

Royal Pharmaceutical Society of Great Britain to split

The Royal Pharmaceutical Society is to split and regulation of the profession will be carried out by a new General Pharmaceutical Council. A royal college-style model is proposed to take on leadership of the profession and the chief pharmaceutical officers of Britain hope that the Society will take this opportunity to transform itself into this professional and clinical leadership body.

The plans were revealed in the Government's White Paper on the regulation of health professionals, presented to Parliament this week. The White Paper sets out landmark proposals for the reform of the regulation of health professionals in the UK and is based on extensive consultation on the chief medical officer's review of medical regulation and the accompanying Foster review of the non-medical health professions.

Hailing the announcement as a historic moment for the profession of pharmacy, Keith Ridge, chief pharmaceutical officer for England, said at a briefing: "I am delighted that the Government has decided to help the profession to establish a royal college alongside a new regulator. Pharmacy needs to embrace this opportunity. It is a good package — a GPC specific for pharmacy, a royal college specific for pharmacy. That type of opportunity does not come along often."

"It is about making regulators fit for the 21st century," added Bill Scott, chief pharmaceutical officer for Scotland.

Explaining the motives behind the decision, the White Paper states: "As the profession takes on an increasingly clinically important and professionally demanding role in the treatment of patients, whereby pharmacists have autonomy to prescribe potent drugs, the Government believes that [the Society's] dual responsibility [as regulator and professional leader] is no longer sustainable if the public are to be reassured that there is effective independent regulation of this role. The RPSGB needs to separate its regulatory system from its system of professional and

Government expectations

General Pharmaceutical Council

- It will be responsible for the regulation of pharmacists, pharmacy technicians, and for the registration of pharmacy premises.
- It will also exercise the role of the current pharmacy inspectorate.
- As a minimum, it will have parity of membership between professional and lay members.
- Members of the GPC will be appointed, not elected.

Society/royal college-type body

- It will have significantly enhanced leadership.
- It will be a learned and authoritative organisation, supporting excellence, professionalism, and innovation in the science and practice of pharmacy.
- It should have an important role in revalidation arrangements and contribute expertise to the new GPC.
- There is an expectation that there will be lay involvement in the royal college-type body but the details are yet to be determined.

clinical leadership, allowing each distinct function to focus solely on its core role."

The Department of Health has set up a working party, chaired by Lord Carter of Coles, a life peer with experience in health care, to work collaboratively with the pharmacy profession to agree an implementation plan. The working party includes the chief pharmaceutical officers for England, Scotland, Wales and Northern Ireland, as well as representatives from the Society's current Council, the Pharmaceutical Society of Northern Ireland and other pharmacists.

In terms of the structure of the royal college-type body, Carwen Wynne Howells, chief pharmaceutical adviser for Wales, said:

"What we are doing is giving the profession the opportunity almost to start with a blank sheet of paper. There are a variety of models that could be used and it is within the remit of the working party to explore the different options to determine what is the best way forward for the profession."

Mr Scott added that he believes the royal college model provides an opportunity for an umbrella organisation to bring together the many different pharmacy organisations, particularly those catering for specialists within the profession.

Commenting on the announcement, Hemant Patel, President of the Royal Pharmaceutical Society, said: "The transition to a General Pharmaceutical Council and the possible establishment of a body akin to a royal college must be properly managed and resourced. There must be sustainable funding arrangements for the long term and there should be no greater risk to patients or the profession. There should also be strong and transparent governance arrangements for both the regulation and professional leadership of the pharmacy profession." He added that the Society wants to see full consultation with the profession and with others who have a key stake in the Society's work.

"The RPSGB is a well established, proven professional and regulatory body with a strong track record of protecting the public and supporting and leading pharmacists. In the process of change, we urge the Government to build on these strengths." The working party will make recommendations to ministers by the end of March. The Government aims to have legislation in place to establish the GPC by mid-2008 with a minimum of two years' transition during which the GPC becomes active.

"Trust, assurance and safety, the regulation of health professionals in the 21st century" is available from the DoH website (www.dh.gov.uk) and via *PJ Online* (www.pjonline.com/links/pj).

