

Consultation on responsible pharmacist launched

A formal consultation on regulations relating to the “responsible pharmacist” — the concept that will replace “personal control” — was launched by the Department of Health as *The Journal* went to press.

The Health Act 2006 amended the Medicines Act 1968 and related NHS legislation in a number of ways, introducing the requirement that each pharmacy must have a responsible pharmacist and providing for changes in the pharmacist supervision requirements. These changes aim to clarify some anomalies, allow pharmacists to take on more clinical roles and make better use of pharmacy staff skills. The Act allows ministers to set out in regulations details of how the re-

sponsible pharmacist will exercise his or her statutory duty. This is what the DoH is now consulting on. Consultations on the pharmacist supervision regulations will follow later.

The consultation document comprises nine chapters, in which views are sought on several issues. These include pharmacy procedures, record keeping, absence of the responsible pharmacist, the qualifications and experience needed for the role, and circumstances in which a pharmacist can be responsible for more than one pharmacy. Other matters, such as enforcement of the regulations, the time needed to prepare for their introduction and the need for guidance to support this are also included.

Priya Sejjal, acting head of professional ethics at the Royal Pharmaceutical Society, said: “The changes to the Medicines Act will rectify some of the anomalies that currently exist. For example, currently, general sale list medicines can only be sold when the pharmacist is present, even though pharmacist presence is not necessary for other retail outlets.

“The Society is preparing a detailed response to the responsible pharmacist consultation and encourages the profession to respond and help to shape the way in which pharmacists will practise in the future.”

Further coverage of the consultation, which ends on 20 January 2008, will begin in next week's *Journal*.

Trust's ratings improve with support from pharmacy initiatives

The NHS is getting better, but there is still room for further improvement. That was the message from the Healthcare Commission when it released its second annual health check of NHS trusts last week.

The report rates all 394 NHS trusts in England on their quality of care and use of resources as excellent, good, fair or weak.

Anthony Sinclair, chief pharmacist at Birmingham Children's Hospital, which was one of two trusts to improve its ratings from fair to excellent across both categories of assessment, said that developments in the pharmacy service and having the trust actively behind the medicines management agenda has had an impact on ratings at his trust.

Overall, there has been a general improvement compared with last year's report. In 2005–06, 40 per cent of trusts scored either excellent or good for quality of care, with 15 per cent achieving this for use of resources. In 2006–07, these figures rose to 46 per cent and 37 per cent, respectively. Although the trusts scoring fair or weak were still in a majority, the trend towards improvement is encouraging, say the report's authors.

A score of excellent for both aspects of the report was achieved by 19 trusts, 17 more than last year. The Royal Marsden NHS Trust is the

only trust to achieve this accolade two years in a row.

At Birmingham Children's Hospital, the medical director has recognised that pharmacy interventions play a prominent role in reducing clinical risks, Mr Sinclair said. “There has been a change in culture towards improving medicines management across all members of staff.” This includes reforming the Drug and Therapeutics Committee, which, now with Mr Sinclair as vice-chairman, focuses heavily on the trusts medicines management agenda.

The pharmacy has revamped its service delivery to allow pharmacists and technicians more time on wards. “We now have several laptop computers with printers on mobile trolleys that the ward-based pharmacy teams use. Patients' own medicines can be relabelled at the bedside and [discharge medicines] can be dispensed from ward stocks.”

Other developments include:

- Delivering pharmacy presentations to medical staff on areas of clinical risk
- Increasing pharmacy presence in areas that previously had no pharmacy link
- Initiating an interface team to improve communication with primary care



Royal Marsden only trust to achieve double excellent rating two years running

- Introducing a “learning at lunch” programme for pharmacists
- Commencing research projects in collaboration with the local university

In contrast, all trusts with weak performance ratings will receive a further visit from the Healthcare Commission to ensure that systems are in place to improve performance. The details of the report can be accessed via *PJ Online* (www.pjonline.com/links/pj).

Talks address whether patients may be able to register for Healthspace at pharmacies

Patients may in future be able to register at community pharmacies to use the NHS web service Healthspace. The service will provide secure online access for patients in England, allowing them to view their summary care record, book appointments and, potentially, order repeat prescriptions.

The issue was discussed earlier this month at the first meeting of the Pan-Pharmacy NHS IT Group, which includes pharmacy bodies and NHS Connecting for Health, and was established to ensure engagement between the profession and all relevant pro-

grammes within NHS CfH (*PJ*, 1 September, p223).

