



PHA/JFD/IEA.7

5 December 1989

PHA Information Exchange System

## ALERT

RECALL OF ORAL CONTRACEPTIVES CONTAININGETHINYLESTRADIOL BECAUSE OF INSTABILITY

*Organon has informed the World Health Organization that it is recalling batches of oral contraceptives containing ethinylestradiol in combination with lynestrenol because of the instability of the product. The Medicines Control Agency has also informed WHO of the action taken in the United Kingdom. The following is a résumé of the background provided by the company:*

ETHINYLESTRADIOL/LYNESTRENOL COMBINATION PRODUCTS

The manufacturer, Organon, of oral contraceptives containing the estrogenic compound, ethinylestradiol, in combination with the progestogen, lynestrenol, has discovered from the results of its regular stability programme that stored tablets show a drop in ethinylestradiol content per tablet below the approved 90% limit. Although the reduced content does not affect the contraceptive efficacy of the products concerned, the company has recalled some older batches. The batches that remain on the market (dating from less than two years) still contain ethinylestradiol in sufficient quantities (>90%), but will nonetheless be closely monitored through regular re-analyses.

The company has now identified the source of the problem and has assured that stable material will be supplied from the beginning of 1990.

It stresses that the observed reduction in ethinylestradiol is lynestrenol-specific, that is it does not apply to combinations with desogestrel (Marvelon<sup>R</sup> and Mercilon<sup>R</sup>).

The products concerned are marketed under the following brand names, *inter alia*:

Ovanon  
Ministat  
Lyndiol  
Minilyn.

The Medicines Control Agency of the Department of Health in the United Kingdom has issued a Drug Alert on this matter to health professionals to inform them that the following batches of Minilyn<sup>R</sup> are being recalled by the manufacturer:

4143  
4304  
4643  
5179  
5877

.../...

The company has contacted health authorities of all other countries where affected batches are marketed:

Bahrain	New Zealand
Belgium	Norway
Bulgaria	Oman
Denmark	Philippines
France	Portugal
Federal Republic of Germany	Sweden
Haiti	Saudi Arabia
Hong Kong	Switzerland
Iraq	Taiwan
Jordan	United Arab Emirates
Kuwait	Yemen
Liberia	

*References:*

- 1) *Communication from Organon International B.V. dated 24 November 1989.*
- 2) *Communication from the Medicines Control Agency, Department of Health, London, dated 23 November 1989.*

\* \* \*