

Is it a balanced package of measures?

Last Friday, the Department of Health published its proposals on reforming the control of entry to pharmacy contracts regulations in England. Clare Bellingham looks at whether or not they constitute the "balanced package" that had been promised

WHEN the Government in England rejected the Office of Fair Trading's recommendation on control of entry regulations earlier in the summer, it promised instead a balanced package of measures. The OFT wanted straightforward deregulation. The Government responded that this was not the way forward presently and announced a package of alternative measures (P7, 26 July, p113). Now a consultation document, published last week, fleshes out the bones of these proposals.

Despite the promises, and although it does not propose complete deregulation, it seems to be the first step towards this goal. The document states that the Government does not believe that now is the time to move to a fully deregulated system. However, it "intends to move cautiously in the direction recommended by the OFT".

Steve Dunn, AAH Pharmaceuticals group managing director, comments: "This statement shows that we are on the road to complete deregulation but the timetable is longer than we thought." It is not clear how far away this might be, but the document does conclude that a further review will take place within three years.

But that is a debate for the future. What does the current consultation document say? The Government claims its proposals will offer "a more competitive environment, fulfil the existing commitment to deregulate and extend this further by introducing more choice to areas where there are market monopolies or heavy concentrations". It also believes this will encourage greater diversity of providers and services.

The Royal Pharmaceutical Society is concerned. The president, Dr Gill Hawksworth, says: "The Society will be seeking reassurance from the Department of Health that their proposals will not result in some people, particularly those living in less commercially attractive settings, having poorer access to a community pharmacy and the expertise of a pharmacist."

John D'Arcy, chief executive of the National Pharmaceutical Association, says: "Although we have always regarded the

OFT recommendation as being 'a solution looking for a problem', we share the Government's commitment to put the needs of patients first and we note its intention to maintain the vital services provided by community pharmacy."

Debate over whether or not deregulation is a good idea has been polarised with current independent contractors on one side and supermarkets on the other. Neither side appears to have won, and both are raising concerns.

Mr Dunn says: "Now we are getting to the detail, the people who thought that they had done OK probably haven't and those who thought they hadn't probably have."

Certainly some of the supermarkets are unhappy. Tesco's group corporate affairs director Lucy Neville-Rolfe says: "I am very disappointed with these proposals. We will continue to press the Government for real changes to bring the consumer benefits that the OFT report highlighted."

Asda is still advocating opening the market up, and warns that unless this happens, patients might be faced with pharmacies with limited opening hours. The company points to the recent closure on Saturdays of six community pharmacies in Aberdeen because of reduced demand since GP practices had closed on Saturday mornings. Asda's superintendent pharmacist John Evans comments: "This is another illustration of why services need to be improved and why the current system is failing patients. As the number of pharmacies increases, patients will have better access to redeem prescriptions and take advantage of improved services we intend to offer. This will be in stark contrast to the last 16 years of stagnation."

What is certain is that community pharmacists face another period of waiting before the Government's final decision is announced. This document is a consultation paper: it does not provide definitive answers to the questions that remain in many pharmacists' minds. What the outcome will be is unlikely to be known until December at the earliest, when the consultation period has ended and a newly set-up advisory group on implementing the reforms has given its advice to Government. The final package of changes will be introduced from April 2004 at the same time as the new community pharmacy contract.

The Government's proposals can be divided into three areas. First, the introduction of new criteria of competition and consumer choice to be considered by primary care trusts in the application procedure. Second, to remove the control of entry restrictions on pharmacies in four categories. And finally, to suggest further mod-

A question of balance: partial deregulation proposed

ernisation and reform of the current system, including changing restrictions on minor relocations (see Panels overleaf).

FOUR EXEMPTIONS

The four exemptions to control of entry regulations are:

- Pharmacies in large shopping developments over 15,000 square metres gross lettable floor space
- Pharmacies that intend to open for more than 100 hours a week
- Pharmacies that form part of a new one-stop primary care centre
- Internet and mail-order pharmacies

In the cases of the first three exemptions, pharmacies would be expected to provide a full range of services, determined by PCTs to be appropriate for local needs. Failure to provide the full range of agreed services could lead to losing the right to dispense NHS prescriptions.

Shopping centres What constitutes "gross lettable floor space" was previously unclear. The consultation document makes it clearer: "Gross lettable floor space includes non-retail sales areas but does not include common areas such as pedestrian areas, corridors, stairs or car parks." Furthermore, it specifies that the developments it has in mind include purpose-built named shopping developments in town centres, on edge-of-centre and out-of-centre sites, major regional shopping centres, retail warehouse parks and factory outlet centres. "Most if not all such developments can be expected to have a number of retail outlets," it adds. The Government says that at present, shopping developments might have no, or only one, NHS pharmacy contractor and that this restricts patient choice.

The Pharmaceutical Services Negotiation Committee will be finding out which of the shopping developments already has a pharmacy, and which has one nearby. "Until

How to comment

The document, "Proposals to reform and modernise the NHS (Pharmaceutical Services) Regulations 1992", is available on the DoH website at www.doh.gov.uk/pharmacyregulationconsultation.

Comments should be sent by 21 November to Peter Dunlevy, Pharmacy and Prescription Branch, Department of Health, Room 155 Richmond House, 79 Whitehall, London SW1A 2NS (e-mail peter.dunlevy@doh.gsi.gov.uk).

we are able to analyse the potential impact of these locations we are uncertain how much this could destabilise the pharmacy network," a spokesperson says.

The exemption does not go far enough for Tesco. "We are concerned that this one-off provision will not have any real impact on access in most areas," a spokeswoman comments.

