



## module 230

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Welcome to the two hundred and thirtieth module in the *Pharmacy Magazine* Continuing Professional Development Programme, which looks at the key therapeutic developments of 2014.

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## for this module

### GOAL:

To provide community pharmacists with an overview of the major clinical developments in pharmacy practice during 2014.

### OBJECTIVES:

After completing this module you should be aware of:

- The safety issues that were raised during the year and their implications for patients
- The clinical guidelines of relevance to pharmacy practice that were either launched or updated
- Other changes that were made during the year that affect community pharmacy.

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## Key therapeutic developments in 2014

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### Introduction

Every year sees the launch of new treatment options as well as the publication of new or updated guidance on how medicines should be used or what pharmacy practice should look like. The last 12 months has been no different.

This module looks at some of the important changes that took place during 2014 and also describes their implications for community pharmacy practice.

### Soluble drugs and CV risk

Patients taking drug formulations that contain sodium (soluble, dispersible or effervescent products) are at increased risk of adverse cardiovascular events than those taking standard formulations of the same medicines, according to a paper published in early 2014 in the *British Medical Journal*.

The study analysed data pulled from the UK Clinical Practice Research Datalink (CPRD) for nearly 1.3m patients who were given at least two prescriptions for sodium-containing formulations or matched standard formulations of the same drug with a mean follow-up time of more than seven years. For the primary endpoint of non-fatal myocardial infarction, non-fatal stroke or vascular death, the adjusted odds ratio for exposure to sodium-containing drugs was 1.16. At an individual morbidity level, the adjusted odds ratios were 7.18 for hypertension,



1.28 for all-cause mortality, 1.12 for non-fatal stroke, 0.98 for heart failure, 0.94 for non-fatal MI and 0.7 for vascular death. The median time from date of first prescription to first event was just under four years.

Although the authors noted several limitations to their work, including the accuracy of information in the database and lack of information on OTC medicine use, family history, dietary sodium intake and health behaviours, they concluded that sodium-containing drug formulations should be avoided altogether in those considered at risk of hypertension, and care should be taken for all other patients to ensure the perceived benefits outweigh the risks. Furthermore, anyone on these formulations should be carefully monitored for the emergence of raised blood pressure.

As well as being aware of the above points, community pharmacists and their teams should bear in mind that someone who is prescribed a soluble drug form is more likely to opt for an OTC product in the same form – and *vice versa* – which may increase sodium load. There is also an element of habit when it comes to drug formulations and this is a topic that could be tackled when dispensed items are collected or during an intervention such as a medicines use review.

More information on this study can be viewed at: [www.bmj.com/content/347/bmj.f6954](http://www.bmj.com/content/347/bmj.f6954).

### Domperidone

Use of domperidone has been restricted to the relief of nausea and vomiting, with the recommendations around dosage and duration of use reduced due to safety concerns.

Cardiac side-effects have been identified as a potential issue, particularly for patients with existing cardiac conditions, impaired liver function or on medicines that may interact with domperidone. The drug should be avoided in

### Prescription charges

Prescription charges in England topped the £8 mark in 2014 when the Department of Health increased them to £8.05, although prepayment certificates remained at £29.10 for three months and £104 for a year, representing even better value for money for patients on a large number of items. Another 20p will be added to the prescription charge in April 2015 bringing the price per item to £8.25, with the cost of prepayments fixed for another year.

• See [www.gov.uk/government/news/nhs-charges-from-april-2014](http://www.gov.uk/government/news/nhs-charges-from-april-2014) for more details.

these groups and only used at the lowest effective dose for the shortest possible time in others.

Although pharmacists were thought to be able to manage the new risks associated with domperidone, their lack of access to full medical records meant it was decided that they wouldn't easily be able to identify those at risk of cardiac side-effects, with the result that the OTC product (Motilium 10) was withdrawn. Anyone asking for it should be referred to their GP so they can continue to access the antiemetic on prescription if appropriate.

Anaphylaxis is another very real problem relating to domperidone that was identified by the MHRA this year. The drug regulator stated that anyone prescribed adrenaline for this reason should carry two auto-injector devices with them at all times in case of emergency. Furthermore, if adrenaline had to be self-administered, an ambulance should be called, with the patient lying down with their legs raised and not left alone while waiting for assistance to arrive.

Full information on the issues that have surfaced around domperidone can be accessed at: [www.mhra.gov.uk/Publications/Safetywarnings/DrugAlerts/CON452547](http://www.mhra.gov.uk/Publications/Safetywarnings/DrugAlerts/CON452547).

### Esomeprazole

The OTC armoury for stomach remedies may be strengthened in the months to come with the introduction of GSL esomeprazole. The drug was approved as a non-prescription medicine by the European Commission in 2013, and Pfizer has applied to the Medicines and Healthcare products Regulatory Agency (MHRA) for a GSL licence.

