

PRESS RELEASE



Historic decision from the European Commission grants 120 million women direct access to ellaOne® emergency contraceptive across the European Union.

Paris, January 8th 2015 - HRA Pharma announced today that the European Commission, in a historic ruling, has authorised its advanced emergency contraceptive, ellaOne® (ulipristal acetate, 30mg), to be accessible direct from pharmacies without the need for a prescription from a doctor. This is the first ever decision of its type regarding any oral contraceptive product applicable to all EU member states, according to national implementation procedures. This new ruling will empower over 120 million women across the whole EU¹ to gain direct access to emergency contraception.

The move follows an earlier positive opinion from the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP), which concluded that ellaOne® works best if used during the first 24 hours, and can be used safely without a medical prescription².

Despite widespread use of regular contraceptives, 44% of all pregnancies in Europe are still unintended³ and a large European survey of over 7000 sexually active women has shown that 30% reported having unprotected sex at least once in the last 12 month, whilst not wanting to get pregnant⁴. Today's decision is a further testament to the acceptance of the need for women to be offered improved access to superior emergency contraceptive option such as ellaOne®.

Erin Gainer, CEO of HRA Pharma commented, "Since its launch in 2009, ellaOne® has increasingly been recognised amongst healthcare professionals as a new standard in emergency contraception^{5,6} and over 3 million women, in 70 countries have used ellaOne® since it became available. It is more effective than the existing option when taken within 24 hours of unprotected sex⁷ because it is shown to work when pregnancy risk is at its highest, right before ovulation⁸.

She went on to add. "As both a woman and the CEO of a company committed to innovation in women's healthcare I see this as a breakthrough moment where, for the first time, a single decision has given so many women across European Union the freedom to decide their own future."

ellaOne® will first be available in pharmacy without a prescription in some European countries from next month (February 2015) with a full launch program taking place across the EU during the rest of the year.

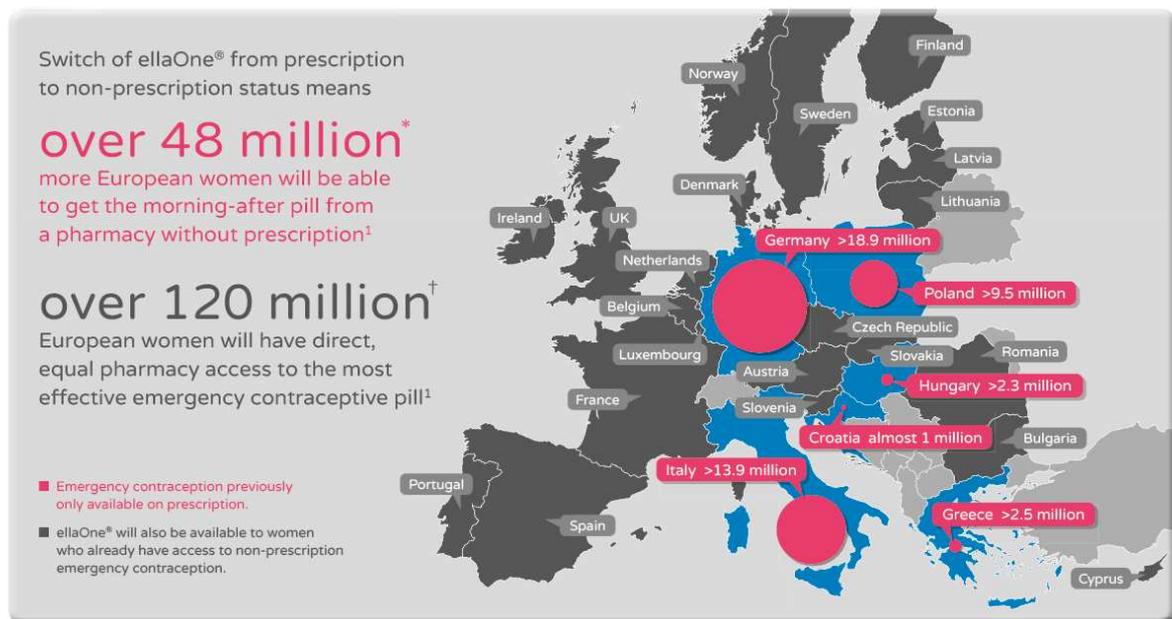
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About HRA Pharma

HRA Pharma is a privately-held European pharmaceutical company that designs products, devices and supporting services in niche areas of health and makes them available to doctors and patients worldwide. The company targets therapeutic gaps in the areas of reproductive health and endocrinology, and uses innovative marketing solutions and socially-conscious programs to promote healthy management of drugs and diseases. Headquartered in Paris, France and with subsidiaries across Western Europe, HRA Pharma has built a strong network of R&D, manufacturing, distribution and NGO partners which enables it to satisfy critical patient needs and improve patient health in over 80 countries across the globe. Visit www.hra-pharma.com for more information.

About the data

1- Map of Emergency Contraception access in Europe



Figures show numbers of women of child-bearing age who now have access¹
^{*} >48 million women of reproductive age in Greece, Croatia, Germany, Hungary, Italy, and Poland previously had no pharmacy access to emergency contraception. Numbers of women calculated from reference 1.
[†] >120 million women of reproductive age now have pharmacy access to emergency contraception. Numbers of women calculated from reference 1.

1. United Nations, Department of Economic and Social Affairs, Population Division (2013). World population prospects: The 2012 Revision.

ellaOne® 30mg tablet contains ulipristal acetate and is indicated for emergency contraception within 120 hours (5 days) of unprotected sexual intercourse or contraceptive failure. Always read the instructions on the package leaflet carefully.

- 2- EMA press release, November 2014
- 3- Guttmacher Institute. Sedgh, et al, Intended and Unintended Pregnancies Worldwide, 2014
- 4- Nappi et al. Use of and attitudes towards emergency contraception: A survey of women in five European countries, Eur Journal of Contraception and Reproductive Health Care. 2014; 19(2): 93-101.
- 5- ISGE statement on oral emergency contraception, Gynecol Endocrinol, 2014; 30(10): 681-682



- 6- Notfallkontrazeption - ein Update Gemeinsame Stellungnahme der Deutschen Gesellschaft für Gynäkologische Endokrinologie und Fortpflanzungsmedizin (DGGEF) e.V. und des Berufsverbands der Frauenärzte (BVF) e.V. – Frauenarzt, 55 (2014); Nr.8 : 774 - 775
- 7- Glasier A et al. Ulipristal acetat versus levonorgestrel for emergency contraception: a randomized non-inferiority trial and meta-analysis. Lancet 2010;375:555–62
- 8- Brache V et al. Ulipristal acetate prevents ovulation more effectively than levonorgestrel: analysis of pooled data from three randomized trials of emergency contraception regimens. Contraception 2013;88:611–18.

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