

Three new faces elected to Council as voting falls

Voting in this year's Royal Pharmaceutical Society Council election fell markedly, with only 16.22 per cent of ballot papers returned, compared with 21.25 per cent in 2006, 21.8 per cent in 2005 and 22.8 per cent in 2004.



Nicholas Barber



Catherine Duggan



Alison Moore

Out of the 47,585 voting papers issued in the election to unreserved places, 7,719 (16.22 per cent) were returned and 43 were disallowed as invalid. For the national seats, 17.43 per cent of papers were returned for England and 21.58 per cent for Scotland.

Martin Astbury, the Society's current Vice-President, topped the poll, receiving the most votes both in the election for three unreserved pharmacist seats (4,214) and for the reserved seat for England, the Channel Islands and the Isle of Man (2,911). In line with Society regulations, he was therefore elected for the national constituency.

Newcomers Nicholas Barber, Catherine Duggan and Alison Moore were successful in being elected to the three unreserved seats. Professor Barber, from London, is professor of the practice of pharmacy and head of the department of practice and policy at the School of Pharmacy, University of London. Dr Duggan, also on the staff of the School of

Pharmacy, is chairman of the United Kingdom Clinical Pharmacy Association, and Alison Moore, from Dumfries, is a hospital and community pharmacist locum who is currently establishing a consultancy business.

The reserved seat for Scotland was closely fought, with current Council member David Thomson narrowly beating new candidate Ian Mullen and being re-elected with 481 votes versus 449.

There was only one candidate for each of the seats reserved for Wales and for a pharmacy technician, so Margaret Allen (Wales) and Yvonne Liddell (technician) were elected unopposed.

Brian Curwain, Richard Daniszewski and Lindsey Gilpin were re-elected to the English Pharmacy Board and were joined by retiring Council member Jonathan Buisson. Retiring members of the Welsh Pharmacy Board Jodine Evans, Diane Heath and Richard Evans were re-elected and were joined by new candidate Brian Hawkins. Mr Hawkins, from Cardiff, is head of pharmacy and medicines management at Rhondda Cynon Taff Local Health Board.

There was no election for the Scottish Pharmacy Board because there were only three candidates for the four seats (*PJ*, 5 April, p418).

Clarke adds urgency to call for transitional committee to prepare new leadership body

It is "absolutely vital" that the transitional committee to oversee the preparation of the new professional leadership body, as recommended by the Clarke Inquiry, is set up as soon as possible, according to inquiry chairman Nigel Clarke.

Mr Clarke was speaking at the annual joint conference for the Guild of Healthcare Pharmacists and the United Kingdom Clinical Pharmacy Association last weekend.

Conference participants asked Mr Clarke for his opinion on the decision made by the Council of the Royal Pharmaceutical Society to consult further with Society members on the findings of the Clarke Inquiry. Several participants thought that this was a peculiar decision, since the inquiry itself was a consultation with Society members.

"The vast majority of the recommendations should be acted upon, as they are incontrovertible," said Mr Clarke. However, he added that there were some areas of the report that required further debate before conclusions could be arrived at.

Mr Clarke told *The Journal* that he believed the main items of debate involved the creation of the committee for special interest groups and the representation arrangement for industrial pharmacy. He repeated that communication with members was an essential component of the transitional process. He believes that this is best achieved by setting up

a transitional committee that is large enough to represent all areas of the profession, and only seeking direct communication with members once formal proposals have been drafted. For example, a proposal to amend the Royal Charter would require a formal ballot, he said.

Dave Roberts, clinical director of pharmacy at Cardiff and Vale NHS Trust, believes that the Guild and UKCPA should be given heavy representation on the transitional committee. "Both of those bodies are financially viable, responsive to membership and have helped their members to develop for many years," he said. "They are the sorts of bodies that I would like to see the new leadership body becoming a bigger and better version of."

A report of the conference will be published in the June edition of *Hospital Pharmacist*.

□ **AGM discussion** A discussion forum to consider findings from the Clarke Inquiry into the future professional body will be held before the Royal Pharmaceutical Society's annual general meeting on 21 May. Nigel Clarke, along with Hemant Patel, the Society's President, and Jeremy Holmes, the Society's Chief Executive and Registrar, will answer questions at the forum, which will take place from 18.45 to 20.00 at 1 Lambeth High Street, London SE1 7JN.

Deputy Registrar appointed as Society FTP head leaves

Pharmacist Wendy Harris, deputy director of healthcare quality and head of patient safety and investigations at the Department of Health, has been appointed as the Royal Pharmaceutical Society's new Deputy Registrar. She will take responsibility for the Society's regulatory functions from 9 June.

The news of the appointment came as the Society announced the departure of Mandie Lavin, its director of fitness to practise and legal affairs, who is to take up the post of director of the Bar Standards Board.

The Society's President Hemant Patel said that Miss Lavin had "made a significant contribution to the modernisation of the Society's fitness-to-practise procedures, work which will lay the platform for the creation of the new General Pharmaceutical Council".

Miss Lavin, who joined the Society in 2003, said: "Pharmacy is entering a new era and I wish the Council and staff every success as they work towards the formation of the new professional body and General Pharmaceutical Council."

On Ms Harris's appointment, Mr Patel said: "I am delighted to welcome Wendy to the Society in what is a crucial strategic position within the organisation. Wendy's career demonstrates that she is an accomplished, astute senior manager with excellent change management and leadership credentials — fundamental requirements for the success of this new role."