“The pharmacy network offers accessibility and a trusted location [where] patients could sign up for access. Patients are likely to visit a pharmacy more often than a GP practice and this would support the profession's expanding role in managing patient care,” said the group in a joint press release.

A rigorous registration process has already been developed for patients in the care record early adopter areas who wish to access the site. The Department of Health has proposed that

pharmacists may in future support this process by validating patient identity. “Further work will be carried out to consider the practicality of this in more detail,” said the group.

Access to NHSmail, the e-mail and directory service designed specifically for NHS staff, was also discussed at the meeting.

The group heard that NHSmail will be piloted in two primary care trust localities before national roll-out. National pharmacy bodies will be able to feed into this process and will receive regular feedback on progress with implementation, said the group.

Society attacks EEA prescriptions

Proposals to allow pharmacists to dispense prescriptions written by non-UK registered doctors from within the European Economic Area and Switzerland will put them at odds with their professional ethics and patients could be put at risk, says the Royal Pharmaceutical Society.

Responding to Government plans that have been put forward because of pressure from the European Commission (*PJ*, 25 August, p199), the Society set out its concerns centred on the first principle of its Code of Ethics, which requires pharmacists (and pharmacy technicians) to ensure that patients have safe and timely access to medicines.

"If the proposals as outlined in the consultation document are implemented, UK pharmacists will face a number of practical problems in meeting their legal and professional requirements. . . . The pharmacist could be placed in a professionally compromising position of a patient requiring vital medicines and a regulatory minefield to nav-

igate in order to verify authenticity," the Society says.

The Society's view is that UK pharmacists could face serious obstacles when trying to verify prescriptions. These include problems verifying the registration status of non-UK prescribers, difficulties reading prescriptions written in a foreign language and further spoken language difficulties if anything on a prescription needed clarification.

"If these difficulties are not overcome, patient safety could be placed at risk," the Society says.

Further concern is expressed over the proposal to exempt foreign prescriptions from the normal UK requirements for information that a prescription must contain.

The Society says that such an exemption would mean that foreign prescriptions were subject to lower controls than domestic ones and that this could undermine patient safety and make it harder for pharmacists to identify forged prescriptions.

Scotland underlines plan to scrap prescription charges

Plans to abolish NHS prescription charges in Scotland hit the headlines this week in the lead-up to a speech that Nicola Sturgeon, cabinet secretary for health and wellbeing, will make this weekend.

The abolition of prescription charges was one of the Scottish National Party's election manifesto promises and it has repeated the aim a number of times since coming to power. Ms Sturgeon will tell this weekend's Scottish National Party conference in Aviemore that the Scottish Government remains committed to the phased abolition of prescription charges and that changes will be brought in within the life of the current Parliament.

AZ direct-to-pharmacy scheme to start in February

AstraZeneca's new direct-to-pharmacy supply and delivery service will start in February next year.

The company announced in April that it would follow Pfizer into a direct-to-pharmacy distribution model, but later said that it would delay its implementation in order to give customers time to set up accounts with its delivery partners — AAH and UniChem — and to make sure that the planned system was robust.

This week, AZ said that the additional time had enabled it to carry out further consultation with its pharmacy customers in order to gain insight on how best to help patients gain the maximum benefits from their medicines while addressing NHS priorities.

"This new relationship has proved to be extremely valuable and AZ will be able to tailor its services much more in line with customer needs as a result," the company said.

Hertfordshire school to unveil robot dispenser

The University of Hertfordshire's mock pharmacy, which includes a robotic dispenser, is due to be opened by Keith Ridge, chief pharmaceutical officer for England, on 5 November.

The mock pharmacy's robotic dispenser has the capacity to hold 360 boxed pharmaceutical items and can dispense 300 of these per hour.



The robotic dispenser can dispense 300 items an hour

Regulators should encourage development of better drugs

European medicines regulators should change their focus so that the licensing system encourages the development of better medicines. This is the view of two Italian researchers writing in last week's *BMJ* (2007:335:803).

Silvio Garattine and Vittorio Bertele, director and head of the regulatory policies laboratory at the Mario Negri Institute for Pharmacological Research, Milan, respectively, believe that it is wrong that manufacturers only have to show that new medicines are of good quality, safe and effective, independent of any reference to comparator drugs that might already be available. This engenders, they say, overuse of placebo trials and comparator trials that are designed to show only equivalence or non-inferiority to current treatments, rather than that a new drug offers better treatment. They say: "It is unethical to experiment on patients with the sole aim of obtaining a marketing authorisation.

