

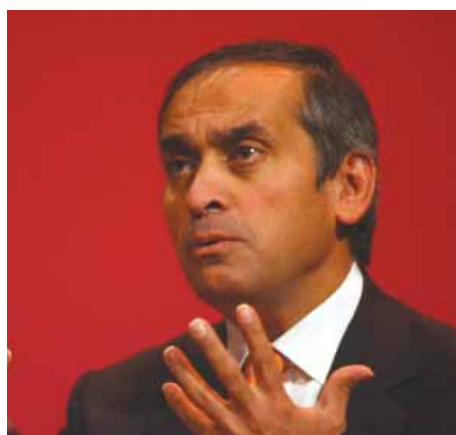
# Innovation needs a new approach

A new approach to innovation in the NHS is needed to enable pharmacy to provide the range of clinical services to which it aspires, according to organisations that represent community pharmacy owners.

In their joint response to the Department of Health's call for policy ideas on how to drive innovation in the NHS (part of the Lord Darzi review), the National Pharmacy Association, the Company Chemists' Association and the Pharmaceutical Services Negotiating Committee highlight two challenges. These are: changing the culture of the NHS, especially around commissioning, to reward and support informed risk taking; and removing professional politics from the commissioning process and creating a more level playing field for new and existing providers.

They identify a number of barriers (see Panel) and propose several policies that they believe would go some way to addressing these, including the introduction of a provider-incentive scheme that builds on the principles of benefit sharing inherent in practice-based commissioning and a new commissioning model that engages everyone as equal partners in service redesign.

The organisations also suggest that commissioners should map the areas in which they are seeking proposals for service reconfiguration, specifying any appropriate quality



Paul Grover/Reax Features

## Lord Darzi is seeking ideas on how policy can drive innovation in the NHS

standards that need to be met and the likely length of contract on offer.

The response also suggests ways in which risk and investment in innovation can be shared, including offering first wave providers guarantees about length of contracts following successful pilot implementation.

Commenting on the consultation, Georgina Craig, commissioning policy lead at the CCA, said: "We welcome the department's focus on driving innovation; it can only be a good thing for community pharmacy. Commissioning pharmacy services is an innovation in itself. We may be existing providers, but in the context of many of the services we aspire to provide, we are new market entrants."

**Access critical services** In its main submission to the Darzi review, the NPA details two proposals for maintaining access-critical services within a well designed hub-and-spoke model of provision. The first is a national minor ailment scheme. The second is that when consulting on relocation of care, for example to polyclinics, primary care trusts should include a neighbourhood access analysis and consider the potential for expanding community pharmacy-based services.

# MPs back pharmacist role in screening

Pharmacists should be involved in the Government's plans to expand screening services, Howard Stoaie (Lab, Dartford) said in a House of Commons debate on preventive health services last week.

The debate followed the announcement by Prime Minister Gordon Brown of an increased focus on screening in the NHS (*PJ*, 5/12 January, p4). Dr Stoaie, who is also chairman of the All-Party Pharmacy Group, said he envisaged pharmacists becoming far more involved in screening.

"They can take blood pressure and cholesterol measurements, recall people for follow-up as necessary, and work with local GPs and others to ensure that that capacity is best used," he said. "As part of the launch of the pharmacy White Paper, I urge [health minister Dawn Primarolo] to include pharmacy as much as possible in the new screening programme."

He also spoke about pharmacy being an untapped resource. "Pharmacies are already open for the extended hours that the Government wants primary care to be available, and they already provide out-of-hours services," he said.

"I believe that, with the right negotiations with the Royal Pharmaceutical Society, the Pharmaceutical Services Negotiating Committee and others, a good deal could be reached to ensure that pharmacists' expertise and capacity are fully utilised for the benefit of patients."

Ms Primarolo supported Dr Stoaie on this point. "I entirely agree with [Dr Stoaie] about pharmacies," she said. "They are a great untapped resource which will expand access in the NHS and ensure that we all get the appropriate treatment at the right time, and that we are able to be involved in and control our own health and well-being and to understand much more about the causes of ill health and therefore how we, as individuals, have a role to play in preventing it."