Implications for the Society and its current Royal Charter

The White Paper says that it may be necessary for the Royal Pharmaceutical Society to seek amendment or replacement of its Royal Charter if it decides to redefine its professional leadership role. One of the objects of the Society is to promote public health and well-being by regulating pharmacists and other people engaged in related activities. *The Journal* has been advised by an expert on royal charters that chartered bodies are under no obligation to pursue all their charter objects, so it is possible that no change would be needed.

It is not clear whether the proposals could raise the prospect of the existing Charter being forcibly revoked. *The Journal* has been advised that royal charters are not revoked by the Queen, but by Act of Parliament.

David Reissner, a solicitor with expertise in pharmacy matters, said: "There is no precedent in living memory for the Queen revoking a royal charter. The Society would cease to exist as a legal entity if the Charter was revoked." Revocation, rather than amendment, would raise the question of what would happen to the Society assets, valued in the 2005 accounts at £5.246m (not including the goodwill value of RPS Publishing). The Charter provides for the Society's assets to be transferred to a "body or bodies with objects similar to those of the Society" if revocation is sought by a special resolution of the Society. The Charter does not provide for distribution of assets if revocation is imposed externally, which means that they would become Crown property.

The Society

New Rules

The Council has made Rules under the Pharmacists and Pharmacy Technicians Order 2007 setting out how the requirements for registration matters and fitness-to-practise procedures are to be implemented (p227); guidance has been issued on transitional arrangements applying to fitness-to-practise investigations (p229 and p230).

Lower fees for members in EEA

Under new Rules, the retention fee payable by members resident in an EEA country and not practising in Britain has been reduced (p228).

Value-based drug pricing scheme needed, OFT says

Value-based approaches to medicines pricing should replace the current Prescription Pricing Regulation System, the Office of Fair Trading recommended this week.

The present system falls short of its objectives and over £500m a year could be saved through more cost-effective prescribing, the OFT argues. "Neither the profit cap nor the price cut helps secure prices that reflect the therapeutic value of the drugs that companies are supplying to the NHS. For a scheme that sets out to deliver value for money for the NHS and give companies the right incentives to invest, we consider this to be a major shortcoming."

In a report published this week the OFT proposes that, under a fully reformed PPRS, maximum prices for branded drugs would be set on value-based principles. The focus of the report was not, however, on whether the aggregate level of prices or the overall amount spent on medicines in the UK is too high. The OFT therefore emphasises that its suggestions would not necessarily reduce spending on medicines since any savings on poor value drugs would release resources for other valuable, but high-cost medicines.

Under the proposed scheme manufacturers would submit a suggested price, along with cost-effectiveness evidence, which would differ across indications. An analysis of value-reflective prices would then be undertaken in a co-ordinated way by the National Institute for Health and Clinical Excellence,

the Scottish Medicines Consortium and the All Wales Medicines Strategy Group.

If these organisations considered that, at the given price, the drug would fall within the cost-effectiveness threshold in all indications, the drug would be recommended for use in the NHS. Recommendations would take the form of guidance similar to that issued by the SMC or through NICE's single technology appraisal process. If the drug were considered too expensive to be cost-effective, the appraising bodies would suggest the highest price that would be acceptable for each indication. Revised NHS list prices or rebates would then be negotiated by the Government and the manufacturer.

The OFT suggests that, in the long term, a commission on the value of medicines could be created to formalise the co-ordination between NICE, the SMC and the AWMSG. At least one pharmacist should contribute to the price recommendation for every drug considered by this commission, the OFT believes.

The Association of the British Pharmaceutical Industry has, however, challenged some of the report's assertions on medicines pricing in the UK. "Medicines in the UK represent excellent value for money, and prices are on a par — or lower — than those of comparator European countries. The current system that controls medicines prices in the UK, the PPRS, has produced £1.2bn savings for the NHS, according to the National Audit



Drugs are priced in a way that does not reflect their therapeutic value, the Office of Fair Trading argues

Office," the ABPI said in a statement. "However, the pharmaceutical industry wholeheartedly supports the desire of the NHS to deliver value for money, and we are ready to sit down with the Government to discuss ways in which this might be better achieved."

The OFT report is available from www.of.gov.uk.

OTC medicines will be considered in contract applications

Primary care trusts will be able to consider the provision of over-the-counter products when deciding between competing applications for community pharmacy contracts in England, draft legislation published last week confirms.