In its application, the company cited the familiarity of the UK public with the symptoms and treatment of heartburn, the safety of proton pump inhibitors as demonstrated by the availability of omeprazole as a Pharmacy-only medicine for a number of years, and the company's belief that no pharmacist intervention is required for the product to be used safely.

More information is available at: [www.gov.uk/government/consultations/classification-of-nexium-control-20mg-gastro-resistant](http://www.gov.uk/government/consultations/classification-of-nexium-control-20mg-gastro-resistant).

### Controlled Drugs

The CD regulations were updated this year, moving tramadol to Schedule 3 (although exempt from safe custody requirements) and lisdexamfetamine to Schedule 2. This means that these drugs may only be prescribed by a UK-registered clinician, all CD prescription requirements have to be met (including 28-day validity) and repeatable scripts are not allowed.

The legal changes also saw zopiclone and zaleplon join zolpidem in Schedule 4, meaning prescriptions are only valid for 28 days after being written. There are also moves afoot to reschedule ketamine from Schedule 4 to Schedule 2.

More information on these changes can be found at: [www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON421308](http://www.mhra.gov.uk/Howweregulate/Medicines/Medicinesregulatorynews/CON421308).

The MHRA also issued a warning that described the risks of accidental exposure to, or inadvertent transfer of, fentanyl following the incorrect disposal of patches. A Drug Safety Update explained the importance of patients and carers following the disposal instructions described on the product packaging and in the accompanying information leaflet.

Details are available at: [www.mhra.gov.uk/home/groups/dsu/documents/publication/con437440.pdf](http://www.mhra.gov.uk/home/groups/dsu/documents/publication/con437440.pdf).

In March 2015, a new law governing driving while under the influence of certain drugs is expected to come into force in England, Scotland and Wales. The substances to be included are cannabis, cocaine, morphine, diamorphine, methadone, ketamine, amphetamine, flunitrazepam, clonazepam,

### Reflection exercise 1

Do you have a clear understanding of terms used in research papers such as 'adjusted odds ratio' and 'primary end point'? Think about how you would explain these concepts to your team members so they, in turn, can describe them to customers and patients.

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## Reflection exercise 2

While Schedule 2 Controlled Drugs have requirements around safe custody and record keeping that clearly mark them out as different to other medicines, the same cannot necessarily be said of Schedule 3 and 4 CDs. However the law is no less clear on these drugs, so make sure you understand all the requirements and restrictions that apply, for example, regarding to prescription validity.

diazepam, lorazepam, oxazepam and temazepam. Pharmacists and their teams should advise patients on any of these drugs to not drive until they are sure that they feel awake and alert and their ability to concentrate and make decisions is not affected.

More information on this is available at: [www.mhra.gov.uk/home/groups/dsu/documents/publication/con437439.pdf](http://www.mhra.gov.uk/home/groups/dsu/documents/publication/con437439.pdf).

## Contraception

Despite concerns that have been raised about emergency contraception being less effective in women who have a higher than normal body mass index (BMI), a European review concluded that both levonorgestrel and ulipristal acetate are suitable for all women regardless of their BMI or body weight if unprotected intercourse or contraceptive failure has occurred.

The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) said the evidence claiming otherwise was too limited and not robust enough to support any other conclusion.

Contraception was also the topic of several guidance documents published by NICE:

- The long-acting reversible contraception guideline was reissued to include additional information on progestogen-only subdermal implants following the withdrawal of Implanon and introduction of Nexplanon, a similar but non-identical product. The full document can be accessed at: [www.nice.org.uk/Guidance/CG30](http://www.nice.org.uk/Guidance/CG30)
- Public health guidance on contraceptive services for young people reminded anyone involved in providing such services to ensure that advice and information is provided on all types of contraception. This helps individuals choose the best method for their own needs and lifestyle, with the result that

the contraceptive is more likely to be used correctly and therefore prove effective, according to the guidance. It can be viewed at: [www.nice.org.uk/guidance/PH51](http://www.nice.org.uk/guidance/PH51).

## Drug allergy

NICE guidance is often specific to adults or children, but the publication of guidance on the diagnosis and management of drug allergy covered both population groups. The paper highlighted major issues, such as poor clinical documentation, an inability of primary care medical record systems to distinguish between intolerance and allergy, and a lack of patient information which may lead to people inadvertently taking drugs they are allergic to.

The guidance recommends documenting and sharing drug allergy information in a structured and standardised way, making patients – and carers, if appropriate – aware of the drugs or drug classes that need to be avoided, and advising people with a history of allergy to seek advice from a pharmacist before purchasing an OTC product or submitting a prescription for dispensing. More information at: [www.nice.org.uk/guidance/CG183](http://www.nice.org.uk/guidance/CG183).

