# Drug Safety Update

MHRA

## Latest advice for all medicines users

The monthly newsletter from the **Medicines and Healthcare products Regulatory Agency** and the **Commission on Human Medicines**

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## Contents

Click on text to go to page


| | | |
|---|---|---|
| **Drug safety advice** | Hormonal contraceptives: cervical cancer—latest evidence | 2 |
| | Combined hormonal contraceptives: venous thromboembolism—update | 3 |
| | Cyproterone acetate with ethinylestradiol (co-cyprindiol): recommended duration of use | 4 |
| | Carbamazepine: genetic testing recommended in some Asian populations | 5 |
| **Yellow Card scheme update** | New addition to the Yellow Card scheme—the online reporting form | 6 |
| **Hot topic** | Advising patients about safe use of herbal medicines—new help available | 7 |
| **Stop press** | Updated advice—Over-the-counter cough and cold medicines for children | 9 |
| | Combined oral contraceptives: prevention of ovarian cancer | 10 |
| | Antidepressants: suicidal thoughts and behaviour—summary report | 10 |
| | Clove oil: life-threatening reactions on overdose | 10 |
| **Other information from the MHRA** | Patient Information Leaflet of the month | 10 |
| | Regulation of unlicensed medicines: informal consultation | 10 |


**The Medicines and Healthcare products Regulatory Agency** is the government agency which is responsible for ensuring that medicines and medical devices work, and are acceptably safe.

**The Commission on Human Medicines** gives independent advice to ministers about safety, quality, and efficacy of medicines. The Commission is supported in its work by Expert Advisory Groups that cover various therapeutic areas of medicine.

Have you considered raising with your colleagues a topic that you may have read about in *Drug Safety Update*? Why not consider: cascading the bulletin to those around you who may be interested; raising topics at a team meeting; or posting a copy of the bulletin on a team noticeboard?

To raise awareness of *Drug Safety Update* among healthcare professionals, we send monthly emails to notify healthcare professionals about a new issue; you can sign-up to this alert by emailing registration@mhradrugsafety.org.uk

We post notifications in and on resources that are commonly used by healthcare professionals—for instance, via the British National Formulary (BNF), Department of Health bulletins, the National electronic Library for Medicines, the National Prescribing Centre's e-Current Awareness service, and the National Library for Health Clinical Knowledge Summaries.

This month, safety information for oral contraceptives dominates the pages. Our article on page 2 summarises the latest evidence for the risk of cervical cancer with hormonal contraceptives; we follow with an update on the thromboembolic risks of combined hormonal contraceptives. New data summarised on p 10, however, is a reminder of one of the benefits of oral contraceptives in the prevention of ovarian cancer. Next time you read an article, please consider whether a colleague may benefit from seeing this information. Word of mouth is one of the most valuable methods of communication, and you can help us ensure that as many healthcare professionals as possible stay up to date on the safety of medicines.


**Claire Tilstone**, Editor

drugsafetyupdate@mhra.gsi.gov.uk

# Drug safety advice

## Hormonal contraceptives: cervical cancer—latest evidence

**Keywords:** combined oral contraceptive, COC, progestogen-only injectable, cervical cancer, human papillomavirus, HPV

Further evidence suggests that long-term use of combined oral contraceptives or progestogen-only injectable contraceptives is associated with a small increased risk of cervical cancer. The level of risk returns to that for never-users within 10 years of stopping use

### Human papillomavirus and cervical cancer

Human papillomavirus (HPV) is a sexually transmitted infection that can cause cervical cancer. Most women are infected with HPV at some point, but most infections, even those caused by high-risk viral subtypes, disappear naturally without causing any problem.

### Contraceptives and cervical cancer: reanalysis of data[1]

Combined oral contraceptives (COCs) have long been thought to be associated with a small increased risk of cervical cancer. Whether this association is due directly to the effect of COCs or whether it reflects, at least partly, confounding effects of other factors such as smoking, number of sexual partners, and age at first intercourse has been unclear. New data[1] add to the evidence that COCs have a role in the development of cervical cancer.