Draft Statutory Instruments amending the NHS (Pharmaceutical Services) Regulations 2007 state that, when determining which of competing applications should be granted, "a PCT may take account of any proposals specified in the applications in relation to ancillary chemist services at the premises in question".

"Ancillary chemist services" means, the regulations say, the sale or supply (other than by way of pharmaceutical services or in accordance with a private prescription) of med-

icines and other products for the prevention, diagnosis, monitoring or treatment of illness or the promotion or protection of health.

The Pharmaceutical Services Negotiating Committee strongly opposed the inclusion of these new criteria when the Government first proposed them in 2005 (*PJ*, 30 July 2005, p129). "If the availability of over-the-counter medicines were to be taken into account by a PCT when considering an application for inclusion in a pharmaceutical list, then it would also need to consider the availability of such medicines from non-pharmacy retail outlets in the neighbourhood. This cannot be an appropriate matter for the PCT to consider and would in any event be almost impossible for the PCT to determine," the PSNC said in its response to the proposals.

New safety criteria to be introduced for animal medicines

Safety criteria under which medicines for use in food-producing animals can be exempt from prescription control have been specified by the European Commission.

To be exempt from prescription control, the use of such medicines must require no specialist knowledge or skills, the medicines must be

free of risk to the animal and the user if used incorrectly, free of serious side effects or adverse reactions, free of interactions with other non-prescription animal medicines, and residues in food must pose no risk to consumers and there must be no possibility of the development of antimicrobial or anthelmintic resistance.

Quality-of-care data to be kept on health professionals

Health care organisations should maintain files on the quality of the care provided by all professional employees, the Government recommends. In its response to the Shipman Inquiry's fifth report and to the recommendations of the Ayling, Neale and Kerr/Haslam inquiries, the Government suggests that such a file — either a set of paper files or interconnected electronic files — should hold all the material relating to the quality of services provided by an individual professional. Guidance on the content of the files will be drawn up by the Government, or by an organisation such as a NHS Employers.

The Government also proposes developments to improve clinical governance processes and the handling of complaints against health professionals. The aim is to create a complaints system which is: demonstrably independent; simple, integrated and consistent across organisations and agencies; focused on the needs of patients; staffed by well trained people with sufficient seniority to bring about improvement; and supported by managers who are committed to learning from mistakes and to delivering specific and systematic changes to organisations.

UK pandemic flu plan tested

The Government's response to a human influenza pandemic was tested this week in an exercise dubbed "Winter willow". The exercise aimed to test the UK's ability to manage the effects of a flu pandemic in terms of how health services, transport, education and food distribution would be maintained during an outbreak.

Sir Liam Donaldson, Chief Medical Officer for England, commented: "This exercise is another part of the continual testing, refining and developing of our plans." The findings from the exercise will be fed into the overall pandemic flu preparedness plan.

Meanwhile, encouraging progress in pandemic flu vaccine development has been reported at a World Health Organization meeting in Geneva. Sixteen manufacturers are developing prototype vaccines against H5N1 avian influenza virus; five of them are also developing vaccines against other avian viruses.

The WHO says that, for the first time, results presented at the meeting convincingly demonstrate that newly developed vaccines can stimulate a potentially active immune response against H5N1 strains identified around the world, some of which work with low doses of antigen. However, the WHO warns that the world still lacks the manufacturing capacity to meet potential global demand during a pandemic.

Antibiotic use and resistance link demonstrated

A study demonstrating the direct link between antibiotic use and emergence of bacterial resistance has been published in *The Lancet*.

Belgian and Dutch researchers took pharyngeal swabs from 224 volunteers before and after treatment with azithromycin (500mg once daily for three days), clarithromycin (500mg twice daily for seven days) or placebo.

Over a period of 180 days, both antibiotics increased the proportion of macrolide-resistant streptococci compared with placebo, peaking at day 8 in the clarithromycin group and at day 4 in the azithromycin group.

The proportion of resistant strains was higher after azithromycin treatment than after clarithromycin treatment. However, clarithromycin use was associated with an increased chance of streptococci carrying the *erm(B)* gene, which confers high-level macrolide resistance (2007;369:482).