## Barriers

The barriers to innovation identified are:

- Lack of access to data to help providers quantify the investment opportunity service redesign represents
- Lack of certainty around commissioning and contracting, making investment decisions risky
- Persistence of an uneven playing field for providers, including within practice-based commissioning
- Lack of incentives to foster collaboration between existing and new providers

# NPA seeks second chief in a year following White's abrupt departure

Alison White has stepped down as chief executive of the National Pharmacy Association, the NPA confirmed this week.

Dilip Joshi, NPA chairman, said: "We wish Alison all the very best for the future. The NPA is a solid organisation and I have no doubt that the team at the NPA will continue to deliver exceptional service to members."

Neal Patel, the NPA's head of communications, would not reveal whether Ms White had resigned or whether she had been dismissed, but said: "The NPA's board of management will provide strategic direction and the executive team will deliver against the board's wishes."

Mr Patel added that discussions had started about Ms White's replacement but said that, for the time being, the NPA would be concentrating on delivering its business plan for the next year.

"There is a huge agenda for pharmacy, including the forthcoming White Paper," he said, "The NPA's team will be getting stuck into that and delivering on what our members want us to do."

Ms White was appointed NPA chief executive in June last year (*PJ*, 30 June 2007, p758). She was the first non-pharmacist to lead the NPA. Ms White was previously interim CEO at Business Link London.



Alison White

# PSNC wants pharmacy to be main provider for minor ailment care

Pharmacy should be the provider of choice for patients with minor ailments and those requiring certain community-based health-care services, such as screening and monitoring of long-term conditions, the Pharmaceutical Services Negotiating Committee believes.

This vision forms the basis for the PSNC's three-year plan, which was formally adopted at its January committee meeting held in London last week. "The plan has been designed to fit with existing Government policy to enable the primary care sector to take on much more work from secondary care by using community pharmacy to both release existing capacity and build new capacity

within the existing system," the PSNC stated. A one-year plan for 2008–09 was also adopted. The five main areas the PSNC will be focusing on are pharmacy planning, the future service framework, service development, service funding and Government policy.

□ **LPC constitution** The PSNC plans to introduce a new model constitution for local pharmaceutical committees (LPCs) after considering responses from LPCs to a recent PSNC consultation. "The new model constitution [which will be drafted and shared with LPCs in the near future] is intended to be used as a guide for LPCs to adopt or change according to local circumstances," the PSNC stated.

## Society calls on pharmacy schools to host PhD awards

Pharmacy schools in the UK are being encouraged by the Royal Pharmaceutical Society to submit applications to host the 2009 Academic Excellence Awards, which allow pharmacy graduates to undertake a PhD.

The Society wants all fully accredited schools of pharmacy to apply to host one of the two awards offered. The successful schools will be responsible for the selection of students and their supervision.

Jeremy Holmes, Chief Executive and Registrar of the Society, said: "The Academic Excellence Awards are a great opportunity for pharmacists to further their careers, and develop skills to play a leading role in the profession of pharmacy. It is also important in raising the academic standard of the profession."

Applications must be completed and submitted by 19 March 2008. Guidance notes and an application form can be found on the Society's website ([www.rpsgb.org](http://www.rpsgb.org)) and via *PJ Online* ([www.pjonline.com/pjlinks](http://www.pjonline.com/pjlinks)).

## GPs prescribe too many branded medicines

At least £200m a year is wasted on NHS medicines in England because GPs continue to prescribe too high a proportion of branded medicines rather than cheaper generic versions, the Public Accounts Committee reported this week.

The cross-party Commons watchdog found that one fifth of all GPs surveyed by the National Audit Office (*PJ*, 19 May 2007, p576) said that when prescribing drugs they are more influenced by pharmaceutical company marketing than by official NHS advice. Its inquiry accepted that there has been substantial increases in generic prescribing in recent years, but insisted there is scope for improvements.

