Proposals to Reform and Modernise the NHS (Pharmaceutical Services) Regulations 1992

Response by the
National Pharmaceutical Association

November 2003

Contents

Executive Summary

- This is the response of The National Pharmaceutical Association (NPA) to the Government's *Proposals To Reform And Modernise The NHS (Pharmaceutical Services) Regulations 1992.*

- Patients are generally well satisfied with access to existing pharmacy services. Indeed the OFT consumer survey confirmed this with 89% of people considering access to be easy from their home and 86% considering access to be easy from their GP's surgery.

- It is essential that the new test and exemptions within the proposals are defined and implemented in such a way that puts the needs of patients first and ensures patients enjoy the benefits of a pharmacy framework that encompasses choice, competition and assures ready access to services. The proposals must not be allowed to thwart the purpose of the existing regulations. Changes must be introduced in a targeted way that addresses unmet need.

- The "balanced package" must also ensure that local pharmacy services can be planned and managed in a rational way and not be implemented in such a way that frustrates the ability of Primary Care Trusts (PCTs) to do this.

- The proposals must be considered alongside the many other issues that are serving to re-shape the face of community pharmacy practice and support a more clinical role for pharmacists, including the new contract, the pharmacy *Vision* document and the proposals for the future supply and reimbursement of generics.

The new test of Choice and Competition

- Improving choice and competition is laudable. But the new test of "choice and competition" should be a proper test by which applications will be assessed against realistic criteria. At its most simplistic, the new test could see the automatic granting of <u>all</u> new applications; on a straightforward basis, all applications have the potential to increase "choice or competition", particularly where there is a single existing pharmacy or a highly concentrated market. The new test should also be subordinate to the principal "necessary or desirable" test and considered in the context of the adequacy of pharmacy services.

- The impact of granting a large number of applications on existing service provision must be taken into account. There is a finite market for pharmacy services and so a balance must be struck between ensuring a high level of choice and competition on the one hand whilst on the other, ensuring that the market can financially support the total number of pharmacies. Of particular significance is the need for pharmacy owners to invest in their

practices to prepare them for the new roles for pharmacy as set out in *the Vision for Pharmacy in the New NHS* document.

- Primary Care Trusts (PCTs) should have a key say in determining the need for new applications. The over-riding principle of "adequacy" of pharmaceutical services should be the principal determinant behind the planning of local pharmacy services and therefore of taking decisions on the granting of new contracts. It should be down to PCTs to make an assessment of "adequacy" as part of the process of factoring pharmacy services into their Strategic Services Development Plan (SSDP). Where gaps in service provision are identified, then existing pharmacies should be invited to plug these gaps. Only where existing players are unwilling, or unable, to plug any gaps should new entrants be considered.

- A needs assessment "toolkit" could be developed for this purpose, so keeping the bureaucracy on already stretched PCTs to a minimum and ensuring that the approach to assessing applications is standardised throughout PCTs.

The Exemptions

- We believe that the exemptions should be exceptions to the rule rather than the rule itself. Only then can the general thrust of the Government's policy – in favour of regulation – be carried through. The exemptions are broadly drafted. Adopting definitions for the exemptions which present a very low barrier to new entrants will have the effect of undermining the pharmacy network which can only support a finite number of pharmacies.

15,000 square metres

- Access is undeniably a key issue for pharmacy services. But access should be viewed primarily from a healthcare, rather than retail, standpoint. The emphasis on shopping centre exemption appears to cut right across the Government's stated view that pharmacists are clinicians rather than "shopkeepers". The 15000 square metres exemption is broadly drafted and will incorporate a wide range of developments, many of which already include pharmacies. Accordingly, it will encourage an over supply of unnecessary pharmacies and is likely to be detrimental to the existing community pharmacy network. It seems inherently flawed to grant an exemption to these centres simply on the basis of their retail size, rather than on the basis of the adequacy of pharmacy service provision. However, should an exemption based on size of shopping development be the favoured option, we believe a bigger definition of "gross lettable space" is needed.

Pharmacies opening more than 100 hours per week

- Assuring convenient patient access to pharmacy services is paramount and a factor that will need to considered carefully by the PCT in formulating its SSDP. A subsequent "gap analysis" may indicate that existing contractors' hours need to be adjusted to meet the demand and, if so, they should be given the option to do so.

- The impact of the 100 hour per week pharmacy could be to suck business away from existing pharmacies, to the extent that they are forced to reconsider the level and range of services on offer to local communities.

One-Stop Primary Care Centres (OSPCCS)

- Given their duty to plan local services, PCTs must have the ability to reject an application for a pharmacy in OSPCC where, in the PCT's judgement, this is not needed for the adequate provision of pharmacy services.

- The definition for OSPCC given in the consultation document is far too loose and, on a strict interpretation, could cover any GP surgery that engages a nurse and any member of the extended primary care team Once covered by the definition, any such GP practice could then open a pharmacy and be exempt from control of entry. The exemptions should be exceptional to the norm. Accordingly, we believe a larger definition should be developed to give some bearing on both size and diversity of services provided by OSPCCs. The definition should see OSPCCs being large centres that go toward bridging the gap between a typical GP surgery and a secondary care unit.

Mail Order/Internet based Pharmacy Service

- There is a need to respond to the potential demand for e-pharmacy services. However the definition should make reference to the need for the provision of appropriate advice or information associated with product supply.

