Status of Emergency Contraceptives in Europe One Year after the European Medicines Agency's Recommendation to Switch Ulipristal Acetate to Non-Prescription Status

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Key Words

Emergency contraceptives · Ulipristal acetate · Levonorgestrel · Europe · Prescription status · Availability

Abstract

Background: In November 2014, the European Medicines Agency (EMA) recommended switching the emergency contraceptive (EMC) ulipristal acetate to non-prescription status. This study's objective is to assess the current legal status of the two EMCs ulipristal acetate and levonorgestrel in Europe and to report on the development of sales figures for EMCs since they were made freely available. **Methods:** Health authorities were contacted in autumn 2015 and asked about the current status of EMCs and whether the sales figures had changed after a switch to non-prescription status. Additionally, data on consumption were collected in 18 German community pharmacies. **Results:** As of November 2015, most countries in the European Union (EU) have followed the EMA recommendation. Hungary kept the prescription-only status. In Malta, EMC drugs are not authorized. Germany and Croatia switched levonorgestrel to non-prescription status as well. Of the EU candidate and European Free Trade Association countries, ulipristal acetate is available without prescription in Norway and Bosnia and Herzegovina only. Sev-

eral countries reported an increase in EMC sales since the switch. **Conclusions:** An EMA recommendation can strongly contribute to the harmonization of a drug's legal status in the EU. In most European countries, ulipristal acetate and/or levonorgestrel are now freely available.

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Introduction

Unintentional pregnancy and terminations of pregnancy are relevant public health issues that, not least, affect adolescent girls [1, 2] and are predicted by socioeconomic factors such as educational background or income [3–8]. In 2009, the active pharmaceutical ingredient 'ulipristal acetate' (UPA) obtained marketing authorization through the centralized procedure of the European Medicines Agency (EMA) to be used for emergency contraception throughout the European Union (EU). Another active ingredient used for emergency contraception is levonorgestrel (LNG; 1.5 mg as a single dose), which is authorized in most European countries on a national level.

An emergency contraceptive (EMC), also known as the 'morning-after pill', can prevent unintended conception in case of, for example, failure of other contraceptive

measures, if it is taken within 72 h (LNG) or 120 h (UPA) after sexual intercourse. Effectiveness is increased by taking EMCs very quickly, preferably within 24 h [9].

In November 2014, the EMA recommended switching the EMC drug UPA (ellaOne®) from prescription to non-prescription status [10]. On January 7, 2015, the European Commission issued a legally binding decision valid (in principle) throughout the EU, which makes this EMC freely available as an over-the-counter (OTC) drug [11]. This decision was also based on the safety profile for UPA, which is considered to be comparable with that of LNG [12], and was supposed to speed up women's access to EMCs. Prior to the EMA recommendation, UPA was available on prescription only in all European countries where it was marketed (with some exceptions in the UK, where it was partly already available without a prescription on a trial basis). At the time of the EMA recommendation, LNG was already available without a physician's prescription to be used for emergency contraception in most European countries.

This study has two main objectives. First, to summarize the current legal and availability status of the two EMC drugs UPA and LNG in Europe. Second, to describe the impact of the switch of EMC drugs to non-prescription status on EMC sales in Germany and other European countries where respective data were available.

Methods

Included Countries

For this study, all 28 member states of the EU and the four members of the European Free Trade Association (EFTA), Iceland, Liechtenstein, Norway, and Switzerland, were addressed. Additionally, EU candidate countries and potential candidates [13] were also considered for assessment.

Assessment of the Prescription Status

To obtain information on the current legal status of EMCs and further data, the countries' national pharmacists' associations, as listed on the homepage of the Pharmaceutical Group of the European Union (PGEU) [14], were contacted by e-mail between September 2015 and November 2015. A list was attached to the e-mail with several questions on EMCs. In detail, the following issues were addressed:

- Current prescription status of UPA and LNG?
- If not yet switched to free availability, implementation process underway?
- Available in pharmacies only?
- Dispensed behind the counter only?
- Any restrictions when dispensing an EMC (e.g. for women aged >18 years)?
- Can EMCs be advertised in the common media such as TV or print media?

- Are the prices of EMCs fixed by legislation or freely calculable?
- Any information available as to whether EMC sales figures have changed markedly since the change to non-prescription status?
- Any information on drug shortages in relation to EMCs available?

If no response was obtained from the pharmaceutical associations, other health authorities (e.g. national medicines agencies, national health ministries, pharmacists' chambers, etc.) were contacted and/or the authorities' homepages as well as the website of the European Consortium for Emergency Contraception [15] were screened for information with regard to the current legislation on EMCs. In addition, the market leader for EMCs in Europe (HRA Pharma) was also contacted and asked to supply market data on EMCs.

