



Llywodraeth Cynulliad Cymru
Welsh Assembly Government

CONSULTATION

PROPOSAL TO REFORM THE NHS (PHARMACEUTICAL SERVICES) REGULATIONS 1992 STATUTORY INSTRUMENT No : 662.

PHARMACEUTICAL SERVICES APPLICATION & APPEAL PROCESSES “CONTROL OF ENTRY”



**BUDDSODDWR MEWN POBL
INVESTOR IN PEOPLE**

Parc Cathays
Caerdydd
CF10 3NQ

Cathays Park
Cardiff
CF10 3NQ

Ffôn ☐ Tel: 02920 823992

Ffacs ☐ Fax: 02920 826331
Epost ☐ Email: Mark.Welsby@Wales.gsi.gov.uk

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SUMMARY.

S.1 The Welsh Assembly Government and Minister for Health & Social Care are committed to developing policies that benefit and deliver effective primary healthcare services to the population of Wales. We are appreciative of all the efforts and hard work that healthcare professionals within the primary care sector in Wales have thus far put into the development and implementation of policies which are designed to deliver better healthcare services for the population of Wales.

S.2 This document is intended as a consultation process to develop a policy which will lead to the implementation of legislation governing the location of pharmaceutical services within Wales.

S.3 Chapter 3 sets out a number of specific proposals and possible options the Welsh Assembly Government is considering to reform and modernise the regulatory system, in terms of the application, decision-making and appeals procedures. The aim is to make the system more business-friendly, more certain and reliable and less time - consuming. This consultation document asks a series of questions about these ideas.

INTRODUCTION.

I.1 The Office of Fair Trading (OFT) report 'The control of entry regulations and retail pharmacy services in the UK' published on 17 January 2003 recommended abolition of the current NHS controls, set out in the NHS (Pharmaceutical Services) Regulations 1992, on pharmacies dispensing NHS prescriptions.

I.2 A summary of the OFT report is at Appendix 1.

I.3 The OFT report that considered the liberalisation of pharmaceutical services within the UK was rejected by Health & Social Care Ministers for Wales because of concern over the impact which the Reports recommendations could have on small pharmacies, particularly in socially disadvantaged and rural parts of Wales.

I.4 The Welsh Assembly Government wishes to maintain and improve access to pharmacists in all communities whilst continuing to raise standards, encouraging innovation and excellence and to reward those providing the fullest range of services. It hopes to set out a balanced package of measures that will continue to raise standards for patients, will support the needs of small businesses, and will do so without jeopardising the vital role played by community pharmacies particularly in poorer and rural areas. In June 2004, the First Minister, in discussion with the then Secretary of State for Trade and Industry, agreed to consult stakeholders on proposals to make regulatory changes to streamline the process, and to inform stakeholders that criteria would be developed to help determine that applications meet the required "Essential Services" to be specified under the pharmacy contractual framework.

I.5 On 09 May 2005 the National Assembly for Wales asked key stakeholders, in a pre – consultation letter, to identify issues which are of concern to those involved in the application and appeal processes and for comments and views of the current application

and appeal processes. The National Assembly for Wales has now received responses to the pre – consultation, which it has carefully considered in determining the formation of this consultation document.

In summary the responses received by the National Assembly for Wales to its pre-consultation have indicated that :

- There is dissatisfaction with the time taken to determine applications and appeals.
- Reform of the current regulatory arrangements needs to be considered.
- There is a perception that applications are submitted on a speculative basis and that a greater requirement should be placed on the applicant to justify the need for the services they intend to provide.
- Community Pharmacies are believed to provide an important role in the provision of pharmaceutical services to the population of Wales.
- There is a perception that allowing an open market for the provision of pharmaceutical services will result in clustering of pharmacies around GP premises and could have negative impacts on the existing distribution of independent pharmaceutical services providers.
- A strategic approach to the provision of pharmaceutical services is beneficial to the population of Wales and that some degree of control of the market is advantageous to the Pharmacy market.

I.6 At present pharmaceutical services within Wales are governed by the NHS Pharmaceutical Services Regulations 1992 SI 662 (As Amended) – ‘The Regulations’.

I.7 This consultation document gives details of the Welsh Assembly Government proposals and invites comments on the consultation document itself and a number of specific questions on which it would particularly welcome views (a summary of questions is at Chapter 1).