PAC chairman Edward Leigh said: "The pharmaceutical industry spends £850m each year on marketing its products to GPs. It's hard to doubt that the blandishments of the industry are having an effect. GPs must concentrate more on following official guidelines, increasing the prescribing of generic drugs where clinically appropriate."

Mr Leigh (Con, Gainsborough) also pointed to the £100m-plus annual cost to the NHS of unused and wasted drugs and said the Department of Health must do more to investigate this. "Given that nearly 90 per cent of prescription items are dispensed free and the rest for a standard charge, the department should start by making it clear on the packaging just how much the medicines in question actually cost," he added.

The committee found that around a quarter of all primary care spending is on drugs and both the volume prescribed and their costs are rising. "Efficient management by the DoH and NHS bodies can, however, make the drugs bill more affordable without affecting patient care," the report says. "There are a number of examples of good practice where



Medicines are prescribed generically in 82 per cent of cases, says the APBI

progress has been made: for example, by supporting GPs to switch patients' medication to lower cost generic forms where appropriate, by working with local opinion-leaders to promote better prescribing, and by using benchmarking data to help GPs peer-review their prescribing practices."

The committee urged action to tackle variations in prescribing between primary care trusts. Ministers are expected to respond to the report in the next two months.

Commenting on the report, the Association of the British Pharmaceutical Industry argued that new, innovative medicines are under-used by the NHS. "The UK lags behind the rest of Europe in the uptake of modern medicines and, if companies did not provide relevant, ethical information to doctors about them, the problem would be worse still." The assertion that NHS doctors prescribe too many branded medicines is contradicted by the fact that 82 per cent of all prescriptions are written generically, it added.

"Would any other industry be expected to spend an average of £500m on developing a new product and then be criticised for telling people about it," asked Richard Barker, director general of the ABPI.

### In brief

#### EPS update

Up to 24 per cent of prescriptions are now prescribed via the electronic prescription service in England but less than 1 per cent are being dispensed using the service, reports the Pharmaceutical Services Negotiating Committee. Live testing of release 2 of the EPS is yet to start because of delays in system software development and accreditation. The PSNC intends to conduct a telephone survey of contractors shortly to gather information about experiences of using the service.

#### MUR uptake increasing

Uptake of medicines use reviews is increasing. In a statement issued this week, the Pharmaceutical Services Negotiating Committee cited updated statistics from the NHS Prescription Pricing Division showing that in October 2007, the number of completed MURs in England was 84,000.

#### Virgin enters health arena

Virgin Group is to open the first of six healthcare centres this year under a new brand — Virgin Healthcare. The company says that the new centres could include a pharmacy and will incorporate NHS GPs, working under existing primary care trust contracts, as well as a range of other services depending on local needs.

# Pharmacist should almost always be on premises

Pharmacies should have a pharmacist present for the vast majority of the time they are open and this should be specified in the responsible pharmacist regulations, according to the National Pharmacy Association response to the Government's consultation on the subject, which closes this week.

The NPA also believes that there should be no extra qualifications needed to become a responsible pharmacist and that no minimum period in practice should be required.

Colette McCreedy, director of pharmacy practice at the NPA, told *The Journal* that it is difficult to separate the responsible pharmacist arrangements from those on supervision, which are due to be consulted on shortly. But, she said, the NPA will make strong representations during both consultations that there should be a pharmacist on the premises for the vast majority of the time that it is open to the public. "That regulation could be met by a pharmacist who is not the responsible pharmacist," she added.

She believes that, in order to provide the services that the public now expect, particularly following clinical developments such as



**Colette McCreedy: no additional experience or qualifications necessary**

ambitious POM to P switches, a pharmacist will need to be present.

The NPA also believes that there should be no additional qualifications and experience required to practise as a responsible pharmacist. "It should be entrenched in the code of ethics that pharmacists do not under-

take tasks that they are not competent to do. Prescribing is the only thing that should be annotated in the Register and require extra qualifications." She added that to introduce any extra qualifications would cause disparity between UK and other EU pharmacists.