New drugs should be required to have some added value (greater efficacy or less toxicity) to current treatments or be cheaper."

They state that the US Food and Drug Administration is apparently changing its mind on the suitability of non-inferiority trials and hope that the European Medicines Agency will follow the same path.

They are also concerned that reports prepared by manufacturers for regulatory authorities tend to maximise the benefits of a new drug and minimise its risks. They suggest that this tendency should be balanced by a requirement that independent research be conducted by non-profit organisations. "For example, the regulatory agency could require one phase III trial (usually two pivotal trials are needed) to be planned and carried out by an independent organisation credited by the agency, particularly for drugs that are going to be reimbursed by national health services."

Access to *PJ Online* is free to all

Vision for pharmacy

A series that profiles pharmacists who have developed services that match the Government's view for the future of pharmacy practice. The latest article looks at a pharmacy sports injuries clinic. www.pjonline.com/vision

National pharmacy boards

Meeting reports from the English, Scottish and Welsh pharmacy boards. www.pjonline.com/reports

Hospital Pharmacist conference

The next *Hospital Pharmacist* conference is on 31 January 2008. www.pjonline.com/hpconference

Initiative aims to encourage men to use pharmacies

Men are going to be encouraged to make better use of pharmacies through an initiative launched this week by the Men's Health Forum.

In conjunction with Royal Mail, specially designed, male-friendly information outlining the services pharmacies offer, and encouraging men to use them, will be given to employees at one major site. The scheme is being backed by the Department of Health, the Royal Pharmaceutical Society, the National Pharmacy Association and Pfizer. The initiative will run until next summer and the organisers hope the findings will encourage the roll-out of similar initiatives across the UK.

"[Pharmacy services] could be used as a major triage service, directing men to the best available source of help," Ian Banks, president of the Men's Health Forum, said. "There is evidence that men are more likely to visit their GP if they have been advised to do so by another health professional." He added that pharmacists could also become involved in

outreach work in venues used by men, such as working men's clubs, sports clubs, public houses and barbers' shops.

Gul Root, principal pharmaceutical officer at the Department of Health, commented: "In our report 'Choosing health through pharmacy', we proposed that pharmacy services should be promoted and developed as a source of advice, information and support for self care for men and that pharmacies should consider how they could make their services and premises more attractive to men."

Graham Phillips, a community pharmacist and a member of the Society's Council, said: "Because many men are reluctant users



Will & Demi McInityre/Science Photo Library

Men should be encouraged to use pharmacies more

of general practice, it is vital that we maximise the potential of pharmacies to help men self care more effectively. Pharmacies are well placed to assist men with long-term conditions, especially those who take a cocktail of prescribed medicines and we can refer men to other services."

Pharmacy contribution to "care closer to home" agenda highlighted

Some of the ways in which services provided by pharmacists might contribute to the Government's "care closer to home" agenda are set out in a report released earlier this week by the Department of Health.

The report — written by clinicians involved in the six specialty subgroups of the "care closer to home" pilot — describes how care has been shifted to community settings in the areas of orthopaedic surgery, urology, general surgery, ear, nose and throat, gynaecology and dermatology.

According to the report, the two areas where pharmacy has the most to contribute are dermatology and gynaecology. The dermatology subgroup includes Rod Tucker, a pharmacist who works as part of a multidisciplinary community dermatology service that is one of the pilot sites (*PJ*, 21 October 2006, p471).

The subgroup writes that community pharmacists could play a potentially valuable role in providing advice about appropriate skin care, particularly since most pharmacies now have a private consultation area. It suggests that the increasing number of topical preparations available without prescription might allow pharmacists to treat a wider range of conditions. However, it warns that the pharmacist's role should not be confused with that of a diagnostician and patients should be referred to their GP if doubts exist.

The subgroup also concedes that there is limited evidence of the effectiveness of pharmacists with special interests (PhwSIs) in dermatology but says that what evidence does exist suggests that both community pharmacists and PhwSIs are capable of successfully providing adequate treatment and advice.

"Providing that PhwSIs are suitably accredited there is no reason why their role should not be developed further as part of an accessible, integrated dermatology service," it concludes.

The gynaecology subgroup, which does not include a pharmacist representative, simply says that there is clear scope for pharmacists and PhwSIs in providing care closer to home alongside, or in some cases within, an integrated gynaecology service. It recommends that this should be further evaluated.