The latest report[1] has reanalysed data for more than 16 500 women with cervical cancer and found that current use of COCs for 5 years or longer is accompanied by an increased risk of cervical cancer (relative risk 1·90 [95% CI 1·69–2·13]). The baseline risk of cervical cancer increases with age, and the number of extra cases in COC users increases with age.

The new report estimates that:

- Women who use COCs for **5 years** from age 20 years have increased cumulative incidence of cervical cancer at age 50 years from **38 cases** per 10 000 (in never-users) to **40 cases** per 10 000 (ie, an extra two cases per 10 000)
- Women who use COCs for **10 years** from age 20 years have increased cumulative incidence of cervical cancer at age 50 years from **38 cases** per 10 000 (in never-users) to **45 cases** per 10 000 (ie, an extra seven cases per 10 000)

Risk falls when COCs are stopped; after about 10 years, risk reaches the same level as that for never-users of COCs.

The data suggest that the risk of cervical cancer in users of progestogen-only injectable contraceptives (ie, Depo-Provera and Noristerat) may be similar to that for COC users.

No epidemiological data are available for the risk of cervical cancer in users of Evra ▼ (a combined hormonal contraceptive patch), NuvaRing, (a combined hormonal intravaginal contraceptive), progestogen-only pills, Implanon (a progestogen-only implant), or Mirena (a progestogen-only intrauterine device).

1 International Collaboration of Epidemiological Studies of Cervical Cancer. *Lancet* 2007; **370:** 1609–21.

For more information about cervical screening see http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4126872

### Cervical screening

Regular cervical screening checks the health of the cervix and can reduce the risk of cervical cancer. Failure to attend cervical screening is one of the biggest risk factors for development of cervical cancer. In England cervical screening is offered at 3–5-year intervals to all women age 25–64 years. In Scotland, cervical screening is offered between age 20 years and 60 years, and in Northern Ireland and Wales the service is offered to women age 20–64 years. Women should be encouraged to attend cervical screening.

### Vaccination

For more information on vaccination against HPV see http://www.gnn.gov.uk/environment/fullDetail.asp?ReleaseID=325799&NewsAreaID=2

For a questions-and-answer sheet and an information sheet for women about cervical cancer and hormonal contraceptives see www.mhra.gov.uk

Routine vaccination against HPV infection will be introduced in autumn 2008 for girls age 12–13 years. A 2-year catch-up programme will start from September 2009 for girls aged up to 18 years. However, girls who have been vaccinated against HPV should attend regular cervical smears when they reach the appropriate age because the vaccine does not protect against all HPV subtypes that may cause cervical cancer.

For updated information about the reduced risk of ovarian cancer associated with COCs, see Stop press page 10.

## Combined hormonal contraceptives: venous thromboembolism—update

**Keywords:** ethinlyestradiol, levonorgestrel, second generation, desogestrel, gestodene, third generation, Yasmin, drospirenone, Evra ▼, norelgestromin, transdermal patch, venous thromboembolism, VTE

The risk of venous thromboembolism in users of Yasmin is in the same range as that for users of combined oral contraceptives that have low ethinylestradiol dose, including second-generation pills. The risk in users of the Evra ▼ contraceptive patch may be slightly increased compared with that for users of second-generation pills

Combined oral contraceptives (COCs) increase the risk of venous thromboembolism (VTE, including deep venous thrombosis, DVT, and pulmonary embolism) compared with no use. Risk rises with increasing ethinylestradiol dose above 50 µg; risks at doses less than 50 µg do not differ from each other and modern contraceptives therefore contain less than 50 µg ethinylestradiol. Epidemiological studies have shown that the type of progestogen in COCs also affects level of risk.

Some epidemiological studies have recorded an annual incidence of VTE in healthy non-users of COCs of about five to ten cases per 100 000. This incidence compares with about 15 cases per 100 000 healthy women who use COCs that contain the progestogen levonorgestrel (the so-called second-generation pills), and about 25 cases per 100 000 healthy women who use COCs that contain the progestogens desogestrel or gestodene (the so-called third-generation pills). The corresponding estimate for pregnant women is 60 cases per 100 000 pregnancies.