Provided the responsible pharmacist requirements are implemented in the way that Mrs McCreedy described, she believes that it will be a positive thing for the profession, strengthening pharmacists' focus on the safe and effective running of pharmacies and giving the necessary flexibility for selling general sale list medicines.

□ **PSNC view** The Pharmaceutical Services Negotiating Committee does not believe it is possible to reach any conclusion about the absence of the responsible pharmacist from the pharmacy without consideration of the framework for supervising supplies of medicines. It considered this and other provisions to be included in the proposed regulations at its January committee meeting. A response is being prepared, which will be available on the PSNC website ([www.psn.org](http://www.psn.org)) in the resources section by 20 January.

## Concept of responsible pharmacist is flawed and too prescriptive

The responsible pharmacist concept is flawed and unnecessarily prescriptive and criminalising, according to Noel Baumber, a non-executive director of the Independent Pharmacy Federation. In his opinion "the cure is worse than the disease".

In response to the Government's consultation on the responsible pharmacist regulations, which closes this week, Mr Baumber said that the concept should not be considered on its own but in the light of new roles, educational requirements, supervision, skill

mix, the responsibility of superintendents and what happens to the non-responsible pharmacist.

He told *The Journal*: "It is a charter for the multiples to reduce their responsibility for proper staffing levels both in ordinary and 100-hour pharmacies."

Mr Baumber argued that the only way to provide sustained and improved quality of service while safeguarding legal liability is to use more part-time locums or additional full-time pharmacists.

Mr Baumber is also concerned that locum pharmacists will be asked to sign off procedures. "Locums as responsible pharmacists — especially those new to a pharmacy — are in no position to take immediate responsibility for a pharmacy and make an all inclusive judgement such as the one proposed.

"The person who signs such a document becomes even more exposed to litigation and criminalised by this legislation if something goes wrong when the dispenser is in charge of a pharmacy."

## PDA Union election results announced

The Pharmacists' Defence Association has announced results from its recent PDA Union elections.

Representatives for five membership groups, each with between three and 13 vacancies, depending on the size of the group, were appointed, along with six directly elected representatives. A number of vacancies were not filled and the successful candidates, who were all unopposed, are as follows:

- Primary care/specialist groups (three vacancies): Duncan Jenkins and Stephen Inns
- Locums (13 vacancies): Lindsey Gilpin, Bob Gartside and Randeep Tak
- Community pharmacists (seven vacancies): Richard Flynn, Dennis Mayers, Jahn Dad Khan and Edward Newell

- Hospital pharmacists (six vacancies): John Farwell, Rebecca Ellis and Joanne Harding
- Preregistration/student (four vacancies): Richard Thornton
- Directly elected representatives (six vacancies): John Murphy, Mark Pitt, Mark Koziol, Elizabeth Doran, Bharat Nathwani and Edward Newell

The PDA Union executive will comprise the six directly elected representatives and five representatives chosen from the membership groups (one from each group).

John Murphy, PDA director and one of the directly elected representatives, told *The Journal* that meetings would be held shortly to appoint officers and to get the union up and running before the PDA's annual conference on 27 April.

## PEC membership guide

Gaining professional executive committee (PEC) membership is the focus of a guide published jointly by national pharmacy bodies this week. The guide was developed in response to the new constitution and format for primary care trust PECs put in place last year (*PJ*, 7 April 2007, p387).

The roles and functions of the new PECs are defined in the guide along with their structure and format. Advice on selection of PEC members through role specifications is also included as well as competencies and guidance on interviews.

The guide is published by the National Pharmacy Association, the Association of Independent Multiple Pharmacies, the Company Chemists' Association, the Pharmaceutical Services Negotiating Committee and the Royal Pharmaceutical Society.

# Training of paediatric prescribers by pharmacists needs evaluating

Paediatric pharmacists are playing a significant role in teaching doctors about prescribing for children, but more needs to be done to evaluate the effectiveness of this training, according to an *Archives of Disease in Childhood* article published online (<http://adc.bmj.com/onlinefirst.dtl>, 11 January).

Researchers conducted a survey of paediatric healthcare professionals and a literature search. They found that centres were using a range of methods to teach paediatricians about prescribing, principally presentations by paediatric pharmacists, but also workbooks and practice questions.