The author of an accompanying comment piece (*ibid*, p442) warns that any drive to reduce the use of macrolide antibiotics in the community and, in turn, to reduce macrolide resistance will require more than a prescribing campaign. "Indeed, if macrolide use was discouraged because of concern over their resistance potential, patients might end up receiving a drug that is more toxic, more expensive, and perhaps even better at selecting for resistance."

Slow initial uptake of MURs

Medicines use reviews (MURs) were slow to take off during the first year of the new community pharmacy contract, with the number provided representing less than 7 per cent of the maximum for which funding was allocated, according to research published in *The Journal* this week (p218).

The study analysed data from a survey of pharmacy leads in a random sample of 31 primary care organisations in England and Wales as well as telephone interviews with pharmacy leads in the Welsh Assembly Government and in over 90 per cent of strategic health authorities.

The results show that pharmacy multiple groups were the quickest to become involved in providing the MUR service, undertaking over 80 per cent of all MURs performed in the PCOs surveyed. Overall, 38 per cent of community pharmacies claimed payment for providing MURs in the first year of the service. This figure ranged from 13 per cent to 60 per cent of pharmacies among the PCOs surveyed. There was a mean of 35.7 MURs conducted per providing pharmacy — this varied widely among PCOs (range 8.3 to 61.2).

Alison Blenkinsopp, professor of pharmacy practice in the department of medicines management at Keele University, and colleagues carried out the research as part of the national

evaluation of the pharmacy contract commissioned by the Pharmacy Practice Research Trust. "MURs provide an opportunity for community pharmacy to develop a service providing direct care to patients. This will make better use of their skills and knowledge and should develop relationships with GPs. Our results show that MURs are working well in some places and that the number of pharmacists accredited is encouraging so early in the life of the service," Professor Blenkinsopp commented. She added: "Most SHAs and PCOs involved in the research viewed MURs as having considerable potential but the research team concluded that further action is needed to support and embed the service."

Hemant Patel, President of the Royal Pharmaceutical Society, said: "The results of this report illustrate that although pharmacists are stepping forward to develop their roles, more can be done to fully realise the potential of MURs and the multidisciplinary relationships they promote. Pharmacists need to be aware of the financial and strategic imperatives in embracing MURs, and greater support is needed for pharmacists to take forward this initiative."

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First prescriptions written by pharmacist independent prescribers in primary care

Beth Hird, senior practice pharmacist at Nottinghamshire County Teaching Primary Care Trust, became the first pharmacist in England to write a prescription independently this week. She was also the first pharmacist to register as an independent prescriber with the Royal Pharmaceutical Society (*PJ*, 20 January, p63).

Mrs Hird runs a weekly asthma clinic at a medical practice in Nottingham. This week she prescribed a salbutamol inhaler for a patient during an annual asthma review.

"I was confident that this patient had asthma and that salbutamol was required. After carrying out my usual assessment and discussion with the patient I was also confident that the patient needed to continue their treatment," explained Mrs Hird. The process was easier than supplementary prescribing because no clinical management plan was generated before the clinic — all other processes and assessments remained the same, she added.

To date, Mrs Hird is the only pharmacist registered in Britain as an independent prescriber. In Northern Ireland, Emma Quinn, locality prescribing adviser at South and East Belfast Eastern Health and Social Services Board, wrote her first prescription as an independent prescriber last week. She prescribed bendroflumethiazide to treat hypertension in



Independent prescriber Beth Hird

a patient who had attended her weekly cardiovascular risk management clinic.

Ms Quinn, along with four other pharmacists, registered with the Pharmaceutical Society of Northern Ireland earlier this year (*PJ*, 27 January, p103).

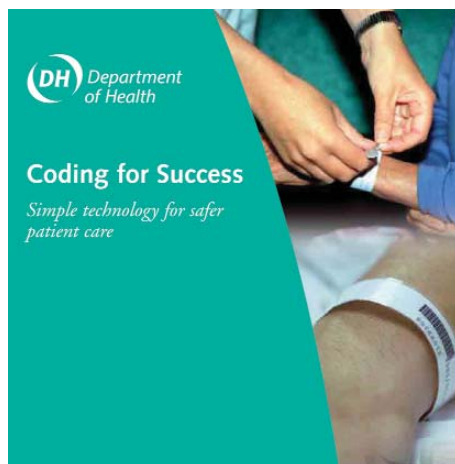
In January, the Northern Ireland Centre for Postgraduate Education and Training at Queen's University Belfast became the first course in the UK to be fully accredited to provide an independent prescribing programme.