This year also saw a review of adrenaline auto-injectors approved in the UK. Triggered by the death of a user who was not able to correctly use a device during an anaphylactic reaction, the recommendations made by the Commission on Human Medicines, an independent panel of experts that advises the MHRA, included:

- Informing people with allergies, their carers and healthcare professionals of the steps to take while waiting for emergency medical help for an anaphylactic reaction
- Updating the same groups of people on the correct use of adrenaline auto-injectors.

Manufacturers are also required to provide technical information that may improve the performance of auto-injectors, plus data on whether the adrenaline delivered by their devices goes into the muscle or fatty tissue. For more information, visit:

[www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Product-specificinformationandadvice-A-F/Adrenalineauto-injectorsareviewofclinicalandqualityconsiderations/index.htm](http://www.mhra.gov.uk/Safetyinformation/Generalsafetyinformationandadvice/Product-specificinformationandadvice/Product-specificinformationandadvice-A-F/Adrenalineauto-injectorsareviewofclinicalandqualityconsiderations/index.htm).



NICE issued guidance on contraceptive services for young adults



'This module looks at some of the **important changes** that took place this year and discusses their **implications for pharmacy practice**'



## SLS drugs

The Drug Tariff is constantly being reviewed and this year saw several changes to the selected list scheme.

For men with erectile dysfunction (ED), the recently launched drug avanafil (Spedra) now appears, alongside tadalafil (Cialis) and vardenafil (Levitra), all of which must be annotated with the letters 'SLS' when written on a NHS prescription. Viagra is still on the list but sildenafil is not, meaning that the generic may now be prescribed more or less without restriction to men who are suffering from ED. This fact is worth mentioning to men who present private prescriptions for sildenafil as they may want to visit their GP with a view to having it prescribed on the NHS in the future.

Other drugs that have been removed from the list are apomorphine hydrochloride, moxislyte hydrochloride and thymoxamine hydrochloride. All can now be prescribed generically without the prescriber needing to add the letters 'SLS' to the prescription.

PSNC is the best source of information for these changes: [www.psn.org.uk/our-news/visions-to-sls-list-drug-tariff-part-xviii](http://www.psn.org.uk/our-news/visions-to-sls-list-drug-tariff-part-xviii).

## Diabetes

Diabetes is always a hot topic in primary care and 2014 was no exception, which saw the launch of alogliptin (Vipidia), a new DPP-4 inhibitor. The drug is licensed to improve glycaemic control in type 2 diabetes alongside other glucose-lowering treatments.

NICE stated that alogliptin appeared effective, had no serious safety concerns and seemed to be a cheaper option to other drugs in this class, although licensing restrictions mean it is not suitable for all. The SPC can be viewed at: [www.medicines.org.uk/emc/medicine/28513](http://www.medicines.org.uk/emc/medicine/28513).

Canagliflozin was the subject of a NICE technology appraisal, which concluded that, in combination with metformin, the drug was an option for people with type 2 diabetes who cannot take a sulfonylurea, or as triple therapy with metformin and either a sulfonylurea or a thiazolidinedione.

It may also be used with insulin, with or without other antidiabetic drugs. The document can be seen at: [www.nice.org.uk/guidance/TA315](http://www.nice.org.uk/guidance/TA315).



Schools can now hold salbutamol inhalers for use in an emergency

## Respiratory medicine

Schools are now allowed to have salbutamol inhalers and spacers for use in an emergency, following changes to the Human Medicines Regulations 2012. A consultation run by the MHRA and Department of Health found that there was overwhelming support for this, with the result that head teachers may now order small quantities on an occasional basis. Requests must be made in writing, preferably on headed paper, and must state the name of the school, the name and quantity of the product, and purpose for which it is required, as well as bear the head teacher's signature.

Further information is available from: [www.gov.uk/government/consultations/proposals-to-allow-the-supply-of-salbutamol-asthma-inhalers-in-schools-for-emergency-use-mlx385](http://www.gov.uk/government/consultations/proposals-to-allow-the-supply-of-salbutamol-asthma-inhalers-in-schools-for-emergency-use-mlx385).

Concerns have been raised over the fluticasone/vilanterol dry powder inhaler (Relvar), which the Midlands Therapeutics Review and Advisory Committee (MTRAC) said could be confused with reliever inhalers due

to its light grey body and pale blue mouthpiece cover. MTRAC also said that the evidence of efficacy for the product was relatively weak.

The full advice can be seen at: <http://centreformedicineoptimisation.co.uk/download/e92adb5a1de0ad47177fe75a517f456e/Fluticasone-furoate-vilanterol-inhaler-final.pdf>.

