

New code includes pharmacy despite opposition

Community pharmacies in England have been made subject to a new code of practice on the promotion of services funded by the NHS (*PJ*, 2 December 2006, p656).

This is despite the Pharmaceutical Services Negotiating Committee, the National Pharmacy Association and the Company Chemists' Association all telling the Government that the code should not apply to pharmacies (*PJ*, 10 March 2007, p272).

Pharmacies, they said, were private businesses that should be allowed to invest their profits in any way they wished and that it would be difficult to decouple the promotion of privately funded services and products from those available through the NHS.

The new code, which was published last week and came into effect immediately, is intended to protect users of NHS services by ensuring that information is not misleading, inaccurate, unfair or offensive, to protect the brand and reputation of the NHS, and to ensure that expenditure of public money on promotional activity is not excessive.

The code recognises that there will be occasions when it is difficult to distinguish between promotional material aimed at NHS and non-NHS patients. To help clarify this, the code says that the NHS logo is a trade mark that can only be used on material that promotes NHS services and that the code applies to any promotion that bears the NHS logo.

NHS service providers will also be expected to adhere to the codes of practice administered by the Advertising Standards Authority that apply to all media, including television and radio.

Neal Patel, head of communications at the NPA, said: "The NPA does not think that the decision to extend the code to cover community pharmacy should be taken at this time — full consultation with the sector is needed first. However, the NPA does recognise there are benefits to being included in a modified code of practice but these need to be weighed up against the considerable practical, professional and commercial implications of applying the code to our sector."

A PSNC spokesman said: "We are disappointed that pharmacy is included in this early version without further consultation particularly where the initial consultation in November 2006 suggested that the code would apply first to secondary care."

Rob Darracott, CCA chief executive, commented: "It is disappointing that in this very broad brush code the DoH has not responded to the specific concerns of those



Code applies to any material that bears the NHS logo

providers of NHS services, like community pharmacies, and in particular businesses like CCA member companies, who use promotion to support their healthcare activities, some of which are more clearly NHS than others. Choice and competition are not new issues for community pharmacy and the importance of brand reputation is not new to CCA member companies either. Pharmacists and pharmacy companies who

promote their services are already subject to both public and professional codes of behaviour. So, while in one respect this kind of regulation is not new, we are concerned that this seems to add another layer of unnecessary bureaucracy."

□ NHS Choices Patients needing routine, elective NHS treatment will be allowed to choose from any hospital provider in England that meets NHS standards from April, the Department of Health has announced. Under "Free choice", money follows the patient and hospitals are paid a tariff rate for each person treated. NHS hospitals will also be allowed to promote their services to the public under the new code of practice.

Hospital pharmacy in Bolton to get access to electronic patient record

Pharmacy staff at the Royal Bolton Hospital will shortly have access to electronic summary care records (SCR) for inpatients, *The Journal* has learnt. Bolton and Bury primary care trusts are early implementer sites for the NHS care records service in England and the hospital's pharmacy department is one of five access points for the SCR.

Brian Smith, the hospital's chief pharmacist, believes that accessing the summary care record is a perfect way to check a patient's medication history without having to track

down his or her GP. "Because it is an extract of current information from the GP's own system it is highly likely to be accurate," he explained.

The pharmacy department hopes eventually to use the SCR as a routine method for verifying drug histories. All pharmacists and technicians who carry out ward-based medicines management services will be issued with a smartcard so that they can access the records. "We are moving towards ward-based technicians doing the vast majority of

drug histories on admission," Mr Smith explained.

It is hoped that staff will be able to access records within the next three to five weeks once smartcards have been obtained.

A spokeswoman for Bolton Primary Care Trust confirmed that community pharmacists in Bolton cannot access the SCR at this stage. There are now more than 165,000 records on the spine for Bolton and Bury residents and less than 1 per cent of people have opted out of having one created.

Consultation on regulation of health and social care launched

Views on which health and adult social care services should require registration with the new Care Quality Commission are being sought by the Department of Health.

In "A consultation on the framework for the registration of health and adult social care providers" proposed regulated activities in primary care do not cover services provided by community pharmacists, only those provided by GPs and dentists.

However, the consultation indicates that, in time, other providers may expand their activity to provide regulated services. For exam-

ple, it says, the forthcoming pharmacy White Paper will set out how services are expected to develop in the future.

All NHS trusts are expected to have to register with the CQC, which will be established subject to Parliamentary approval of the Health and Social Care Bill. The new registration system will come into force from April 2010.

The consultation closes on 17 June and is available on the Department of Health website at www.dh.gov.uk and via *PJ Online* (www.pjonline.com/pjlinks).