I.8 Chapter 1 summarises the main elements to the Welsh Assembly Government’s proposal of reform. These elements are described in detail in Chapter 3, and are intended to :

- Deliver improved pharmaceutical service provision to the population of Wales.
- Deliver improved time scales for the making of determinations at the application and appeal stages.
- Take account of and implement the pharmaceutical services strategies outlined in *‘Remedies for Success – A Strategy for Pharmacy in Wales’* (http://www.wales.gov.uk/keypubconsultation/content/archive_02/index.htm)and *‘Designed for Life : Creating world class Health and Social Care for Wales in the 21st Century’* (<http://www.wales.gov.uk/subihealth/content/keypubs/pdf/designed-life-e.pdf>)
- Take account of the business operations of community pharmacies.

I.9 It is the intention of the National Assembly for Wales that its policy for the provision of pharmaceutical services within Wales in the future is developed to take account of providing the best possible delivery of pharmaceutical services to the population of Wales whilst taking account of the interests of those who deliver pharmaceutical services within Wales.

I.10 A list of organisations which the Welsh Assembly Government is consulting is at Appendix 2 but comments from others are welcome. The below summarises questions on which views are particularly welcome.

Comments and views should be sent, by 23 November 2005, to :

Mark Welsby
Pharmaceutical Services
Health & Social Care Directorate
National Assembly for Wales
4th Floor
Cathays Park
Cardiff
CF10 3NQ.

Mark.Welsby@Wales.gsi.gov.uk

I.11 In keeping with its commitment to the policy of Open Government the National Assembly for Wales will make copies of all comments received available on request, unless you indicate, in replying, whether some or all of your comments are to be treated as confidential. Normally, the name and address (or part of the address) of its author are published along with the response, as this gives credibility to the consultation exercise. If you do not wish to be identified as the author of your response, please state this expressly in writing to us.

Chapter 1

Summary of Questions.

1.1 Within the chapters of this paper are a number of questions designed to prompt thinking and on which the Government would particularly welcome views. The below questions summarise the main elements to the Welsh Assembly Government's proposal of reform. These elements are described in detail in Chapter 3.

Commentators are of course welcome to express views on any part of this paper.

1.2 Determining Adequacy.

Is it appropriate for the LHB to carry out a pharmaceutical services needs assessment in regard to the neighbourhood for which an application for inclusion in the list has been made ?

If so, should an assessment be consistently applied by all LHBs ?

Does it help to identify certain questions as key questions which must be answered positively for an application to proceed ?

What questions would be appropriate for LHBs to consider when assessing applications ?

Should such questions be introduced as part of the regulatory framework to promote consistent decision making or left to local discretion to apply ?

1.4 Deciding applications.

Is the introduction of a timetable for LHBs to decide applications, and the proposed deadlines, reasonable ?

Are shorter time limits for determination of applications reasonable, for example 90 days where there was no oral hearing ?

1.5 Consultation on applications.

Should LHBs consult more widely on applications ?

If so, is 30 days adequate time for patient and consumer groups to comment ?

1.6 'First past the post'.

Should the 'first past the post' option for deciding competing applications, which are in all other respects equal, be retained or removed from the guidance ?

1.7 Minor relocations.

Would an automatic grant of a minor relocation based on distance improve the operation of the Regulations ?

If so, is 500 metres a suitable limit in all cases ?

Should a minimum trading period be applied following a minor relocation and, if so, is 12 months reasonable ?

Are there other factors to consider here? For example, is there a case for not allowing minor relocations to within a certain distance (e.g. 100 metres) of a GP surgery without LHB approval ?

1.8 Cross LHB boundary minor relocations.

Should minor relocations across LHB boundaries be allowed ?

Are there safeguards needed to support this reform ?

1.9 Preliminary consent.

Should preliminary consent be retained or abolished completely ?

If retained, should the maximum period for grant be reduced – for example to 6 months?

Are there other factors to take into account ?

1.10 Grant of full consent.

Should the maximum period for grant of full consent be reduced ?

Is a maximum period of 6 months reasonable ?

Are there other factors to take into account ?

1.11 Requirement to commence services.

Should LHBs have the right to require commencement of services within a given period ?

If so, is a period of 6 months reasonable ?

Should LHBs be able to make exceptions to the commencement period ?

What factors might an LHB take into account when making exceptions to such a requirement ?

1.12 Dispensing doctor applications.

Would it be appropriate for dispensing doctor applications to pass similar criteria as those imposed on applications made by pharmacists ?

Would it be appropriate for all applications made within a controlled locality to pass the 'necessary or desirable' test ?

Would it be appropriate for all applications made within a controlled locality to pass the 'prejudice' test ?

Should there be conditions imposed on a grant of application if thought necessary by the LHB ?

Are there any disadvantages in applying the 'necessary or desirable' test to dispensing doctor applications within controlled localities ?

Is it reasonable to review an application for dispensing doctor following its grant ?

Is 5 years a reasonable period at which to review an application grant ?

1.13 The appeals mechanism.

Are there types of appeals which ought to be dismissed on lack of reasonable grounds ?