Review

- The impact of the proposals will need to be carefully assessed. The Government has said that a Review will take place in 2006. The form and timing of amended regulations will depend upon the outcome of the consultation and the deliberations of the Advisory Group. Accordingly, it seems to be pre-emptive to pin down a review date. Rather, this should be done when there is a clearer idea of the time frame. In setting the date for review, there should be sufficient time allowed for a proper assessment of the implications of the regulatory changes on overall service provision and PCTs' ability to plan and manage these. The Advisory Group should give consideration to the scope of the review as part of its deliberations.

A Rational Approach

- Pharmacy services, are a key component of overall healthcare provision and should be planned. The responsibility for the planning and provision of pharmacy services lies with PCTs and the proposals must be implemented in a way that does not frustrate their ability to plan services in a truly rational way.

- The general principle should be to grant applications on the basis of adequacy of services, measured against a "gap analysis" of existing service provision. The routine granting of applications which will inevitably flow from broadly drafted exemptions, could lead to an over – and unnecessary - provision of services, thereby frustrating PCTs' ability to plan local service provision.

- An assessment of "adequacy" of pharmaceutical services could form part of the baseline audit process supporting the development of the Strategic Services Development Plan (SSDP). Where gaps in service provision exist, existing pharmacies should then be invited to plug these gaps. The targeted use of more discerning exemptions could help speed up the gap filling process. In most cases, the most cost effective and least disruptive solution for plugging gaps will be by extending the services provided by existing pharmacies. Where existing players are unwilling, or unable, to plug any gaps new entrants could be considered. Such a system would get round the problem highlighted in the OFT Report of some PCTs frustration at not being able to plan local service provision in a sufficiently responsive way to meet unanswered need.

- A needs assessment toolkit could be developed to help PCTs with this process. The NPA would welcome the opportunity to contribute to the development of this toolkit.

Introduction

This is the response of The National Pharmaceutical Association (NPA) to the Government's *Proposals To Reform And Modernise The NHS (Pharmaceutical Services) Regulations 1992.*

The NPA represents the owners of around 11000 community pharmacies in the UK. We have, in membership, virtually all pharmacy owners. Virtually all of our members contract with the NHS for the provision of NHS pharmaceutical services.

The NPA is pleased to have the opportunity to comment on the "balanced package" proposals. Whilst we recognise the difficulty the Government has faced in developing the 'balanced package of measures', we do remain very concerned about the impact of the package on the community pharmacy network – and thus services to patients. We believe, therefore, that the proposals must be implemented in a way that allows patients to enjoy the benefits of a pharmacy framework that encompasses choice, competition and assures ready access to services, whilst at the same time ensuring that local pharmacy services can be planned and managed in a rational way. In doing this, we see Primary Care Trusts (PCTs) playing a key role.

The NPA had campaigned for an outright rejection of the OFT report (as has happened in Scotland, Wales and Northern Ireland) on the basis that, as part of overall healthcare provision, pharmacy services have to be planned and managed. There was widespread political and consumer support for this view. Whilst pleased that the OFT's overall recommendation has not been accepted, the NPA is extremely concerned that the proposed additional tests of competition and choice and the exemptions within the package may frustrate PCTs' ability to plan expanded pharmacy services at a critical time when increasing responsibility for local health care planning is being devolved to them. The NPA is also concerned that the balanced package is simply a 'transit camp' on the way to full deregulation.

The publication of the 'balanced package' comes at a critical time for pharmacy. A new contract is being negotiated between the Department of Health, NHS Confederation and Pharmaceutical Services Negotiating Committee (PSNC); there are two separate consultations on the Government's generics review; and there is a consultation on the DH's pharmacy policy paper *A Vision for Pharmacy in the New NHS*. All of these issues interrelate, and the effects of the 'balanced package' cannot, and should not, be evaluated in isolation.

The balanced package conveys a mixed message to pharmacists. On the one hand, Government is encouraging pharmacists to expand their contribution to healthcare through an increased clinical role and, as part of this, to invest in their pharmacy practices. On the other, the Government is proposing, through the package, a considerable freeing-up of the pharmacy sector, thereby creating uncertainty for pharmacists and for the pharmacy network.

At a time when pharmacists should be dedicating their energies to investing in developing their clinical role and enhancing their healthcare contribution they will, instead, be diverted into protecting their practices from opportunistic applicants. It is essential that, in implementing the proposals, a proper balance is struck to ensure that the proposals do not frustrate local healthcare provision.

The consultation document acknowledges pharmacy's vital and enhanced future clinical role in paragraph 1.3. The same paragraph points out that the OFT did not look at this role, as it was not part of the OFT's remit. This is a serious deficiency of the OFT Report and casts very real doubts about the validity of its conclusions, which form the basis for drawing up the balanced package proposals. Indeed, given the extremely narrow focus of the OFT Report, (on a relatively small component of the total pharmacy turnover) we find the conclusion in paragraph 1.5, that the Government "accepts that the OFT had made a strong case that the current control of entry rules impeded competition and reduced benefits for consumers" a *non-sequitur*. The general thrust of the consultation document is in the direction of pharmacy as a retailer. This is wrong - and pays insufficient regard to pharmacy's present and future healthcare role.

The Government is therefore right to "move cautiously" in the direction recommended by the OFT. However, we are concerned that the proposals may simply be a means of delaying deregulation, with the review – scheduled for 2006 – being simply a review of the timing of a decision on deregulation, rather than a full review of the impact of the proposals (we assume modified in the light of the consultation) on services to patients.