In the report's foreword, health minister Ben Bradshaw says that the Government wants people to use the report to catalyse local changes.

The report is available from the Department of Health website (www.dh.gov.uk) and via *PJ Online* (www.pjonline.com/links/pj).

One in six happy to buy self-diagnostic tests

One in six adults is happy to buy a self-diagnostic test from a pharmacy, according to a report published last week.

Consumer and product analyst Mintel surveyed 1,017 adults and found that 16 per cent would buy home health care kits, including home pregnancy tests, urine tests and blood pressure kits, from a pharmacy where advice is available. This varied from 20 per cent of women to 12 per cent of men and from 22 per cent among those aged 15–24 years to 12 per cent for those aged 55–64 years. However, over half (54 per cent) said that they would prefer to have tests done at the doctor's surgery or at a hospital.

The report reveals that sales of self-diagnostic kits have increased by 29 per cent in the past five years and are set to reach £99m this year and an estimated £158m by 2012.

Mintel also highlights the influence of the internet on the growing use of at-home testing kits.

CPS stimulates debate on access to records

Community Pharmacy Scotland's call to give pharmacists access to electronic patient records has sparked a debate in Scotland.

CPS made the call in its manifesto, published last week (*PJ*, 20 October, p427). A report about the manifesto in *The Herald* newspaper on 22 October drew a number of comments from members of the public, many of whom said pharmacists should not be given access to records.

Alex Mackinnon, head of corporate affairs, CPS, said: "This has shown that we clearly have quite a bit to do in terms of engaging with patients to explain what we mean by appropriate access to records. The good thing is that the debate has now been opened." He added: "Pharmacists are taking on more roles, such as the urgent supply of medicines when surgeries are closed. So we do not think it unreasonable to ask for access to the medicines part of patients' records to help pharmacists make informed decisions on behalf of patients."

Patients should be more involved in insulin choice

People with diabetes must be given more information about the risks and benefits of using different insulins and more choice about the insulins they use, according to the Insulin Dependent Diabetes Trust.

“As a largely self-managed condition, being involved in treatment decisions is extremely important for people with diabetes,” the IDDT says. “Different insulins have different speeds and durations of action and it is important that patients have the choice of insulin which is the most suitable for their lifestyle, while providing the best possible control of blood glucose levels.”

In a report published to coincide with the 30th anniversary of the first clinical trial of a synthetic insulin, the IDDT describes the

lack of information about risks and benefits given to patients switched from animal insulin to genetically engineered (human) insulin.

Reports of symptoms such as loss of warning of hypoglycaemia and personality changes are ignored, and patients are neither allowed to revert to animal insulin treatment nor allowed to try it for the first time.

A similar failure to provide information about risks and benefits is occurring as patients are switched to analogues, and choice of treatment is becoming increasingly limited as animal and human insulins are discontinued, the report warns.

The IDDT says that there should be no further discontinuations of insulins until the

safety of all synthetic insulins has been established for everyone requiring insulin treatment.

The IDDT also highlights the fact that many primary care trusts are failing to meet targets for standards of care and treatment for people with diabetes, while funding treatment with insulin analogues.

“Insulin analogues are significantly more expensive for the NHS than either ‘human’ or animal insulins and the evidence of benefit for the majority of patients is negligible,” the report says.

The report calls for research into the effect of different insulins on outcomes such as mortality, complication rates and quality of life, and into the long-term safety of insulin analogues.

Pfizer ceases production of inhaled insulin

Pfizer is to cease production of Exubera, its inhaled insulin product, following disappointing worldwide sales.

Announcing the decision alongside the company's latest financial results, Jeff Kindler, chairman and chief executive of Pfizer, said that the company initially had high expectations for Exubera.

However, he said, Exubera has failed to gain acceptance among patients and doctors and the company had decided that further investment is unwarranted. Pfizer is to work with doctors to help transfer Exubera patients to other treatment options over the next three months.

A spokeswoman for Pfizer UK said that patients taking Exubera should consult their diabetes care team to discuss treatment options.

She emphasised that the decision had been taken on a purely commercial basis and patients need not be concerned about the safety or efficacy of Exubera.



Exubera did not gain patient acceptance

FDA issues warning over pancreatitis risk of exenatide

The US Food and Drug Administration has issued a warning to health care professionals over reports of acute pancreatitis associated with the antidiabetic medicine exenatide (Byetta).