Is it reasonable to expect the National Assembly for Wales to process appeals on similar deadlines as to those proposed for LHBs ?

Is there further scope to speed up appeals cases, or improve targets for the National Assembly for Wales, and therefore reduce the time appeals cases are decided ?

What other changes to the current applications, decisions and appeals processes might the Welsh Assembly Government consider ?

Chapter 2 Background

2.0 The Regulatory System.

This Chapter summarises the current regulatory system. Various publications ⁽¹⁾ provide a comprehensive account of the law governing community pharmacies. In addition, Annex A to the OFT report itself gives a detailed overview of the UK position.

(1) For example, Dale and Appelbe's Pharmacy Law and Ethics Pharmaceutical Press, London

2.1 The NHS Act 1977 was amended in 1986 and new Regulations introduced from April 1987 to pave the way for the current system. In essence, Sections 41 – 43 set out the main provisions governing

- The powers to the NHS to govern arrangements for pharmaceutical services;
- The regulations to underpin these arrangements – including control of entry (see Chapter 3 for more detail); and
- various provisions about those authorised to provide services, including remuneration arrangements.

2.2 The NHS (Pharmaceutical Services) Regulations 1992 as amended (referred to as the “Regulations” from now on) derive from this legislation. The Regulations apply to ‘chemists’ which includes not only pharmacists but also appliance contractors. The Regulations and subsequent amendments can be found on the HMSO website at <http://www.opsi.gov.uk/stat.htm>

2.3 The application and decision processes

Under the Regulations, applications are made by new pharmacy contractors, or existing pharmacy contractors who wish to vary their services or change the premises from which the services are provided, to the relevant local LHB in Wales. Applicants use the form in Schedule 3 to the Regulations. New applicants are in effect applying to be admitted to the LHB pharmaceutical list. This list gives details of current pharmacy contractors, their premises and the days and hours at which NHS services are generally available.

2.4 Control of entry for new applicants

‘Control of entry’ is shorthand to describe the system whereby LHBs assess under Regulation 4(4) of the Regulations whether it is necessary or desirable for a new pharmacy to dispense NHS prescriptions in order to secure adequate pharmaceutical services in a particular neighbourhood.

2.5 Once an application is received, the LHB invites, as soon as practicable, a range of interested local parties to give views. Those invited are:

- the Local Medical Committee (LMC) and Community Pharmacy Wales (CPW);
- any current pharmacy contractor whose interests might, in the LHB’s opinion, be significantly affected if the application were granted;
- any other LHB or Primary Care Trust (PCT) within 2 kilometres of the proposed premises (who in turn consults similar organisations in its area); and

- the relevant Community Health Council (CHC) serving such areas.

2.6 Views have to be made known to the LHB within 30 days of the date the notification is sent out.

2.7 LHBs determine applications under Regulation 6 and are generally free to determine them as they see fit.

2.8 LHBs can make decisions on the basis of the written documentation received or may decide to hold an oral hearing. If they do so, they must give at least 14 days' notice to the applicant and to those who have sent in views. If an LHB receives more than one application and the LHB considers they relate to the same neighbourhood, it can consider them together. There are no time limits for deciding cases.

2.9 Once a decision has been made, the LHB notifies the applicant and those who have sent in views giving a statement of the reasons for the decision and the rights of appeal.

2.10 Similar procedures apply where an LHB determines :

- whether or not an area is “controlled” (i.e. rural in character) under Regulation 9;
- applications to open a pharmacy in a controlled area under Regulation 11; and
- applications to be given preliminary consent for inclusion in the LHB list under Regulation 14. Preliminary consent is discussed further in Chapter 3.

2.11 **Appeals against LHB decisions on pharmacy applications.**

Under the Regulations, LHB decisions can be appealed to the National Assembly for Wales.

2.12 The main provisions regarding pharmacy appeals are set out in Regulation 8. There are also appeals mechanisms in relation to decisions on determining controlled (rural) areas and on applications in respect of rural areas which are broadly similar.

2.13 An appeal has to be made to the National Assembly for Wales within 30 days from the date on which the LHB's decision letter is sent. The appeal should contain a concise statement of the grounds of appeal. Appeals may be sent by letter or by fax or by e – mail attachment.

2.14 An appeal can only be made by the applicant or by a pharmacist who has been notified of the decision by the LHB. An appeal cannot be made, for example, by a local professional representative committee. The LHB decides who is or who is not in its opinion affected by the decision. Where more than one appeal is received in relation to a decision, the National Assembly for Wales can determine them at the same time.

2.15 The National Assembly for Wales deliberations are not limited to simply reviewing the LHB's decision. It will reconsider the application de novo (i.e. anew).

