Subject: Concern about the fourth-generation contraceptive pill

In March 2002, the 'Noorderlicht' radio programme reported that use of the 'Yasmin' contraceptive pill in Europe had resulted in forty cases of thrombosis, two of which proved fatal. This contraceptive has been available on the Dutch market since April 2001 and is taken by some 35 000 women. The 'Noorderlicht' report, which was later taken up by the press, has caused great concern.

On the basis of research findings, the KNMP (Royal Dutch Society for the Advancement of Pharmacy) concluded that insufficient emphasis is currently placed on the fact that taking 'Yasmin' results in a higher risk of thrombosis than taking other oral contraceptives.

Nevertheless, reports appear quite regularly that third-generation contraceptive pills, such as 'Yasmin', result more frequently in thrombosis. Third-generation contraceptive pills present no manifest advantages over second-generation contraceptive pills and are actually more expensive.

Can the Commission confirm the media reports that forty cases of thrombosis have been recorded, two of which proved fatal, and that the 'Yasmin' contraceptive pill was the cause thereof?

Can the Commission confirm the accuracy of the advice given by the Netherlands Society of General Medical Practitioners that older (second-generation) contraceptive pills should be taken rather than the new third- and fourth-generation contraceptive pills, which are more likely to cause a thrombosis?

Can the Commission confirm that the price of fourth-generation contraceptive pills comes to around EUR 36 (for a six-months supply), while second-generation contraceptive pills cost no more than EUR 9?

Answer given by Mr Liikanen on behalf of the Commission

(7 January 2003)

Yasmin is a combined oral contraceptive (COCs) with 30 micrograms (mg) of ethilylestradiol and 3 mg of the progestagen drospirenone.

The Committee for Proprietary Medicinal Products (CPMP) of the European Agency for the Evaluation of Medicinal Products on 28 September 2001 adopted a Public Assessment Report on 'Combined oral contraceptives and venous thromboembolism' and a Position Statement after its assessment of 'third generation' combined oral contraceptives containing the progestins desogestrel or gestodene and the risk of venous thromboembolism. The CPMP stated that venous thromboembolism (VTE) is a rare side effect of all COCs. The level of this risk is low, and overall the balance benefits and risks remains favourable with all available COCs. Thus, there is no reason for women currently using any brand of COCs to stop taking it on basis of the available findings.

Consequently, the CPMP, after having considered all option for safety measures, recommends that differences in risk should be reflected in the Summaries of products characteristics and user package leaflets for the relevant products and should be communicated to prescribers of COCs, as well as to women in need of contraceptives advice.

This information was included on the Summary product characteristics of Yasmin authorised by the national authorities of the Member States.

Nevertheless, in order to assess the raised pharmacovigilance signals on venous thromboembolism and, in view of the available data, the 'Third generation oral contraceptives' and in particular Yasmin are currently involved in a specific study and review at the Pharmacovigilance working group of the Committee for Proprietary Medicinal Products. There is not yet a definitive scientific position as the evaluation is still going on.

Regarding the price of this product in the Netherlands, this aspect falls under the Member States competencies.