

Pharmacy welcomes health and social care paper

Pharmacy organisations have broadly welcomed this week's Government White Paper on health and social care, which calls for an expansion of the role of pharmacists in primary care.

At the launch of "Our health, our care, our say — a new direction for community services", Health Secretary Patricia Hewitt said: "Over the next 10 years, I want to see 5 per cent of resources shifted from secondary to primary care, which will help to make primary and community services more responsive to people's needs."

In the introduction to the White Paper, Prime Minister Tony Blair says: "We can make better use of the skills and experience of those working in the NHS to improve care, cut delays and make services more convenient. We want, for example, to expand the role of practice nurses and local pharmacists."

The Company Chemists Association, the National Pharmacy Association, the Pharmaceutical Services Negotiating Committee and the Royal Pharmaceutical Society have all welcomed the main messages.

Sue Sharpe, chief executive of the PSNC, said that there has never been such a great opportunity for community pharmacy to develop its NHS role. However, she warned that it will be essential for pharmacy to work collaboratively with GP and nurse colleagues if the benefits described in the White Paper



are to be realised. It will also be important, she said, for the NHS to ensure that the future commissioning of NHS primary care services supports the developing use of pharmacy. "In poorer areas with perhaps the biggest health care needs, the potential gains from developing use of pharmacies, is enormous," she added.

John D'Arcy, chief executive of the NPA, commented: "The White Paper provides not just a vision of what needs to be done, but also a means of achievement. Community pharmacy is poised to make an enhanced

contribution to primary care — and has the potential to deliver on many of the White Paper's priorities. But, if it is to do so, the warm and welcome words of support from ministers must be translated into action."

The White Paper emphasises that partnership working and practice-based commissioning will be key to delivering the changes outlined, Gerald Alexander, Vice-President of the Society, said. "It is important that pharmacists are fully engaged with this process," he added. "In addition, the transfer of services from secondary to primary care will require pharmacists in both these areas to work together to ensure the smooth transition and development of services. I would encourage my pharmacist colleagues to embrace these new and exciting opportunities."

Georgina Craig, head of communications and partnership development at the CCA, commented: "Where expansion into a broader portfolio of primary care services is a good strategic fit with future plans, it will be exciting to see how pharmacy businesses respond to the new incentives. The opportunities are great; but it is also important for pharmacy to recognise that in the future, competition will come in many shapes and guises — and not just from neighbouring pharmacies."

Leading article p122
News feature p129

Pharmacists report a fifth of adverse drug reactions sent to MHRA

Nearly one in five adverse drug reaction reports sent to the Medicines and Healthcare products Regulatory Agency comes from a pharmacist.

The agency's annual report for 2004–05, published this week, says that community pharmacists submitted 5 per cent of yellow card ADR reports and hospital pharmacists 13 per cent. GPs submitted most reports (28 per cent) followed by hospital doctors (25 per cent).

The total number of ADR reports from health professionals was up 4.4 per cent on the previous year, largely due to an increase in

electronic reports received via the yellow card website (www.yellowcard.gov.uk).

The annual report also reveals that the MHRA assesses more centralised European medicines applications on behalf of the European Medicines Agency than any other national medicines regulator in the EU. The next most frequently appointed are the German, French and Swedish national regulators.

The MHRA is quick, too, achieving a mean assessment time of 37 days for new active substances. The annual report also reveals that the MHRA enforcement and intelli-

gence group is the largest such group in Europe.

Anthony Cox, pharmacovigilance pharmacist, West Midlands Centre for Adverse Drug Reaction Reporting, said: "A culture of pharmacist reporting of adverse drug reactions to the yellow card scheme appears to be developing. As a measurable footprint of pharmacists' involvement in patient care and public health, pharmacists should ensure that this performance continues to improve, especially given the increased opportunities for discovering adverse drug reactions in extended services and in prescribing roles."

Prescriptions rise by 4.5 per cent in England and Wales

Community pharmacies in England and Wales dispensed almost 675 million prescriptions in 2004–05 — a 4.5 per cent increase on the previous year, according to Government statistics released this week.