Determining the Adequacy of Pharmaceutical Service Provision

Paragraph 3.5 suggests that the current necessary or desirable test is stifling new applications. This appears to reflect a focus in the debate surrounding control of entry on reacting to applications to open pharmacies, rather than an active process toward determining where the provision of services is deficient. Whilst it is true that the necessary or desirable test does place the burden of proof upon an applicant, the necessary or desirable test must not be taken out of context of the regulations. Regulation 4(4) of the existing regulations (NHS (Pharmaceutical Services) Regulations 1992) links the necessary or desirable criteria to the adequacy of pharmaceutical services in any given neighbourhood. Viewing the necessary or desirable test in the context of adequacy positions the regulations not as a charter for the status quo, but as a framework by which PCTs can assess the need or desirability (or otherwise) of applicants on the adequacy of overall service provision. We recognise that the Government, through its proposals, wishes to introduce the concept of greater competition into the regulations (paragraph 3.7). The "necessary or desirable" test is to be retained in the regulations and thus must be the principal test underpinning the granting of applications. The choice and competition test must be subordinate to this principal test.

The choice and competition test will be associated with a reversal of the burden of proof (paragraph 3.10) in favour of new applicants and away from existing players. We are concerned that the new "choice and competition" test should be a proper one, by which applications will be assessed against realistic criteria. At its most simplistic, a new test of "choice and competition" could see the automatic granting of all new applications. On a straightforward basis, all applications have the potential to increase "choice or competition", particularly where there is a single existing pharmacy or a highly concentrated market. However, the impact of granting a large number of applications on existing service provision must be taken into account. There is a finite market for pharmacy services. Thus, a balance must be struck between ensuring there is a high level of choice and competition in the market on the one hand, whilst, on the other, ensuring that the market can financially support the total pharmacy market. This is particularly relevant to pharmacy owners' need to invest in their practices to prepare them for the new roles for pharmacy - as set out in the *Vision for Pharmacy in the New NHS* document.

The consultation document, as written, would appear to suggest that consideration under the new choice and competition criteria presents a very low hurdle for applicants. Paragraph 3.10 suggests that the application would proceed unless it was "clearly detrimental" to the adequate provision of pharmaceutical services. This suggests that both existing pharmacies – and PCTs – could face an uphill struggle in objecting to applications against the new test. Our view is that PCTs should have the final say in determining the need for new applications.

The over-riding principle of "adequacy" of pharmaceutical services should be the principal determinant behind the planning of local pharmacy services and therefore of taking decisions on the granting of new contracts.

It should be down to PCTs to make an assessment of "adequacy" of pharmaceutical services as part of the baseline audit process supporting the development of the Strategic Services Development Plan (SSDP). Where gaps in service provision exist, existing pharmacies should then be invited to plug these gaps. Only where existing players are unwilling or unable to plug any gaps should new entrants be considered. Such a system would get round the problem highlighted in the OFT Report of some PCTs frustration at not being able to plan local service provision in a sufficiently responsive way to meet unanswered need.

An approach based on fulfilling unmet need would fit in with the general thrust of the approach set out in paragraph 3.11 – 3.17. Issues that would need to be considered by PCTs in assessing whether services were adequate and delivering sufficient competition and choice to local communities would include:

- Population density
- Ethnic diversity
- Opening hours – particularly extended hour service provision
- Range of existing services
- Particular pharmaceutical need identified by SSDP
- Accessibility/location of existing pharmacies
- Level of complaints
- Levels of deprivation

A needs assessment toolkit could be developed to help PCTs with this process. The NPA would welcome the opportunity to contribute to the development of such a toolkit if this would be helpful.

We include as an Appendix, the NPA's understanding of the SSDP process. A toolkit as we have described, would assist the PCT in completing the audit survey and service mapping as the preliminary step in the table set out in this Appendix.

As the consultation document highlights, the current regulatory test relates to the provision of adequate pharmaceutical services in the "neighbourhood". There is no statutory definition of neighbourhood – which, as a consequence, is thus open to considerable subjective interpretation.

The regulations were written at a time when Family Practitioner Committees (FPCs) (later to become Family Health Services Authorities (FHSAs)) maintained pharmaceutical lists. FPCs/FHSAs had much larger boundaries than PCTs. It may be reasonable to make neighbourhoods consistent with PCT boundaries, given their smaller size. This would tie in with PCTs' obligations to consider the adequacy of pharmaceutical services within their area of jurisdiction and would create certainty of neighbourhood boundaries, thereby removing some of the subjectivity from decision making. It would also help PCTs by making the administrative process of considering applications much simpler.

In implementing the new test, one of the priorities must be to keep PCT bureaucracy to a minimum. We are concerned that the introduction of the choice and competition test will see a flood of applications from both new entrants and existing players seeking to protect market share. The new test will also be seen as an opportunity to revisit applications that have been rejected previously. This will be so, in spite of any charge on applicants. PCTs already have a huge workload and limited resources. They therefore need help in administering the new test. A needs assessment toolkit would go a long way towards easing the burden on PCTs and helping them plan a rational pharmacy service - based on health need rather than commercial opportunities alone.

It is also important to ensure that the approach to assessing applications is standardised throughout PCTs. A variable approach will lead to widespread uncertainty and a lack of consumer equity in accessing pharmacy services. The importance of standardisation will be particularly significant for pharmacy owners who have pharmacies included in more than one PCT pharmaceutical list.

Exemptions from Control of Entry

Whilst the exemptions are intended to improve service access to patients and to provide choice and competition, we are concerned about the impact of the exemptions on the community pharmacy network. In short, we believe that the exemptions should be exceptions to the rule rather than the rule itself. Only then can the general thrust of the Government's policy – in favour of regulation – be carried through. Adopting definitions for the exemptions which present a very low barrier to new entrants, will have the effect of undermining the pharmacy network which, as we have already said, can only support a finite number of pharmacies.