Assessment of Pharmacy Dispensing Data in Germany

Own data on EMC sales figures were assessed in 18 community pharmacies from various German regions (Baden-Württemberg, Bavaria, Hesse, North Rhine-Westphalia, Saarland, Schleswig-Holstein) by directly contacting the pharmacy owners. Sales figures were collected for the period between January 2014 and October 2015.

Results

EU Member Countries

As of November 2015, nearly all EU countries followed the European Commission's decision and made UPA freely available. The decision was transposed to national legislation very quickly (by January 2015), for example in Spain, Austria, Belgium, Lithuania, and the UK. UPA is registered but not yet available (expected by 2016) in Estonia. One country (Hungary) did not follow the recommendation and decided in January 2015 to classify all orally administered contraceptives (including UPA for emergency contraception) as prescription drugs. No EMCs containing UPA or LNG are licensed in Malta.

Normally, UPA is available in pharmacies behind the counter only. In the Netherlands and Sweden, UPA is also sold outside pharmacies. In Luxembourg, for example, UPA is additionally distributed in family planning centers, whereas the UK also offers access through UK-based internet sites.

In the context of the UPA implementation process, Germany and Croatia (where LNG was subject to medical prescription before November 2014) switched LNG to non-prescription status as well. LNG remained a prescription drug in Hungary, Italy and Poland. In Cyprus, LNG has non-prescription status, but is not available on the market because of the financial crisis since 2013. LNG is also partly available outside pharmacies (The Nether-

Fig. 1. EMC packages sold in 18 German community pharmacies (all four EMC brands of LNG and all reimported medicinal products of UPA currently available in Germany were considered).

lands, Portugal, Sweden). In Luxembourg and Romania, for example, UPA is additionally distributed in family planning centers, whereas the UK and France also offer access through government-based internet sites.

In the Principality of Monaco, formally not part of the EU, both UPA and LNG are freely available. No data were available for San Marino and Andorra, two further microstates closely related to the EU.

EFTA Countries

UPA is available without prescription in Norway (switch by the end of December 2014), but still requires a prescription in Liechtenstein (according to Swiss law) and Switzerland. UPA is not yet available in Iceland. LNG is available without prescription in all four EFTA countries. In Norway, both UPA and LNG are also sold outside pharmacies, whereas in Iceland, Liechtenstein and Switzerland, only pharmacies are allowed to sell UPA or LNG.

EU Candidate and Potential Candidate Countries

UPA is not marketed in Albania, the Former Yugoslav Republic of Macedonia, and Montenegro, but it is available as a prescription drug from pharmacies in Serbia. According to the information provided by the Istanbul Chamber of Pharmacists (Istanbul Eczacı Odası), although subject to medical prescription, UPA may sometimes be sold without prescription in Turkish pharmacies. Bosnia and Herzegovina is the only candidate or potential candidate country (no data were available for Kosovo on UPA or LNG) where UPA can be bought without a physician's prescription.

LNG has prescription-only status in Albania and the Former Yugoslav Republic of Macedonia, whereas it

needs no prescription in Montenegro and Serbia. LNG has non-prescription status in Turkey as well, but has not been available since 2014. LNG is also not available in Bosnia and Herzegovina.

Development of Sales Figures

Although only UPA was included in the EMA recommendation, the German administration switched both UPA (restricted to the brand product ellaOne®) and LNG contemporaneously to non-prescription status by a respective modification of the ordinance on prescription-only medicinal products. The relevant decision was published in the Federal Law Gazette dated March 13, 2015. Dispensing a drug as an OTC product requires packages to be labelled accordingly. By the middle of March 2015, only ellaOne® was available in German pharmacies as an OTC-compatible product. Suitable LNG products were available about 1 month later by the middle of April 2015. Figure 1 shows the number of EMCs sold (data available for 18 community pharmacies) per month for the assessment period from January 2014 until October 2015. The 18 included pharmacies were distributed over 6 different federal states of Germany. Ten pharmacies were located in small cities (5,000–20,000 inhabitants) and five in mid-sized cities (20,000–100,000 inhabitants). A further two pharmacies were in larger cities (>250,000 inhabitants). One pharmacy was located in a town with a rather rural character (2,500 inhabitants).