The statistics record the continuing rise of multiple pharmacy companies, with over half (54.1 per cent) of the 10,447 pharmacy contracts held with English primary care trusts or Welsh local health boards on 31 March 2005 now being held by multiples with at least five pharmacies. The equivalent figure a year ear-

lier was 53 per cent of 10,462 pharmacies. The average number of prescriptions dispensed per pharmacy last year was 5,384 per month. The lowest monthly average — 1,722 — was for Westminster PCT in London.

The bulletin records wide variations in the population per pharmacy, with Uttlesford PCT in Essex having only 96 pharmacies per million resident population, while Westminster PCT in London has 455. The average across England and Wales is 198 pharmacies per million people.

The Society

Violence in pharmacies

The Society's Practice Committee has welcomed moves by the NHS Security Management Service that should help to reduce violence against pharmacy staff in England (p149).

Society's dual role "a strength"

The Society's dual roles are a strength that confers political influence and the opportunity to help shape the profession, says the Vice-President (p150).

Half of Lipitor recalled in counterfeit scare was fake

Over 50 per cent of Lipitor (atorvastatin) packs recalled from pharmacies by Pfizer in a counterfeit scare last year were fake (*PJ*, 6 August 2005, p155).

This was revealed during a House of Commons debate on counterfeit medicines last week by Charles Walker (Con., Broxbourne).

Mr Walker said that a "Bermuda triangle" of medicine supply had been formed by parallel trade, counterfeits and online pharmacies. There were now 2,300 websites selling drugs directly to the consumer and the four most advertised drugs were Viagra (sildenafil), Adipex (phentermine), Xenical (orlistat) and Propecia (finasteride), he said.

"In the UK, internet pharmacies pose a growing threat to public health," he said. "They are largely unregulated. In the best case these illegal pharmacies are dispensing sugar and, in the worst case, poison."

Responding, health minister Jane Kennedy said that 103 cases involving internet sales of counterfeit medicines were currently being investigated by the Medicines and Healthcare products Regulatory Agency.

She said that the agency would "not hesitate in taking appropriate enforcement action" for illegal supply and pointed to 12 prosecutions since 2000.

Mrs Kennedy agreed that the counterfeit trade was increasingly being taken over by organised criminals who were "growing in enterprise and sophistication".

She said: "It is certainly true that some websites offering medicines belong to unscrupulous vendors . . . who sell unlicensed and prescription-only medicines and counterfeit drugs that are potentially harmful.

"That is particularly true of so-called lifestyle drugs — medicines aimed at male impotence, slimming products or hair loss products. We are keen to ensure that the public make informed choices about their health, and they need to be aware that products purchased in that way cannot be guaranteed for safety, quality or efficacy.

"Given the uncontrolled nature of the internet, and the fact that many sites will be based abroad, a key aim is to ensure that the public understand the risks of buying medicines from such sites and are warned against them."



Genuine Lipitor (above) was less than half of what was recovered from the legitimate supply chain

She said that the MHRA was targeting information and advice with respect to specific products, and liaised with other regulatory and enforcement agencies at home and abroad. It was leading a Europe-wide counterfeit Tamiflu surveillance project and recently seized 6,800 packets of the medicine in London with a retail value of over £1m.

Mrs Kennedy added that the legitimate supply chain in the UK was tightly controlled and internationally recognised as difficult to penetrate. She said that there was little evidence that parallel traders had been used to get counterfeit products into the UK.

News in brief

Keele accepts students this year

Keele University has been granted approval by the Royal Pharmaceutical Society to accept students onto its new MPharm course in September 2006. The university announced its plans for a new school of pharmacy, headed by Stephen Chapman, last year (*PJ*, 10 September 2005, p302). The university says it has been inundated by applications and is inviting potential students for interview. Full accreditation will be awarded when the first set of students graduate.

Animal rights extremists less active compared with 2004

Damage to company, personal and public property by animal rights extremists nearly halved last year compared with 2004, according to recent figures from the Association of the British Pharmaceutical Industry. Only 85 cases of damage were reported for 2005 compared with 177 in 2004. The number of abusive or threatening messages received by companies and their suppliers fell by two thirds, from 108 in 2004 to 36 in 2005. Despite the reduced number of incidents, there were more aggressive attacks.