A recent epidemiological study[1] assessed the thromboembolic potential of Yasmin (30 µg ethinlyestradiol plus 3 mg drospirenone—a new progestogen). The incidence of VTE in Yasmin users was in the same range as that for users of other low-dose COCs, including second-generation pills (hazard ratio 1·14 [95% CI 0·66–1·97]).

Another recent study (unpublished) has examined the risk of VTE in users of Evra ▼—the first hormonal contraceptive patch, which delivers 20 µg ethinlyestradiol plus

1 Dinger JC, et al. *Contraception* 2007; **75:** 344–54.

150 µg norelgestromin (an active metabolite of norgestimate) transdermally per day. The results suggest that the risk of VTE in Evra ▼ users may be slightly increased compared with that for users of COCs that contain levonorgestrel (odds ratio 1·4 [95% CI 0·9–2·3]), although this risk is not statistically significant.

Product information for Yasmin and Evra ▼ are being updated to reflect these new data.

## Cyproterone acetate with ethinylestradiol (co-cyprindiol): recommended duration of use

**Keywords:** cyproterone acetate, Dianette, ethinylestradiol, co-cyprindiol, hyperandrogenism, acne, hirsutism, treatment duration, oral contraception, venous thromboembolism, VTE

**Most women will be able to stop cyproterone acetate with ethinylestradiol (co-cyprindiol) 3–4 months after resolution of symptoms. This should not be interpreted as stopping treatment after 3–4 months. For women with known hyperandrogenism who attend specialist clinics, co-cyprindiol may be the only effective treatment for severe symptoms. Under these circumstances, co-cyprindiol can be prescribed in the longer-term with regular specialist review**

Has your colleague seen this bulletin?

Cyproterone with ethinylestradiol (co-cyprindiol, brand leader Dianette) is licensed as a second-line treatment for women with severe acne or moderately severe hirsutism. In 2002, the Committee on Safety of Medicines (CSM, now called the Commission on Human Medicines) concluded that the risk of venous thromboembolism (VTE) was higher in users of co-cyprindiol compared with users of low-oestrogen-dose (ie, <50 µg ethinylestradiol) combined oral contraceptives. Recent review of evidence by an Expert Advisory Group of the Commission on Human Medicines also suggests a higher risk of VTE with co-cyprindiol than with conventional low-dose combined oral contraceptives. However, how much of this extra risk is due to higher cardiovascular risk of women with, for example, polycystic ovarian syndrome is unclear.

On the basis of these findings, previous advice from the Committee on the Safety of Medicines remains, and co-cyprindiol:

- should be used only in its licensed indication
- should not be used solely for contraception
- should be discontinued 3–4 months after complete resolution of symptoms

Treatment with co-cyprindiol should rapidly resolve acne and improve hirsutism, and an attempt should be made to stop treatment in those with less-severe symptoms 3–4 months after their resolution.

In women with severe hyperandrogenism, symptoms usually recur when treatment is stopped because of the underlying condition and, in these women, co-cyprindiol may be continued until the symptoms are judged unlikely to recur when treatment is stopped. The decision of when to stop treatment may not be easy and should be made on a case-by-case basis using clinical judgement.

In all women, co-cyprindiol can be re-started at any time if acne or hirsutism recurs on stopping treatment.

## Carbamazepine: genetic testing recommended in some Asian populations

**Keywords:** carbamazepine, epilepsy, genetic testing, Asian populations, Stevens-Johnson syndrome

The risk of carbamazepine-induced Stevens-Johnson syndrome is strongly associated with presence of the *HLA-B*1502* allele in individuals of Han Chinese, Hong Kong Chinese, or Thai origin. It is recommended that these individuals should be screened for *HLA-B*1502* before prescription of carbamazepine. Those who test positive should not start carbamazepine unless the benefits clearly outweigh the risks of Stevens-Johnson syndrome

Carbamazepine is authorised for the treatment of epilepsy and paroxysmal pain of trigeminal neuralgia, and for the prophylaxis of manic depressive psychoses in patients who are unresponsive to lithium.

Severe, potentially life-threatening, skin reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis can occur rarely in association with carbamazepine. The frequency of such skin reactions is estimated to be about one to six cases per 10 000 new users of carbamazepine in the USA and Europe.

