

# PSNC publishes top tips to prepare for new contract

Ten top tips to help contractors prepare for the new community pharmacy contract in England and Wales have been published.

The Pharmaceutical Services Negotiating Committee said this week that it will be producing guidance on the new contract for both contractors and local pharmaceutical committees (LPCs) in the next few months. But, in the meantime, the PSNC has come up with 10 tips to help contractors get started now (see Panel).

Implementation of the new contract will begin in April but contractors will have six months before they have to comply with the requirements of the essential services. From October, primary care trusts (PCTs) will begin to monitor compliance.

## The 10 top tips for community pharmacy contractors

1. Brief your staff on the basics of the new contract
2. Assess your readiness for providing the essential services
3. Assess staffing requirements — think about developing your skill mix
4. Assess training and development needs for all staff (do not forget yourself)
5. Decide whether you want to provide advanced services early in the implementation of the new contract
6. Assess your premises in the light of new contract requirements (in particular, consider the requirements for consultation areas for providing advanced services and about how consultation areas will be used in the future so they can be used to provide other services)
7. Start thinking about your future IT requirements
8. Develop an action plan to make any necessary changes to your pharmacy procedures ensuring you involve all your staff
9. Assess your relationships with other local health care professionals and the PCT — start developing them if they are poor
10. Work with your LPC and keep an eye on the PSNC website for developments ([www.psnc.org.uk/contract](http://www.psnc.org.uk/contract))

## Government proposes price cuts on branded generic medicines

Branded generic medicines should be reimbursed in the same way as generic medicines and not be covered by the Pharmaceutical Price Regulation Scheme (PPRS), a Government consultation proposes this week.

The Department of Health aims to stop manufacturers being able to achieve higher prices for generic medicines simply by giving them a brand name. However, such a move would have implications for community pharmacists, wholesalers and dispensing doctors.

A new PPRS scheme started on 1 January (*PJ*, 6 November 2004, p669 and *PJ*, 18/25 December 2004, p873) with the promise that there would be a consultation on branded generics. The consultation proposes that “standard” branded generics should no longer be covered by PPRS and instead be transferred to the new arrangements for the reimbursement of generic medicines.

A “standard” branded generic medicine is defined as: “An out of patent product to which the manufacturer/supplier, who is not the originator company, has applied a brand name and that is comparable to a true generic



Changes on way for generic medicines

that is readily available.” There are currently 125 substances with such generics on the market. Modified-release branded generic preparations which the Medicines and Healthcare products Regulatory Agency requires to be identified by brand name will remain within PPRS. The proposals do not apply to branded products produced by the originator manufacturer that are out of patent.

“The reason for the proposed transfer is that the PPRS recognises the cost of research

and development in the prices of branded medicines supplied to the NHS,” the consultation states. “The Government does not believe that it is acceptable for the NHS to pay a similar price to the originator branded product for branded generic medicines which have not incurred significant R&D and where a comparable true generic is available.”

Therefore, it proposes that the future reimbursement price of standard branded generic medicines will be the lesser of the revised Drug Tariff price of the comparable true generic medicine or the list price of the standard branded generic medicine. The consultation closes on 15 April 2005.

A consultation on future arrangements for reimbursement of generic medicines closed in October 2003 (*PJ*, 6 September 2003, p295) and an announcement on the outcome is awaited. However, this week’s consultation document states: “The revised Drug Tariff price will be determined by new arrangements whereby quarterly data will be collected from manufacturers and wholesalers and an index for determining the Drug Tariff price will be calculated from that data.”

## Initial reaction to branded generics proposals is positive

Initial reaction to the proposals on changes to the way in which branded generic medicines are reimbursed (see above) has been positive.

Martin Sawer, executive director of the British Association of Pharmaceutical Wholesalers, commented: “Moving branded generics out of the Pharmaceutical Price Regulation Scheme seems to make sense — the PPRS is about setting prices for companies who need to be rewarded for the investment they make in research and development of new products. Including branded generics clouds the agreement.”

A spokesman for the British Generic Manufacturers Association said: “The BGMA

believes that all products sold in the off-patent market should be covered by the new generics pricing scheme — this should include the original brand.” He added: “We do not feel there is any justification for the original brand to be dealt with in a different way to generics once a product’s patent has expired.”