2.16 The majority of cases are decided on the basis of correspondence with the National Assembly for Wales and other documentation related to the original decision. Occasionally, e.g. if there are material differences in the facts presented by the parties, the National Assembly for Wales will convene a panel to hold an oral hearing, usually lasting a half day. The National Assembly for Wales gives interested parties including

the LHB at least 14 days' notice of the hearing. Interested parties can attend with any representatives they wish to accompany them.

2.17 Whilst there are standard complaints procedures as apply to any NHS body, there are no further powers for review of an appeal decision once it has been issued. The National Assembly for Wales decision can only be set aside by the High Court.

2.18 Rural issues.

The system applies equally to urban and rural areas. However, where an LHB has determined that an area is "controlled" (i.e. rural in character), provided certain conditions are met, doctors as well as pharmacies can dispense NHS medicines. General Practitioners ("GPs") may, in general, dispense NHS prescriptions only with NHS approval and only to their own patients who live in such controlled localities and more than one mile from a pharmacy. The main purpose is to ensure patients in rural areas who might have difficulty getting to their nearest pharmacy can access the medicines they need.

2.19 A GP who wishes to apply to dispense to patients need only show that to do so would not prejudice the proper provision of medical or pharmaceutical services locally (the 'prejudice' test). There is no 'necessary or desirable' ('control of entry') test.

2.20 A pharmacy wishing to open in a rural area must pass both the 'control of entry' and the 'prejudice' tests.

Chapter 3

Reforming the current application and appeals system.

Introduction.

3.0 This Chapter discusses a number of elements the Welsh Assembly Government is considering for implementation. The Welsh Assembly Government believes the measures proposed in this chapter (Chapter 3) will help provide greater certainty for business and, whilst introducing new elements, will help speed up the decision making process generally. However it also believes that the application and appeal processes can be reformed. Views are invited not only on the measures proposed and the way in which they may be implemented, but on further options which organisations and individuals may wish to recommend.

Determining the adequacy of Pharmaceutical Services Provision.

3.1 Introducing Needs Assessment.

The Regulations provide that a LHB shall grant an application to be included in a list of persons who undertake to provide pharmaceutical services, only if it is satisfied, in accordance with the Regulations, that it is necessary or desirable to grant the application in order to secure, in the neighbourhood in which the premises from which the applicant intends to provide the services are located, the adequate provision, by persons included in the list, of the services, or some of the services, specified in the application.

3.2 In summary, a LHB's task is to assess the adequacy of pharmaceutical services in a given neighbourhood. The concept of neighbourhood is not defined here.

3.3 The Welsh Assembly Government believes there is a key question which should be assessed positively by the LHB and National Assembly for Wales on appeal, for any application to proceed. That question being :

Does the application offer the minimum expected essential services and in due course undertake to provide the enhanced levels of service provision within the proposed new contractual framework for community pharmacy which was introduced from April 2004 ?

This question would help determine if the application would meet the minimum essential levels of NHS service.

3.4 LHBs might wish to make use of further supplementary questions to augment their assessment, for example, are current levels of service adequately responding to the changing healthcare needs of patients, or to the LHBs' development plans. Examples here might include improved access to pharmaceutical services for certain minority ethnic groups, people with disabilities, or services for patients with specific local healthcare needs (e.g. respiratory disease in industrial areas, substance misuse).

Examples of such questions could be :

Does the application offer additional services (e.g. services to care homes) which meet the needs the LHB has identified locally? Conversely, could it reduce the ability of existing pharmacies to provide those services ?

Are current providers responding adequately to the changing needs of the community they serve or to local LHB delivery plans designed to meet primary care policy objectives ?

Would the application provide specialist or innovative services which improve choice and access for specific populations or vulnerable groups (e.g. older people, substance misusers, patients whose first language is not English) ?

Questions :

Q1. Are the questions for LHBs to consider when assessing applications relevant and helpful ?

Q2. Do they reduce or increase bureaucracy for business and for LHBs ?

Q.3 Is it appropriate for the LHB to carry out a pharmaceutical services needs assessment in regard to the neighbourhood for which an application for inclusion in the list has been made ?

Q4. Does it help to identify certain questions as key questions which must be answered positively for an application to proceed ?

Q5. If so, should an assessment be consistently applied by all LHBs ?

Q.6 Are the supplementary questions contained within paragraph 3:4 useful for business and for LHBs ?

Q.7 Should the supplementary questions contained within paragraph 3:4 be introduced as part of the regulatory framework to promote consistent decision making or left to local discretion to apply ?

Simplifying the decision process.

