It is important to highlight that in November 2014 the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) recommended a change in classification status from prescription to non-prescription for the emergency contraceptive ellaOne (ulipristal acetate).² Following EMA's assessment, the European Commission issued an implementing decision in January 2015, amending the marketing authorisation granted in 2009 for this brand of

2. European Medicines Agency. *EMA recommends availability of ellaOne emergency contraceptive without prescription. November 21, 2014.* http://www.ema.europa.eu/docs/en_GB/document_library/Press_release/2014/11/WC500177649.pdf visited on April 28, 2015.

UPA ECPs³, allowing sale without prescription. While the European Commission decision is not legally binding, this change of classification triggered major changes in EC accessibility in the EU region. The vast majority of EU countries followed the recommendation and since 2015 UPA ECPs are available directly in the pharmacy without prescription in all countries except Malta, where no dedicated products are registered, and Hungary, where the national government explicitly refused to follow the EU recommendation.

4. Age restrictions

According to the Summary of Product Characteristics (SmPC) of some LNG products, at least in Croatia, Latvia, Lithuania, Romania, Bulgaria, Slovakia, Slovenia, Poland and the United Kingdom, women 16 years old and younger should obtain a prescription in order to buy LNG EC, and in the the Czech Republic women under 17. In addition in Poland, those under 18 years old need their parents' consent to procure and use LNG ECPs, and to make any other medical decision. It is not clear how and to what extent these restrictions are applied in different countries. In Finland, the restriction on LNG ECP for those younger than 15 was removed in March 2015.

With regards to UPA ECP, women under 18 in Italy, and women under 15 in Poland, need a prescription.

5. Where can ECPs be obtained?

There is significant variation on where ECPs can be obtained. In all countries, ECPs are available in pharmacies. In many countries, they can also be obtained at family planning clinics, health care centres, and public hospitals. At least in France and the United Kingdom, ECPs (both LNG and UPA) are also for sale from websites based in these countries. In the Netherlands and Portugal, ECPs are available from other retailers, both in-store and online.

Where ECPs can be obtained without a prescription from pharmacies, there are two main accessibility modalities. ECPs may be stored *behind the counter* (BTC), meaning they are not displayed on the pharmacy shelf and the customer needs to interact with the pharmacy personnel. In some cases there may be a dispensing protocol that requires the patient to respond to questions from

3. European Commission. *COMMISSION IMPLEMENTING DECISION of 7.1.2015 amending the marketing authorisation granted by Decision C(2009)4049 for "ellaOne - ulipristal acetate", a medicinal product for human use*. Accessed on May28th 2015. http://ec.europa.eu/health/documents/community-register/2015/20150107130448/dec_130448_en.pdf

the pharmacist, and allows the pharmacist to decide if that patient should or should not use EC. ECPs can also be available *over the counter* (OTC), meaning customers do not need to interact with the pharmacist or store clerk, as ECPs are stored directly on retailers' shelves. In the Netherlands and Portugal, LNG ECP can be obtained OTC in some premises (retailers and para-pharmacies).

6. Who can prescribe EC?

Physicians are the main prescribers in all countries. However, in some countries, other health care providers are also allowed to prescribe EC, particularly pharmacists, nurses, or midwives. These countries are Estonia, France, Ireland, Lithuania, the Netherlands, Portugal, Romania, Sweden and the United Kingdom. In these cases, a prescription is often needed for reimbursement or gratuity, rather than for access. An interesting model of care is one in which physicians and other health service providers cooperate in order to enable these other providers to prescribe ECPs. These providers may include nurses, midwives, and pharmacists. In the United Kingdom, this is done by means of 'patient group directives'.

7. Common practice

In practice, pregnancy tests or pelvic exams are generally not required before providing ECPs. Italy was the only country where a pregnancy test was required before providing UPA ECPs until 2014, but this requirement has been removed in 2015. In some countries, pregnancy tests or pelvic exams may be requested by some doctors or under specific circumstances, such as when a pregnancy is suspected.

8. Estimated use of ECPs

Fifteen of the 28 EU member states have some statistics on ECP use (see Table 1). These include Austria, Belgium, Bulgaria, Denmark, Estonia, France, Germany, Italy, Latvia, the Netherlands, Portugal, Slovakia, Spain, Sweden, and the United Kingdom. Some of these data are rather old. Furthermore, the methodology of these studies does not allow for comparisons between countries. However, according to the data available, there appears to be significant differences in use within the EU region. The highest proportion of women who have ever used EC was reported in

the United Kingdom (61%) and Sweden (59%). In most countries, about 20% have ever used EC. Germany is the country where this percentage was the lowest (13%). The proportion of women who have used EC in the past year ranges from below 1% (Belgium) to 18% (Bulgaria). Elsewhere, this percentage lies between 2% and 7%.

In the countries where LNG ECPs have been available without a prescription for some time, the majority of women seem to prefer to obtain their ECPs directly from the pharmacy, and less than 10% obtain a prescription first. However, data from Spain and the United Kingdom show that, in these countries, at least one-third of ECP users obtain EC without a prescription, while the remaining two-thirds obtain it from health services or hospitals. This may reflect differences in health care systems and possibilities of reimbursement. Data on repeat use is scarce, but, from the data available, it seems to be rare (2% or less). No data is available on Cu IUDs for EC use.

9. Cost and reimbursement policies

There are large differences in the price of ECPs across the EU. UPA ECPs are consistently more expensive than LNG ECPs in all EU member states. LNG ECPs are priced the lowest in France, where they are available for € 7. In the same country, women also pay the least amount for UPA ECPs at € 20. Higher prices can be found in the United Kingdom and Ireland, where women pay approximately € 40 for LNG ECPs and almost € 60 for UPA ECPs.