## Vaccines

What initially appeared to be a straightforward product discontinuation earlier this year became suddenly more complicated when the manufacturer of ACWY Vax wrote to health professionals to tell them that immunity against *Neisseria meningitidis* only lasted one to two years, and not longer than three years as stated in the product literature. Previous recipients may need to be revaccinated earlier than they may originally have thought, using an alternative conjugate vaccine.

For more information, take a look at: [www.mhra.gov.uk/home/groups/comms-ic/documents/drugsafetymessage/con425089.pdf](http://www.mhra.gov.uk/home/groups/comms-ic/documents/drugsafetymessage/con425089.pdf).

More encouraging news came in the form of the vaccine that protects against whooping cough. Public Health England announced plans to continue its programme of pertussis vaccination for pregnant women for a further five years. The programme started in 2012.

Administering the vaccine to women between 28 and 38 weeks of pregnancy confers immunity to the unborn child, offering babies protection until they receive their first pertussis vaccine at two months of age. There has been an overall fall in whooping cough cases since the programme started, with analysis of figures from the CPRD finding no evidence that the vaccine poses a risk to the expectant mother or her unborn child.

More information at: [www.mhra.gov.uk/NewsCentre/Pressreleases/CON435837](http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON435837).

Two new vaccination programmes were introduced in England this year:

- A meningitis C catch-up scheme to vaccinate first-time university entrants under the age of 25 years who have not been vaccinated against the disease since reaching the age of 10 years
- Hepatitis B immunisation for newborn babies considered at high-risk of contracting the disease. The first dose should be given in hospital after birth, with the three remaining doses given at the GP surgery at one and two months and shortly after the child's first birthday.

Catch-up vaccination programmes were put in place for the following:

- Shingles vaccination for patients aged 78 and 79 years (in addition to the standard immunisation provided to 70-year-olds)
- Pneumococcal vaccination for those aged 65 years and older, and those deemed at risk of complications. This is usually administered alongside the annual flu jab
- Measles, mumps and rubella vaccination for patients up to 18 years in Wales who did not receive or complete their childhood MMR schedule.

### Reflection exercise 3

Would you be confident about filling out and submitting a Yellow Card for an adverse reaction? If you don't already have one, consider starting a folder that contains blank forms with some notes on how to complete a Yellow Card and where it should be sent to.

More information on the changes to England's national immunisation programmes can be viewed at: [www.england.nhs.uk/wp-content/uploads/2014/06/flu-pneumo-immu-spec.pdf](http://www.england.nhs.uk/wp-content/uploads/2014/06/flu-pneumo-immu-spec.pdf).

The annual influenza vaccination scheme was extended with all two-to-four year-olds in England offered vaccination, plus 11 and 12-year-olds in 12 pilot areas. In most cases, the live nasal vaccine (Fluenz) is used, with the inactivated intramuscular vaccine reserved for those who cannot have the nasal vaccine.

More information is available at: [www.gov.uk/government/collections/annual-flu-programme](http://www.gov.uk/government/collections/annual-flu-programme).

### Keep a lookout for...

**The interaction between** St John's wort and hormonal contraceptives was featured in one of the MHRA's Drug Safety Updates, following Yellow Card reports of women who had fallen pregnant when using the herbal supplement at the same time as the etonogestrel implant. The same publication highlighted absorption issues that can occur if orlistat is taken at the same time as antiretroviral medication, recommending that HIV patients should seek medical advice before purchasing the OTC obesity drug.

The full update can be read at: [www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON392869](http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON392869).

**New product warnings** have been added to the packaging of renin-angiotensin system blocking agents following a review that showed the drugs increase the risk of hyperkalaemia,

hypotension and renal impairment. Aliskiren should not be used at the same time as an angiotensin-converting enzyme inhibitor (ACEi) or an angiotensin receptor blocker (ARB) in patients with renal impairment or diabetes, and people with diabetic nephropathy should not be prescribed an ACEi plus an ARB due to the higher risk this group has of increased potassium levels. Information is available at: [www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON426905](http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON426905).

**Patients on capecitabine** who experience a severe skin reaction, such as Stevens-Johnson syndrome or toxic epidermal necrolysis, should stop taking the drug immediately and seek urgent medical care, the MHRA announced. Although the reaction is rare – fewer than one in 10,000 patients will experience it – the seriousness of the reaction means community pharmacists should be aware of the risk posed by the drug, which is taken orally for several different cancers including breast, colon, rectal, stomach, oesophageal and pancreatic cancer. The full announcement can be viewed at: [www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON364168](http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON364168).

**Hepatic problems**, including failure, have been reported with temozolomide (Temodal), which is taken orally in the treatment of some brain tumours. Liver function testing is recommended before starting the drug and in between chemotherapy cycles, but pharmacists should be aware that hepatic damage can occur at any stage and even after treatment is complete. Information on this issue may be accessed at: [www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON364167](http://www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON364167).

