

New contract in danger without more clarity on control of entry, PSNC warns

PHARMACY contractors may not vote for the proposed new contract unless they receive clarification about the impact of the Government's proposals for control of entry in England, Pharmaceutical Services Negotiating Committee chairman Barry Andrews warned this week.

Speaking at a joint PSNC and National Pharmaceutical Association briefing, held on 21 July to talk about the Government's response to the Office of Fair Trading report, he said: "Contractors will be uncertain until clarification is provided. They will be unwilling to support a new contract while such uncertainties exist." He added that the PSNC would be unlikely to put any proposed contract to a vote if a negative result was expected.

Mr Andrews said that the Government's proposals on control of entry (see below) were "flawed, ill-considered and invite more questions than answers". This was an inevitable result of discussions and compromises between at least five different Government departments, including the Treasury and the Office of the Deputy Prime Minister.

"There is a lack of clarity about all of this," Mr Andrews said. "We do need to

understand where the Government is coming from." The PSNC raised a number of key questions at a scheduled meeting to discuss the new contract with the Department of Health and the NHS Confederation on 23 July. Talks on the new contract are expected to continue pending clarification.

Mr Andrews said that the PSNC would be demanding a meeting with Health Minister Rosie Winterton in order to express its concerns and to hear an explanation of the Government's thinking. Particular areas of concern relate to exemptions from control of entry for large shopping developments, extended hours opening and one-stop primary care centres.

John D'Arcy, chief executive of the NPA, said that he is concerned that the proposals could amount to "deregulation by the back door". He added that, as ever, the devil



United front: John D'Arcy of the NPA (left) and Barry Andrews of the PSNC want more details about the Government's proposals

will be in the detail. "We know that the current system isn't perfect, but it has had around 15 years to settle out." The NPA and the PSNC would not be sitting back but would be doing all they could to influence discussions about the detail. "Our unanswered questions will form the basis of a continuing campaign."

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Government to loosen regulations on control of entry

CONTROL of entry to pharmacy contracts in England is to be loosened, but retained, Trade and Industry Secretary Patricia Hewitt announced on 17 July.

Under proposals put forward as the Government's long-awaited "balanced package of measures", control of entry will be lifted from pharmacies in large shopping developments, from those open for more than 100 hours a week and from pharmacies in one-stop primary care centres. Internet and mail-order pharmacy will also be made easier to establish (see Panel).

However, the Government has rejected the Office of Fair Trading recommendation that control of entry should be abolished in its entirety. In a written statement Mrs Hewitt said: "We do not believe that simple deregulation is the best way to achieve our aims." She added that the Government "intends to move cautiously in the direction recommended by the OFT" but that "this is not the time to move to a fully deregulated system".

A shortage of pharmacists, which is expected to persist for some years, and plans to expand the role of pharmacists within the National Health Service were given as reasons as to why the time was not right for full deregulation.

The regulations governing control of entry will be modified incorporating new criteria for the "necessary or desirable" test. Primary care trusts will have an obligation

"to promote consumer choice and harness the benefits of increased competition", Mrs Hewitt said. This will apply to applications for new pharmacies and to existing pharmacies that wish to extend service provision. Application and appeals processes are to be simplified. Secondary legislation to implement this is to be introduced in April 2004.

The Department of Health is to publish a consultation document by the end of August on how the proposals to modify control of entry should be implemented. This will be followed by a 12-week consultation process. In addition, an advisory group, with

representatives from pharmacy, medicine, the National Health Service, patient, consumer and competition groups and persons with a track record on regulatory reform, is to be set up to advise on the details of the implementation.

The Government is promising to review the impact of any changes after three years, involving the OFT in the process, and to publish its findings.

The OFT recommendation for deregulation has previously been expressly rejected by the Scottish Executive and the Welsh Assembly Government.

Proposed exceptions to control of entry

Under the Government's proposals, control of entry will be removed from:

- Pharmacies in large shopping developments (over 15,000 sq m gross floor space)
- Pharmacies that intend to open for more than 100 hours a week
- Consortia pharmacies in one-stop primary care centres

These pharmacies, however, will have a duty to provide a full and prescribed range of services laid down by the local primary care trust.

- Internet and mail-order pharmacies will be permitted in line with provisions in the Health and Social Care Act 2001, subject to services being agreed within the proposed national contractual framework
- Local pharmaceutical services contracts, which are not subject to control of entry, will no longer need PCTs to get approval from the Department of Health

New strategy document for pharmacy in England published by Government

WHAT community pharmacy could look like in the future is set out in a new strategy document published by the Government on 17 July.