Ephedrine/pseudoephedrine restrictions start 1 April

Restrictions on the sale of products that contain ephedrine or pseudoephedrine come into force on 1 April. Packs for pharmacy sale will be restricted to 720mg of pseudoephedrine or 180mg of ephedrine. Multiple packs may not be sold unless the total quantity of active ingredient does not exceed these limits. It will be an offence to sell an ephedrine-containing product and one that contains pseudoephedrine at the same time.

Law and Ethics Bulletin p377

Independent safety review lacking in paediatric trials

Only 2 per cent of paediatric clinical trials include independent safety monitoring, a seven-year review suggests (*Acta Paediatrica* 2008; 97:474).

Researchers from the University of Nottingham's academic division of child health analysed 739 trials, published between 1996 and 2002, that examined therapeutic use of oral and intravenous medicines in children. They found that 71 per cent of the trials reported adverse events, 20 per cent of which reported serious adverse events. Adverse drug reactions were recorded in 36.5 per cent of trials and 11 per cent had a moderate or severe ADR. Although 74 per cent of the trials described how safety monitoring was performed during the study, only 13 (2 per cent) had independent safety monitoring committees.

Having "an independent monitor who has the ability to swiftly question any ADRs or inequalities in morbidity or mortality is essential", the researchers say. They report that six of the trials included in the review were terminated early due to drug toxicity and all of these had independent safety monitoring committees.

Lead author Helen Sammons, clinical associate professor in child health, based at Derbyshire Children's Hospital, added that although "all trials have safety checks by the trial team and report adverse events to the regulatory authorities", an independent safety monitoring committee, which can look at any reactions without bias, "is an important extra step to safeguard safety".

Commenting on the review, Ian Wong, director and professor of paediatric medicines research, Centre for Paediatric Pharmacy Research, London, said that the number of trials reported to have a safety monitoring committee was unusually low and may reflect old practice or that simply the investigators did not report them in their publications.

"Nevertheless, good clinical practice recommends clinical trials set up an independent data monitoring committee to review the accruing trial data and to assess whether there are any safety issues that should be brought to participants' attention or any reasons for the trial not to continue," said Professor Wong.

Richard Ley, a spokesman for the Association of the British Pharmaceutical Industry, told *The Journal*: "If you are conducting a small trial in one centre or a couple of centres you do not need an independent data safety monitoring board. It is not necessary. Where companies would consider setting up such a body is if there was a large trial over many sites, perhaps in many different countries, and then a safety committee could be a valuable tool." He also pointed out that there is a regulatory requirement on people conducting clinical trials to report ADRs within 15 days of them occurring.

Drug companies want to be doing everything they can to ensure safety but it is down to them to decide whether or not to have an independent safety monitoring committee, he added.

In brief

Velcade cardiopulmonary safety

Bortezomib (Velcade) should not be used to treat multiple myeloma patients with certain severe pulmonary or heart problems, says the European Medicines Agency (EMA). The EMA has concluded that the benefits of bortezomib are greater than its risks, except in patients with acute diffuse infiltrative pulmonary and pericardial disease. The EMA also recommends that patients with pulmonary disorders should have chest X-rays and that their individual benefit-risk profiles should be considered before using the drug.

Tysabri liver warnings

Europe wants stronger warnings to be included in the product information for natalizumab (Tysabri). Following a safety review, the European Medicines Agency said there is a need to warn patients and prescribers that liver injury may occur when the multiple sclerosis drug is used. The agency also recommends that patients treated with natalizumab should have their liver function monitored.

New perindopril tablets mean a change in dosage for patients

Patients taking perindopril products Coversyl and Coversyl Plus will need to be switched to one of Servier Laboratories's new perindopril arginine presentations in April. Prescribers, pharmacists and patients should be aware that the new products — Coversyl Arginine (perindopril arginine) and Coversyl Arginine Plus (perindopril arginine/indapamide) — come in strengths and packaging that are different from the current formulations and that both existing and new stock will be present in the supply chain for a number of weeks.

A spokesman for Servier told *The Journal* that special patient leaflets describing the change would be available from Servier representatives. According to the company, Coversyl 2mg, 4mg and 8mg tablets are bio-equivalent to Coversyl Arginine 2.5mg, 5mg and 10mg tablets, respectively.

The move is part of Servier's plans to harmonise its global manufacturing of perindopril products. In warmer climates strips of Coversyl tablets needed to be foil-wrapped to



Coversyl Arginine comes in 2.5mg, 5mg and 10mg tablets

ensure the products' stability. The new perindopril arginine products do not require this additional packaging. Due to the capacity of the supply chain it may take a number of weeks for the new product to reach patients depending on individual stock levels, the Servier spokesman pointed out.

"It will take a few weeks until all prescribing/dispensing systems are updated as several steps — most of them outside our control — are involved in this process," he said. "We have been informing the relevant bodies to ensure it will be straightforward to prescribe and dispense. We anticipate this will start mid to late April. Pharmacists should continue to dispense Coversyl and Coversyl Plus as appropriate during this transition."