Moreover, the opening of a significant number of pharmacies as a result of the exemptions will frustrate the abilities of PCTs to plan local services. Indeed, if pharmacy services were planned against a background of a needs assessment, as we have suggested, we would query whether the exemptions are in fact needed?

1. 15,000 square metres

It is proposed that control of entry be removed in the case of pharmacies wishing to provide service in "shopping developments" where the gross lettable floor space is 15000 square metres or more. We are told that the British Council of Shopping Centres (BCSC) compiles a list of such centres. But it is not made clear why such a list is kept nor of the basis for the 15000 square metres criterion. We assume, however that this is the "average" size of shopping centre. Previous Government policy in respect of pharmacies in large shopping areas – as enshrined in the *Pharmacy in the Future* (PIF) document (Paragraph 4.13) – suggested a much larger shopping development than is now under consideration. In PIF, the examples of Meadowhall and Bluewater were given. These are regional shopping centres of the order of 100,000 square metres. Against this background, there appears to be a considerable reduction in the size of shopping centres in the new proposals. Our concern is that the adoption of a definition which is at the low end of the range will maximise the detrimental effect upon the community pharmacy network. Further, with a low level definition such as this, the number of shopping areas falling under the definition – and therefore further impacting on the community pharmacy network – will increase more rapidly as new shopping developments emerge, or existing areas expand.

The concept of "shopping development" appears to be new and is not included in the list of "Types of Shopping Centres" listed in Annex A to the Department of the Environment's Planning Policy Guidance No 6 *Town Centres and Retail*

Developments (PPG6). A review of the Basic's list (which is still being updated) shows that a range of shopping centres are included in a variety of settings – town centre and out of town, and predominantly shopping mall and Retail Park formats. Many of the listed centres already include pharmacies and it seems inherently flawed to grant an exemption to these centres simply on the basis of their retail size rather than on the basis of the adequacy of pharmacy service provision.

And the 15000 square metre exemption could theoretically include single large retail outlets. A study of the "Types of Shop" List in Appendix A of PPG6 defines seven types of retail outlet that have the potential to quality under this exemption. It is not suggested that all of these would wish to open pharmacies but it does illustrate the "all embracing" nature of an exemption based simply on size rather than a more discerning definition.

As we have already said, the general principle should be to grant applications on the basis of adequacy of services measured against a "gap analysis" of existing service provision. The routine granting of applications in such developments could lead to an over – and unnecessary - provision of services in these areas thereby frustrating PCTs' ability to plan local service provision.

There is also a related issue, (which applies equally to the 100 hours exemption) of the selected shopping area size being a "moving target". Where there is no robust basis or reasoning behind the definition, the question will inevitably be asked why 15,000, and not 10,000 or 5,000? Or, in the case of the 100 hour exemption, why 100 hours and not 90, 80 and so on? In both instances the NPA is concerned that that "creepage" will occur and that over time this will lead to 'deregulation through the back door'.

This poses a fundamental question about the exemptions: what specific problem do they seek to fix?

The section on "why change is needed" is not much help. It suggests that pharmacy needs to "react to changes in shopping patterns". Whilst this is undoubtedly the case, changing shopping patterns cannot be viewed in isolation. There are already examples where Government intervention is necessary to deal with situations where the free market is impacting negatively on local shopping access – or on the prosperity of the local community. Examples include the national strategy for neighbourhood renewal and the work around improving shopping access for people living in deprived neighbourhoods, assistance for post offices and "mainstreaming" by local agencies to earmark resources for localities and communities most in need of support

There is an assumption in the proposals that "shoppers" and "patients" are the same group. We cannot accept this. Further, the wording in paragraph 4.6 appears to cut right across the Government's stated view that pharmacists are clinicians rather than "shopkeepers".

Access is undeniably a key issue for pharmacy services. But access to pharmacy services should be viewed primarily from a healthcare rather than retail standpoint.

When implemented, it is crucial that the exemption avoids any diminution of access to pharmacy healthcare services in local communities as a result of opening up the market by exemptions in retail environments. Accordingly, on the basis of achieving a true "balance" between a regulated healthcare role and the free market, we believe a much higher threshold of "gross lettable space" is needed to ensure that a proper balance is struck.

Paragraph 4.8 talks about the effect on community pharmacy, "if any", and suggests effects will be diluted. This supposition may be reasonable, but equally it may not. As far as we are aware no detailed modelling has been done on this and so effects will be unpredictable. Logic and straightforward commercial reasoning would dictate that there will be a negative commercial impact upon existing community pharmacies – particularly the independent sector. New pharmacies will only open if there is an expectation of gaining business, and that business will come at the expense of existing pharmacies. Clearly, where the dilution of business on existing pharmacies is significant, this will result in reduction in the depth and breath of services offered to local communities.

In the consultation document we are asked for views on the maintenance of a list of exempt shopping areas. We believe it would be simpler to refer to a list.

2. Pharmacies opening more than 100 hours per week

The consultation document quite rightly points out that meeting consumer and patient need in terms of access are paramount. As we have already said, opening hours is a factor that should be included in the assessment of adequacy. It may be that existing contractors' hours need to be adjusted to meet the demand and, if so, we believe they should be given the option to do so before any decisions are taken on the granting of new contracts.

We are told (paragraph 4.13) that the 100 hour exemption is designed to improve access for patients who cannot access pharmacy during normal hours. The need for pharmaceutical services "out of hours" cannot be viewed in isolation of the current developments in out of hours medical care and the reform of emergency care. Flowing from developments in these areas will be new practice models including community pharmacy in the combination of out of hours medical care and pharmaceutical services during extended hours. The opportunity to explore new practice model along these lines may not require pharmacies to remain open for such long periods as 100 hours per week, and the creation of such pharmacies may in fact stifle the development of models of this type.