Barcode all medicines and patients, DoH suggests

All medicines and patients in England should be given barcodes that use the coding system developed by GS1 and which is already used for most medicines, the Department of Health has recommended.

In a report published last week on the use of autoidentification, the DoH highlights the benefits to patient safety and efficiency of barcodes and similar technologies. Adoption of these technologies could, the report argues, reduce medication errors, facilitate the retrieval of medicines in the event of a recall and prevent counterfeit medicines entering the supply chain. However, scanning a barcode or tag should not replace communication between clinicians and patients, the report emphasises.

"The GS1 system should be adopted through the health care system in England, both for manufactured products and for coding systems used within health care settings, such as patient identification codes on wristbands. . . . It is for the NHS and industry, working together with technology suppliers,



"Coding for success" was published last week by the Department of Health

to take up the challenge and move the agenda forwards," the report argues.

"Most medicines already have a GS1 Global Trade Item Number (GTIN) product

code on the patient pack but this needs to be on all medicines," the report says. "Medicines not carrying codes are mostly those manufactured or repackaged in hospital laboratories and manufacturing units, highly specialised medicines, and some parallel traded products. . . . A simple product code following the GS1 coding standard in a barcode format would be straightforward to implement for the few manufactured items that do not currently have this."

Coding standards should be developed and applied on a voluntary basis, the DoH believes, because regulation might restrict technological progress and the development of the requisite legislation could be a complex and time-consuming process.

"Coding for success — simple technology for safer patient care" is available from the DoH website (www.dh.gov.uk) and via *PJ Online* (www.pjonline.com/links/pj). Progress on the implementation of autoidentification technologies will be reviewed by the end of 2008, the DoH says.

CD guidance issued in Scotland

Guidance on managing Controlled Drugs has been issued this week by the Scottish Executive Health Department. It specifies how NHS Scotland will respond to the requirements of last year's Health Act 2006 and subsequent Controlled Drug Regulations (*PJ*, 1 July 2006, p25).

The guidance falls into three areas: the requirement for each NHS board to appoint an accountable officer to monitor the use of CDs, a duty on health bodies to co-operate with each other and new powers of inspection.

Implications for pharmacy include a need to review regularly how CDs are managed. The guidance states that NHS board accountable officers should review community pharmacies once a year. Part of this will include pharmacists completing a periodic (probably every two years) self-assessment declaration form, an example of which is provided in the guidance.

The form includes sections on whether the pharmacy stocks CDs, the procedures it has in place for managing CDs and possible concerns about unusual CD prescribing. Management of CDs will include having standard operating procedures in place to cover issues such as storage of CDs and record-keeping.

On inspection, the guidance states that NHS board accountable officers should arrange routine inspections of premises where CDs are stored, dispensed, supplied or used. It recommends such visits are announced in advance. It also notes that the Royal Pharmaceutical Society will take over responsibility from the police for inspecting CDs in community pharmacies.

The regulations come into force on 1 March, although NHS boards have until 1 July to appoint accountable officers. The guidance can be accessed via *PJ Online* (www.pjonline.com/links/pj).

Doctors need calculations training

The ability of junior doctors to perform drug dose calculations has been called into question by the results of a survey published this week (*International Journal of Clinical Practice* 2007;61:189). The authors recommend that drug administration training should be reinforced during doctors' first years of practice.

Researchers analysed the results of nearly 3,000 doctors who participated in an online test (on the www.doctors.net.uk network) that involved drug solution calculations expressed as percentages, ratios and mass concentrations, and calculations of amounts to administer in various clinical scenarios. They found that, when all correspondents were considered, there was no clear association between the number of years of experience and test scores. However, a significant relationship between experience and calculation scores was seen ($P < 0.001$) when retired doctors and those working in the community were excluded from the analysis.

The study also showed a high variation in scores between doctors trained at different medical schools ($P < 0.0001$). The authors conclude that "all medical school curricula should include formal teaching and testing of drug administration skills, and that this should be extended into the training programmes of newly qualified doctors".

"This study also highlights the potential dangers of expressing the concentrations of drug solutions as ratios and percentages to those who rarely give them," they add.