However, the risk of carbamazepine-induced Stevens-Johnson syndrome is greater in patients with a particular human leukocyte antigen (HLA) allele, *HLA-B*1502*. The frequency of this allele varies worldwide and is highest in some Asian populations. Studies have shown that in some Asian populations—Han Chinese, Hong Kong Chinese, and Thai—*HLA-B*1502* increases the risk of Stevens-Johnson syndrome. Whether the same risk applies to other Asian populations is unknown because studies are not available. Furthermore, whether this allele increases the risk of toxic epidermal necrolysis and Stevens-Johnson syndrome with other aromatic anticonvulsants (ie, oxcarbazepine, phenytoin, or phenobarbitone) is unknown. In two studies, *HLA-B*1502* was not associated with carbamazepine-induced Stevens-Johnson syndrome in white European patients.

Therefore, individuals of Han Chinese, Hong Kong Chinese, or Thai origin should be screened for *HLA-B*1502* before starting treatment with carbamazepine. If they test positive, carbamazepine should not be started unless the expected benefit clearly outweighs the risk of serious skin reactions. Tested patients who are found to be negative for *HLA-B*1502* have a low risk of Stevens-Johnsons syndrome and toxic epidermal necrolysis from carbamazepine, although the reactions can occur rarely.

**Advice for healthcare professionals:**

- Carbamazepine is associated with a risk of potentially life-threatening skin reactions including Stevens-Johnson syndrome
- The risk of developing carbamazepine-induced Stevens-Johnson syndrome is strongly associated with presence of *HLA-B*1502* in individuals of Han Chinese, Hong Kong Chinese, or Thai origin
- Individuals with the above Asian ethnic origin should be screened for *HLA-B*1502*. Those who test positive should not start carbamazepine treatment unless the benefits clearly outweigh the risk of Stevens-Johnson syndrome

# Yellow Card scheme update

The Yellow Card scheme collects information on suspected adverse drug reactions. See www.yellowcard.gov.uk

See also *Drug Safety Update* February 2008. http://www.mhra.gov.uk/Publications/Safetyguidance/DrugSafetyUpdate/index.htm

## New addition to the Yellow Card scheme—the online reporting form

February 2008 saw a major drive to welcome the public's reports to the Yellow Card scheme. To support this initiative, the scheme was promoted in community pharmacies during February and March. Coinciding with this promotion, an updated online reporting form was launched on Feb 18, 2008.

Accessible from www.yellowcard.gov.uk reporting online is a simple, fast, and paper-free way to report adverse drug reactions (ADRs). As online resources are being used more in everyday life, the option to tell us about an ADR via the web makes reporting more efficient and easier to access. Paper Yellow Cards will remain available and can be found in the British National Formulary (BNF) and the MIMS companion for healthcare professionals, and in pharmacies for the public.

Clarity and usability of the Yellow Card website by healthcare professionals and the public has become increasingly important, and the new online reporting form has been redesigned with these features in mind. Moreover, several new features have been incorporated.

The site has been designed to assist the reporter as much as possible: a drop-down choice of suspect drug and adverse reaction is provided (see figures 1 & 2). Other features allow a reporter who is registered on the site to save the Yellow Card at any point, allowing completion at a later time. This feature may be beneficial—especially in a busy hospital or community environment when further information may be required to complete fully a report.

As you use this site, please tell us what you think of it, and if you have ideas for how we can continue to improve it please email us at pharmacovigilance@mhra.gsi.gov.uk