Postmarketing reports of acute pancreatitis in patients taking exenatide have been reviewed by the FDA, which suspects an association with the drug in some of the cases.

It is advising health professionals to instruct patients to seek prompt medical care if they experience unexplained persistent severe abdominal pain. If pancreatitis is suspected, exenatide should be discontinued.

The UK summary of product characteristics for Byetta states that cases of pancreatitis have been reported in patients taking the drug since it came to market.

A spokesman for the European Medicines Agency said that the agency was aware of such reports and that the safety of exenatide would be kept under review.

Life expectancy increases

Deaths from cancer, heart disease and stroke are falling and life expectancy is increasing, according to the Health Profile of England 2007, published this week by the Department of Health. But rates of diabetes, obesity and alcohol-related hospital admissions are rising and regional health inequalities still exist, it says.

First published in 2006, the Health Profile of England provides a collation of national and regional data on public health and wellbeing as well as a section on international comparisons.

Compared with the 15 countries in the EU before 2004, premature deaths from cancer and circulatory disease are reducing faster in England. However, England has the highest prevalence of obesity and the highest proportion of births to women under 20 years old in Western Europe.

Benefits of glitazones continue to outweigh risks

Concerns about an increased risk of bone fractures and heart attacks for patients taking thiazolidinedione drugs for type 2 diabetes have been put in perspective by the European Medicines Agency (EMA), following a review of evidence.

The EMA has concluded that the benefits of rosiglitazone and pioglitazone continue to outweigh the products' risks for the approved indications.

The EMA's Committee for Medicinal Products for Human Use (CHMP) reviewed all of the available information on the risk of bone fractures in women for both drugs, and on the possible risk of ischaemic heart disease for rosiglitazone.

The CHMP recommended that the prescribing information for rosiglitazone-con-

taining products should be updated to include a warning that for patients with ischaemic heart disease rosiglitazone should only be used after careful evaluation of each patient's individual risk.

The combination of rosiglitazone and insulin should only be used in exceptional cases and under close supervision, the committee specified.

No changes to the prescribing information for medicines containing pioglitazone were considered necessary.

The CHMP has announced its intention to review the results of trials that are currently in progress and has recommended that further studies should be undertaken to increase the level of knowledge about this class of drugs.

Anti-TNFs accepted by NICE for rheumatoid arthritis

Adalimumab (Humira) has been added to the anti-tumour necrosis factor (TNF) therapies that can be prescribed for rheumatoid arthritis in the latest round of guidance issued by the National Institute for Health and Clinical Excellence.

The guidance replaces a technology appraisal issued in 2002 (*PJ*, 30 March, p419) that endorsed infliximab (Remicade) and etanercept (Enbrel) as treatments for rheumatoid arthritis. The latest guidance additionally includes adalimumab and takes into account changes in the marketing authorisations for infliximab and etanercept. The therapies are recommended as options for the treatment of active rheumatoid arthritis in patients in England and Wales who have already tried two disease-modifying antirheumatic drugs, including methotrexate (see Panel).

NICE recommends that the drugs should be initiated and the patients followed up only by a specialist rheumatology team and that the drugs should normally be used in combination with methotrexate. However, they may be given as monotherapy if the patient is intolerant to methotrexate or it is considered inappropriate, it adds.

The technology appraisal specifies that treatment should be continued only if there is

an adequate response, defined as an improvement in disease activity score of at least 1.2 points, six months after starting therapy.

NICE advises that treatment should normally be initiated with the least expensive drug but that this may be varied because of differences in the mode of administration and treatment schedules.

An alternative TNF inhibitor can be considered for those patients whose treatment is withdrawn due to adverse effects before the first six-month assessment of efficacy.

Sequential use, defined as the use of a second TNF inhibitor where there had been no response to, or loss of response to a first TNF inhibitor, will be the subject of later guidance.

Andrew Dillon, NICE chief executive and executive lead for the appraisal, explained: "So that we could issue guidance as quickly as possible to benefit people with rheumatoid arthritis, NICE has published the recommendations relating only to the first use of the drugs. The independent appraisal committee will give further consideration to the sequential use of these drugs, and will produce separate guidance on this specific use."

The guidance is available on the NICE website at www.nice.org.uk and via *PJ Online* (www.pjonline.com/links/pj).