This underscores the importance of giving PCTs the final say in whether they want this exemption in line with their identified aspirations for integrated service delivery within the SSDP and their Local Pharmacy Development Plans.

Paragraph 4.13 says that a 100 hour per week pharmacy will improve access and choice. This implies a huge demand for services beyond the actual opening hours of existing pharmacies. This may be true. But equally it may be that hours of opening

are tailored to meet local demand, since it is highly likely that if demand for services was sufficient to warrant extended opening, existing pharmacies would stay open voluntarily. Certainly if there is an unmet need, the PCT should be empowered to request existing pharmacies to extend hours – and to properly resource pharmacies for doing so. Establishing unmet need will of course flow from the needs assessment process we refer to regularly throughout our response. The requirement to open 100 hours per week will be onerous, but where such a pharmacy opens it will suck business away from existing pharmacies to the extent that they are forced to reconsider the level and range of services on offer to local communities.

An issue which will have an important bearing on the number of pharmacies opening under this exemption will be any changes to the current pharmacy supervisory requirements. The Department of Health's *Vision* document suggests that whilst pharmacists will continue to be professionally and legally responsible for everything that goes on in a pharmacy, there may be instances where the sale and supply of medicines can take place in the absence of a pharmacist. Any relaxation of supervision requirements, in line with the proposals outlined in the Vision document, would hugely affect the number of applications under the 100 hour pharmacy exemption and thus the impact on existing and future planning of pharmacy services.

We also have concerns about how this regulation will be "policed". The 100 hour exemption will appear at first sight to be attractive to some pharmacy operators. But maintaining a pharmacy service from 8.30 to 22.30 Monday through to Sunday will be very difficult. Accordingly, the risk of non-compliance with a 100 hour week requirement is very high. If this exemption is truly about improved service to patients rather than commercial opportunism, it must be rigidly enforced and where contractors are falling short of the 100 hour opening requirement - and indeed any other aspects of service provision – they should be removed from the pharmaceutical list. On this point we should say that, for these purposes, the current provisions for removal from the pharmaceutical list – as set out in Regulation 17 of the current Regulations - are totally unworkable.

We note the point about the Sunday Trading Act (STA) This is no different from the current practice of large retailers providing Sunday rota services. If such pharmacies were to open 100 hours per week, they should be required to partition off the pharmacy, as per paragraph 4.16. We should also point out that the STA prohibits opening at all by "large retailers" on Easter Sunday and on Christmas Day when it falls on a Sunday.

3. One-Stop Primary Care Centres (OSPCCS)

We are confused and concerned by the reference to the word "consortium" in paragraph 4.18 *et seq*. It is not clear why the exemption should only apply to "consortia" and we would welcome clarification on this point. Our concern on limiting the exemption to "consortia" is that it would favour "preferred provider" applicants – for example those associated with a LIFT scheme – to the detriment of other potential pharmacy service providers. It seems to us that anyone should be

entitled to apply for a pharmacy, with applications being judged on merit rather than through an exclusive regime.

Where a consortium application includes a PCT as a partner, the PCT will have a clear vested interest in the application. Appropriate measures of probity will need to be applied in such instances - to ensure that a fair and open procedure is adopted in the consideration process.

Paragraph 4.20 states that the exemption "consortia" will be free from the uncertainty of knowing whether an application is successful or not. However, the paragraph goes on to say that consortia applications will need to be part of the PCT's SSDP and, as such, PCTs will retain the ability to influence local pharmacy provision and the services provided by such centres. There appears to be a contradiction here. If PCTs do have the ability to influence local pharmacy service provision – and we agree wholeheartedly that they should – then it follows that they should have the ability to reject an application for a pharmacy in an OSPCC where, in the PCT's judgement, this is unnecessary for the adequate provision of pharmacy services.

Accordingly it seems to us that rather than having this as an automatic exemption it should be made subject to the PCT's discretion based on the PCT's assessment of patient need for pharmacy service provision. Those OSPCCs requiring a pharmacy – and thus subject to exemption - could be identified by the PCT as part of the SSSDP. This would ensure certainty for applicants.

We note the definition of OSPCC as set out in Annex D. It is our view that this definition is far too loose - and on a strict interpretation could cover any GP surgery that engages a nurse and any member of the extended primary care team Once covered by the definition, any such GP practice could then open a pharmacy and be exempt from control of entry. As we have already said, the exemptions should be exceptions to the norm. Accordingly, we believe a larger definition should be developed to give some bearing on both size and diversity of services provided by OSPCCs. The definition should see OSPCCs being large centres that go toward bridging the gap between a typical GP surgery and a secondary care unit. Clearly, any definition that allows the large majority of GP surgeries to fall within it and thus to be covered by it, will lead to a significant negative impact on existing pharmacy service provision.

We have already talked about the need for PCTs to have flexibility to plan and manage services and to tailor these according to local need. We believe, in response to the questions following paragraph 4.28, that this should be linked to the new contract. However, PCTs should at all times plan pharmacy service provision as an integral part of its SSDP. As part of this, PCTs should be entitled to consider the impact of the exemptions on overall service provision, and thus in having flexibility to limiting exemption pharmacies to providing services only where they fill a gap in service provision. The SSDP partners will also need to guard against any potential reduction of social or economic capital arising from any withdrawal from pharmacy services, especially in deprived neighbourhoods.