However, the authors point out that no guidelines on what paediatric prescribers need to know or how they should be assessed are available and that no validated tool for assessing prescribing exists. "Evaluation and determination of the best teaching methods and competency assessments is needed, as is research to establish whether education does indeed reduce prescribing errors," the researchers say. "No centre could provide us with evidence that it does."

Sharon Conroy, lecturer in paediatric clinical pharmacy at the University of Nottingham and one of the authors of the paper, told *The Journal* that doctors provided positive feedback on the pharmacist presentations. "They saw it as a useful way of meeting the pharmacy team and finding out what pharmacists do," she said.

As well as giving presentations to junior doctors at their induction, she believes pharmacists should reinforce that advice a few weeks later and talk to junior doctors about their prescribing experiences so far.

Pharmacists should also stress the importance of accurate prescribing and the conse-



Ron Chapple Studios/Dreamstime.com

## Paediatric pharmacists should stress the importance of accurate prescribing

quences of mistakes in prescribing for children, she believes. They should use real-life examples, set out the ways in which prescribing for children needs to differ from approaches used for adults and explain how the BNF for Children works and why it is important.

She added: "Ensuring prescribing for children is appropriate requires a multidisciplinary approach. Paediatric pharmacists have a huge role to play. The Neonatal and Paediatric Pharmacists Group is very involved, but it needs to be a collaborative effort."

"You can't introduce national prescribing competency assessment standards without paediatricians on board and nursing staff would also need to be involved. They are the ones who are ultimately giving medicines to patients and are often the ones who pick up dosing errors."

# Statins suggested for all patients with diabetes

Statin therapy reduces the risk of major vascular events in a wide range of patients with diabetes, including those with no history of vascular disease, and the benefits are similar to those for people without diabetes, a recently published study reveals (*Lancet* 2007;371:117). The researchers say that all people with diabetes should be considered for statin therapy unless their risk of major vascular events is low (for example, type 1 diabetes in children).

Researchers conducted a meta-analysis of 14 trials involving 18,686 individuals with diabetes (mainly type 2) and 71,370 without diabetes.

During a mean follow-up of 4.3 years, there was a 9 per cent proportional reduction in all-cause mortality per mmol/L reduction in low-density lipoprotein cholesterol in participants with diabetes (rate ratio 0.91, 99 per cent confidence interval 0.82–1.01;  $P=0.02$ ). This was similar to the 13 per cent reduction seen in patients without diabetes (0.87, 0.82–0.92;  $P<0.0001$ ).

In all diabetic participants, statin therapy reduced the five-year incidence of major vascular events by 21 per cent per mmol/L reduction in LDL cholesterol, say the researchers. There were also reductions seen in myocardial infarction, coronary revascularisation and stroke in diabetic patients. Although most participants had type 2 diabetes, there was no evidence that the effects of statins on major vascular events in those with type 1 diabetes differed.

The authors say that the effect of statin therapy in those with diabetes was similar irrespective of various risk factors. They add that the benefits seemed to be linearly related to the absolute LDL cholesterol reduction, without any lower threshold, suggesting that guidelines which recommend titration of therapy to achieve a particular target may need to be reviewed.

# Etanercept works for paediatric psoriasis

Tumour necrosis factor inhibitor etanercept has been shown to reduce the severity of plaque psoriasis in children and adolescents with moderate to severe disease in a recently published study (*New England Journal of Medicine* 2008;358:241).

Researchers randomised 211 patients aged four to 17 years to receive weekly injections of etanercept (0.8mg/kg) or placebo for 12 weeks, followed by weekly open-label injections of etanercept for all subjects for 24 weeks. The researchers then randomised 138 of the patients to receive a further 12 weeks' treatment with either etanercept or placebo to observe the effects of withdrawal and retreatment.

At week 12, 57 per cent of etanercept-treated patients had achieved the primary endpoint for efficacy (at least 75 per cent improvement in psoriasis severity; PASI 75) compared with 11 per cent of patients on placebo ( $P<0.0001$ ).