Conservatives uncover 130 per cent increase in deaths due to medicines adverse effects

Research carried out for the Conservative Party has found that the number of deaths associated with adverse drug reactions has risen by 130 per cent over the past 10 years.

Fatal ADR reports rose from 447 in 1997 to 1,031 last year, according to data collected by the Medicines and Healthcare products

Regulatory Agency. The number of prolonged hospital admissions resulting from ADRs increased by 82 per cent from 2,484 to 4,545 over the same period. And the total number of reports received rose by 30 per cent to 21,600.

Shadow health secretary Andrew Lansley said: "These figures show a worrying trend

towards more serious drug reaction leading to hospitalisation and a sharp increase in the number of deaths.

"This warrants further investigation but clearly indicates that alongside the benefits of new drug treatments, we must have an improved system of patient safety."

Scotland's community pharmacy representatives oppose plans to register and regulate technicians

Community Pharmacy Scotland, the body that negotiates on behalf of community pharmacy contractors in Scotland, is opposing plans for the Royal Pharmaceutical Society to take on the regulation and registration of pharmacy technicians.

The CPS also questions the need for technicians working in the community to face statutory regulation at all.

The comments come in its response to a Department of Health consultation on the Healthcare and Associated Professions (Miscellaneous Amendments) No 2 Order — part of the Government's plans to reform professional regulation.

The CPS argues that while technicians in hospital may operate more independently, community technicians always work supervised by a pharmacist or according to set procedures. "We are not convinced at this moment that demonstrable need for the regulation of technicians working within the community has been shown," the CPS says.

And since only 526 technicians in Scotland have put their names on the



Society regulation of technicians in Scotland opposed

Society's voluntary register, the CPS questions whether technicians themselves are committed to registration. Opposition to registration from technicians could, the CPS warns, affect recruitment in community pharmacy and damage patient safety.

"Our view is that we need to consider

more carefully the distinction between registration and regulation," the CPS says. "We are not opposed to moves towards the creation of a register or list of technicians working within the community, but at this time we would question the need for statutory powers to regulate and whether it is in fact what technicians want."

The organisation also doubts the appropriateness of a GB-wide body like the Society taking on the regulatory and registration duties because of the differences to practice brought about by devolution.

It also points out that the Society will lose its regulatory powers in 2011.

The comments have disappointed the Association of Pharmacy Technicians UK.

Its president, Sarah Wilcox, said technician regulation and registration was in the best interests, of patient safety and that a separate system for registration and regulation would prevent the free movement of technicians across the UK. She said: "If the Society has agreed to regulate technicians then it should be UK-wide."

In brief

Pneumococcal vaccine supply

Fees and reimbursement prices for supplying pneumococcal vaccines on NHS stock orders and prescriptions in Scotland are to remain the same as last year. Arrangements for vaccine supply in 2008–09 were published in an NHS circular last week. It states that GPs should tell community pharmacists how many vaccines they require as soon as possible.

Munro Pharmacy sold

Munro Group announced this month that it has sold its retail pharmacy division to Admenta Holdings Ltd, the holding company of LloydsPharmacy Limited. In a statement, Munro Group said that ownership of its wholesale division has not changed.

Senecio ban formalised

Sale, supply or importation of unlicensed medicinal products for internal use which contain *Senecio* species will be prohibited from 1 April when the Medicines for Human Use (Prohibition) (Senecio and Miscellaneous Amendments) Order 2008 comes into force.

Clearer evidence needed of OTC dose benefits

Regulators should insist on better evidence to support the use of over-the-counter doses of medicines, a *BMJ* article argues this week (*BMJ* 2008;336:694).

Medicines may be less effective in low doses and so regulators should ask for clearer evidence of benefit at the OTC dose if this is lower than the dose usually prescribed, the authors say.

They add that the benefits of OTC availability and self-treatment probably only apply to a small subset of medicines and that

patients may misdiagnose themselves. "Pharmacists can provide clinical advice to minimise the risk of misuse of pharmacy-only drugs, but supervision by a busy community pharmacist in the UK may be perfunctory," they say.

The authors also warn that, despite the Royal Pharmaceutical Society's internet logo initiative (*PJ*, 5/12 January, p3), the lack of medicines regulation in much of the world and access to medicines through the internet could compromise patient safety.

Use paracetamol or ibuprofen to treat colds in children

Children suffering from a cold should only be treated with paracetamol or ibuprofen to treat fever and with a cough syrup if they have a cough, according to new Government advice.

Following a review of over-the-counter products used to treat cough and colds in children, the Medicines and Healthcare products Regulatory Agency says that the following medicines should no longer be licensed for children under the age of two years: the antihistamines brompheniramine, chlorphenamine and diphenhydramine; the anti-tussives dextrometorphan and pholcodine; the expectorants guaifenesin and ipecacuanha; and the decongestants phenylephrine, pseudoephedrine, ephedrine, oxymetazoline and xylometazoline.