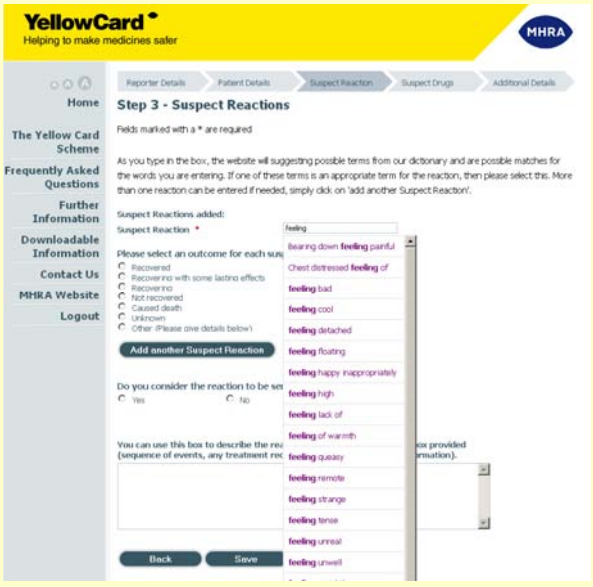


Figure 1: Link to MedDRA (Medical Dictionary for Regulatory Activities) terms on entering a suspect reaction

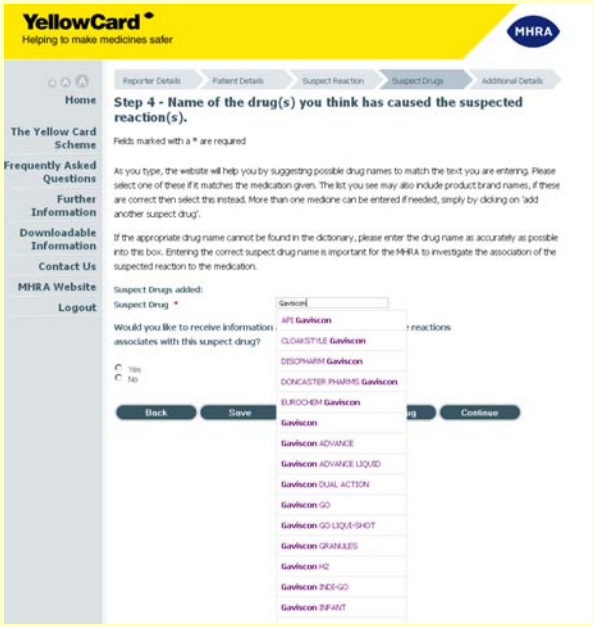


Figure 2: Options on entering a suspected drug

# Hot topic

## Advising patients about safe use of herbal medicines—new help available

Most herbal medicines on the UK market are currently unlicensed products. Standards vary widely, and it is difficult for consumers or healthcare professionals to identify which products are manufactured to acceptable standards with reliable product information. The Herbal Medicines Advisory Committee was set-up 2 years ago to advise the MHRA about safety issues related to herbal medicines.

The MHRA has previously issued warnings about herbal products that contain the toxic ingredient *Aristolochicia* species, heavy metals, or potent pharmaceutical substances (eg, fenfluramine).

For further information about the Herbal Medicines Advisory Committee see http://www.mhra.gov.uk/Committees/Medicinesadvisorybodies/HerbalMedicinesAdvisoryCommittee/index.htm

For further information about OSAS, see *Drug Safety Update* February 2008, p 9 and http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON2033358

For further examples of previous warnings about herbal medicines that contain potent or toxic ingredients, see http://www.mhra.gov.uk/Howweregulate/Medicines/Herbalandhomoeopathicmedicines/Herbalmedicines/HerbalSafetyNews/Currentsafetyissues/index.htm

See also our warning for the public to be vigilant about herbal medicines, issued March 4, 2008 at http://www.mhra.gov.uk/NewsCentre/pressreleases/CON014134

**Safety case studies:**

- Recently, we warned consumers about a herbal body lotion (OSAS) that claimed to contain natural ingredients, but tested positive for betamethasone. The product was brought to our attention by a paediatric dermatologist who was concerned that a parent of a baby he was treating for eczema had started using the product on the infant
- Reports of suspected adverse drug reactions were linked to an unlicensed herbal product that was marketed for diabetes, which gave dangerous advice to patients to stop taking prescribed medication

### New regulation to safeguard public health

Regulation safeguards will be improved by the recent introduction of the Traditional Herbal Registration (THR) scheme. The first products registered in the UK under this scheme are now coming onto the market. As at March 2008, 11 products have been registered covering a total of ten different herbs. Registered products have been assessed by the MHRA and meet systematic standards of safety, quality, and patient information. Registered products are suitable for use without medical supervision, and indications are based on traditional use rather than proven efficacy. Herbal medicines with a Marketing Authorisation also continue to be available.