New angina drug has unique mode of action

Ivabradine, a new drug that can be prescribed for patients with chronic stable angina who are intolerant of beta-blockers, was launched by Servier this week.

Ivabradine (Procoralan) has a unique mode of action. It selectively inhibits sinus node I_f channels, thereby reducing heart rate while maintaining cardiac contractility and atrioventricular conduction. Servier says that ivabradine is not associated with the most common side effects of beta-blockers, such as fatigue, low libido and cold extremities.

In trials, 14.5 per cent of patients experienced visual effects, consisting of transient light spots. All visual effects resolved, most during treatment (77.5 per cent).

The recommended starting dose of ivabradine is 5mg twice daily, which can be increased after three or four weeks to 7.5mg twice daily. If heart rate decreases persistently below 50 beats per minute at rest or if symptoms related to bradycardia occur, the dose should be titrated down to 2.5mg twice daily and treatment stopped if necessary.

Notice-board p131

European Medicines Agency reviews cases of liver injury associated with telithromycin

A preliminary review of cases of serious liver injury associated with telithromycin (Ketek) has led the European Medicines Agency to ask for warnings concerning liver disorders to be strengthened in product information.

Serious acute hepatitis, including liver failure, starting during or immediately after treatment with telithromycin, has been reported to, and assessed by, the EMEA. In most cases the reactions were reversible but some were fatal. Three particular cases of serious liver injury, one fatal, were recently

described in an article published online on 20 January in *Annals of Internal Medicine* (www.annals.org).

The EMEA will now conduct a full risk/benefit assessment of the product to determine whether further actions are warranted. In the meantime, it reminds prescribers that telithromycin should be used with caution in patients with liver impairment, and that patients should stop treatment and contact their doctors if signs and symptoms of liver disease develop.

Prescription charge overhaul for Scotland likely

Exemption categories for NHS prescription charges in Scotland are to be overhauled after consultation, although charges will remain in place.

This seems the most likely outcome now that a Bill that aimed to abolish prescription charges was defeated in the Scottish Parliament last week. On the same day, the Scottish Executive announced the start of a three-month consultation on prescription charge exemption categories (see Panel).

The Bill, which was put forward by Colin Fox MSP, was defeated by 77 votes to 40, with one abstention. The vote followed a heated debate in which health minister Andy Kerr said the Bill would rob the poor to give to the rich by diverting NHS resources from hospitals and staffing into free prescriptions for all.

"The alternative is set out in our consultation," he said. "It will consider whether exemptions for people on low incomes might be extended, how the medical exemption arrangements might be reformed to be fairer for all, whether exemptions should be extended to people in full-time education and training, and whether payment arrangements

for high users should be reformed." But Mr Fox hit back, saying that the Executive showed disdain for the Parliament by waiting until just three hours before the debate to an-

nounce the consultation when the Bill had been before Parliament for two years. Despite gaining support for this protest, the Bill was defeated.

Consultation on possible reforms

Views are being sought by the Scottish Executive on a number of issues:

- On chronic conditions, it asks whether exemptions should continue to be given on medical grounds alone and, if so, whether the list of conditions needs amending. Another possibility is allowing the exemption to cover drugs related to the exempt condition, only, and not to all prescriptions for the patient. Alternatively, exemptions could be based on a list of drugs rather than a list of conditions.
- Possible changes to exemptions based on age include extending the student exemption to include those in tertiary education.
- Exemptions based on income are also discussed, along with pre-payment certificates. Suggested reforms include issuing retrospective pre-payment certificates once a certain number of charges have been paid, introducing a form of capping to the total charge that can be paid, or introducing a concessionary rate for patients requiring regular prescriptions.
- Another potential approach is introducing a lower flat fee that is payable by everyone except those exempt by age or low income.

Responses should be e-mailed to prescriptioncharges@scotland.gsi.gov.uk by 30 April. The consultation document can be accessed via a link on *PJ Online* (www.pjonline.com/links/pj).

