



Historic decision grants Italian women direct access to ellaOne® oral emergency contraceptive

Rome, May 11, 2015 - HRA Pharma Italy has announced today that after an historic decision granted by the Italian Medicines Agency (AIFA)¹, ellaOne® (ulipristal acetate, 30mg), the advanced emergency contraceptive, decree authorizing the accessibility from pharmacies without the need for a prescription or mandatory pregnancy test was published. This move will empower thousands of women over the age of 18 to gain direct access to emergency contraception.

The announcement is following a ruling from the European Commission (EC) which granted access to ellaOne® via pharmacy across EU. The EC's decision followed recommendations from the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) which stated that ellaOne® works best if used during the first 24 hours, and can be used safely without a medical prescription².

Alberto Aiuto, General Manager of HRA Italy commented, "Since its launch in 2009, ellaOne® has increasingly been recognised amongst healthcare professionals as a new standard in emergency contraception^{3,4} and over 4.5 million women in 70 countries have used it. It is more effective than the existing option when taken within 24 hours of unprotected sex⁵ because it is shown to work when pregnancy risk is at its highest, right before ovulation."⁶

He went on to say, "As General Manager of a company committed to innovation in women's healthcare I see this as a breakthrough moment for Italy. We are delighted to see that also in Italy women will have an easier access to this important contraceptive method."

Emilio Arisi, President of Italian Medical Society of Contraception (SMIC), added: "We are pleased that AIFA has recognised a women's right to manage their own healthcare options, something which has not always been the case in our country. I can only welcome this decision which has been due for a long time."

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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- <http://www.gazzettaufficiale.it/eli/id/2015/05/08/15A03360/sg;jsessionid=DaEIT8C29qxX5Ovc6jCAoA.ntc-as2-guri2b>
- 2- EMA press release, November 2014
- 3- ISGE statement on oral emergency contraception, Gynecol Endocrinol, 2014; 30(10): 681–682
- 4- 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
- 5- Glasier A et al. Ulipristal acetat versus levonorgestrel for emergency contraception: a randomized non-inferiority trial and meta-analysis. Lancet 2010;375:555–62
- 6- 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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