According to the cumulated data from the 18 participating pharmacies (fig. 2), the overall increase in EMC sales in 2015 (May to October) for both UPA and LNG together was 38% for all pharmacies together, compared with the same period in 2014. However, the increase in

Fig. 2. Consumption of UPA- and LNG-containing EMCs since the switch to free availability, in comparison with the corresponding period in 2014.

consumption was visible for UPA only (+62%), whereas the number of LNG packages used remained at an almost stable level (+1%). In the 2 months before the change in prescription status, the consumption of EMCs was very similar to the corresponding months in 2014 (January and February 2015: 88 EMCs sold vs. 85 EMCs sold in January and February 2014). Since May 2015, exactly 74% of the EMCs sold were purchased without presenting a physician's prescription [based on dispensing data (99 EMC packages sold) from 2 of the 18 included pharmacies only].

Further information on the impact of the switch on German sales of EMCs is shown in table 1, which also summarizes the development of EMC consumption in Europe for those countries with available studies or reports on consumption since the change in classification status.

Discussion

EMCs and the linked aspect of unintended pregnancy are relevant public health topics and important issues with relevance to women's self-determination and empowerment as well. However, the debate on EMC drugs, also in terms of their availability without a physician's prescription, is not free from emotions or ethical objections. Hence, it might have been assumed that harmonization of the legal status across the various European countries would be quite difficult. This study showed that a decision by the European Commission in relation to the legal status of an active pharmaceutical ingredient may be

followed and transposed to national legislation by most of the EU members within a time period of approximately 1 year or less, despite existing possibilities for circumventing the Commission's decision (e.g. in the case of EMCs, by adopting Article 4 §4 of the Directive 2001/83/EC [24]). Even in countries that used to have a negative attitude towards freely available EMCs (e.g. Germany, Italy, Poland) before the EMA recommendation, the national administrations decided to liberalize access to EMCs (at least for UPA). Evidently, in the context of the EMA recommendation for UPA, some countries such as Germany or Croatia generally reassessed their attitude towards EMCs and switched LNG to non-prescription status as well. Nevertheless, other EU countries (Italy, Poland) did not extend the EMA recommendation to LNG, but limited the change in classification status to UPA-containing EMCs only.

As expected, the option of getting EMCs directly over the counter resulted in greater use of EMCs in most of the countries with available data on drug consumption. Apparently, women make use of this new possibility quickly. Additionally, most pharmacists may not refuse (for whatever reason, e.g. no need to use, ethical aspects [25], etc.) to dispense EMCs if requested without prescription. For instance, in Ireland, where LNG has been freely available since spring 2011, only 3% of the consultations with a pharmacist resulted in no delivery of EMCs (based on data from the 2014 annual report of the Irish Pharmacy Union). Almost the same refusal rate of 2% of pharmacists (on account of moral or religious beliefs) was reported for pharmacies in Boston, Mass., Atlanta, Ga., and Philadelphia, Pa., USA [26]. The magnitude of the increase in EMC use may also depend on the local setting and may vary between urban and more rural regions [18, 19]. It is also conceivable that women might prefer 'anonymous' urban pharmacies to a more rural pharmacy in their hometown where everybody would know everybody, although, in theory, discretion at the counter should be given in all pharmacies. At the same time, women should bear in mind that the use of EMCs cannot prevent sexually transmitted diseases (in Switzerland, the use of condoms has decreased since the switch of LNG to OTC status [22]) and are also not appropriate for regular use as an ongoing contraceptive method [27]. However, in some countries, the change in prescription status has had only a weak impact on the use of EMCs (e.g. UK [23]).

In the context of consumption figures, it should also be mentioned that the change in classification status touches different economic interests. Evidently, first and foremost, pharmaceutical manufacturers of EMCs will

Table 1. Development of EMC consumption since the change in classification status