"A vision for pharmacy in the new NHS" largely focuses on community pharmacy, but one chapter of the document is devoted to hospital pharmacy. It reviews progress to date on "Pharmacy in the future" and proposes where pharmacy in England should be heading next.

"More than ever, the last three years have demonstrated the unique and valuable contribution that pharmacy makes to patient care. We believe pharmacy's full potential is only now beginning to be realised," the document states.

Launching the strategy, Rosie Winter-ton, health minister with responsibility for pharmacy, said: "Community pharmacists are highly valued by patients and the public because of the professional help and advice they give on health and medicines.

"Pharmacy has even greater potential as a fully integrated part of the NHS and there

is scope for making even greater progress in improving the accessibility and range of pharmacy services in the community."

Exactly what pharmacists should be able to offer in the future is set out by Dr Jim Smith, chief pharmaceutical officer for England, who describes 10 key roles for pharmacy. These include providing access to medicines, giving advice on the safe and effective use of medicines, medicines management, preventing adverse drug reactions and medication errors, prescribing medicines, a role in public health and reducing medicines wastage.

A wider role for pharmacists in public health is proposed. A framework for a pharmacy public health strategy, which will be integrated into the Government's overall approach to improving public health, will be published by 2005.

Independent prescribing is also mentioned, with the Government promising to begin discussions in early 2004 on developing a framework for independent prescribing by pharmacists.

The five areas that need to be tackled for the vision to become a reality, according to the strategy, are the way community pharmacists are paid, skill mix, information technology, a supporting infrastructure and strong professional leadership.

The strategy also describes how changes in the way that the NHS is being reformed, with movement of decision making and funding from central Government to primary care trusts, will affect pharmacy.

"A vision for pharmacy" is an important further stage in improving pharmacy services across the NHS, building on the achievements of recent years to ensure that the NHS makes the best use of the skills of pharmacists and their staff to deliver high quality patient care," commented Dr Smith.

The strategy has been issued as a consultation and comments should be made by 17 October to Mary Grafton, Department of Health, Richmond House, 79 Whitehall, London SW1A 2NS (fax 020 7210 4953, e-mail mary.grafton@doh.gsi.gov.uk).

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New UniChem service aims to help pharmacists cope with change

UNICHEM described how it plans to help community pharmacists meet the demands of the proposed new pharmacy contract at a press briefing on 16 July.

Last summer, the company said it would be launching "Profile" but provided little detail about the scheme. Now it is able to expand on exactly what is involved.

"My personal belief is that there are a lot of very concerned pharmacists looking for support," said

Martyn Ward, sales and marketing director. "What we have done is added value: instead of fighting the discount war we will help our customers get through the changes."

UniChem believes that the various packages of added value schemes it has offered in the past have been too complicated, at least in terms of the number of schemes. So it plans to bring them all together in one offering called "Portfolio". The Portfolio package allows added value services to be linked to discounts. An increased spend in a certain area will allow an incremental discount in another area.

"We will tailor an individual package of services for every one of our independent pharmacists," Mr Ward explained. Pharmacists will be assigned to one of four "value



Martyn Ward: offers support

zones" according to the amount they are prepared to spend. Each zone entitles customers to certain amounts of value-added services that can be obtained either free of charge or at a discounted price. Services can be purchased if the value zone the pharmacist is in does not provide it. "The more committed a customer is to UniChem, the more added value that customer can access free of charge," said Mr Ward.

The added value services in each portfolio will be divided into three sections: retail, dispensary and business support. UniChem also plans to expand its range of training packages.

The Portfolio package has been piloted in between 30 and 40 stores and the roll-out will start in August.

BRIEFLY

New walk-in centres

The Department of Health is to spend £40m over three years opening 11 new walk-in centres in England, mainly based at accident and emergency departments.

LIFT poses threat to local pharmacies

THE Government's initiative to improve primary care premises poses a significant threat to community pharmacists, according to Mike Smith, non-executive chairman of UniChem.

However, many pharmacists are simply not aware of the programme, known as Local Improvement Finance Trust (LIFT). Speaking at a press briefing on 16 July, Mr Smith said that a UniChem survey had revealed that 60 per cent of pharmacists do not know what LIFT is.

LIFT will involve up to 3,000 GP premises being refurbished or replaced and 500 new one-stop care centres being established. The priority locations for LIFT are deprived areas with a lot of illness and consequently high volumes of prescriptions.

"Some of the new centres will have pharmacies and some won't, but all will have implications for the pharmacists in the local area," said Mr Smith.

There will be significant investment from the private sector. This means the private sector will have more influence over the building and will also want return for their investment in terms of rent and up-front deposits.

