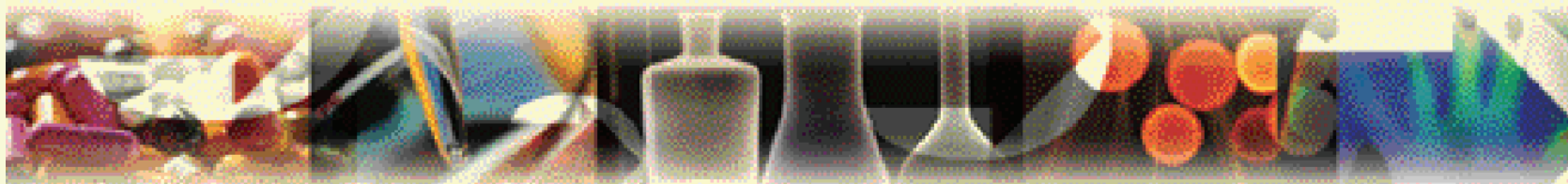




THE CONTINUING PROFESSIONAL DEVELOPMENT PROGRAMME



This module is suitable for use by pharmacists as part of their continuing professional development cycle. After reading this module, complete the learning scenarios and post-test at www.pharmacymag.co.uk and include in your CPD portfolio. Previous modules in the Pharmacy Magazine CPD Programme are also available to download from the website

MODULE 182

Welcome to the one hundred and eighty second module in the *Pharmacy Magazine* Continuing Professional Development Programme, which looks at key therapeutic developments in 2010. It is valid until November 2013.

Continuing professional development (CPD) is now a legal requirement for pharmacists. Journal-based educational programmes are an important means of keeping up-to-date with clinical and professional developments and form a significant element of your CPD. Completion of this module will contribute to the nine pieces of CPD that must be recorded a year.

Before reading this module, test your existing understanding of the topic by completing the pre-test at www.pharmacymag.co.uk. Then after studying the module in the magazine, work through the six learning scenarios and post-test on the website. Record your learning and how you applied it in practice using our new CPD report form, available online and on pviii.

Self-assess your learning needs:

- On what basis were the drugs sibutramine and rosiglitazone withdrawn?
- What are the insulin alternatives for patients previously on Mixtard 30?
- What POM to P switches took place in 2010?

This module supports the following CPD competences: C1c, C1b, C4g and C4h. More details on pvii

CURRENT THINKING ON...

KEY THERAPEUTIC DEVELOPMENTS IN 2010

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Introduction

This module will review some of the important changes in therapeutics that have occurred during 2010, their implications, significance and practical aspects.

Sibutramine

January saw the European Medicines Agency (EMA) announce that the weight loss drug sibutramine (Reductil) was to be suspended on the basis that its cardiovascular risk might outweigh any clinical benefit the drug might provide. Sibutramine is a serotonin and noradrenaline reuptake inhibitor (SNRI) that acts centrally to promote a feeling of fullness or having eaten. It was used as an adjunct to diet and exercise to promote weight loss.

Since it received UK approval in July 2001, prescribers had been advised in the Summary

of Product Characteristics (SPC) to monitor regularly all patients taking sibutramine for increases in blood pressure and heart rate. Cardiovascular safety concerns were the reason why the Sibutramine Cardiovascular OUTcomes (SCOUT) study was undertaken at the request of the EMA's committee for medicinal products for human use (CHMP) to determine the effects of sibutramine in obese and overweight patients with cardiovascular risk factors.

SCOUT was a randomised, double-blind, placebo-controlled study in approximately 10,000 obese and overweight patients with cardiovascular disease and/or type 2 diabetes treated over a six-year period. The results of the study showed that patients treated with sibutramine experienced a 16 per cent increased risk of cardiovascular events, such as myocardial infarction and stroke, compared with placebo-

FOR THIS MODULE

pharmacy MAGAZINE
FIRST IN PROFESSIONAL & BUSINESS DEVELOPMENT

GOAL: To provide community pharmacists with a review of the major therapeutic developments in primary care during 2010.

OBJECTIVES: After completing this module, you should be able to:

- Identify medicines that were launched and withdrawn in 2010
- Understand the important safety issues that came to light
- Discuss the clinical guidelines of importance to practitioners in primary care.



treated patients (hazard ratio 1.161 [95 per cent CI 1.029-1.311]; p=0.016).