After the 24 weeks of open-label etanercept, 68 per cent of patients from the initial treatment group and 65 per cent of patients who were formerly on placebo achieved PASI 75. The investigators observed a loss of response in 42 per cent of patients assigned to placebo for the final phase of the trial.

# Possible cardiac risks with calcium identified

Use of calcium supplements is associated with an increased likelihood of cardiovascular events for post-menopausal women, according to a study published online this week (*BMJ Online First*, 16 January, [www.bmj.com/onlinefirst\\_date.dtl](http://www.bmj.com/onlinefirst_date.dtl)).

The authors say that the study — a secondary analysis of a randomised trial of 1,471 women receiving calcium or placebo — does not provide definitive conclusions, but that the data "do flag cardiac health as an area of concern in relation to calcium use and mandate that this is assessed carefully in future studies of calcium supplementation".

Myocardial infarction was more commonly reported for women taking calcium (1g of elemental calcium per day) than those on placebo (45 versus 19 events;  $P=0.01$ ), and the composite endpoint of myocardial infarction, stroke or sudden death was also more likely in the treatment group (101 versus 54 events;  $P=0.008$ ). However, when the reported events were independently adjudicated and unreported events were added from hospital admission databases the findings lost significance.

The authors recommend that the potential for cardiac events be balanced against the likely benefits of calcium on bone in older women.

# Guidance on sexual boundaries launched by CHRE

Guidance on keeping appropriate sexual boundaries between healthcare professionals and patients has been published by the Council for Healthcare Regulatory Excellence.

It warns that any form of sexualised behaviour, including asking for, or accepting, a date or even accepting an invitation to a birthday party, could constitute professional misconduct.

The guidance, which is intended to be used by professional regulators as a basis for the production of profession-specific advice, sets out a series of questions that health professionals should ask themselves if they feel attracted in any way to a patient, or a patient shows any signs of attraction to them. Whatever the case, the guidance says that the professional should discuss the matter with a colleague and consider giving up responsibility for that patient's care.

Examples of sexualised behaviour that the guidance warns about include: revealing intimate details to a patient; giving or accepting social invitations; visiting patients unan-



Adam Gaulf/Science Photo Library

**Any form of sexualised behaviour could constitute professional misconduct**

nounced or without an appointment; seeing patients outside normal practice; clinically unnecessary communications.

The guidance also warns that a sexual relationship with a former patient will often be

inappropriate, no matter how much time has passed.

It lists five points that should be considered. They are:

- How much time has passed since the professional relationship ended
- Whether the professional relationship involved any imbalance of power
- Whether the former patient was, or is, vulnerable
- Whether advancing the sexual relationship involves any knowledge gained during the professional relationship
- Whether there is, or might be, a professional relationship with any of the former patient's family

"However consensual a relationship appears to be, if a complaint is made the onus will always be on the healthcare professional to show that they have acted professionally by considering [these points] in relation to the circumstances in question, and by seeking appropriate advice," the guidance states.

## Influenza vaccine orders in Scotland must be placed with three sources to maintain supply

Community pharmacists in Scotland must order influenza vaccines from at least three different sources, according to guidance published this week.

An NHS circular states that for the 2008–09 season: "It is for community pharmacists to satisfy themselves that the three sources of supply chosen are independent such that a technical manufacturing problem attributable to decisions made at one source of supply would be self contained within that source of supply and would not be linked to a systematic supply failure across all three sources."

Harry McQuillan, chief executive officer of Community Pharmacy Scotland, explained that one manufacturer might offer two sources if it manufactures two vaccines separately (ie, using different processes and in dif-

ferent countries). He also pointed out that some manufacturers produce vaccines for other suppliers.

The circular also states that the flat rate and risk minimisation fees paid previously are being merged into a single flu vaccine supply fee. Pharmacists who split their order between three suppliers will receive a supply fee of £1.10 per vaccine (the same total fee as last year), while pharmacists who fail to split their order will receive a lower rate of 75p per vaccine. An incentive fee to encourage pharmacists to seek value for money when purchasing vaccines is also being retained.