**Strontium ranelate** should only be used in people with cardiac or circulatory problems if they are unable to take alternative osteoporosis drugs, the MHRA said in early 2014. The reason is because the drug appears to increase the risk of heart problems in these groups, although there is no increased risk in other patient groups. Information can be viewed at: [www.mhra.gov.uk/home/groups/comms-po/documents/news/con382707.pdf](http://www.mhra.gov.uk/home/groups/comms-po/documents/news/con382707.pdf).

### The Yellow Card scheme

The Yellow Card form has been updated in order to gather information on the use of medicines during pregnancy. The date of the last menstrual period and expected date of delivery now have allocated fields on the form and details such as previous pregnancies can be input using the 'additional information' section.

There is now no requirement to report all suspected adverse drug reactions in children following feedback that this measure was impractical and, in fact, deterred reporting. Instead, a Yellow Card should be completed for all suspected ADRs associated with black triangle drugs and those that result in harm or are considered serious (i.e. are fatal, life threatening, disabling, incapacitating, cause a congenital abnormality or result in hospitalisation). This brings the guidelines for reporting ADRs in children in line with those for adults.

In a Drug Safety Update, the MHRA highlighted the difference in the presentation of ADRs in children compared to adults and took the opportunity to remind clinicians that Yellow Cards may be used to report suspected ADRs to medicines, vaccines, herbal or complementary products, whether self-medicated or prescribed, and also in cases where misuse, overdose or use outside the licensing restrictions has taken place.

For more information, go to [www.mhra.gov.uk/Safetyinformation/Howwemonitorthesafetyofproducts/Medicines/TheYellowCardScheme/Informationforhealthcareprofessionals/Whattoreport/index.htm](http://www.mhra.gov.uk/Safetyinformation/Howwemonitorthesafetyofproducts/Medicines/TheYellowCardScheme/Informationforhealthcareprofessionals/Whattoreport/index.htm)



## Specials

The General Pharmaceutical Council published guidance on the preparation of unlicensed medicines to be used in conjunction with its standards for registered pharmacies. GPhC chief executive Duncan Rudkin commented at the time: "We recognise that preparing an unlicensed medicine in a pharmacy is an activity that can pose a risk to patients and may potentially have consequences if processes are not managed properly." The document had been written with the aim of helping pharmacies keep patients safe, he added.

The guidance applies to all cases in which an unlicensed medicine is prepared in a pharmacy, whether it is a one-off extemporaneous preparation, the making up of stock for supply at a later date, preparation of methadone, or manufacturing chemists' nostrums for sale or supply. The guidance does not apply to unlicensed medicines that pharmacies obtain from elsewhere, for example a specials' manufacturer, importer or distributor, nor to products that require dissolving or diluting as part of the dispensing process, such as the reconstitution of antibiotic suspensions.

Aspects covered in the document include:

- The need for risk assessment, regular audit, defined lines of accountability and responsibility, and meticulous record keeping
- The necessity of establishing a recall process should a problem arise with an unlicensed medicine that has been made on the premises
- Appropriate training to be provided to all staff

## Pharmacy publications

Publication of the British National Formulary has been reduced from twice to once a year because more clinicians are accessing the information via digital formats. Content is available on the NHS Evidence website and BNF app, and is updated each month.

The change in distribution of the print version brings the BNF in line with the Children's BNF (more commonly known as the BNFC), which is distributed annually. More information on this change is available at [www.evidence.nhs.uk/evidence-search-content/bnf](http://www.evidence.nhs.uk/evidence-search-content/bnf).

NICE has urged clinicians to use the digital formats of both the BNF and BNFC, stating that these are the most appropriate way to access up-to-date information. Community pharmacists should note that the BNF can no longer be accessed online via [www.bnf.org](http://www.bnf.org), and instead is available via the Medicines Complete website at [www.medicinescomplete.com](http://www.medicinescomplete.com).

Notable changes that have been made to the BNFC over the past year include significant dose changes for amoxicillin, paracetamol and metronidazole, new advice on switching between anti-epilepsy brands, updated guidance on pertussis prevention, and the addition of the rotavirus vaccine to the childhood immunisation schedule.

### Drug Tariff

The Drug Tariff is sent to pharmacies each month, but NHS England has now stopped distributing paper copies to GP surgeries. This change was implemented in January but with general practice staff not huge users of the Drug Tariff, community pharmacy teams should be mindful that they may need to support those who have not previously accessed information electronically via [www.ppa.org.uk/ppa/edt\\_intro.htm](http://www.ppa.org.uk/ppa/edt_intro.htm).