Society presents evidence at inquiry into NHS charges in England

Abolition of NHS prescription charges in Wales next year could influence what happens to the system in England, the Royal Pharmaceutical Society predicted this week.

Rob Darracot, director of corporate and strategic development at the Society, said that what happens in Wales would provide some clues as to what might happen in England were that system to be followed.

His comments came ahead of the meeting of the House of Commons Health Committee on 2 February where he was due to give evidence to its inquiry into NHS charges, which includes prescription charges.

Mr Darracot welcomed the inquiry because reviewing charges, particularly prescription charges "has always been considered to be one of those things which is so difficult that nobody wants to go there. I also think it is interesting that the Health Committee has raised the subject in the first year of the new government. I think it has done that because



Rob Darracot: difficult issue

the issue is so difficult." The Society is one of 10 organisations, including the British Medical Association, the King's Fund and

patient charities, which were due to give evidence to the committee at its resumed inquiry this week.

The inquiry in England comes a year before prescription charges in Wales are due to be abolished following an earlier decision by the Welsh Assembly (*PJ*, 1 November 2003, p606).

Elsewhere in the UK, the Scottish Parliament has just launched an overhaul of exemptions of prescription charges, following the failure of a private member's bill that would have meant Scotland following Wales's lead and abolishing charges (above).

In Northern Ireland a spokeswoman for the department of health, social services and public safety confirmed it had no plans to change the current NHS charging system. She said: "We have been following the normal increases in prescription charges in line with the Department of Health in England. We have no plans to follow the Welsh proposal."

News feature p128

Wide regional variations in access to cancer drugs "unacceptable", says PAC report

Regional variations in the supply and prescription of approved cancer drugs have been dubbed "unacceptable" by the All-Party Public Accounts Committee.

The inquiry found, as an example, that between 12 and 18 months after approval by the National Institute for Clinical Excellence in early 2002, the use of trastuzumab (Herceptin) for metastatic breast cancer ranged across cancer networks

from 90 per cent to under 10 per cent of eligible women. The report entitled "The NHS cancer plan: a progress report", said: "While improvements have been made, unacceptably wide variations in usage of NICE approved cancer drugs persist [in] different parts of the country."

In 2004 the Department of Health looked at all 16 cancer drugs appraised by NICE and reported that regional variations were largely

due to staffing and capacity issues. Recommendations to promote the rapid uptake of cancer treatments recommended by NICE were accepted and are now in the course of being implemented.

The PAC report said: "The department believes that unacceptable variations should therefore be addressed while allowing some room for professional differences of approach."

LIFT programme continues to expand this year

One new surgery or health centre is due to open under the Local Improvement Finance Trust (LIFT) programme every week this year. Health minister Lord Warner has revealed that 60 new primary care LIFT developments are due to open during 2006 following an investment of £270m as the Government's multimillion pound initiative to redevelop primary care premises gains momentum.

He said: "The NHS has never witnessed such a sustained investment in GP surgeries and health centres. These are purpose-built facilities where GP services are often on the same site as pharmacies and social services, and are not simply like-for-like replacements."

The Government has already invested £700m in 54 LIFT projects that have either created brand new premises or brought improvements to existing sites. Many of the projects have created one-stop shops for health care, bringing together different health professions under the same roof.

Community pharmacist Neil Farrimond is manager at the Manor Pharmacy, which is part of Worsley Mesnes Health Centre in Wigan, built under LIFT and opened last June. He said the development had brought together a range of different health care professionals as well as providing shared learning resources, including teaching rooms on the same site.

He said: "There is better liaison between the different professionals. If I have a query about a prescription I can easily approach the GP about the problem."

"I think it will also make it easier for us to provide services under the new contract like smoking cessation because patients are presenting all the time and they don't have to face a half mile walk down the road to see you."

The National Pharmacy Association, however, continues to have some reservations about the initiative. Tonia Morton, the NPA's NHS development manager for the

Midlands, East and North England, said there were concerns that the developments can take pharmacy business away from other local pharmacists.

She pointed out that consultation about the scheme was not always as "thorough" as it could be. Centralising GP services can also sometimes reduce patient access to services, she added.

