

Suicide prevention strategy considers safety warnings for OTC packaging

THE Government is to consider introducing safety warnings on packs of over-the-counter aspirin and paracetamol to highlight the dangers of overdose as part of its National Suicide Prevention Strategy.

The National Institute for Mental Health in England (NIMHE), which forms part of the National Health Service's Modernisation Agency, will consult with the Medicines Control Agency on how the dangers of paracetamol overdose can be publicised more effectively, possibly through safety warnings on packaging. It will also consider including a helpline number with any warning.

National director for mental health Professor Louis Appleby, who will lead implementation of the strategy, told *The Journal*: "We are very much in favour of the safety messages. Of course, we will also have to talk to manufacturers about doing that."

A spokesperson for the PAGB commented: "It's really an issue for the MCA, but we will work with them and help them in any way we can. We are not going to argue against stronger safety messages if the MCA believe these are necessary."

The PAGB also welcomes the recognition in the strategy that reductions in pack size for over-the-counter paracetamol and

aspirin, made in 1998, have led to a fall in overdose deaths from these medicines: "We think the pack size reduction is about right," he added.

One of the six goals outlined in the new strategy, published this month, is to reduce the availability and lethality of suicide methods. The NIMHE is therefore going to look at promoting safe disposal of unwanted medicines by the public and the recall of unused prescribed antidepressants by clinicians.

But Professor Appleby said it was first necessary to identify the scale of the problem associated with certain drugs through research. He said: "We know there are deaths from these drugs, but we actually don't have the full evidence. One of the first steps will be to spend a short time collecting the evidence on paracetamol and codeine deaths so that we can issue guidance to primary care and pharmacy."

Questions the research also would need to answer, Professor Appleby said, included how much of the drugs were being prescribed for which conditions, whether most of the prescriptions were being issued by primary care, and what proportion of drugs remained unused by patients and were kept around the house. One suggestion is that



Unused medicines may need to be returned before new medicines are dispensed

when patients are changed over from one drug to another, it could be stipulated that they must bring back any unused stocks of the old medicine to the pharmacy before the new medicine is dispensed.

"We will use the research for the basis of some clearer rules, or greater publicity for the need to return medicines," said Professor Appleby. "It's a question of making the public aware and making it higher profile so it becomes part of everyday clinical and pharmacy practice."

Welsh pharmacy strategy released

THE draft Welsh pharmacy strategy was published on 24 September.

The foreword to the strategy, which is open for consultation until 31 December, says that it aims to ensure that Wales offers an attractive environment in which pharmacists can fulfil their potential and deliver high quality pharmaceutical services.

The document sets out 50 "action points", most of which set targets for finding out what needs to be done, rather than state changes and improvements that are to

be made. For example, the first action point is a recommendation to the Welsh Assembly Government to review the future role, organisation and nature of community pharmacy in Wales.

Nevertheless, the report has been welcomed by the chairman of the Royal Pharmaceutical Society's Welsh Executive, Andrea Robinson, as an integrated strategy that will strengthen the standing of the pharmacy profession in Wales.

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Most pharmacists see a clinical future

AN OVERWHELMING majority of community pharmacists believe that their future lies in clinical practice and direct patient care.

A survey conducted among 400 community pharmacists in England aged under 50 years by Professor David Taylor, professor of pharmaceutical and public health policy at London University's School of Pharmacy, found that 95 per cent of pharmacists agreed that pharmacy had a clinical future. There was also strong support for Government policies to involve community pharmacists more closely in medicines management and other forms of primary care improvement.

Another finding of the survey is that most pharmacists are dissatisfied with the profession's leadership. Only 0.5 per cent agreed strongly that pharmacy had enjoyed strong and effective professional leadership over the past 10 years. In contrast, 30 per cent believed that nurses had had such leadership. Those surveyed were evenly divided on questions about the role of the Royal Pharmaceutical Society and the extent to which bodies like it should focus on defending public interests and regulating pharmacy, as opposed to protecting members' interests.