Country	General description of the impact since EMCs have been made freely available
Austria	An increase in LNG sales of 30% was reported for the Austrian federation state 'Vorarlberg' within only 2 months after the switch to OTC status in December 2009. For the rest of Austria, no such clear trend was reported. The increase especially in Vorarlberg may be explained by the short distance from Germany, where LNG was available by prescription only in 2009, and Switzerland, where prices for LNG may be higher [16].
Croatia	Some increase in UPA sales (not further quantified) after the switch to non-prescription status in April 2015 was reported for Croatia by the Croatian Pharmaceutical Society (Hrvatsko Farmaceutsko Društvo). LNG was not yet switched at the time this information was provided, but was expected to gain non-prescription status very soon.
Denmark	Prior to the switch to availability without prescription in 2001, the use of LNG increased slightly from 23,000 DDD in 1996 to 29,000 DDD in 2000. After the change in classification status in 2001, LNG use increased from 39,000 DDD (in 2001) to 103,000 DDD in 2008. Since then, the sales figures have remained almost stable. For UPA, an increase in market share from 4% before the switch in May 2015 to 10% in autumn 2015 was reported by the Association of Danish Pharmacies (Apothekerforeningen).
Estonia	According to the 2015 yearbook of the Estonian agency of medicines (Ravimiamet), the consumption of LNG was almost stable in the period 2010–2014 at levels between 0.06 and 0.07 DDD/1,000 inhabitants/day.
Finland	In Finland, LNG has been available as an OTC drug since 2002. In 2002, EMC sales increased by 62% [17].
France	LNG was switched to non-prescription status in 1999. The proportion of women aged 15–24 years who had ever used EMCs rose from 14.6% in 1999 to 31.7% in 2004 [18].
Germany	Based on data collected by a market research company (IMS Health), the consumption of emergency contraceptives increased by about 30% in the first 6 weeks after the change in classification status (compared with consumption in the corresponding period in 2014). Compared with the week prior to the change (9,500 packages), consumption increased by 42% in the week directly after the switch (13,500 packages) [19]. Similar data provided by the Federal Union of German Associations of Pharmacists (ABDA) based on results from another market research company (Insight Health) suggest an increase in EMC consumption from 37,330 packages in February 2015 to 49,298 packages (+32%) in March 2015 and 60,152 (+61%) packages in May 2015 (the mean consumption per month in 2013 and 2014 was about 38,000 packages).
Iceland	LNG was switched to OTC status in 2001. A 2009 publication [20] stated that the use of LNG has become more common since the switch (consumption roughly doubled).
Latvia	No increase in emergency contraceptives use during the last year was reported for Latvia by the State Agency of Medicines (Zāļu valsts aģentūra).
Montenegro	A stable consumption of 0.04 DDD/1,000 inhabitants/day of LNG between 2012 and 2014 was reported by the Agency for Medicines and Medical Devices of Montenegro (Calims – Agencija za lijekove i medicinska sredstva Crne Gore).
Poland	According to a newspaper article in 'Die Welt', ellaOne® was sold out in Warsaw pharmacies shortly after the classification switch to non-prescription status, presumably because women feared that the decision regarding the switch might be reversed again [21].
Switzerland	In Switzerland, LNG was made freely available in 2002. About 8,000 packages of the leading brand of EMCs were sold in the year of the switch. This figure increased to 78,500 packages in 2007 and 93,500 packages in 2008 (based on data from the Swiss Pharmaceutical Union 'pharmaSuisse'). Simultaneously, the use of condoms steadily decreased in the Swiss population [22].
UK	LNG has been available without prescription since January 2001 in the UK. Compared with 2001, when 8.4% of women aged 16–49 years used EMCs once, the proportion of women using EMCs did not change significantly in 2001 (7.9%) and 2002 (7.2%). However, in the youngest age group (16–19 years), there was a (not significant) rise from 15.3% in 2000 to 21.5% in 2001, and a significant drop to 8.9% in 2002 of women using EMCs. At the same time, the proportion of women obtaining EMCs directly from a pharmacy increased from 0% in 2000 to 19.7% in 2001 and 32.6% in 2002 [23].
DDD = Defined daily dose.	

benefit economically from facilitated access to EMCs that may result in higher demand for those medicines [28]. Additionally, according to the data on EMC consumption in Germany, UPA sales may profit the most from the switch to OTC status. This may be explained in part by more intense promotion of the use of UPA, not simply because of possibly favorable pharmacological properties in comparison with LNG, but also because of the higher prices of UPA (e.g. listed prices in Germany are about EUR 30.00 for UPA vs. EUR 16.00–18.00 for LNG). Furthermore, without the need for a prescription, women are more likely to consult a pharmacist directly rather than a physician. In Germany, shortly after the change in classification status, about 78% of EMCs were sold without a physician's prescription [19]. Similar trends were observed in the UK and in France [23, 29]. As a consequence, physicians may consider the switch as an intrusion into their sphere of competence. However, they may also lose consultancy fees and may therefore try to impede a switch to non-prescription status, even if the physicians' organizations mainly use drug compliance and safety problems as arguments for their reluctant attitude [21, 30, 31] towards a change in classification status.