Within all studies (including SCOUT), the mean additional weight loss achieved with sibutramine was modest (approximately 2-4kg more than placebo) and may not be sustained when treatment is stopped. Consequently, in January, the CHMP recommended that the EU marketing authorisations for sibutramine should be suspended because it considered that the risks of the medicine outweigh its benefits.

Doctors were advised not to issue any new prescriptions for sibutramine and asked to review the treatment of those taking the medicine. Pharmacists were advised not to dispense any further prescriptions and asked to advise patients to make an appointment to see their doctor at the next convenient time.

In October, testing by the Medicines and Healthcare products Regulatory Agency (MHRA) found that two supposedly "natural" products, Payouji tea and Pai You Guo Slim capsules, contained sibutramine. Anyone using these products was advised to stop taking them and seek medical guidance immediately. "People need to be aware that Payouji tea and Pai You Guo Slim capsules are unlicensed herbal medicines and therefore have not met assured standards," said a MHRA spokesperson.

DVT prevention guidelines

Reduction of avoidable death, disability and chronic ill health from venous thromboembolism (VTE) was the clinical priority for the NHS in 2010/11. VTE accounts for up to 25,000 preventable deaths each year, which often occur after discharge from hospital. Steps were taken to ensure that:

- A patient's risk from VTE was assessed
- Preventive measures were taken for those at higher risk

■ Patients and their families were told of the signs and symptoms of VTE to look out for after being in hospital.

A NICE clinical guideline for the management of VTE for patients going into hospital – a key part of the NHS strategy – was issued in January 2010. A patient's risk of developing VTE depends partly on why he/she has been admitted to hospital and the type of treatment received during the stay (e.g. whether there has been an operation). According to NICE 30 per cent of surgical patients develop VTE, which is often asymptomatic and can lead to death from pulmonary embolism (PE).

Some people also have certain risk factors that make them more likely to develop DVT (see Table 1). If a woman is pregnant or has recently given birth, she may have additional special risk factors.

The NICE guideline advises temporarily stopping the combined oral contraceptive pill or HRT four weeks before surgery. Aspirin and other antiplatelet drugs will not offer sufficient protection against a possible DVT and could increase the risk of bleeding during surgery.

NICE advises, in relation to preventing VTE:

- Avoiding dehydration unless there is a specific clinical reason
- Encouraging early mobilisation
- Aspirin or antiplatelet agents should not be considered adequate prophylaxis.

Depending on their risk factors patients may be offered anti-embolism stockings or an intermittent pneumatic compression device to help keep the blood in their legs circulating. They may also be given an anticoagulant that thins the blood and helps prevent blood clots forming. However, before being offered any of these, patients should be given advice and a leaflet on the risks of DVT, what might happen if they develop DVT, how to use stockings or devices for

Reflection exercise 1

In the future it is likely that community pharmacists will be encouraged to undertake MURs after patients are discharged from hospital.

- What is your local hospital(s) policy regarding medicines prescribed in the VTE prevention protocol?
- How long are these supposed to be continued once the patient is out of hospital?

helping to prevent DVT and how they can reduce their risk of DVT (e.g. hydration and, if possible, moving around and exercising).

Symptoms and signs of DVT or pulmonary embolism

NICE advises seeking immediate medical help if any of the following occur within days or weeks of having surgery:

- There is pain or swelling in the leg
- The skin on the leg feels hot or is discoloured (red, purple or blue), other than bruising around the area where the operation has occurred
- The veins near the surface of the legs appear larger than normal or are more noticeable
- There is shortness of breath
- There is pain in the chest or upper back
- Blood is coughed up.

At discharge from hospital, pharmacological thromboprophylaxis may be:

- a) Discontinued at discharge, or
- b) Extended for a fixed period post-discharge.

Rosiglitazone

Rosiglitazone (Avandia, Avandamet), a treatment for patients with type 2 diabetes, was withdrawn in the UK in 2010. It was in the thiazolidinedione class of drugs (glitazones). With an estimated 90,000-100,000 patients taking rosiglitazone, the average UK pharmacy might expect to have had seven or eight patients on the drug.