"Realising the promise: community pharmacy in the new NHS" is to be published in November.

NPA to advise on pet dispensing

ADVICE to community pharmacists on dispensing animal medicines is to be published by the National Pharmaceutical Association in November.

In the light of the Competition Commission's provisional conclusion that veterinary surgeons are complicit in a complex monopoly in the supply of prescription medicines to animal owners (*PJ*, 21 September, p383), the NPA believes that pharmacists will soon have greater opportunities to dispense veterinary prescriptions.

NPA chief executive John D'Arcy said: "We have battled long and hard for this, not only because it will provide a valuable service to pet owners but also because it will

provide a great business opportunity for our members. . . . Visiting a pharmacy, particularly for repeat prescriptions, will be so much more convenient for owners without any compromise of safety. The commission has already said that the current monopoly has kept prices artificially high and we are sure that community pharmacy will be able to change this."

A new guide 'Pet medicines in pharmacy' will explain marketing, legal, product knowledge and training aspects of dispensing animal medicines. The NPA believes that rural and urban pharmacies alike will be able to benefit from this market, which it estimates to be worth over £350m.

Bedtime aspirin could help prevent pre-eclampsia and premature labour

TAKING low-dose aspirin before going to bed can decrease a woman's risk of developing pre-eclampsia and lessen her chances of a pre-term birth, according to the results of an American study.

The double-blind randomised controlled trial involved 341 women who had a high risk of developing blood pressure problems. They were divided into six groups and treated either with 100mg aspirin or placebo on waking, eight hours later, or at bedtime. Treatment was initiated 12 to 16 weeks into the pregnancy.

The researchers found that the incidence of pre-eclampsia was 1.7 per cent among women taking aspirin just before going to bed, compared with 14.3 per cent in the placebo group. Gestational hypertension occurred in only 6.8 per cent of women taking aspirin, compared with 30.4 per cent of women taking placebo.

Furthermore, 17.9 per cent of women in the placebo group went into premature labour, while none of those taking aspirin delivered early. Taking aspirin first thing in the morning did not reduce blood pressure compared with placebo, but women taking

it eight hours after waking had lower blood pressure than those taking placebo.

The greatest decrease in blood pressure was seen in women taking aspirin at bedtime — a mean reduction of 12.6/8.5mmHg for systolic/diastolic pressure at the time of delivery, compared with placebo given at bedtime.

Lead researcher Dr Ramon Hermida, from the University of Vigo in Spain, said the results had come as a surprise to him: "This study has shown remarkable reductions in all gestational high blood pressure and pre-eclampsia complications. But there is more — women who took aspirin at bedtime gave birth to children 250g heavier on average compared with women who took placebo, or who took aspirin in the morning instead of at night."

However, Dr Hermida stressed that women should not take aspirin during pregnancy without a doctor's supervision, due to the potential risk of increased bleeding at the time of delivery. "Despite the potential advantages, not necessarily all pregnant women could benefit from taking aspirin," he added. The results were presented at the

American Heart Association High Blood Pressure Research conference in Orlando, Florida, this week.

Importers can repack medicines without breaching trademark rights

PARALLEL importers can repack medicines which have centrally issued European marketing authorisations in order to match the manufacturer's packaging in destination member states.

The European Court of Justice ruled earlier this month that importers were precluded from bundling together medicines which were subject to marketing authorisations for different pack sizes. Instead, they should repack the product concerned and relabel it using the appropriate marketing authorisation number and manufacturer's trademark.

The judgment arose from a dispute between Aventis and a German parallel importer over packs of Insuman insulin. Insuman is marketed by Aventis in packs of five cartridges in France and packs of 10 in

Germany (*P7*, 16 March, p352). Aventis argued that the importer should bundle two packs of five cartridges together and overlabel them, while the importer wanted to repackage and relabel the French product in boxes of 10 to match the German presentation.