Various partial or full reimbursement mechanisms are in place in seven countries: Belgium, France, Germany, Ireland, the Netherlands, Spain, and the United Kingdom. In some countries, EC is publicly subsidised, and women can obtain it for free from certain facilities, such as family planning clinics, public hospitals, primary health care centres, and even in pharmacies in parts of the United Kingdom. In some countries, reimbursement is contingent on age, insurance plan, or whether a prescription was obtained. In 16 countries (Austria, Bulgaria, Croatia, Cyprus, Denmark, Estonia, Finland, Hungary, Italy, Latvia, Lithuania, Poland, Portugal, Romania, Slovakia, and Slovenia), the full cost of EC must come directly from the user.

10. Guidelines for EC provision

Most EU countries have official guidelines or other publications that aim at guiding clinical practice (Table 2). In some countries, advice on EC provision is incorporated in more comprehensive guidelines on the broad range of contraceptives. Three countries have no guidelines at all. These

are Austria, Latvia and Malta. In Cyprus and Lithuania, the World Health Organization (WHO) *Medical eligibility criteria for contraceptive use* are used as main reference.

In 2015, national contraception societies and/or family planning associations took the lead in developing new guidelines in Italy and Romania, and in updating the current recommendations at least in Spain and France.

In addition, in at least two countries (Croatia and Germany) dispensing protocols have been developed by pharmaceutical associations.

In most countries, gynecological societies issue contraceptive guidelines. In some cases, primary care societies take the lead or guidelines are developed cooperatively with several societies. Pharmacists are rarely involved in developing guidelines, although their role has become more prominent since ECPs became available without prescription. Where published books or papers are used for guidance, it is unclear whether these were endorsed by medical societies as guidelines.

11. Summary

In 2015 the EU countries witnessed the largest changes in EC accessibility. With the change of status of UPA ECPs, ECPs can be directly available to women in pharmacies, without prescription, in 26 out of the 28 EU countries. EC is almost universally available in European Union member states. Malta is the only exception, where no method of emergency contraception is legally available. Both UPA and LNG ECPs are registered to be sold without prescription in all countries but in Malta and Hungary. The extent to which all EC pills formulations are readily available in a given setting has not been assessed. For Cu IUDs, a prescription is always necessary. In some countries, women need to be of a certain age (most often 16) to have access to EC without prescription. There is a wide variation in out-of-pocket costs and possibilities for reimbursement within the EU, and in 16 countries EC is not provided free of cost under any circumstance. Women need to pay between € 7 and € 60 euros for ECPs. Use of EC differs between countries as well, although differences in research methods make a rigorous comparison difficult. The switch of UPA ECPs to non-prescription status has resulted in more updated guidelines and also in new dispensing protocols developed by pharmaceutical associations.

TABLE 1. ECP USE*

	EVER USE OF EC	EC USE DURING THE PAST 12 MONTHS	% WITH NO PRESCRIPTION	REPEATED USE OF EC DURING THE PAST 12 MONTHS
AUSTRIA	18% (2012)			
BELGIUM		0.6% (2004)		
BULGARIA	38% (2012)	18% (2012)		2% (2012)
DENMARK	20% (2010)		99%	
ESTONIA	41.3% (2014)			
FRANCE	22% (2010)	4.5% (2010)	95% (2013)	1.4% (2010)
GERMANY	13% (2011)			
ITALY		2.5%-2.7% (2009)	0.3% (2009)	
LATVIA		2% (2011)		
NETHERLANDS	21% (2009)	2% (2009)		0.5% (2009)
PORTUGAL			>95% (2012)	3.7% (2006)
SLOVAKIA			96.88% (2011)	0.1%-1% (2011)
SPAIN	14.7% (2013)	3.95% (2013)	47.3% (2013)	0.42% (2011)
SWEDEN	59% (2011)	4% (2012)	>90%	
UNITED KINGDOM	61% (2010)	7% (2008-2009)	33% (2002)	1-2% (2000- 2002)

* Only countries that provided use statistics are included. To see the data sources please visit the countries' profiles at <http://www.ec-ec.org>. As these data have been gathered using different methodologies, they may not be comparable for different countries.

TABLE 2. TYPES OF GUIDELINE IN EUROPEAN UNION COUNTRIES*

Countries with official guidelines dedicated exclusively to EC	Countries with official family planning guidelines that include EC among other contraceptive methods	Countries that use a published paper or book as a reference to guide EC provision**	Countries without guidelines
Croatia (2015)	Lithuania (2008)	Cyprus (2015)	Austria
Denmark (2015)	Slovakia (2009)	Belgium (2009)	Latvia
Finland (2010)		Bulgaria (2010)	Malta
France (2015)		Czech Republic (2007)	
Germany (2015)		Estonia (2015)	
Greece (2013)		Ireland (2011)	
Hungary (2012)			
Italy (2015)			
Netherlands (2015)			
Poland (2011)			
Portugal (2015)			
Romania (2015)			
Slovenia (2011)			
Spain (2015)			
Sweden (2005)			
United Kingdom (2011)			

* If there are more than one different guidelines, the most recent one is listed

** Including reference guides of international bodies like WHO

No information about guidelines in Luxembourg was received.

The European Consortium for Emergency Contraception is a network of individuals and organizations that aim to increase **knowledge** and **access** to emergency contraception in Europe.

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