NPA responds to polyclinic threat to community pharmacy network

Moves to secure the community pharmacy network in the face of plans to establish polyclinics have been made by the National Pharmacy Association.

The NPA has written to all local authority overview and scrutiny committees (OSCs) in England to ask them to use their powers to ensure that adequate consultation takes place over the development of these health centres. Local public consultations are currently taking place following recommendations from Lord Darzi in the interim report of his NHS review (*PJ*, 13 October 2007, p393).

The NPA wants OSCs to use their powers under the Consolidated NHS Act 2006 to ensure that consultations are underpinned by information that explains the full impact on services and communities surrounding the health centre, and that the next stages of the procurement and implementation process apply this same logic. It also wants the committees to ensure that primary care trusts commit to a "neighbourhood access analysis" that assesses whether a care "void" could be created in pockets and also considers the potential for expanding community pharmacy-based services to ensure continued and improved access to services.

The NPA believes that this impact assessment could be incorporated into the health inequality impact assessment that PCTs are already required to carry out.

Stephen Fishwick, head of external relations at the NPA, said: "We are not anti-polyclinics per se. Indeed, if these centres are



Michael Williams/Dreamstime.com

Local communities: NPA urges local authorities to assess polyclinics' impact

sensitively integrated with existing health infrastructures, they present opportunities for community pharmacy. But we are concerned that co-location is being enacted by PCTs with less attention given to integration — the terms are far from interchangeable in this context."

Mr Fishwick added that the NPA suspects that PCT public consultations may not in all cases have explained this tension. For example, they may have asked whether people would like a pharmacy in the polyclinic but without giving information about the implications for services provided outside the immediate vicinity of the clinic.

"Commissioners need to look at the needs and services in and around the polyclinics," he argued. Access-critical services, such as chlamydia screening, emergency hormonal contraception and minor ailments schemes, need to be expanded, particularly where GPs have relocated to join a health centre, he added.

The NPA's call came as Lord Darzi published "Leading local change", a report that sets out five pledges on how the NHS will handle changes to services (see right).

□ **Society** The Royal Pharmaceutical Society has issued a statement that calls for guaranteed impact assessments to be carried out in every locality where a polyclinic is planned. It suggests economic, social and healthcare factors that should be considered in an assessment.

Local authority OSCs

Local authority overview and scrutiny committees comprise elected councillors with responsibility to consider issues affecting the health of local people. The outcomes of local consultations are subject to scrutiny by the OSCs. Where a committee is not satisfied with the content of the consultation, or that the proposal is in the interests of the health service in the area, it has powers to refer these issues to the Secretary of State for Health.

Pharmacy should be consulted on plans to expand GP services

The pharmacy profession must be consulted as part of the Government's plans to invest in GP services, including creating 12 new practices in under-doctored areas, the Royal Pharmaceutical Society said this week.

Health secretary Alan Johnson last week announced that £13.2m was being given to 12 primary care trusts to invest in new GP premises. The Government is also planning to consult with the British Medical Association on how another £105m will be spent on de-

veloping more GP services in England, including extending the opening hours of surgeries to increase patient access.

Society President Hemant Patel said: "While the Society supports the Government's commitment . . . we would also expect to see pharmacy included in the planning and commissioning of these new healthcare services. In many areas where there is not currently a GP surgery there may already be a pharmacy, able to offer professional healthcare advice."

Darzi advises on tackling NHS changes

Five pledges on how the NHS should handle changes to services are set out by Lord Darzi in his report "Leading local change", published last week. This comes ahead of Lord Darzi's final report on the NHS, expected next month.

The pledges — which primary care trusts will have a duty to "have regard to" — include making sure that change always benefits the patient, is based on good clinical evidence, is led locally instead of imposed nationally and depends on the involvement of patients, the public and other key partners. The final pledge is that existing services should not be withdrawn until the new service has proved itself.

Georgina Craig, lead on commissioning policy for the Company Chemists' Association, believes that Lord Darzi's five pledges are important, but largely self evident. "From a CCA perspective, it matters not that Lord Darzi has made these pledges, but that he and the Government are committed to honouring them in new and fundamentally different ways, moving forward," she added.

Darzi's report refers to eight key steps to deciding on substantive service changes to make the five pledges a reality. These eight steps are included in detailed operational guidance, "Changing for the better", also published last week.

Over the next month, every strategic health authority in England will publish a clinically-led vision document for improving health and healthcare over the next decade. Lord Darzi is expected to publish his final report in June, which aims to enable and support the improvements identified locally.

All documents are available on the Darzi review website at www.ournhs.nhs.uk.

□ **NHS Reform Bill** A new NHS Reform Bill — which will take forward any proposals arising from Lord Darzi's next stage review that require primary legislation — was included in the Government's draft legislative programme, published this week.

NAO progress report on NPfIT

All elements of the National Programme for IT are advancing and some are complete but the original timescales for the electronic Care Records Service were unachievable from the beginning, raised unrealistic expectations and put confidence in the programme at risk, says the National Audit Office in its second report on the programme.

The NAO concludes that the original vision remains intact and still appears feasible but that it is likely to take until 2014–15 before every NHS trust in England has fully deployed the care records system, four years later than planned.

The report is available via the NAO website at www.nao.org.uk.

Cancer pharmacists recognised in patient survey

The high quality of medicines management advice given by cancer pharmacists to their patients when they leave hospital has been recognised in the annual patient survey carried out by the Healthcare Commission.

But, overall, the provision of information and advice about medicines at NHS trusts in England has deteriorated over the past year, according to the results of the survey, which were published this week.