Patients with diabetes are at an increased risk of cardiovascular disorders, including heart failure and ischaemic heart disease, due to the underlying condition. However, thiazolidinediones may cause fluid retention which, in turn, may make some heart problems worse or lead to heart failure. This was added to existing concerns regarding rosiglitazone's

Table 1: Advice for patients admitted to hospital about the risk of DVT

If you have any one of the following you may be at risk of DVT:

- You are having an operation that takes longer than 90 minutes, or 60 minutes if the operation is on your leg, hip or abdomen
- You are having an operation for an inflammatory or abdominal condition such as appendicitis
- For at least three days you are confined to bed, or are unable to walk without help, or spend a large part of the day in bed or in a chair
- You are much less active than usual, or you are having an operation, or you have a serious injury **and** any one of the following applies to you. You have/are:
 - Having treatment for cancer
 - Aged over 60 years
 - Being treated in the hospital critical care unit
 - Dehydrated
 - Thrombophilia (a disorder that makes your blood more likely to clot)
 - Seriously overweight (your body mass index is 30 or more)
 - A medical condition, such as a heart or lung problem, an infectious disease such as hepatitis or an inflammatory condition such as rheumatoid arthritis
 - A close relative who has had DVT
 - Taking an oestrogen-containing contraceptive pill (the 'combined pill')
 - On hormone replacement therapy (HRT)
 - Varicose veins with phlebitis (pain and swelling).

Source: NICE

side-effects: fluid retention, weight gain, increased fracture risk among post-menopausal women and worsening of lipid levels.

A Europe-wide review in 2006 of the available data from clinical trials had provided new evidence about the risk of heart failure in patients taking rosiglitazone but had also suggested that patients may be at an increased risk of ischaemic heart disease (e.g. heart attack). The product information was updated to reflect the findings of this review including additional information on the risk of ischaemic heart disease.

MHRA advice in 2007 was that "rosiglitazone and pioglitazone should not be used in people with heart failure or history of heart failure; incidence of heart failure is increased when rosiglitazone or pioglitazone are combined with insulin. Closely monitor patients during treatment for signs and symptoms of fluid retention, including weight gain or oedema". Then, in 2010, the fortunes of rosiglitazone took a further turn for the worse.

A Europe-wide review of rosiglitazone was initiated in July 2010 at the request of the European Commission following the availability of data from new studies (Graham *et al*, *JAMA* 2010; 304: 411-418; and Nissen and Wolski, *Arch Intern Med* 2007; 201: 207:1-15) questioning the cardiovascular safety of rosiglitazone.

This review considered all available data, including these newly published studies and information from the US Food and Drug Administration (FDA). To inform and contribute to the European review, the MHRA sought the advice of the CHM, which considered that the new studies were well-conducted and involved a large number of diabetic patients and therefore added to the evidence. The CHM concluded that the accumulated data support an increased cardiovascular risk associated with rosiglitazone compared with both placebo and pioglitazone, of clinical and public health importance.

In view of the restrictions already in place on the use of rosiglitazone, the CHM could not identify additional measures that would mitigate the cardiovascular risk and advised that, on the evidence available, the risks outweighed the

Primary Care Diabetes Society (PCDS) advice for GPs, nurses and pharmacists at the time of the withdrawal of rosiglitazone

The PCDS notes the Europe-wide withdrawal of rosiglitazone in all formulations (Avandia and Avandamet in the UK). Prescribers should no longer prescribe rosiglitazone in any formulation, either as an acute item or as a repeat prescription. PCDS suggests that rosiglitazone prescriptions be changed at the earliest time convenient to the person with type 2 diabetes, but preferably within the next two months.

For people with well-controlled diabetes and without evident heart failure or significant risk of fracture, a direct switch to pioglitazone (Actos) – 4mg rosiglitazone to 30mg pioglitazone, or 8mg rosiglitazone to 45mg pioglitazone – would be appropriate. There are three formulations of the combination product Avandamet: 2mg rosiglitazone with either 500mg or 1g metformin, and 4mg rosiglitazone with 1g metformin. There is, however, only one preparation of pioglitazone with metformin (Competact): 15mg pioglitazone with 850mg metformin. The table below gives some advice on changing Avandamet to Competact in those people whose type 2 diabetes is well controlled and without contraindications to the use of thiazolidinediones (TZDs). Please remember that such a change of medication has the potential to increase the risk of hypoglycaemic episodes.

For those not well controlled with TZDs, or with relative contraindications to TZDs, this time should be used as an opportunity to review overall care and consider other therapeutic options in accordance with the NICE guidelines.