Sue McDonald/Stockphoto

Rheumatoid arthritis: adalimumab added to drug arsenal

Definitions

The technology appraisal specifies that a trial of a disease-modifying antirheumatic drug is defined as being normally of six months' duration, with two months at standard dose, unless significant toxicity has limited the dose or duration of treatment.

Active rheumatoid arthritis is defined by a disease activity score (DAS28) greater than 5.1, confirmed on two or more occasions one month apart.

NICE gives response-rebate scheme for bortezomib the go-ahead

A scheme in which the NHS is refunded the cost of bortezomib (Velcade) for multiple myeloma patients who fail to respond adequately to the drug will go ahead.

The response-rebate scheme was proposed by the drug's manufacturer Janssen-Cilag and modified by the National Institute for Health and Clinical Excellence during its technology appraisal of the drug (*PJ*, 9 June, p663).

This week NICE issued final guidance that recommends bortezomib monotherapy as an option for the treatment of progressive multiple myeloma in people who are at first relapse, have received one prior therapy and have already undergone, or are unsuitable for, bone marrow transplantation. However, the guidance specifies that treatment should only be continued in people who have a complete or partial response to the drug after four cycles. A complete or partial response is defined as a reduction in serum M protein of 50 per cent or more.

For people who have less than a partial response after a maximum of four cycles, bortezomib should be stopped and the manufacturer will reimburse the full cost of the drug.

Andrew Dillon, chief executive of NICE, commented: "The scheme proposed by the manufacturer and amended by NICE will ensure that all patients suitable for treatment with bortezomib at first relapse will get the chance to see if the drug works well for them. This is a win-win situation for patients and the NHS."

The Department of Health and Janssen-Cilag will be responsible for setting up the scheme, which will continue until NICE's next review of bortezomib scheduled for September 2010.

The guidance is available on the NICE website at www.nice.org.uk and via *PJ Online* (www.pjonline.com/links/pj).

Behaviour change Guidance on behaviour change is issued by NICE this week (available via www.nice.org.uk). The public health guidance sets out principles surrounding the delivery of health behaviour change interventions at the individual, community and population levels. NICE highlights the need for practitioners to be equipped with the necessary competencies and skills to support behaviour change, using evidence-based tools. Plans for behaviour change programmes should ensure specific funding is provided for monitoring and evaluation, NICE recommends.

Government report advocates expansion of pharmacy smoking cessation services

Commissioners of stop smoking services are reminded of the potential for partnerships with pharmacy in a Department of Health publication released last week.

The guidance document on provision and monitoring of NHS stop smoking services says: "Pharmacies have a good track record of providing stop smoking services to the general public. They are ideally placed to provide this service, based in the heart of communi-

ties and accessible to those people who may not access GPs." The publication continues: "Commissioners should be encouraged to commission services from pharmacies and should continue to work in partnership with them." It adds that pharmacy smoking cessation services should be expanded, where possible, to improve public access.

The report also deals with the need for stop smoking service providers to be rigorous

when reporting the number of smokers entering treatment and in deciding who has successfully quit after four weeks. The document says that the purpose of such data monitoring is to evaluate the effectiveness and reach of NHS stop smoking interventions, not a mechanism for counting all people who have stopped smoking. "Quits that have not been the result of structured stop smoking intervention . . . should not be included," it says.

Interim CD guidance for England

Two new interim guidance documents on future requirements for requisitions and record keeping for Controlled Drugs have been produced by the Department of Health. A third document updates and replaces earlier guidance on good CD practice in secondary care.

The interim guidance on requirements for requisitions for Schedule 1, 2 and 3 CDs is intended to apply where the requisition is fulfilled by any supplier other than an NHS hospital trust, care home, pharmaceutical wholesaler or manufacturer. From 1 January 2008, the name and address of the supplier will have to be indelibly recorded on any CD requisition form. Pharmacy stamps are expected to fulfil this requirement. The forms will then have to be sent to the supplier's NHS pricing office in the same way as prescriptions for CDs.

To facilitate consistency, pricing offices are developing a standard CD requisition form that those requisitioning CDs will be expected to use.

However, there will be no legal obligation to do so, provided requisitions contain the legally required information (name, address and profession or occupation of person placing the order, the purpose for which the CD is required, the name, form, strength and total quantity of the drug, and the date). Once they

have been finalised, the new requisition forms will be available from the primary care trust that is responsible for the practitioner placing the order.

The interim guidance on record keeping, which applies from 1 February 2008, sets out how CD registers can be maintained when the requirement to keep records in a specified format is abolished and replaced by a requirement to keep information under specified headings.