Trusts providing specialist oncology services scored the highest marks in three of the four questions relating to patient satisfaction around medicines information.

Geoff Saunders, chairman of the British Oncology Pharmacy Association, said the survey results reflect pharmacists' recognition of the importance of medicines information for cancer patients who are increasingly expected to self-medicate at home.

He said: "We have understood for a long time that empowering the patient is really important because they are the people who need to understand their treatment enough to report back on side effects and help us monitor their treatment and make adjustments."

The issue of good quality medicines management has become more important as traditional oncology practice has changed with patients taking oral treatments at home rather than attending hospital clinics to receive their medicines, he explained.

The results of the patient survey reveal that 94 per cent of patients who attended the Royal Marsden NHS Foundation Trust in London said that staff explained the purpose of the medicines they were taking at home in a way that they could understand and 95 per cent of them reported they were also told clearly how to take their medicines.

The Clatterbridge Centre for Oncology NHS Trust in the Wirral was also one of the highest scoring trusts with 72 per cent of patients reporting that they were told what side effects to watch out for when they received their medicines.

Another high-scoring trust was the specialist cardiothoracic Papworth Hospital in Cambridgeshire, where 86 per cent of patients said they were given clear written information about their medicines.

However, not all trusts performed well for provision of medicines information. West Hertfordshire Hospitals NHS Trust had the lowest score in two of the four questions about medicines management.

Only 31 per cent of patients said they were told about what medicine side effects to



Papworth Hospital NHS Foundation Trust was rated highly by patients for provision of medicines information

look out for when they went home and just over half of patients (59 per cent) said they were given clear written information about their medicines.

The national medicines management picture was also poor. Forty-six per cent of patients in 2007 received no information about medicine side effects, compared with 45 per cent in 2006. On average, 9 per cent of patients said they did not understand how to take their medicines, with lack of appropriate information ranging from 2 per cent in some trusts up to 19 per cent in others.

The results of the annual survey were based on the responses to questionnaires from 76,000 adult inpatients at 165 trusts in England.

Representative ordered to pay damages following prescription fraud

A medical representative who supplied stolen prescriptions in a widespread fraud, which cost the NHS hundreds of thousands of pounds, is facing financial ruin after a High Court ruling last week.

Girish Pandya, of Kenton Lane, Harrow, was ordered to pay £213,448 in damages to the London Strategic Health Authority (LSHA), as well as at least £190,000 in legal costs and £156,000 in interest after the civil court hearing in London.

In a lengthy written judgement, Sir Andrew Park said Mr Pandya was "involved in the organisation and implementation of the fraud or frauds" that involved seven London pharma-

cies. Between 1998 and 2001, the pharmacies used thousands of forged prescription forms to obtain large payments from the NHS for prescriptions that had not been dispensed.

Sir Andrew said that there were at least 3,773 forged forms — taken from 40 doctors' surgeries in London — and the total cost to the NHS was calculated at £429,249.

In the only fraud detailed by the judge, Sir Andrew said Mr Pandya would receive regular supplies of prescription drugs in return for his role in the scam.

"There is no evidence of what Mr Pandya did with the drugs which were supplied to him by the pharmacy without paying for them,"

said the judge. "It has been conjectured that he may have sold them on the black market."

Sir Andrew said there was "considerable force" in the suggestion that Mr Pandya stole the forms himself, as he often had "unsupervised access to rooms where some prescription forms were located". He refused permission for Mr Pandya, who has never been prosecuted in the criminal courts, to appeal against his ruling.

The court heard that individuals or companies that owned or ran seven pharmacies involved in the fraud have already settled with the LSHA after agreeing to pay substantial sums, interest and costs.

Samuel Ashby allowed to proceed with High Court appeal case despite facing deportation

Samuel Ashby, who was struck off the Royal Pharmaceutical Society's Register of Pharmacists for a second time in February 2008 following an attack on a member of the Society's staff when his first ban was announced in October 2006, is allowed to proceed with his High Court challenge to the first striking off decision without paying into court in advance, a High Court judge has ruled.

Since Mr Ashby is facing deportation to Australia as soon as papers can be arranged, the Society last week sought an order that, as a condition of being allowed to proceed with his judicial review claim, he should be made to pay £17,000 into court as "security" for the Society's legal costs in preparing for the case. There is doubt that Mr Ashby will be in the country for the appeal and the Society said it is unlikely to be able to recover these costs

once he has been deported. Moreover, the Society added, the case is academic because if he succeeds in overturning his first ban, he will remain struck off from the Register as a result of the second decision (*PJ*, 1 March, p239).

But the judge Mr Justice William Blair has ruled that making such an order would be likely to have the effect of "stifling" Mr Ashby's appeal, because he would be unlikely to be able to pay.

Demos highlights importance of talking to patients

Concordance, rather than compliance, should underpin conversations pharmacists have with patients about their medicines, a report published this week by the think tank Demos recommends.

Access to information on the internet makes patients more informed about their medicines and, coupled with the Government's choice agenda, patients increasingly expect to negotiate decisions about their medicines, says the report called "The talking cure: why conversation is the future of healthcare". But replacing "compliance" with "concordance" in the NHS vocabulary has little to do with political correctness and requires a "fundamental re-think" about the health professional and patient relationship, the document points out.

"Concordance involves recognising patients' expertise rather than just finding medicines to fit their chaotic lives," the report says. "It asks professionals to agree goals with patients rather than assume them. It asks that the role of the patient in decisions and ongoing care is brought to the fore."