The Herbal Medicines Advisory Committee believes it is important to use the growing availability of regulated products and reliable information to enhance patient safety. Healthcare professionals will be increasingly better placed to advise patients who wish to self-medicate with over-the-counter herbal products on how they can make an informed choice in appropriate situations.

**How to identify regulated herbal products:**

- Herbal medicines with a Traditional Herbal Registration have a THR number on the product label
- Herbal medicines with a Marketing Authorisation have a PL number on the product label

**Hot topic** *continued*

The image below shows part of the label, including THR, for **Niteherb** (valerian, for temporary relief of sleep disturbances due to symptoms of mild anxiety):


THR number

The image below shows an extract from the leaflet for **Prostasan** (saw palmetto, for relief of symptoms of an enlarged prostate), which has a THR:

## 2. Before you take this product

- You must have been told by your doctor that you have BPH.
- This product is not suitable for anyone under 18 years of age.

### Do not take this product if you are allergic to:

- Saw Palmetto fruit. This product contains Saw Palmetto fruit.
- Any of the other ingredients of this product. (See Section 6 Further Information)

### Take special care with this product – see your doctor if:

- Your symptoms of urinary discomfort worsen
- You have blood in your urine
- You have a fever

### If you are due to undergo surgery

- Tell your doctor you are taking this product.

**Sources of information about herbal medicines on the MHRA's website:**

Use the A–Z index at www.mhra.gov.uk to find:

- Public assessment reports for herbal medicines
  Covers products with a THR, and contains full information on registered products (including the Summary of Product Characteristics)
- Herbal information sheets
  Aimed at consumers; gives non-product-specific information about safe use of individual herbs; a reference collection of these sheets will progressively be prepared, making use of the MHRA's assessment of THR applications
- Advice to consumers—safe use of herbal medicines
  Gives general advice, including avoidance of low-grade unlicensed products

# Stop press

## Updated advice—Over-the-counter cough and cold medicines for children

### information from Professor Rosalind Smyth, Chair of the Paediatric Medicines Expert Advisory Group

For further information about the Paediatric Medicines Expert Advisory Group, see http://www.mhra.gov.uk/Committees/Medicinesadvisorybodies/CommissiononHumanMedicines/ExpertAdvisoryGroups/PaediatricMedicines/index.htm

For further information about the US Food and Drug Administration safety review, see http://www.fda.gov/bbs/topics/NEWS/2008/NEW01778.html

The Paediatric Medicines Expert Advisory Group and the Commission on Human Medicines have recently assessed the safety of cough and cold medicines for children. This assessment follows recent advice from the US Food and Drug Administration about the safety of these medicines in children.

The Commission noted that although UK data do not raise the same level of concern as those for the USA, five reports of deaths (the first in 1981) associated with use of cough and cold medicines in children younger than 2 years have been received via the Yellow Card scheme. Moreover, the Commission noted a lack of robust evidence for the efficacy of these medicines in children. It was noted that medication does not affect the course of the illness: it can only provide, at best, symptomatic relief.

Information for these medicines contains age-appropriate dose advice and many are sold under the supervision of a pharmacist. However, parents and carers may be unaware of the risk of overdose that results from the simultaneous use of different products that may duplicate ingredients. The small body size of children younger than 2 years increases the risk of serious adverse events from such dosing errors.

Both the Expert Advisory Group and the Commission concluded, on the basis of available evidence, that the balance of risks and benefits associated with the use of cough and cold medicines for children younger than 2 years is no longer favourable. Furthermore, the Commission advised that medicines in this therapeutic range that are suitable for children age 2–6 years should contain updated information.