## Ebola dominates world headlines in 2014

The global health topic that will probably be most associated with 2014 is the Ebola outbreak in West Africa. First reported in March it quickly became the deadliest occurrence of the disease since it was discovered in 1976. As *Pharmacy Magazine* went to press, nearly 7,000 deaths had been attributed to the virus, and the World Health Organization said it expected to see as many as 20,000 cases by the end of the year.

The Ebola virus spreads through direct contact via broken skin, or via the mouth or nose, of the blood, vomit, faeces, urine or semen of someone who has the disease. It isn't clear how long the virus can live for, but some evidence points to it being up to six days. People with the virus are infectious when symptoms start and for up to seven weeks after they recover.

The first symptoms, which can take anything from two to 21 days to become apparent, are usually fever, myalgia, fatigue, sore throat and headache. Vomiting, diarrhoea, rash and bleeding soon follow, which is both external and internal, and gives the name 'viral haemorrhagic fever' or 'VHF', which many medics use for the condition.

A modelling study found that the probability of Ebola spreading outside Africa was small, but not negligible, with the UK named as the country outside the region that has the highest risk of importation. For this reason, screening has been put in place at major ports of entry such as Heathrow and Gatwick airports and the Eurostar terminal at St Pancras station in London, to enable the identification of people who have travelled from countries affected by Ebola (currently Sierra Leone, Guinea and Liberia). These individuals will have their temperature checked and be required to complete a questionnaire about their health, travel history and contact with Ebola patients, and undergo full clinical assessment if necessary.

Although Ebola is relatively difficult to catch and easy to prevent – hygiene measures such as handwashing, the use of protective clothing, properly disposing of any bodily waste from infected patients make a huge difference to the risk of an individual becoming infected – the fact that the fatality rate is high, problems with identifying cases as being Ebola, and the lack of an effective treatment mean that it is of public health importance. Community pharmacists and their teams are in an ideal position to provide accurate and up-to-date information, aided by the wealth of resources available at [www.gov.uk/government/collections/ebola-virus-disease-clinical-management-and-guidance](http://www.gov.uk/government/collections/ebola-virus-disease-clinical-management-and-guidance).

involved in manufacturing unlicensed products

- The provision of a manufacturing environment and equipment is suitable for the activity and minimises the risk of microbial or cross-contamination, alongside robust quality assurance systems
- Provision of advice and information on unlicensed medicines to patients is particularly important as there is no legal requirement to supply detailed written information as there is with other products. The document can be read in full at: [www.pharmacyregulation.org/sites/default/files/guidance\\_for\\_registered\\_pharmacies\\_preparing\\_unlicensed\\_medicines\\_23\\_05\\_14.pdf](http://www.pharmacyregulation.org/sites/default/files/guidance_for_registered_pharmacies_preparing_unlicensed_medicines_23_05_14.pdf).

### NICE guidance

There were several documents published this year by NICE that impacted on primary care. Some have already been mentioned in this module, but others of note include:

- The 2006 atrial fibrillation guidance was updated to endorse the use of a new tool to assess stroke risk in patients with AF in order to decide who requires anticoagulation therapy and highlight the use of novel oral anticoagulants (NOACs) as an alternative to

warfarin and/or aspirin. The full guideline is available at [www.nice.org.uk/guidance/CG180](http://www.nice.org.uk/guidance/CG180)

- Public health guidance on individual approaches to behaviour change covers alcohol misuse, poor diet, lack of physical exercise, unsafe sex and smoking, and how they can impact on health. The document explains the importance of taking a person-centred approach when helping people make changes to their behaviour that can improve their health and wellbeing, either as a single intervention or over a number of sessions. ([www.nice.org.uk/guidance/PH49](http://www.nice.org.uk/guidance/PH49))
- New lipid modification guidance recommends using non-HDL cholesterol rather than LDL cholesterol as a measurement of cardiovascular disease risk, describes the cardio-protective diet that should be recommended to people at high risk of or with CVD, and endorses atorvastatin 20mg as first-line primary prevention and the same drug at an 80mg dose for secondary prevention. ([www.nice.org.uk/guidance/CG181](http://www.nice.org.uk/guidance/CG181))
- Public health guidance on weight management of overweight and obese adults has replaced a section of NICE's 2006 clinical guidance on obesity. The document urges all involved in this area to adopt an integrated

approach, making clear to both healthcare professionals and the public all the options available, from medication to community walking or gardening schemes. The need for a respectful and non-judgemental attitude towards adults with a raised BMI is also emphasised, as is the need for ongoing care to ensure weight lost wasn't regained.

