

[March 2010: Bayer Says It Will Update Yasmin Label In Europe To Add Results From Four Medical Studies](#)

Two Newer Studies Found An Increased Venous Thromboembolism (VTE) Risk in Yasmin Users Compared To Levonorgestrel-Containing Birth Control Pills

(Posted by Tom Lamb at www.DrugInjuryWatch.com on March 30, 2010; see <http://bit.ly/buAykR>)

In October 2009 we reported that [Yasmin and YAZ birth control pills were under scrutiny by drug regulators in Europe](#).

Now, a March 26, 2010 press release issued by Bayer HealthCare and Bayer Schering Pharma gives us an update on this safety review in the European Union (EU), in particular the part which focused on the risk for venous thromboembolism (VTE) in Yasmin users.

The bulky, and perhaps promotional, title of this March 2010 Bayer press release is: "[CHMP's Pharmacovigilance Working Party completes review: Bayer will update Yasmin® label in the EU -- Positive benefit/risk profile of Yasmin® confirmed](#)".

From it we learn that Bayer will update the prescribing information -- also referred to as the package insert, or label -- for Yasmin (drospirenone / ethinylestradiol) in the EU to include results of the following four epidemiological studies:

- 1) Dinger, Jürgen et al.: The safety of a drospirenone-containing oral contraceptive: final results from the European Active Surveillance study on Oral Contraceptives based on 142,475 women-years of observation. In: *Contraception*, 75, 2007, 344–354. [Publication of EURAS data]
- 2) Seeger, John et al.: Risk of Thromboembolism in Women Taking Ethinylestradiol/Drospirenone and Other Oral Contraceptives. In: *Obstetrics & Gynecology*, Vol. 110, No. 3, September 2007, 587–893. [Publication of INGENIX data]
- 3) Lidegaard O, Lokkegaard E, Svendsen AL, Agger C. Hormonal contraception and risk of venous thromboembolism: national follow-up study. *BMJ*. 2009;339:b2890. [Lidegaard publication]
- 4) Van Hylckama Vlieg A, Helmerhorst FM, Vandenbroucke JP, Doggen CJ, Rosendaal FR. The venous thrombotic risk of oral contraceptives, effects of oestrogen dose and progestogen type: results of the MEGA case-control study. *BMJ*. 2009;339:b2921. [Van Hylckama Vlieg publication]

Also from this Bayer press release about the Yasmin label change in Europe we get this "interpretation" of those four medical studies:

Bayer sponsored two large observational post authorization safety studies (EURAS and Ingenix) on combined oral contraceptive (COC) use for European and US (Food and Drug Administration) Health Authorities. These prospective cohort studies conducted by independent investigators found that the risk for venous thromboembolism (VTE) in Yasmin users is comparable to the risk found for women who use levonorgestrel-containing COCs. Bayer Schering Pharma will update the European Summary of Product Characteristics for Yasmin with these results.

At the request of the Pharmacovigilance Working Party (PhVWP) of the Committee for Medicinal Products for Human Use (CHMP) two recently published retrospective studies (Lidegaard et al., van Hylckama Vlieg et al.) will also be included in the update. These two studies found the VTE risk in Yasmin users to be between the risk associated with levonorgestrel-containing COCs and desogestrel/gestodene-containing COCs. The results of one of these two studies were not statistically significant. Leading epidemiologists as well as Bayer Schering Pharma,[sic] have

identified several methodological issues in these recently published studies that need to be clarified before a final conclusion on Yasmin's VTE risk can be made. Bayer Schering Pharma is working with the PhVWP on a reanalysis of some of these data.

It is unclear whether the Yasmin label change will be done in the near future or only after this "reanalysis" by Bayer of [the two studies \(#3 and #4, above\) which found an increased VTE risk in Yasmin users compared to levonorgestrel-containing COCs](#).

We will watch for the revised Yasmin label to come out in the EU, and we ask our European readers for their assistance in that regard.

Of course, one cannot help but wonder if and when a similar change to the package insert for Yasmin (and perhaps YAZ) will be made by Bayer in the U.S.

Attorney [Tom Lamb](#) represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
<http://www.DrugInjuryWatch.com>