

New European policy could abolish control of entry whatever NHS wants

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In 1970, the Restrictive Practices Court saved the resale price maintenance scheme by exempting medicines from the Resale Prices Act 1964. Sixteen years later the Director General of the Office of Fair Trading (OFT) announced that he would ask the court to discharge this order, which it subsequently did in March 1999.

Recently, the OFT turned its attention to control of entry regulations for pharmacy under Section 2 of the Fair Trading Act 1973. These regulations place restrictions on how and where contracts to dispense NHS prescriptions in the UK are awarded, and do not cover the provision of other services by pharmacists. In other words, the study concentrated on regulatory barriers to competition between pharmacies within the UK and did not investigate barriers to trade in other types of pharmacy services, such as drug utilisation reviews. After detailed enquiry, the body concluded and recommended to the Government that control of entry regulations should be lifted, because they stifle competition, efficiency, innovation and choice.

Although the OFT provided the evidence and analysis, it was for the Government to decide what action, if any, to take in the light of its findings. The Department of Health (DoH) decided to save control of entry as a regulatory system while:

- Introducing criteria of "competition and choice" to the current regulatory test
- Exempting four types of pharmacy applications from that test
- Reforming and modernising the current regulatory system

In August 2003, the DoH published a consultation document that explained the Government's proposals in more detail and sought views on how best to implement them.¹ As part of this process, 270 responses were received and an official advisory group was established to give advice on the best way ahead. After weighing the evidence, the Government decided to maintain its position

of reform, not abolition, but to review the situation in 2006.

Although some pharmacy bodies welcomed this policy compromise as better than deregulation, others believed the result would be pharmacy closures. The OFT chairman, on the other hand, said: "We regret that the Government has now decided on even less liberalisation for the time being, but we look forward to the further review of the rules in 2006."

In response to these views, this article examines the possible future for NHS entry regulations and suggests that recent developments in EU policy may soon force the Government to respond differently to the OFT's findings.

The pharmacy frame

In recent years, psychologists, sociologists, lawyers and economists have shown growing interest in the reasons why people do not always make rational decisions. A major theme in this expanding field is the way in which "frames" or "framing effects" affect our choices.² For instance, the OFT presented its evidence on medicines pricing within the legal framework operated by the Restrictive Practices Court.

Using real experiments, researchers have found that our frames of reference can affect the conclusions we draw, with the results that these structures can influence our thinking more than logical reasoning. For instance, community pharmacists with their own outlets are likely to use a frame of reference different from that of the OFT when thinking about control of entry and draw different conclusions about what should be done.

In response to the limitations of the OFT analysis, the present Labour Government reframed the control of entry debate in terms of NHS policy, not free market economics.³ Using concepts used by both lawyers and economists, we could say that that the Government confirmed that control of entry is an "institutional" issue (that is, concerned with the rules, norms and conventions governing the NHS). The OFT, on the other hand, tried to make these regulations a "com-

petition" issue (that is, concerned with the efficient operation of the pharmacy market).

By taking this move, the Government switched the frame within which control of entry was analysed, with the result that the debate centred around the rules governing the NHS not the ideology of competitive market economics. However, as discussed below, the introduction of new European policy may soon force the Government to consider this issue within a new analytical frame.

The EU Services Directive

Although the Government successfully reframed the control of entry debate, recent developments in EU policy suggest that things may soon change again.

The European Commission (EC) recently published proposals to improve the flow of services around the EU in order to unlock business potential, increase productivity, create jobs and benefit consumers through greater competition. The proposals, which were part of the Lisbon economic reform agenda agreed by European leaders in 2000, were described by the Internal Market Commissioner as "potentially the biggest boost to the internal market since its launch in 1993".

The full scope of the proposals was published by the EU Commission, in the proposed EU Services Directive (Com[2004]2 [03]), which aims to cut excessive red tape that prevents businesses from offering their services across borders or from opening premises in other member states.

In a survey published in 2002, the EU identified 91 barriers affecting a wide range of service sectors throughout the business process, including lengthy and complex administrative formalities for setting up "shop" in another country.

The directive in its proposed form covers any business activity that constitutes a service provided to consumers or businesses — this could include pharmacy services — and will establish a general legal framework applicable to all economic activities (for example, dispensing and drug utilisation reviews).

If the proposed directive is passed, like all EU directives, it will bind the UK to the overall objective of eliminating existing legal obstacles to a genuine internal market in services but will leave the question of exactly how to achieve this goal for our own Parliament to decide.

As such, pharmacists will not be exempt from this framework unless they will be cov-

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ered by a “derogation”, which is a special provision in a directive that can be applied to particular groups of people or organisations in different ways.

A derogation is not simply an exemption; it usually just permits greater flexibility in the application of the law to take into account special circumstances. For example, although security workers were given a derogation in the Working Time Directive, an employer must still provide for compensatory time off to comply with the general working time limitations.

If the UK Government could show that the proposed directive would impact upon on the delivery of NHS prescriptions in such a way that it would adversely affect patients’ health and health care, this would arguably be sufficient grounds to allow a derogation and some maintenance of controlled entry. Given the uncertainty about the success of this line of reasoning, the proposed EU Services Directive poses a real threat to UK community pharmacists. If there is no derogation, a single market for pharmacy services will expose pharmacies to greater competition.