3.6 The Welsh Assembly Government proposes that : a LHB be required to determine applications within a set period.

3.7 The Regulations require LHBs to consult on applications (e.g. Regulation 5, 12 etc) and 30 days is allowed for views to be sent in. However, no time limit is set for LHBs to initiate the consultation or to determine applications (e.g. Regulation 6 or 12). Whilst the Welsh Assembly Government considers that LHBs must be left free to determine applications in the manner they see fit – including whether to hold an oral hearing or not – the Welsh Assembly Government believes that it is reasonable to set a time limit within which normally views should be invited and applications determined. The Welsh Assembly Government therefore thinks that LHBs should be required to invite views within a given period of, for example, 28 days, and to determine applications within, say, 120 days, of receipt of the application.

Questions :

Q11. Is the introduction of a timetable for LHBs to decide applications, and the proposed deadlines, reasonable ?

Q12. Are shorter time limits for determination of applications reasonable, for example 90 days from receipt of application ?

Consulting on applications.

3.18 Currently the list of organisations consulted on applications (see Chapter 2) is limited to the local professional committees, affected contractors and the local Community Health Council. The views of local patient and consumer groups may not be given adequate weight as a consequence. The Welsh Assembly Government believes LHBs should invite such groups with a direct interest in local pharmaceutical service provision to comment too.

Questions :

Q13. *Do you agree LHBs should consult more widely ?*

Q14. *If so, is 28 days adequate time for patient and consumer groups to comment ?*

Removing the ‘first past the post’ principle.

3.9 At present, under Regulation 6(7), a LHB may, where it thinks fit, consider two or more applications together in relation to each other. This allows the LHB discretion in deciding applications which relate to the same or a similar site where they are received at the same time.

Questions :

Q15. *Should the ‘first past the post’ option for deciding competing applications which are in all other respects equal be retained or removed from the guidance ?*

Minor Relocation.

3.10 One of the case studies in the OFT report concerns a pharmacy which relocated twice in order to achieve its new desired location – trading for just one day en route – in order to be near a relocated medical centre. This appears unacceptably bureaucratic and unnecessarily time consuming for all concerned. The Welsh Assembly Government believes that a business’ desire or need to relocate should not normally be restricted in such a way. On this basis the Welsh Assembly Government believes there may be merit in allowing all minor relocations within 500 metres of an existing site without recourse to consultation or appeal. This could significantly reduce the burdens on business and the NHS as the majority of all LHB decisions involve minor relocations.

3.11 However, distance is only one, albeit it an important, factor in decisions on minor relocations. Whether the same neighbourhood, or population who rely on the pharmacy for its services, would continue to have adequate service provision, are also be factors to be considered. In addition, a possible unintended effect of this would be to allow pharmacies within 500 metres of a GP surgery to automatically relocate closer to the surgery. Currently the majority of GP practices have a pharmacy located within 500m of their surgery premises. Such a provision might lead to a resurgence of pharmacies “leapfrogging” each other to achieve the best possible location. To reduce this risk, a minimum time period could be introduced in which a pharmacy would be required to trade from the new site before being able to apply to relocate again. The Welsh Assembly Government proposes that 12 months might be such a reasonable minimum trading period though there would need to be some flexibility to allow further relocations where there was good cause and provided the LHB was satisfied with the reasons the applicant put forward.

3.12 The Welsh Assembly Government would therefore welcome further views on this proposal and the concept of a required trading period.

Questions :

Q16. *Would an automatic grant of a minor relocation based on distance improve the operation of the Regulations ?*

Q17. *If so, is 500 metres a suitable limit in all cases ?*

Q18. *Should a minimum trading period be introduced following a minor relocation and if so, is 12 months reasonable ?*

Q19. *Are there other factors to consider here? For example, is there a case for not allowing minor relocations to within a certain distance (e.g. 100 metres) of a GP surgery without LHB approval ?*

Cross LHB boundary minor relocations.

3.13 Current regulations make no provision for minor relocations across LHB boundaries (e.g. a pharmacy may not be able to cross the street if this means it transfers from the area of one LHB to the area of another LHB). Whilst there has been little evidence of this type of movement within Wales however, the Welsh Assembly Government recognises that there is a potential for this type of move. As LHB areas are much smaller than those of Health Authorities who previously decided applications, this problem may increase in the future. The Welsh Assembly Government believes that in such circumstances this would be an unnecessary restriction on trade and on the provision of services to patients. Removing this restriction for an across LHB boundary application would reduce bureaucracy and simplify the movement process in such cases.