It also gives guidance on how additional information that is not legally required, such as running balances, can be recorded and how often running balances should be checked against stocks. Guidance is also given on making records of who has collected dispensed CDs and what evidence of that person's identity was seen, if any.

The updated guidance on good practice in secondary care incorporates advice on the possession and supply of CDs by operating department practitioners, record keeping requirements, the appointment of destruction witnesses by accountable officers and clarification on prescribing by doctors who have not achieved full General Medical Council registration.

All three new documents apply in England only.

SOP guide for Scotland

Guidance on how to write a standard operating procedure (SOP) for handling Controlled Drugs was published this week by the Scottish Government.

The NHS guidance has been produced in response to the Controlled Drugs (Supervision of Management and Use) Regulations 2006 that require anyone who holds stocks of Controlled Drugs to have a SOP in place.

This week's guidance explains that the SOP must cover people who have access to the drugs, where drugs are stored, security arrangements for storage and transportation, disposal and destruction, who should be alerted if complications arise, and record keeping. It then lists points that should be considered when developing a SOP in order to meet these requirements.

The guidance can be accessed via *PJ Online* (www.pjonline.com/links/pj).

New health regulator planned

There is to be a new health regulator with the power to order the closure of hospital wards that fail cleanliness inspections.

The Care Quality Commission will replace the Healthcare Commission, the Commission for Social Care Inspection and the Mental Health Act Commission.

Third of NHS has cash trouble

One in three NHS bodies remains in poor financial health, even though NHS finances have now moved out of deficit as a whole, the Audit Commission revealed this week.

The Audit Commission assessed NHS trusts and primary care trusts across England on their financial management. It found that steps taken by the Department of Health and NHS bodies had generally been successful and that, overall, the NHS recovered from a deficit of £547m in 2005–06 to a surplus of £515m for 2006–07. Nonetheless, 31 per cent of trusts failed to meet minimum requirements relating to use of resources.

Steve Bundred, chief executive of the Audit Commission, warned that there was a "worrying gap" between the top performers and those still failing to balance their books. "The NHS needs to focus urgently on the management of this small group of NHS bodies that are failing across the board," he said.

The Audit Commission's analysis also revealed the impact of last year's NHS reorganisation. This was associated with short-term costs of £192m. The Audit Commission says the NHS will have to show that this investment will produce savings in the medium to long term. The commission also found that NHS bodies that were not involved in the reorganisation tended to perform better financially: only 7 per cent of newly merged bodies performed well or strongly.

Transdermal treatment for Alzheimer's

Patients with Alzheimer's disease could benefit from a transdermal patch formulation of rivastigmine (Exelon), now available from Novartis.

The 24-hour patches are available in two strengths — 4.6mg/24 hours and 9.5mg/24 hours — and could, according to a specialist pharmacist, be an alternative for some Alzheimer's disease patients.

Joan Kelly, senior clinical pharmacist at Lothian Memory Treatment Centre, told *The Journal* that the patch is a welcome development because remembering to take tablets can be a problem for Alzheimer's disease patients. She said that although a patch formulation of rivastigmine would not remove all compliance issues for such patients it signalled a move away from them needing to take oral medicines.

Ms Kelly believes that the overall benefit of the patch will be the same as with the oral formulation.

Treatment is initiated with the 4.6mg/24h patch and, if tolerated, the dose should be increased to 9.5mg/24h after at least four weeks — this maintenance dose can be continued



Rivastigmine is now available in a patch

for as long as the patient experiences benefit.

Based on comparable exposure between oral and transdermal rivastigmine the manufacturer recommends the following doses for patients switching from Exelon capsules or oral solution to Exelon transdermal patch:

- Those receiving 3mg/day or 6mg/day oral rivastigmine can be switched to the 4.6mg/24h patch
- Those on a dose of 12mg/day oral rivastigmine and those taking a stable and well tolerated dose of 9mg/day oral rivastigmine can receive the 9.5mg/24h patch. (If the oral dose of 9mg/day has not been stable and well tolerated, switching to the 4.6mg/24h patch is recommended)

Notice-board p464

Chest infection complications reduced by antibiotics

Prescribing antibiotics following a chest infection substantially reduces the risk of pneumonia, particularly in patients over 65 years old, according to research published online (*BMJ Online First*, 18 October, www.bmj.com). However, in general, prescribing antibiotics to reduce the risk of serious complications after upper respiratory infection, sore throat or otitis media is not justified, it adds.

