

Duncan McNeil MSP
The Scottish Parliament
Edinburgh
EH99 1SP

11th March 2013

Dear Mr. McNeil,

Confirmation of the removal of the Black Triangle of ulipristal acetate (ellaOne)

On reading the Official report of the Health and Sport Committee, dated 5th March, I noted with interest the Minister's comments in response to the question by Nanette Milne concerning 'longer acting emergency contraception'. The Minister referred to; *'...regulations around that form of medication. I think that the medication has possible side effects and that its use is monitored, which is partly why its availability is restricted to prescription only.*

I wanted to make the Committee aware that ulipristal acetate (ellaOne) is not now subject to special monitoring of side effects. All new chemical entities launched in the UK are assigned a Black Triangle (▼) by the MHRA which is intended to serve as a reminder to healthcare professionals that they should report any adverse effects.

I can confirm that the Committee's view, as expressed by Dr. Simpson, that the 'Black Triangle' has been removed is entirely accurate. It was removed by the MHRA in November 2012 and I have attached with this letter the formal notification from the MHRA advising us of the same.

It is important to clarify that ulipristal acetate is a prescription only medicine, but this in itself does not preclude inclusion in a pharmacy Patient Group Direction (PGD), as evidenced by its recent addition to the Bradford Community Pharmacy PGD, and several others across the UK. (http://www.lpc-online.org.uk/bradford_airedale_lpc/ehc.html)

Ulipristal acetate has been shown in clinical studies to have a safety profile similar to levonorgestrel and in the general population has been used globally by one million women since October 2009, with no safety signals arising. I understand that the MHRA decision to remove the Black Triangle was based on this post marketing surveillance evidence.

We hope this information clarifies and informs the deliberations of the Health Committee to consider ulipristal acetate(ellaOne) as an aid to helping to reduce teenage pregnancy in Scotland.

Yours sincerely,

Tony Fraser
General Manager

Mr Henri Guenard
Laboratoire HRA Pharma
15 Rue Beranger
F-75003 Paris
France

h.guenard@hra-pharma.com

Date: 09 November 2012

Re: Authorisation to remove the Black Triangle for Ellaone (Ulipristal)

Dear Mr Guenard

In July 2012 new pharmacovigilance legislation came into effect across the EU. One of the requirements of the new pharmacovigilance legislation is the introduction of a European 'Additional Monitoring' scheme for medicines that will be subject to more intense scrutiny.

In the UK the 'Additional Monitoring' list will replace the MHRA's 'Black Triangle' list and, to ensure that the two schemes do not overlap, the MHRA will be phasing out the Black Triangle Scheme over the coming months. To achieve this we are currently reviewing the Black Triangle list and will be removing those medicines that we consider no longer require intense monitoring.

Following review of the benefits and risks of the above drug, I am writing to confirm that Ellaone will no longer require a Black Triangle. You may, therefore, remove the Black Triangle symbol from all material in the UK where it currently appears. You should also note the change in your reporting requirements for Ellaone. For UK spontaneous reports, only serious reactions need now be reported in an expedited manner.

The editors of MIMS and the British National Formulary will require a copy of this letter as authorisation for removal of the Black Triangle symbol. You should also amend your Summary of Product Characteristics and the proofs for inclusion in the ABPI Compendium of Data Sheets and Summaries of Product Characteristics if applicable.

Please acknowledge receipt of this letter.

Yours sincerely,



Mrs Olutoyin Agbaje

Signal Assessor

Vigilance Intelligence & Research Group

Vigilance and Risk Management of Medicines

Email: blacktriangle@mhra.gsi.gov.uk

Cc: Mrs Alison Banner –Simpson – Scientific Assessor