GPs are asked to inform community pharmacists of the volume of flu vaccine they require by 31 January. Pharmacists should then place orders by 28 February.

### In brief

#### CPP deadline extended

Community pharmacists in Scotland now have until 15 March to claim for phase 2 contract preparation payments (CPP). The original deadline has been extended because of delays in the distribution of the IT toolkit that must be completed to qualify for CPP, a recent NHS circular explains. The deadline for phase 3 payments (31 March) remains the same.

#### ETP leaflets

All pharmacies and GP surgeries in Scotland will receive NHS patient information leaflets about the electronic transfer of prescriptions this month. A recent NHS circular says the leaflets will be distributed in January and, from February, further supplies can be ordered from Banner Business Supplies.

#### eMAS update

Updated questions and answers about the minor ailment service in Scotland have been published on the Scottish community pharmacy contract website. Issues covered reflect the most frequent enquiries to the ePharmacy helpdesk, and include registration difficulties and prescribing guidance. See [www.communitypharmacy.scot.nhs.uk](http://www.communitypharmacy.scot.nhs.uk) for further details.

## Combination inhaler accepted for use within NHS Scotland

A new combination inhaler containing beclomethasone 100µg and formoterol 6µg has been accepted for use within NHS Scotland. Fostair was launched by Trinity-Chiesi Pharmaceuticals this week (see p47) and has been endorsed by the Scottish Medicines Consortium for the regular treatment of asthma where use of a combination inhaled corticosteroid and long-acting beta<sub>2</sub>-agonist is appropriate.

In its latest round of advice, the SMC also approved Pfizer's Xalacom (latanoprost/timolol) eyedrops for reduction of intraocular

pressure in patients with open angle glaucoma and ocular hypertension who are insufficiently responsive to topical beta-blockers or prostaglandin analogues.

The SMC has again rejected Grazax — a standardised allergen extract of grass pollen developed by ALK-Abelló. The product failed to gain approval for the treatment of grass pollen-induced rhinitis and conjunctivitis in adult patients. The SMC said that although modest clinical benefit has been shown, the manufacturer did not put forward a sufficiently robust economic case.

# Patient-controlled fentanyl device requires no needle

A needle-free, patient-controlled device for postoperative pain relief was launched in the UK this week (p47). Ionsys, a credit card-sized device that contains a gel-based reservoir of ionised fentanyl, is licensed for the management of moderate-to-severe postoperative pain.

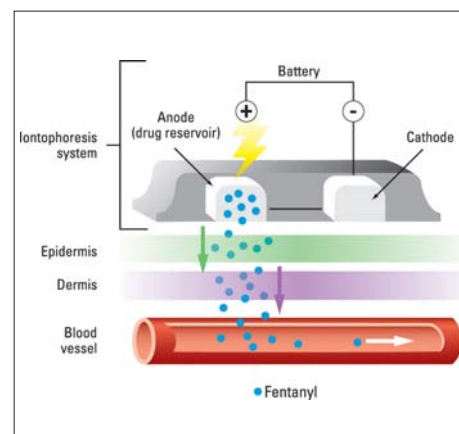
Stuck to the patient's arm or chest, the battery-operated device is activated by double pressing a button on its outer surface. Upon activation, an electrical circuit in the device is completed with the gel reservoir acting as the anode. This repels the positively charged fentanyl molecules from the reservoir and their high lipophilicity allows them to cross the skin and enter the bloodstream. Every time the device is activated, 40µg of fentanyl is delivered over 10 minutes.

Roger Knaggs, specialist pharmacist for anaesthesia and pain management at Nottingham University Hospitals NHS Trust, has been involved in phase III trials of the device. He suggested that while the device was unlikely to revolutionise the management of postoperative pain, it could prove beneficial

for some patients. "Unlike other options for postoperative pain relief, such as intravenous morphine in a PCA [patient-controlled analgesia] device, the skin is not punctured so there is no infection risk. Also, the patient's mobility is not restricted by attachment to an IV delivery device," he said.