The MHRA adds that the pharmaceutical industry has agreed to remove the dosage instructions on products for children under two years and to add further instructions for treating children aged two to six years. Products with updated packaging will be in pharmacies by October.

A US safety review of children's cough and cold medicines revealed a number of serious reports, mostly involving children under two years. In many cases children were given too much medicine because parents were confused about the correct dose or had given more than one product with the same ingredient. UK data suggest that children under two years are at a greater risk of potential harm and so new advice is being issued as a precautionary measure.

Medicines funded through risk-sharing must offer tangible value

Costs and benefits of medicines used within risk-sharing schemes should be assessed as carefully as the costs and benefits of other medicines to make sure they genuinely offer the NHS value for money, according to a position statement from the Cancer Network Pharmacists Forum that is endorsed by the British Oncology Pharmacy Association.

Following approval by the Department of Health of the Velcade response scheme — as part of the National Institute for Health and Clinical Excellence appraisal of bortezomib for multiple myeloma (*PJ*, 27 October 2007, p461) — an increasing number of risk-sharing initiatives are being offered to NHS trusts by pharmaceutical companies. The schemes are proposed as a means of securing entry of new drugs into the challenging UK market, says the CNPF (see Panel).

Such initiatives are inconsistent in the way they work, which increases the financial, administrative and governance risks to NHS organisations, the statement says. Although the schemes save on drug acquisition costs they can require significant extra work from pharmacy and finance departments to ensure their



Calculations of benefits need to factor in additional workload costs

success. These costs need to be factored into the overall evaluation of the benefits to the NHS, it adds.

The CNPF warns that NHS organisations are under increasing scrutiny about the decisions they make, particularly for oncology medicines, and there is a risk that the offer of a discount scheme may lead trusts to make decisions outside their established policies.

Several recommendations are made, including that the industry should offer these schemes across the NHS and should not target specific organisations where uptake of the drug in question is slow. The forum also believes that the DoH should develop a position on whether risk-sharing schemes offered only as an interim measure are acceptable.

The CNPF says the DoH is not planning to issue guidance for NHS organisations on the adoption of schemes outside of NICE appraisals but that the Association of the British Pharmaceutical Industry has been asked to produce good practice guidance for the industry on preparing and administering the schemes. The CNPF has published the position statement to inform this process and to provoke wider debate. It is available on the BOPA website at www.bopaweb.org.

Apathy may undermine supplementary prescribing

Medical apathy and the introduction of independent prescribing may undermine the success of supplementary prescribing, according to a study published in *Health Policy* this month (2008;85:277).

Richard Cooper, a research fellow at the school of pharmacy, University of Nottingham, and colleagues conducted a review of the nursing and pharmacy supplementary prescribing literature — empirical research and grey literature — from 1997 to 2007. They found that nurse and pharmacist supplementary prescribers were positive and generally confident about non-medical prescribing and that it has been successfully implemented in a range of settings. However, they also discovered that doctors are more critical of the development and lack awareness and understanding of it.

Several underlying tensions became evident during the review, say the researchers. For example, training needs and existing competencies differ among pharmacists and nurses, suggesting that educational reviews of joint courses may be needed. The researchers also propose that a review of the clinical management plan may be necessary to make it more flexible and quicker to set up and use.

The researchers question whether, because of its inflexibility, supplementary prescribing will become viewed as simply a transitional prescribing model providing newly qualified non-medical prescribers with confidence before prescribing independently. "This may have significant policy implications for the commissioning and funding of non-medical prescribing services," they comment.

During the review, the authors identified a lack of research in several areas, including patients' experiences of supplementary prescribing, patient safety and the economic or NHS cost implications of supplementary prescribing.

They suggest that methodologically robust research that focuses on key concerns such as patient safety and economic outcomes is urgently needed to inform the implementation of supplementary prescribing.

Risk-sharing schemes

There appear to be three scenarios for which risk-sharing schemes are being proposed:

- Where a company wants to get a foothold in the market before a National Institute for Health and Clinical Excellence appraisal and competitor therapies are cheaper
- Where a company wishes to reduce the cost per quality adjusted life year (QALY) after a negative NICE appraisal
- Where a company wishes to reduce the cost per QALY and allow the product to hit the NICE threshold at the time of a technology appraisal

Epoetin delta approved for use in NHS Wales

Epoetin delta and intravenous topotecan have been recommended for use within NHS Wales, following Ministerial ratification of recommendations made at the February meeting of the All Wales Medicines Strategy Group.