Sue Sharpe, the Pharmaceutical Services Negotiating Committee’s chief executive, said that the PSNC is considering its response. “The new contract funding arrangements will include reduction in reimbursement prices for many generic medicines, and we expect this to have a significant impact on branded generic prescribing,” she commented.

### UniChem guide to new contract

UniChem has launched a guide to help pharmacy contractors meet the requirements of essential services under the new community pharmacy contract. “Solutions” has been designed to advise pharmacists on practical ways to meet the new requirements in each core area while also maximising their business opportunities. It also outlines the sources of support available to contractors. The guide will be provided to UniChem customers from their account managers from next week.

### News in brief

# NICE issues guidance on drugs for osteoporosis

Guidance on the use of bisphosphonates, raloxifene and teriparatide for the secondary prevention of osteoporotic fragility fractures in postmenopausal women has been issued this week by the National Institute for Clinical Excellence.

The guidance refers to treatment of postmenopausal women who have normal calcium and/or vitamin levels and does not cover treatment of corticosteroid-induced osteoporosis.

It recommends that the bisphosphonates alendronate (Fosamax), etidronate (Didronel) and risendronate (Actonel) be used for the secondary prevention of osteoporotic fractures in the following groups of women:

- Women aged 65–74 years if osteoporosis is confirmed by dual energy X-ray absorptiometry (DEXA) scanning
- Women aged 75 years and older without the need for DEXA scanning
- Postmenopausal women younger than 65 years old with a very low bone mineral density or confirmed osteoporosis plus an additional age-independent risk factor

Regarding choice of bisphosphonates, the guidance says that health professionals and

patients need to balance the drug's proven effectiveness profile against tolerability and adverse effects.

NICE says that the selective oestrogen receptor modulator raloxifene (Evista) is recommended as an alternative treatment option in women for whom bisphosphonates are contraindicated or not tolerated, those who have not responded to bisphosphonates and those who are physically unable to comply with the recommendations for use of the drugs.

NICE now recommends that teriparatide (Forsteo) should be used as a treatment option for secondary prevention of osteoporotic fractures in women aged over 65 years of age who have had an unsatisfactory response to or intolerance to bisphosphonates and either an extremely low bone mineral density or a very low bone mineral density, multiple fractures plus an additional risk factor.

NICE adds that it is not possible to provide precise data on the overall impact of this guidance on NHS prescribing costs, but acknowledges that it is possible that it will increase the use of bisphosphonates in women with osteoporotic fragility fractures and increase the demand for DEXA scanning.

The full guidance is available via a link on *PJ Online* ([www.pjonline.com/links/pj](http://www.pjonline.com/links/pj))



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## More osteoporotic fractures may be prevented by wider use of drugs

NICE guidance on the use of bisphosphonates and raloxifene for the primary prevention of osteoporotic fractures in postmenopausal women is also in the pipeline, although a publication date is not yet available. Guidance on the prevention of osteoporotic fractures in individuals at high risk and the use of strontium ranelate for the prevention of fractures is expected in February 2006 and March 2006, respectively.

## Mycophenolate endorsed for transplant rejection in Scotland

Mycophenolate sodium (Myfortic) can be used within the NHS in Scotland for the prevention of acute transplant rejection, the Scottish Medicines Consortium has announced.

In guidance issued earlier this month, the SMC recommended that mycophenolate be used in combination with ciclosporin and corticosteroids in adult patients receiving kidney transplants.

A further four products, three used in the treatment of epilepsy, were accepted for restricted use by the SMC.

Pregabalin (Lyrica) is endorsed for use as adjunctive therapy in adults with partial seizures with or without secondary generalisation. The SMC advises that it should be used principally to treat patients who have not benefited from other antiepileptics such as carbamazepine or sodium valproate, or for

whom these drugs are not suitable. Levetiracetam (Keppra) 750mg tablets and 100mg/ml oral solution are recommended as additional dosage forms also for use as adjunctive therapy in the treatment of partial seizures with or without secondary generalisation.

Caspofungin (Cancidas) is also recommended for restricted use — to treat presumed fungal infections in febrile, neutropenic adult patients who are under the care of a fungal disease specialist.