Rosiglitazone combination products	Pioglitazone combination products
Avandamet (2mg rosiglitazone + metformin 500mg) twice daily	Competact (15mg pioglitazone + metformin 850mg) twice daily. <i>Note: some people may have difficulty tolerating 1,700mg metformin. If this is the case, use Competact once daily or prescribe pioglitazone and metformin separately.</i>
Avandamet (2mg rosiglitazone + metformin 1g) twice daily	Competact (15mg pioglitazone + metformin 850mg) twice daily
Avandamet (4mg rosiglitazone + metformin 1g) twice daily	Competact (15mg pioglitazone + metformin 850mg) twice daily + pioglitazone 15mg

benefits and that it no longer had a place in UK clinical use. In addition, the CHM considered action should be taken promptly and ideally within the appropriate EU framework.

In September *BMJ* editor Fiona Godlee noted: "The tale of rosiglitazone is a cautionary one from which we must hope the main parties will learn for the future. Hailed as a much needed new approach for patients with type 2 diabetes, the drug was licensed 10 years ago with only limited evidence of its effectiveness and concerns over its safety. While allowing the drug onto the market, the regulators asked the manufacturer GlaxoSmithKline to do additional trials. This the company did while marketing the drug around the world. Millions of prescriptions later, the results of the open label RECORD trial are hotly disputed.

"GlaxoSmithKline says it shows the drug is safe and the European Medicines Agency seems to have taken this conclusion on trust. Officers at the Food and Drug Administration, however, prompted by concerns about GlaxoSmithKline's

conduct (*BMJ* 2010; 340:c1848, doi:10.1136/bmj.c1848) and aided by the FDA's requirement for individual patient data, decided earlier this year to take a closer look. They uncovered errors in the way the trial was done that systematically favoured the company's drug."

Every 4mg of rosiglitazone is roughly equivalent to pioglitazone 30mg in HbA_{1c} reduction. Both rosiglitazone and pioglitazone caused weight gain and fluid retention. Rosiglitazone had a detrimental effect on lipid profiles whereas pioglitazone has a slight beneficial effect. In the PROACTIVE study pioglitazone was shown to have a more favourable cardiovascular risk profile than rosiglitazone but nevertheless is not free of cardiovascular problems.

Beta-blockers in patients with asthma or chronic obstructive pulmonary disease

The BNF issued updated guidance in September on the use of cardioselective beta-blockers to





Nothing better than ABCD... new guidance released for avoiding malaria

treat co-existing cardiac conditions in patients with well-controlled asthma or chronic obstructive pulmonary disease (COPD). Beta-blockers can cause bronchospasm and should usually be avoided in patients with asthma.

However the updated BNF advice says that it may sometimes be necessary to use a beta-blocker in a patient with well-controlled asthma or COPD (without significant reversible airways obstruction) for a co-existing cardiac condition, such as heart failure, or following a myocardial infarction. In these circumstances, it says, a cardioselective beta-blocker may be used, initiated at a low dose by a specialist, and the patient monitored closely for adverse effects.

The BNF states that "atenolol, bisoprolol, metoprolol, nebivolol, and (to a lesser extent) acebutolol, have less effect on beta₂ (bronchial) receptors and are, therefore, relatively *cardio-*

selective, but they are not *cardiospecific*. They have a lesser effect on airways resistance but are not free of this side-effect".

An alternative to warfarin?

In October the FDA in America approved Pradaxa (dabigatran etexilate) capsules to reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation (AF). Approval for this indication in the UK is currently being evaluated. The current UK licence is for primary prevention of venous thromboembolic events in adult patients who have undergone elective total hip replacement surgery or total knee replacement surgery.

Dabigatran, an oral direct thrombin inhibitor discovered and developed by Boehringer Ingelheim, is the first new oral anticoagulant approved in the US in more than 50 years. As

demonstrated in the RE-LY trial, dabigatran 150mg taken twice daily has been shown to significantly reduce stroke and systemic embolism by 35 per cent beyond the reduction achieved with warfarin, the current standard of care for patients with non-valvular atrial fibrillation. Pradaxa 150mg taken twice daily significantly reduced both ischaemic and hemorrhagic strokes compared to warfarin.

The FDA's approval of dabigatran provides a new treatment to reduce the risk of stroke for the increasing number of patients with AF. The safety and efficacy profile of dabigatran was established based on the results of the 18,113-patient RE-LY trial, the largest stroke prevention trial in AF patients completed to date.