DTI consultation

As a champion of the European single market, the UK Government strongly supports the market-opening aim of these proposals and shares its objective to see the internal market become a reality for services as well as goods.

At the Government’s request, the Department of Trade and Industry (DTI) recently launched a domestic consultation on the EU proposals. It seeks views from service providers, recipients and regulators of services, and other interested parties. The deadline for responses to the consultation was 30 June 2004. A detailed submission was made to the DTI by all the major pharmacy bodies calling for NHS services to be excluded from the scope of the directive.

In its role as professional regulator, the Royal Pharmaceutical Society replied to questions in the consultation questionnaire about the main articles listed in the directive. For instance, the Society was given the opportunity to respond to Article 14(5) of the proposed directive, which specifies that member states shall not make access to, or the exercise of, a service activity in their territory subject to compliance with “the case-by-case application of an economic test making the granting of authorisation subject to proof of the existence of an economic need or market demand, or an assessment of the potential or current economic effects of the activity, or an assessment of the appropriateness of the activity in relation to the economic planning objectives set by the competent authority”.

In our view, this article prohibits case-by-case application procedures like the pharmacy control of entry regulations, even after the Government’s proposed reforms.

If this article is applied to the letter in the UK, the Government will have to scrap NHS entry regulations for pharmacists because

they may constitute a case-by-case application of an economic test.

With this in mind, the Society informed the DTI that the Government was planning to reform pharmacy entry regulations by introducing a “balanced package of measures” to foster competition. However, the Society warned: “Having achieved this potential concession in the public interest, we would be concerned if the UK Government’s ‘balanced package of measures’ to replace ‘control of entry’ were to be swept away under Article 14(5).”

As this quotation suggests, Article 14(5) has the real potential to override the UK Government’s desire to maintain some form of pharmacy entry control. Given this possibility, a DoH spokesperson told us: “We are aware of concerns raised that the current ‘control of entry’ system would be prohibited under Article 14 of the draft directive. Whether these provisions (as they currently are or as amended) would be caught by the directive is not entirely clear. The possibility cannot be ruled out and we will be seeking clarification as discussions on the directive proceed and discussing further with the DTI. This does not affect our intention to reform the current system in response to the Office of Fair Trading report.”

The DoH response makes it clear that the Government will continue with its current plans to reform pharmacy entry regulations, but cautiously acknowledges that the proposed services directive could possibly lead to the abolition hoped for by the OFT.

With this outcome in mind, the OFT press office informed us that: “The EU Services Directive was not considered as part of the OFT study. It was outside of the scope of the study which concentrated on regulatory barriers to competition between pharmacies within the UK, not barriers to trade in pharmacy services between member states. The OFT’s role was to make recommendations to Government on the regulations. The process since then (January 2003) and the legalities of the revised pharmacy policy has not involved the OFT but has been the responsibility of Government. We do not believe will be asked to look at the market again in the light of the EU Services Directive.”

In other words, the work of the OFT is done and EU policy may now decide the fate of pharmacy control of entry rules.

Conclusions

The proposed Services Directive is a new piece of European policy that emerged during the current control of entry debate. On the surface, EU policy seems more in keeping with the OFT’s desire for free markets than the present Government’s position, which will be reviewed in 2006.

With the OFT investigation, pharmacy bodies lobbied UK ministers about NHS pol-

icy. Although this approach worked, the proposed EU Services Directive changes the framework within which the arguments of lobbyists will be heard. Consequently, any attempts to save NHS entry controls must be aimed at thwarting EU policy, which will in turn affect subsequent UK legislation. However, attempts to change the primary legislation — for instance, removing Article 14(5) — are likely to be unsuccessful because they cover all services and all countries so must be maintained.

Since the same problems may be faced in all member states, an effective strategy may be to seek a derogation for all pharmacies in Europe, and to create a Europe-wide lobby to this end.

For instance, the Pharmaceutical Group of the European Union (PGEU), with support from UK pharmacy bodies, has been actively analysing and discussing the EU Services Directive and its possible implications for pharmacists among the association’s membership for over a year now.

Flora Giorgio-Gerlach, secretary general of the PGEU, told us: “Several

member states and a number of European associations active in the health sector have already publicly expressed concerns about the application of the directive to health services (including pharmacy services) and these concerns have also been communicated to the European Commission’s DG Internal Market, which drafted the proposal. The services directive is probably one of the most significant pieces of EU legislation for pharmacists in recent years, and clearly one that requires co-ordinated action on the national and European level. The PGEU is convinced that only through this kind of co-ordinated and open actions, both at EU level and at national level, can the services directive be properly addressed. PGEU members are committed to continuing to work together on this proposal, to ensure that the directive, if applied to health services, safeguards the quality and accessibility of pharmacy services across Europe.”

With this policy timetabled for introduction by 2010, the future position regarding control of entry is again uncertain, and abolition could be a reality within six years.

In response, we conclude that UK pharmacy bodies should continue lobbying Europe and the DTI, and not the OFT, in order to continue fighting the control of entry cause.

UK pharmacy bodies should continue lobbying Europe and the DTI, and not the OFT

References

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Correction

Catherine Hale is a lecturer in medical law and ethics at the University of Birmingham and not a senior research fellow at King's College London.