Epoetin delta (Dynepe) has been recommended for the treatment of anaemia in patients with chronic renal failure. Intravenous topotecan (Hycamtin) has been approved for two indications. It is recommended for patients with relapsed small cell lung cancer for whom retreatment with the first-line regimen is not considered appropriate. It has also been approved, in combination with cisplatin, for cisplatin-naïve patients with carcinoma of the

cervix recurrent after radiotherapy or with stage IVB carcinoma of the cervix.

A positive recommendation by the AWMSG places an obligation on trusts and local health boards in Wales to fund treatment, but AWMSG advice is interim to any subsequent National Institute for Health and Clinical Excellence guidance.

Tacrolimus (Advagraf) was not recommended for the indications the AWMSG assessed: prophylaxis of transplant rejection in adult kidney or liver allograft recipients and treatment of allograft rejection resistant to treatment with other immunosuppressive medicines in adult patients.

Desktop clinical information resource launched for NHS

NHS employees in England will be able to search for clinical information — from resources such as the British National Formulary and the National Library for Health — via their Windows desktop and Microsoft Office from April using a new service launched by the NHS Common User Interface team at NHS Connecting for Health. A range of NHS Medical Search tools, developed by Microsoft as part of an agreement with NHS CfH, can be downloaded from the N3 network at www.medicalresearchservices.nhs.uk.

Digital versions of new BNF include extra entries

Digital versions of the latest British National Formulary now include a range of multi-ingredient preparation monographs not available in print.

Historically, the BNF has included only a few monographs for medicinal products with two active ingredients. Monographs for ramipril/felodipine, triamterene/furosemide, co-amilofruse (amiloride/furosemide) and co-tenidone (atenolol/chlortalidone) will be the first of a large number of additional entries in the digital version of BNF 55.

"This development provides a more accurate representation of the characteristics of these preparations than has hitherto been possible in print, and crucially presents this information in a single location within the publication," states a leaflet accompanying BNF 55.

The latest edition contains guidance on the community management of emergencies such as anaphylaxis, meningococcal disease and myocardial infarction. This new information is located in the reference pages at the back of the printed BNF and includes doses



Detail from the cover of the new BNF

of drugs to be used for immediate care by community healthcare professionals.

BNF 55 also includes updated advice on the use of adrenaline for anaphylaxis and folic acid for the prevention of neural tube defects, as well as new safety considerations for the use of erythropoietin products.

BNF editors and clinical advisers have reviewed the National Institute for Health and Clinical Excellence guidelines on antimicro-

bial prophylaxis against infective endocarditis for adults and children undergoing interventional procedures. In line with these guidelines, the BNF now states that antimicrobial prophylaxis is no longer recommended for the prevention of endocarditis for patients having dental and non-dental procedures. Prophylaxis may expose patients to the adverse effects of antimicrobials when the evidence of benefit has not been proven.

Also added is the latest advice on INR (international normalised ratio) monitoring for anticoagulated patients who require dental surgery.

BNF newsletter Healthcare professionals wishing to be updated with the latest changes affecting clinical practice can sign up to receive joint newsletters from the BNF and BNF for Children (<http://bnf.org/newsletter>). The newsletters, to be issued several times a year, will include: details of significant updates; tips for using the BNF and BNFC effectively; latest developments on BNF and BNFC publications; and links to case studies and examples of prescribing excellence.

NICE offers advice on helping mothers and pregnant women make decisions about lifestyle

Guidance on how to help pregnant women and mothers make decisions about their diet and lifestyle has been issued by the National Institute for Health and Clinical Excellence.

Health professionals are asked to advise pregnant women and parents of young children about the Healthy Start scheme, to support families in changing their diet, to check

that women at risk of vitamin D deficiency are following advice on supplementation and to advise women who could become pregnant about the benefits of taking folic acid supplements.

In separate guidance, NICE says that women with diabetes who are planning to become pregnant should be informed that es-

tablishing good glycaemic control before conception and continuing this throughout pregnancy will reduce the risk of miscarriage, stillbirth and neonatal death and of the baby having a malformation at birth. NICE also says that women with pre-existing diabetes should access specialist services before conception.

EU sets out plans to make it easier to spot counterfeit medicines

Consultation has started on plans to make it harder for counterfeit medicines to circulate in the EU and to make it easier to spot them when they do.

Central to the proposals, which were published on 11 March by the European Commission's Directorate General for Enterprise and Industry, is a plan to make European pharmaceutical law apply to everyone who trades in medicines in the EU, whether or not they actually handle products or even intend to place them on the European market. This would mean that brokers, agents and traders who only use Europe as a staging post in the distribution of medicines from one country to another would be subject to the same requirements as manufacturers and wholesalers.

In addition, manufacturers might be required to seal all packs of medicines and to mark individual packs so that they can be identified and traced at all stages in the supply chain, with records of all transactions other than final supply to a patient being kept in a central record accessible to everyone involved in the process. It would be illegal for anyone other than the market authorisation holder and an end user (hospital, healthcare professional or patient) to repackage or open any product.