Although guidelines advise against routine prescribing of antibiotics for upper respiratory tract infection, sore throat or otitis media, antibiotics are often prescribed for patients with these conditions, researchers from University College London and the Health Protection Agency explain.

The researchers analysed 3.36 million episodes of respiratory tract infection recorded between 1991 and 2001 on the UK General Practice Research Database. They calculated and compared the risk of serious complications in treated and untreated patients in the month following diagnosis.

The researchers found that serious complications — mastoiditis after otitis media, quinsy after sore throat and pneumonia after upper respiratory tract infection — were rare, with a number needed to treat of over 4,000. However, they identified a high risk of pneumonia following chest infection, which was substantially reduced by treatment with antibiotics (the number needed to treat was 39

in those aged over 65 years and over and between 96 and 119 in those under 65 years).

Smoking and chronic respiratory disease did not affect the risk of complications or the protective effect of antibiotics, say the researchers.

The authors of an accompanying editorial highlight a major confounding factor in that sicker patients and those more likely to have adverse outcomes were offered antibiotics more often, potentially leading to an underestimation of the protective effect of antibiotics. However, they acknowledge that, although randomisation would eliminate this bias, randomised controlled trials generally lack the power to study rare events.

MDS that can accommodate liquids unveiled



Biodose incorporates a patented antimicrobial technology

A monitored dosage system (MDS) that can accommodate liquid medicines has been launched by Protomed, the company behind Nomad MDS.

The company claims that the system, known as Biodose, is the first in the world that can accommodate liquid medicines as well

as tablets and capsules. It also incorporates a patented antimicrobial technology — Biocote — which, Protomed says, protects against the transfer of infections such as methicillin-resistant *Staphylococcus aureus*.

Protomed plans to make Biodose available in the first quarter of 2008.

MHRA publishes latest batch of decisions for complaints about medicines promotion

Results of five investigations into the way medicines are promoted were published by the Medicines and Healthcare products Regulatory Agency this week.

An internet advertisement for NeoClarityn (desloratadine, Schering-Plough) claimed that the antihistamine had no adverse psychomotor effects, although its summary of product characteristics lists psychomotor hyperactivity as a very rare adverse effect. Schering-Plough agreed to withdraw the advertisement.

Netto Foodstores agreed to limit the sale of paracetamol tablets to two packs at a time after the MHRA investigated an allegation that six packs of 16 tablets had been sold.

Pfizer agreed to strengthen warnings not to drive, operate machinery or engage in other potentially hazardous activities in advertisements for Champix (varenicline) after the MHRA's pharmacovigilance risk management group received data that confirmed the potential for adverse effects.

A complaint about a promotional leaflet for Tradorec XL (prolonged release tramadol, Recordati) was referred by the MHRA to the Prescription Medicines Code of Practice Authority because it included purported MHRA advice on prescribing branded prolonged release preparations.

The MHRA took the view that the claim was misleading, since it had issued no formal advice. The Association of the British Pharmaceutical Industry's code of practice forbids the mention of the MHRA in promotional material unless required to do so by the MHRA. The PMCPA upheld the complaint.

The MHRA rejected a complaint about the promotion of Nicotinell chewing gum (nicotine replacement therapy, Novartis) at football matches, involving the handing out of free samples.

Award for UniChem obesity pilot

UniChem's professional services team has been recognised for its work in facilitating an obesity management pilot (*PJ*, 25 August, p202) with an award from the National Obesity Forum. The team won the primary care category of NOF's annual Best Practice Awards for Excellence in Weight Management, presented in London last week.

Prednisolone for Bell's palsy

Early use of prednisolone in patients with Bell's palsy is effective, a study of 496 patients suggests (*New England Journal of Medicine* 2007;357:1598). The study found no evidence of benefit of aciclovir.

Funding source of clinical studies affects authors' interpretation of results

The funding source of clinical studies affects authors' interpretation of results, an analysis of 504 studies examining the effects of inhaled corticosteroids suggests (*Archives of Internal Medicine* 2007;167:2047).

Manufacturer-funded trials are less likely to identify adverse effects of inhaled corticosteroids than studies without pharmaceutical company funding, a finding partly explained by differences in trial design. In addition, authors of manufacturer-funded trials are less likely to conclude that statistically significant adverse effects are clinically important than authors of non-pharmaceutical-funded studies, researchers found.