**Advice for healthcare professionals:**

- Parents and carers should be encouraged to use the following medicines to alleviate the symptoms of coughs and colds in children: single-constituent paracetamol or ibuprofen; simple cough medicines (eg, those that contain glycerol or honey and lemon); vapour rubs and inhalant decongestants (which can be applied to a child's clothing); and, particularly in infants, saline nasal drops
- Non-prescription cough and cold medicines that contain the following active ingredients **should not be used in children younger than 2 years**:
  – brompheniramine, chlorphenamine, and diphenhydramine (antihistamines)
  – dextromethorphan and pholcodine (antitussives)
  – guaifenesin and ipecacuanha (expectorants)
  – phenylephrine, pseudoephedrine, ephedrine, oxymetazoline, and xylometazoline (decongestants)
- Products that contain these active substances and that are licensed for use in **children age 2–6 years** will be updated to include: information on maximum daily dose; a warning not to take other cough and cold medicines at the same time; and an instruction for parents or carers to seek the advice of a pharmacist or other healthcare professional before using the medicine
- For **children older than 2 years**, cough and cold medicines are considered safe at the recommended doses, which should be followed carefully and not exceeded. Parents and carers should be advised not to give a child more than one cough and cold medicine because different brands may contain the same active ingredient(s)

I hope that you find this information useful to your practice. Further information, including an information leaflet for parents and carers, is available at www.mhra.gov.uk

Rosalind Smyth

Chair of the Paediatric Medicines Expert Advisory Group and Brough Professor of Paediatric Medicine, University of Liverpool, Alder Hey Children's Hospital, Liverpool

# Stop press *continued*

## Combined oral contraceptives: prevention of ovarian cancer

A new study[1] of more than 23 200 women with ovarian cancer has confirmed that use of combined oral contraceptives (COC) reduces the risk of ovarian cancer. This effect increases with longer duration of use and persists for many years after stopping. The researchers estimate that about two cases of ovarian cancer and one death from the disease before age 75 years are prevented for every 5000 women-years of use of combined oral contraceptives.

1 Collaborative Group on Epidemiological Studies of Ovarian Cancer. *Lancet* 2008; **371:** 303–14.

## Antidepressants: suicidal thoughts and behaviour—summary report

A report by the European Pharmacovigilance Working Party on the risk of suicidal thoughts and behaviour with antidepressants has recently been published. The report summarises the data for this risk that have been assessed both within Europe and by the US Food and Drug Administration. The benefits of selective serotonin reuptake inhibitor antidepressant medicines continue to outweigh the risks in their licensed indications.

Access the report at http://www.hma.eu/222.html

## Clove oil: life-threatening reactions on overdose

Clove oil is traditionally used to treat toothache. Literature reports[1–4] suggest that accidental ingestion of excessive amounts (reported cases involve volumes ≤5 mL) of clove oil by children can result in life-threatening reactions, including liver failure. Healthcare professionals are reminded to tell users of clove oil and other essential oils to keep these products out of the reach of children.

1 Janes SEJ, et al. *Eur J Pediatr* 2005; **164:** 520–22.

2 Eisen JS, et al. *J Toxicol Clin Toxicol* 2004; **42:** 89–92.

3 Hartnoll G, et al. *Arc Dis Child* 1993; **69:** 392–93.

4 Lane BW, et al. *Hum Exp Toxicol* 1991; **10:** 291–94.

# Other information from the MHRA

## Patient Information Leaflet of the month

New legal requirements on manufacturers require them to test Patient information leaflets (PILs) with potential patients. User-testing makes sure that the presentation of the information enables patients to find and understand key messages for safe and effective use of the medicine. To promote this new initiative, we are publishing a series of examples of best practice on our website. The latest in this series is the PIL for **Hedrin**—a dimeticone product used to treat infestation of head lice.

Access PIL of the month at http://www.mhra.gov.uk/Howweregulate/Medicines/Labelspatientinformationleaflets andpackaging/Patientinformationleaflet (PIL)ofthemonth/index.htm

## Regulation of unlicensed medicines: informal consultation

We have launched an informal consultation to seek views on current arrangements in the UK for the regulation of unlicensed medicines. These regulations allow an authorised healthcare professional to commission an unlicensed medicine to meet the special needs of an individual patient.

The consultation closes on June 30, 2008. For more information, see http://www.mhra.gov.uk/Publications/Consultations/Medicinesconsultations/Othermedicinesconsultations/CON014086

**Read more about the Commission on Human Medicines including summaries of minutes from meetings, at**
**http://www.mhra.gov.uk/mhra/CommissiononHumanMedicines**

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