3.14 The Welsh Assembly Government therefore believes there is a strong case for reform to allow minor relocations across LHB borders within Wales. The removal of the cross LHB boundaries restriction would require safeguards as outlined in the previous section on minor relocations to prevent abuse. For example, if the applicant was not already on the LHB list for the new location, it would be unreasonable to expect entry to the new LHB's list without the contractor having to pass the necessary or desirable tests. The LHB would have to assess the application in the usual way. Since the receiving LHB will wish to assure itself that the contractor is providing services to a required standard, it will need to agree the transfer. The LHB in which the premises currently are located will also need to be able to ensure that withdrawal of the contractor from its list would not result in a significant loss of pharmaceutical services provision to the population before the contractor commences services in the new LHB area.

Questions :

Q20. *Should minor relocations across LHB boundaries be allowed ?*

Q21. *Are there safeguards needed to support this reform ?*

Preliminary consent.

3.15 Regulation 14 allows an applicant to submit a proposal for preliminary consent. This consent, once granted, lasts for 12 months but can be extended for such further period as the LHB considers reasonable. This right was introduced so that potential pharmacies, who had yet to find or build premises, did not incur unnecessary expense before they knew whether their application was likely to be successful.

3.16 However, preliminary consent and extended periods can have an unintended effect of freezing the market in a given location. Whilst consent has been given, the LHB has no means to enforce provision. This effectively prevents other contractors from applying to

move in. It may be that this provision should be removed entirely, or a maximum time limit imposed on the period for which preliminary consent can be granted. If a maximum time limit were to be imposed, this would need to be seen as fair and reasonable to all parties.

Questions :

Q22. *Should preliminary consent be retained or abolished completely ?*

Q23. *If retained, should the maximum period for grant of such consent be reduced to 6 months ?*

Q24. *Are there other factors to take into account ?*

Grant of full consent.

3.17 Under Regulation 4(9) similar provisions apply where a LHB grants a full application. A LHB can allow a contractor up to 24 months to commence services before the grant expires. The Welsh Assembly Government is concerned that this may have the potential to freeze the market for an unacceptably long time. If a pharmacy is assessed as being necessary or desirable, then patients and consumers should not have to wait such a long period for services to begin.

3.18 The Welsh Assembly Government would therefore welcome views on whether the rules should be amended to allow for a more limited period. The Welsh Assembly Government believes this should be in step with any changes in the maximum time limit for preliminary consent, if that concept were to be retained.

Questions :

Q25. *Should the maximum period for grant of full consent be reduced ?*

Q26. *Is a maximum period of 6 months reasonable ?*

Q37. *Are there other factors to take into account ?*

Requirement to commence services.

3.19 In addition, where preliminary or full consent has been granted, LHBs currently have no right to require the commencement of services. The Welsh Assembly Government believes that it is in the best interests of patients that there should be a right to require commencement of the provision of services, unless there is good cause not to do so, from a stipulated date (e.g. within 3 months of notification).

Questions :

Q28. *Should LHBs have the right to require commencement of services within a given period ?*

Q29. *If so, is a period of 3 months reasonable ?*

Q.30 *Should LHBs be able to make exceptions to the commencement period ?*

Q30. *What factors might a LHB take into account when making exceptions to such a requirement ?*

Dispensing Doctor applications.

3.23 Currently, once a GP has been given approval to dispense to his eligible patients there is no mechanism to evaluate or review the right to dispense in the future. Given the Welsh Assembly Government is committed to a policy of pharmaceutical services being primarily provided by pharmacists it therefore wishes to consider the arrangements whereby GP's provide dispensing services.

3.24 The Welsh Assembly Government believes there is a disparity between the criteria imposed in determining applications for pharmacists and doctors who wish to provide NHS pharmaceutical services in an area which has previously been determined to be a controlled locality (rural in nature).

3.25 A GP who wishes to apply to dispense to patients need only show that to do so would not prejudice the proper provision of medical or pharmaceutical services locally (the 'prejudice' test). There is no 'necessary or desirable' ('control of entry') test.

3.26 Whilst pharmacists wishing to be included in the list in a controlled area must pass both the 'necessary or desirable' ('control of entry') and the 'prejudice' tests the GP need only pass the prejudice test. The Welsh Assembly Government believes this disparity in the tests applied, to be a disincentive to the opening of pharmacy premises by pharmacists who may provide pharmaceutical services in rural areas. The Welsh Assembly Government also believes that doctors are potentially advantaged over pharmacists when making applications for dispensing. The Welsh Assembly Government therefore wishes to remove any criteria disparity between similar types of application.

Questions:

Q.34 Would it be appropriate for dispensing doctor applications to pass similar criteria as those imposed on applications made by pharmacists ?

Q.35 Would it be appropriate for all applications made within a controlled locality to pass the 'necessary or desirable' test ?

Q.36 Would it be appropriate for all applications made within a controlled locality to pass the 'prejudice' test ?