4. Mail Order/Internet based Pharmacy Service

We recognise that there is a need to respond to the potential demand for e pharmacy services. Indeed this was recognised in PIF (para ref). As far as the definition is concerned, we believe a reference to the need for the provision of appropriate advice or information associated with product supply should be included. We believe the definition given in the document is reasonable. In particular, it is essential that mail order pharmacies are just that. The nature of the business should be to deliver arm's length services and as such be "closed door" operations excluding "drop in" access.

Modernisation and Reform of the Current System

1. PCTs to be able to invite applications

PCTs now have a responsibility for pharmacy services and as part of this need to include pharmacy services as part of their SSDP. To do this properly PCTs will need to carry out a pharmaceutical needs assessment, by which to measure adequacy of existing service provision and to identify gaps in service provision. Where gaps are identified, PCTs need to fill them. In most cases, the most cost effective and least disruptive solution for plugging gaps will be by extending the services provided by existing pharmacies. However, where existing players are unwilling or unable to do this, then new applicants should be invited to apply by PCTs.

We must disagree with the comment made in paragraph 5.1 that with the introduction of the new tests of choice and competition, PCTs will "for the first time" provide questions for applicants and PCTs to apply consistently. The necessary or desirable test already provides a consistent framework. However, it is not the regulatory test or questions that pose any problem, rather their interpretation. What constitutes "choice and competition" in any given neighbourhood will always be down to subjective interpretation.

2. Introducing Charges for Applications

It is not clear what the over-arching principle behind the charge for applications is. The tone of the document appears to suggest it is everything to do with income generation and little to do with improving patient care. What the system of control of entry should be about is ensuring a rational distribution of pharmacies and ready access to high quality pharmacy services. We cannot see how charging for applications affects this objective. Once again, we see the dilemma arising of whether pharmacy is a healthcare or commercial operator. Whilst it is true that community pharmacies are both, the control of entry regulations should be considered in a healthcare context. If pharmacy is to be (and seen to be) a true NHS primary care player (as the Vision document tells us it must) then it must be subject to the same set of rules as other NHS players. For example the location of GP surgeries are dependent upon consideration and approval by PCTs. No charge is levied on GPs – successful or otherwise – for participation in the process. It seems to us therefore to be both illogical and inequitable for pharmacy to have to pay.

3. Revisions of the Current Application Form

We have already expressed the view that PCTs should take a more proactive role in determining the need for pharmacy services. However, this should be done on the basis of a full and proper pharmaceutical needs assessment. This will be particularly important if PCTs become entitled to charge for applications. If they are, clearly they will have a vested interest in inviting (but not necessarily granting) applications.

4. Simplifying the Decision Process

Given the need to improve certainty for business (and we have doubt about whether the proposals will necessarily achieve this) we believe it is right for PCTs to be required to work to a reasonable and consistent timetable. The timetable included at paragraph 5.13 seems to us to be reasonable. Giving PCTs greater flexibility in inviting applications and powers to identify pharmaceutical need on the back of a needs assessment, will in our view, provide an incentive for PCTs to respond to a fixed timetable.

5. Consulting on Applications

Meeting the needs of consumers in terms of pharmacy service is of critical importance. We are therefore fully supportive of the need for consultation, particularly with patient groups. However, we are not clear what problem the consultation document is attempting to address in paragraph 5.14. Consultation on applications must be through any group considered by the consultation group to be representative of their interests. If CHCs (or patient forums) are not considered to be sufficiently representative of the target audience, then patients/consumers should be asked to elect or nominate a group specifically for this purpose. However, for the purpose of consultation we believe the preferred method has to be consultation with a group that is part of a nationally recognised structure.

We believe that 30 days is an adequate time period for comment.

6. Removing the First Past the Post Principle

We do not believe that paragraph 5.15 accurately reflects the current guidance The current guidance is “Pharmaceutical Services Revised Arrangements for Considering Application to Dispense” (ref HSG (92) 13, FPN 560). Paragraph 76 of this guidance cover “Identical or Overlapping Applications”. The guidance says that applications should generally be considered in the order in which they are received “only” if there are no other deciding factors. The existing guidelines do therefore give PCTs discretion in the manner in which they are judged.

Having said this, we can see the difficulties associated with a “first past the post” system. Given what we have already said about the need to give PCTs greater flexibility in the way they ensure adequacy of pharmacy services, it seems to us only

right and proper that PCTs should be able to judge applications on the basis of whether they best meet local service requirements. On this basis, PCTs should also have a considerable input into exercising discretion over exempted applications where, in the opinion of the PCT, these would cut across existing service provision, thereby frustrating local service planning.

7. Minor Re-locations

The principle of a minor relocation under the current regulations is that there should be no significant impact on population served by the pharmacy relocating. In essence, could patients who use the pharmacy in its existing location, still reach the pharmacy in the relocated position? If the answer is yes, this is a minor relocation. Therefore, in the absence of any significant barrier, for example a busy road, river, railway, steep gradient and so on, any move over a small distance must be a relocation. There is a need to remove some of the subjectivity and thus uncertainty from the minor relocation process. We believe this could be achieved by introducing a distance criterion to minor relocations, for example by automatically allowing any application for minor relocation over a distance of say 500m as the crow flies. The problem of applicants using successive minor relocation applications to substantially alter the location of pharmacies could be dealt with by requiring applicants to provide services at the new location for a minimum period of time – say twelve months – after the minor relocation has been granted.

8. Cross PCT Boundary Minor Relocations

We believe that cross PCT border relocations should be allowed. And, we believe that the relocating contractor should be obliged to comply with the standards of service set by the recipient PCT.