Dr Knaggs also noted that during the trials, he had witnessed benefits to nursing staff as well as patients. "The device is easy to set up and there is no risk of error in administering the right dose, therefore from a risk-management perspective, it could prove highly valuable," he added.

However, he concluded that the current cost of the unit means that it is unlikely that any trusts will use Ionsys to replace morphine as the first-line choice for managing pain in all postoperative patients. "The unit only lasts for one day and must be replaced by a second unit if required for an additional day. Although most of the trial patients only used the device for one day anyway, this will still be considered by trusts when approving funding," he said.



How the Ionsys system works

For the device to deliver a drug effectively, the drug molecule must be charged and highly lipophilic and morphine is not sufficiently lipophilic to be delivered in this way. However, Dr Knaggs hypothesised that other lipophilic opioids such as alfentanil could also be delivered using this technology.

## New drug class for HIV patients with highly drug-resistant disease

People with HIV who have become resistant to existing antiretroviral medicines may be suitable for treatment with raltegravir, the first of a new class of antiretroviral medicines known as integrase inhibitors (see Panel).

Available from Merck Sharp and Dohme as Isentress, raltegravir is licensed for treatment of HIV-1 infection in treatment-experienced adult patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy. The drug should be used in combination with other antiretroviral medicines.

The usual dose of raltegravir is one 400mg film-coated tablet taken twice a day. Patients have taken raltegravir at any time in relation to food during clinical studies.

Brett Marett, principal pharmacist for HIV and sexual health, St Mary's Hospital, Imperial College Healthcare NHS Trust,

London, commented on behalf of the HIV Pharmacy Association: "This is a major step forward in the treatment of antiretroviral experienced patients with triple-class drug resistant HIV. It will help some patients achieve the previously unattainable treatment goal of becoming virologically undetectable. In the licensing trials it was generally well tolerated with a discontinuation rate comparable to

placebo plus optimised background regimen. It should ideally be used in combination with two other active agents for optimal response."

He said that funding for the medicine would be subject to it being prescribed according to HIV consortium guidance in London and to local funding arrangements elsewhere.

Notice-board p47

### Mechanism of action

Merck Sharp and Dohme describes the drug's mechanism of action as follows:

- Raltegravir is an integrase strand transfer inhibitor active against HIV-1. Raltegravir inhibits the catalytic activity of integrase, an HIV-encoded enzyme that is required for viral replication.
- Inhibition of integrase prevents the covalent insertion, or integration, of the HIV genome into the host cell genome. HIV genomes that fail to integrate cannot direct the production of new infectious viral particles.

## NICE should not assess cost-effectiveness for all new medicines, industry body believes

Uptake of innovative medicines will not be improved by assessing the cost-effectiveness of all medicines at launch, pharmaceutical industry representatives believe.

Responding to last week's Health Committee report (*PJ*, 5/12 January, p4), the Association of the British Pharmaceutical Industry argued that requiring the National Institute for Health and Clinical Excellence to assess all medicines at launch could hamper access to new medicines.

"British patients already have worse access to new medicines than others in Europe," said Richard Barker, director general of the ABPI. "Faster, 'quick and dirty' assessments of medicines against tougher cost-effectiveness hurdles will actually make this problem worse," he said.

The association welcomed the report's recommendations that NICE explores the use of broader definitions of value and makes

greater use of specialist advice. However, Dr Barker added: "While the report does contain many positives, patients will note that finally there is official acknowledgement of NICE's role as a 'rationing' body rather than an organisation designed to promote clinical excellence and to improve access to medicines for all NHS patients."

Both the ABPI and the NHS Confederation have welcomed the Health Committee recommendation that NICE focus on challenging ineffective patterns of care. David Stout, director of the NHS Confederation's primary care trust network, commented: "It is important that disinvestment becomes an increasing priority for NICE, and that older treatments are reviewed to ensure primary care trusts can provide the most cost-effective care to patients, as highlighted in our evidence to the committee. However, we must be careful not to over-estimate the scale of savings that could be made in the NHS."