Concordance also creates an opportunity to give the debate around choice more force because it suggests that patients should be intimately involved in choosing the things that matter to them — such as treatment and care plans — and rejecting the things that they think are less important, the report says.

If concordance is allowed to rise to the top of the medicines agenda it would have a profound effect on the development of health services and new medicines, Demos suggests.

The focus, Demos says, would change from one that concentrated on developing ever more powerful drugs to one, which is already emerging, centred on improving patient information and patient decision aids.

Demos refers to an editorial in the *BMJ* (11 October 2003), which said that "concordance doesn't come easy" but adds: "Given that compliance, coercion and other approaches have routinely failed, it is worth working out how to make concordance work."

The report's author Jack Stilgoe said at its launch: "Patients are becoming experts too and the NHS needs to acknowledge this and listen to them. As Lord Darzi puts the finishing touches to his review on the future of the

NHS the focus should be less about the mechanics of the system and more about the people who are at the heart of healthcare."

Among its recommendations Demos suggests that GPs and patients with chronic conditions should establish "outcome statements" that spell out shared goals; patients with long-term conditions should be given personal budgets to design their own package of healthcare. They should also be given patient packs detailing what they can expect from consultations, what their rights are and what kind of questions to ask healthcare professionals to ensure they get the most out of their care.

The think tank also calls on the Government to create what it calls "Wikirecords" — online accessible patient records that patients can contribute to and comment on.

Pharmacists expected to fill in the blanks left by GPs

The nature of conversations that pharmacists have with their patients was also considered in the Demos report. Pharmacists who contributed told researchers that their conversational role with patients is in flux. They said the profession is increasingly expected to fill in the blanks after patients have consulted their GP.

The report says: "The power relationship is less well established than with a doctor so conversations [with a pharmacist] can be more exploratory. . . . Where once they would be the source of information about medicines, pharmacists are now increasingly arbiters of conversation with an informed public."

The conversations the profession has with patients, especially on hospital wards, is today "more open and honest than those that people feel they should be having with doctors", says the report.

Design guide recommends simple changes to injectable medicines

Graphic designers from the Royal College of Art have helped develop new National Patient Safety Agency guidelines for the labelling and packaging of injectable medicines.

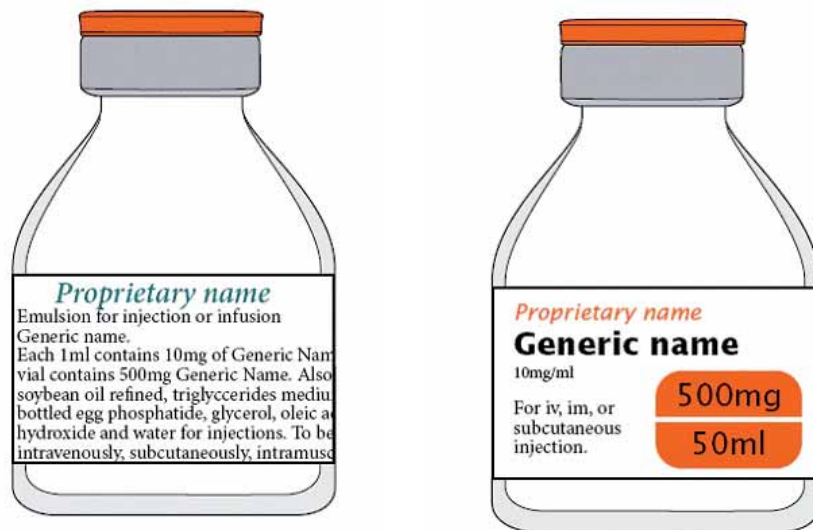
The guidelines recommend simple changes in design, such as using paper labels and different coloured print, to help distinguish similar medicines from each other and prevent mistakes in administering the drugs.

The guidelines — "Design for patient safety: a guide to labelling and packaging of injectables" — apply to all injectable medicines, including ampoules, vials, prefilled syringes and infusion bags.

The NPSA recommends creating an area on a vial — no wider than the container's width — that incorporates key information and ensures that the generic drug name can be read at a glance.

Where possible, labels on ampoules should be made of paper because text on transparent labels can show through on the reverse, making reading confusing, the guidelines suggest. Where ampoules do have clear plastic labels it may be better to highlight key information by inverting the text colour, the NPSA recommends.

The agency also proposes that a two-dimensional barcode that includes key information, such as batch number and expiry



Dense text can be hard to read so the guide recommends creating an area that highlights key information and using appropriate fonts and formatting

date, should appear on vial and infusion products. The barcode could also include a unique product identifier, to be used in the dispensing and medicine preparation process, as well as for administrative purposes.

The guidelines are the latest in a series around design and patient safety and are

aimed at pharmaceutical companies as well as those involved in the procurement of NHS medicines. They are also expected to help NHS trusts carry out a risk assessment of their injectable medicines and products following recommendations made by the NPSA last year (*PJ*, 7 April 2007, p392).

Direct distribution no immediate threat to quality

Service quality for patients has not been affected by the decision of some pharmaceutical manufacturers to bypass the conventional wholesale system and supply medicines direct to pharmacies, the Government has decided. Ministers are confident that service quality will remain undamaged in the foreseeable future and have no plans to introduce legislation to protect standards, it says.

The decision comes in the Department for Business Enterprise and Regulatory Reform's response, published earlier this month, to last December's Office of Fair Trading's market study into the distribution of medicines (*PJ*, 15 December 2007, p667).