It is unclear what impact the prohibition on opening packs would have on parallel imports. The EC's consultation paper notes that the ban would make it impossible for package leaflets to be changed and says that the consequences of this, and ways round it, will be addressed in an impact assessment.



Zoran Siminir/Stockphoto

EU proposals could make it illegal for anyone but the licence holder or an end user to repackage medicines

But the European Association of Pharmaceutical Companies sees no problem. EAEP secretary general Heinz Kobelt said: "DG Enterprise confirms the principle, supported by the EAEP, that repackaging should only be carried out by market authorisation holders, which includes manufacturers and licensed parallel importers."

The EC consultation comes after a sharp increase in seizures of counterfeit medicines at EU borders. In 2006, 2.75 million packs of counterfeit products were seized, representing a 384 per cent increase over the previous year. There have also been trends towards counterfeiting life-saving medicines, as opposed to lifestyle medicines, and trying to get them into the licensed distribution chain, rather than selling them over the internet.

Italy to offer international pharmacy degree

A new pharmacy degree course with an international focus is to open its doors to students later this year.

The five-year course, which will be based at the University of Rome Tor Vergata, will be taught in English and will allow students to specialise in three subject areas, such as pharmacy, pharmaceutical biotechnologies and pharmacy regulations.

The school of pharmacy at the University of Nottingham and Alliance Boots have both agreed to help the University of Rome Tor Vergata establish the course. "This will be a wholly new endeavour for them," said Saul Tendler, head of the school of pharmacy at Nottingham, which has already established a "2+2" MPharm course, where students spend the first two years studying at its campus in Malaysia and the final two years studying at its UK campus (*PJ*, 24 June 2006, p761). Professor Tendler explained that the new

course is being designed by staff at Tor Vergata to follow national requirements in Italy and will ultimately be accredited in Italy.

"It is not envisaged that the course will seek to be accredited by the Royal Pharmaceutical Society," he said. However, he added: "Students will have the same mobility rights as others in the EU. As the course is taught in English it might be that once registered the students will ultimately find work in the UK."

As part of the course, students will spend six months within a pharmacy environment. Theoretically, students on the course could spend time at the University of Nottingham. Professor Tendler said: "Through Erasmus exchanges it might be possible for student mobility to occur." He added: "One positive development is that it will be possible for our year four students to undertake their final year projects in Rome."

Europe

Smoking ban cuts heart attacks

Banning smoking in public places in Italy preceded an immediate reduction in acute coronary events, such as heart attacks. Researchers identified acute coronary events in Rome from hospital discharge reports and from regional registers of causes of deaths for five years preceding the smoking ban and compared them with those occurring one year after the ban. They found an 11.2 per cent reduction in acute coronary events in persons aged from 35 to 64 years and a 7.9 per cent reduction in those from 65 to 74 years (*Circulation* 2008;117:1183).

Records plan to spot ADRs

The electronic health records of 30 million patients from around Europe, including the UK, are to be used to try to identify adverse drug reactions that clinicians have failed to spot. The EU is to spend €4.5m on the project, which is being co-ordinated by Erasmus University Medical Centre in Rotterdam, and will concentrate on data mining and epidemiological computation techniques to identify ADRs in children.

EU applications up

Applications for new marketing authorisations under the EU's centralised procedure are expected to rise by 12 per cent in 2008, according to the European Medicines Agency's 2007 annual report. The report notes that applications in 2007 were 15 per cent up on 2006, with 65 opinions being finalised for submission to the EC. Cancer medicines were the most represented therapeutic category, followed by anti-infective agents.

Irish pharmacies face cuts

Pharmacies in Ireland face a dramatic cut in income as the Health Services Executive seeks to reduce the on-cost payments it makes when prescriptions are dispensed. The HSE wants to impose reductions without consultation because, it says, to negotiate with the Irish Pharmaceutical Union, rather than individual businesses, would break competition law.

Parallel traders complain

Parallel traders have complained to the EC that a government-endorsed dual pricing scheme in Spain restricts competition and consumer choice. In Spain, pharmaceutical companies are allowed to charge wholesalers higher prices for medicines that are to be exported than for medicines for domestic use. Pfizer, Lilly, MSD, Sanofi and Janssen have all adopted dual-pricing policies.

Age to start HIV therapy in children needs research

Large randomised controlled trials to determine when to initiate treatment with anti-retroviral therapy in children with HIV are urgently needed, according to two consultant paediatricians who debate the issue in the on-line, open access journal *PLoS Medicine* (www.plosmedicine.org, 25 March).

Steven Welch, consultant in paediatric HIV and infectious diseases at Heartlands Hospital in Birmingham, argues that treatment should be deferred. However, Di Gibb, professor in epidemiology and a consultant paediatrician at the Medical Research Council Clinical Trials Unit, London, lays the case for treatment to be initiated earlier.