Two drugs failed to receive an endorsement from the SMC: nicotinic acid modified release tablets (Niaspan) is not recommended either as monotherapy or in combination with statins for the treatment of dyslipidaemia and primary hypercholesterolaemia, and efalizumab (Raptiva) is not recommended for treatment of adults with moderate to severe chronic plaque psoriasis.

## Cinacalcet launched

Patients with chronic end stage renal disease at risk of developing bone disease, bone pain or fractures as a result of secondary hyperparathyroidism (SHPT) may benefit from a new treatment launched this week.

Cinacalcet (Mimpara), launched by Amgen, is an oral calcimimetic that acts on the calcium-sensing receptor on parathyroid gland cells, reducing the levels of parathyroid hormone that become elevated in SHPT.

Amgen says that in clinical trials patients taking cinacalcet plus standard therapy suffered fewer broken bones than those taking placebo plus standard therapy and were less likely to have to undergo parathyroidectomy.

Cinacalcet is also licensed for the treatment of elevated calcium levels in patients with cancer of the parathyroid gland.

**Notice-board p107**

## Industry gives evidence

The Health Committee inquiry into the influence of the pharmaceutical industry heard from the industry itself last week. The industry claimed that focusing on patients was the way to achieve a balance between commercial imperatives and public health concerns. Other topics covered included accusations of the industry inventing diseases, direct-to-consumer advertising and "evergreening" (extending the life of a product beyond patent expiry).

## MHRA consults again on herbal medicines committee

Revised proposals on the setting up of a herbal medicines advisory committee have been made by the Medicines and Healthcare products Regulatory Agency.

The MHRA first consulted on the possibility of establishing an advisory body on herbal medicines in February 2004 (*PJ*, 21 February 2004, p206). In the light of responses to that consultation the MHRA revised its plans. It now proposes that the

committee will give advice directly to Government ministers and to the MHRA and that it will offer advice relating to the regulation of traditional herbal medicinal products and of unlicensed herbal medicines.

A spokeswoman for the MHRA said that the consultation document (MLX 318) will be published on the MHRA website ([www.mhra.gov.uk](http://www.mhra.gov.uk)) shortly. Comments should be made to the MHRA before 22 April.

# New smoke-free hospital guide

NHS hospital trusts will receive guidance from the Health Protection Agency this week on how to introduce no-smoking policies, mentioning specific roles for pharmacists.

The Government has pledged that the NHS will be smoke free by the end of 2006 (*PJ*, 20 November p739). "Guidance for smokefree hospital trusts" outlines the steps needed to implement these policies, describes how to work with local NHS stop smoking services and stresses the importance of consultation and communication with staff and patients.

The guidance says that working parties set up to draft the policy should include pharmacy representation. "This is particularly relevant in mental health institutions where there are some important interactions between antipsychotic medication and stopping smoking. Pharmacists can lend specific expertise in this area," it says.

The guidance also states that the pharmacy budget will need to take into account greater demand for smoking cessation treatment, but points out that both nicotine replacement therapy and bupropion are cost effective. It recommends that these drugs should be made available on the hospital formulary, and says



Victor de Schwaberg/SPL

**No-smoking policies should be developed with pharmacy involvement**

that pharmacists can assist with securing their supply.

The guidance can be accessed via a link on *PJ Online* ([www.pjonline.com/links/pj](http://www.pjonline.com/links/pj)).

## Lambing season warning

Pregnant women should be advised to avoid close contact with sheep during the lambing season. And those who have had contact with sheep who go on to develop a fever or influenza-like symptoms should be referred to a doctor immediately.

The reason for the advice, which has been issued by all three UK government health departments, is that a number of infections, such as chlamydia, toxoplasmosis and listeriosis can be passed from sheep to humans. These infections are common causes of abortion in ewes and can cause infections and miscarriage in pregnant women.

Mac Armstrong, chief medical officer in Scotland, commented: "While the number of reported infections and human miscarriages resulting from contact with sheep is extremely small, pregnant women need to be aware of the potential risks."