A database of existing developments, and those under construction, is currently being compiled by the British Council of Shopping Centres. It hopes to have the list available on its website (www.bcs.org.uk) at the end of next week.

Long hours Pharmacies that intend to open for more than 100 hours a week should be exempt from control of entry restrictions, the Government proposes. This is because it believes that full account should be taken of the needs of patients who cannot access services during normal shopping hours.

Suggestions that such hours, perhaps 8am to 10.30pm seven days a week, are unfeasible because of Sunday trading laws are quashed by the document. The restrictions do not apply to small shops (internal trading area less than 280 sq m) and to registered pharmacies provided they are not open for the sale of anything other than medicinal products. So large shops could provide pharmacy services, provided the pharmacy is partitioned off and the rest of the store is closed, or the pharmacy has its own entrance. If a pharmacy consistently failed to open for the full 100 hours then it would be removed from the pharmaceutical list, the document notes.

A spokeswoman for Tesco points out: "We already operate pharmacy services for 75 hours a week — some of the longest pharmacy opening hours in the sector. One hundred hours a week is far too high a threshold. This could frustrate the limited moves to provide greater competition."

One-stop centres Pharmacies that are part of a consortium to establish a new one-stop primary care centre should also be exempt, the document states. The Government says that the uncertainty of not knowing if an application for a pharmacy will be successful is a hurdle for consortia developing one-stop centres. But it adds that PCTs should remain influential over the development of these centres and the services they provide.

New test criteria for applications

Applications for new pharmacies to provide NHS pharmaceutical services are currently considered on the basis of a new pharmacy being "necessary or desirable". Current regulations set out grounds under which a PCT can refuse applications, rather than accept them. So the Government proposes a series of measures to "promote competition and choice and at the same time greater certainty for businesses making applications and PCTs in deciding them".

It suggests two questions to which a positive answer would be needed in order for an application to proceed. They are: "Does the application meet the minimum expected essential, and in due course undertake to provide the enhanced, levels of service provision within the proposed new contractual framework for community pharmacy planned to be introduced from April 2004?" and "Does the application lead to the provision of additional or higher quality services in the relevant neighbourhood as a whole, and/or does it increase choice and competition in the relevant neighbourhood?"

This second question will include a consideration of whether the local market can sustain another pharmacy, "with the assumption being that it can, unless clear evidence is provided to the contrary". In addition, competition is considered on the basis of whether an application would be likely to secure an "unduly dominant" position in the market or a monopoly of NHS pharmaceutical service provision. This could be a particular concern for regional multiples or contractors who have a sole position in a neighbourhood and wish to expand, such as into a GP practice.

The minimum team that such centres should comprise is a general practitioner and their practice staff, staff provided by NHS trusts (such as district nurses and midwives) and other primary care practitioner services such as pharmacy, dentistry, optometry, podiatry and physiotherapy.

One-stop centres can be developed as part of NHS Local Improvement Finance Trust (LIFT) plans, by PCTs developing a trust-owned site, by GPs who own premises or by third party developers (including pharmacy contractors) who buy a site for development.

These centres represent a potential threat to community pharmacy. And it is the area of most concern to the PSNC. "There are still a number of uncertainties here and this is most worrying exemption. It is not sufficiently defined within the proposals set out to prevent misuse," a spokesperson says.

This concern is recognised in a question posed in the consultation document. "Many GP surgeries already provide additional ad hoc services such as physiotherapy and may have a pharmacy attached. The exemption is not intended to create an automatic loophole for such sites since it would quite easily thwart the current control of entry legislation," it states, and asks what additional safeguards are needed to prevent manipulation of this exemption.

Internet and mail-order The document states that wholly mail-order or internet-based pharmacies can face obstacles in meeting the current adequacy test to provide NHS pharmaceutical services, partly because patients are drawn from a wide area rather than the immediate vicinity. So it proposes that these types of pharmacies should be exempt from control of entry.

Although the document says that this exemption should apply to "wholly" mail-order and internet-based pharmacies, in its attempts to define these types of pharmacy it fails to include the word "wholly".

IMPACT ASSESSMENT

The Government carried out an impact assessment of the costs and benefits of various reforms. It concluded that retaining current regulations would lead to "stagnation in the market, and costs to consumers and businesses seeking to enter". Full deregulation, would "put strains on the workforce, could jeopardise access for vulnerable groups and could result in additional costs to pharmacies and their reducing investment in services". A figure much publicised at the time of the OFT report was that deregulation would result in an estimated saving of £25–30m for consumers because of lower priced over-the-counter medicines. The Government's own estimate is more conservative at £15–20m.

Another option considered in the impact assessment was allowing PCTs to tender contracts. However, this was considered to be expensive to set up and would increase uncertainty for small businesses.

So the Government recommended that control of entry should be retained but with changes to encourage competition and choice, increase service provision and simplify the regulations. It believes this will offer "the most benefit to the public with the smallest detrimental impact".

Whether this is true will be the subject of the debate that is bound to follow during the consultation period.

Further reforms to modernise the system

The consultation document also puts forward a number of further changes. These are divided into proposals, which the Government intends to introduce subject to consultation, and possible options about which it is seeking views. Proposals include:

- To allow all minor relocations within 500 metres of an existing site to go ahead without consultation. It notes that this might lead to a resurgence of pharmacies "leapfrogging" each other to achieve the best location so pharmacies might have to trade for a minimum time period before being able to apply to relocate again
- To enable PCTs to invite applications from contractors to stimulate the market
- To set time limits in which PCTs have to respond to applications
- To remove the "first past the post" principle of assessing competing applications