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Start of review of combined hormonal contraceptives containing chlormadinone, desogestrel, dienogest, drospirenone, etonogestrel, gestodene, nomegestrol, norelgestromin or norgestimate

The European Medicines Agency (EMA) has started a review of several combined hormonal contraceptives authorised in the EU. Combined hormonal contraceptives contain two types of hormones, an oestrogen and a progestogen. The review includes all contraceptives containing the following progestogens: chlormadinone, desogestrel, dienogest, drospirenone, etonogestrel, gestodene, nomegestrol, norelgestromin and norgestimate.

The review of these contraceptives was requested by the French medicines agency ANSM following concerns in France about the risk of venous thromboembolism (VTE or blood clots in veins). The risk of VTE with combined hormonal contraceptives is known to depend on both the level of oestrogen and the type of progestogen they contain. While the overall risk with these products is low, the risk is known to be higher for some progestogens than the risk associated with the progestogen levonorgestrel.

The EMA will now review all available data on the risk of VTE with these contraceptives and issue an opinion on whether any changes are needed to their prescribing advice across the EU. The review will also cover the risk of arterial thromboembolism (blood clots in arteries, which can potentially cause a stroke or heart attack). This risk is very low and is not currently known to be higher with any particular type of progestogen.

Previous EMA reviews of combined oral contraceptives[1,2] concluded that that their absolute risk of VTE is low and extensive information on the risk and its management is included in their product information.

[1] http://www.ema.europa.eu/docs/en_GB/document_library/Report/2009/12/WC500017870.pdf
[2] http://www.ema.europa.eu/docs/en_GB/document_library/Report/2011/05/WC500106708.pdf

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More about the medicines

The combined hormonal contraceptives being reviewed are sometimes referred to as 'third generation' or 'fourth generation' contraceptives and are available as pills, skin patches and vaginal rings.

With the exception of Zoely (nomegestrol acetate/estradiol), Ioa (nomegestrol acetate/estradiol) and Evra (norelgestromin/ethinylestradiol), which are centrally authorised, all other combined contraceptives in the EU have been authorised via national procedures.

More about the procedure

The review of combined hormonal contraceptives has been initiated at the request of France, under Article 31 of Directive 2001/83/EC.

The review is being carried out by the Pharmacovigilance Risk Assessment Committee (PRAC), the Committee responsible for the evaluation of safety issues for human medicines, which will make a set of recommendations. The PRAC recommendations will then be forwarded to the Committee for Medicinal Products for Human Use (CHMP) which will adopt an EMA opinion. The final stage of the review procedure is the adoption by the European Commission of a legally binding decision applicable in all EU Member States.