Pregnant women should:

- Not help to lamb or milk ewes
- Avoid contact with aborted lambs, newborn lambs and the afterbirth
- Avoid handling clothing and boots that have come into contact with ewes or lambs. If this is unavoidable, rubber gloves should be worn

# US study estimates excess heart disease events caused by Vioxx

Use of rofecoxib (Vioxx) in the US between 1999 and 2004 could have been responsible for between 80,000 and 140,000 cases of serious coronary heart disease, a study reveals.

David Graham, from the office of drug safety at the US Food and Drug Administration, and colleagues used data collected from 1.4 million patients treated under a Kaiser Permanente managed care system in California. Patients had received various non-steroidal anti-inflammatory drugs (NSAIDs), including celecoxib (Celebrex, around 40,000 users), ibuprofen (just under a million users), naproxen (around 435,000 users) and rofecoxib (around 27,000 users).

The researchers identified 8,143 cases of serious coronary heart disease, 2,210 of which were fatal, and matched each case with four controls. By comparing the incidence of coronary events among users of the cyclooxygenase-2 (COX-2) inhibitors rofecoxib and celecoxib and among users of other NSAIDs the researchers found evidence that

rofecoxib increased risk of serious coronary heart disease (see Panel).

The researchers estimate that 88,000–140,000 excess cases of serious coronary heart disease probably occurred in the US over the market life of rofecoxib. "In the future, when trials show that a new treatment confers a greater risk of serious adverse effect than a standard treatment, we must be much more careful about allowing its unrestrained use," they conclude (published online in *The Lancet* on 25 January, [www.thelancet.com](http://www.thelancet.com)).

In an accompanying editorial, Simon Maxwell and David Webb, of the University of Edinburgh, remark that increased attention will now be directed towards the cardiovascular safety of other COX-2 inhibitors. "It now falls to the manufacturers, under the careful review of the regulatory authorities, to provide all the evidence that this class of drugs is safe, if necessary including studies that directly address cardiovascular morbidity as a primary outcome."

A spokeswoman for Merck, Sharp & Dohme, the company that manufactured Vioxx, said Dr Graham's estimates were speculation based on observational studies. "In addition, Dr Graham's conclusion is based on the assumption that the relative risks he identified applied equally to patients who took Vioxx for two days as it did to patients taking Vioxx for two years."

Merck estimates that there were 105 million US prescriptions written for Vioxx from May 1999 through to August 2004 and that the number of patients who have taken Vioxx in the US since its launch is approximately 20 million.

The company was unable to provide similar figures for the UK but estimates that approximately 400,000 patients were prescribed Vioxx in the three months before the end of August 2004.

*The Lancet* study coincides with others published this week that add to the growing body of evidence on the cardiovascular risks associated with COX-2 inhibitors (*Archives of Internal Medicine* 2005;165:161 and 181).

□ **EMA review** In response to an ongoing review of COX-2 inhibitors by the European Medicines Agency, Pfizer has agreed not to launch its celecoxib product Onsenal in Europe until the EMA has finalised its assessment.

Onsenal has orphan status for the treatment of adenomatous intestinal polyps in familial adenomatous polyposis.

## Risk of serious coronary heart disease

Patients treated with rofecoxib (all doses) were found to have a 34 per cent higher risk of coronary heart disease compared with patients who had previously been treated with other NSAIDs (adjusted odds ratio 1.34, 95 per cent confidence interval 0.98–1.82,  $P=0.066$ ). For patients treated with rofecoxib at a dose higher than 25mg daily the risk increased (3.00, 1.09–8.31,  $P=0.03$ ).

Risk was amplified with recent use of any NSAID, current use of naproxen, and current use of other NSAIDs (attributable to the effects of diclofenac). In current users of celecoxib, a slightly reduced risk was noted (0.84, 0.67–1.04,  $P=0.12$ ).

# Medicine-related symptoms fail to be addressed

Doctors fail to address up to a quarter of medicine-related symptoms reported by patients, according to US researchers.

Saul Weingart, Beth Israel Deaconess medical centre, Boston, Massachusetts, and colleagues interviewed 661 patients and reviewed their medical records to establish how many adverse drug reactions (ADRs) the patients experienced over a three-month period. Where adverse reactions relating to prescribed medicines were identified, the researchers also questioned the patients' doctors to find out how the events were dealt with.