□ **GMC research** The General Medical Council's research and development board has agreed to fund a project to look at the prevalence and causes of prescribing errors. The research, due to begin later this year with up to £100,000 of GMC money, will look at errors across the whole medical profession, not just those of junior doctors.

Discharge medication lists miss out a fifth of medicines taken by patients, study finds

Accuracy of medication lists for patients discharged from hospital needs to be improved to prevent inappropriate use of medicines and adverse drug reactions, a recent study suggests (*Quality and Safety in Healthcare* 2007;16:34).

Researchers in Denmark interviewed 200 patients within a week of their discharge from hospital, and found that a fifth of prescription medicines being used after discharge were unknown to the hospital. They also found that only half of medicines

used in hospital appeared on the discharge letter.

They say: "Systematic follow-up after discharge focusing on an updated medication list might be effective in reducing medication errors."

Consultation starts on contract application fees

Charges of up to £3,000 could be levied on contractors applying to provide pharmaceutical services in England.

A Government consultation published last week proposes amendments to the 2005 Regulations to implement the provisions of the Health Act 2006. These are to enable "reasonable charges" to be introduced for applications concerning inclusion on an NHS primary care trust's list.

The fees are designed to defray the costs of assessing each application and to deter speculative and time-wasting applications, the DoH says. "There is, even within the reformed regime now in place, no deterrent to a business which wishes to enter speculative

bids to open a new chemist, either as a fishing expedition in the hope that one or more may be granted or to have the effect of blocking other applicants being considered."

The fees proposed vary from £150 for a minor relocation or change of ownership to £3,000 for a duplicate application submitted within 180 days of the failure of a previous application. The consultation adds: "The DoH proposes that the fee shall not be refundable whether the application is successful or not because a PCT will incur costs in all cases in determining an application, whatever its outcome."

When the Government originally suggested introducing these changes, the

Pharmaceutical Services Negotiating Committee argued that fees should not be payable for pharmacy relocations or changes to ownership and that all fees should be refunded to successful applicants.

Steve Lutener, head of regulation at the PSNC, told *The Journal* this week that the committee would be considering carefully whether its position on refundability had changed.

The consultation document is available from the DoH website (www.dh.gov.uk) and via *PJ Online* (www.pjonline.com/links/pj). Comments can be sent to Gillian Farnfield by 11 May (e-mail gillian.farnfield@dh.gsi.gov.uk).

Society meets Scottish minister at party conference



Lyndon Braddick (left), director of the Royal Pharmaceutical Society's Scottish Office, met Nicol Stephen MSP, Deputy First Minister and leader of the Liberal Democrats in Scotland, at last week's Scottish Liberal Democrat spring conference. The stand was jointly organised by the Society and the Scottish Pharmaceutical General Council.

Carers to benefit from pharmacists' advice through Ask About Medicines initiative

A project in which pharmacists teach carers about the importance of medicines management and patient concordance achieved national recognition earlier this month when it won a £1,000 ASK grant towards expanding its work.

The scheme, run by the charity Brent Carers in North London, was among 20 projects which shared £20,000 awarded by Ask About Medicines — the national organisation devoted to improving concordance in medicines taking.

Brent Carers' chief officer Shirley Bickers said: "We've had community pharmacists from the primary care trust come to our centre to talk to carers about specific medicines, such as those for mental health, as well as give general advice about medicines management, such as the best way to give medicines and how to store them.

"The grant will enable us to expand the programme to our carers in our support groups. It's really important that carers understand about medicines because it's often they who are in charge of medication on behalf of a relative or friend."

More than 40 organisations and individuals involved with medicines management

projects applied for ASK grants, which have now been awarded for two years running.

This year's winners, who each receive £1,000, covered a range of different projects from both primary and secondary care and from the public and voluntary sectors.

They include an "ask your pharmacist about eczema" initiative in Nuneaton, a home visit service in Northumberland to help housebound patients understand their medicines better, a medicines counselling service for inpatients at the Heart of England NHS Foundation Trust in Birmingham and revision of a Blood Pressure Association booklet about hypertension medicines.

Chairman of Ask About Medicines Joanne Shaw said: "We were impressed with the range of innovative ideas generated to take forward Ask About Medicines activities throughout the year and we are delighted to be able to support so many valuable initiatives. We look forward to seeing these projects come to life over the coming months and to sharing their results more widely."