The response says: "The Government is unconvinced of the need to bring forward legislation to clarify service standards at this stage, but will keep this matter under review and may consider taking action at a later date in the event that this becomes necessary."

It says the decision by some manufacturers to side-step wholesalers and deliver direct to pharmacies is a commercial matter for the businesses concerned.

However, the Government agrees with the OFT's warning that the new system could increase the price of NHS medicines, since it removes competition from the wholesale level of the supply chain. It also agrees that the possible impact on NHS costs should be addressed as part of the current renegotiation of the Pharmaceutical Price Regulation Scheme (PPRS).

The response to the OFT report has been examined by the British Association of Pharmaceutical Wholesalers whose members

include UniChem, AAH Pharmaceuticals and Phoenix Healthcare Distribution, all of which have taken on direct-to-pharmacy distribution on behalf of manufacturers.

In a statement, the BAPW said: "The announcement by Government recognises the role of full-line wholesalers and the critical role played by the UK's medicines supply chain in guaranteeing that the NHS delivers on its promise to patients, both at a service level and in value-for-money for the taxpayer." It added that competition needs to be maintained but that it hopes that a formal distribution margin will be established in the PPRS.

Mark James, group managing director of AAH Pharmaceuticals, said: "Distribution change has now been extensively reviewed and accepted by the relevant competition authority — the OFT — and the UK Government." He welcomed the decision to involve wholesalers in the PPRS negotiations but added: "It is important that the Government understands and assesses fully the potential impact on wholesalers of any proposed changes to the PPRS."

Mark Stephenson, commercial and supplier relations director at UniChem, said of the Government's response: "UniChem is



UniChem is the only wholesaler to reach an exclusive direct-to-pharmacy deal with a manufacturer

particularly pleased to note the Government's conclusion that, following the introduction of the direct-to-pharmacy model, there has been no real change in the standard of service offered to patients and no evidence to suggest that this will be the case in the foreseeable future."

On behalf of Pfizer Ltd, which began its exclusive distribution deal with UniChem over a year ago, managing director John Young said: "The introduction of our direct-to-pharmacy distribution model has allowed us to take full responsibility for our medicines from the point at which they leave our manufacturing centres right until they reach pharmacies. This security in supply ensures the availability of genuine Pfizer medicines for patients."

Review planned for warnings on medicines

Warnings used on medicines labels are likely to be overhauled, according to the latest report from the Better Regulation of Medicines Initiative (BROMI).

The third report from BROMI (a group set up to look at ways of simplifying and speeding up the system of medicines regulation and which includes health professionals and representatives from the pharmaceutical industry and the Medicines and Healthcare products Regulatory Agency) reveals that it wants to review, update and improve statutory label warnings.

"These warnings have been required since the late 1970s and there is an increasing body

of evidence that some revisions to the warnings may be beneficial for patient understanding," the report says.

The report also highlights some of BROMI's successes since it was set up in 2005. These include a new self-certification system for minor changes to patient information (such as changes to the shape of labels on medicine bottles), which BROMI says has not had a serious impact on public health.

A new code of practice around the redesign of non-statutory packaging information means that the time taken by the MHRA to approve minor changes has been reduced from 90 to 30 days.

Manufacturers obliged to tell patients to report ADRs

Pharmaceutical companies are to be obliged to tell patients to report adverse reactions to their drugs as part of a revised voluntary code of practice for the industry that comes into effect on 1 July. The current code only suggests that information included with medicines should direct patients who suffer adverse effects to the website of the national yellow card reporting system.

Drug companies have also been expected under the current code of practice developed by the Association of the British Pharmaceutical Industry to ask that patients inform the drug company as well if they suffer any side effects from their medication.

But after 1 November all patient information produced by drug companies will have to stipulate that patients "should" report any adverse reactions to the yellow card system as well as to the pharmaceutical company.

The change in emphasis follows a request from the Medicines and Healthcare Products Regulatory Agency, a spokesman from the ABPI confirmed this week.

NPA brings group together to solve pharmacy IT dilemmas

An IT supply chain forum has been formed by the National Pharmacy Association.

The forum brings together patient medication record system suppliers, broadband providers and others in the IT supply chain. The aim of the forum is to discuss IT prob-

lems in community pharmacies with those responsible for implementing IT (and the electronic prescription service in particular) and to identify potential solutions.

Meeting quarterly, its first full meeting was held in March.

Avoid parallel-imported Clexane

Some packs of Clexane (enoxaparin sodium) pre-filled syringes supplied to overseas markets have higher levels of the contaminant over-sulphated chondroitin sulphate (OSCS) than is considered acceptable by the Commission on Human Medicines. The Medicines and Healthcare products Regulatory Agency does not want to see these batches supplied to the UK as parallel imports.

Last month the MHRA issued a Class 4 drug alert about Clexane (*PJ*, 3 May, p529) but stated that batches contaminated with levels of OSCS below 5 per cent could continue to be supplied. This advice still stands



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but the MHRA is now advising parallel importers not to distribute certain batches of Clexane pre-filled syringes (as well as Lovenox-branded enoxaparin products) within the UK and reminding potential recipients of these batches that parallel importers may modify the originator's batch number by adding a prefix or suffix or by using their own number. It advises recipients to contact the parallel importer for clarification if they have any concerns.

The relevant batch numbers can be found on the MHRA website at www.mhra.gov.uk and via *PJ Online* (www.pjonline.com/pjlinks).