The researchers found that although many patients experienced ADRs (179 patients identified 286 medicine-related symptoms), they failed to report 31 per cent of them to their doctors. This failure to discuss medicine-related symptoms resulted in 21 adverse reactions (23 per cent) — 19 of which could have been ameliorated and two of which could have been prevented.

Doctors made changes to patients' therapies in response to 76 per cent of reported symptoms. However, their decision not to change therapy in 48 cases resulted in 31 adverse reactions (65 per cent).

"For every symptom that patients experienced but failed to report, one in five resulted in an adverse drug event that could have been prevented or been made less severe," Dr Weingart commented. "For every symptom that patients did report but doctors failed to act on, two thirds resulted in an adverse drug event," he continued.

The researchers observed that patients discussed fatigue, gastrointestinal problems, sexual problems and mood changes more often than headache and incontinence.

In addition, patients who took multiple medicines and who had drug-related allergies were more likely to discuss symptoms with their doctor.

Doctors were more likely to make changes to patients' therapy if they reported muscular aches, problems with sleep, gastrointestinal



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## Patients' comments about their medicines should be taken seriously

problems and rash or itching than if they reported fatigue and sexual problems.

"Patients have a lot to tell us about symptoms they experience due to their medications," Dr Weingart said, adding that by asking questions regularly and taking patients' comments seriously there is an opportunity to prevent harm. The study is published in *Archives of Internal Medicine* (2005;165:234).

# Suspected transmission of avian flu from person to person reported

The first documented case of probable human to human transmission of the avian influenza virus was reported this week (*New England Journal of Medicine* 2005;352:333).

Asian researchers describe the case of an 11-year-old girl in Vietnam who, after being exposed to dying chickens, became ill and died several days later. The child's mother, who lived in a different province, came to look after the child and also died after developing pneumonia but having had no known contact with poultry.

The girl's aunt who lived in the same house also developed pneumonia after looking after the child. The aunt had no contact with poultry for over two weeks. Autopsy tissue samples from the mother and nasopharyngeal throat swabs from the aunt were both positive for influenza A (H5N1), the avian flu virus. The researchers say that the women probably became ill from direct person to person transmission of avian flu after contact with the ill child.

However, because the disease was not transmitted to any other people who had been in contact with the family, the researchers say that the virus may not have adapted to efficient human spread. Furthermore, tests on the viral genes provided no evidence that the gene had mutated. The researchers warn that this should not trigger complacency, saying: "The person to person transmission of one of the most lethal human pathogens in the modern world

should serve as a reminder of the urgent need to prepare for a future influenza pandemic."

The avian flu virus has infected at least 47 people in Asia since last January, killing 34. No evidence of efficient person to person transmission has yet been reported (*PJ*, 22 January, p76).

**Research needs** Klaus Stohr, co-ordinator of the World Health Organization global influenza programme, outlined this week areas in which information is urgently needed in light of a threatening flu pandemic. These include case management and infection control, research on the immunogenicity of vaccines and the role of bird and animal species in the epidemiology of these viruses (*New England Journal of Medicine* 2005;352:405).

# Heart failure treatment sub-optimal in primary care

Many GPs are failing to diagnose and treat heart failure effectively, a UK survey has revealed. It also showed that public awareness of heart failure symptoms is low.

The survey, conducted on behalf of SHAPE (study group on heart failure awareness and perception in Europe), an industry-sponsored organisation, shows that as many as two thirds of GPs are prescribing sub-optimal heart failure treatment.

In particular, it revealed that only 22 per cent of GPs prescribe an angiotensin-converting enzyme inhibitor alone as first-line therapy, a strategy recommended by the

National Institute for Clinical Excellence and the Scottish Intercollegiate Guidelines Network. NICE guidance also recommends adding a beta-blocker to improve survival rates. The survey indicates that 24 per cent of GPs do not follow this advice.

Awareness of the symptoms of heart failure was low among the 879 members of the public who were questioned as part of the survey. Although 93 per cent had heard of the disease, only 2 per cent could identify its signs and symptoms.

The survey involved interviews with 372 GPs and 610 specialists.