Many patients in the study had not received treatment for their AF so the study cannot address the question of whether dabigatran would be as effective as warfarin in those people who are already well controlled on warfarin. Treatment with dabigatran does not require blood monitoring or related dose adjustments and has no recommended dietary restrictions. The FDA also approved a 75mg twice daily dose for the small subset of patients who have severe renal impairment.

If used in AF in the UK, dabigatran costs significantly more than warfarin, but warfarin has additional costs from INR monitoring and dosage adjustment.

Malaria prophylaxis

In August the Health Protection Agency (HPA), together with the National Travel Health Network and Centre, issued a leaflet (Malaria – Information for People Travelling Overseas) promoting ABCD:

A = Aware

B = Bite prevention

C = Chemoprophylaxis

D = Diagnosis.

Pop star Cheryl Cole's brush with malaria in July 2010 following her holiday in Tanzania publicised the risks and brought the need for prophylaxis to the fore in 2010.

The HPA advice on bite prevention suggests five actions:

1. Use of repellents: The HPA's advisory committee on malaria prevention (ACMP) strongly recommends DEET-based insect repellents as these are the most effective.

2. Insecticides: These should be used to kill any resting mosquitoes in a room.

3. Use of nets: If sleeping outdoors or in unscreened accommodation, insecticide-treated mosquito nets should be used. Mosquito bed nets must be free of tears and should be tucked in under the mattress. Those that are impregnated with insecticide can provide extra protection.

4. Clothing: Where possible, cover up with long-sleeved, loose-fitting clothing, long trousers and socks if out of doors after sunset, to minimise accessibility to skin for biting mosquitoes. Cotton clothing can be sprayed with DEET.

5. Room protection: Air conditioning reduces the likelihood of mosquito bites as a result of substantial reduction in night-time temperature. Ceiling fans can also reduce mosquito nuisance. Doors, windows and other possible mosquito entry routes to sleeping accommodation should be screened with fine mesh netting, which must be close-fitting and free from tears.

The HPA also drew attention to some common myths about malaria prevention:

■ **Herbal remedies:** The ACMP strongly advises against relying on any herbal remedies for the prevention of malaria. Herbal remedies have not been tested for their ability to prevent or treat malaria

■ **Homeopathy:** The ACMP strongly advises against relying on any homeopathic remedies for the prevention of malaria. There is no scientific proof that homeopathic remedies are effective in either preventing or treating malaria

■ **Buzzers:** Electronic buzzers (emitting high frequency sound waves) are completely ineffective as mosquito repellents

■ **Vitamin B1:** There is no evidence that vitamin B1 taken orally repels mosquitoes

■ **Garlic:** There is no evidence that garlic taken orally repels mosquitoes

■ **Savoury yeast extract spread:** There is no evidence that Marmite taken orally repels mosquitoes, either by giving off a cutaneous

odour repellent to mosquitoes or via its vitamin B1 content

■ **Tea tree oil:** There is no evidence that tea tree oil is an effective mosquito repellent

■ **Bath oils:** There is no evidence that proprietary bath oils provide effective protection against mosquito bites.

Discontinuation of Mixtard 30

The manufacturer of Mixtard 30 (the only Mixtard preparation still available) plans to discontinue it by December 31, 2010, saying that demand is declining. With an estimated 90,000 adults and children who use Mixtard 30 having to be transferred onto other products, the average pharmacy in the UK is likely to have seven or eight patients who will be affected.

Mixtard 30 is a biphasic insulin, a ready-mixed combination of short- and intermediate-acting insulins. Biphasic insulins provide a rapid initial effect, then a more prolonged effect, and are

typically used twice daily, before breakfast and the evening meal. The Innolet device is also being discontinued, so patients using it face the dual problem of having to change both the insulin and the delivery device. Because Innolet has a large dosing dial it has been useful for patients with limited manual dexterity and visual impairment. There is no other similar device.

Diabetes UK reminds health professionals to ensure patients are aware that any change in the type of insulin used may result in changes in their blood glucose management and may increase the risk of hypoglycaemia. UK Medicines Information (UKMI) warns that "symptoms of hypoglycaemia may be different or even absent when changing from one insulin to another". Extra care is therefore needed during the change.