9. Preliminary Consent

We believe preliminary consent should be retained. We see preliminary consent as being an essential component of encouraging service development in local neighbourhoods. However, we do recognise the potential for, and difficulties associated with preliminary consent "freezing the market". The principal reason for delay in turning preliminary consent into full consent is local planning or building difficulties. Accordingly, these need to be differentiated from an applicant simply "freezing the market", which we have to say is unusual. We believe the correct approach here would be not to have any time constraints. This would give PCTs the power to over-ride preliminary consent where it becomes clear that an identified service need was going unfulfilled and a provider of that service was being prevented from providing the service simply because another contractor was holding on to a "blocking application".

10. Grant of Full Consent

We see the solution here as being very similar to that we have proposed for preliminary consent. Generally, contractors request an extension due to delays associated with planning and/or building. Where delays are genuine and beyond the reasonable control of the applicant, it would seem wrong for another application to be approved. Indeed, this would result in the applicant suffering a severe financial loss. However, where an applicant is clearly "dragging" his or her feet, the permission should be withdrawn in favour of another applicant.

11. Requirement to Commence Services

We believe PCTs should have the right to require the commencement services and that, subject to there being no reasonable grounds for a delay in provision, three months is a reasonable period.

12. Abolish Appeals for a Change of Ownership

We agree that the appeal in respect of change of ownership should be abolished.

13. Introducing Charges for Appeals

We can see merit in charging for appeals, but do have the reservations we expressed in respect of charging for applications. A right of appeal is a basic right, and applicants should be entitled to have this and not be dissuaded – financially or otherwise – from exercising this. Having said this, if a fee was set at a reasonable level – and we would suggest £1,000 – this is unlikely to be a major deterrent to genuine appeals. It will, however, strip out frivolous or vexatious appellants. At this level, there is unlikely to be a significant advantage to the larger better resourced players.

We believe that the fee should be refunded to successful appellants.

One consequence of a charge for appeals will be the creation of a conflict for the Appeal Authority, who will face a clear financial incentive to reject appeals. This conflict will need to be managed.

14. Dismissing certain kinds of Appeals

We believe the Appeal Authority should exercise its powers to dismiss frivolous or vexatious appeals more often. The charging for appeals is likely to reduce the rate of such appeals.

Review

Whilst Patricia Hewitt's statement of the 17th July 2003 makes reference to a review, the only reference to this we can see in the document is in the Impact Assessment. Patricia Hewitt's statement suggests that the Review will take place in 2006. At this stage, we have no idea of the precise form the regulatory change will take, nor when it will be implemented.

Clearly, the form and timing will depend upon the outcome of the consultation and the deliberations of the Advisory Group. Accordingly, it seems to be pre-emptive to pin down a review date. Rather, we should do this when we have a clearer idea of the time frame. In setting the date for review, there should be sufficient time allowed for a proper assessment of the implications of the regulatory changes on overall service provision and PCTs' ability to plan and manage these. The Advisory Group should give consideration to the scope of the review as part of its deliberations.

Patricia Hewitt's statement indicates that the review is simply to assess whether the time is right to move to full deregulation. During the campaign to reject the OFT recommendation there was widespread political and consumer support in favour of retaining the regulations. This view was borne out of concern about the potential impact of deregulation on community pharmacy service provision. These concerns are still very valid on the back of the implementation of the balanced package proposals. Accordingly, it is our view that the review should be a complete review of the impact of the changes to the regulations (as appears to be suggested in paragraph 9.1 of the Draft Regulatory Impact Assessment) on the community pharmacy sector generally - and the services to patients in particular.

Summary – A Rational Approach to the Planning of Pharmacy Service

To conclude, the NPA welcomes the Government's assertion that the issue goes well beyond that of the retail free-market and must be seen in a healthcare context.

Pharmacy services, as a key component of overall healthcare provision, should be planned. The responsibility for the planning and provision of pharmacy services lies with PCTs and the proposals must be implemented in a way that does not frustrate their ability to plan services in a truly rational way.

The general principle should be to grant applications on the basis of adequacy of services measured against a "gap analysis" of existing service provision. The routine granting of applications which will inevitably flow from broadly drafted exemptions, could lead to an over – and unnecessary - provision of services, thereby frustrating PCTs' ability to plan local service provision.

An assessment of "adequacy" of pharmaceutical services could form part of the baseline audit process supporting the development of the Strategic Services Development Plan (SSDP). Where gaps in service provision exist, existing pharmacies should then be invited to plug these gaps. The targeted use of more discerning exemptions could help speed up the gap filling process. Only where existing players are unwilling, or unable, to plug any gaps should new entrants be considered. Such a system would get round the problem highlighted in the OFT Report, of some PCTs frustration at not being able to plan local service provision in a sufficiently responsive way to meet unanswered need.

A needs assessment toolkit could be developed to help PCTs with this process. The NPA would welcome the opportunity to contribute to the development of this toolkit.

Appendix

The Strategic Service Development Plan (SSDP) and the New Regulations

The NPA recognises that the Government is wedded to the principles of a new test of choice and competition and the exemptions set out in the proposals. However, this could lead to a wide variation in approach and thus service provision depending on the way in which the proposals are implemented.

Pharmacists are taking on an increasingly clinical role and supporting patients through self care. Accordingly, the NPA believes that it is crucial for the future of pharmacy as a key player in primary care (as outlined in Vision for Pharmacy) that the implementation to the changes to control of entry fit neatly with existing planning mechanisms at PCT level. Since, using the vehicle of the new pharmacy contract, community pharmacy will increasingly take on work traditionally done by GPs (who will in turn do work previously done in secondary care), it is essential that community pharmacy premises are seen as part of the planned primary care estate, albeit that they are premises wholly funded by the pharmacy owner.