"Pharmacists need to get involved; standing by is not an option," he said. As a first step, he suggests that pharmacists find out what is happening in their local area and speak to the local primary care organisation's pharmaceutical adviser.

Local pharmaceutical committees and local pharmacy groups should also be involved, he added.

Start with ACE inhibitor then add beta blocker in heart failure, says NICE

ANGIOTENSIN converting enzyme (ACE) inhibitors should be considered first line treatment for all patients diagnosed with heart failure caused by left ventricular systolic dysfunction, the National Institute for Clinical Excellence says.

Diuretic therapy should be routinely used to relieve congestive symptoms. Then, regardless of whether symptoms persist or not, a beta blocker licensed for use in heart failure — currently carvedilol (Eucardic) or bisoprolol — should be initiated.

These recommendations are made in NICE's latest clinical guideline, its fifth, published earlier this week.

Dr Mike Pearson, director of the National Collaborating Centre for Chronic Conditions, which developed the guideline on behalf of NICE, said: "The guideline challenges some previously accepted habits, recommending, for example, using ACE inhibitor drugs as the first line — in the expectation that this will prolong life for many."

At the launch of the guideline, Professor Martin Cowie, National Heart and Lung Institute, Imperial College, London, explained that the guideline was an extension of the National Service Framework for

Coronary Heart Disease. "The guideline is more specific about the use of drugs to manage heart failure. It doesn't contradict the NSF in any way." Professor Cowie also highlighted the value of a multidisciplinary approach to the care of patients with heart failure. Dr Pearson added that although the guideline sets out what needs to be done, it does not stipulate which health professional should be doing it. Dr Roger Boyle, national director for heart disease, Department of Health, echoed this view saying that a whole range of staff, including pharmacists, could be involved. "It's more about what is done rather than who does it," he said.

The guideline gives specific recommendations about which ACE inhibitor and beta blocker to use and at what dose. It also sets out when other drugs should be introduced.

In addition, the guideline makes recommendations for heart failure diagnosis and monitoring of patients. It stipulates that all patients should be monitored and that this should include a review of medication, looking at the need for changes and possible side effects.

Patients with heart failure should be offered annual vaccination against influenza and should be encouraged to make lifestyle

changes, such as stopping smoking.

The guideline is available via the NICE website (www.nice.org.uk). A full version can be purchased from the Royal College of Physicians (tel 020 7935 1174, e-mail publications@rcplondon.ac.uk), price £25.

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England not prepared to fight infection

THE Government must review its policy for vaccine procurement if it is to deal successfully with the threat of infectious diseases, the House of Lords select committee on science and technology has warned.

In a report entitled "Fighting infection" published last week, the committee calls for improvements in infection control, including a more secure supply of vaccines and better collaboration between health professionals involved in fighting infection.

It points out that few vaccines are made in England with most being purchased from manufacturers abroad. "In the event of a major global epidemic it is likely that overseas suppliers of vaccines would be under pressure to give priority to their own country's requirements," it warns.

The committee also says that, although England has not experienced major epidemics of infection in recent years, this "owes as much to good fortune as to good management". It points out that many organisations and health professionals are involved in infection control and that all relevant organisations need to understand their roles and responsibilities.

Lord Soulsby, chairman of the committee, said: "Arrangements for formal collaboration between those involved in the fight

against infection are poor and lines of accountability unclear. The government should address this as a matter of urgency."

He added: "Pharmacists can provide information about infections and play an important role in surveillance in the local area." Pharmacists also have an important role in antibiotic management and in warning against the inappropriate use of antibiotics, he said.

The Royal Pharmaceutical Society's science secretary, Dr John Clements, agreed that information available in pharmacies about the prevalence and degree of different infections could become part of a wider approach to surveillance at the local level.

"Additionally, we strongly support the committee's call for research funding. There are simply too few scientists and professionals who are trained in microbiology to put proper systems of infection control in place and, like the Lords, we wish to see this remedied."

He added that recent Department of Health funding for pharmacists to play a more central role in tackling the problem in hospitals (*PJ*, 14 June, p813) is a crucial step forward. "We also need to increase general understanding of the scientific basis of resistance, and work together to avoid squander-

ing the effectiveness of our antibiotics," he said.

The report is published by the Stationery Office, ISBN 010 400262 X, price £12.50. The report is also available via *PJ Online* (www.pjonline.com/links/pj).

Safety controls rise after first NPSA alert

THE number of hospitals implementing formal safety controls on potassium chloride has more than doubled since the National Patient Safety Agency issued its first safety alert in July 2002.

Research conducted by the NPSA and the University of York showed that, before the alert, formal written safety controls were in place in only 25 per cent of National Health Service trusts. This had risen to 68 per cent six months after the alert was issued and is expected to continue to rise, says the NPSA.