The SPC for Mixtard 30 advises: "Usually, the first symptoms of **hyperglycaemia** set in gradually, over a period of hours or days. They



Mixtard withdrawal – pharmacists warned to look out for increased hypoglycaemia risk

Advice on Mixtard 30 discontinuation

• Diabetes UK has produced a list of other mixed insulins and analogue mixtures, which can be found at www.diabetes.org.uk

• UKMI has produced advice for health professionals, which can be found at www.nelm.nhs.uk/en/NeLM-Area/Evidence/Medicines-Q--A/Mixtard-30-discontinuation-suggested-alternatives-for-primary-care/?query=mixtard+30+alternatives&rank=100

• Any questions or queries about the withdrawal can be directed to manufacturer Novo Nordisk on 0845 600 5055 or at www.novonordisk.co.uk





Cough medicines containing codeine no longer recommended for children

include thirst, increased frequency of urination, nausea, vomiting, drowsiness, flushed dry skin, dry mouth, loss of appetite as well as acetone odour of breath” and that “usual warning symptoms may disappear in longstanding diabetes”. Beta-blockers may mask the symptoms of, and delay recovery from, hypoglycaemia. Alcohol may intensify and prolong the hypoglycaemic effects of insulin.

Codeine-containing cough remedies

On the advice of the CHM, the MHRA Drug Safety Bulletin for October announced that OTC codeine-containing liquids are no longer recommended for treating cough in children (under 18s).

The MHRA review examined both the safety and efficacy of OTC liquid cough medicines containing codeine for the treatment of children and concluded that:

- There is a lack of evidence of efficacy for codeine in the symptomatic treatment of cough in children of any age group
- There are safety concerns regarding the use of codeine for the treatment of cough in children

Reflection exercise 2

Review the actions you and your staff have already taken in relation to codeine-containing cough medicines.

- Is there anything further that you need to do?
- Consider making a CPD entry on your response to the MHRA advice starting at 'Action'.

due to its central mode of action and the significant variability in its metabolism to morphine

■ Overall, the risks of OTC cough medicines for children containing codeine outweigh the possible benefits.

DNA studies have shown that genetic variations result in people responding very differently to codeine, which is inactive until it is metabolised to morphine. Codeine is converted into morphine by the cytochrome P450 CYP2D6, which has substantial variation of expression in individuals. A medical journal editorial commented that this “can result in toxic doses of morphine, even at conventional doses of codeine. For infants and young children in particular, this can be deadly”.

Products containing dextromethorphan (DXM), the most widely used opioid in OTC cough remedies, are not affected by the advice. DXM has fewer side-effects than codeine but has been the subject of misuse. Indeed the FDA reviewed DXM in 2010 and considered, but decided against, making it a prescription only medicine.

Until new packs of codeine products are available with revised label information pharmacies can continue to sell existing stock. However the MHRA has asked pharmacists to consider the new advice when recommending cough medicines, namely: “Pharmacists should continue to manage adult sales and we expect that pharmacists will consider alternative treatments or only supply the up-to-date labelled product where there are children under 18 years in the family.”

Therefore if an OTC liquid medicine containing codeine in the old packaging is recommended for an adult, pharmacy staff should confirm whether there are also children under the age of 18 years within the same household, and where there are, explain that the medicine should not be used in under-18s.

OTC liquid medicines containing codeine include codeine linctus BP, Pulmo Bailly, Galcodine Linctus and Galcodine Paediatric Linctus.

According to the Royal Pharmaceutical Society: “It is expected that codeine products

CPD competences

This module supports the following community pharmacy competences:

Competence	Where this module supports competence development
C1c Reviewing medication with patients to identify difficulties and potential risks	The module includes information about new drugs, clinical trials, safety alerts and clinical guidelines in 2010, including issues that patients and other healthcare professionals might have questions about. For example, reflection exercise 1 encourages pharmacists to check local hospital protocols on VTE management and use this information when reviewing medicines
C1b Reviewing medication for its clinical effectiveness	The module summarises key clinical data (e.g on dabigatran)
C4g Working across professional boundaries	Evidence-based information that can be used as a source when dealing with queries from other healthcare professionals is provided
C4h Providing training and education to pharmacy staff	The module provides factual information as well as examples of the type of issues that are important for the education of pharmacy staff – in particular dispensing technicians. Reflection exercise 3 involves identifying which information from the module will be shared and used with staff

containing new packaging and leaflets will start to appear in April 2011 and will be packaged in child resistant containers by June 2012 in order to address additional concerns about accidental ingestion by young children.” It also stressed that “pharmacists should check that their support staff have been trained on the new CHM advice where appropriate”.