Q.37 Should there be conditions imposed on a grant of application if thought necessary by the LHB ?

Q.38 Are there any disadvantages in applying the 'necessary or desirable' test to dispensing doctor applications within controlled localities ?

Q.39 Is it reasonable to review an application for dispensing doctor following its grant ?

Q.40 Is 5 years a reasonable period at which to review an application grant ?

The appeals process.

3.27 The current process provides a relatively speedy appellate procedure. However, there are a number of possible reforms which might be introduced to modernise procedures and decrease the time period in which the National Assembly for Wales takes to determine and inform appellants and interested parties of its decision.

Dismissing certain kinds of appeals.

3.28 Under Regulation 8(7), where the National Assembly for Wales "after considering the notice of appeal, is of the opinion that it discloses no reasonable grounds of appeal or

that the appeal is otherwise vexatious or frivolous, [it] may determine the appeal by dismissing it.”

3.29 Although the National Assembly for Wales therefore already has powers to dismiss certain kinds of appeals, in practice it rarely invokes this procedure. This is because the letters of appeal meet the basic requirements for reasonable grounds and the concepts of vexatious and frivolous in relation to appeals cases are difficult to define and defend in law.

3.30 However, the Welsh Assembly Government is concerned that, whilst wishing to protect full access to a fair and robust appeals process, the appeals procedures themselves might be open to abuse in that they could be used simply as a gambit by an aggrieved party to try to achieve a different result.

Questions :

Q34. Are there types of appeals which ought to be dismissed on lack of reasonable grounds ?

Q.35 Is it reasonable to expect the National Assembly for Wales to process appeals on similar deadlines as to those proposed for LHBs ?

Q36. Is there further scope to speed up appeals cases, or improve targets for the National Assembly for Wales, and therefore reduce the time in which appeals cases are decided ?

Q37. What other changes to the current applications, decisions and appeals processes might the Welsh Assembly Government consider ?

Revisions to the current application form.

3.17 The Welsh Assembly Government recognises that the current application form (Schedule 3 to the Regulations) will need to be amended to reflect the introduction of any new procedures which may be adopted.

Chapter 4

Conclusions and the way forward.

4.0 This paper has set out details of the Welsh Assembly Government's proposals to reform and modernise the current regulatory system governing the provision of NHS community pharmacy services.

4.1 The Welsh Assembly Government welcomes comments on this paper and further ideas for reform and modernisation. A summary of questions is at the end of Chapter 1. Comments will be considered by the Welsh Assembly Government.

4.2 Comments and views should be sent, by 14 November 2005, to:

Mark Welsby
Pharmaceutical Services
Health & Social Care Directorate
National Assembly for Wales
4th Floor
Cathays Park
Cardiff
CF10 3NQ.

Mark.Welsby@Wales.gsi.gov.uk

4.3 This document can be freely photocopied and further copies are available on request from the above address.

4.4 The Welsh Assembly Government will carefully consider all responses it receives in regard to this consultation document and will then consider making amendments to the Regulations if necessary.

Appendix 1

Extract from Office of Fair Trading Report - The control of entry regulations and retail pharmacy services in the UK.

Findings

Competition and entry of new pharmacies

1.9 Since 1987, when the control of entry regulations were introduced, there has been very little change in the number of pharmacies as measured by either gross or net entry. In the ten years after 1990, the average annual net change in the number of NHS contractor pharmacies in England and Wales was four. By contrast, in the five years before 1985 (two years before entry controls were introduced), the average annual net increase was 130 contractor pharmacies per year.

1.10 The structure of the pharmacy market has changed somewhat since 1987. While the share of the national market is not dominated by any one or two chains, existing national pharmacy chains and supermarkets have increased their share of the market significantly, and since 1990 one new national chain (Superdrug Ltd) has entered.

1.11 Nevertheless, the effect of the control of entry regulations has been to constrain such change. In particular, the regulations have acted to impede entry and expansion by pharmacies that offer consumers lower prices, more convenient opening times, or valued and innovative services. Moreover, by limiting the numbers and location of pharmacies in a local area, the regulations have restricted competition between pharmacies, in terms of both prices and quality of service.

1.12 It is difficult to estimate precisely the potential benefits to consumers that would derive from deregulation, in the form of increased price and quality competition. We note, though, that some of the national supermarket pharmacy chains offer substantial price savings on OTC medicines, of up to around 30 per cent. Currently, access to such low priced pharmacies is limited. However, with free entry into the market, we estimate that increased sales from such low priced supermarket pharmacies would lead to annual customer savings of around £20 - 25 million on P-medicines, and a further £5 million on GSL medicines.