The ASK Grants were supported by Merck Sharp and Dohme Ltd. This year's Ask About Medicines Week takes place from 5 to 9 November.

Public health developments to pharmacy contract in Lothian Pfizer/UniChem deadlines

All community pharmacies in Lothian will be visited during the next two weeks as part of the development of the public health service (PHS) in Scotland.

The PHS is a core service within the new contract in Scotland. It comprises two tiers, the first of which is already in place. The Lothian visits relate to the second tier.

This second tier will involve displaying NHS public health materials either in the pharmacy window or on the pharmacy frontage.

Alison Strath, principal pharmaceutical officer, Scottish Executive Health Department, told *The Journal* that the aim of the visits, to be conducted by CJC Media, is to examine the range of windows and frontages that pharmacies have, and to consider the implications for producing, supplying and maintaining display materials.

Following this, a solution that can be rolled out across Scotland will be finalised by the Scottish Executive and Scottish Pharmaceutical General Council.

Pharmacists who have signed up to Pfizer's direct-to-pharmacy distribution scheme but are concerned that they have not been notified of order-cut-off and delivery times will find out what is happening next week. UniChem said this week that details will be in a guide to be sent out from 26 February.

□ **Shortages** AAH Pharmaceuticals has said that it could run out of Pfizer products before Pfizer's distribution scheme starts on 5 March. Pfizer has refused to accept orders from wholesalers after 23 February, AAH claims.

New treatment available for grass pollen allergy

Patients who suffer from allergic rhinitis brought on by grass pollen could benefit from a new immunotherapy launched this month by ALK-Abelló, a company that specialises in specific allergy treatments.

Grazax, a grass pollen allergen extract from the *Phleum pratense* (timothy) grass, is available as a sublingual tablet for once-daily use. The treatment — the mechanism for which is not fully understood but is thought to involve inducing a systemic competitive antibody response towards grass, along with an increase in specific IgG — is indicated for adults with clinically relevant symptoms of grass-pollen-induced rhinitis and conjunctivitis and diagnosed with a positive skin prick test or specific IgE test.

Sekhar Pillai, product manager, ALK-Abelló, told *The Journal* that Grazax treatment is patient-specific — for people with confirmed allergy — and stressed the importance of patients not sharing the medicine with other people. He also emphasised that the



Grazax sublingual tablet contains pollen allergen extract from timothy grass

treatment should be started at least two months before the pollen season begins.

The summary of product characteristics states that clinical effect in the first treatment season is obtained if Grazax is initiated at least four months before the expected start of the grass pollen season and continued throughout

the entire season. It says that some efficacy may be obtained if treatment is started two to three months before the season. The treatment should be initiated by physicians who have experience in treating allergic conditions.

A study supported by ALK-Abelló was published in the *Journal of Allergy and Clinical Immunology* last year (2006;118:434). It found that patients experienced a 30 per cent reduction in rhinoconjunctivitis symptoms score ($P<0.0001$) and a 38 per cent reduction in medication score ($P<0.0001$) compared with placebo.

The study concludes that Grazax treatment is well tolerated with minor local side effects. However, it showed that oral pruritus (46 per cent Grazax versus 4 per cent placebo), mouth oedema (18 per cent versus 1 per cent), nasopharyngitis (15 per cent versus 19 per cent) and ear pruritus (12 per cent versus 1 per cent) were the most common adverse events, but their significance was not published.

Notice-board p214

Montelukast/salmeterol combination not recommended

Patients with moderate asthma should not change from an inhaled corticosteroid/long-acting beta₂ agonist (LABA) to a combination of a leukotriene receptor antagonist (LTRA) and a LABA, data from a crossover study of 192 patients indicate (*American Journal of Respiratory and Critical Care Medicine* 2007;175:228). Patients treated with the LTRA montelukast in

combination with the LABA salmeterol experienced a shorter time to treatment failure ($P=0.0008$), poorer lung function (26L/min difference in morning peak expiratory flow rate; $P=0.011$) and reduced asthma control (0.22 difference in Asthma Control Questionnaire score; $P=0.038$) compared with those taking beclometasone plus salmeterol.



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