OTC medicines

■ In 2010 domperidone maleate (marketed as the OTC product Motilium 10) was additionally licensed for OTC use for the relief of nausea and vomiting of less than 48 hours’ duration. The drug is already approved for OTC use for the relief of symptoms of excessive fullness, nausea, bloating, belching, trapped wind and heartburn after a meal.

As a dopamine antagonist, domperidone increases gastrointestinal motility. It is used for the relief of functional dyspepsia and nausea and vomiting of various causes. It acts at the chemoreceptor trigger zone so is unlikely to be effective in motion sickness and other vestibular disorders.

■ A new POM to P switch, the antifibrinolytic tranexamic acid, was approved for the treatment

of heavy menstrual bleeding (menorrhagia) in women aged 18-45 years with a history of regular heavy menstrual bleeding over several consecutive menstrual cycles.

Treatment starts once bleeding has begun and continues for up to four days. Referral to the doctor is advised if there is no improvement after three cycles. The OTC product will be called Cyklo-F. Its launch is anticipated in early 2011.

Some one in 10 women of reproductive age have menstrual blood loss exceeding 80ml (the definition of ‘heavy bleeding’) and five to 15 per cent of women are thought to be affected by blood loss to such a degree that treatment should be considered. In most cases of menorrhagia no underlying cause is found. Tranexamic acid is the most effective treatment for menorrhagia, reducing blood loss by 40-50 per cent and studies have shown positive effects on quality of life.

Reflection exercise 3

Summarise here what you have learned from reading this module. Have you encouraged relevant staff to read the version of this module in *Training Matters*? Once they have read the module, which aspects will you discuss with them?

Although tranexamic acid is the most effective treatment, audits of prescribing in primary care in the UK find that less effective drugs (mefenamic acid and norethisterone) are still commonly prescribed.

Tranexamic acid has been available as an OTC medicine for menorrhagia in Sweden since 1997 and by 2006 an estimated 15 million tablets had been sold with an estimated exposure of 64,000 woman-years. The commonest adverse reactions are nausea, vomiting, diarrhoea and allergic skin reactions.

■ A second POM to P switch was Flomax Relief MR, an OTC version of tamsulosin capsules for the treatment of benign prostatic hypertrophy, which has now been advertised on TV.

■ Pantoloc Control is a POM to P switch pack of pantoprazole tablets for treating heartburn and regurgitation.

■ The CHMP reviewed the use of topical ketoprofen following reports of photoallergic reactions and recommended that the product should no longer be available for OTC use and be restricted to use on prescription. The committee advises that patients should make sure that areas treated with ketoprofen are protected from sunlight during treatment and for two weeks after stopping treatment.

■ In November the MHRA consulted on the advertising of homeopathic products. In response the Royal Pharmaceutical Society said that “any advertising for a homeopathic product or remedy kit needs to include the statements that: ‘There is no scientific evidence for homeopathy nor any evidence to support the clinical efficacy of homeopathic products beyond a placebo effect... Unless, or until such a time as the efficacy of a homeopathic product can be demonstrated using methodology currently applied to conventional medicines, labelling on the homeopathic product should make it very clear that the efficacy of the homeopathic product has not been proven.’”



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ASSESSMENT QUESTIONS

KEY THERAPEUTIC DEVELOPMENTS

1. Codeine-containing cough medicines should not be sold if children under what age live in the household?

- a. 12 years
- b. 15 years
- c. 16 years
- d. 18 years

2. Rosiglitazone 4mg is roughly equivalent to:

- a. 15mg of pioglitazone
- b. 20mg of pioglitazone
- c. 25mg of pioglitazone
- d. 30mg of pioglitazone

3. Patients using Mixtard 30 need to be more closely monitored during the changeover to another insulin if they are taking:

- a. An ACE inhibitor
- b. A beta-blocker
- c. A diuretic
- d. An antiarrhythmic

4. Which beta-blocker does the BNF describe as least cardioselective?

- a. Atenolol
- b. Bisoprolol
- c. Acebutolol
- d. Nebivolol

5. For patients with COPD or well-controlled asthma who have existing cardiac conditions such as heart failure and after a myocardial infarction (MI):

- a. Beta blockers are contraindicated
- b. A cardioselective beta-blocker can be initiated by a specialist

c. A beta-blocker can be used with caution after a MI but not in heart failure

d. A cardioselective or non-cardioselective beta-blocker can be initiated by a specialist