([www.nice.org.uk/guidance/PH53](http://www.nice.org.uk/guidance/PH53))

- The osteoarthritis guideline now states that glucosamine and chondroitin should not be offered as a management option because of inadequate evidence of effectiveness, and stresses the importance of long-term monitoring, including the effectiveness and tolerability of any treatments being used. The guidance also states that all osteoarthritis patients should be offered advice on weight management, activity and exercise.

([www.nice.org.uk/guidance/CG177](http://www.nice.org.uk/guidance/CG177))

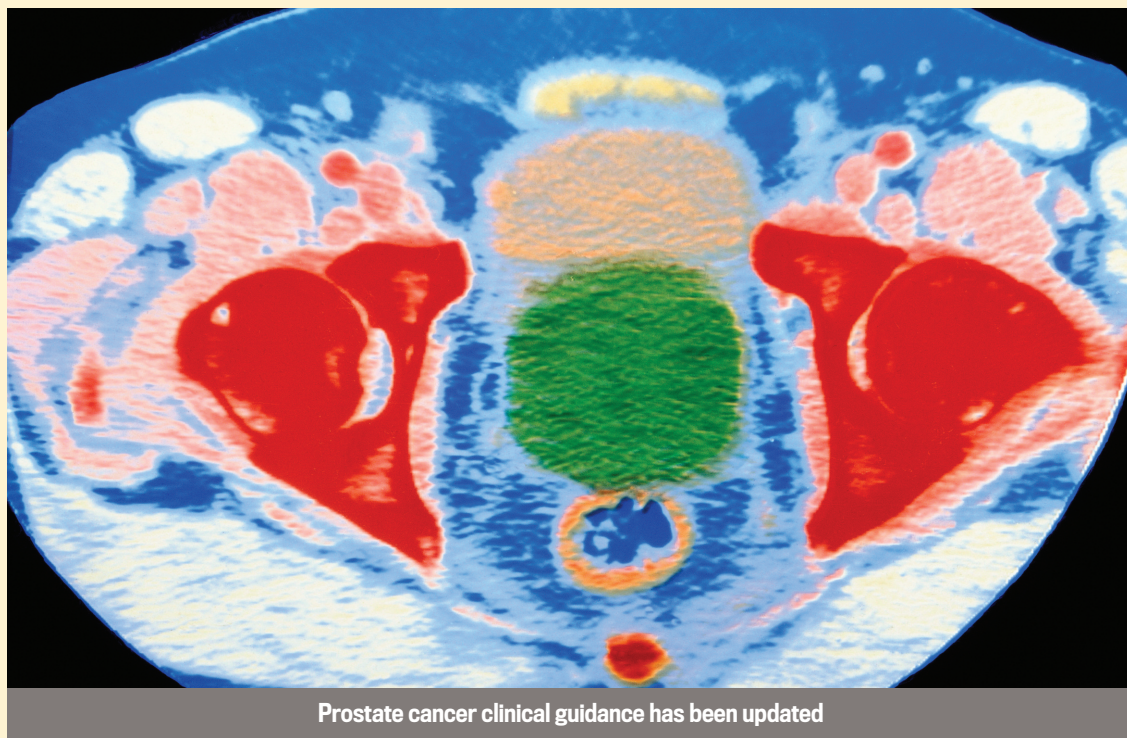
- Guidance on dyspepsia and gastro-oesophageal reflux disease has been updated with new recommendations on the use of proton pump inhibitors and regimens for eradicating *Helicobacter pylori*.

([www.nice.org.uk/Guidance/CG184](http://www.nice.org.uk/Guidance/CG184))

- Guidance on pressure ulcers is relevant to pharmacists and their teams who are well positioned to discuss the importance of prevention with patients and their carers and signpost appropriate sources of advice and support. ([www.nice.org.uk/guidance/CG179](http://www.nice.org.uk/guidance/CG179))

- Guidance on the management of psychosis and schizophrenia in adults contains important information on the need for care to be taken when people with one of these conditions reduces or stops smoking because of the impact it can have on the metabolism of drugs such as clozapine and olanzapine.

The guidance also details the increased risk of neuro-psychiatric symptoms that affect this population when taking bupropion or varenicline. ([www.nice.org.uk/guidance/CG178](http://www.nice.org.uk/guidance/CG178))



Prostate cancer clinical guidance has been updated

- The updated multiple sclerosis guidance also appears at first glance to be aimed at hospital and primary care clinicians, but pharmacy teams have a valuable role in providing advice on exercise, flu vaccination, pregnancy and smoking. ([www.nice.org.uk/guidance/CG186](http://www.nice.org.uk/guidance/CG186))

- Guidance on head injuries was updated. Although most of the recommendations are aimed at hospital staff and ambulance crews, the document stresses the importance of recognising the signs that a head injury is potentially serious, such as seizures, repeated vomiting or loss of consciousness, which pharmacists and their teams should be aware of. ([www.nice.org.uk/guidance/CG176](http://www.nice.org.uk/guidance/CG176))

- Similarly, public health guidance on domestic violence highlights the need for wider understanding in all sectors of society, including healthcare, in order that the signs can be recognised and sufferers signposted to appropriate sources of help and support.