Benevolent Fund seeks ideas for services

The Benevolent Fund, the independent welfare charity for present and past members of the Royal Pharmaceutical Society and their dependants, is seeking ideas from pharmacists across the UK to develop its services.

The Benevolent Fund recently carried out an online survey, attracting responses from more than 1,100 pharmacists, which will be used to help shape the organisation's future.

"A number of the participants stressed there is a real need for support across the profession, from general advice and support to counselling, [and] debt and legal services. As an organisation we believe there is a voice out there which needs to be heard to enable us to

adapt our services to the changing needs of the 21st century pharmacist," said David Qualter, Benevolent Fund manager.

The fund provides assistance at every stage of a professional pharmacist's life and in response to a range of problems, including illness, stress, bereavement and unemployment. The focus for the future will be about offering an interactive and proactive service and the fund's trustees wish it to be seen as the starting point for help, not the last resort.

Three focus groups are to be held in Cardiff, London and Glasgow in May and June. Further details can be obtained by e-mailing information@rpsgb.org.

Numark launches bursary scheme to further staff training

A bursary scheme that will meet up to 90 per cent of the cost of a training course to help boost the clinical or business skills of pharmacy staff working for Numark is being launched. The bursary applications will be decided by a new training panel that is also being established and which will meet quarterly. The panel will also give verdicts on the value of external training programmes.

The two initiatives come under the umbrella of the new Numark Academy, which

pulls together all the company's training opportunities and learning resources for its pharmacy staff.

Training manager at Numark Jane Lumb said: "We recognise that our members don't have the time to weigh up the various merits of countless training courses offered by manufacturers and others. Our new training panel will do that for them, provide their comments on what is available and make recommendations."

Help with financing pharmacy degree offered by Teva UK

Students who are suffering financial hardship but hope to gain a degree-level qualification in pharmacy could benefit from a bursary scheme set up by generics manufacturer Teva UK.

The scheme is open to any UK student who is either already attending, or who has

been offered a place on, any full-time UK-based undergraduate course approved by a school of pharmacy or similar. Up to 10 bursaries — £500 for each year of study — will be awarded each year. Further information at www.tevauk.com/careers/bursary.

Europe

Information to patients

The UK Government strongly supports the maintenance of the current ban on direct-to-consumer advertising of prescription-only medicines to the public, the Medicines and Healthcare products Regulatory Agency has said in the Government's response to a European Commission consultation. The EC Enterprise and Industry Directorate-General's proposals on provision of information to patients (*PJ*, 19 April, p457) closed for comments last month. The Government argues that the purpose of information about medicines, rather than its source, is the key factor when considering if information is advertising or information. Instead of attempting to define information, EU legislation should set out specific categories of acceptable information that could be promulgated by the pharmaceutical industry, the Government suggests.

Regulation of medical devices



Plans to modernise and simplify EU legislation on medical devices have been put forward for public consultation. The European Commission is

suggesting that the current regulatory framework for medical devices could be strengthened by merging the numerous directives pertaining to such products under one legal text. The EC also raises the idea of extending the competence of the European Medicines Agency to include evaluation of high-risk medical devices, such as coronary stents, pacemakers or HIV test kits, in the interest of public health.

Qualifications to transfer more easily

The European Qualifications Framework — a voluntary scheme designed to improve transfer of people's educational qualifications between member states — was formally adopted by the European Parliament last month. At the EQF's core are eight reference levels of qualification, ranging from those obtained at the end of compulsory schooling through to doctorate-level. The framework will act as a "translation device to make qualifications more readable and understandable to employers, individuals and institutions", the EC reported. It is expected that member states will relate their national qualifications systems to the EQF by 2010 and that their qualifications will contain a reference to the framework by 2012.

Efavirenz more effective than lopinavir/ritonavir

A regimen of efavirenz plus two nucleoside reverse-transcriptase inhibitors (NRTIs) is more effective than lopinavir/ritonavir plus two NRTIs for initial therapy of HIV-1 infection, new data show (*New England Journal of Medicine* 2008;358:2095).

In an open-label study, US researchers set out to compare three regimens: they randomly assigned 757 HIV-1 infected patients, aged at least 13 years, and who had not received previous antiretroviral therapy, to receive efavirenz plus two NRTIs (efavirenz group), lopinavir/ritonavir plus two NRTIs (lopinavir/ritonavir group) or lopinavir/ritonavir plus efavirenz (NRTI-sparing group).

At a median follow-up of 112 weeks, the time to virologic failure was found to be longer in the efavirenz group than in the lopinavir/ritonavir group ($P=0.006$). However, those patients receiving either of the lopinavir/ritonavir regimens had greater increases in CD4 cell count than those in the efavirenz group at week 96 (but not at week 48).

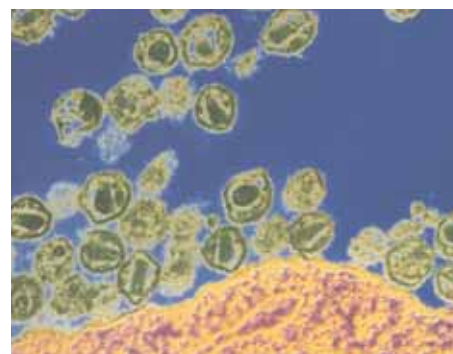
The researchers say that the regimen of efavirenz plus two NRTIs had a greater overall virologic efficacy even when the analysis

was restricted to patients with a high level of adherence. They add that this regimen seemed to suppress HIV-1 levels more rapidly than regimens containing lopinavir/ritonavir — although the clinical significance of the difference is unknown.