Both experts agree that in infants less than one year old high susceptibility to life-threatening opportunistic infections and irre-

versible brain damage from HIV encephalopathy during such a critical period of development means that early initiation of antiretroviral therapy (ART) is warranted.

However, Dr Welch argues that, for children older than one year, treatment should be delayed until it is really needed. He highlights results from the SMART trial in adults, which indicate that treatment interruption increases risk of opportunistic disease or death, and emphasises that the only way of minimising exposure, and hence cumulative adverse effects, is to avoid starting treatment too early.

Dr Welch also points out that a lack of palatable paediatric formulations and problems related to families not disclosing their child's diagnosis to friends and schools creates a risk of learned poor drug adherence prac-

tices and possible limitation of future treatment options because of drug resistance.

Professor Gibb counters that the lack of paediatric formulations should, rather than defer ART, spur lobbying of pharmaceutical companies to make more appropriate formulations. She argues that delaying treatment is no longer an option and that early initiation of ART for children is more important than for adults because in children HIV disease progression is faster, significant immune recovery is better, bacterial infections are more common and serious, occur at high CD4 counts and are reduced by ART, better growth occurs if ART is started earlier and, finally, HIV encephalopathy is particularly dangerous for children exposed to HIV during brain development.

Pharmacists can play a role in identifying patients at risk of typhoid

Incidence of typhoid and paratyphoid among UK travellers visiting friends and relatives in the Indian subcontinent is increasing, according to the Health Protection Agency. Community pharmacists have a key role in identifying at-risk patients and raising awareness of the need for thorough hygiene as well as pre-travel vaccination.

Almost 500 cases of typhoid and paratyphoid (enteric fever) were reported in England, Wales and Northern Ireland in 2006, the highest level for 10 years.

HPA data collected during a pilot study of enhanced surveillance between May 2006 and April 2007 show that most cases occurred in people of Indian, Pakistani or Bangladeshi ethnicity, whether UK or non-UK born, who had travelled from the UK to visit friends and family. This group were also least likely to have sought pre-travel health advice.

Most cases were reported in London, followed by the West Midlands, Yorkshire and



Denise Breau/Stockphoto

Handwashing can prevent paratyphoid and other gastrointestinal infections

Humber, and the South East — all regions with a large population of migrants, particularly from the Indian subcontinent, says the HPA. Risk of infection was six-fold greater for those travelling to visit friends and relatives than for those travelling for other rea-

sons. The highest rate of infection was in Bangladesh.

The symptoms of typhoid and paratyphoid include sudden onset of fever, severe headache, nausea, loss of appetite, constipation and sometimes diarrhoea. Around two-thirds of cases were infected with strains that were resistant to first-line antibiotics, the HPA points out.

Typhoid, but not paratyphoid, can be prevented by vaccination, which is available free at most GP practices in the UK. However, it is also important that health professionals emphasise the importance of food and water hygiene, including handwashing, to prevent paratyphoid and other gastrointestinal infections, the HPA advises.

Jane Jones, head of the HPA's travel and migrant health section, which co-ordinated the study, said: "Healthcare professionals have a key role here to identify their at-risk patients and raise awareness of the simple steps necessary to protect their health when travelling."

Strategies needed to increase access to drug paraphernalia

Strategies are needed to increase the distribution of needles and syringes to injecting drug users, according to research published by the Scottish Government last week.

The research, led by Jenny Scott, senior lecturer in pharmacy practice and medicines use at the University of Bath, aimed to identify which items of paraphernalia and injection preparation methods present the least risk to health and to investigate the impact of supply of paraphernalia on health.

The report recommends increased needle distribution to prevent sharing; increased both in terms of improved access and the quantity supplied. It also says that convenience and accessibility should be maximised for the supply of paraphernalia. However, pharmacy schemes receive mixed reviews from the drug users in-

terviewed for the research. "Some specifically mentioned increasing the number of needle exchange pharmacies, recognising that pharmacies are already common and this may increase geographical spread. However, others spoke against pharmacy needle exchange, describing concerns about confidentiality and attitude of staff putting them and their peers off from using pharmacy services," the report states.

The Scottish Government is expected to publish a national drugs strategy later this year.

Working group In response to a Parliamentary question last week, Scotland's public health minister Shona Robison said she would consider whether to establish a working group to develop guidelines for services that provide injecting equipment to drug users.

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NHS pharmacy workforce rises by 2 per cent between 2006 and 2007

The number of qualified pharmacy staff working in the NHS rose by nearly 2 per cent from September 2006 to September 2007, new figures show.