1.13 If deregulation were to increase competition between pharmacies more generally, we would expect to see substantially higher customer savings from lower prices and also improvements in service quality. The charges (if any) that the consumer pays for NHS prescription medicines are fixed, and thus one would not expect to see immediate direct price benefits from entry deregulation in this area. However, any improvements in service quality would also benefit customers for NHS prescriptions, while in the longer term improvements in the efficiency of pharmacies might be expected to reduce the overall cost of the NHS prescription system to the taxpayer.

1.14 We reviewed published and other data for the three largest national chains, and also commissioned a valuation study of smaller pharmacies. None of this provided evidence of excess profitability in pharmacy activities. High prices are paid on occasion for NHS contracts, in particular by supermarkets, but these may reflect a variety of factors, of which profitability is but one, and as such cannot be taken as evidence of excessive profitability.

Access

1.15 The UK is currently well served geographically by pharmacies. Most people live within a short distance of a CP. Indeed, 79 per cent of people in Great Britain have a CP within one kilometer of their home and 47 per cent have a pharmacy within 500m. Furthermore, around nine out of ten people consider it easy to get to a pharmacy from their home and 86 per cent considers access to a pharmacy easy from their General Practitioner (GP). In practice, for at least half of the cases, prescriptions are picked up following a visit to a GP from a pharmacy near the surgery. Around 98 per cent of GPs have a community pharmacy within one kilometer and around 75 per cent have one within a short walk of 300 meters.

1.16 International comparisons show that the UK ranks only slightly above the average for the number of pharmacies per head. France, Ireland, Italy, Australia, Germany and Canada all have more pharmacies per head than does the UK.

1.17 Nevertheless, the picture across these various aspects of access is not uniformly strong. The location of UK community pharmacies has essentially been little changed since the control of entry system was introduced in 1987. This is despite changes in the distribution of where people live and changes in consumer habits. There are a number of areas where access could usefully be improved, particularly in opening hours.

1.18 Without entry controls we would expect to see more firms entering the market over time and offering a wider range of services and opening times. Over time, we would also expect some existing pharmacies to exit the market, as happens in any competitive market. However, we would not expect to see substantial *net* exit of pharmacies. Analysis of recent pharmacy entries and exits – and common sense support the view that entry into a given area tends to increase the total number of outlets in that area.

1.19 Moreover, empirical modeling of a variety of entry and exit scenarios shows that there would only be a limited reduction in local access even in an extreme scenario where pharmacies are opened in all medium to large supermarkets and, for each new entrant, the two nearest community pharmacies close as a result. This scenario modeling also found that impacts on access were broadly the same for low income groups and the elderly as for the general population.

1.20 There is, in any case, more to access than location. Opening hours, convenience and other services, such as home delivery, are also important. There is substantial room for improvement on these aspects of access. For example, the average independent pharmacy is open for around 50 hours per week. This provides relatively limited access compared to, for example, supermarket pharmacies which tend to be open for much longer hours – around 80 hours per week on average. We would expect the ending of entry controls to bring substantial benefits to consumers in terms of these other forms of access to pharmacies and their services. Consumers would use those pharmacies that are most convenient to them, and offer the services that they value most.

1.21 Overall, therefore, we believe that local access will improve following deregulation. Moreover, if localised problems do occur, other support mechanisms – such as the Essential Small Pharmacies Scheme (ESPS) – are much better targeted at problem areas than are universal control of entry regulations.

1.22 Moreover, in areas where there are no NHS dispensing pharmacies, dispensing by GPs offers a further mechanism to ensure appropriate access to prescribed medicines. We would expect this important safeguard to be maintained under deregulation of community pharmacies.

Costs of the current system

1.23 There are also substantial administrative savings to be made from deregulation of entry. Any estimate of the costs of administering the current system is necessarily approximate. Our central estimate of the annual costs to pharmacy businesses and taxpayers directly attributable to the control of entry system is around £26 million. This is made up of £10m in NHS administration costs and around £16m in compliance costs to business. These costs are borne by the taxpayer and by pharmacies and, indirectly, by their customers.

Alternative remedies

1.24 A variety of other potential remedies were put to us during the course of our investigation. However, changes that fall short of abolition of the control of entry regulations for community pharmacies would not, in our view, address the failings of the existing system and the costs it imposes on business and consumers. More modest changes would add complexity to an already complex and time-consuming process.

Recommendation

1.25 We recommend that the control of entry regulations for community pharmacies in the UK should be ended. This would mean that all registered pharmacies with qualified staff may dispense NHS prescriptions.

*Source : The control of entry regulations and retail pharmacy services in the UK
A report of an OFT market investigation
January 2003*

(<http://www.offt.gov.uk/Search+Results>)

Appendix 3

Distribution List.

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