Don Macarthur, secretary general of the European Association of Euro-Pharmaceutical Companies (www.eaepec.org), which represents parallel importers, said that companies preferred to use new packaging, rather than to stick labels on foreign language packs, especially if there was a risk to public health from patient confusion or concern.

The full judgment (case C-433/00) can be found in the case law section of the ECJ website (curia.eu.int/en/juris/index.htm).

NSAID use could reduce Alzheimer's risk

ALZHEIMER'S disease is less prevalent in people with a history of non-steroidal anti-inflammatory drug (NSAID) use, according to the results of an American study (*Neurology* 2002;59:880).

Researchers investigated medicine use among 3,227 people aged 65 years and over, 104 of whom were identified as having Alzheimer's disease. They found that the longer people had been taking NSAIDs, the lower their chance of developing dementia.

Those who had been taking NSAIDs for over two years more than halved their risk of Alzheimer's (hazard ratio 0.42, confidence interval 0.16–0.90).

The researchers conclude that regular use of aspirin and other NSAIDs may reduce dementia risk among the elderly, but only if taken for over two years. They add that recently initiated trials are unlikely to show similar treatment effects, unless participants are followed for a number of years.

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MMR uptake rate falls

MMR vaccination uptake among children in England has dropped just over 3 percentage points since last year, according to the Government's latest immunisation statistics. They show that 84.1 per cent of children were immunised with the measles, mumps and rubella triple vaccine in 2001–02, compared with 87.4 per cent in 2000–01.

Advice on thrombolytics in acute MI

Draft guidance on thrombolytic drugs for patients suffering acute myocardial infarction has been published by the National Institute of Clinical Excellence. Stakeholders have until October 4 to appeal against it (www.nice.org.uk).

Combination HRT raises stroke risk

The risk of stroke among women taking combination hormone replacement therapy doubles after six months of therapy, researchers have found (*Archives of Internal Medicine* 2002;162:1954). They studied 726 cases of ischaemic and 213 cases of haemorrhagic stroke among post-menopausal women taking HRT, and 2,525 controls. The relative risk of having a stroke after six months of HRT was 2.16 for ischaemic and 2.20 for haemorrhagic stroke. In addition, the risk of ischaemic stroke increased with estrogen dose ($P=0.03$).

2002–03 remuneration offer rejected

An opening offer of increased remuneration for 2002–03 for England and Wales has been rejected by the Pharmaceutical Services Negotiating Committee.

Following the PSNC's September meeting, PSNC chief executive Sue Sharpe said: "We received the offer immediately before our subcommittee meeting. We have discussed it, but have not yet analysed its impact. The offer is not acceptable to the PSNC."

The PSNC is now beginning the process of discussing the offer with Department of Health officials and will be writing to set out reasons why the offer is unacceptable. Details have not been revealed.

Mrs Sharpe also reported that she and PSNC chairman Barry Andrews had met the Parliamentary Under-Secretary of State for Health who has ministerial responsibility for pharmacy (David Lammy). Responding to PSNC concerns about the pace of change in the National Health Service while there had been no real movement in relation to pharmacy, Mr Lammy had said that he did not want to see pharmacy in the slipstream of primary health care, but as a mainstream service. The Minister had indicated that he was keen to see progress over negotiations on the new contract.

"We expect weeks, if not months, of discussions," Mrs Sharpe said. "We are not looking at a new contract for 2003. That is a great disappointment to us, but we recognise that a new contract has to be agreed within a different funding strategy and that this is not something that is going to be put in place quickly."

The PSNC and the Department intend to develop a cost of service model for community pharmacy and hope to test data collection forms before the end of the year.

"We are looking to build a model that can be used to understand the cost of services under the new contract and what is

needed for fair funding for the service, to which the Minister has expressly committed himself," said Mrs Sharpe.

Both the Minister and his officials had been clear that they had no ideal what the OFT's report on the pharmacy market, which is not now expected to be published until November, would contain.

Other matters arising at the PSNC's September meeting are reported below.