The latest workforce survey, published by the Department of Health, shows that the number of qualified pharmacy staff rose from 13,536 to 13,800 over this period (a rise of 1.95 per cent), equating to an increase in full-time equivalent staff from 11,902 to 12,139 (1.99 per cent). This is an increase on the year 2005–06 when pharmacy staff numbers were almost static, but follows an increasing trend, with numbers of pharmacy staff up by 30 per cent since 2001.

Pharmacy support staff have seen a massive expansion in number, with a 129 per cent increase between 1999 and 2007. However, there was a fall of 1.6 per cent during 2006–07 (from 3,322 to 3,268).

The latest figures show that of all qualified pharmacy staff working in the NHS, there are 10,776 full-time equivalents working in trusts,



Pharmacy staff numbers grew in 2006–07 after being almost static over the previous year

1,355 working for primary care trusts, and just two working in strategic health authorities (seven people were classed as “other”).

David Miller, vice-president of the Guild of Healthcare Pharmacists, commented: “This lack of regional pharmaceutical presence is regrettable since local action on pharmacy issues will be more difficult and thus may require more central professional intervention. Without this intervention there may be missed opportunities for identifica-

tion of workforce needs and associated planning based on denominators such as beds, population and patient activity.”

He continued: “For example, the Department of Health in England has given a clear commitment to increase the number of hospital preregistration graduates over the next few years to address the vacancy issue and, while we consider this is best addressed by a national recruitment and retention premium, this survey could at least allow those resources to be targeted more effectively.”

Supply of invoice information to become statutory in April

Voluntary invoice inquiries — used to find out how much community pharmacies in England pay for medicines so that reimbursement prices can be fixed in the Drug Tariff — are to be made statutory again. From 21 April, pharmacies will be obliged to supply any information requested, such as invoices, to the Secretary of State for Health or his nominee within 30 days.

Currently, the Department of Health sends a list of pharmacies to the Pharmaceutical Services Negotiating Committee, which then collects invoices from them on a voluntary basis and analyses the data for the DoH. Although the PSNC has always encouraged pharmacies to supply invoice information there has been no obligation to do so.

Steve Lutener, head of regulation at the PSNC, said: “These are enabling Regulations. The voluntary scheme at present works well and there is nothing to prevent a voluntary scheme.”

However, he explained that statutory underpinning for the voluntary scheme had been included in the NHS (Pharmaceutical Services) Regulations 2005 and in the 1992 Regulations that applied before them. The clause had been left out when amendments were made to the Regulations in 2007 and this change reinstates it.

Collection of data on patient outcomes will become routine, predicts OHE commission

Collection of data on patient outcomes will become routine for most conditions and NHS activity in the next five years, according to a health economics commission.

Within 10 years it will be common practice to collect data that measure the impact of NHS services on a patient in terms of their life expectancy, quality of life and the experience of their care, says a report from the Office of Health Economics commission on NHS outcomes, performance and productivity.

The commission, set up in the autumn of 2006 to look at what patient data should and could be routinely collected and analysed in the NHS, concludes that measurement of patient outcomes is both “practical and essential”.

It predicts collecting data will bring better outcomes for patients as well as encourage better performance from providers and improve productivity costs.

The commissioners recommend that generic measures of health outcomes — such as those covering quality of life before, during and after treatment — should be collected as well as other groups of data that are disease-specific.

Data for patients suffering from long-term conditions, such as chronic obstructive pulmonary disease, should be collected at regular intervals, it recommends.

The commission also proposes that routine information should be collected about patients’ personal experience of their care, which should address issues such as access to care, personal dignity, choice and the support available for carers.

PCT decisions should be scrutinised locally

Primary care trusts must be held to account for their decisions locally as well as nationally, according to four pharmacy organisations in their joint response to a Local Government Association inquiry in England. To this end, decisions made by PCTs should be scrutinised by local councillors through local authority overview and scrutiny committees, they say.

The Company Chemists’ Association, the National Pharmacy Association, the Pharmaceutical Services Negotiating Committee and the Royal Pharmaceutical Society argue that decisions made by PCTs have an enormous impact on the health of their local population and on healthcare providers. “It is therefore appropriate that they are accountable to taxpayers and patients, in line with their core responsibilities for securing best value,” the four organisations say.

They suggest that accountability at a national level should involve evaluation of PCTs’ performance against national targets and benchmarks, including high-level indicators such as morbidity and mortality, access to care and health inequalities.

The organisations add that scrutiny by local authorities would compensate for the “democratic deficit” in the NHS. “We believe that systems of accountability that sit outside the NHS — including local authority overview and scrutiny arrangements — are extremely important. Indeed, we would like to see overview and scrutiny committees take a still more active role, since councillors, like community pharmacies, are truly grounded in local communities,” the pharmacy organisations conclude.

The Local Government Association is examining how NHS services can be made more accountable to local people through the LGA health commission, which it set up in November 2007.