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### Law and ethics bulletin

The bulletin is available online, from 2001. Bulletins are listed in date, keyword and subject order, including community and hospital pharmacy. [www.pjonline.com/lawandethics](http://www.pjonline.com/lawandethics)

### Reunions

Details of academic, company and other reunions are available online. Details of future reunions can be e-mailed to [reunions@pharmj.org.uk](mailto:reunions@pharmj.org.uk) [www.pjonline.com/reunions](http://www.pjonline.com/reunions)

# Pharmacy NHS fraud reporting scheme is hailed a great success

Over 1,000 pharmacists have reported fraudulent prescriptions to the NHS Counter Fraud and Security Management Service (CFSMS) since the scheme was revised in February 2003.

The achievement has been marked this week by the presentation of a reward to the pharmacist who made the 1,000th report: Tracy Ellam of Rowlands Pharmacy in South Elmsall, West Yorkshire. Ms Ellam identified a stolen prescription in October and contacted the police immediately. The offender was arrested and four unused stolen prescription forms were found in his pockets.

David Grey, acting head of the CFSMS compliance unit, said: "A total of 1,000 rewards highlights the commitment shown by pharmacists in tackling fraud throughout England and Wales. We now want to push on, and present even more rewards to pharmacists during 2005."

Pharmacists can claim a £70 reward if they:

- Withhold a fraudulent prescription, notify the local primary care trust (PCT) and police immediately, and contact the CFSMS within seven days



Tracy Ellam receives her award from David Grey

- Report a prescription that has been dispensed but later suspected to be fraudulent to the police, local PCT and CFSMS within 14 days of the incident
- Provide valuable information to any investigation

Sue Sharpe, chief executive of the Pharmaceutical Services Negotiating Committee, commented: "[This week's] announcement proves how worthwhile the pharmacy reward scheme has become. Every year the NHS is seeing record reductions in prescription fraud. This is not only due to the overall approach taken by the CFSMS but to the support given by pharmacists around the country."

## Call for end to prescribing variations for cancer drugs

The All-Party Public Accounts Committee has recommended that a deadline be set for ending the current wide variations in prescribing of anti-cancer drugs, such as trastuzumab (Herceptin).

Their inquiry into regional inequalities in cancer mortality rates found that such drugs, which can roughly double the survival time for women with advanced breast cancer, were prescribed less often in deprived parts of the north of England. Local NHS cancer networks reported that "uneven availability is not due to problems in getting funding for drug purchases, but rather to lack of specialist staff and unsuitable pharmacy accommodation, and variations in clinical practice in the prescribing of approved drugs, leading to local variations in the implementation of National Institute for Clinical Excellence guidelines."

The PAC concluded: "The recommendations of the national cancer director regarding resources, clinical practices and enhancements in NICE guidance should be implemented speedily, with a clear timetable for monitoring their impact and reviews of progress."

## The Society

### Student day at BPC 2005

A special day rate of £5 plus VAT is being made available for final-year pharmacy students and preregistration trainees who wish to attend the third day of this year's British Pharmaceutical Conference (Wednesday 28 September), when there will be a special session for students and trainees (p127).

## Workforce planning

The Scottish Parliament Health Committee this week published a report that examines workforce planning in the NHS in Scotland. The document largely concentrates on doctors and nurses. However, pharmacy workforce planning is due to be examined in more detail separately as part of the implementation of The Right Medicine. The Health Committee report can be accessed via *PJ Online* ([www.pjonline.com/links/pj](http://www.pjonline.com/links/pj)).

## Abolition of prescription charges

A Bill that proposes the abolition of NHS prescription charges in Scotland was introduced in the Scottish Parliament on 20 January. Introduced as a member's Bill by Colin Fox MSP, it will now be considered by Parliament and can be accessed via *PJ Online*.

## Super surgeries with pharmacy services open in Yorkshire



Tricia Kennerley, chief services officer for Moss Pharmacy, which is providing pharmacy services at the Worsbrough centre, talks to John Hutton at the launch

The first one-stop primary care centres outside London, funded by the NHS Local Improvement Finance Trust, were opened last week in Yorkshire.

The surgeries at Worsbrough and Goldthorpe were launched by health minister

John Hutton and will offer a range of health care services. As well as pharmacy services, the centres will provide services traditionally available only in hospitals, such as blood tests, ultra sound scans and minor surgery.

A third centre was opened in Thurnscoe.