She said: "Primary care trusts and local authorities could ensure that frequently used primary care services — such as the management of minor ailments and monitoring of long-term conditions — can continue to be provided from the high street and close to patients, by commissioning such services via the community pharmacy network."

A hub and spoke model of provision, with the LIFT centre as the hub and the local community pharmacy network as the spokes, may be appropriate in many areas, particularly rural ones, she added.

News in brief

NHS reform manual launched

A manual to help guide the NHS in England through its present reform process was launched by the Department of Health last week. "The operating framework for 2006/7" sets out priorities and expectations for progress on reform, as well as rules on financial management. It is available from the DoH website (www.doh.gov.uk) and via *PJ Online* (www.pjonline.com/links/pj).

PBC guidance published

Further guidance on practice-based commissioning has been published by the Department of Health. The guidance sets out how universal coverage of practice-based commissioning will be achieved by 31 December 2006. It is available from the DoH website (www.doh.gov.uk) and via *PJ Online* (www.pjonline.com/links/pj).

"Know about pneumo" campaign launched



Postcards will be available from selected pharmacies

A campaign to raise awareness of pneumococcal disease has been launched by the British Lung Foundation, Help the Aged and the Meningitis Research Foundation this month.

The campaign aims to advise people at risk about the conditions and potentially

lethal complications associated with pneumococcal infection. As part of the "Know about pneumo" campaign, postcards containing information about the disease will be available in selected pharmacies.

The campaign is supported by an educational grant from Sanofi Pasteur MSD.

Uptake of supplementary prescribing grants slow in Scotland

More supplementary prescribers in Scotland should make use of the grants and payments available to them, the Scottish Pharmaceutical General Council has said.

"To date the uptake of this money has been slow in relation to the number of qualified supplementary prescribers," the Scottish Pharmaceutical General Council said. "This is new money that the SPGC has negotiated for

community pharmacy. It would therefore be helpful if as many pharmacists as possible made use of the money before the end of the fiscal year."

NHS circular PCA(P)(2005) 13 gives details of how supplementary prescribers can access a grant of £500 towards setting up clinics and a payment of £150 per day for the running costs, it added.

PJ Online

Access to *PJ Online* is free to all

Reprints and photocopies

Reprints and photocopies of articles from *PJ* publications are available, subject to payment of a fee. www.pjonline.com/about

Checklists

This section offers checklists, fact sheets, advice to patients and dietary advice tips. www.pjonline.com/tips

Novo Nordisk to withdraw animal insulin products

Novo Nordisk has announced that it is withdrawing its animal insulin products from the UK market in response to dwindling demand.

The decision comes after the company held off its plans to do so last year (*PJ* 1 October 2005, p401). However, animal insulin products will remain available from Novo Nordisk until December 2007. The move away from animal insulins is financially motivated, with the company citing a 20 per cent decline in demand over the past year. With that in mind, the company is expecting to fund further research into diabetes care.

Viggo Birch, managing director of Novo Nordisk, said: "We have been in discussions with the Department of Health, Diabetes UK and diabetes specialists across the UK. This announcement is part of our commitment to provide adequate warning of the discontinuation, so as to ensure that the few patients still on Novo Nordisk's animal insulin in the UK are transferred to suitable alternative insulins."

The decision has been made despite health minister Jane Kennedy saying last year that the animal insulins should remain available. She confirmed that the Department of Health fully recognised animal insulin better suited some people.

Patients affected by the change will be able to obtain alternative animal insulin



Animal insulins are still used by some patients with diabetes

products from Wockhardt UK. Gordon Urquhart, head of regulatory and drug safety at Wockhardt UK said that the company has been committed to providing naturally derived porcine and bovine insulins for many years.

He said: "We have always recognised the medical needs and preferences of each individual person with diabetes and believe in maintaining freedom of choice for those needing insulin. We have no plans to discontinue any of our [animal] insulin range."