In addition, the NRTI-sparing group was found to have a virologic efficacy similar to that of efavirenz group, but resistance to non-nucleoside reverse-transcriptase inhibitors and lipid abnormalities, especially elevated triglycerides, were more frequent, the researchers say. They suggest that these effects “should dampen enthusiasm for routine use of this [lopinavir/ritonavir plus efavirenz] regimen”. However, the data support the use of such treatment in specific clinical situations in which options are limited, they add.

The number of regimen-failure outcomes owing to adverse events was similar among all three study groups and there was no significant difference in the time to treatment-limiting toxicity, the researchers report.

They comment: “These results highlight the complexity of choosing initial therapy. Selection of initial therapy for an individual



NBSC/Science Photo Library

HIV levels were suppressed more rapidly with efavirenz regimen

patient should take into consideration many factors, including virologic and immunologic response, tolerability, short-term and long-term toxicity and the resistance consequence associated with virologic failure.”

The authors of an accompanying editorial (*ibid*, p2170), from Geneva University Hospital, Switzerland, add: “On the basis of this study, it seems that efavirenz plus two NRTIs is hard to beat.”

Breastfeeding linked to lower arthritis risk

Women who breastfeed for more than a year have a reduced risk of developing rheumatoid arthritis, according to a study published online (13 May, *Annals of the Rheumatic Diseases*, <http://ard.bmj.com>).

Using a community-based health survey, researchers compared data for 136 women aged 44 to 74 years who suffered from RA with data for 544 age-matched controls. They found that the reduced risk of RA seen in the group of women who breastfed for 13 months or more was dose dependent and remained significant after adjustment for smoking and

level of education (odds ratio 0.46, 95 per cent confidence interval 0.24 to 0.91, compared with those who had never breastfed). They also found that neither taking oral contraceptives nor being pregnant had any significant effect on the risk of RA.

The researchers say: “Possible explanations for the protective effect of breastfeeding include long-term immunomodulation, such as the development of progesterone receptors on lymphocytes, dysregulated hypothalamic-pituitary-adrenal axis and differences in cortisol concentrations.”

Intravenous prodrug of oral aprepitant launched in UK

Fosaprepitant, an intravenous alternative to the anti-emetic drug aprepitant, has been launched in the UK. Marketed as Ivemend, fosaprepitant is a lyophilised prodrug of oral aprepitant, indicated for prevention of nausea and vomiting associated with cancer chemotherapy.

The pharmacological effects of fosaprepitant are attributed to aprepitant.

Intravenous fosaprepitant 115mg can be substituted for oral aprepitant 125mg ahead of chemotherapy on day 1 only of an anti-emetic regimen that includes a corticosteroid and a 5-HT₃ antagonist.

Fosaprepitant should be infused intravenously over 15 minutes.

Notice-board p591

Biosimilar erythropoietin product now available

Epoetin zeta (Retacrit) — a biosimilar erythropoietin product — has been launched in the UK by Hospira this week. Registered through the European Medicines Agency's biosimilar medicinal products procedures, epoetin zeta has demonstrated comparable efficacy and safety to epoetin alfa (Eprex).

Data presented at a European Renal Association and European Dialysis and Transplant Association annual congress in Stockholm this week showed equivalent correction of haemoglobin levels between patients with renal anaemia receiving epoetin zeta and those given epoetin alfa. A separate study of over 300 patients showed equivalent responses to maintenance therapy with the agents.

Notice-board p591

Naproxen and celecoxib not effective as preventives for Alzheimer's disease

Naproxen and celecoxib do not appear to improve cognitive function in adults with a family history of Alzheimer's disease, researchers say.

In the Alzheimer's disease anti-inflammatory prevention trial (ADAPT) researchers randomly assigned 2,528 cognitively normal men and women aged 70 years and older to receive celecoxib 200mg twice daily, naproxen 220mg twice daily or placebo. They say that they tested these drugs as primary prevention agents because of the strong epidemiological evidence of a lower incidence of Alzheimer's disease in people taking non-steroidal anti-inflammatory drugs (NSAIDs).

The researchers comment that the trial's cognitive function results did not show a protective effect with the use of NSAIDs. There was, in fact, weak evidence for a detrimental effect of naproxen, they point out. The researchers add that continued follow-up appears warranted to investigate treatment effects with respect to timing of exposure. However, they say: “For now we suggest that naproxen and celecoxib should not be used for the prevention of Alzheimer's disease.”

The findings are published online in the *Archives of Neurology* (<http://archneur.ama-assn.org>). These contrast with further epidemiology data published recently in *Neurology*, which suggest that long-term NSAID use might be protective against Alzheimer's disease (2008;70:1672).

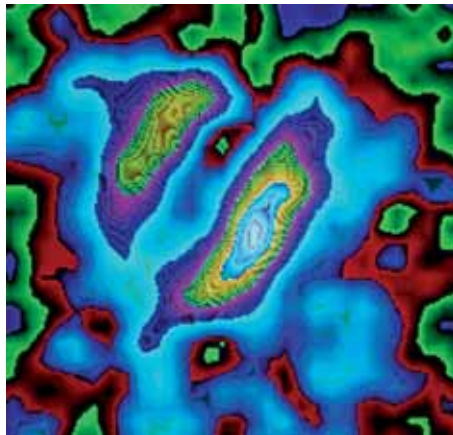
Reconsider advice on beta-blocker use in surgery

Peri-operative beta-blockers in non-cardiac surgery reduce the risk of non-fatal heart attack but increase the risk of death and stroke, according to research published online in *The Lancet* (www.thelancet.com, 13 May). The authors suggest that guidelines advocating the use of peri-operative beta-blockers should be reconsidered.