Repeat dispensing The PSNC is to repeat its advice to contractors not to make any firm commitments to pathfinder projects for repeat dispensing. "We are not at one with the Department on workload and the interventions that pharmacists will have to make," Mrs Sharpe said. "We are not happy that the service could be portrayed as a commodity supply." The PSNC view is that pharmacists will have to take on a higher level of responsibility for medication.

Prepayment certificates The PSNC has advised pharmacy contractors to withdraw from any local agreements to sell prescription charge prepayment certificates with effect from 1 October because the Department has withdrawn funding for such schemes.

BRIEFLY

New PSNC website

The Pharmaceutical Services Negotiating Committee has redesigned and expanded its website (www.psnc.org.uk). It now includes areas from which resource materials for pharmacy contractors and local pharmaceutical committees can be downloaded.

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NPA seeks meeting with Minister on violence in community pharmacies

A MEETING with John Hutton, Minister for Health, has been sought by the National Pharmaceutical Association to discuss aggression against community pharmacy staff.

The NPA says that although community pharmacists and their staff are not NHS employees, they are among those who work for the NHS who face the greatest threat of violence, because of their ready availability on the high street. The association welcomes a recently announced NHS initiative to tackle violence and harassment of NHS workers and says that it wants to be included in a consultation group of health professionals, along with nurses and general practitioners.

A recent British Retail Consortium survey found that pharmacists and their staff were assaulted more frequently than staff in other high street settings. They suffer 34 attacks per 1,000 staff annually — more than eight times the national average.

"This is a growing problem, requiring some pharmacies to employ full time secu-



Their ready availability makes pharmacy staff more susceptible to attack than any other high street worker

city staff to protect their premises and staff," John D'Arcy, the NPA chief executive, said. The NPA says that a minority (mainly drug

abusers) of the many thousands of people who visit community pharmacies daily pose a threat.

UniChem launches Portfolio plan

UniChem has launched a scheme for total pharmacy management.

Participants in the UniChem convention in Mauritius this week have been told that the scheme, called Portfolio, offers enormous benefits to those who join. To do so, pharmacies will have to pay a fee and meet targets and compliance requirements.

"If we are raising the game for pharmacists who commit to being a part of Portfolio we cannot afford to have any weak links," Nick England, chief executive of Alliance UniChem Retail International, said.

In return for compliance, UniChem will

seek to negotiate with primary care trusts on behalf of independent pharmacists and provide other benefits.

Matthew Price, an independent pharmacist from Cowbridge, suggested that the initiative might remove the entrepreneurial spirit of independent pharmacists. "For all intents and purposes, we would be managing UniChem's shops," he said.

Andrew Gush, from Porthcawl, said that although he had embraced UniChem's support services in full, he would not obtain maximum benefit unless they were adopted by many pharmacists.

Ombudsman rules against DoH and MCA over patient information leaflets

THE Parliamentary Commissioner for Administration (ombudsman) has ruled that the Department of Health and the Medicines Control Agency were guilty of maladministration in their handling of the requirement for all dispensed medicines to be accompanied by patient information leaflets.

In an as yet unpublished adjudication, the ombudsman says that the Department should have said how the requirement was to be satisfied. The complaint was brought by a member of the public.

The *Journal* understands that MLX 285, issued by the MCA recently (*PJ*, 10 August, p181) is the Department's plan for recovering from the complaint. MLX 285 proposes a statutory defence against breach of copyright for health professionals who photocopy PILs.

The Pharmaceutical Services Negotiating Committee says that, although a one-off payment of £500 and a small annual fee have been proposed to help pharmacy contractors, the requirement places a considerable burden on pharmacists and that it cannot see a practical way to meet it.

Not all PILs are available on the internet and the paper of many of those provided with medicines is so thin that they cannot be photocopied. Other PILs, notably those provided with oral contraceptives, take the form of small booklets.

Welsh groups look at safe prescribing

A PARTNERSHIP of four medicines organisations in Wales has been created to advise on safe and effective prescribing. The Welsh Medicines Partnership, includes the University of Wales College of Wales Therapeutics and Toxicology Centre, the Welsh Medicines Information Centre, the Committee on Safety of Medicines and the Welsh Medicines Resource Centre, and is expected to make a significant contribution to improving clinical standards.