A further aspect of presumably growing importance in the context of approving new drugs or switching already approved drugs to free availability is the issue of personalized pharmacotherapy. LNG and UPA as well are mainly metabolized through the cytochrome P450 3A4/5 systems [32, 33], which are known to be subject to genetic variability between individuals of the European population. Genetic polymorphism may influence the efficacy and tolerance of EMCs. For instance, high LNG doses (1.5 mg) as administered for emergency contraception can cause nausea and vomiting, which in turn may result in an increased failure risk of emergency contraception (if no further LNG dose is applied). In theory, side effects such as nausea could occur even more frequently among slow metabolizers, owing to increased LNG plasma concentrations. However, only few data are available on the influence of genetic polymorphism on UPA or LNG metabolism [32]. Hence, the aspect of pharmacogenetics may not have been investigated sufficiently yet with regard to EMC drugs. Furthermore, also personal body parameters such as body weight may influence the efficacy of EMCs. Results from a 2012 publication [34] suggest that the effectiveness of 30 mg UPA for emergency contraception is lower among obese women. However, UPA is only available as a tablet with a dose of 30 mg so far.

In general, prescription-only status for EMCs might not appear very meaningful if those products are available

without a prescription in neighboring countries. This may presumably lead to an increase in drug tourism in border regions, probably including communication problems between customers and dispensing pharmacists because of insufficient language skills which, in sum, are likely to have a negative effect on drug compliance. In particular, Maltese women may perceive their situation as rather unsatisfactory, as neither LNG nor UPA is available even on prescription in their country. This is a remarkable state of affairs, especially as the World Health Organization recommends LNG for EMC and included this active ingredient in the essential medicines list [35]. Nevertheless, Maltese women could adopt the Yuzpe method (by prescription only), which is, however, less effective and less well tolerated [36, 37]. Of course, they may, for example, also undertake a trip by speedboat to Sicily (which would be the nearest EU territory with freely available EMCs), but this would be rather strenuous, hypothetical and quite unreasonable. Presumably, women living in countries without freely available EMCs are also more likely to stock up with those products whenever they have the opportunity to do so (for instance when travelling to other European countries), which might be contrary to the original intention of the legislators.

Reimbursement policies vary across the European health care systems [15]. Some countries fully cover the costs of UPA or LNG if prescribed or procured in family planning clinics, whereas in other countries EMCs have to be paid out-of-pocket (in Germany, free for girls aged <18 years, EUR 5.00 prescription charge for women aged <20 years, not covered for women aged ≥20 years). This may also have socioeconomic implications, as mainly women from lower socioeconomic levels are known to be more affected by unintended pregnancy [3–5]. High prices may discourage especially women from a lower socioeconomic background from purchasing an EMC [38]. If concerned, they may just be tempted to take nothing, resulting, of course, in a higher risk of unintended pregnancy. Results drawn from our own research on the use of OTC drugs among adolescents in Germany (study sample size, $n = 4,677$; data not yet published) imply that a price of EUR 10.00 or more for an OTC drug may represent a psychological threshold beyond which (socioeconomically weaker) adolescents are likely not to buy an OTC drug (75% of the OTC drugs utilized cost less than EUR 10.00). This may be relevant especially for those countries (e.g. Italy, Poland) where EMCs are not covered by the social system and UPA is the only EMC drug available without prescription, as UPA normally has a much higher price than LNG and is usually marketed at prices

roughly between EUR 20.00 and 40.00 in the EU [15]. Presumably, potential socioeconomic disparities regarding access to EMCs would have been further reduced if the relevant national authorities had not limited the change in classification status to UPA, but had implemented free availability of LNG as well.

This study has some limitations. The sample consisting of 18 included pharmacies cannot be considered representative of Germany, although the results are roughly in line with findings (cumulated for UPA and LNG together) for the first 3 months after the switch reported by the Federal Union of German Associations of Pharmacists (ABDA). However, no other data source for the period under research was available that could provide sales figures specified by active ingredient (UPA, LNG). Additionally, for five EU countries, we had to refer to data from the European Consortium for Emergency Contraception [15] only, as no response was obtained directly from the relevant national authorities.

Conclusions

Based on the results of this study, it may finally be concluded that Europe is able to harmonize the positions of the single European countries after an EMA recommendation or decision, even towards controversially dis-

cussed health topics such as the legal status of EMCs. At the same time, European countries can and do use their scope of action to adapt their positions regarding (current) political and societal circumstances and attitudes, e.g. by recommending checklists for pharmacists as a tool for dispensing EMCs (e.g. Austria, Croatia, Finland, Liechtenstein, Germany, Ireland, Spain, Switzerland), setting advertising restrictions or prohibitions (e.g. Croatia, Germany, Hungary, Lithuania), setting minimum age limits for customers (e.g. Bulgaria, Croatia, Italy, Latvia, Poland, Slovenia) or implementing a ban on internet sales (e.g. Germany, Italy). Nevertheless, there still remain (very few) countries within the European community that persist in their own legitimately different position, which may change with time or might even be reduced to absurdity by the versatility of concerned women who will know where to procure EMCs when necessary.

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