Researchers in Canada conducted a trial to assess the effects of peri-operative beta-blockers in non-cardiac surgery after previous trials showed conflicting results.

They recruited 8,351 patients with or at risk of atherosclerotic disease in 190 hospitals across 23 countries. Patients were randomised to receive extended-release metoprolol or placebo, which was started two to four hours before surgery and continued for 30 days. The primary endpoint was a composite of cardiovascular death, non-fatal myocardial infarction and non-fatal cardiac arrest.

Fewer patients in the metoprolol group than in the placebo group reached the pri-



Scintigram showing ischaemia resulting from a heart attack

Centre Jean Perrin/Science Photo Library

mary endpoint ($P=0.0399$), as a result of fewer heart attacks in the metoprolol group (hazard ratio 0.73, 95 per cent confidence interval 0.60–0.89; $P=0.0017$). However, more

people in the metoprolol group had a stroke (2.17, CI 1.26–3.74; $P=0.0053$) and more people died (1.33, CI 1.03–1.74; $P=0.0317$) than in the placebo group.

The results suggest that for every 1,000 patients undergoing non-cardiac surgery, extended-release metoprolol would prevent 15 heart attacks, three cardiac revascularisations and seven patients from developing atrial fibrillation. However, it would result in an excess of eight deaths, five strokes, 53 episodes of hypotension and 42 of bradycardia, say the researchers.

In an accompanying editorial (*ibid*), Lee Fleisher, University of Pennsylvania, Philadelphia, and Don Poldermans, Erasmus Medical Centre, Rotterdam, agree that high-dose beta-blockers are associated with greater risk than benefit but say that they believe low-dose long-acting agents titrated to effect at least seven days in advance (as used in the DECREASE trials) are associated with overall benefit.

Folic acid and vitamin B fail to reduce CV events in high-risk women

Folic acid combined with vitamin B supplementation does not reduce the risk of cardiovascular events in women at high risk of cardiovascular disease, researchers confirm. This is despite significant lowering of homocysteine levels (*JAMA* 2008;299:2027).

In the women's antioxidant and folic acid cardiovascular study (WAFACS), part of an ongoing randomised study of antioxidant vitamins in women, researchers randomly assigned 5,442 women aged 42 years or older, with a history of CVD or three or more coronary risk factors, to receive either a combination pill containing 2.5mg folic acid, 50mg vitamin B₆ and 1mg vitamin B₁₂, or placebo.

During 7.3 years of follow-up, 406 women (14.9 per cent) in the active treatment group experienced at least one cardiovascular event included in the primary endpoint (myocardial infarction, stroke, coronary revascularisation or cardiovascular mortality) compared with 390 women (14.3 per cent) in the placebo group.

In a substudy of 300 patients, the researchers found that the geometric mean homocysteine level was 18.5 per cent lower in the active group than in the placebo group (95 per cent confidence interval, 12.5–24.1; $P<0.001$).

They comment: "Our results are consistent with prior randomised trials performed primarily among men with established vascu-

lar disease and do not support the use of folic acid and B vitamin supplements as preventive interventions for CVD in these high-risk fortified populations."

The author of an editorial (*ibid*, p2086) concludes: "B vitamin supplements cannot currently be recommended for the prevention of CVD events (with the exception of rare genetic disorders) and there is no role for routine screening for elevated homocysteine levels. However, ongoing clinical research should provide further evidence on whether there may be any role for homocysteine-lowering B vitamin supplements in CVD prevention and for the overall importance of homocysteine as a CV risk factor."

Combination of NRT and nortriptyline unlikely to be more effective than single therapies in smoking cessation

A combination of nortriptyline and nicotine replacement therapy (NRT) is unlikely to be more effective at helping people stop smoking than offering the therapies separately, according to the results of a study published online by the *BMJ* last month (27 April 2008, www.bmj.com).

Researchers discovered that 16 per cent of smokers taking the combination therapy were still not smoking six months after starting treatment compared with 12 per cent using NRT and a placebo. At 12 months, 11 per cent of smokers on dual therapy were still not smoking compared with 9 per cent in the placebo group. The differences were not statistically significant. The researchers, led by Paul Aveyard from the division of primary

care and public health, University of Birmingham, point out that those in the combined therapy group reported higher rates of dry mouth and constipation as well as feeling shaky and sweating compared with the placebo group. Taking nortriptyline did reduce feelings of depression and anxiety but both groups of smokers reported they still had the urge to smoke.

The researchers conclude: "Although nortriptyline alone has a place in smoking cessation clinics, the data show that the efficacy of combination treatment is slight and should not be used routinely."

The results of the study were based on data from 901 people attending NHS smoking cessation services.

Further data required before varenicline can be regarded as first-choice for quitters

Varenicline (Champix) should not be regarded as the first-line choice for smoking cessation therapy until further data are available and reports of depression and suicidal ideation have been further reviewed, according to the latest *Drug and Therapeutics Bulletin*.

"Use of the drug should follow discussion with the patient of current safety concerns and treatment should be combined with regular advice and support from a healthcare professional," it says (2008;46:33).

Diabetes care The May *DTB* also reviews specific advice women with diabetes should receive before conception to help reduce the risk of poor pregnancy outcomes (*ibid*, p36).