Announcing the move on 24 September, Welsh Health Minister, Jane Hutt, said: "These organisations which now form the partnership have worked previously on an informal basis. I have now provided funding to enable them to enter into a more formal strategic partnership."

YPG to seek broad support for its views

PARTICIPANTS at a Young Pharmacists Group meeting expressed their concern about the way the Society's modernisation programme has developed. The meeting, held on 22 September before the British Pharmaceutical Conference, was attended by past presidents and a previous secretary and registrar, as well as other leading figures from the profession.

The meeting agreed that there should be a large scale exercise to disseminate information about their concerns about the Society's proposals, that opinion would be sought to determine whether the Society's current position was legal and the broader membership would be consulted in order to produce a more acceptable model for the Society in the future.

Long-term HRT use can increase breast cancer and stroke risk

WOMEN who take hormone replacement therapy (HRT) for five years are more likely to contract a life-threatening disease than be protected against one, a British study has concluded.

Researchers at the Cancer Research UK epidemiology unit in Oxford calculated there would be six extra cases of breast cancer, stroke or pulmonary embolism per 1,000 HRT users aged 50–59 years. And there would be twice as many cases among the 60–69 age group.

In contrast, there would only be 1.7 fewer cases of bowel cancer or hip fracture per 1,000 women aged 50–59 taking HRT for five years, and 5.5 fewer cases among those aged 60–69 years. The researchers found no change in the risks of developing endometrial cancer or coronary heart disease after five years of HRT therapy.

The study reviewed the incidence of seven life-threatening conditions from four major clinical trials, involving 20,000 postmenopausal women who had taken HRT for about five years. Three of the trials had used combined HRT, and one involved estrogen alone.

The researchers found that the relative risks for each of the seven conditions were similar in all four trials and applied to all women, regardless of their background, risk

of disease and personal characteristics. The researchers calculated that the increased incidence of any one of the seven conditions studied was greater than any reduction, with the estimated net excess over five years being one per 230 users aged 50–59 and one per 150 aged 60–69.

Lead author of the study, Professor Valerie Beral, said the estimates provided healthy women using HRT with “a rough guide to the likely overall change in incidence of these conditions over a five-year period”.

She added: “Each woman may, understandably, give different weight to the importance of each condition, as well as to the relief of menopausal symptoms with HRT. The issues are different for every woman.”

However, the research team also says that existing trials are too small to provide reliable information on conditions such as ovarian cancer, or on cause-specific mortality. In addition, these trials are not looking at specific types of estrogen and progestogen used in HRT formulations. They conclude: “Observational studies will thus be needed to answer many outstanding questions about the effects of HRT.”

The research was published in *The Lancet* (2002;360:942).

NICE trastuzumab guidance questioned

THE place of trastuzumab (Herceptin) monotherapy as a third-line treatment for patients with metastatic breast cancer is unclear, according to the *Drug and Therapeutics Bulletin* (2002;40:65).

Six months ago, the National Institute for Clinical Excellence recommended trastuzumab monotherapy as a third-line option for women who have advanced breast cancer that greatly over-expresses human epidermal growth factor receptor 2 (HER2), where treatment with an anthracycline, a taxane and hormonal therapy has failed.

The *DTB* review has criticised this recommendation. It argues that there has only been one, uncontrolled trial that has used trastuzumab monotherapy to treat women with this form of breast cancer that was resistant or refractory to chemotherapy regimens. The *DTB* says NICE’s recommendation of trastuzumab monotherapy was based on this trial and states: “Before we can recommend this, we would wish to see evidence of the advantages from randomised controlled trials.”

However, the *DTB* agrees with NICE’s recommendation that trastuzumab be used in combination with paclitaxel (Taxol) as a first line treatment for these breast cancer patients, since it has been shown to delay disease progression by three to four months in this setting.

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