The main planning tool for primary care estate is the Strategic Service Development Plan (SSDP). Recent briefings on the implementation of the GMS contract (NatPaCT and NHS Confederation, 2003) reiterate previous Department of Health guidance that all PCTs need to develop a strategic service development plan (SSDP) to underpin and prioritise strategic estate investment.

The SSDP identifies what services are available in primary care settings and what changes are needed to improve access and to ensure future service plans can be realised.

A recently published guide outlining good practice around the development of SSDPs (NatPaCT, 2003) states that a comprehensive SSDP, amongst other things should:

- Be integrated with the local development plan (LDP)
- Describe a whole health systems approach to capacity planning of primary care and related services
- Describe the PCT's service vision within the local and national strategic context
- Reflect the local priorities for meeting health needs, tackling social exclusion and contributing to urban regeneration
- Reflect local aspirations of all stakeholders (including independent contractors) to develop integrated services and around the design and development of the estate
- Be inclusive of all local health services – including those provided by local contractor professions and other providers
- Act as a joint planning document and describe planned service changes.

In addition, it can also act as a procurement document (as it does already within LIFT areas) and as a consultation document. It should also be widely available to all local stakeholders, including to including community pharmacists.

The NPA recognises that most PCTs are still getting to grips with the concept of the SSDP and related planning processes, but nevertheless, a planning process that has all the features outlined above provides an ideal vehicle for planning the pharmacy network in the context of the proposed changes to control of entry.

Since PCTs will be undertaking this process anyway, it also has the added benefit of only creating additional work for them at the margin.

We would like to suggest that the following would be the key steps in the SSDP process as they related to pharmacy:

Step in the generic SSDP process	**Pharmacy aspects of the process**
Audit survey of primary care estate and other NHS services; service mapping	Audit of pharmacy premises Audit of existing service provision in pharmacy Identification of current gaps in service provision e.g. areas where a pharmacy is needed and anticipated future gaps e.g. where there are plans to relocate services from acute to primary care and pharmacy support services will be needed to support the transfer
Visioning	Engagement of local pharmacy leaders in and consultation with local pharmacy owners about the PCT vision for primary care Inclusion of both national pharmacy policy developments e.g. pharmacy contract, impact of repeat dispensing on usage patterns of pharmacy and local pharmacy service development plans e.g. development of OOH services, minor ailments schemes, use of patient group directions (PGDs), development supplementary prescribing rights in pharmacy within the visioning process. Dovetailing of pharmacy service development plans with other primary care service developments e.g. implementation new general medical services (including enhanced services), development of GPs with special interest and shifts in care from acute to primary cares, walk-in centres, and local authority regeneration plans.

	Development of principles for the development of the pharmacy service e.g. hub and spoke models, consortia pharmacy ownership in one stop centres
Option appraisal and impact assessment	Consideration of different ways of delivering the agreed vision for pharmacy within primary care in the locality, with accompanying assessment of the impact on access, choice, competition and the health of the local economy.
Identification of approach to change	Description of gaps in current service provision and of the way in which the PCT intends to develop pharmacy services. Description of principles for development e.g. hub and spoke models, PCT subsidised pharmacy service. Identification of PCT *designated* exempt areas or premises for purposes of control of entry.
Financial analysis and affordability action plan	Projected capital cost investments. Sources of funding – private finance, capital, joint ventures, regeneration. Level of rental income. Aggregate resource requirement (including service delivery costs). Cross references to funding in LDP or LA budgets setting processes.
Consultation	Consultation on SSDP with local pharmacists
Procurement	Use of SSDP to inform procurement of pharmacy services in one stop centres and to help potential contract applicants to identify areas within the PCT where the need for a pharmaceutical service or for improved choice and competition in the existing service has been identified.

By integrating the planning of pharmacy services into the SSDP process in this way, PCTs can ensure that they also meet very recently published PCT competence related to management of the pharmacy contract application process, as outlined in the NaTPaCT competency framework for PCTs on medicines management, pharmacy and prescribing, which states:

"PCTs will need access to competent and appropriate levels of pharmaceutical advice and medical advice to interpret and implement control of entry to Pharmaceutical Lists and Dispensing Doctor lists. PCTs will need to ensure a process for decision making which is robust and accurate enough to withstand challenge, both on appeal to the Family Health Services Appeal Authority and, on occasion, Judicial Review through the courts. In dealing with applications which allegedly impact upon other existing contracts (i.e. application by a pharmacist in a controlled locality) PCTs will need to act impartially, empathetically and be able to make decisions which withstand public scrutiny". (NatPaCT, 2003)

The NPA would like to propose that the Department of Health and the Advisory Group on implementation of the regulations use the SSDP process as the basis for implementation of these revised rules around Control of Entry and that detailed guidance is prepared for PCTs on how pharmacy can be integrated into existing SSFP processes, along the lines outlined above.

References

Medicines Management, Pharmacy and Prescribing Significant Issues Group. (2003) *Medicines management, pharmacy and prescribing competencies (M1: pharmacy contract1).* Available at: www.natpact.nhs.uk

NatPaCT. (2003) *A guide: strategic service development plans ("SSDPs").* Gateway ref 1079. Available at: www.natpact.nhs.uk

NHS Confederation, NaTPaCT. (2003) *The New GMS contract: moving to implementation - briefing: premises under the new GMS contract*. NHS Confederation and NatPaCT. Available at: www.natpact.nhs.uk