

YAZ / Yasmin / Ocella / Beyaz / Safyral: Drug Safety Regulators Focus On Blood Clot Side Effects

EMA Orders New Warning About Risk Of Venous Thromboembolism, While FDA And Health Canada Begin Safety Review

(Posted by Tom Lamb at www.DrugInjuryWatch.com on July 29, 2011; see <http://bit.ly/qnBQn6>)

In recent months there has been a flurry of activity by drug safety regulators in North America as well as Europe concerning the progestin drospirenone and its apparent association with an increased risk of venous thromboembolism, e.g., pulmonary embolus, more commonly called pulmonary embolism, or pulmonary emboli (when there are more than a single blood clot causing a blockage of an artery in the lungs).

Drospirenone is used in combination with an estrogen in the following oral contraceptives: YAZ (generics Gianvi and Loryna), Yasmin (generics Ocella, Syeda, and Zarah), Beyaz, and Safyral.

Here is a quick survey of the actions taken by the European Medicines Agency (EMA), the U.S. Food and Drug Administration (FDA), and Health Canada.

The EMA announced on May 27, 2011 that it was [updating the product information on oral contraceptives containing drospirenone \(DRSP\) regarding the risk of venous thromboembolism](#) after a review of all available data, including some newly published data.

In more detail, from "[Yasmin: risk of venous thromboembolism higher than levonorgestrel-containing pills](#)", which was published in the June 2011 *Drug Safety Update*:

Epidemiological studies have shown that the risk of venous thromboembolism (VTE) for drospirenone-containing combined oral contraceptives (COCs), including Yasmin, is higher than for levonorgestrel-containing COCs (so-called 'second generation' pills)....

Yasmin contains drospirenone, a relatively new progestogen, and was first licensed in 2000. Evidence of the level of VTE risk associated with Yasmin has been accruing since then. The results of two early prospective cohort studies suggested no difference in risk of VTE between Yasmin and levonorgestrel-containing pills or 'other' COCs. However, in 2009, a Danish cohort study and a Dutch case-control study of the risk of VTE in association with a number of COCs found the risk with drospirenone-containing pills to be higher than the risk associated with levonorgestrel-containing pills. Two further studies were recently published: one using the US PharMetrics database and the other using the UK General Practice Research Database. Both corroborated the findings of the Danish and Dutch studies of an increased risk of VTE in association with use of drospirenone-containing pills relative to levonorgestrel-containing pills.

Recent unpublished re-analyses of data from the Danish study directly compared VTE risk for drospirenone-containing pills, levonorgestrel-containing pills, and desogestrel/gestodene-containing pills. These data strengthen and confirm the original findings, and have enabled firmer conclusions about the relative risk associated with drospirenone-containing pills. [footnotes omitted]

The EMA action pertaining to the YAZ / Yasmin label change in Europe was quickly followed in the U.S. by the ["FDA Drug Safety Communication: Safety Review of possible increased risk of blood clots with birth control pills containing drospirenone"](#), which was issued on May 31, 2011:

The U.S. Food and Drug Administration (FDA) is informing the public about new information that is being assessed as part of FDA's ongoing safety review of birth control pills that contain drospirenone. This review will further evaluate the risk of blood clots in women who use these products....

A blood clot that forms in a deep vein in the body is called a deep vein thrombosis (DVT). A DVT is a rare side effect of taking birth control pills. A blood clot can break loose from the vein, move through the body to the lung, and cause a serious problem in the lung, called a pulmonary embolism (PE). This can lead to death.

Several days later came this press release, ["Health Canada reviewing safety of drospirenone-containing oral contraceptives \(Yasmin and Yaz\) and risk of venous thromboembolism"](#), issued on June 7, 2011:

Health Canada is informing health professionals and consumers, particularly women, that it is conducting an ongoing safety review of drospirenone-containing oral contraceptives to evaluate the potential for an increased risk of venous thromboembolism (VTE, which are blood clots) relative to other birth control pills.

We will watch the DRSP safety reviews being done by the FDA and Health Canada to see if either of these drug safety regulators order a stronger warning about blood clot side effects like pulmonary embolism (PE) and deep vein thrombosis (DVT) on the labels for YAZ, Yasmin, Ocella, Beyaz, and Safyral, similar to what the EMA did in Europe.

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>