- The prostate cancer clinical guideline was updated to include active follow-up in primary care for men who had been diagnosed with localised prostate cancer and who have decided against immediate radical prostatectomy or radiotherapy. The provision of information and decision support on management options for men with the condition, their partners and carers is also reinforced. ([www.nice.org.uk/guidance/CG175](http://www.nice.org.uk/guidance/CG175))



#### Reflection exercise 4

The BNF is an invaluable resource but the paper version can soon go out of date. Make sure you are signed up to one of the digital formats available, so you are always accessing the latest information.



Pharmacy Magazine's CPD modules are available on Cegedim Rx's PMR systems, Pharmacy Manager and Nexphase. Just click on the 'Professional Information & Articles' button within Pharmacy KnowledgeBase and search by therapy area. Please call the Cegedim Rx helpdesk on 0844 630 2002 for further information.



KEY THERAPEUTIC DEVELOPMENTS IN 2014

# assessment questions

**1. Which statement about domperidone is FALSE?**

- a. The OTC product is no longer available
- b. Cardiac side-effects were identified as a risk
- c. Patients who may be allergic to domperidone should carry two adrenaline auto-injectors at all times
- d. Domperidone may now only be used for vomiting

usually have a thorough understanding of the products they can and cannot take

- d. Drug intolerances are sometimes noted in patient records as allergies

**5. Which drug does NOT require a SLS endorsement?**

- a. Tadalafil
- b. Vardenafil
- c. Sildenafil
- d. Viagra

**2. Which statement about Controlled Drugs is TRUE?**

- a. Tramadol became a Schedule 2 drug
- b. All the 'z-drugs' are now Schedule 4 CDs
- c. Both lisdexamfetamine and tramadol now need to be kept in the CD cupboard
- d. Ketamine is a Schedule 2 CD

**6. Which statement is FALSE regarding vaccines?**

- a. The ACWY vaccine confers immunity against certain strains of meningitis for one to two years
- b. Pregnant women should be vaccinated against pertussis between 18 and 24 weeks
- c. University freshers can ask for a meningitis C jab if they haven't been vaccinated in the last eight years
- d. Patients aged 70, 78 and 79 years of age are eligible for shingles vaccination

**3. Which statement regarding contraception is FALSE?**

- a. Morbidly obese women need to double the dose of levonorgestrel if taking it for emergency contraception
- b. Nexplanon is the progestogen-only subdermal implant currently used in the UK
- c. Ulipristal and levonorgestrel may both be used as emergency hormonal contraceptives
- d. NICE recommends giving young people advice on all forms of contraception

**7. The GPhC's guidance on specials does NOT cover:**

- a. Products obtained from a specials manufacturer
- b. Making up a batch of stock for use later that week
- c. Risk assessment
- d. Talking to patients about specials

**4. Find the TRUE statement:**

- a. All adrenaline auto-injectors are used in the same way
- b. All adrenaline auto-injectors deliver the drug to a muscle
- c. Patients with drug allergies

**8. Which was NOT the subject of NICE guidance this year?**

- a. Bipolar disorder
- b. Dyspepsia
- c. Osteoarthritis
- d. Weight management

Use this form to record your learning and action points from this module on **key therapeutic developments in 2014** and include it in your CPD portfolio and record online at [www.uptodate.org.uk](http://www.uptodate.org.uk). Any training, learning or development activities that you undertake for CPD can also be recorded as evidence as part of your RPS Faculty practice-based portfolio when preparing for Faculty membership. Start your Faculty journey today by accessing the portfolio and tools at [www.rpharms.com/development/faculty.asp](http://www.rpharms.com/development/faculty.asp)

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

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 my 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 to meet these action points?)

*(REFLECT & PLAN)*

\* 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](http://www.pharmacymag.co.uk)

**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.**

- |    |                             |    |                             |    |                             |    |                             |    |                             |    |                             |    |                             |    |                             |
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| 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"/> |
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Name (Mr, Mrs, Ms) \_\_\_\_\_

Business/home address \_\_\_\_\_

Town \_\_\_\_\_ Postcode \_\_\_\_\_ Tel \_\_\_\_\_ GPhC/PSNI Reg no.

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 Marketing Group, Precision House, Bury Road, Beyton, Bury St Edmunds IP30 9PP (tel: 01284 718912; fax: 01284 718920; email: [cpd@precisionmarketinggroup.co.uk](mailto:cpd@precisionmarketinggroup.co.uk)), 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 assessors' decision is final and **no correspondence** will be entered into.