6. In the UK the oral anticoagulant dabigatran is licensed for use in:

- a. The prevention of VTE
- b. The prevention of VTE, treatment of acute VTE and treatment of atrial fibrillation
- c. The treatment of acute VTE and treatment of atrial fibrillation
- d. It is not yet licensed for use in the UK

7. Which statement is TRUE? OTC domperidone:

- a. Is an effective treatment for motion sickness
- b. Can be used for nausea and vomiting of less than 72 hours' duration
- c. Has a maximum treatment duration in nausea and vomiting of 36 hours
- d. Cannot be used in children under 16 years

8. Which product was not a POM to P switch in 2010?

- a. Flomax Relief
- b. Pantoloc Control
- c. Topical ketoprofen
- d. Tranexamic acid

PHARMACY MAGAZINE CPD RECORD – DECEMBER 2010

USE THIS FORM TO RECORD YOUR LEARNING AND ACTION POINTS FROM THIS MODULE ON KEY THERAPEUTIC DEVELOPMENTS IN 2010 OR DOWNLOAD FROM WWW.PHARMACYMAG.CO.UK AFTER COMPLETING THE ONLINE LEARNING SCENARIOS

Activity completed. (Describe what you did to increase your learning. Be specific) (Act)

Name/date:

Time taken to complete activity:

What did I learn that was new in terms of developing my skills, knowledge and behaviours? Have my learning objectives been met? (Evaluate)

How have I put this into practice? (Give an example of how you applied your learning. Why did it benefit your practice? How did your learning affect outcomes?) (Evaluate)

Do I need to learn anything else in this area? (List your learning action points. How do you intend meeting these action points?) (Reflect)

* If as a result of completing your evaluation you have identified another new learning objective, start a new cycle – this will enable you to start at **Reflect** and then go on to **Plan, Act** and **Evaluate**. This form can be photocopied to avoid having to cut this page out of the module. Complete the learning scenarios at www.pharmacymag.co.uk

MODULE 182 ANSWER SHEET

ENTER YOUR ANSWERS HERE Please mark your answers on the sheet below by placing a cross in the box next to the correct answer. Only mark one box for each question. Once you have completed the answer sheet in ink, return it to the address below together with your payment of £3.75. Clear photocopies are acceptable. **You may need to consult other information sources to answer the questions.**

- | | | | | | | | | | | | | | | | |
|-----------|-----------------------------|-----------|-----------------------------|-----------|-----------------------------|-----------|-----------------------------|-----------|-----------------------------|-----------|-----------------------------|-----------|-----------------------------|-----------|-----------------------------|
| 1. | a. <input type="checkbox"/> | 2. | a. <input type="checkbox"/> | 3. | a. <input type="checkbox"/> | 4. | a. <input type="checkbox"/> | 5. | a. <input type="checkbox"/> | 6. | a. <input type="checkbox"/> | 7. | a. <input type="checkbox"/> | 8. | a. <input type="checkbox"/> |
| | b. <input type="checkbox"/> | | b. <input type="checkbox"/> | | b. <input type="checkbox"/> | | b. <input type="checkbox"/> | | b. <input type="checkbox"/> | | b. <input type="checkbox"/> | | b. <input type="checkbox"/> | | b. <input type="checkbox"/> |
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| | d. <input type="checkbox"/> | | d. <input type="checkbox"/> | | d. <input type="checkbox"/> | | d. <input type="checkbox"/> | | d. <input type="checkbox"/> | | d. <input type="checkbox"/> | | d. <input type="checkbox"/> | | d. <input type="checkbox"/> |

Name (Mr, Mrs, Ms) _____

Business/home address _____

Town _____ Postcode _____ Tel: _____ RPSGB/PSNI Reg no.

I am a PM subscriber I confirm the form submitted is my own work (signature): _____

Please charge my card the sum of £3.75 Name on card _____ Visa Mastercard Switch/Maestro

Card No. _____ Start date _____ Expiry date _____

Date _____ Switch/Maestro Issue Number _____

Processing of answers
Completed answer sheets should be sent to Precision Direct Marketing, Precision House, Bury Road, Beyton, Bury St Edmunds IP30 9PP (tel: 01284 718918; fax: 01284 718920; email: cpd@precisiondm.com), together with credit/debit card/cheque details to cover administration costs. This assessment will be marked and you will be notified of your result and sent a copy of the correct answers. The examiners' decision is final and no additional correspondence will be entered into.