The alert also prompted a 27 per cent drop in the use of undiluted potassium chloride, which is being replaced by safer, diluted quantities of the drug.

Autism cases no longer increasing

THE number of children being diagnosed with autism each year has levelled out, say researchers from the Royal Free and University College medical school, London.

They identified 567 children with autistic spectrum disorder in five districts in north east London who were born between 1979 and 1998. The prevalence of autism, which appeared to rise from 1979 to 1992, reached a plateau from 1992 to 1996 with a rate of 2.6 per 1,000 live births. The researchers also observed a decrease in the age at which children were diagnosed with autism from 1985.

They conclude that the earlier recorded rise was likely to be due to factors such as increased recognition, a greater willingness to accept autism as a diagnostic label and

better recording systems (*Archives of Disease in Childhood* 2003;88:666).

The study was funded by the Department of Health.

n Head circumference The onset of autism appears to be preceded by brain growth abnormality, say researchers.

They examined the medical records of 48 children with autistic spectrum disorder and found that head circumference at birth was smaller than that for healthy children and was followed by a sudden and accelerated increase between birth and six to 14 months. The accelerated growth appears before any clinical signs of autism and could be used as an early warning signal of risk, suggest the researchers (*JAMA* 2003; 290:337).

Support staff survey in Scotland

ALL pharmacists in Scotland are being asked to take part in a survey about pharmacy support staff.

The questionnaire aims to gather information about the numbers, titles and qualifications of pharmacy support staff in both primary and secondary care. It is being sent to pharmacists by a working group that was set up to examine the developmental needs of support staff, something that was a requirement in the Scottish pharmacy plan.

Frank Owens, chairman of the Scottish Pharmaceutical General Council, told *The*

Journal: "It is important that pharmacists return their forms as quickly as possible in order to allow the group to continue its work in identifying both the current number of staff engaged in the service and the future likely educational needs of those staff."

Bill Scott, the chief pharmaceutical officer in Scotland, added: "The survey will be of considerable value in identifying future workforce planning requirements and in helping define an explicit career structure for pharmacy support staff in Scotland."

BRIEFLY

Coronavirus is cause of SARS

A novel coronavirus has been confirmed as the primary cause of severe acute respiratory syndrome (SARS). Researchers tested clinical and postmortem samples from 436 SARS patients and diagnosed SARS-associated coronavirus in 75 per cent of the samples. Other respiratory pathogens were diagnosed only sporadically, they say. The study appears as an early online publication on *The Lancet's* website (www.thelancet.com).

More evidence that eating fish often can reduce risk of Alzheimer's disease

PEOPLE who eat fish at least once a week have a 60 per cent lower risk of developing Alzheimer's disease than those who eat fish less frequently, new data indicate. This finding adds to growing evidence that intake of long-chain n-3 polyunsaturated fatty acids (PUFAs), found in fish, vegetable oils and nuts, has an impact on disease development.

Researchers from the Rush-Presbyterian-St Luke's medical centre in Chicago, Illinois, prospectively studied 815 adults aged 65 to 94 years for an average of 3.9 years. Participants completed a dietary questionnaire and Alzheimer's disease was subsequently diagnosed in 131 of these adults (an average of 2.3 years later).

The researchers observed that, over the

four years of the study, intake of PUFAs and docosahexaenoic acid (omega-3) was associated with a reduced risk of developing Alzheimer's disease. In addition, people with the apolipoprotein E-4 allele were protected by increased intake of alpha-linolenic acid, found in vegetable oils and nuts. Total n-3 fatty acid intake was protective only in women.

The study is published in *Archives of Neurology* (2003;60:940).

Data from the study add to growing evidence that diet may influence Alzheimer's disease risk, says Dr Robert Friedland, Case Western Reserve University school of medicine, in an accompanying editorial (*ibid*, p923).

He points out that the beneficial effects of PUFAs from fish may be counterbalanced by toxins such as mercury. However, he suggests that people should consume fish frequently and lower their intake of saturated fat in meat and dairy products. Fruit and vegetables that contain antioxidants should be consumed and obesity should be avoided. Dr Friedland goes on to suggest that fish oil, other than cod liver oil, can be taken in capsule form.

Medicines leaflet research grant for Leeds

RESEARCHERS at Leeds University have been awarded \$25,000 (£15,625) together with colleagues in the United States and Australia for a comparative evaluation of consumer medicines information in the US, Europe and Australia. The work is to be led by Professor Theo Raynor, head of pharmacy practice and medicines management.