Bill Hartnett, speaking on behalf of Diabetes UK, said that the decision by Novo Nordisk was disappointing. "It is important that Novo Nordisk and the Department of Health, as well as any health professionals working with these patients, ensure that the transition is dealt with effectively, and that people are not left on the fringes with their diabetes less well managed. There needs to be a genuine dialogue between doctors and patients to make sure that the concerns of patients — particularly those who may have significant problems transferring from their current choice of insulin — are taken on board."

□ **Inhaled insulin** The first inhaled human insulin, Exubera (developed as a joint venture between Aventis and Pfizer), has been granted marketing authorisation by the European Commission, on the recommendation of the European Medicines Agency.

This allows production of the dry powder insulin formulation and its inhaler device to commence. The product represents a new treatment option for certain patients with type 1 diabetes or with type 2 diabetes requiring insulin.

Pfizer will be launching an education and support programme in the coming weeks, and Exubera is expected to become available in the UK in May this year.

Antiplatelet bleeds assessed

Aspirin does not increase the risk of recurring intracerebral haemorrhage (ICH) in some patients, according to a study published in *Neurology* (2006;66:206).

Researchers in the US followed 207 survivors of ICH and recorded the use of antiplatelet drugs — mostly aspirin — and the outcome of recurrent ICH. The results indicate that use of antiplatelet therapy is not associated with a substantially increased risk of either lobar or deep ICH (the two different types of ICH).

Patients who have had ICH may also be at risk of ischaemic cardiovascular events, and clinicians need to assess whether antiplatelet treatment is more clinically important than the risk of recurrent haemorrhage. Accordingly, because the antiplatelet treatment group was not randomly assigned, the results of the study need to be applied with caution. Indeed, treating physicians may have appropriately avoided prescribing antiplatelets based on their perceived higher risk of bleed.

Because only one patient was taking a non-aspirin antiplatelet agent, the data can only provide insight into aspirin-treated patients and cannot be extended to combination antiplatelet therapy.

An editorial commenting on the study advises that, in this setting, antiplatelet drugs be used in "highly selected patients with a compelling indication and with a relatively low risk of recurrent bleeding" (*ibid*, p162).

Blood glucose control worse in South Asians

Blood glucose levels in South Asian patients with diabetes are more poorly controlled than in white patients, a study of 1,767 patients has found.

The research, published last month in *Diabetic Medicine* (2006;23:94), showed that average HbA_{1c} levels for South Asians and white patients were similar at diagnosis — 7.43 per cent and 7.27 per cent, respectively ($P=0.221$). But five years later, average HbA_{1c} levels were higher in South Asian patients — 8.74 per cent compared with 8.09 per cent in white patients ($P<0.001$).

South Asians also showed smaller improvements in blood pressure and cholesterol levels ($P<0.001$ and $P=0.044$) and a smaller proportion were prescribed angiotensin-

converting enzyme inhibitors ($P<0.0001$) and angiotensin receptor antagonists and beta-blockers ($P=0.041$).

Pharmacist Alia Gilani, who runs a medicines review clinic in a mosque, commented: "Health care services need to be conducted in a culturally sensitive way as culture has a huge impact on the management of diabetes, in terms of therapy, concordance and exercise."

"Management of diabetes needs to be tackled aggressively in South Asian patients and innovative health care services need to be set up to do this — we need to take services to patients in community settings in order to catch those who slip through the net and tackle the at-risk group of patients."

COX-2 inhibitor drugs may reduce the risk of breast cancer

Women taking selective cyclo-oxygenase 2 (COX-2) inhibitor drugs on a daily basis for two or more years are at reduced risk of breast cancer, according to a case control study partly funded by Pfizer (*BMC Cancer* 2006;6:27).

A risk factor questionnaire was used to assess 323 women with breast cancer alongside 649 cancer-free controls.

The authors found significant risk reductions for selective COX-2 inhibitors as a

group (odds ratio 0.29, 95 per cent confidence interval 0.14–0.59) and suggested COX-2 over-expression and up-regulation of the prostaglandin cascade as possible targets for the agents in breast cancer cells.

A significant reduction in breast cancer risk was also seen for women taking two or more doses per week of aspirin (OR 0.49, 95 per cent CI 0.26–0.95) and ibuprofen or naproxen (OR 0.37, 95 per cent CI 0.18–0.72).