Professor Raynor said that written medicines information is increasingly relied upon to empower consumers and inform them about their medicines. But the lack of an evidence base has led to a variety of approaches in different countries.

The study will be undertaken with a view to proposing an evidence-based way forward.

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Hospital manufacturing to be improved

HOSPITAL pharmacies in England have been asked to bid for a share of £42m to be spent on improving their manufacturing facilities.

An implementation plan, published by the Department of Health, sets out priorities for the hospital manufacturing service, saying that its key role is to provide medicines tailored to the specific needs of individual patients where these needs cannot be met by licensed medicines. Other important roles include the early development of new products, supporting medicines research, manipulating licensed products so that they are fit for purpose at patients' bedsides, making products that are not commercially viable and filling in when commercial shortages arise.

This service is currently provided from about 100 hospital manufacturing units,



A wide range of terminally sterilised and non-sterile products will be manufactured by lead units

some of which are expected to close. Others are expected to redirect their effort towards local, rather than national, needs.

Concern over the continued viability of hospital manufacturing led to an inquiry which decided that it should be restructured as a national service facilitated by an implementation board. It is this board that will assess bids and decide where the money is to be spent. Final decisions will be made by 17 October.

The aim is to arrive at a system of lead units, supported by strategic support units. Lead units will be expected to manufacture a wide range of terminally sterilised and/or non-sterile products and to have spare capacity to take on more work. Strategic support units will manufacture a range of sterile or non-sterile products and have collective capacity to back up their area lead units.

The improvement money is to be spent over two years, with £28m being spent in 2004-05 and £14m in 2005-06.

PSNC appoints head of regulation

STEVE Lutener, the Royal Pharmaceutical Society's head of professional conduct, has been appointed head of regulation at the Pharmaceutical Services Negotiating Committee.

Mr Lutener is expected to assume his post at the PSNC in October following the retirement of Dr Gordon Geddes early in September. His chief responsibilities will be the legal provisions affecting community pharmacy contractors, including the terms of service and regulations governing new contracts, repeat dispensing and pharmacist prescribing.

PSNC chief executive Sue Sharpe commented: "Steve has expertise in this field from his work at the Society and will play an important role in ensuring that we are able to influence future regulations and provide information and advice to local pharmaceutical committees and contractors."

Mr Lutener has held various posts in the Society's law department and professional standards directorate since 1987. His depart-

ure means that the three senior members of the Society's professional standards directorate will all have left in the space of two years. The first to go was Sue Sharpe, who moved to the PSNC as chief executive in August 2001. Next was head of ethics Helen Darracott, who became the Proprietary Association of Great Britain's director of legal and regulatory affairs earlier this year. No replacements have been appointed.

The Society's regulatory structures are being substantially revised with the former professional standards directorate losing its registration function to the education division and the professional regulation function being divided into two new directorates — fitness to practise and legal affairs, and practice and quality improvement.

The Society advertised for a director of fitness to practise and legal affairs and a director of practice and quality improvement in June and the appointment process is ongoing.

Sex shop using pharmacy title

A SEX shop based in Bristol and operating on the internet is using the restricted title "pharmacy" on part of its website selling various items.

Section 78(4) of the Medicines Act 1968 makes it an offence to use the title "pharmacy" in connection with the retail sale of any goods except in respect of a pharmacy registered by the Royal Pharmaceutical Society or the pharmaceutical department of a hospital or health centre.

Steve Lutener, head of professional conduct at the Society, said: "This applies to the internet just as much as to anything else. We shall, as we would with any case brought to our attention, take the matter up with the company concerned."

Researchers may soon see yellow card data

A REVIEW of the yellow card adverse drug reaction reporting scheme is to consider whether ADR data can be made available to researchers.

The review is being carried out by Dr Jeremy Metters, a former Department of Health deputy chief medical officer and currently Her Majesty's Inspector of Anatomy. It is in response to increasing requests for access to yellow card data which raise major issues in relation to public health.

Dr Metters said: "There are issues around the confidence of health professionals in the confidentiality of the scheme and how the data could be used to unlock the potential for so-called designer medicines."

Lord Warner, Parliamentary Under-Secretary of State for Health, said: "Our aim

is to maintain the capacity of the scheme to deliver public health benefits and prevent potential abuse of these important data in the future." The minister added that it is essential to decide in what form the data should be made available.

The Association of the British Pharmaceutical Industry's director of medicine, Dr Richard Tiner, said that some data gathered under the yellow card scheme are of great value to the medicines developers. "At the same time, we understand that patient confidentiality is paramount, and this review will be wanting to look at how this can be maintained."

The findings and recommendations of the review will be published and sent out for consultation.

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